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UTILITY PATENT APPLICATION TRANSMITTAL (Only for new nonprovisional applications under 37 CFR 1.53(b))	Attorney Docket No.	910000-3080.1
	First Inventor	Dieter Manstein
	Title	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT USING NEEDLE ARRAYS
	Express Mail Label No.	EV 345016445 US

APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents.	Addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
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<p>1. <input checked="" type="checkbox"/> Fee Transmittal Form (e.g., PTO/SB/17) (Submit an original, and a duplicate for fee processing)</p> <p>2. <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.</p> <p>3. <input checked="" type="checkbox"/> Specification [Total Pages 22] Both the claims and abstract must start on a new page (For information on the preferred arrangement, see MPEP 608.01(a))</p> <p>4. <input checked="" type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets 4]</p> <p>5. Oath or Declaration [Total Pages 2] a. <input checked="" type="checkbox"/> Unexecuted b. <input type="checkbox"/> Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional with Box 18 completed) i. <input type="checkbox"/> DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).</p> <p>6. <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76.</p> <p>7. <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)</p> <p>8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary) a. <input type="checkbox"/> Computer Readable Form (CFR) b. Specification sequence Listing on: i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or ii. <input type="checkbox"/> paper c. <input type="checkbox"/> Statements verifying identity of above copies</p>	<p>ACCOMPANYING APPLICATION PARTS</p> <p>9. <input type="checkbox"/> Assignment Papers (cover sheet & documents(s)) Name of Assignee _____</p> <p>10. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input type="checkbox"/> Power of Attorney (when there is an assignee)</p> <p>11. <input type="checkbox"/> English Translation Document (if applicable)</p> <p>12. <input type="checkbox"/> Information Disclosure Statement (PTO/SB/08 or /PTO-1449) <input type="checkbox"/> Copies of citations attached</p> <p>13. <input type="checkbox"/> Preliminary Amendment</p> <p>14. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) (Should be specifically itemized)</p> <p>15. <input type="checkbox"/> Certified Copy of Priority Document(s) (if foreign priority is claimed)</p> <p>16. <input type="checkbox"/> Nonpublication Request under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach from PTO/SB/35 or its equivalent.</p> <p>17. <input checked="" type="checkbox"/> Other: <u>Communication Accompanying Fee Transmittal</u></p>
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18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

<input type="checkbox"/> Continuation	<input type="checkbox"/> Divisional	<input type="checkbox"/> Continuation-in-part (CIP)	of prior application No.: _____ / _____
Prior application information: Examiner: _____			Group/Art Unit: _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS			
<input checked="" type="checkbox"/> Customer Number <u>20999</u> or <input type="checkbox"/> Correspondence address below			
Name _____			
Address _____			
City _____		State _____	Zip Code _____
Country _____		Telephone _____	Fax _____
Name (Print/Type)	Thomas J. Kowalski Deborah L. Lu Steven P. Marsh	Registration No. (Attorney/Agent) <i>Steven Marsh</i>	32,147 50,940 53,271
Signature	Date		April 1, 2005

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) and application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.1 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the complete application to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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00268535

Lumenis Ex. 1004
U.S. Patent No. 9,510,899

Effective on 12/08/2004

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL**For FY 2005****Complete if Known**

Application Number	To Be Assigned
Filing Date	On Even Date Herewith
First Named Inventor	Dieter Manstein
Examiner Name	To Be Assigned
Art Unit	To Be Assigned
Attorney Docket No.	910000-3080.1

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT DUE (\$ \$500.00)**METHOD OF PAYMENT (check all that apply)**
☐ Check ☐ Credit Card ☐ Money Order ☒ None ☐ Other (please identify): _____

☐ Deposit Account Deposit Account Number: 50-0320 Deposit Account Name: Frommer Lawrence & Haug LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee
☐ Charge any additional fee(s) or underpayments of fee(s) ☐ Credit and overpayments
WARNING: Information on this form may become public. Credit Card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Due (\$)
	Fee(\$)	Small Entity Fees(\$)	Fee(\$)	Small Entity Fees(\$)	Fee(\$)	Small Entity Fees(\$)	
Utility	300	150	500	250	200	100	\$500.00
Design	200	100	100	50	130	65	_____
Plant	200	100	300	150	160	80	_____
Reissue	300	150	500	250	600	300	_____
Provisional	200	100	0	0	0	0	_____

2. EXCESS CLAIM FEES**Fee Description**

Fee Description	Fee(\$)	Small Entity Fees(\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims
19	-20 or HP = _____ x	_____ =	_____	Fee (\$)
HP = highest number of total claims paid for, if greater than 20				Fee Paid (\$)
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	
2	-3 or HP = _____ x	_____ =	_____	
HP = highest number of total claims paid for, if greater than 3				

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 or small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

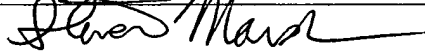
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
22 - 100 = _____	_____/ 50 = _____	_____ (round up to a whole number) x	_____ =	_____

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity)

Other: _____

Fee Paid (\$)**SUBMITTED BY**

Signature		Registration No. 32,147; 50,940; (Attorney/Agent) 53,271	Telephone 212-588-0800
Name (Print/Type)	Thomas J. Kowalski, Deborah L. Lu, Steven P. Marsh	Date	April 1, 2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1540. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Date of Deposit: April 1, 2005

I hereby certify that this Utility Patent Application Transmittal, Fee Transmittal, Patent Application (22 pages), Formal Drawings (4 sheets) and an Unexecuted Declaration and Power of Attorney are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on **April 1, 2005** and are addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Barnet Shindlman
(Typed or printed name of person mailing paper or fee)

Barnet Shindlman
(Signature of person mailing paper or fee)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Dieter Manstein
Serial No. : To Be Assigned
For : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT USING NEEDLE ARRAYS
Filed : On Even Date Herewith
Examiner : To Be Assigned
Art Unit : To Be Assigned

745 Fifth Avenue
New York, NY 10151

COMMUNICATION ACCOMPANYING FEE TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450


Dear Sir:

In the accompanying Fee Transmittal, Applicant calculated the fee for the filing of the above-identified patent application to be \$500.00. However, Applicant does not enclose a check for the payment of the fee, nor does Applicant authorize the Director to charge the Deposit Account.

Applicant will pay the filing fee upon receipt of a Notice to File Missing Parts.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By:



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TITLE OF THE INVENTION

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE
RESHAPING

RELATED APPLICATION

5 This application claims priority to U.S. Provisional Application Serial No.
60/558,476, filed on April 1, 2004.

INCORPORATION BY REFERENCE

10 The foregoing applications, and all documents cited therein or during their
prosecution (“appln cited documents”) and all documents cited or referenced in the appln
cited documents, and all documents cited or referenced herein (“herein cited documents”),
and all documents cited or referenced in herein cited documents, together with any
manufacturer’s instructions, descriptions, product specifications, and product sheets for any
products mentioned herein or in any document incorporated by reference herein, are hereby
incorporated herein by reference, and may be employed in the practice of the invention.

15 FIELD OF THE INVENTION

 The present invention is directed to an improved method for treatment of skin and
other tissues. More specifically, it is directed to a method of fractional wounding using
arrays of needles to damage selected regions of the skin or subdermal tissue and thereby
promote beneficial results including skin tightening and tissue remodeling.

20 BACKGROUND OF THE INVENTION

 Skin is primarily made of two layers. The outer layer, or epidermis, has a depth of
approximately 100 μm . The inner layer, or dermis, has depth of approximately 3000 μm from
the outer surface of the skin and is primarily composed of a network of fibrous protein known
as collagen.

25 There is an increasing demand for repair of skin defects, which can be induced by
aging, sun exposure, dermatological diseases, traumatic effects, and the like. Aging skin
tends to lose its elasticity, leading to increased formation of wrinkles and sagging. Other
causes of undesirable wrinkles in skin include excessive weight loss and pregnancy. There
are several well-known surgical approaches to improving the appearance of skin that involve
30 incisions being made in the skin followed by the removal of some tissue and rejoining of the
remaining tissue. These surgical approaches include facelifts, brow lifts, breast lifts, and
“tummy tucks.” Such approaches have many negative side effects including scar formation,
35 long healing times, displacement of skin from its original location relative to the underlying
bone structure, and nonuniform skin tightening.

Many treatments have been developed that use electromagnetic radiation to improve skin defects by inducing a thermal injury to the skin, which results in a complex wound healing response of the skin. This leads to a biological repair of the injured skin and may be accompanied by other desirable effects. Various techniques providing this objective have been introduced in recent years. The different techniques can be generally categorized in two groups of treatment modalities: ablative laser skin resurfacing ("LSR") and non-ablative collagen remodeling ("NCR"). The first group of treatment modalities, LSR, includes causing fairly extensive thermal damage to the epidermis and/or dermis, while the second group, NCR, is designed to avoid thermal damage of the epidermis.

LSR is considered to be an effective laser treatment for repairing skin. In a typical LSR procedure, shown schematically in Fig. 1, a region of the epidermis 100 and a corresponding region of the dermis 110 beneath it are thermally damaged to promote wound healing. Electromagnetic energy 120 is directed towards a region of skin, ablating the skin and removing both epidermal and dermal tissue in region 130. LSR with pulsed CO₂ or Er:YAG lasers, which may be referred to in the art as laser resurfacing or ablative resurfacing, is considered to be an effective treatment option for signs of photo aged skin, chronically aged skin, scars, superficial pigmented lesions, stretch marks, and superficial skin lesions. However, patients may experience major drawbacks after each LSR treatment, including edema, oozing, and burning discomfort during first fourteen (14) days after treatment. These major drawbacks can be unacceptable for many patients. A further problem with LSR procedures is that the procedures are relatively painful and therefore generally require an application of a significant amount of analgesia. While LSR of relatively small areas can be performed under local anesthesia provided by injection of an anestheticum, LSR of relatively large areas is frequently performed under general anesthesia or after nerve blockade by multiple injections of anesthetic.

A limitation of LSR is that ablative resurfacing in areas other than the face generally have a greater risk of scarring because the recovery from skin injury within these areas is not very effective. Further, LSR techniques are better suited for correction of pigmentation defects and small lesions than for reducing or eliminating wrinkles.

In an attempt to overcome the problems associated with LSR procedures, several types of NCR techniques has emerged. These techniques are variously referred to in the art as non-ablative resurfacing, non-ablative subsurfacing, or non-ablative skin remodeling. NCR techniques generally utilize non-ablative lasers, flashlamps, or radio frequency current to damage dermal tissue while sparing damage to the epidermal tissue. The concept behind

NCR techniques is that thermal damage of the dermal tissue is thought to induce collagen shrinkage, leading to tightening of the skin above, and stimulation of wound healing which results in biological repair and formation of new dermal collagen. This type of wound healing can result in a decrease of structural damage related to photoaging. Avoidance of epidermal damage in NCR techniques decreases the severity and duration of treatment-related side effects. In particular, post-procedural oozing, crusting, pigmentary changes and incidence of infections due to prolonged loss of the epidermal barrier function can usually be avoided by using NCR techniques.

In the NCR method of skin treatment, illustrated schematically in Fig. 2, selective portions of dermal tissue 135 within the dermal layer 110 are heated to induce wound healing without damaging the epidermis 100 above. Selective dermal damage that leaves the epidermis undamaged can be achieved by cooling the surface of the skin and focusing electromagnetic energy 120, which may be a laser beam, onto dermal region 135 using lens 125. Other strategies are also applied using nonablative lasers to achieve damage to the dermis while sparing the epidermis in NCR treatment methods. Nonablative lasers used in NCR procedures generally have a deeper dermal penetration depth as compared to ablative lasers used in LSR procedures. Wavelengths in the near infrared spectrum can be used. These wavelengths cause the non-ablative laser to have a deeper penetration depth than the very superficially-absorbed ablative Er:YAG and CO₂ lasers. Examples of NCR techniques and apparatus are disclosed by Anderson et al. in U.S. Patent Publication No. 2002/0161357.

While it has been demonstrated that these NCR techniques can assist in avoiding epidermal damage, one of the major drawbacks of these techniques is their limited efficacies. The improvement of photoaged skin or scars after the treatment with NCR techniques is significantly smaller than the improvements found when LSR ablative techniques are utilized. Even after multiple treatments, the clinical improvement is often far below the patient's expectations. In addition, clinical improvement is usually several months delayed after a series of treatment procedures. NCR is moderately effective for wrinkle removal and is generally not effective for dyschromia. One advantage of NCR is that it does not have the undesirable side effects that are characteristic of the LSR treatment, such as the risk of scarring or infection.

Another limitation of NCR procedures relates to the breadth of acceptable treatment parameters for safe and effective treatment of dermatological disorders. The NCR procedures generally rely on an optimum coordination of laser energy and cooling parameters, which can result in an unwanted temperature profile within the skin leading to

either no therapeutic effect or scar formation due to the overheating of a relatively large volume of the tissue.

Another approach to skin tightening and wrinkle removal involves the application of radio frequency ("RF") electrical current to dermal tissue via a cooled electrode at the surface of the skin. Application of RF current in this noninvasive manner results in a heated region developed below the electrode that damages a relatively large volume of the dermis, and epidermal damage is minimized by the active cooling of the surface electrode during treatment. This treatment approach can be painful, and can lead to short-term swelling of the treated area. Also, because of the relatively large volume of tissue treated and the need to balance application of RF current with surface cooling, this RF tissue remodeling approach does not permit fine control of damage patterns and subsequent skin tightening. This type of RF technique is monopolar, relying on a remote grounding of the patient to complete the current flow from the single electrode. The current in monopolar applications must flow through the patient's body to the remote ground, which can lead to unwanted electrical stimulation of other parts of the body. In contrast, bipolar instruments conduct the current between two relatively nearby electrodes through a more localized pathway.

In view of the shortcomings of the above methods of dermatological treatment and tissue remodeling, there is a need to provide a procedure and apparatus that combine safe and effective treatment for tissue remodeling, skin tightening, and wrinkle removal with minimal side effects, such as intra-procedural discomfort, post-procedural discomfort, lengthy healing time, and post-procedural infection.

Citation or identification of any document in this application is not an admission that such document is available as prior art to the present invention.

SUMMARY OF THE INVENTION

It is therefore one of the objects of the present invention to provide an apparatus and method that combines safe and effective treatment for an improvement of dermatological disorders with minimum side effects. Another object of the present invention is to provide an apparatus and method that promotes skin tightening and wrinkle removal by creation of a pattern of small localized regions of thermal damage within the dermis. Still another object of the present invention is to provide a method and apparatus for skin tightening or other forms of tissue remodeling by using an array of electrode needles to controllably deliver electrical or thermal energy to predetermined locations within the dermis or other tissue.

These and other objects can be achieved with an exemplary embodiment of the apparatus and method according to the present invention, in which portions of a target area of

tissue are be subjected electromagnetic radiation, such as radio frequency pulses, or thermal energy. Electromagnetic radiation is directed to portions of a target area within the skin or deeper tissue using minimally invasive methods, causing fractional wounding of the portions of the target area. The electromagnetic radiation may be generated by an electromagnetic radiation source, which is configured to deliver heat, radio frequency pulses, electrical current, or the like to a plurality of target areas.

In yet another exemplary embodiment according to the present invention, an electromagnetic radiation source is configured to generate electromagnetic radiation, and a delivery device comprising an array of needles, coupled to the electromagnetic radiation source, is configured to penetrate the skin to a desired depth to deliver the electromagnetic radiation directly to a plurality of target areas.

One method in accordance with the present invention comprises inserting an array of needles into a region of skin to a predetermined depth. Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles.

In an alternate aspect of the invention, one or more of the needles in the array may be hollow and used to deliver small amounts of analgesic or anesthetic into the region of skin being treated. These hollow needles may be interspersed among the electrode needles in the array, and they may also function as electrodes.

In another embodiment of the invention, the electrode needles may also be connected to a second source of electrical current in the milliamperage range. Detection of a nerve close to any of the inserted needles of the array is achieved by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, the nearby needle or needles can be deactivated during the subsequent application of RF current to other electrode needles in the array to avoid damaging the nerve.

In yet another embodiment of the invention, the methods and apparatus described herein can be used to heat portions of cartilage, such as that located in the nose, using a minimally invasive technique, allowing reshaping of the pliant heated cartilage to a desired form.

A further understanding of the nature and advantages of the present invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The following detailed description, given by way of example, but not intended to limit the invention solely to the specific embodiments described, may best be understood in conjunction with the accompanying drawings, in which:

Fig. 1 is a schematic drawing of a cross section of a tissue treated using the ASR method.

Fig. 2 is a schematic drawing of a cross section of a tissue treated using the NSR method.

Fig. 3 is a schematic illustration of an apparatus for conducting tissue reshaping using electromagnetic energy according to one embodiment of the present invention.

Fig. 4 is a schematic illustration of portions of an apparatus for conducting tissue reshaping according to one embodiment of the present invention.

Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present invention will now be described in detail with reference to the Figures, it is done so in connection with the illustrative embodiments and is not limited by the particular embodiments illustrated in the Figures.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to methods and apparatus for improvement of skin defects including, but not limited to, wrinkles, stretch marks, and cellulite. In one embodiment, skin tightening or tissue remodeling is accomplished by creating a distribution of regions of necrosis, fibrosis, or other damage in the tissue being treated. The tissue damage is achieved by delivering localized concentrations of electrical current that is converted into heat in the vicinity of the tips of the electrode needles. Inducing regions of local thermal damage within the dermis results in an immediate shrinking of collagen, leading to beneficial skin tightening response. Additionally, the thermal damage tends to stimulate the formation of new collagen, which makes the local skin tissue fuller and gradually leads to additional skin tightening and reduction of wrinkles.

In an exemplary embodiment of the present invention, tissue treatment apparatus 300 shown in Fig. 3 may be used to create regions of damage within the tissue being treated. The tissue reshaping apparatus may comprise a plurality of needles 350 attached to a base 310. The base is attached to housing 340 or formed as a part of the housing. A source of RF current 320 is electrically connected to each of the needles 350. A control module 330 permits variation of the characteristics of the RF electrical current, which can be supplied

individually to one or more of the needles. Optionally, energy source 320 and/or control module 330 may be located outside of the housing.

In one exemplary embodiment, the energy source 320 is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range. In another exemplary embodiment, the energy source is capable of outputting an AC or DC electric current. The control module 330 provides application-specific settings to the energy source 320. The energy source 320 receives these settings, and generates a current directed to and from specified needles for selectable or predetermined durations, intensities, and sequences based on these settings.

In yet another embodiment of the present invention, a spacer substrate 315 containing a pattern of small holes through which the array of needles protrudes may optionally be provided between the base 310 and the surface of the skin 306. This spacer substrate may be used to provide mechanical stability to the needles. Optionally, this substrate may be movably attached to the base 310 or housing 340 and adjustable with respect to base 310, supporting the array of needles to control the depth of the needles protruding from the lower surface 316 of spacer substrate 315, and thus controlling the depth to which the needles are inserted into the skin.

In practicing a method in accordance with the present invention, the sharp distal ends of needles 350 pierce the surface 306 of skin tissue 305 and are inserted into the tissue until the bottom surface 316 of spacer substrate 315 (or the bottom surface 311 of base 310 if a spacer substrate 315 is not used) contacts the surface 306 of the skin 305. This configuration permits reliable insertion of the array of needles to a predetermined depth within the tissue being treated. Control module 330 is then configured to deliver controlled amounts of RF current to one or more needles 350.

Base 310 and/or spacer substrate 315, if used, can be planar or they may have a bottom surface that is contoured to follow the shape of the region of tissue being treated. This permits penetration of the needle array to a uniform depth within the targeted tissue even if the surface of the skin is not planar, e.g., along the eye sockets.

In another embodiment, base 310 and/or a spacer substrate 315, if used, may be cooled by any suitable means (such as by embedded conduits containing circulating coolant or by a Peltier device) to cool the surface of the skin when the needle array penetrates the skin to reduce or eliminate pain. The surface region of the skin being treated and/or the needles themselves may also be precooled by separate means, including convective or conductive means, prior to penetration of the skin by the array of needles.

In a preferred embodiment of the present invention, the shafts of conductive needles 350 are electrically insulated except for the portion of the needle near the tip. In the apparatus of Fig. 3, application of RF current to the needles 350 causes heating in the exposed tip region, inducing thermal damage regions 370 around the tip of each needle.

Thermal damage regions 370 result from operation of the apparatus in monopolar configuration, in which a remote grounding electrode, not shown in Fig. 3, is attached to a remote part of the patient's body to complete the circuit of electricity conveyed to needles 350 by energy source 320. In this monopolar configuration, RF current causes heating of the tip regions of the needles 350, generating thermal damage in tissue regions 370 adjacent to the needle tips that are approximately spherical or slightly elongated in shape.

In one embodiment of the invention, current may be delivered simultaneously to all needles in the array to produce a pattern of thermal damage around the tip of each needle. In alternative embodiments, control module 330 and energy source 320 can be configured to supply electrical current to individual needles, to specific groups of needles within the array, or to any combination of individual needles in any desired temporal sequence. Providing current to different needles at different times during treatment (instead of heating all needles in the array at once) may help to avoid potential local electrical or thermal interactions among needles that can lead to excessive local damage.

In yet another embodiment of the present invention one or more vibrating means, such as a piezoelectric transducer or a small motor with an eccentric weight fixed to the shaft, may be mechanically coupled to housing 340 and/or base 310 that supports the array of needles 350. Vibrations conductively induced in needles 350 by such vibrating means can facilitate the piercing of the skin by the needle tips and subsequent insertion of the needles into the tissue. The vibrating means can have an amplitude of vibration in the range of about 50-500 μm or, more preferably, between about 100-200 μm . The frequency of the induced vibrations can be from about 10 hz to about 10 khz, more preferably from about 500 hz to about 2 khz, and even more preferably about 1 khz. The particular vibration parameters chosen may depend on the size and material of the needles, the number of needles in the array, and the average spacing of the needles. The vibrating means may further comprise an optional controller capable of adjusting the amplitude and/or frequency of the vibrations.

Additional details and embodiments of the present invention are shown in Figure 4. Conductive needles 410 and 415 are shown attached to base 310. Insulation 420 covers the shaft of needles 410 and 415 protruding from base 310 except for the region near the lower tip, and electrically insulates each conductive needle shaft from surrounding tissue 305.

Electrical conductors 430 and 431, which may be wires or the like, extend from an upper portion of needles 410 and 415 respectively, and are connected to the energy source (not shown here). Suitable insulating materials for insulation 420 include, but are not limited to, Teflon®, polymers, glasses, and other nonconductive coatings. A particular material may be chosen as an insulator to facilitate penetration and insertion of needles 410 and 415 into tissue 305.

Needles 410 and 415 are shown operating in bipolar mode in another embodiment of the present invention. Needle 410 is a positive electrode delivering RF or other current to the tip region of the needle from the energy source via conductor 430. Needle 415 functions as a grounding electrode that is connected to the ground of the energy source via conductor 431. In this configuration the applied current will travel through the tissue between the tips of needles 410 and 415, generating an elongated region of thermal damage 425 around and between the tips of the two needles.

An elongated region of damaged tissue 425 can be created between any two adjacent or nearby needles in the array through proper configuration of control module 330 and energy source 320. In an embodiment of the present invention, elongated damage regions 425 are formed between several pairs of needles within the array of needles to form a desired damage pattern in the tissue 305. The regions of thermal damage 325 created in bipolar operation of the apparatus may be formed simultaneously or, alternatively, sequentially, using any combinations of proximate needles in the array to form each region. A wide variety of thermal damage patterns can be created using a single array of needles through appropriate configuration of energy source 320 and control module 330 to deliver predetermined amounts of current between selected pairs of needles. This apparatus thus allows for the creation of complex damage patterns within the tissue 305 that may be macroscopically elongated in preferred directions to produce anisotropic shrinkage and reshaping.

In practicing the methods and apparatus of the present invention, the needles can have a width of about 500-1000 μm or preferably about 700-800 μm . Needles less than 500 μm in diameter may also be used if they are mechanically strong enough. Needles thicker than about 1000 μm in diameter may be undesirable because of the difficulty in forcing larger needles to penetrate the skin and because of the increased propensity for pain and scarring. The length of the needles extending into the skin will depend on the targeted depth for damaging the tissue. A typical depth for targeting collagen in the dermis is about about 1500-2000 μm , although shallower or deeper distances may be preferred for different treatments

and regions of the body being treated. Needles within a single array may protrude by different lengths from the base 310 or spacer substrate 315. This will cause the tips of the needles to be positioned at different depths within the tissue being treated, and allow creation of damaged tissue at more than one depth. This variation in needle depth can achieve formation of damaged tissue over a larger volume within the tissue being treated.

The needle arrays may have any geometry appropriate for the desired treatment being performed. The spacing between adjacent needles is preferably greater than about 1mm apart, and may be as large as about 2 cm. The spacing between needles in an array need not be uniform, and can be closer in areas where a greater amount of damage or more precise control of damage in the target area of tissue is desired. In one embodiment, the array of needles may comprise pairs of needles separated from adjacent pairs by larger distances. This geometry may be well-suited for inducing damage in bipolar mode between pairs of needles. Needles may also be arranged in a regular or near-regular square or triangular array. In any array geometry, the pattern of damage and resultant tissue reshaping may be controlled with some precision by adjusting the intensity and duration of power transmitted to single needles or pairs of needles.

The amount of energy directed to a given needle will vary depending on the tissue being treated and the desired extent of thermal damage to induce. For typical needle spacings noted above, the energy source should be configured to deliver about 1-100 mJ per needle or pair of needles in the array. It may be preferable to initially use lower amounts of energy and perform two or more treatments over the same target area to better control the damage patterns and extent of reshaping.

In yet another embodiment of the present invention, one or more of the needles in the array may be hollow, such as needle 440 in Fig. 4. Center channel 450 may be used to deliver a local analgesic such as lidocaine 2% solution from a source (not shown) located within or above base 310 into the tissue 305 to reduce or eliminate pain caused by the thermal damage process.

In yet another embodiment of the present invention, hollow needle 440 is bifunctional, capable of conducting RF current or other energy via conductor 432 and also capable of delivering a local analgesic or the like through center channel 450. Similar to needles 410 and 415, bifunctional needle 440 has insulation 445 covering the shaft extending from base 310 except for the region near the lower tip. Analgesic may be supplied to the tissue either before or during application of RF or other current to the needle 450.

In one embodiment of the invention, one or more of the needles in the array may be bifunctional like needle 440. Alternatively, one or more needles may be hollow and optionally nonconductive, suitable only for delivering a local analgesic or the like. The array of needles used for a given application may comprise any combination of solid electrodes, bifunctional needles, or hollow nonconductive needles. For example, one type of needle array may comprise pairs of electrode needles operating in bipolar mode, with a hollow needle located between each pair. In this configuration, the hollow needle can deliver analgesic to the tissue between the tips of the electrode needles prior to applying current to the electrodes and causing thermal damage in the numbed tissue.

In yet another embodiment of the present invention, one or more of the needles in the array may be further connected to an electronic detection apparatus and perform the additional function of a probe to detect the presence of a nerve near the tip. The electronic detection apparatus may comprise a source of electrical current in the milliamperage range and control means to send small currents on the order of a milliamp to specific needles in the array. Detection of a nerve close to any of the inserted needles of the array is performed by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, control module 330 can be configured to deactivate the needle or needles close to the nerve during the subsequent treatment to avoid damaging the nerve. A nerve detection method based on principles similar to those described herein is disclosed by Urmey et al. in Regional Anesthesia and Pain Medicine 27:3 (May-June) 2002, pp. 261-267.

In still another embodiment, one or more of the needles may be hollow, and a light fiber or light guide is inserted into the hollow needle such that one end of it extends to or slightly protrudes from the needle tip. The other end of the light fiber or light guide in communication with a source of optical energy. Optical energy supplied to the tip of the light guide or light fiber may then be used to heat the tip, which then heats the surrounding tissue, i.e., the target area, to cause fractional wounding at the needle tip. An array of needles used in accordance with the present invention may comprise a mix of electrode needles and light-guide needles. Alternatively, each needle may carry a light guide and all of the energy used to cause thermal damage may be generated by the optical energy source instead of using RF or other electrical current. A portion of the light guide or light fiber, such as the portion at the tip of the needle, may be configured to absorb energy and facilitate conversion of the optical energy to heat. In these embodiments, the optical energy source may comprise, but is not limited to, a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG

laser, an argon-ion laser, a He-Ne laser, a carbon dioxide laser, an excimer laser, or a ruby laser. The optical energy conveyed by a light guide or light fiber may optionally be continuous or pulsed.

Treatments performed in accordance with the present invention may be used to target collagen in the dermis. This can lead to immediate tightening of the skin and reduction of wrinkles overlying the damaged tissue arising from contraction of the heated collagen. Over time, the thermal damage also promotes the formation of new collagen, which serves to smooth out the skin even more.

An alternative application of the methods of the present invention may be to reduce or eliminate the appearance of cellulite. To achieve this, the arrays of needles are configured to target the dermis and optionally the upper layer of subcutaneous fat directly. Creating dispersed patterns of small thermally-damaged regions in these layers can tighten the networked collagen structure and suppress the protrusion of the subcutaneous fat into the dermal tissue that causes cellulite.

Yet another application of the methods and apparatus of the present invention is to reshape cartilage. It is known that cartilage softens upon heating, and heating it to about 70 degrees C can soften the cartilage sufficiently to permit reshaping that persists upon cooling. Currently, specialized lasers are used to heat and soften cartilage in the nasal passages for reshaping. Using the methods and apparatus described herein, cartilage can be targeted by an array of needles and heated in a suitably gradual way, using lower power densities and longer times, to provide relatively uniform heating. Shaping of the cartilage is thus possible using a minimally invasive technique that can be used where laser heating may not be feasible.

Any of the thermal damaging and tissue reshaping methods practiced in accordance with the present invention may be performed in a single treatment, or by multiple treatments performed either consecutively during one session or at longer intervals over multiple sessions. Individual or multiple treatments of a given region of tissue can be used to achieve the appropriate thermal damage and desired cosmetic effects.

The invention is further described by the following numbered paragraphs:

1. A tissue reshaping apparatus comprising:
 - a plurality of needles attached to a base, wherein the base is attached to a housing or part of the housing;
 - an energy source in communication with one or more of the needles; and
 - optionally comprising a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

2. The apparatus of paragraph 1 wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles.

3. The apparatus of paragraph 2 wherein the energy source and/or control module is located outside of the housing.

4. The apparatus of any one of paragraphs 1 to 3 wherein the energy source is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range.

5. The apparatus of any one of paragraphs 1 to 4 wherein the energy source is capable of outputting an AC or DC electric current.

6. The apparatus of any one of paragraphs 1 to 5 wherein the control module provides application-specific settings to the energy source, and wherein the energy source receives the settings, and generates a current directed to and optionally from specified needles for selectable or predetermined durations, intensities, and sequences based on the settings.

7. The apparatus of any one of paragraphs 1 to 6 wherein the needles comprise sharp distal ends capable of piercing the surface of skin tissue and penetrating into the tissue until the lower side of the base contacts the surface of the skin.

8. The apparatus of any one of paragraphs 1 to 7 wherein the control module is configured to deliver controlled amounts of RF current to one or more of the needles.

9. The apparatus of any one of paragraphs 1 to 8 further comprising a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes.

10. The apparatus of paragraph 9 wherein the substrate is movably attached to the base or the housing and wherein the position of the substrate is adjustable relative to that of the base to control the depth of the needles protruding from the lower surface of the spacer substrate.

11. The apparatus of any one of paragraphs 1 to 10 wherein the base and/or optionally, the spacer substrate, is planar or has a lower surface that is contoured to follow the shape of the region of tissue being treated.

12. The apparatus of any one of paragraphs 1 to 11 wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminate pain when the plurality of needles penetrates the skin surface.

13. The apparatus of paragraph 12 wherein said cooling comprises embedded conduits containing circulating coolant or a Peltier device.

14. The apparatus of any one of paragraphs 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a monopolar configuration.

15. The apparatus of any one of paragraphs 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a bipolar configuration.

16. The apparatus of any one of paragraphs 1 to 15 further comprising a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft.

17. The apparatus paragraph 16 wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz.

18. The apparatus paragraph 17 wherein the vibrational amplitude of said vibrating means is between about 50-500 μm or between about 100-200 μm .

19. The apparatus of any one of paragraphs 1 to 18 wherein the energy source and the control module are configured to deliver energy to a plurality of pairs of needles in bipolar mode..

20. The apparatus of any one of paragraphs 1 to 19 wherein the diameter of the needles is between about 500-1000 μm or between about 700-800 μm .

21. The apparatus of any one of paragraphs 1 to 20 wherein the average spacing of needles is between about 1 mm and 2 cm, and wherein the needles optionally are not uniformly spaced.

22. The apparatus of any one of paragraphs 1 to 21 wherein one or more of the needles are hollow and are configured to deliver a local analgesic to the tissue surrounding the tip of the needle.

23. The apparatus of any of paragraphs 1 to 22 further comprising an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles.

24. The apparatus of paragraph 23 wherein the detection device is in communication with the control module and the control module is configured to prevent the energy source from supplying energy to any needle if a nerve has been detected near that needle.

25. The apparatus of any of paragraphs 1 to 24 further comprising a source of optical energy and one or more hollow needles containing light fibers or light guides, wherein

the apparatus is configured to deliver a controlled amount of electromagnetic energy through the light fiber or light guide and into the tissue surrounding the tip of the hollow needle.

26. The apparatus of paragraph 25 wherein the optical energy source comprises a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG laser, an argon-ion laser, a He-Ne laser, a carbon dioxide laser, an excimer laser, or a ruby laser, and wherein the electromagnetic energy conveyed by the light guide or light fiber is continuous or pulsed.

27. A method of treating skin comprising the steps of:
providing a plurality of needles attached to a base;
providing an energy source in communication with one or more of the needles;
inserting the needles into the skin to a predetermined depth; and
supplying energy to more than one of the needles to induce a pattern of damage in the tissue surrounding the needles.

28. The method of paragraph 27 further comprising:
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

29. The method of paragraph 28 further comprising:
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin.

30. The method of paragraph 29 wherein the energy is RF current and the needles are insulated except near their tips.

31. The method of paragraph 30 further comprising:
providing a detection device in communication with one or more of the needles;
supplying low current to one or more of the needles sequentially to detect the presence of a nerve near the needles; and
preventing the energy source from supplying energy to any needle if a nerve has been detected near that needle.

32. The method of paragraph 27 further comprising:
providing one or more hollow needles attached to the base and injecting an analgesic through the hollow needles into the surrounding tissue after the needles are inserted into the skin.

33. The method of paragraph 29 further comprising:
providing hollow needles containing light fibers or light guides in communication with the energy source, wherein the energy source is a source of optical

energy;

supplying energy to the light fibers or light guides to induce thermal damage in a portion of the tissue surrounding the hollow needles.

* * *

Having thus described in detail preferred embodiments of the present invention, it is to be understood that the invention defined by the above paragraphs is not to be limited to particular details set forth in the above description as many apparent variations thereof are possible without departing from the spirit or scope of the present invention.

WHAT IS CLAIMED IS:

1. A tissue reshaping apparatus comprising:
a plurality of needles attached to a base, wherein the base is attached to a housing or part of the housing;
an energy source in communication with one or more of the needles; and
optionally comprising a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.
2. The apparatus of claim 1 wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles or
wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles and
wherein the energy source and/or control module is located outside of the housing.
3. The apparatus of claim 1 wherein the energy source is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range or
wherein the energy source is capable of outputting an AC or DC electric current.
4. The apparatus of claim 1 wherein the control module provides application-specific settings to the energy source, and wherein the energy source receives the settings, and generates a current directed to and optionally from specified needles for selectable or predetermined durations, intensities, and sequences based on the settings.
5. The apparatus of claim 1 wherein the needles comprise sharp distal ends capable of piercing the surface of skin tissue and penetrating into the tissue until the lower side of the base contacts the surface of the skin.
6. The apparatus of claim 1 wherein the control module is configured to deliver controlled amounts of RF current to one or more of the needles.
7. The apparatus of claim 1 wherein the apparatus further comprises a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes or
wherein the apparatus further comprises a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes and
wherein the substrate is movably attached to the base or the housing and wherein the position of the substrate is adjustable relative to that of the base to control the depth of the needles protruding from the lower surface of the spacer substrate.

8. The apparatus of claim 1 wherein the base and/or optionally, the spacer substrate, is planar or has a lower surface that is contoured to follow the shape of the region of tissue being treated or

wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminats pain when the plurality of needles penetrates the skin surface or

wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminats pain when the plurality of needles penetrates the skin surface and

wherein said cooling comprises embedded conduits containing circulating coolant or a Peltier device.

9. The apparatus of claim 1 wherein said apparatus is configured to deliver RF energy to one or more needles in a monopolar configuration or

wherein said apparatus is configured to deliver RF energy to one or more needles in a bipolar configuration.

10. The apparatus of claim 1 wherein the apparatus further comprises a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft or

wherein the apparatus further comprises a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft and

wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz or

wherein the apparatus further comprises a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft and

wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz and

wherein the vibrational amplitude of said vibrating means is between about 50-500 μm or between about 100-200 μm .

11. The apparatus of claim 1 wherein the energy source and the control module are configured to deliver energy to a plurality of pairs of needles in bipolar mode..

12. The apparatus of claim 1 wherein the diameter of the needles is between about 500-1000 μm or between about 700-800 μm or

wherein the average spacing of needles is between about 1 mm and 2 cm, and wherein the needles optionally are not uniformly spaced.

13. The apparatus of claim 1 wherein one or more of the needles are hollow and are configured to deliver a local analgesic to the tissue surrounding the tip of the needle.

14. The apparatus of claim 1 wherein the apparatus further comprises an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles or

wherein the apparatus further comprises an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles and

wherein the detection device is in communication with the control module and the control module is configured to prevent the energy source from supplying energy to any needle if a nerve has been detected near that needle.

15. The apparatus of claim 1 wherein the apparatus further comprises a source of optical energy and one or more hollow needles containing light fibers or light guides, wherein the apparatus is configured to deliver a controlled amount of electromagnetic energy through the light fiber or light guide and into the tissue surrounding the tip of the hollow needle or

wherein the apparatus further comprises a source of optical energy and one or more hollow needles containing light fibers or light guides, wherein the apparatus is configured to deliver a controlled amount of electromagnetic energy through the light fiber or light guide and into the tissue surrounding the tip of the hollow needle and

wherein the optical energy source comprises a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG laser, an argon-ion laser, a He-Ne laser, a carbon dioxide laser, an excimer laser, or a ruby laser, and wherein the electromagnetic energy conveyed by the light guide or light fiber is continuous or pulsed.

16. A method of treating skin comprising the steps of:
providing a plurality of needles attached to a base;
providing an energy source in communication with one or more of the needles;
inserting the needles into the skin to a predetermined depth; and
supplying energy to more than one of the needles to induce a pattern of damage in the tissue surrounding the needles.

17. The method of claim 16 further comprising:
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source or
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin or
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin and wherein the energy is RF current and the needles are insulated except near their tips or
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin and wherein the energy is RF current and the needles are insulated except near their tips and
providing a detection device in communication with one or more of the needles;
supplying low current to one or more of the needles sequentially to detect the presence of a nerve near the needles; and
preventing the energy source from supplying energy to any needle if a nerve has been detected near that needle.

18. The method of claim 16 further comprising:
providing one or more hollow needles attached to the base and injecting an analgesic through the hollow needles into the surrounding tissue after the needles are inserting into the skin.

19. The method of claim 16 further comprising:
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin and
providing hollow needles containing light fibers or light guides in communication with the energy source, wherein the energy source is a source of optical

energy;

supplying energy to the light fibers or light guides to induce thermal damage in a portion of the tissue surrounding the hollow needles.

ABSTRACT OF THE DISCLOSURE

The present invention provides improved methods and apparatus for skin treatment and tissue remodeling. The apparatus includes an array of needles that penetrate the skin and serve as electrodes to deliver radio frequency current or other electrical or optical energy into
5 the tissue being treated, causing thermal damage in controlled patterns. The damaged regions promote beneficial results such as uniform skin tightening by stimulation of wound healing and collagen growth.

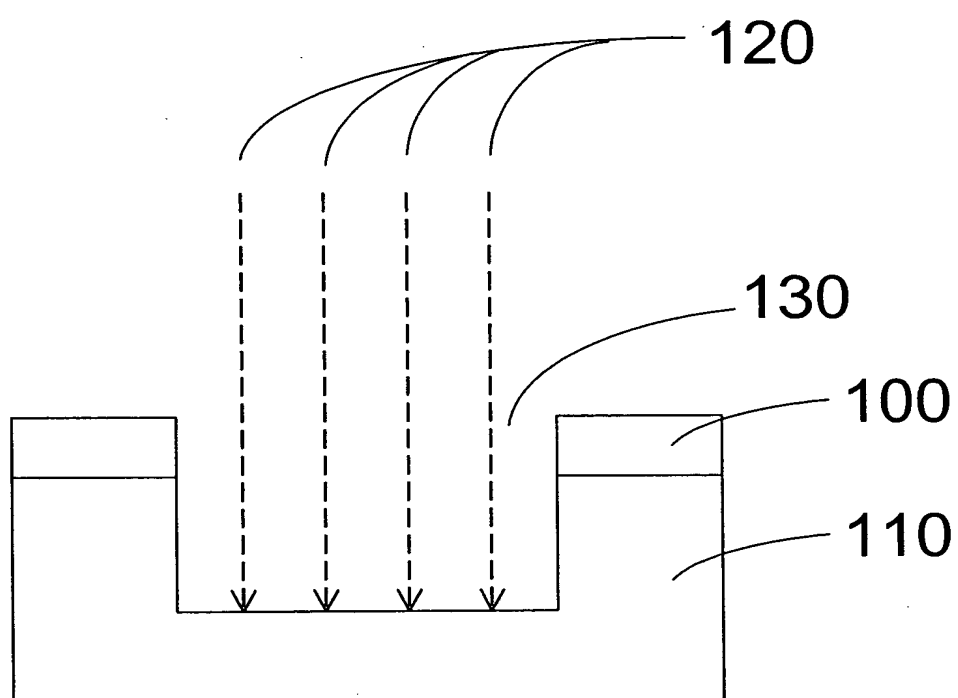


FIG. 1

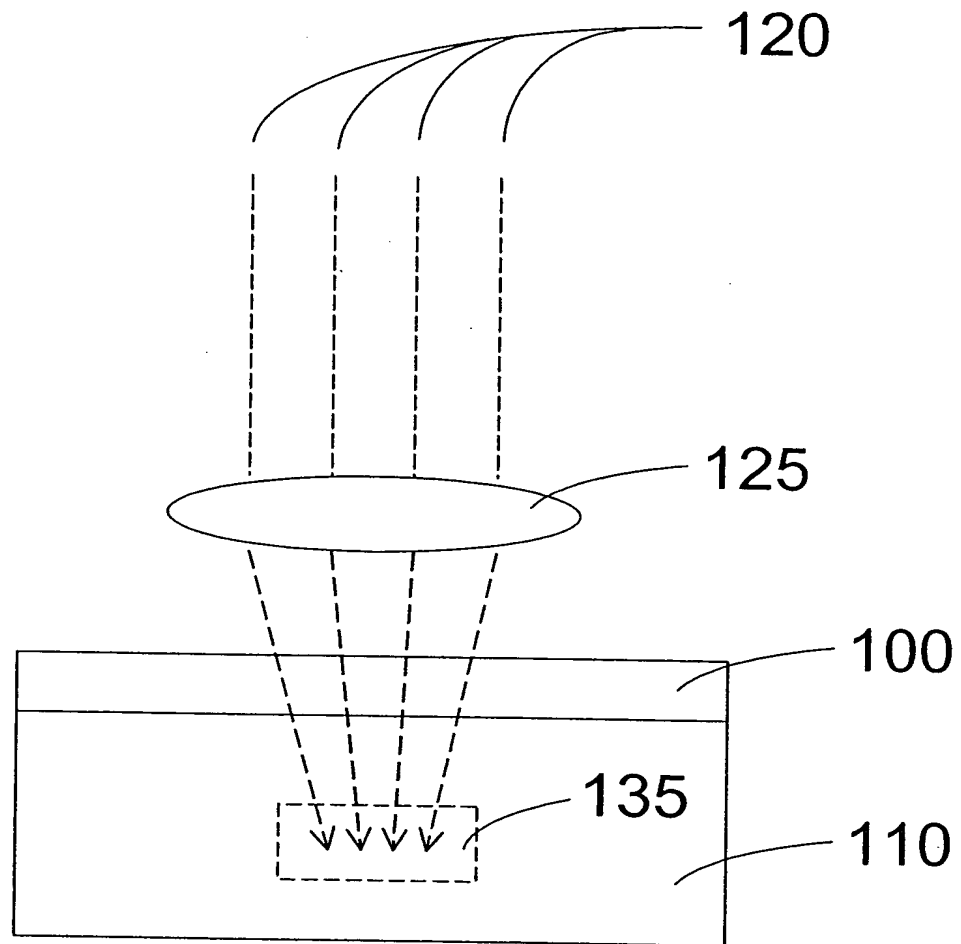


FIG. 2

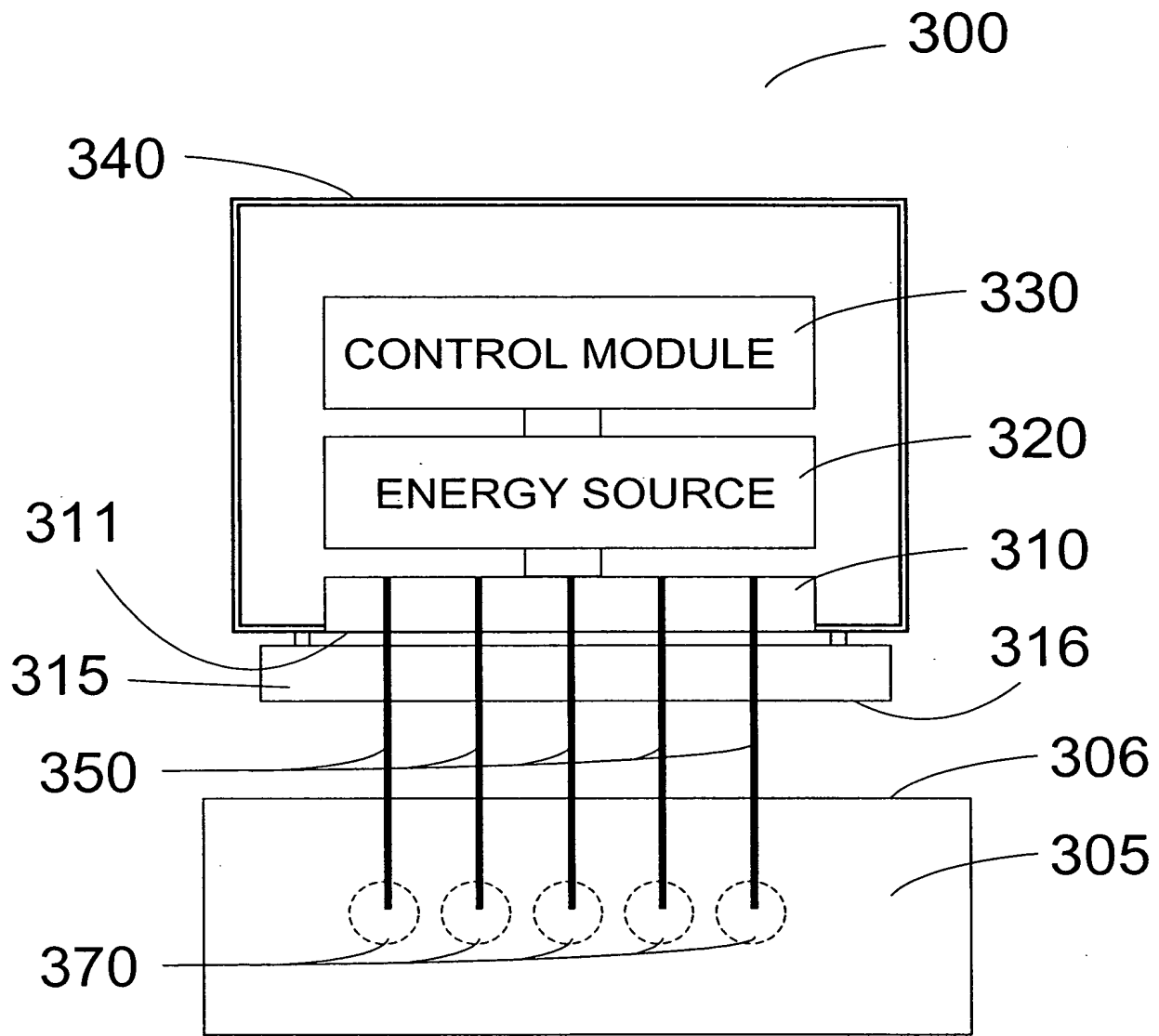


FIG. 3

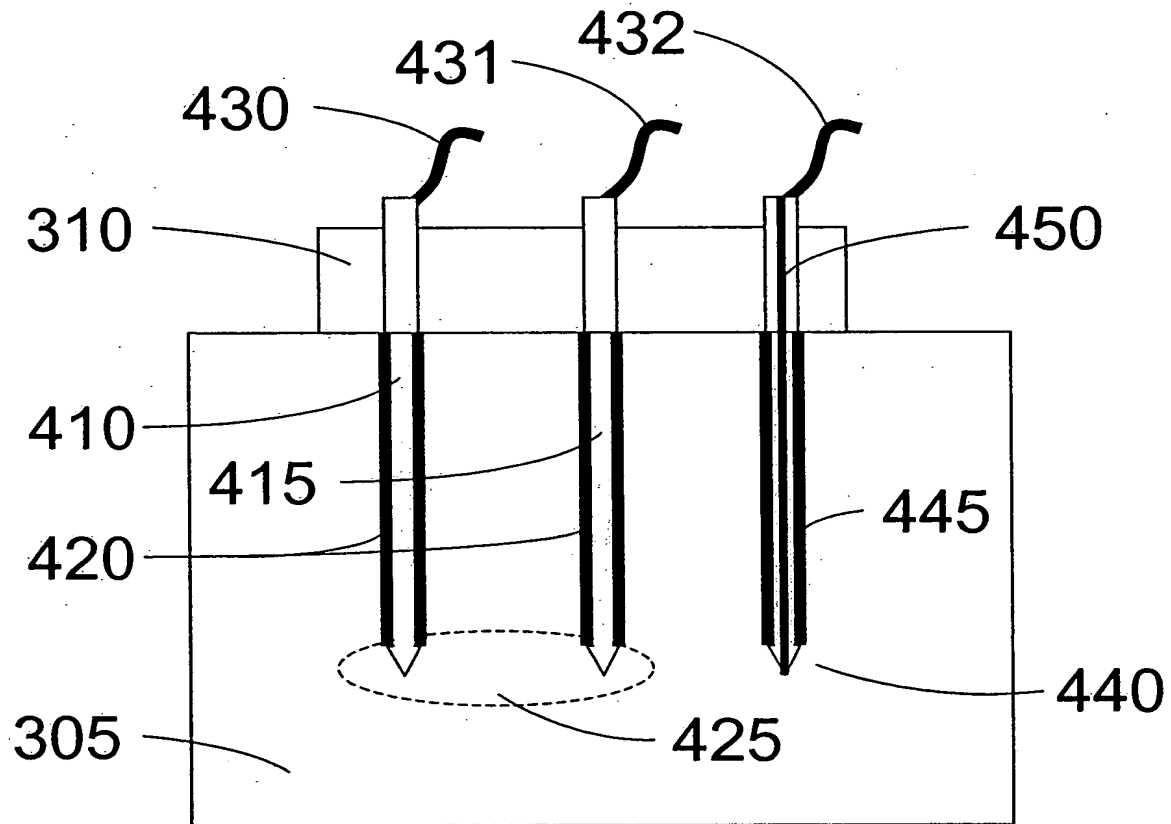


FIG. 4

DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

(Under 37 CFR § 1.63; includes reference to PCT International Applications)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention ENTITLED:

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT USING NEEDLE ARRAYS

the specification of which:

- ☒ is attached hereto
☒ was filed on 1 April 2005 as:
☒ United States Application Serial No. To Be Assigned
☐ which claims priority to U.S. Provisional Patent Application No. 60/558,476, filed 1 April 2004
☐ as a National Phase or Continuation or Continuation-in-Part or Divisional of
PCT Application No. _____, filed _____
and designating the U.S., and published as _____ on _____
☐ with amendments through _____ (if applicable, give details).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT International application(s) designating at least one country other than the United State of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT International applications designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) on which priority is claimed:

Prior Foreign/PCT Application(s) [list additional applications on separate page]:

<u>Country (or PCT)</u>	<u>Application Number:</u>	<u>Filed (Day/Month/Year)</u>	Priority Claimed:	
			<u>Yes</u>	<u>No</u>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States application listed below:

<u>60/558,476</u>	<u>1 April 2004</u>
(Application Number)	(Filing Date)

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S. (or U.S.-designating PCT) Application(s) [list additional applications on separate page]:

U.S. Serial No.: Filed (Day/Month/Year) PCT Application No. Status (patented, pending, abandoned)

I hereby appoint Thomas J. Kowalski, Registration No. 32,147, Steven P. Marsh, Registration No. 53,271 and Frommer Lawrence & Haug LLP, or their duly appointed associate, my attorneys, with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to file continuation and divisional applications thereof, to receive the Patent, and to transact all business in the Patent and Trademark Office and in the Courts in connection therewith, and to insert the Serial Number of the application in the space provided above, and specify that all communications about the application are to be directed to the following correspondence address:

Thomas J. Kowalski, Esq.
c/o FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151

Direct all telephone calls to: (212) 588-0800
to the attention of: Thomas J. Kowalski

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

INVENTOR(S):

Signature: _____	Date: _____
Full name of sole or first inventor: Dieter Manstein	
Residence: 4 Longfellow Place, Apt. 2005, Boston, MA 02114	
Citizenship: Germany	

PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 8, 2004

11098030

CLAIMS AS FILED - PART I

(Column 1) (Column 2)

TOTAL CLAIMS	19	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	19 minus 20=	* 0
INDEPENDENT CLAIMS	2 minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT <input type="checkbox"/>		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

(Column 1) (Column 2) (Column 3)

AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>				

(Column 1) (Column 2) (Column 3)

AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>				

(Column 1) (Column 2) (Column 3)

AMENDMENT C		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>				

SMALL ENTITY TYPE ☐

OR OTHER THAN SMALL ENTITY

RATE	FEE		RATE	FEE
BASIC FEE	150	OR	BASIC FEE	
X\$ 25=		OR	X\$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL	150	OR	TOTAL	

SMALL ENTITY

OR OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 25=		OR	X\$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 25=		OR	X\$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 25=		OR	X\$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."

***If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 8, 2004

11098030

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	19	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	19 minus 20 =	* 0
INDEPENDENT CLAIMS	2 minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT <input type="checkbox"/>		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	* 19	Minus **	=
Independent	* 2	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

- * If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
 - ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
 - *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
- The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

SMALL ENTITY TYPE ☐

OR OTHER THAN SMALL ENTITY

RATE	FEE		RATE	FEE
BASIC FEE	150	OR	BASIC FEE	
X\$ 25=		OR	X\$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL	150	OR	TOTAL	

SMALL ENTITY OR OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 25=	150	OR	X\$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE	150	OR	TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 25=		OR	X\$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 25=		OR	X\$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/098,030	04/01/2005	Dieter Manstein	910000-3080.1

CONFIRMATION NO. 6055

20999
 FROMMER LAWRENCE & HAUG
 745 FIFTH AVENUE- 10TH FL.
 NEW YORK, NY 10151

FORMALITIES LETTER



OC000000015853535

Date Mailed: 04/25/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

*Filing Date Granted***Items Required To Avoid Abandonment:**

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
Applicant must submit \$ 150 to complete the basic filing fee for a small entity.
- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(f) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$565** for a Small Entity

- **\$150** Statutory basic filing fee.
- **\$65** Late oath or declaration Surcharge.
- The application search fee has not been paid. Applicant must submit **\$250** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **\$100** to complete the examination fee for a small entity in compliance with 37 CFR 1.27

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

M - WAIVE

Office of Initial Patent Examination (703) 308-1202

PART 3 - OFFICE COPY

06-10-05

JFW



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/098,030	04/01/2005	Dieter Manstein	910000-3080.1

20999
 FROMMER LAWRENCE & HAUG
 745 FIFTH AVENUE- 10TH FL.
 NEW YORK, NY 10151



CONFIRMATION NO. 6055

FORMALITIES LETTER



OC000000015853535

Date Mailed: 04/25/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

*Filing Date Granted***Items Required To Avoid Abandonment:**

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

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Applicant must submit \$ 150 to complete the basic filing fee for a small entity.
- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(f) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

06/13/2005 BABRAHA1 00000080 11098030

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$565** for a Small Entity

01 FC:2011	150.00 OP
02 FC:2111	250.00 OP
03 FC:2311	100.00 OP
04 FC:2051	65.00 OP

- **\$150** Statutory basic filing fee.
- **\$65** Late oath or declaration Surcharge.
- The application search fee has not been paid. Applicant must submit **\$250** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **\$100** to complete the examination fee for a small entity in compliance with 37 CFR 1.27

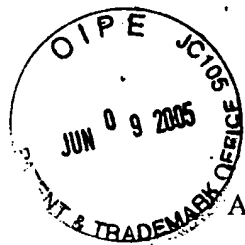
Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

*A copy of this notice **MUST** be returned with the reply.*

M-WAILE

Office of Initial Patent Examination (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE



PATENT
910000-3080.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Dieter Manstein
Serial No. : 11/098,030
For : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Filed : April 1, 2005
Examiner : To Be Assigned
Art Unit : 3739

745 Fifth Avenue
New York, NY 10151

EXPRESS MAIL

Mailing Label Number: *EV723363356US*

Date of Deposit: *June 9, 2005*

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Adam Ahmed
(Typed or printed name of person mailing paper or fee)

79C-0 831
(Signature of person mailing paper or fee)

RESPONSE TO NOTICE TO FILE MISSING PARTS

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Notice to File Missing Parts of Nonprovisional Application mailed April 25, 2005, setting a two-month term for reply. As this response is being filed prior to the end of the period for reply, it is believed that no extension fees are required. However, the Commissioner is hereby authorized to charge any necessary fee, or to credit any overpayment in fees, to Deposit Account 50-0-320.

The Notice to File Missing Parts of Nonprovisional Application required the submission of an executed declaration and the associated surcharge as well as the statutory

basic filing fee, application search fee and application examination fee. It is respectfully submitted that these requirements are satisfied by the enclosures herein.

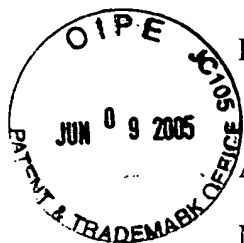
Enclosed is a Declaration for Patent Application and Power of Attorney executed by the inventor Dieter Manstein on April 20, 2005. In accordance with appointment paragraph in the Declaration for Patent Application and Power of Attorney, the filing date and the Serial Number of the application was inserted in the space provided on the Declaration to comply with the identification requirement of 37 C.F.R. § 1.63.

Also enclosed is a copy of the Notice to File Missing Parts of Nonprovisional Application and a check for \$565.00.

In view of the enclosures herein, it is respectfully submitted that the application now complies with all requirements set forth in the Notice. Reconsideration and withdrawal of the Notice to File Missing Parts of Nonprovisional Application is earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: Deborah L. Lu
Thomas J. Kowalski
Reg. No. 32,147
Deborah L. Lu
Reg. No. 50,940
Steven P. Marsh
Reg. No. 53,271
Tel. No. (212) 588-0800
Fax No. (212) 588-0500

**DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY**

(Under 37 CFR § 1.63; includes reference to PCT International Applications)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention ENTITLED:

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

the specification of which:

- ☐ is attached hereto
☒ was filed on 1 April 2005 as:
☒ United States Application Serial No. 11/098,030
☒ which claims priority to U.S. Provisional Patent Application No. 60/558,476, filed 1 April 2004
☐ as a National Phase or Continuation or Continuation-in-Part or Divisional of
 PCT Application No. _____, filed _____
 and designating the U.S., and published as _____ on _____
☐ with amendments through _____ (if applicable, give details).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT International application(s) designating at least one country other than the United State of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT International applications designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) on which priority is claimed:

Prior Foreign/PCT Application(s) [list additional applications on separate page]:

Country (or PCT)Application Number:Filed (Day/Month/Year)

Priority Claimed:

YesNo
☐
☐
☐
☐

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States application listed below:

60/558,476

(Application Number)

1 April 2004

(Filing Date)

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

FLH Docket No. 910000-3080.1

Prior U.S. (or U.S.-designating PCT) Application(s) [list additional applications on separate page]:

U.S. Serial No.: Filed (Day/Month/Year) PCT Application No. Status (patented, pending, abandoned)

I hereby appoint Thomas J. Kowalski, Registration No. 32,147, Steven P. Marsh, Registration No. 53,271 and Frommer Lawrence & Haug LLP, or their duly appointed associate, my attorneys, with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to file continuation and divisional applications thereof, to receive the Patent, and to transact all business in the Patent and Trademark Office and in the Courts in connection therewith, and to insert the Serial Number of the application in the space provided above, and specify that all communications about the application are to be directed to the following correspondence address:

Thomas J. Kowalski, Esq.
c/o FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151

Direct all telephone calls to: (212) 588-0800
to the attention of: Thomas J. Kowalski

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

INVENTOR(S):

Signature: 

Full name of sole or first inventor:

Dieter Manstein

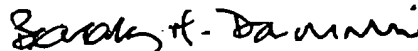
Residence:

4 Longfellow Place, Apt. 2005, Boston, MA 02114

Citizenship:

Germany

Date: 4/20/05

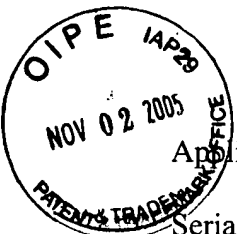

Beverly H. Dammin, Notary Public
Commonwealth of Massachusetts
My Commission Expires 6/30/2006



11-03-05

PATENT
910000-3080.1

Jfu



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Dieter Manstein et al.
Serial No. : 11/098,030
For : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT
Filed : April 1, 2005
Examiner : To Be Assigned
Art Unit : 3739

745 Fifth Avenue
New York, NY 10151

EXPRESS MAIL

Mailing Label Number: EV 713813585US

Date of Deposit: November 2, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to: **Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Charles Jackson
(Typed or printed name of person mailing paper or fee)

Charles Jackson
(Signature of person mailing paper or fee)

INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. §§ 1.97(b)(3) AND 1.98

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The Examiner's attention is respectfully drawn to the enclosed documents listed on the accompanying PTO Form 1449.

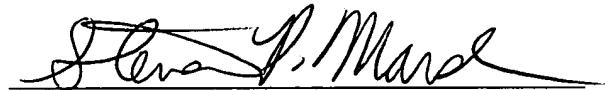
Pursuant to 37 CFR §1.97(b)(3), Applicants request the Examiner to consider this Information Disclosure Statement, and to make of record the documents cited on the accompanying PTO form 1449 and that a copy of Form PTO-1449 be initialed by the Examiner and returned to the undersigned.

The filing of this Information Disclosure Statement is not an admission that the documents identified herein constitute prior art to the present application.

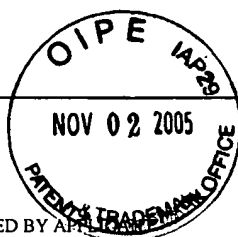
It is believed that no fees are required by the instant submission as it is prior to receipt of the first Office Action on the merits. However, if any fees are required, or if any overpayment has been made, please charge Deposit Acct. No. 50-0320.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By:



Thomas J. Kowalski
Reg. No. 32,147
Deborah L. Lu
Reg. No. 50,940
Steven P. Marsh
Reg. No. 53,271
Tel. No. (212) 588-0800
Fax No. (212) 588-0500

Based on Form PTO-1449
(3/90)LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY. DOCKET NO.

910000-3080.1

SERIAL NO.

11/098,030

APPLICANT

Manstein

FILING DATE

April 1, 2005

GROUP

3739

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,569,242	10/29/96	Lax et al.			
	AB	5,697,281	12/16/97	Eggers et al.			
	AC	5,755,753	05/26/98	Knowlton			
	AD	5,861,002	01/19/99	Desai			
	AE	5,919,219	07/06/99	Knowlton			
	AF	5,948,011	07/07/99	Knowlton			
	AG	6,277,116	08/21/01	Uteley et al.			
	AH	6,377,855	04/23/02	Knowlton			
	AI	6,405,090	06/11/02	Knowlton			
	AJ	6,723,092	04/20/04	Brown et al.			
	AK	6,749,624	06/15/04	Knowlton			
	AL	6,766,202	07/20/04	Underwood et al.			
	AM	2003/0130655	07/10/03	Woloszko et al.			
	AN	2003/0212394	11/13/03	Pearson et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
	AO	WO 04/086947	10/14/04	PCT			
	AP						

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AQ		Urney et al., "Percutaneous Electrode Guidance: A Noninvasive Technique For Prelocation of Peripheral nerves to Facilitate Peripheral Plexus or Nerve Block," Regional Anesthesia and Pain Medicine, vol. 27, no. 3, 2002, pp. 261-267.
	AR		Tschopp et al., "Comparison of Various Methods of Electromyographic Monitoring of the Recurrent Laryngeal Nerve in Thyroid Surgery," Ann. Otol. Rhinol. Laryngol., 111:2002, pp. 811-816.

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
14 October 2004 (14.10.2004)

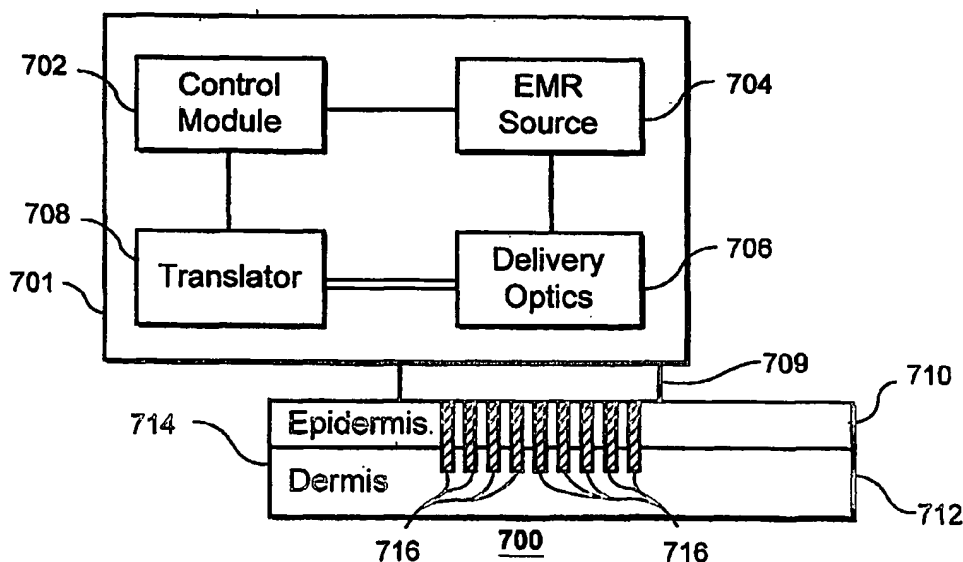
PCT

(10) International Publication Number
WO 2004/086947 A2

- (51) International Patent Classification⁷: **A61B** (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (21) International Application Number:
PCT/US2004/009452
- (22) International Filing Date: 25 March 2004 (25.03.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/458,770 27 March 2003 (27.03.2003) US
- (71) Applicant (for all designated States except US): THE GENERAL HOSPITAL CORPORATION [US/US]; 55 Fruit Street, Boston, MA 02114 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): MANSTEIN, Dieter [DE/US]; 1 Longfellow Place, #2624, Boston, MA 02114 (US). ANDERSON, Richard [US/US]; 399 Marrett Road, Lexington, MA 02421 (US).
- (74) Agent: ABELEV, Gary; Baker Botts L.L.P., 30 Rockefeller Plaza, New York, NY 10112-4498 (US).
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND FRACTIONAL SKIN RESURFACING



(57) Abstract: A system and method for performing fractional resurfacing of a target area of skin using electromagnetic radiation are provided. An electromagnetic radiation is generated by an electromagnetic radiation source. The electromagnetic radiation is caused to be applied to a particular portion of a target area of skin. The electromagnetic radiation can be impeded from affecting another portion of the target area of the skin by a mask. Alternatively, the electromagnetic radiation may be applied to portions of the target area of the skin, other than the particular portion.

BEST AVAILABLE COPY

WO 2004/086947 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND FRACTIONAL SKIN RESURFACING

SPECIFICATION

5 CROSS REFERENCE TO RELATED APPLICATIONS

The present application claims priority from U.S. Provisional Patent Application Serial No. 60/458,770 filed March 27, 2003, the entire disclosure of which is incorporated herein by reference.

10 BACKGROUND OF THE INVENTION

1. Field Of The Invention

The present invention relates to methods and apparatus that use electromagnetic radiation for dermatological treatment and, more particularly to a method and apparatus that use optical radiation to ablate or damage a target area of skin surface for dermatological treatment, which skin surface includes the epidermis and parts of the dermis as the objective or side effect of the desired treatment.

2. Background Art

There is an increasing demand for repair of or improvement to skin defects, which can be induced by aging, sun exposure, dermatological diseases, traumatic effects, and the like. Many treatments which use electromagnetic radiation have been used to improve skin defects by inducing a thermal injury to the skin, which results in a complex wound healing response of the skin. This leads to a biological repair of the injured skin.

Various techniques providing this objective have been introduced in recent years. The different techniques can be generally categorized in two groups of treatment modalities: ablative laser skin resurfacing ("LSR") and non-ablative collagen remodeling ("NCR"). The first group of treatment modalities, i.e., LSR, includes causing thermal damage to the epidermis and/or dermis, while the second group, i.e., NCR, is designed to spare thermal damage of the epidermis.

LSR with pulsed CO₂ or Er:YAG lasers, which may be referred to in the art as laser resurfacing or ablative resurfacing, is considered to be an effective treatment option for signs of photo aged skin, chronically aged skin, scars, superficial

pigmented lesions, stretch marks, and superficial skin lesions. However, patients may experience major drawbacks after each LSR treatment, including edema, oozing, and burning discomfort during first fourteen (14) days after treatment. These major drawbacks can be unacceptable for many patients. A further problem with LSR procedures is that the procedures are relatively painful and therefore generally require an application of a significant amount of analgesia. While LSR of relatively small areas can be performed under local anesthesia provided by injection of an anesthetic, LSR of relatively large areas is frequently performed under general anesthesia or after nerve blockade by multiple injections of anesthetic.

Any LSR treatment results in thermal skin damage to the treatment area of the skin surface, including the epidermis and/or the dermis. LSR treatment with pulsed CO₂ lasers is particularly aggressive, causing thermal skin damage to the epidermis and at least to the superficial dermis. Following LSR treatment using CO₂ lasers, a high incidence of complications can occur, including persistent erythema, hyperpigmentation, hypopigmentation, scarring, and infection (e.g., infection with Herpes simplex virus). LSR treatment with the Er:YAG laser has been introduced as a more gentle alternative to the CO₂ laser, due to the lesser penetration depth of the Er:YAG pulsed laser. Using the Er:YAG laser results in a thinner zone of thermal injury within the residual tissue of the target area of the skin. However, LSR that uses the Er:YAG laser produces side effects similar to those made by LSR that uses the CO₂ laser within the first days after treatment.

A limitation of LSR using CO₂ or Er:YAG lasers is that ablative laser resurfacing generally can not be performed on the patients with dark complexions. The removal of pigmented epidermis tissue can cause severe cosmetic disfigurement to patients with a dark complexion, which may last from several weeks up to years, which is considered by most patients and physicians to be unacceptable. Another limitation of LSR is that ablative resurfacing in areas other than the face generally have a greater risk of scarring. LSR procedures in areas other than the face result in an increased incidence of an unacceptable scar formation because the recovery from skin injury within these areas is not very effective.

In an attempt to overcome the problems associated with LSR procedures, a group of NCR techniques has emerged. These techniques are variously referred to in the art as non-ablative resurfacing, non-ablative subsurfacing, or non-ablative skin remodeling. NCR techniques generally utilize non-ablative lasers,

flashlamps, or radio frequency current to damage dermal tissue while sparing damage to the epidermal tissue. The concept behind NCR techniques is that the thermal damage of only the dermal tissues is thought to induce wound healing which results in a biological repair and a formation of new dermal collagen. This type of wound healing can result in a decrease of photoaging related structural damage. Avoiding epidermal damage in NCR techniques decreases the severity and duration of treatment related side effects. In particular, post procedural oozing, crusting, pigmentary changes and incidence of infections due to prolonged loss of the epidermal barrier function can usually be avoided by using the NCR techniques.

Various strategies are presently applied using nonablative lasers to achieve damage to the dermis while sparing the epidermis. Nonablative lasers used in NCR procedures have a deeper dermal penetration depth as compared to ablative lasers used in LSR procedures. Wavelengths in the near infrared spectrum can be used. These wavelengths cause the non-ablative laser to have a deeper penetration depth than the very superficially-absorbed ablative Er:YAG and CO₂ lasers. The dermal damage is achieved by a combination of proper wavelength and superficial skin cooling, or by focusing a laser into the dermis with a high numerical aperture optic in combination with superficial skin cooling. While it has been demonstrated that these techniques can assist in avoiding epidermal damage, one of the major drawbacks of these techniques is their limited efficacies. The improvement of photoaged skin or scars after the treatment with NCR techniques is significantly smaller than the improvements found when LSR ablative techniques are utilized. Even after multiple treatments, the clinical improvement is often far below the patient's expectations. In addition, clinical improvement is usually several months delayed after a series of treatment procedures.

Another limitation of NCR procedures relates to the breadth of acceptable treatment parameters for safe and effective treatment of dermatological disorders. The NCR procedures generally rely on an optimum coordination of laser energy and cooling parameters, which can result in an unwanted temperature profile within the skin leading to either no therapeutic effect or scar formation due to the overheating of a relatively large volume of the tissue.

Yet another problem of non-ablative procedures relates to the sparing of the epidermis. While sparing the epidermis is advantageous in order to decrease the side effects related to complete removal of the epidermis, several applications of

NCR procedures may benefit from at least partial removal of epidermal structures. For example, photoinduced skin aging manifests not only by the dermal alterations, but also by epidermal alterations.

A further problem of both ablative and nonablative resurfacing is that the role of keratinocytes in the wound healing response is not capitalized upon. Keratinocyte plays an active role in the wound healing response by releasing cytokines when the keratinocyte is damaged. During traditional ablative resurfacing procedures, the keratinocytes are removed from the skin along with the epidermis, thereby removing them from the healing process altogether. On the other hand, in traditional non-ablative procedures, the keratinocytes, which are located in the epidermis, are not damaged, therefore they do not release cytokines to aid in the healing process.

Another major problem with all LSR and NCR techniques now used is the appearance of visible spots and/or edges after treatment due to inflammation, pigmentation, or texture changes, corresponding to the sites of treatment. Devices for LSR and NCR produce macroscopic (easily seen) exposure areas. For example, laser exposure spot diameters typically vary from about 1 to 10 mm, and NCR exposure spot diameters from about 3 to 50 mm. Some devices, such as intense pulsed light devices, leave "boxes" of skin response due to rectangular output patterns on the skin. Patients do not like such spot or box patterns, easily seen as red, brown or white areas ranging from on the order of millimeters to centimeters in size, which remain for days or even years after treatment.

Therefore, there is a need to provide a procedure and apparatus that combine safe and effective treatment for improvement of dermatological disorders with minimum side effects, such as intra procedural discomfort, post procedural discomfort, lengthy healing time, and post procedural infection.

SUMMARY OF THE INVENTION

It is therefore one of the objects of the present invention to provide an apparatus and method that combines safe and effective treatment for an improvement of dermatological disorders with minimum side effects. Another object of the present invention is to provide an apparatus and method that cause thermal skin damage to only a fraction of a target area of skin.

These and other objects can be achieved with the exemplary embodiment of the apparatus and method according to the present invention, in which portions of a target area to be subjected to irradiation are masked. The exemplary apparatus can include at least one shielding member configured to mask at least one
5 portion of a target area of skin from electromagnetic radiation, in which the shielding members are formed such that a minimal amount of electromagnetic radiation is reflected back towards an electromagnetic radiation source.

In another advantageous embodiment of the present invention, electromagnetic radiation can be generated by an electromagnetic radiation source,
10 thus causing the electromagnetic radiation to be applied to a target area of the skin. At least one portion of the target area of the skin is then masked from the electromagnetic radiation using a mask.

In yet another advantageous embodiment of the present invention, an apparatus and method for treating dermatological conditions is provided. In
15 particular, a delivery module and translator are utilized. The delivery module is configured to direct electromagnetic radiation generated by an electromagnetic radiation source to a predetermined area within a target area of skin, wherein the predetermined area is located in a location relative to the delivery module, and wherein the electromagnetic radiation is adapted to cause thermal damage to
20 epidermal tissue and dermal tissue of the predetermined area within the target area of the skin. The translator is capable of moving the delivery module, such that the delivery module targets a plurality of spatially separated individual exposure areas of the predetermined area.

In a further advantageous embodiment of the present invention, the
25 electromagnetic radiation can be applied to a first individual exposure area of the target area of the skin. The electromagnetic radiation can then be applied to a second individual exposure area of the target area of the skin, which is separated from the first individual exposure area by a non-irradiated skin section.

30 BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention and its advantages, reference is now made to the following description, taken in conjunction with the accompanying drawings, in which:

Figs. 1A – 1C show progressive illustrations of a first exemplary embodiment of a fractional resurfacing system for conducting various dermatological treatments at various stages of use according to the present invention;

Fig. 2 shows a top view of a first exemplary embodiment of a mask
5 according to the present invention;

Fig. 3 shows a cross-sectional view of the mask of Fig. 2;

Fig. 4 shows a top view of a second exemplary embodiment of the mask according to the present invention;

Fig. 5 shows a cross-sectional view of the mask of Fig. 4;

10 Fig. 6 shows a cross-sectional view of another variant of the mask of Fig. 4;

Figs. 7A and 7B show progressive illustrations of a second exemplary embodiment of the fractional resurfacing system for conducting various dermatological treatments at various stages of use according to the present invention;

15 Fig. 8 shows a top view of small individual exposure areas created by the fractional resurfacing system of Figs. 7A and 7B; and

Fig. 9 shows an exemplary embodiment of a system for monitoring the location of the fractional resurfacing system of Figs. 7A and 7B.

Throughout the drawings, the same reference numerals and characters,
20 unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present invention will now be described in detail with reference to the Figures, it is done so in connection with the illustrative embodiments.

25 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figs. 1A – 9 illustrate various embodiments of a method and apparatus for fractional resurfacing of a target area of skin. Generally, the exemplary methods and apparatus deliver an electromagnetic radiation to the patient's skin defined by various patterns, so as to induce thermal injury of the skin surface corresponding to
30 such patterns and involving only a fraction of the targeted surface area of the skin. Such technique combines the efficacy of ablative resurfacing procedures with the minimal side effects of non-ablative procedures. The delivery of the electromagnetic radiation to the skin in a predetermined pattern is achieved by either masking parts of the target area of the skin surface in order to protect the masked parts of the skin

surface from the electromagnetic radiation, or by utilizing a light beam of relatively small diameter which is scanned across the skin surface by various means in order to generate a specific pattern for affecting superficial thermal skin injury.

Fractional resurfacing is defined as the controlled ablation, removal,
5 destruction, damage or stimulation of multiple small (generally less than 1 mm)
individual exposure areas of skin tissue with intervening spared areas of skin tissue,
performed as a treatment to improve the skin. The individual exposure areas may be
oval, circular, arced and/or linear in shape. The spatial scale of fractional resurfacing
is chosen to avoid the appearance of various spots or boxes on a macroscopic scale,
10 while still providing effective treatment because the multiple small areas can be
exposed to greater than a minimal stimulus. For example, removal or photothermal
destruction of thousands of 0.1 mm diameter individual exposure areas, spaced 0.2
mm apart, and extending into the skin up to a depth of 0.5 mm, is well tolerated and
produces effective improvement of photoaging, without apparent spots and with rapid
15 healing. Spared skin between the individual exposure areas rapidly initiates a wound
healing response, which is better tolerated than conventional LSR.

During the exemplary fractional resurfacing procedure of the present
invention, certain portions of the target area remain undamaged, thereby preserving
keratinocytes and melanocytes, which serve as a pool of undamaged cells to promote
20 reepithelialization. This procedure differs from the traditional resurfacing procedures,
such that the entirety of the target area is damaged. In traditional resurfacing
procedures, reepithelialization is generally initiated from the depth of an undamaged
follicular epithelium. Because the traditional procedures remove the entire
epithelium, an important factor for the time of reepithelialization is the density of
25 follicles. The vellus hair density of the face (439 hairs/cm^2) of the subject is
significantly higher than on the back of the subject (85 hairs/cm^2). Therefore, the face
of the subject, generally experiences better and faster reepithelialization in comparison
to other body areas with a lower hair density.

The resurfacing of the dark pigmented skin is currently not very
30 frequently performed because of the prolonged repigmentation process. The
fractional resurfacing technique improves the repigmentation process but,
melanocytes do not migrate well. By sparing certain portions of the target area of the
skin, the travel distance of melanocytes can be decreased, thereby reducing the
repigmentation time and allowing the resurfacing of all skin types.

Figs. 1A – 1C illustrate a progressive use of a first exemplary embodiment of a fractional resurfacing system 100 for conducting various dermatological treatments using electromagnetic radiation (“EMR”) and generating a superficial pattern of skin damage of a target area by using a mask according to the present invention. The system 100 may be used for collagen remodeling, removal of unwanted pigment or tattoo, and/or other dermatological applications. As shown in Figs. 1A-1C, the system 100 includes a case 101, a control module 102, an EMR source 104, delivery optics 106 and a mask 108. The case 101 contains the control module 102, the EMR source 104, and the delivery optics 106. An aperture is provided through a sidewall of the case 101. The mask 108 is placed in registration with the aperture formed through the sidewall of the case 101. By placing the mask 108 in registration with the aperture of the case 101, the focal length of the EMR emitted by the delivery optics 106 is fixed, and can be configured such that it does not impact the side of the mask 108, so as to cause injuries to the operator of the fractional ablation system 100. The control module 102 is in communication with the EMR source 104, which in turn is operatively connected to the delivery optics 106.

In one exemplary variant of the present invention, the control module 102 can be in wireless communication with the EMR source 104. In another variant, the control module 102 may be in wired communication with the EMR source 104. In another exemplary variant of the present invention, the control module 102 can be located outside of the case 101. In another variant, the EMR source 104 is located outside of the case 101. In still another variant, the control module 102 and the EMR source 104 are located outside of the case 101. It is also possible that the mask 108 is not connected to the case 101.

The control module 102 provides application specific settings to the EMR source 104. The EMR source 104 receives these settings, and generates EMR based on these settings. The settings can control the wavelength of the EMR, the energy delivered to the skin, the power delivered to the skin, the pulse duration for each EMR pulse, the fluence of the EMR delivered to the skin, the number of EMR pulses, the delay between individual EMR pulses, the beam profile of the EMR, and the size of the area within the mask exposed to EMR. The energy produced by the EMR source 104 can be an optical radiation, which is focused, collimated and/or directed by the delivery optics 106 to the mask 108. The mask 108 can be placed on a target area of a patient’s skin, and may provide a damage pattern on the target area of

the skin with a fill factor in the range from 0.1% to 90%. The fill factor is the percentage of the target area exposed to the EMR that is emitted by the EMR source 106.

In one exemplary embodiment, the EMR source 106 is one of a laser, a flashlamp, a tungsten lamp, a diode, a diode array, and the like. In another exemplary embodiment, the EMR source 106 is one of a CO₂ laser and a Er:YAG laser.

Prior to being used in a dermatological treatment, the system 100 shown in Fig. 1A can be configured by a user. For example, the user may interface with the control module 102 in order to specify the specific settings usable for a particular procedure. The user may specify the wavelength of the EMR, the energy delivered to the skin, the power delivered to the skin, the pulse duration for each EMR pulse, the fluence of the EMR delivered to the skin, the number of EMR pulses, the delay between individual EMR pulses, the beam profile of the EMR, and the size of the area within the mask exposed to EMR. The EMR source 104 may be set to produce a collimated pulsed EMR irradiation with a wavelength ranging from 400 to 11,000 nm, and preferably near 3.0 μm when using an Er:YAG laser and near 10.6 μm when using a CO₂ laser as the EMR source. The collimated pulsed EMR irradiation may be applied which has a pulse duration in the range of 1 μs to 10 s, preferably in the range of 100 μs to 100 ms, and more preferably in the range of 0.1 ms to 10 ms, and fluence in the range from 0.01 to 100 J/cm², and preferably in the range from 1 to 10 J/cm². The applied EMR should be able to achieve at least a temperature rise within the exposed areas of the skin that is sufficient to cause thermal damage to the epidermis 110 and/or the dermis 112. The peak temperature sufficient to cause thermal damage in the exposed tissues is time dependant and at least in the range of 45° C to 100° C. For exposure times in the range of 0.1 ms to 10 ms the minimum temperature rise required to cause thermal damage is in the range of approximately 60° C to 100° C. The depth of thermal damage can be adjusted by proper choice of wavelength, fluence per pulse and number of pulses.

During the dermatological treatment, the system 100 produces EMR 120 which is directed to the target area of the skin 114, as shown in Fig. 1B. The EMR 120 may be pulsed multiple times to create the appropriate affect and irradiation in the target area of the skin 114.

After the dermatological treatment is completed, the target area of the skin 114 is likely damaged in specific places. The application of the EMR 120 creates a prearranged thermal skin damage 130 in an epidermal tissue 110 and the dermal tissue 112. It should be noted that the thermal skin damage 130 extends through the epidermal tissue 110 and into the dermal tissue 112 only to a predetermined depth. The mask 108 controls in a location where the thermal skin damage 130 is created. The thermal skin damage 130 generally accounts for only 0.1% to 90% of the skin surface area in the target area. A fill factor is defined as the ratio of surface area of the target area of skin thermally damaged by EMR to surface area of the target area of the skin.

In an exemplary embodiment of the present invention, the thermal skin damage 130 may extend through the epidermal tissue 110 and through the entirety of the dermal tissue 112. In another exemplary embodiment of the present invention, the thermal skin damage 130 may occur principally in the dermal tissue 112 and minor skin damage may occur in the epidermal tissue 110. It should be noted that it is possible that the penetration depths of each of the micro areas of the thermal skin damage 130 may be different from one another or same as one another. This may be because pigment removal or dermal removal can be separately regulated by varying the density of the micro-damaged areas for either the deeper or superficial damages, e.g., dermal remodeling and pigment adjustment, respectively.

Fig. 2 illustrates a top view of a first exemplary embodiment of the mask 108 according to the present invention. The mask 108 includes shielding structured 202. The diameter of the mask 108 should preferably be matched to greater than the size of the diameter of the target area. The target area is defined as the area targeted by the collimated EMR emitted by the EMR source 104, which can be in the range 1 - 100 mm in diameter, preferably within the range of 5 to 20 mm. This diameter of most of the currently commercially available CO₂ and Er:YAG laser systems can match the diameter of the exposed area. The width of shielding structures 202 within the mask 108 should be in the range of 50 to 300 μ m. The width of the apertures of the mask 108 that are formed by the shielding structures should be in the range of 10 - 1000 μ m, and preferably in the range of 50 to 300 μ m. The shielding-exposure ratio surface area covered by the of shielding structures 202 to the surface area exposed by the apertures effects the clinical efficacy and provides

side effects of the dermatological treatment. This also determines the fill factor and the pattern of the thermal damage of the skin. The depth of thermal damage is determined by the number of pulses, the fluence of the EMR and the wavelength of the EMR. The shielding-exposure ratio of the mask 108 will vary for different
5 dermatological treatments, particular patient needs, particular patient indications, skin types and body areas.

The mask 108 may have a large shielding-exposure ratio at the edge of the mask 108 to generate a transition zone at the edge of resurfaced area. This technique is called "feathering." It avoids a sharp macroscopically visible
10 demarcation between treated and untreated areas. In another preferred embodiment, a mask may be used that has a large shielding-exposure ratio at the edge of a conventionally resurfaced area to generate a transition zone.

The surface of the mask 108 should preferably have a minimal absorption at the wavelength generated by the EMR source 104 for the particular
15 dermatological process. Such absorption can decrease the undesirable heating of the mask 108. The mask 108 may be coated by a metal material for affectuating a minimal absorption of the EMR. The design of the shielding structures 202 of the mask 108, a cross-section A-A of which is shown in Fig. 3; generally takes into consideration safety aspects, including a back-reflected EMR in order to avoid EMR
20 inflicted accidents. The shielding structures 202 are shaped in a peaked manner to minimize the amount of back reflected EMR. Also, with the mask 108 being connected to the case 101 the distance between the delivery optics 106 and the mask 108 is fixed, thereby minimizing the chances that EMR would be reflected back towards the user by hitting the edge of the mask 108. Additionally, the microstructure
25 of the mask 108 can have a periodicity preferably in the range of the wavelength of the EMR emitted by the delivery optics 106. This configuration can diffuse the collimated EMR emitted by the delivery optics 106 into a highly scattered beam so as to decrease the risk of EMR-related accidents.

In one exemplary embodiment, the metal coating of the mask 108 may
30 be composed of gold, silver, or copper materials, or the like. In another exemplary embodiment, the microstructure of the surface of the mask 108 may have a periodicity in the range of the wavelength of the EMR emitted by the delivery optics 106.

The mask 108 may also have a configuration so as to provide effective skin cooling during the exposure thereof with the EMR radiation. Skin cooling

provides significant anesthetic effects, and has other advantages related to the pattern induced by the EMR radiation. The mask 108 can be cooled prior to the beginning of the dermatological procedure, during the procedure by spraying an evaporative agent or a precooled liquid onto the mask 108 between the successive EMR pulses, or
5 during the procedure by introducing a cool or cold liquid into microchannels 302 (shown in Fig. 3) running through the mask 108. The cooling of the mask 108 has a secondary advantage in that such cooling of the mask 108 decreases the rate of the EMR absorption by the mask 108, as the rate of the EMR absorption by the metals increases with the increasing temperature.

10 In order to provide skin cooling as described above, the temperature of the mask 108 should be in the range of 37° C to -20° C, and preferably 10° C to -4° C. The mask 108 can both protect and cool the portions of the skin surface that are not exposed to EMR emitted by the EMR source 104. In addition to cooling and shielding portions of the skin surface, the mask 108 allows the debris ejected during
15 ablative procedures to escape, and thereby not interfere with the beam delivery for successive pulses. For example, the areas that are not exposed to the laser are being cooled by the mask 108, i.e., the areas that are provided between the affected areas. In another exemplary embodiment, all areas (i.e., both the affected and nonaffected areas) are cooled to provide anesthesia, and to reduce over-damaging the superficial
20 levels of the damaged areas.

Fig. 3 illustrates a cross-section A-A of the mask 108 of Fig. 2. The cross-section A-A shows the microchannels 302 that run through at least the shielding structures 202 of the mask 108. A cooling agent, e.g., either a liquid or gas, may circulate through these microchannels 302 during a dermatological procedure, thereby
25 removing heat from the protected skin and the mask 108 itself.

Fig. 4 illustrates a top view of a second embodiment of the mask 400 according to the present invention. The mask 400 differs from the mask 108 only in the layout and design of the shielding structures 402. The details of the mask 400 are in all other respects substantially similar to those of the mask 108. The shielding
30 structures 402 are cylindrical in shape, as indicated in cut-away cross-sections B-B and C-C, shown in Figs. 5 and 6, respectively. The shielding structures 402 of the mask 400 contain microchannels 502 and 602, which are capable of carrying a cooled liquid or gas so as to cool the mask 400 and the masked portions of the target area of

the skin. The microchannels 502, 602 intersect at the intersection of the shielding structures 402.

In an exemplary embodiment of the present invention, the microstructures 502, 602 are not required to intersect at the intersection of the shielding structures 402.

In an exemplary embodiment of the present invention, the mask 108 is an ablative mask. An ablative mask includes multiple sections having various thicknesses. Prior to a procedure, the ablative mask is attached to the skin with an adhesive. During the procedure having multiple EMR pulses, the ablative mask is ablated, such that the thickness of each of the multiple sections is diminished, potentially gradually exposing different areas of the skin to the EMR pulses. The ablative mask can be composed of various materials including polymer materials. The ablative mask can be easily produced by imprinting a pattern therein.

A particular dermatological treatment, i.e., the removal of tattoos, shall be described in further detail. Tattoo removal may be performed with a combination of an ablative EMR and the mask 108. In particular, utilizing the CO₂ laser and/or the Er:YAG laser may be appropriate for this application. During this dermatological procedure, the tattoo can be exposed to ablative EMR radiation with the mask 108 providing a fill factor of the target area in the range of 10 to 90%, and preferably in the range of 25 to 70%. Preferably, the mask 108 is applied under pressure to the skin, which minimizes the blood flow during the procedure. Limiting the blood flow during the procedure allows a deeper ablation of the skin surface before blood can interfere with the EMR radiation, thereby limiting the ablation depth. Multiple pulses of ablative EMR radiation can be applied to the individual areas of the tattoo until the desired ablation depth is reached. The desired ablation depth can be in the range of 100 μ m to 5 mm. This exemplary procedure can cause a specific fraction of the tattoo that is controlled by the mask 108 to be immediately ablated. Wound healing may be enhanced because only a fraction of the surface is ablated.

The removal of tattoos utilizing fractional resurfacing may be augmented using a short pulsed EMR, preferentially absorbed by the tattoo particles either before or after the application of the fractional resurfacing. In a short pulsed-laser application, the laser may be pulsed for short periods of time, preferably for less than 1 μ s in duration. The EMR source used in this type of procedure can preferably be a Q-switched ruby laser, a Nd:YAG laser, a KTP laser and/or an Alexandrite laser.

The objective of this procedure is to release the pigment within areas that are not exposed to fractional resurfacing ablation. The released pigment particles may drain in the ablated channels, and can be flushed from the area after the procedure by the blood resident in the target area and/or an external rinsing agent, e.g., saline. Several
5 such procedures may be utilized until the desired clearance of the tattoo has occurred.

As an alternative to the fractional resurfacing using a mask, a second embodiment of a fractional resurfacing system 700, as shown as the progressive use thereof in Figs. 7A – 7B, can be used. The system 700 can include a case 701, a control module 702, an electromagnetic radiation (“EMR”) source 704, delivery
10 optics 706, an x-y translator 708 and an optically transparent plate 709. The case 701 may contain the control module 702, the EMR source 704, the delivery optics 706 and the translator 708. As with the system 100, an aperture may be formed through a sidewall of the case 701. The optically transparent plate 709 may be placed in registration with the aperture that is formed through the sidewall of the case 701.
15 Placing the plate 709 in registration with the aperture formed through the sidewall of the case 701 seals the system 700, which contains sophisticated translation mechanisms, e.g., the delivery optics 706 and the translator 708. The control module 702 is in communication with the translator 708 and the EMR source 704, and the EMR source 704 is operatively connected to the delivery optics 706.

20 In one exemplary variant of the present invention, the control module 702 can be located outside of the case 701. In another exemplary variant, the EMR source 704 is located outside of the case 701. In still another variant, the control module 702 and the EMR source 704 are located outside of the case 701.

The control module 702 provides application specific settings to the
25 EMR source 704, and controls the x-y translator 708. The EMR source 704 receives these settings, and generates EMR based on these settings. The settings can control the wavelength of the energy produced, the intensity of the energy produced, the fluence of the energy produced, the duration of the dermatological procedure, the pulse length of each of the EMR pulses administered during the procedure, the spatial
30 distance between individual exposure areas 716 (shown in Fig. 8), the shape of individual exposure areas 716, the pattern defined by individual exposure areas 716, and the fill factor of the target area. It should be noted that the thermal skin damage caused to individual exposure areas 716 extends through the epidermal tissue 710 and into the dermal tissue 712 only to a predetermined depth. The EMR source 704 can

be a laser or other light source. The EMR produced by the EMR source 704 can be delivered through a fiber, waveguide or mirrors if the source is located outside the delivery optics 706. Alternatively, if the EMR source 704 is located in a close vicinity to the skin 714, the EMR source 704 produces the EMR directly to the
5 delivery optics 706. The energy produced by the EMR source 704 may be focused and/or directed by focusing optics in the delivery optics 706 to one of the an individual exposure areas 716, shown in Fig. 8. Each of the individual exposure areas 716 are located within the target area of the skin 714, and are relatively small compared to the target area of the skin 714. The target area of the skin 714 can
10 generally be 1 cm^2 in size and each of the individual exposure areas 716 may be $100\text{ }\mu\text{m}$ in diameter.

In an exemplary embodiment of the present invention, the optics of the delivery optics 706 may contain a beam collimator or focusing optics. In another exemplary embodiment of the present invention, the thermal skin damage caused to
15 individual exposure areas 716 may extend through the epidermal tissue 710 and through the entirety of the dermal tissue 712. In another exemplary embodiment of the present invention, the thermal skin damage caused to individual exposure areas 716 may principally occur in the dermal tissue 712 and only minor thermal damage may occur in the epidermal tissue 710. It should be noted that it is possible that the
20 penetration depths of each of the micro areas of the thermal skin damage caused to individual exposure areas 716 may be different from one another or same as one another. This may be because pigment removal or dermal removal can be separately regulated by varying the density of the micro-damaged areas for either the deeper or superficial damages, e.g., dermal remodeling and pigment adjustment, respectively.
25 In a further exemplary embodiment of the present invention, the predetermined depth of the thermal skin damage caused to individual exposure areas 716 is approximately $300\text{ }\mu\text{m}$.

Prior to use in a dermatological treatment and similarly to the use of system 100, the system 700, as shown in Fig. 7A, can be configured by a user. In
30 particular, the user interfaces with the control module 702 in order to specify the specific settings to be used for a particular procedure. The user may specify the desired damage pattern, the wavelength of the energy produced by the EMR source 704, the intensity of the energy produced, the fluence of the energy produced, the length of time the treatment will take and the pulse duration of the EMR source 704.

During the treatment, the translator 708 moves the delivery optics 706 across sequential portions of the target area of the skin 714 in order to treat the entire target area. The target area is treated when the system 700 delivers EMR to individual exposure areas 716 of the target area. The individual exposure areas 716 may be
5 targeted serially and/or in parallel. When one of the portions of the target area has been completely treated, the system 700 is moved to the next portion of the target area. For example, the system 700 is moved at the completion of irradiation of each portion of the target area until the desired skin surface damage pattern is achieved for the entire area. The system 700 can be moved using discrete movements from one
10 sequential portion to the next, i.e., stamping mode, or using continuous movement across the skin surface, i.e., continuous scanning mode. In either case, the movement of the delivery optics 706, driven by the translator 708, is controlled by the control unit 702 and likely matched with the movement of the system 700 by the operator (or the user) in order to provide the desired surface damage pattern to the target area of
15 the skin 714.

In an exemplary embodiment of the present invention, the system 700, while operating in the continuous scanning mode, can deliver EMR to a particular individual exposure area 716, then, after exposure of such area 716, translate along the skin of the target area, and thereafter deliver a further EMR to another individual
20 exposure area 716 separated from the previous particular individual exposure area 716 by non-irradiated region. In another exemplary embodiment of the present invention, the system 700, while operating in the continuous scanning mode, can deliver EMR to a particular group of individual exposure areas 716, for example the top row of individual exposure areas 716 (shown in Fig. 8), then, after exposure of such areas
25 716, translate along the skin of the target area, and deliver a further EMR to another group of individual exposure areas 716, for example the second row of individual exposure areas 716 (shown in Fig. 8), separated from the particular group of individual exposure areas 716 by non-irradiated areas.

In an exemplary embodiment of the present invention, the system 700
30 includes a position sensor, which is in communication with the control module 702. The position sensor is capable of sensing the relative velocity as between the skin 114 and the case 701. The position sensor can be an optical mouse, wheels, track ball, conventional mouse, and the like.

In another exemplary embodiment of the present invention, the system 700 targets individual exposure areas 716 one at a time. Administering EMR to the individual exposure areas 716 one at a time decreases the amount of pain experienced by the subject. A time period of 50 milliseconds may be provided between each administration of EMR to each of the individual exposure areas 716. Thereby controlling the amount of pain experienced by the subject and avoiding bulk heating of the tissue targeted by the system 700. In still another exemplary embodiment of the present invention, the system 700 targets a predetermined number of individual exposure areas 716 at a time. Limiting the number of predetermined target areas 716 targeted at one time limits the amount of pain experienced by a patient. Targeting a large number of individual exposure areas 716 at one time requires targeting a collectively large area of skin, which excites many nerve endings simultaneously, therefore causing the subject a proportionally large amount of pain. Targeting fewer individual exposure areas 716 causes a subject less pain, but causes a procedure to take longer.

In a further exemplary embodiment of the present invention, the system 700 creates individual exposure areas 716 having a separation distance between each of the individual exposure areas 716 of approximately at least 125 μm and at most 500 μm , preferably, the separation distance is approximately at least 250 μm .

Before the initiation of a dermatological procedure, the optically transparent plate 709 can be brought in a direct contact with the skin surface covering the target area. The optically transparent plate 709 can be composed out of any material having good thermal conductivity, and being transparent over a broad range of the visible and near infrared spectrum. The plate 709 seals the system 700, which contains sophisticated translation mechanisms, and provides cooling to the target area of the skin 714. The plate 709 can provide cooling to the target area of the skin 714 in two ways: heat conduction and heat convection. Heat conduction transfers heat through the optically transparent plate 709 to the case 701, which provides cooling by circulating a coolant agent through the case 701 of the system 700. The entire optically transparent place 709 can also be cooled prior to application to the target area of the skin 714. Alternatively, heat convection can be utilized for this procedure. An evaporating agent sprayed onto the optical window or onto a compartment in good thermal contact with the window may also be utilized. The delivery of the

evaporating agent can be administered during the procedure between EMR pulses through a valve, which can be controlled by a thermostat with a temperature sensor at the optical plate.

In one embodiment, of the present invention the optically transparent plate 709 can be composed of sapphire or quartz. In another embodiment of the present invention, the system 700 can be moved multiple times over the same portion of the skin 714 until the desired fill factor is achieved. In yet another embodiment, multiple procedures can be performed to achieve the desired effect.

During the dermatological procedure, the EMR source 704 emits EMR having a wavelength in the range of 400 - 12,000 nm. Preferably the EMR has a wavelength in one of the following ranges: 1,300 to 1,600 nm, 1,850 to 2,100 nm, 2,300 to 3,100 nm and around 10,640 nm. Depending on the application, a single wavelength or a combination of different wavelengths may be utilized. The EMR source 704 can be a diode laser, a fiber laser, a solid state laser, a gas laser, and the like. The pulse duration can range from 100 μ s to 100 ms, and preferably in the range from 500 μ s to 15 ms, and more preferably in the range from 1.5 ms to 5 ms. The energy density per pulse within an individual exposure area 716 may be in the range of 0.1 to 100J/cm², preferably 1 to 32 J/cm², and more preferably 1.5 to 3 J/cm². The energy per pulse within an individual exposure area 716 may be in the range of 1 mJ and 10 mJ, and preferably 5 mJ.

In an exemplary embodiment of the present invention, the EMR source 704 is a 1.5 μ m laser system, preferably a Reliant FSR prototype, manufactured by Reliant Technologies, Palo Alto, CA, is used.

After the dermatological treatment is completed, the target area of the skin 714 is damaged in a specific pattern. The application of EMR creates the thermal skin damage in an epidermis 710 and a dermis 712 of the skin 714. The radiation provided by the EMR source 704 is delivered to the skin 714 within multiple small individual exposure areas 716, shown in Fig. 7B, through the delivery optics 706. The delivery optics 706 can deliver multiple individual beams across the target area of the skin surface.

Fig. 8 illustrates a top view of the small individual exposure areas 716 of the epidermis. The shape of the individual exposure areas 716 may be circular (shown in Fig. 8), elliptical, rectangular, linear or irregular with a lateral diameter of

the smallest dimension in the range of 1 – 500 μm . The fill factor of the target area can be approximately 20 – 40%.

The system 700 can create multiple individual exposure areas 716 through heating, ablation, removal, photothermal coagulation, thermal necrosis and/or stimulation. The multiple areas can be exposed sequentially or simultaneously. Sequential exposure may be achieved by scanning or moving an energy source which may be either pulsed, shuttered or continuous. Simultaneous exposure can be achieved, for example, by an array of sources or a multi-array of lenses. The array of sources may be a uni-dimensional array, a bi-dimensional array or the like. The array can be moved relative to the skin, and one or multiple passes of treatment can be performed in a target area.

Fig. 9 illustrates an exemplary embodiment of a monitoring system 900 according to the present invention. The monitoring system 900 tracks the movement of the system 700, and feeds such positional information to the control module 702. The control module 702 utilizes this information to appropriately instruct the translator 708 to position the delivery optics 706, such that the appropriate damage pattern is achieved across the target area of the skin 714. The monitoring system 900 may use a computer 902, a mouse 904, and a charge coupled device (“CCD”) camera 906. In particular, the computer 902 receives the positional information about the system 700 from the CCD camera 906. The computer then updates the control module 702 based on this positional information as to the current position of the system 700. The control module 702 utilizes this information to cause the system 700 to create the appropriate damage pattern on the skin 714 within the target area. In addition, the monitoring system can utilize additional motion detecting devices, including, wheels or any other motion sensor.

The shape of the individual exposure areas 716 and the relative pattern represented by all of the individual exposure areas 716 may vary. The individual exposure areas 716 can have a circular, elliptical, rectangular, linear or irregular shape. The average distance between individual regions of unexposed skin surface may be in the range between 10 to 2000 μm , and preferably in the range of 100 to 500 μm . The macroscopic pattern of the individual exposure areas 716 may be a field of uniformly distributed individual exposure areas 716 with constant spacing throughout the target area, randomly distributed individual exposure areas 716 within the target area, and/or regularly distributed individual exposure areas 716 with constant average

spacing with randomly shifted location. In particular, having regularly distributed individual exposure areas 716 with constant average spacing with randomly shifted location may be useful to minimize undesirable effects, which may occur during multiple treatments. Such multiple treatments are utilized to cover the entire area as
5 homogeneously as possible by the individual exposure areas 716 during the course of multiple treatments. However, uniformly distributed individual exposure areas 716 with constant spacing throughout the target area may create unwanted spatial distributions similar to moiré patterns, resulting in spatial interference macroscopic patterns generated with a distance in between the areas of exposure which have a
10 significant spatial period. In order to minimize the occurrence of moiré patterns, a randomized shift within the range of 10 to 50% of the average distance between individual exposure areas 716 during a single scan may be utilized.

The treatment can be performed in by a single treatment covering the skin surface with a specific surface damage pattern, or by multiple treatments either
15 performed at the same visit or during different treatment visits. Individual or multiple exposures can be used to achieve the appropriate thermal damage in particular individual exposure areas 716.

Fractional resurfacing may cause portions of the epidermis to be thermally damaged or ablated, thereby reducing the efficacy of the barrier function of
20 the epidermis and in particular decreasing the stratum corneum. This facilitates the delivery of drugs or specific substances to the dermis and epidermis which can either enhance the effects of the treatment, or decrease the side effects caused by partial damage of the epidermis and/or dermis. Groups of drugs and substances, which may enhance the efficacy of skin remodeling include growth factors, collagen byproducts,
25 collagen precursors, hyaluronic acid, vitamins, antioxidants, amino acids and supplemental minerals among others. Groups of drugs and substances, which may decrease side effects, can be steroidal anti-inflammatory drugs, non-steroidal anti-inflammatory drugs, antioxidants, antibiotics, antiviral drugs, antiyeast drugs and antifungal drugs.

30 In an exemplary embodiment of the present invention, the vitamins that are used may be vitamin C and/or vitamin E. The supplemental minerals used are copper and zinc. The antioxidants can be vitamin C and/or vitamin E.

In a clinical observation, enhanced wound healing was observed for fractional resurfacing as compared to conventional resurfacing. The forearm skin of a

white, male Caucasian was exposed to pulsed CO₂ laser radiation with identical settings of the illuminating laser beam with a beam diameter of approximately 3 mm, a Coherent Ultra Pulse Laser, CPG handpiece, at approximately 300mJ/pulse. One area was exposed to the laser beam without benefit of a mask while another area was partially shielded by a cooled mask. More pronounced erythema was evident at the conventionally resurfaced test site as compared to the fractionally resurfaced test site.

The fill factor of the target area may be monitored by sensing the electrical impedance of the skin from a location on the skin within the target area to a remote location on the skin outside of the target area during or after treatment. An indicator capable of staining the defects in the stratum corneum (for example, trypan glue) or transdermal waterloss are effective indicators of the fill factor of the target area.

The foregoing merely illustrates the principles of the invention. Various modifications and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. It will thus be appreciated that those skilled in the art will be able to devise numerous techniques which, although not explicitly described herein, embody the principles of the invention and are thus within the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An apparatus, comprising:
at least one member configured to mask at least one portion of a target area of skin from an electromagnetic radiation provided by an electromagnetic radiation
5 source, wherein at least one member is configured such that a particular amount of the electromagnetic radiation that impacts the at least one member is reflected in a direction of the electromagnetic radiation source.
2. The apparatus of claim 1, wherein the target area is a predetermined area of the skin.
- 10 3. The apparatus of claim 1, wherein each of the at least one shielding member is configured to reflect the impacted electromagnetic radiation away from the apparatus.
4. The apparatus of claim 1, wherein each of the at least one shielding member is configured to absorb a minimal amount of electromagnetic radiation.
5. The apparatus of claim 1, wherein the electromagnetic radiation is optical
15 radiation.
6. The apparatus of claim 1, wherein the electromagnetic radiation source is an ablative laser.
7. The apparatus of claim 1, wherein the electromagnetic radiation source is generated by a carbon dioxide laser.
- 20 8. The filtering apparatus of claim 1, wherein the electromagnetic radiation source is an Er:YAG laser.
9. The apparatus of claim 1, wherein the at least one shielding member masks at least 0.1% of the target area from the electromagnetic radiation.
10. The apparatus of claim 1, wherein the at least one member masks at most 90%
25 of the target area from the electromagnetic radiation.
11. The apparatus of claim 1, wherein the at least one member masks the at least one portion of the target area such that the electromagnetic radiation is prevented

from affecting the at least one portion of the target area.

12. The apparatus of claim 1, wherein the at least one member is at least 50 μm in width and at most 300 μm .

13. The apparatus of claim 1, wherein the at least one member is configured to
5 define at least one aperture.

14. The apparatus of claim 13, wherein the at least one aperture has a width of at least 50 μm and at most 1000 μm .

15. The apparatus of claim 1, wherein the at least one member is cooled.

16. The apparatus of claim 1, wherein the at least one member is adapted to be
10 cooled to at least 37°C and at most negative 20°C .

17. The apparatus of claim 1, wherein the at least one member includes at least one channel extending therethrough.

18. The apparatus of claim 17, wherein the at least one channel is configured to facilitate a cooling agent.

15 19. A method for treating dermatological conditions, comprising:
controlling an electromagnetic radiation source to generate an electromagnetic radiation;
causing the electromagnetic radiation to be applied to a target area of skin; and
masking at least one portion of the target area of the skin from the
20 electromagnetic radiation.

20. The method of claim 19, wherein the masking step is performed using a mask which includes at least one member.

21. The method of claim 20, wherein the at least one shielding member masks at least 0.1% of the target area from the electromagnetic radiation.

25 22. The method of claim 20, wherein the at least one member masks at most 90% of the target area from the electromagnetic radiation.

23. The method of claim 20, wherein the at least one member masks the at least

one portion of the target area such that the electromagnetic radiation is prevented from affecting the at least one portion of the target area.

24. The method of claim 20, wherein the at least one member masks the at least one portion of the target area such that the electromagnetic radiation has an affect on
5 the at least one portion than an affect to other portions of the target area.

25. The method of claim 20, wherein the at least one member is at least 50 μm in width and at most 300 μm .

26. The method of claim 20, wherein the at least one member is configured to define at least one aperture.

10 27. The method of claim 26, wherein the at least one aperture has a width of at least 50 μm and at most 1000 μm .

28. The method of claim 20, wherein the at least one member is cooled.

29. The method of claim 20, wherein the at least one member is adapted to be cooled to at least 37°C and at most negative 20°C .

15 30. The method of claim 20, wherein the at least one member includes at least one channel extending therethrough.

31. The method of claim 30, wherein the at least one channel is configured to facilitate a cooling agent.

20 32. The method of claim 19, wherein the mask is configured to reflect a predetermined amount of the electromagnetic radiation in a direction of the electromagnetic radiation source.

33. The method of claim 19, wherein the mask is configured to reflect the electromagnetic radiation away from the electromagnetic radiation source.

25 34. The method of claim 19, wherein the mask is configured to diffuse the electromagnetic radiation.

35. The method of claim 19, wherein the electromagnetic radiation has a particular wavelength.

36. The method of claim 35, wherein a surface of the mask has a microstructure having a periodicity approximately in the range of the particular wavelength.
37. The method of claim 19, wherein the mask is configured to absorb a predetermined amount of the electromagnetic radiation.
- 5 38. The method of claim 19, wherein the electromagnetic radiation source is an ablative laser.
39. The method of claim 19, wherein the electromagnetic radiation source is a carbon dioxide laser.
40. The method of claim 19, wherein the electromagnetic radiation source is a
10 Er:YAG laser.
41. The method of claim 19, further comprising the steps of:
controlling a further electromagnetic radiation source to generate a further electromagnetic radiation; and
applying the further electromagnetic radiation to the target area of the skin.
- 15 42. The method of claim 41, wherein the further electromagnetic radiation source is substantially the same as the electromagnetic radiation source.
43. The method of claim 41, wherein the further electromagnetic radiation source is different than the electromagnetic radiation source.
44. The method of claim 41, wherein the further electromagnetic radiation source
20 is one of a Q-switched ruby laser, a Nd:YAG laser, a KTP laser and an Alexandrite laser.
45. The method of claim 19, further comprising the step of introducing a substance to the target area, wherein the substance is one of growth factors, collagen byproducts, collagen precursors, hyaluronic acid, vitamins, antioxidants, amino acids
25 and supplemental minerals.
46. An apparatus for treating dermatological conditions, comprising:
a delivery module configured to direct an electromagnetic radiation generated by an electromagnetic radiation source to a target area of skin; and

a mask including at least one member configured to mask at least one portion of the target area of the skin from the electromagnetic radiation.

47. The apparatus of claim 46, wherein the at least one member is configured to reflect a predetermined amount of the electromagnetic radiation in the direction of the
5 electromagnetic radiation source.

48. The apparatus of claim 46, wherein each of the at least one member is configured to reflect the electromagnetic radiation away from the electromagnetic radiation source.

49. The apparatus of claim 46, wherein each of the at least one member is
10 configured to diffuse the electromagnetic radiation.

50. The apparatus of claim 46, wherein the electromagnetic radiation has a particular wavelength.

51. The apparatus of claim 50, wherein each of the at least one member includes a microstructure having a periodicity in the range of the particular wavelength.

15 52. The apparatus of claim 46, wherein each of the at least one member is configured to absorb a minimal amount of the electromagnetic radiation.

53. The apparatus of claim 46, wherein the electromagnetic radiation source is an ablative laser.

54. The apparatus of claim 46, wherein the electromagnetic radiation source is a
20 carbon dioxide laser.

55. The apparatus of claim 46, wherein the electromagnetic radiation source is a Er:YAG laser.

56. The apparatus of claim 46, wherein the at least one shielding member masks at least 0.1% of the target area from the electromagnetic radiation.

25 57. The apparatus of claim 46, wherein the at least one member masks at most 90% of the target area from the electromagnetic radiation.

58. The apparatus of claim 46, wherein the at least one member masks the at least

one portion of the target area such that the electromagnetic radiation is prevented from affecting the at least one portion of the target area.

59. The apparatus of claim 46, wherein the at least one member masks the at least one portion of the target area such that the electromagnetic radiation is prevented from affecting the at least one portion of the target area.

60. The apparatus of claim 46, further comprising a case having an aperture formed in a sidewall of the case, wherein the case contains the electromagnetic radiation source and the delivery module, and wherein the at least one member is in registration with the aperture.

61. The apparatus of claim 46, wherein the delivery module includes a beam collimator.

62. The apparatus of claim 46, wherein the delivery module includes optical components.

63. An apparatus for treating dermatological conditions, comprising:
a delivery module configured to direct electromagnetic radiation generated by an electromagnetic radiation source to a predetermined area within a target area of skin, wherein the predetermined area is located in a location relative to the delivery module, and wherein the electromagnetic radiation is adapted to cause thermal damage to epidermal tissue and dermal tissue of the predetermined area within the target area of the skin; and

a translator capable of moving the delivery module, such that the delivery module targets a plurality of spatially separated individual exposure areas of the predetermined area.

64. The apparatus of claim 63, wherein the electromagnetic radiation source is an ablative laser.

65. The apparatus of claim 63, wherein the electromagnetic radiation source is one of a diode laser, a fiber laser, a solid state laser and a gas laser.

66. The apparatus of claim 63, further comprising a case having an aperture formed in a sidewall of the case, wherein the case contains the electromagnetic

radiation source, the delivery module and the translator.

67. The apparatus of claim 66, further comprising a transparent plate in registration with the aperture, wherein the transparent plate seals the case.

68. The apparatus of claim 67, wherein the electromagnetic radiation has a particular wavelength.

69. The apparatus of claim 68, wherein the transparent plate absorbs a predetermined amount of the electromagnetic radiation at the particular wavelength.

70. The apparatus of claim 67, wherein the transparent plate is cooled to provide an asthetic affect to the target area of the skin.

71. The apparatus of claim 67, wherein the transparent plate is configured to be cooled to at least 37°C and at most negative 20°C.

72. The apparatus of claim 63, wherein the delivery module includes a beam collimator.

73. The apparatus of claim 63, wherein the delivery module includes optical components.

74. The apparatus of claim 63, wherein the dermal tissue of the skin of the plurality of spatially separated individual exposure areas is damaged down to a predetermined depth thereof.

75. The apparatus of claim 63, wherein the plurality of spatially separated individual exposure areas cover at least five percent of the target area and at most sixty percent of the target area.

76. The apparatus of claim 63, wherein an average distance between each of the plurality of spatially separated individual exposure areas is at least 10 μm and at most 2000 μm .

77. The apparatus of claim 63, wherein each of the plurality of spatially separated individual exposure areas have a diameter of approximately 0.1 mm.

78. The apparatus of claim 63, wherein each of the plurality of spatially separated

individual exposure areas have a lateral diameter of a smallest dimension of at least 1 μm and at most 500 μm .

79. The apparatus of claim 63, further comprising an optically transparent plate disposed between delivery module and the target area of the skin.

5 80. The apparatus of claim 79, wherein the optically transparent plate is cooled.

81. The apparatus of claim 79, wherein the optically transparent plate cooled to at least 37°C and at most negative 20°C .

82. The apparatus of claim 63, wherein a first one of the plurality of spatially separated individual exposure areas is separated from a second one of the plurality of spatially separated individual exposure areas.
10

83. The apparatus of claim 82, wherein the first one of the plurality of spatially separated individual exposure areas is separated from the second one of the plurality of spatially separated individual exposure areas by non-irradiated skin section.

84. The apparatus of claim 63, wherein a first one of the plurality of spatially separated individual exposure areas is exposed to electromagnetic radiation associated with a first set of parameters and a second one of the plurality of spatially separated individual exposure areas is exposed to electromagnetic radiation associated with a second set of parameters.
15

85. The apparatus of claim 63, wherein at least two of the individual exposure areas are separated from one another by an unaffected area.
20

86. The apparatus of claim 85, wherein the at least two of the individual exposure areas are separated from one another by at least approximately 125 μm .

87. The apparatus of claim 85, wherein the at least two of the individual exposure areas are separated from one another by at most approximately 500 μm .

88. The apparatus of claim 63, wherein one of at least one hundred of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one hundred of the individual exposure areas by an unaffected area.
25

89. The apparatus of claim 63, wherein one of at least one thousand of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one thousand of the individual exposure areas by an unaffected area.
- 5 90. A method for treating dermatological conditions, comprising the steps of:
- (a) controlling an electromagnetic radiation source to generate first and second electromagnetic radiation;
 - (b) causing a first electromagnetic radiation to be applied to a first individual exposure area of a plurality of spatially separated individual exposure areas of a target
 - 10 area of skin, wherein epidermal tissue and dermal tissue of the first individual exposure area are thermally damaged; and
 - (c) causing a second electromagnetic radiation to be applied to a second individual exposure area of a plurality of spatially separated individual exposure areas of the target area of the skin, wherein epidermal tissue and dermal tissue of the second
 - 15 individual exposure area are thermally damaged, wherein the first electromagnetic radiation is one of the same as and different from the second electromagnetic radiation, and wherein the first and second individual exposure areas are separated from one another by an unaffected area.
- 20 91. The method of claim 90, wherein the target area has a surface area of approximately 1 cm².
92. The method of claim 90, wherein the electromagnetic radiation source is an ablative laser.
93. The method of claim 90, wherein the electromagnetic radiation source is one of a diode laser, a fiber laser, a solid state laser and a gas laser.
- 25 94. The method of claim 90, wherein the dermal tissue of the skin of the plurality of spatially separated individual exposure areas is damaged down to a predetermined depth thereof.
95. The method of claim 90, wherein the plurality of spatially separated individual exposure areas cover at least twenty percent of the target area and at most forty
- 30 percent of the target area.

96. The method of claim 90, wherein an average distance between each of the plurality of spatially separated individual exposure areas is at least approximately 10 μm and at most approximately 2000 μm .
97. The method of claim 90, wherein each of the plurality of spatially separated
5 individual exposure areas have a diameter of approximately 0.1 mm.
98. The method of claim 90, wherein each of the plurality of spatially separated individual exposure areas have a lateral diameter of a smallest dimension of at least approximately 1 μm and at most approximately 500 μm .
99. The method of claim 90, further comprising the step of:
- 10 (d) placing an optically transparent plate in registration with the target area.
100. The method of claim 99, wherein the optically transparent plate is cooled.
101. The method of claim 99, wherein the optically transparent plate cooled to at least approximately 37°C and at most approximately negative 20°C .
102. The method of claim 90, wherein the first individual exposure area is
15 separated from a second individual exposure area.
103. The method of claim 90, wherein the first individual exposure area is separated from the second individual exposure area by non-irradiated skin.
104. The method of claim 90, wherein the first electromagnetic radiation is associated with a first set of parameters, and wherein the second electromagnetic
20 radiation is associated with a second set of parameters.
105. The method of claim 90, wherein at least two of the individual exposure areas are separated from one another by an unaffected area.
106. The method of claim 105, wherein the at least two of the individual exposure areas are separated from one another by at least approximately 125 μm .
- 25 107. The method of claim 105, wherein the at least two of the individual exposure areas are separated from one another by at most approximately 500 μm .

108. The method of claim 90, wherein one of at least one hundred of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one hundred of the individual exposure areas by an unaffected area.

109. The method of claim 90, wherein one of at least one thousand of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one thousand of the individual exposure areas by an unaffected area.

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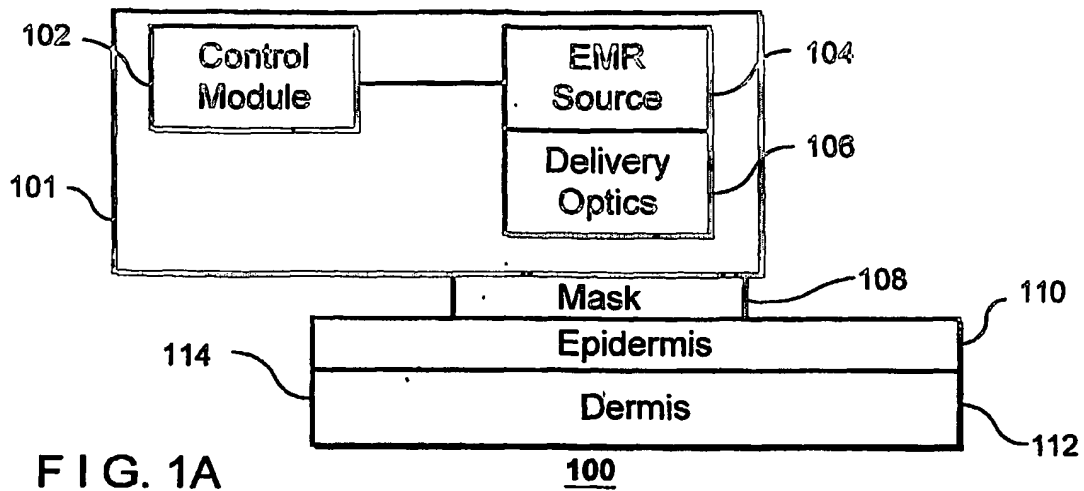


FIG. 1A

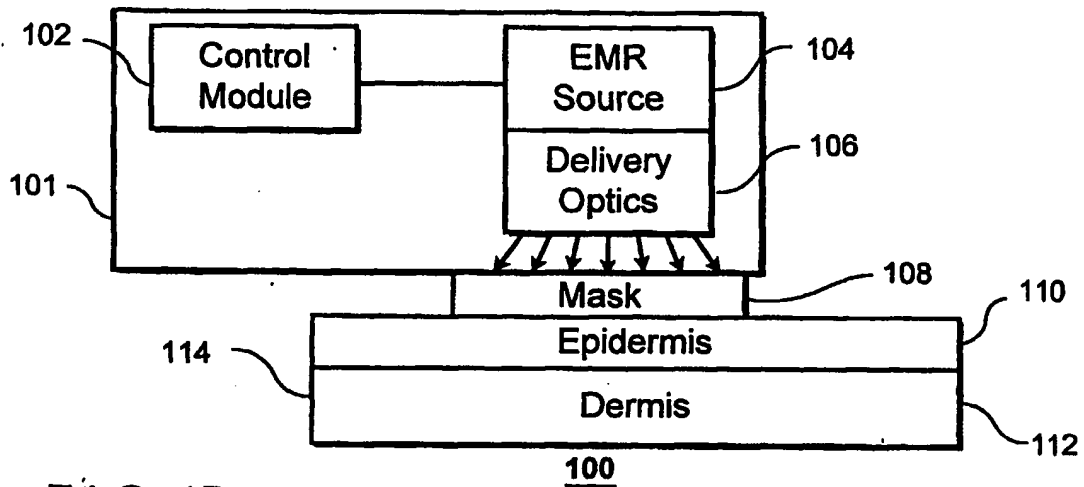


FIG. 1B

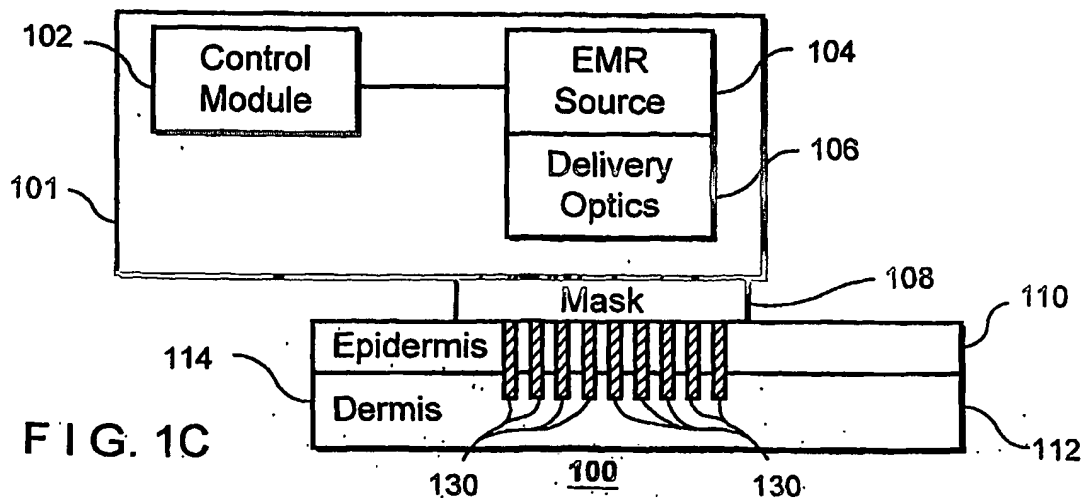


FIG. 1C

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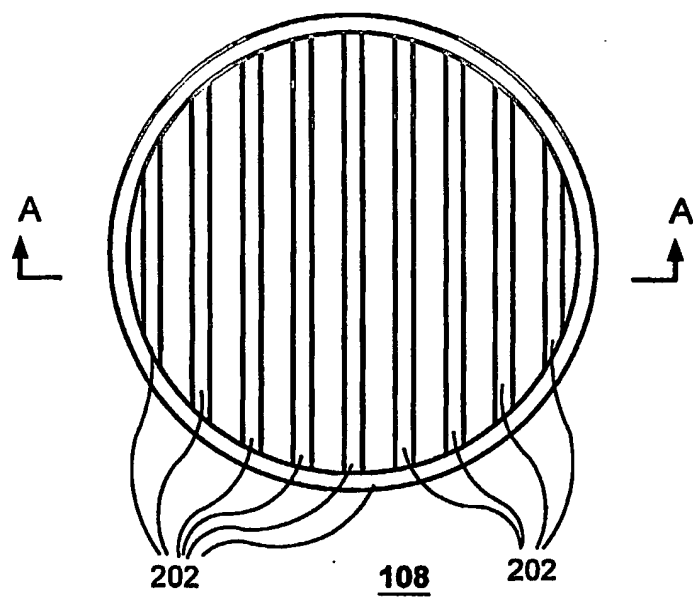


FIG. 2

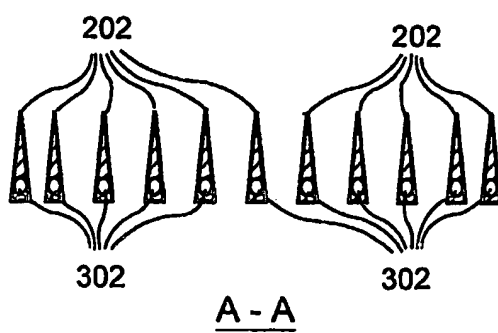


FIG. 3

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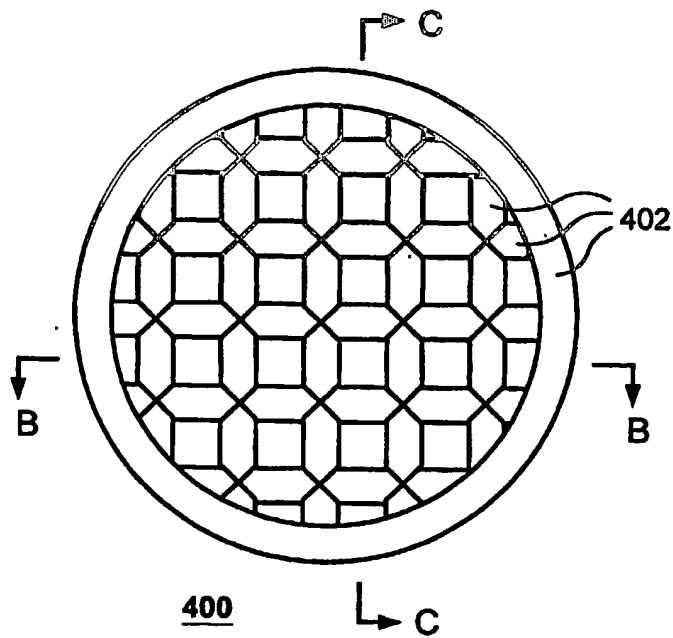


FIG. 4

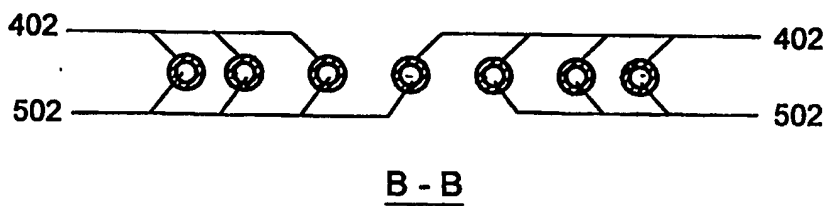


FIG. 5

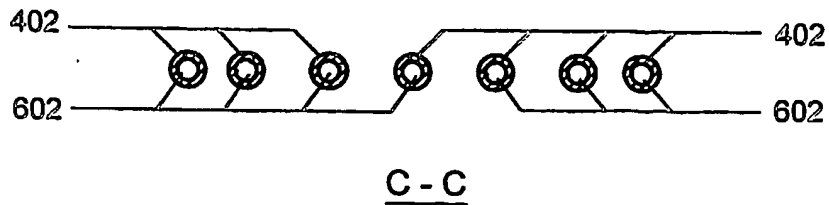
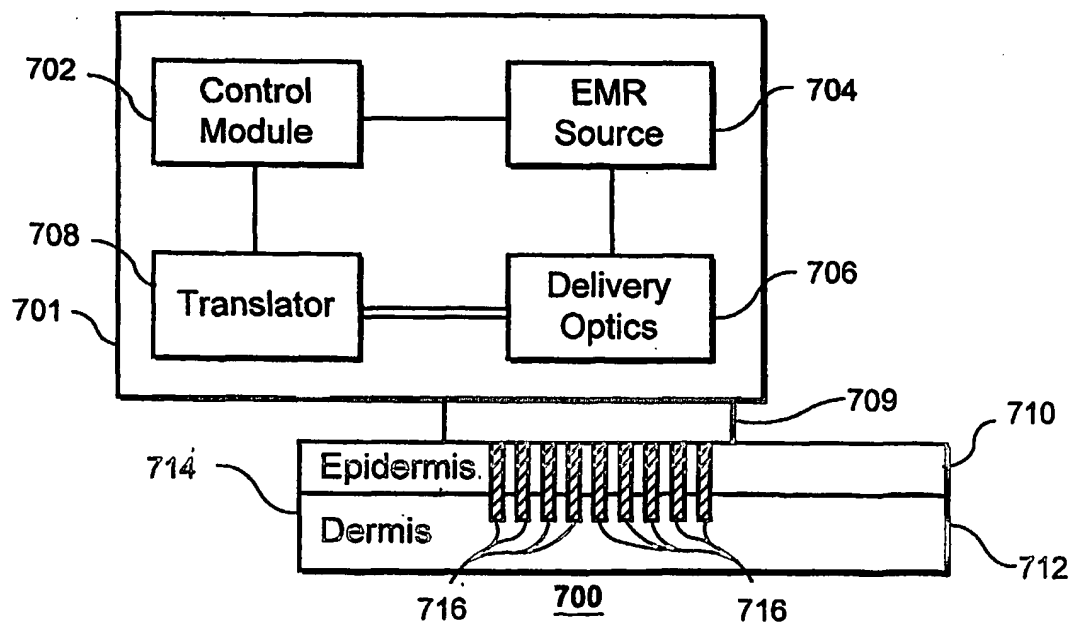
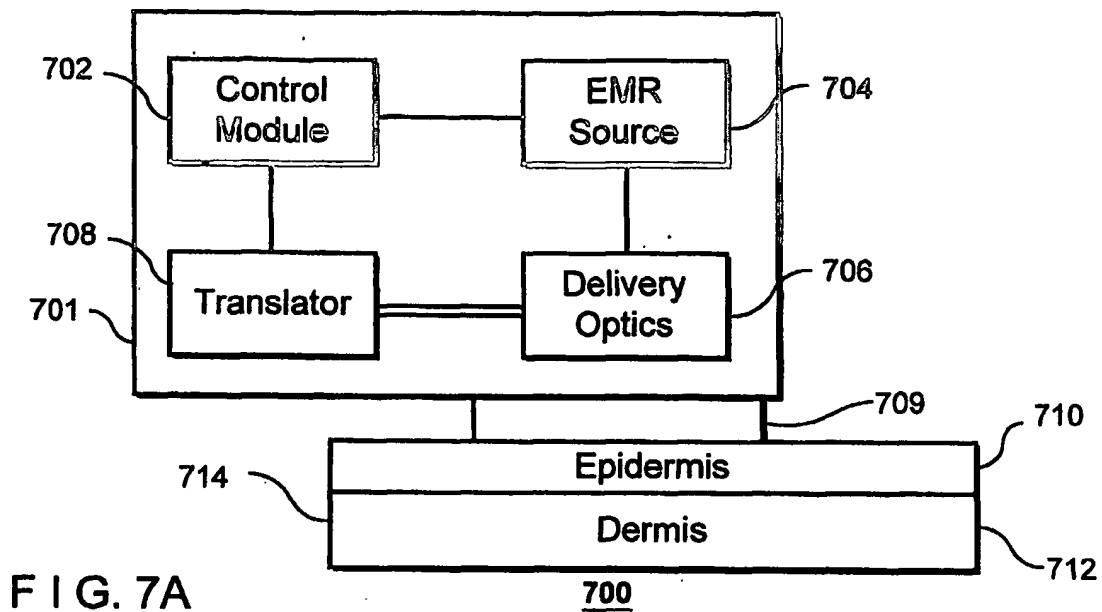


FIG. 6

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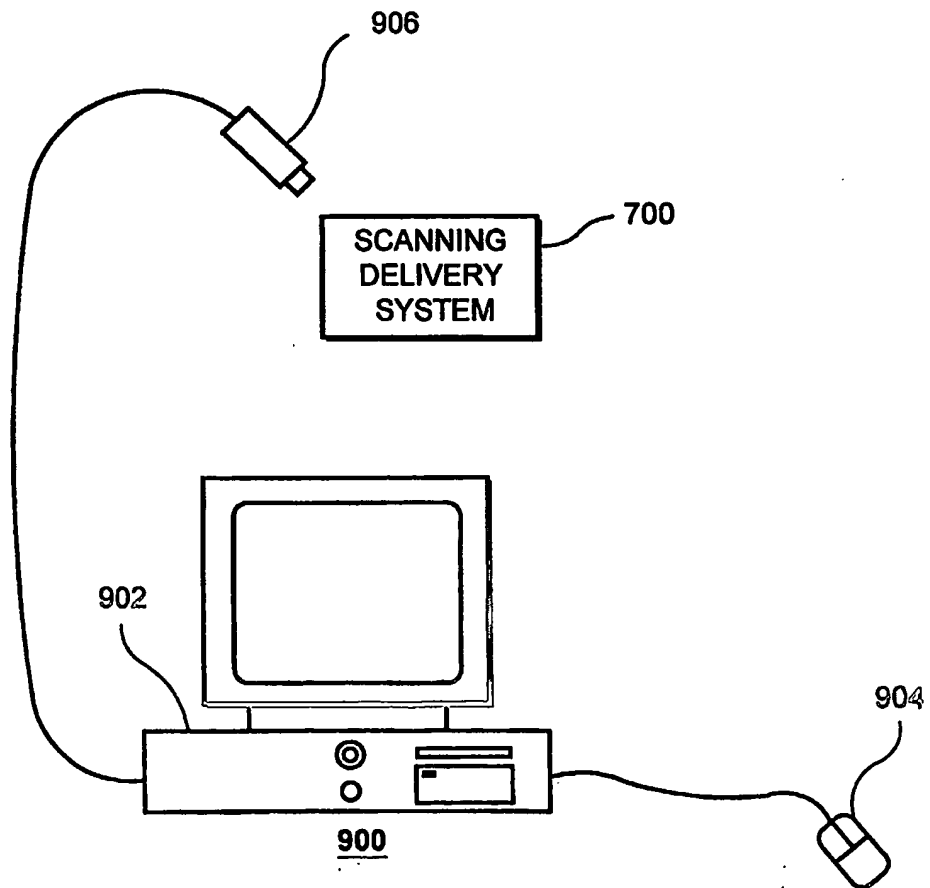
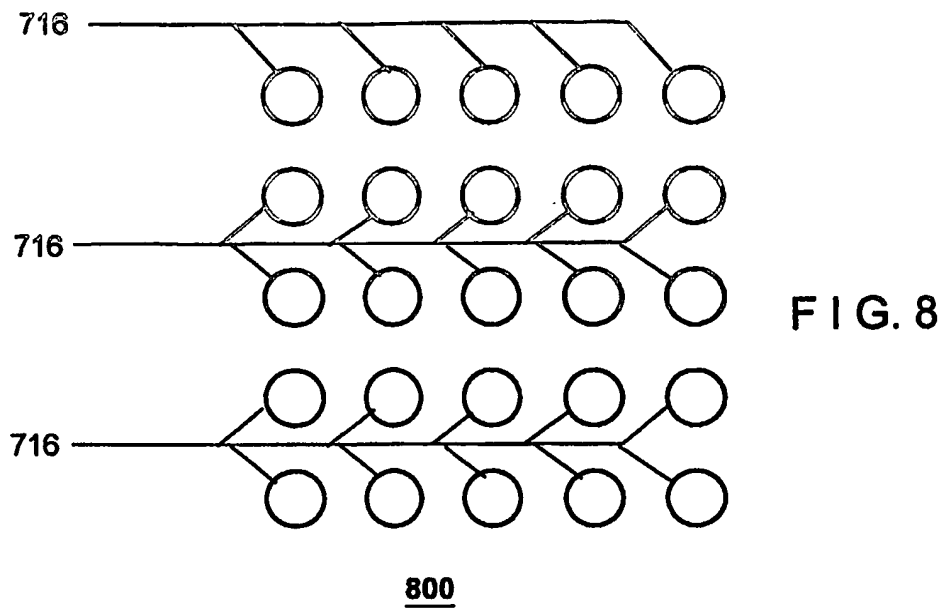


FIG. 9

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**REVOCATION OF POWER OF
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Application Number	11/098,030
Filing Date	April 1, 2005
First Named Inventor	Dieter Manstein
Art Unit	3739
Examiner Name	To be assigned
Attorney Docket Number	036213/US/2 - 475387-00230

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

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I am the:

☐ Applicant/Inventor.☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)**SIGNATURE of Applicant or Assignee of Record**

Name	Kris Bettes, an authorized party of General Hospital Corp.		
Signature	Kris Bettes		
Date	April 14, 2006		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of _____ forms are submitted.

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STATEMENT UNDER 37 CFR 3.73(b)Applicant/Patent Owner: Dieter MansteinApplication No./Patent No.: 11/098,030 Filed/Issue Date: April 1, 2005Entitled: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

The General Hospital Corp.

a Corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.
The extent (by percentage) of its ownership interest is _____%
in the patent application/patent identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

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B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

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☐ Additional documents in the chain of title are listed on a supplemental sheet.

☒ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

April 14, 2006

Date

Kris Betess

Typed or printed name

Kris Betess

Signature

LICENSING MGR

Title

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/098,030	04/01/2005	Dieter Manstein	036213/US/2-475387-00230

30873
DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

CONFIRMATION NO. 6055



Date Mailed: 04/27/2006

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/18/2006.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

WTA
WUBALEM TSIGE
PTOSS (703) 305-3006

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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/098,030	04/01/2005	Dieter Manstein	910000-3080.1

20999
FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

CONFIRMATION NO. 6055



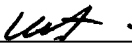
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Date Mailed: 04/27/2006

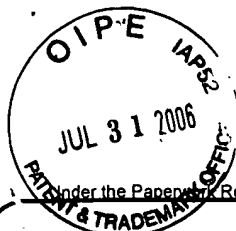
NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/18/2006.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).


WUBALEM TSIGE
PTOSS (703) 305-3006

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PTO/SB/21 (09-04)
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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	11/098,030
	Filing Date	April 1, 2005
	First Named Inventor	Dieter Manstein
	Art Unit	3739
	Examiner Name	To be assigned
Total Number of Pages in This Submission	Attorney Docket Number	036213/US/2 - 475387-00230

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	PTO-1449 form and Return Receipt postcard
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Remarks	

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Dorsey & Whitney, L.L.P.		
Signature			
Printed name	Steven P. Marsh, Esq.		
Date	July 27, 2006	Reg. No.	Reg. No. 40,479

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
Signature			
Typed or printed name	Steven P. Marsh, Esq.	Date	July 27, 2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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187627/US/2 – 475387-00233 PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter Manstein et al.
Serial No. : 11/098,030
Filed : April 1, 2005
Entitled : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Group Art Unit : 3739
Examiner : To be assigned

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I hereby certify that this document is being sent via First Class U. S.
mail addressed to: Commissioner for Patents, P.O. Box 1450,
Alexandria, Virginia 22313-1450 on this day of July 27, 2006.


(Signature)

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant brings to the attention of the Examiner the documents listed on the attached Form PTO 1449, and respectfully request that the listed documents be considered by the Examiner and made of record in the above-captioned application. Copies of the references listed on the Form PTO-1449 are not enclosed.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute “prior art.” If the Examiner applies the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute “prior art” under United States law, applicant reserves the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

This submission is being filed before any action by the U.S. Patent and Trademark Office on the merits. Therefore, applicant does not believe that any fee is due in connection with the submission of this paper. However, if any fee is due, or if any overpayment has been made, the Commissioner is authorized to charge any such fee or credit any overpayment, to our Deposit Account No. 50-2054.

Respectfully submitted,

DORSEY & WHITNEY, LLP

A handwritten signature in black ink, appearing to read "Steven Marsh", written over a horizontal line.

Steven P. Marsh, Esq.
PTO Reg. No. 53,271
Attorneys for Applicants
(212) 415-9371

JUL 31 2006

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.
036213/US/2 - 475387-00230

Serial No.
11/098,030

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**
(Use several sheets if necessary)

Applicant(s)
Dieter Manstein

Filing Date
April 1, 2005

Group
3739

U.S. PATENT DOCUMENTS

*Exam. Init.	Document No.	Date	Name	Class	Subclass	Filing Date if Appropriate
	6 2 7 7 1 1 6	August 21, 2001	Utely et al.			
	6 7 6 6 2 0 2	July 20, 2004	Underwood et al.			

FOREIGN PATENT DOCUMENT

Document No.	Date	Country	Class	SubClass	Translator Yes No

OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)

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4821-1526-2209\1

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/098,030	04/01/2005	Dieter Manstein	036213/US/2-475387-00230	6055

30873 7590 03/31/2008
DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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03/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/098,030	Applicant(s) MANSTEIN, DIETER	
	Examiner Ahmed M. Farah	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-19 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/2/2005; 7/31/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

(Presence of possible 112, sixth paragraph, limitations)

Claim 10 is objected to because of the following informalities: the claim recites "vibrational means" in line 2. It is not clear to the examiner whether the applicants want to invoke the 35 U.S.C. 112, sixth paragraph.

When it is not clear whether a claim limitation should be treated under 35 U.S.C. 112, sixth paragraph, determining the patentability of that claim is difficult because the scope of the claim and the relevance of the prior art cannot be readily determined. Applicants have an opportunity and obligation to define their inventions precisely during proceedings before the PTO. They are required to specify their inventions, consistent with the guidelines described in MPEP 2181, when a claim limitation invokes 35 U.S.C. 112, sixth paragraph.

A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for" or "step for";*
- (B) the "means for" or "step for" must be modified by functional language; and*
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.*

If the applicants wish to have the claim limitations under 112, sixth paragraph interpretation, they must: show why the claim language properly invokes 35 U.S.C. 112, sixth paragraph; identify the function; and identify the corresponding structure. They must either: (A) amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines; or (B) show that even though the phrase "means for" or "step for" is not used, the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of

35 U.S.C. 112 , sixth paragraph. See Watts v. XL Systems, Inc., 232 F.3d 877, 56 USPQ24 1836 (Fed. Cir. 2000).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. These claims are omnibus type claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11, 13, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Utely et al. US Patent No. 6,277,116.

Utely et al. discloses a system and methods of use for shrinking collagen tissue, the apparatus comprising;

a plurality of needles 82, 90, attached to a base 80,88, wherein the base is attached to a housing or part of the housing (see Figs. 6 and 8); energy source in communication with one or more of the needles (see Fig. 2); and a control module 48 configured to permit variation of the characteristics of the energy supplied by the energy source as claimed (see col. 6, line 59 through col. 7, line 3).

As to claims 2, 3, 6, and 9, the source is a radiofrequency source, which is capable of outputting a desired RF signals.

As to claim 7, the spacer substrate comprises a pattern of small holes through which the plurality of the needles protrude (see Figs. 7-9).

As to claim 11, the energy source is configured to deliver energy to a plurality of pairs of needles in bipolar mode (see col. 7, lines 64-67).

As to claims 13 and 18, the needles are hollow and are configured to deliver therapeutic fluid to the tissue surrounding the tip of the needles (see col. 9, lines 11-17).

Claims 1, 4, 5, 12, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Prausnitz et al. US Patent No. 6,503,231.

Prausnitz et al. discloses a micro-needle device and methods of use for transporting therapeutic and diagnostic materials and energy across tissue barriers, the system comprising;

a plurality of micro-needles 12, attached to a base 11 wherein the base is attached to a housing or part of the housing (see Fig. 2 and col. 3, lines 55-60); and an energy source in communication with one or more of the needles (see col.5, lines 26-27).

As to claim 12, the diameter of the needles is between 10 nm to 1 mm (see the abstract).

As to claim 15, the micro-needles are hollow and are configured to permit passage of light delivery optical fibers (see col. 5, lines 34-38).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Utely et al. (116) in view of Prausnitz et al. ('231), both described above.

Utely et al. (116) teaches the claim as recited with exception of optical energy and delivery fibers. However, the use of optical energy as alternative treatment energy is well known in the art. Prausnitz et al. teaches the use of optical energy and delivery fibers to provide the treatment. Prausnitz et al. further teaches the equivalence of different forms of energy for tissue treatment (see col. 5, lines 34-38). Therefore, at the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify Utely et al. in view of Prausnitz et al. and use optical energy and delivery fibers as an equivalent alternative means to provide the treatment energy.

Allowable Subject Matter

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon, Tue, Thur and Fri between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marmor II Charles can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Art Unit: 3735

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ahmed M Farah/
Primary Examiner, Art Unit 3735

March 27, 2008.

Notice of References Cited	Application/Control No. 11/098,030		Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER	
	Examiner Ahmed M. Farah		Art Unit 3735	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,277,116 B1	08-2001	Utely et al.	606/42
*	B	US-6,503,231 B1	01-2003	Prausnitz et al.	604/272
*	C	US-7,331,953 B2	02-2008	Manstein et al.	606/9
*	D	US-6,048,352 A	04-2000	Douglas et al.	606/181
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

JUL 31 2006

Page 1 of 1

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark OfficeAtty. Docket No.
036213/US/2 - 475387-00230Serial No.
11/098,030**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**
(Use several sheets if necessary)Applicant(s)
Dieter MansteinFiling Date
April 1, 2005Group
3739**U.S. PATENT DOCUMENTS**

*Exam. Init.	Document No.	Date	Name	Class	Subclass	Filing Date if Appropriate
/AF/	6 2 7 7 1 1 6	August 21, 2001	Utely et al.			
/AF/	6 7 6 6 2 0 2	July 20, 2004	Underwood et al.			

FOREIGN PATENT DOCUMENT

Document No.	Date	Country	Class	SubClass	Translator Yes No

OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)

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4821-1526-2209\1

Examiner /Ahmed Farah/ (03/27/2008)

Date Considered

03/27/2008

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L10	29	(US-20050222555-\$ or US-20050049625-\$ or US-20020177839-\$ or US-20020123675-\$ or US-20020111600-\$ or US-20070038181-\$ or US-20060079919-\$ or US-20050222565-\$). did. or (US-7186235-\$ or US-7182747-\$ or US-6497719-\$ or US-6607513-\$ or US-6855131-\$ or US-6835184-\$ or US-6790372-\$ or US-6743211-\$ or US-6689100-\$ or US-6611707-\$ or US-6591124-\$ or US-6503231-\$ or US-5879326-\$ or US-6440096-\$ or US-6083196-\$ or US-6168590-\$ or US-6048352-\$ or US-5803093-\$ or US-2397757-\$ or US-5569368-\$ or US-5306143-\$).did.	US-PGPUB; USPAT	OR	OFF	2008/03/27 20:55
L11	3	10 and ('rf' radiofrequenc\$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/03/27 20:56
L12	19	(micro adj (knife blade needle)) same ('rf' radiofrequency)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/03/27 20:57
L13	2	((("6149644") or ("7090670")).PN.	USPAT; USOCR	OR	OFF	2008/03/27 21:14
L14	1	("7331953").PN.	USPAT; USOCR	OR	OFF	2008/03/27 21:19

L15	29	("20030032950" "20030216719" "20050222565" "20070038181" "2397757" "5306143" "5569242" "5643252" "5755753" "5879326" "5919219" "5948011" "6048352" "6083196" "6273884" "6277116" "6377855" "6405090" "6440096" "6497719" "6511475" "6591124" "6656147" "6749624" "6766202" "6835184" "6855131" "7186235").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2008/03/27 21:21
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Sheet 1 of 1

Based on Form PTO-1449 (3/90) LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	ATTY. DOCKET NO. 910000-3080.1	SERIAL NO. 11/098,030
	APPLICANT Manstein	
	FILING DATE April 1, 2005	GROUP 3739

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
/AF/	AA	5,569,242	10/29/96	Lax et al.			
	AB	5,697,281	12/16/97	Eggers et al.			
	AC	5,755,753	05/26/98	Knowlton			
	AD	5,861,002	01/19/99	Desai			
	AE	5,919,219	07/06/99	Knowlton			
	AF	5,948,011	07/07/99	Knowlton			
	AG	6,277,116	08/21/01	Uteley et al.			
	AH	6,377,855	04/23/02	Knowlton			
	AI	6,405,090	06/11/02	Knowlton			
	AJ	6,723,092	04/20/04	Brown et al.			
	AK	6,749,624	06/15/04	Knowlton			
	AL	6,766,202	07/20/04	Underwood et al.			
	AM	2003/0130655	07/10/03	Woloszko et al.			
	AN	2003/0212394	11/13/03	Pearson et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
	AO	WO 04/086947	10/14/04	PCT			
	AP						

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

/AF/	AQ	Urney et al., "Percutaneous Electrode Guidance: A Noninvasive Technique For Prelocation of Peripheral nerves to Facilitate Peripheral Plexus or Nerve Block," Regional Anesthesia and Pain Medicine, vol. 27, no. 3, 2002, pp. 261-267.
/AF/	AR	Tschopp et al., "Comparison of Various Methods of Electromyographic Monitoring of the Recurrent Laryngeal Nerve in Thyroid Surgery," Ann. Otol. Rhinol. Laryngol., 111:2002, pp. 811-816.

EXAMINER	DATE CONSIDERED
/Ahmed Farah/ (03/27/2008)	03/27/2008

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Dieter MANSTEIN
Appln. Serial No. : 11/098,030
Filed : April 1, 2005
Entitled : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Group Art Unit : 3735
Confirmation No. : 6055
Examiner : Ahmed M. Farah
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO NON-FINAL OFFICE ACTION

SIR:

This paper is filed in response to a non-final Office Action dated March 31, 2008 (the "Office Action"). Prior to further examination, please amend the application, and consider the remarks as set forth herein below.

IN THE CLAIMS:

Please amend claims 1, 2, 7, 8, 10, 11, and 13-19 as provided below, cancel claims 3-6, 9, and 12, and add new claims 20-33. A complete listing of all claims and their current status is provided on separate sheets.

1. (currently amended) An ~~tissue reshaping~~ apparatus for tissue treatment, comprising:

a base;

a plurality of needles attached to a the base, ~~wherein the base is attached to a housing or part of the housing;~~

an energy source provided in communication with at least one ~~or more~~ of the needles;

a spacer arrangement for controlling penetration depths of the needles ; and

~~optionally comprising a control module, wherein the control module permits variation of the~~ configured to vary characteristics of energy supplied by the energy source.

2. (currently amended) The apparatus of claim 1 wherein ~~one or more~~ more than one of the needles are electrically conductive, and wherein the energy source is configured to supply ~~RF current individually~~ radio frequency electromagnetic energy to individual ones ~~or more~~ of the needles ~~or wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles and wherein the energy source and/or control module is located outside of the housing.~~

3. (canceled)

4. (canceled)

5. (canceled)

6. (canceled)

7. (currently amended) The apparatus of claim 1, wherein the ~~apparatus further~~ spacer arrangement comprises a ~~spacer~~ substrate comprising a pattern of small holes through which the plurality of needles protrudes or wherein the apparatus further comprises a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes, and wherein the substrate is movably attached to the base, ~~or the housing and~~ wherein the position of the substrate is adjustable relative to that of the base to control ~~the depth~~ a distance between distal ends of the needles ~~protruding from the lower~~ and a surface of the spacer substrate.

8. (currently amended) The apparatus of claim 1, ~~wherein the base and/or optionally, the spacer substrate, is planar or has a lower surface that is contoured to follow the shape of the region of tissue being treated or~~ wherein at least one of the base and/or a or the spacer substrate further comprises a cooling ~~means arrangement~~ configured to cool a skin surface, ~~to reduce or eliminats pain when the plurality of needles penetrates the skin surface or~~ wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminats pain when the plurality of needles penetrates the skin surface and wherein said the cooling arrangement comprises at least one of an embedded conduits ~~containing circulating~~ configured to circulate a coolant or a Peltier device.

9. (canceled)

10. (currently amended) The apparatus of claim 1, ~~wherein the apparatus further comprises comprising a vibrational means~~ vibrating arrangement provided in communication with the base, ~~where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft or~~ wherein the apparatus further comprises a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft and wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz or wherein the apparatus further comprises a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft and wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about

~~1 khz and wherein the vibrational amplitude of said vibrating means is between about 50-500 .mu.m or between about 100-200 .mu.m.~~

11. (currently amended) The apparatus of claim 1, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to a ~~plurality of~~ the pairs of needles in bipolar mode.

12. (canceled)

13. (currently amended) The apparatus of claim 1, wherein at least one ~~or more~~ of the needles ~~are~~ is nonconductive and hollow, and ~~are~~ is configured to deliver a local analgesic to ~~the~~ tissue ~~surrounding the tip proximal to a distal end~~ of the needle.

14. (currently amended) ~~The apparatus of claim 1 wherein the apparatus further comprises~~ An apparatus for tissue treatment, comprising:

a base;

a plurality of needles attached to the base;

an energy source provided in communication with at least one of the needles;

a control module configured to vary characteristics of energy supplied by the energy source; and

an electronic detection device in electrical communication with at least one ~~or more~~ of the needles that is configured to detect the presence of a nerve near the tip of the at least one ~~or more~~ of the needles ~~or wherein the apparatus further comprises an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles and wherein the detection device is in communication with the control module and the control module is configured to prevent the energy source from supplying energy to any needle if a nerve has been detected near that needle.~~

15. (currently amended) The apparatus of claim 1, ~~wherein the apparatus further comprises~~
comprising:

a source of optical energy; and

at least one or more hollow optical needles containing comprising at least one of a
light fibers or a light guides, wherein the distal ends of the needles are configured to penetrate
into at least one of the dermis or subdermal tissue, and wherein the apparatus is configured to
deliver a controlled amount of ~~electromagnetic~~ optical energy through the at least one optical
needle light fiber or light guide and into the tissue ~~surrounding the tip~~ proximal to a portion of
the at least one hollow optical needle, ~~or wherein the apparatus further comprises a source of~~
optical energy and one or more hollow needles containing light fibers or light guides, wherein
the apparatus is configured to deliver a controlled amount of electromagnetic energy through the
light fiber or light guide and into the tissue surrounding the tip of the hollow needle and wherein
the optical energy source comprises a diode laser, a diode pumped solid state laser, an Er:YAG
laser, a Nd:YAG laser, an argon ion laser, a He-Ne laser, a carbon dioxide laser, an excimer
laser, or a ruby laser, and wherein the electromagnetic energy conveyed by the light guide or
light fiber is continuous or pulsed.

16. (currently amended) A method of treating skin tissue, comprising ~~the steps of:~~

~~providing a plurality of needles attached to a base;~~

~~providing an energy source in communication with one or more of the needles;~~

~~inserting the~~ an array of needles into the skin tissue to at least one predetermined
depth;

detecting presence of a nerve in proximity to particular ones of the needles; and

supplying providing energy to more than one certain ones of the needles which do
not have a nerve in proximity thereto. ~~to induce a pattern of damage in the tissue surrounding the~~
~~needles.~~

17. (currently amended) The method of claim 16, wherein the energy comprises radio frequency
electromagnetic energy. ~~further comprising: providing a control module, wherein the control~~
~~module permits variation of the characteristics of energy supplied by the energy source or~~
~~providing a control module, wherein the control module permits variation of the characteristics~~
~~of energy supplied by the energy source and providing cooling means to cool the surface of the~~

~~skin, and optionally the plurality of needles, before inserting the needles into the skin or providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin and wherein the energy is RF current and the needles are insulated except near their tips or providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin and wherein the energy is RF current and the needles are insulated except near their tips and providing a detection device in communication with one or more of the needles; supplying low current to one or more of the needles sequentially to detect the presence of a nerve near the needles; and preventing the energy source from supplying energy to any needle if a nerve has been detected near that needle.~~

18. (currently amended) The method of claim 16, wherein the tissue is skin tissue, ~~16 further comprising: providing one or more hollow needles attached to the base and injecting an analgesic through the hollow needles into the surrounding tissue after the needles are inserting into the skin.~~

19. (currently amended) The method of claim 16 further comprising:

~~providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin and providing hollow needles containing light fibers or light guides in communication with the energy source, wherein the energy source is a source of optical energy;~~

~~supplying optical energy to the at least one of a light fibers or a light guides provided in at least one needle to induce thermal damage in a portion of the tissue surrounding proximal to the hollow at least one needles.~~

20. (new) The apparatus of claim 1, wherein the plurality of needles protrude a plurality of distances from the base.

21. (new) The apparatus of claim 15, wherein a portion of the at least one needle is configured to absorb a portion of the optical energy and convert the optical energy to thermal energy.

22. (new) The apparatus of claim 14, wherein the control module is configured to prevent the energy source from supplying energy to a particular needle if a nerve has been detected near the particular needle.

23. (new) The apparatus of claim 14, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between two needles in a pair of needles is less than a distance between each one of the two needles and any other needle, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

24. (new) An apparatus for dermatological treatment, comprising:

a base;

a plurality of needles attached to the base;

an energy source provided in communication with at least one of the needles; and

a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles protrude a plurality of distances from the base.

25. (new) The apparatus of claim 24, wherein the energy source is a source of electromagnetic energy.

26. (new) The apparatus of claim 24, wherein a plurality of the needles are electrically conductive, and wherein the energy source is configured to supply radio frequency electromagnetic energy to individual ones of the needles.

27. (new) The apparatus of claim 24, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle, and wherein the energy source

and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

28. (new) The apparatus of claim 24, further comprising:

at least one optical needle comprising at least one of a light fibers or a light guide, wherein the apparatus is configured to deliver a controlled amount of optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle, wherein the energy source comprises a source of optical energy.

29. (new) A method of treating tissue, comprising:

inserting an array of needles into the tissue; and
providing energy to a plurality of the needles,
wherein at least a portion of the energy is absorbed by tissue proximal to the needles, and wherein distal ends of the needles are provided at a plurality of depths within the tissue.

30. (new) The method of claim 29, wherein the energy comprises radio frequency electromagnetic energy.

31. (new) The method of claim 29, wherein the energy comprises optical energy.

32. (new) An apparatus for tissue treatment, comprising:

a base;
a plurality of needles attached to the base;
an energy source provided in communication with at least one of the needles; and
a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

33. (new) A method of treating tissue, comprising:

inserting an array of needles into the tissue; and

providing radio frequency electromagnetic energy to a plurality of pairs of the needles in bipolar mode,

wherein a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array.

WHAT IS CLAIMED IS:

1. (currently amended) An apparatus for tissue treatment, comprising:
 - a base;
 - a plurality of needles attached to the base;
 - an energy source provided in communication with at least one of the needles;
 - a spacer arrangement for controlling penetration depths of the needles; and
 - a control module configured to vary characteristics of energy supplied by the energy source.
2. (currently amended) The apparatus of claim 1 wherein more than one of the needles are electrically conductive, and wherein the energy source is configured to supply radio frequency electromagnetic energy to individual ones of the needles.
3. (canceled)
4. (canceled)
5. (canceled)
6. (canceled)
7. (currently amended) The apparatus of claim 1, wherein the spacer arrangement comprises a substrate movably attached to the base, wherein the position of the substrate is adjustable relative to that of the base to control a distance between distal ends of the needles and a surface of the substrate.
8. (currently amended) The apparatus of claim 1, wherein at least one of the base or the substrate further comprises a cooling arrangement configured to cool a skin surface, and wherein the cooling arrangement comprises at least one of an embedded conduit configured to circulate a coolant or a Peltier device.

9. (canceled)

10. (currently amended) The apparatus of claim 1, further comprising a vibrating arrangement provided in communication with the base.

11. (currently amended) The apparatus of claim 1, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

12. (canceled)

13. (currently amended) The apparatus of claim 1, wherein at least one of the needles is nonconductive and hollow, and is configured to deliver a local analgesic to tissue proximal to a distal end of the needle.

14. (currently amended) An apparatus for tissue treatment, comprising:

- a base;

- a plurality of needles attached to the base;

- an energy source provided in communication with at least one of the needles;

- a control module configured to vary characteristics of energy supplied by the energy source; and

- an electronic detection device in electrical communication with at least one of the needles that is configured to detect the presence of a nerve near the tip of the at least one of the needles.

15. (currently amended) The apparatus of claim 1, further comprising:

- a source of optical energy; and

- at least one optical needle comprising at least one of a light fiber or a light guide, wherein the distal ends of the needles are configured to penetrate into at least one of the dermis or subdermal tissue, and wherein the apparatus is configured to deliver a controlled amount of

optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle.

16. (currently amended) A method of treating tissue, comprising:

inserting an array of needles into the tissue to at least one predetermined depth;
detecting presence of a nerve in proximity to particular ones of the needles; and
providing energy to certain ones of the needles which do not have a nerve in proximity thereto.

17. (currently amended) The method of claim 16, wherein the energy comprises radio frequency electromagnetic energy.

18. (currently amended) The method of claim 16, wherein the tissue is skin tissue.

19. (currently amended) The method of claim 16 further comprising:

supplying optical energy to at least one of a light fiber or a light guide provided in at least one needle to induce thermal damage in a portion of tissue proximal to the at least one needle.

20. (new) The apparatus of claim 1, wherein the plurality of needles protrude a plurality of distances from the base.

21. (new) The apparatus of claim 15, wherein a portion of the at least one needle is configured to absorb a portion of the optical energy and convert the optical energy to thermal energy.

22. (new) The apparatus of claim 14, wherein the control module is configured to prevent the energy source from supplying energy to a particular needle if a nerve has been detected near the particular needle.

23. The apparatus of claim 14, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between two needles in a pair of needles is less than a distance between each one of the two needles and any other needle, and wherein the energy

source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

24. (new) An apparatus for dermatological treatment, comprising:

a base;

a plurality of needles attached to the base;

an energy source provided in communication with at least one of the needles; and

a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles protrude a plurality of distances from the base.

25. (new) The apparatus of claim 24, wherein the energy source is a source of electromagnetic energy.

26. (new) The apparatus of claim 24, wherein a plurality of the needles are electrically conductive, and wherein the energy source is configured to supply radio frequency electromagnetic energy to individual ones of the needles.

27. (new) The apparatus of claim 24, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

28. (new) The apparatus of claim 24, further comprising:

at least one optical needle comprising at least one of a light fibers or a light guide, wherein the apparatus is configured to deliver a controlled amount of optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle,

wherein the energy source comprises a source of optical energy.

29. (new) A method of treating tissue, comprising:

inserting an array of needles into the tissue; and

providing energy to a plurality of the needles,
wherein at least a portion of the energy is absorbed by tissue proximal to the needles, and
wherein distal ends of the needles are provided at a plurality of depths within the tissue.

30. (new) The method of claim 29, wherein the energy comprises radio frequency electromagnetic energy.

31. (new) The method of claim 29, wherein the energy comprises optical energy.

32. (new) An apparatus for tissue treatment, comprising:

- a base;
- a plurality of needles attached to the base;
- an energy source provided in communication with at least one of the needles; and
- a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

33. (new) A method of treating tissue, comprising:

- inserting an array of needles into the tissue; and
- providing radio frequency electromagnetic energy to a plurality of pairs of the needles in bipolar mode,

wherein a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array.

REMARKS

I. INTRODUCTION

Claims 3-6, 9, and 12 have been canceled, without prejudice. Applicants reserve the right to file one or more continuing applications in which the subject matter recited in these claims would be prosecuted. Claims 1, 2, 7, 8, 10, 11, and 13-19 have been amended as indicated in the claim listing above. New claims 20-33 have been added. Accordingly, claims 1, 2, 7, 8, 10, 11, and 13-33 are now under consideration in the present application. Provided above, please find a claim listing indicating the current amendments to the previously-pending claims and the addition of new claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

Applicant thanks the Examiner for indicating that claim 14 recites allowable subject matter.

II. REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, SHOULD BE WITHDRAWN

Claims 10 and 17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner alleges that claims 10 and 17 are “omnibus type claims” and that they fail to point out what is included or excluded by the claim language.

Claims 10 and 17 have been amended to more clearly recite what Applicant considers to be his invention. Applicant submits that the amendments to claims 10 and 17 address the Examiner’s basis of rejection, and respectfully requests that the rejection of these claims under 35 U.S.C. § 112, second paragraph, be withdrawn.

III. REJECTIONS UNDER 35 U.S.C. § 102 SHOULD BE WITHDRAWN

A. Rejections Based on the Utely Patent

Claims 1-9, 11, 13, 16, and 18 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,277,116 to Utely et al. (the “Utely Patent”). (See Office Action, page 3). The Utely Patent describes methods and apparatus for shrinking collagen tissue by applying energy to tissue beneath the epidermal skin region using an array of electrodes.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; *see also Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984). Applicant respectfully asserts that the Utely Patent fails to disclose the subject matter recited in amended independent claims 1 and 16, and the claims which depend therefrom, for at least the reasons set forth below. Note that rejected claims 3-6, 9, and 18 have been canceled as provided herein, rendering their rejection moot.

Claim 1

Independent claim 1 has been amended to recite an apparatus which includes a plurality of needles attached to a base, and **a spacer substrate movably attached to the base which includes a plurality of holes through which the needles protrude**. Support for this amendment is provided, *inter alia*, in para. [0033] and FIG. 3 of the published application (U.S. Publication No. 2005/0222565). Applicant respectfully asserts that the Utely Patent fails to disclose such an adjustable spacer substrate. (A more detailed discussion of this feature is provided with respect to claim 7, below.) Accordingly, the rejection of amended independent claim 1 under 35 U.S.C. §102(b) based on the Utely Patent should be withdrawn.

Claim 2

Claim 2 has been amended to correct minor informalities. Applicant respectfully asserts that the rejection of amended dependent claim 2 based on the Utely Patent should be withdrawn for at least the reasons provided above with respect to claim 1, from which claim 2 depends.

Claim 7

Claim 7 has been amended to correct minor informalities, and to recite the apparatus of claim 1 where **the spacer substrate is adjustable relative to that of the base to control a distance between distal ends of the needles and a surface of the substrate**. Support for this amendment is provided, *inter alia*, in para. [0033] and FIG. 3 of the published application. The Examiner alleges that the Utely Patent discloses such a spacer substrate in FIGS. 7-9. (See Office Action, page 4). Applicant respectfully disagrees. The needle electrodes

86 in FIG. 6 of the Utely Patent are firmly affixed to a carrier 80 which is provided on an energy carrier 30(2). The apparatus shown in FIG. 8 of the Utely Patent has these same features. There is no disclosure of **a spacer substrate movably attached to the base which includes a plurality of holes through which the needles protrude**, nor such a substrate with an adjustable position such that **the distance between the substrate and the base is controlled**. Accordingly, the rejection of amended claim 7 under 35 U.S.C. §102(b) based on the Utely Patent should be withdrawn.

Claim 8

Claim 8, which depends from independent claim 1, has been amended to correct minor informalities, and recites an apparatus which includes **a substrate that has a cooling arrangement** to cool the surface of the skin being treated, where **the cooling arrangement includes an embedded conduit for circulating a coolant or a Peltier device**. Applicant respectfully asserts that the Utely Patent fails to disclose such a cooling arrangement. Accordingly, the rejection of amended claim 8 under 35 U.S.C. §102(b) based on the Utely Patent should be withdrawn for at least these reasons, as well as for the reasons provided above with respect to independent claim 1, from which claim 8 depends.

Claim 10

Claim 10, which depends from independent claim 1, has been amended to correct minor informalities and to address the Examiner's rejection under 35 U.S.C. § 112, second paragraph. Amended claim 10 recites the apparatus of claim 1 which further includes **a vibrating arrangement provided in communication with the base**. Applicant respectfully asserts that the Utely Patent fails to disclose such a vibrating arrangement. Accordingly, Applicant respectfully asserts that claim 10 as amended is not anticipated by the Utely Patent for at least these reasons, as well as for the reasons provided above with respect to independent claim 1, from which claim 10 depends.

Claim 11

Claim 11, which depends from independent claim 1, has been amended to correct minor informalities, and recites the apparatus of claim 1 in which **the needles are configured as a plurality of pairs of needles that are closer to each other than to other needles**, and where

radio frequency electromagnetic energy is provided to the pairs of needles in bipolar mode.

Support for this amendment is provided, *inter alia*, in para. [0044] of the published application. Applicant respectfully asserts that the Utely Patent fails to disclose such a configuration of closely-spaced pairs of needles in the electrode array described therein. The electrodes described in the Utely Patent are provided in a **uniformly-spaced** array. (*See* the Utely Patent, FIGS. 6-9). Accordingly, the rejection of amended claim 11 under 35 U.S.C. §102(b) based on the Utely Patent should be withdrawn for at least these reasons, as well as for the reasons provided above with respect to independent claim 1, from which claim 11 depends.

Claim 13

Claim 13, which depends from independent claim 1, has been amended to correct minor informalities, and recites the apparatus of claim 1 in which **at least one of the needles in the array is nonconductive and hollow**, and is configured to deliver a local analgesic to the tissue being treated. Support for this amendment is provided, *inter alia*, in para. [0048] of the published application. Applicant respectfully asserts that the Utely Patent fails to disclose providing such a **nonconductive** hollow needle or electrode in the array of electrodes. The Utely Patent discloses an array of needle electrodes in which some **conductive electrodes** contain interior fluid passages. (*See* the Utely Patent, col. 9:11-16). Accordingly, the rejection of amended claim 13 under 35 U.S.C. §102(b) based on the Utely Patent should be withdrawn for at least these reasons, as well as for the reasons provided above with respect to independent claim 1, from which claim 13 depends.

Claims 16 and 17

Independent claim 16, as amended herein, recites a method for treating skin which includes, *inter alia*, inserting an array of needles into the skin, **detecting presence of a nerve in proximity to certain needles**, and **providing energy to needles which do not have a nerve in proximity thereto**. Support for the amendment to claim 16 is provided, *inter alia*, in para. [0049] of the published application. Applicant respectfully asserts that the Utely Patent fails to disclose detecting a nerve in proximity to certain needles in an array of needles. The Examiner did not provide specific reasons for rejecting original claim 16 based on the Utely patent. However, the Examiner acknowledged that original claim 14, which recites similar subject matter relating to nerve detection using a needle array, contained allowable subject matter. (*See*

Office Action, page 6). Accordingly, Applicant respectfully asserts that claim 16 as amended herein is not anticipated by the Utely Patent for at least these reasons.

Claim 17, which depends from independent claim 1, has been amended to correct minor informalities and address the Examiner's rejection under 35 U.S.C. § 112, second paragraph. Claim 17 recites the method of claim 1 in which the energy supplied to the needles is radio frequency electromagnetic energy. Applicant respectfully asserts that amended dependent claim 17 is not anticipated by the Utely Patent for at least the reasons provided above with respect to independent claim 16.

B. Rejections Based on the Prausnitz Patent

Claims 1, 4, 5, 12, 15, and 16 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,503,231 to Prausnitz et al. (the "Prausnitz Patent"). (See Office Action, page 4). The Prausnitz Patent describes methods and apparatus for transport of therapeutic materials and/or energy across tissue barriers using microneedle arrays which penetrate into the epidermal layer of skin.

Applicants respectfully assert that the Prausnitz Patent fails to disclose the subject matter recited in amended independent claims 1 and 16 and dependent claim 15, for at least the reasons set forth below. Note that rejected claims 4, 5, and 12 have been canceled as provided herein, rendering their rejection moot.

Claim 1

Independent claim 1 has been amended to recite an apparatus which includes a plurality of needles attached to a base, and **a spacer substrate movably attached to the base such that the distance between the substrate and the base is adjustable**. Support for this amendment is provided, *inter alia*, in para. [0033] and FIG. 3 of the published application. Applicant respectfully asserts that the Prausnitz Patent fails to disclose such an adjustable spacer substrate. Accordingly, the rejection of amended independent claim 1 under 35 U.S.C. §102(b) based on the Prausnitz Patent should be withdrawn.

Claim 15

Claim 15, which depends from independent claim 1, has been amended to correct minor informalities. Claim 15 recites the apparatus of claim 1 in which **at least one needle includes a light fiber or a light guide**, where **the needles are configured to penetrate into the dermis or subdermal tissue**, and where the apparatus delivers optical energy through the at least one needle and **into tissue proximal to the needle tip**. Support for this amendment is provided, *inter alia*, in the original claims and in paras. [0030], [0043], [0050], and [0052] of the published application.

The Examiner alleges that the Prausnitz Patent discloses hollow micro-needles which permit passage of light delivery optical fibers. (*See* Office Action, page 5; and the Prausnitz Patent, col. 5:34-38). Applicant respectfully asserts that the Prausnitz Patent fails to disclose an apparatus which includes a needle array and **an adjustable spacer substrate**, as recited in amended independent claim 1 from which claim 15 depends. Further, the microneedle arrays disclosed in the Prausnitz Patent are not **configured to penetrate into the dermis or subdermal tissue**, as recited in claim 15 as amended herein. In contrast, the microneedles disclosed in the Prausnitz Patent are configured to penetrate only into the upper epidermal layer, through the stratum corneum tissue barrier. (*See* the Prausnitz Patent, FIG. 3; col. 2:60-67; and col. 5:55-67). The Prausnitz Patent *teaches away* from providing microneedles which penetrate into the dermis, to avoid contacting nerves therein. (*See* the Prausnitz Patent, col. 5:55-60). Accordingly, for at least the reasons provided above, the rejection of amended claim 15 under 35 U.S.C. §102(b) based on the Prausnitz Patent should be withdrawn.

Claim 16

Independent claim 16, as amended herein, recites a method for treating skin which includes, *inter alia*, inserting an array of needles into the skin, **detecting presence of a nerve in proximity to certain needles**, and **providing energy to needles which do not have a nerve in proximity thereto**. Support for the amendment to claim 16 is provided, *inter alia*, in para. [0049] of the published application. Applicant respectfully asserts that the Prausnitz Patent fails to disclose detecting a nerve in proximity to certain needles in an array of needles. The Examiner also noted that original claim 14, which recites similar subject matter relating to nerve detection using a needle array, contained allowable subject matter. (*See* Office Action, page 6).

Accordingly, Applicant respectfully asserts that claim 16 as amended herein is not anticipated by the Prausnitz Patent for at least these reasons, and that the rejection of amended independent claim 16 under 35 U.S.C. §102(b) based on the Prausnitz Patent should be withdrawn.

IV. REJECTION UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN

Claim 19 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Utely Patent in view of the Prausnitz Patent. (*See* Office Action, page 5). Applicant respectfully submits that it would not be obvious to one of ordinary skill in the art to combine the teachings of the Utely Patent with those of the Prausnitz patent.

As noted above, the Utely Patent describes methods and apparatus for shrinking collagen tissue by applying energy to tissue using an array of electrodes configured to penetrate **beneath the epidermal skin region**. In contrast, the Prausnitz Patent describes methods and apparatus for transport of therapeutic materials and/or energy across tissue barriers using microneedle arrays **which penetrate only into the epidermal layer of skin**. As noted earlier, the Prausnitz Patent *teaches away* from providing microneedles which penetrate into the dermis, to avoid contacting nerves therein. (*See* the Prausnitz Patent, col. 5:55-60).

Even if the cited references were combined, the alleged combination fails to teach or suggest the subject matter recited in claim 19 as amended herein. The Utely Patent fails to teach, suggest or disclose the subject matter recited in dependent claim 19, which depends from amended independent claim 16, for at least the same reasons described above with respect to amended independent claim 16. The Prausnitz Patent fails to cure this deficiency

Accordingly, Applicant respectfully submits that the Utely Patent is not combinable with the Prausnitz Patent and, even if combined, the alleged combination does not teach, suggest or disclose the subject matter recited in claim 19. Thus, withdrawal of the rejection of this claims under 35 U.S.C. § 103(a) is respectfully requested.

V. ALLOWABLE SUBJECT MATTER

Claim 14 stands objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form. (*See* Office Action, page 6). Claim 14 has been rewritten in independent form which includes the substantial limitations provided in

original claim 1 from which original claim 14 depends. Claim 14 has also been amended to correct minor informalities.

Accordingly, Applicant respectfully requests a confirmation of allowance of the claimed subject matter identified by the Examiner in the Office Action as recited in independent claim 14.

VI. NEW CLAIMS ARE NOT ANTICIPATED OR RENDERED OBVIOUS BY THE CITED ART

Claim 20

New claim 20 depends from claim 1, and further recites that the **needles protrude a plurality of distances from the base**. Support for this amendment is provided, *inter alia*, in para. [0043] of the published application. Such variation in needle lengths allows a larger volume of tissue to be treated by applying energy at different depths. Applicant respectfully asserts that neither the Utely Patent nor the Prausnitz Patent discloses such a needle array in which the needles have a plurality of lengths. In contrast, all of the needles in the arrays disclosed in the Utely Patent and the Prausnitz Patent have a single, uniform length. (*See* the Utely Patent, FIGS. 6-9; and the Prausnitz Patent, FIGS. 2-6). Accordingly, for at least these reasons, in addition to those provided above with respect to amended independent claim 1, Applicant respectfully asserts that new claim 20 is neither anticipated by nor rendered obvious in view of the Utely Patent or the Prausnitz Patent, taken separately or in an alleged combination.

Claim 21

Claim 21 recites the limitation that **a portion of at least one needle is configured to absorb a portion of the optical energy and convert the optical energy to thermal energy**. Support for this amendment is provided, *inter alia*, in para. [0050] of the published application. Applicant respectfully asserts that neither the Utely Patent nor the Prausnitz Patent discloses a needle array in which any of the needles are configured to absorb a portion of optical energy and convert it to thermal energy. Accordingly, for these reasons, in addition to those provided above with respect to amended claim 15 from which claim 21 directly depends, Applicant respectfully asserts that new claim 21 is neither anticipated by nor rendered obvious in view of the Utely Patent or the Prausnitz Patent, taken separately or in an alleged combination.

Claims 22 and 23

New claims 22 and 23 depend from claim 14, which has been rewritten in independent form and which contains allowable subject matter as identified by the Examiner. (See Office Action, page 6). Accordingly, Applicant respectfully asserts that new claims 22 and 23, which depend from amended independent claim 14 and contain the allowable subject matter therein as identified by the Examiner in the Office Action, also recite allowable subject matter.

Claims 24-26

New independent claim 24 recites, *inter alia*, an apparatus which includes a plurality of needles attached to a base and an energy source provided in communication with the needles, where **the needles protrude a plurality of distances from the base**. Support for this new claim is provided, *inter alia*, in the originally-filed claims and in para. [0043] of the published application. As described above with respect to new claim 20, neither the Utely Patent nor the Prausnitz Patent discloses such a needle array in which the needles have a plurality of lengths. Accordingly, for at least these reasons, Applicant respectfully asserts that new independent claim 24 is neither anticipated by, nor rendered obvious in view of, the Utely Patent or the Prausnitz Patent, taken separately or in an alleged combination.

New claims 25 and 26 depend from independent claim 24, and Applicant respectfully asserts that claims 25 and 26 are also not anticipated by nor rendered obvious in view of the Utely Patent and/or the Prausnitz Patent, for at least the reasons provided above with respect to claim 24.

Claim 27

New claim 27 depends from independent claim 24, and further recites that **the needles are configured as a plurality of pairs of needles that are closer to each other than to other needles**, and that **radio frequency electromagnetic energy is provided to the pairs of needles in bipolar mode**. Support for this amendment is provided, *inter alia*, in para. [0044] of the published application. For at least the reasons provided above with respect to claim 11, which recites similar features, and the reasons provided above with respect to new claim 24 from which claim 27 depends, Applicant respectfully asserts that new claim 27 is neither anticipated

by nor rendered obvious in view of the Utely Patent or the Prausnitz Patent, taken separately or in an alleged combination.

Claim 28

New claim 28 depends from independent claim 24, and further recites that **at least one needle includes a light fiber or a light guide**, where **the needles are configured to penetrate into the dermis or subdermal tissue**, and where the apparatus delivers optical energy through the at least one needle and **into tissue proximal to the needle tip**. Support for this new claim is provided, *inter alia*, in the original claims and in paras. [0030], [0043], [0050], and [0052] of the published application. For at least the reasons provided above with respect to claim 15, which recites similar features, and the reasons provided with respect to new claim 24 from which claim 28 depends, Applicant respectfully asserts that new claim 28 is neither anticipated by nor rendered obvious in view of the Utely Patent or the Prausnitz Patent, taken separately or in an alleged combination.

Claims 29-31

New independent claim 29 recites a method for treating tissue which includes, *inter alia*, inserting an array of needles into the tissue and providing energy to the needles, where **distal ends of the needles are provided at a plurality of depths within the tissue**. Support for this new claim is provided, *inter alia*, in the originally-filed claims and in para. [0043] of the published application. As described above with respect to new claim 24, neither the Utely Patent nor the Prausnitz Patent discloses providing energy to an array of needles where the needles are provided at a plurality of depths within the tissue. Accordingly, for at least these reasons, Applicant respectfully asserts that new independent claim 29 is neither anticipated by, nor rendered obvious in view of, the Utely Patent or the Prausnitz Patent, taken separately or in an alleged combination.

New claims 30 and 31 depend from independent claim 29, and Applicant respectfully asserts that these claims are also not anticipated by nor rendered obvious in view of the Utely Patent and/or the Prausnitz Patent, for at least the reasons provided above with respect to claim 29.

Claims 32 and 33

New claim 32 recites an apparatus which includes a plurality of needles **configured as a plurality of pairs of needles that are closer to each other than to other needles**, and where **radio frequency electromagnetic energy is provided to the pairs of needles in bipolar mode**. Support for this claim is provided, *inter alia*, in para. [0044] of the published application. New claim 33 recites a method for treating tissue which includes similar subject matter. Applicant respectfully asserts that the Utely Patent fails to disclose such a configuration of closely-spaced pairs of needles in the electrode array described therein. The electrodes described in the Utely Patent are provided in a **uniformly-spaced** array. (*See* the Utely Patent, FIGS. 6-9).

Accordingly, for at least these reasons Applicant respectfully asserts that new claims 32 and 33 are neither anticipated by nor rendered obvious in view of the Utely Patent or the Prausnitz Patent, taken separately or in an alleged combination.

VII. CONCLUSION

In light of the foregoing, Applicants respectfully submit that the pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited. The Examiner is invited to contact the undersigned to expedite the prosecution of this application if any issues remain outstanding.

Respectfully submitted,

Date: June 30, 2008

By: /Steven P. Marsh/
Steven P. Marsh
Patent Office Reg. No. 53,271

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620 Eighth Avenue
New York, New York 10018

Attorney for Applicant
(212) 459-7065

Electronic Patent Application Fee Transmittal

Application Number:	11098030			
Filing Date:	01-Apr-2005			
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping			
First Named Inventor/Applicant Name:	Dieter Manstein			
Filer:	Steven Paul Marsh/Tammy Beckwith-Hein			
Attorney Docket Number:	036213/US/2-475387-00230			
Filed as Small Entity				
Utility Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	2202	7	25	175
Independent claims in excess of 3	2201	4	105	420
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				595

Electronic Acknowledgement Receipt

EFS ID:	3539810
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Steven Paul Marsh/Tammy Beckwith-Hein
Filer Authorized By:	Steven Paul Marsh
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	30-JUN-2008
Filing Date:	01-APR-2005
Time Stamp:	17:04:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$595
RAM confirmation Number	3049
Deposit Account	071700
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
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1		MGH002NPreponse.pdf	345153 ca89a2d27690592ac2d3abe5cd1e1b6e90b7b751	yes	25				
	Multipart Description/PDF files in .zip description								
	Document Description		Start	End					
	Amendment - After Non-Final Rejection		1	1					
	Claims		2	14					
	Applicant Arguments/Remarks Made in an Amendment		15	25					
Warnings:									
Information:									
2	Fee Worksheet (PTO-06)	fee-info.pdf	8325 6ddaa9040d31aea057afc4caecae427c6a5681bc	no	2				
Warnings:									
Information:									
Total Files Size (in bytes):			353478						
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>									

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/098,030		Filing Date 04/01/2005		<input type="checkbox"/> To be Mailed					
APPLICATION AS FILED – PART I														
(Column 1)			(Column 2)		SMALL ENTITY <input checked="" type="checkbox"/> OR			OTHER THAN SMALL ENTITY						
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)						
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A								
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))		N/A		N/A		N/A								
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A								
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 =		*		X \$ =		OR		X \$ =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 =		*		X \$ =		OR		X \$ =				
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).												
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))														
* If the difference in column 1 is less than zero, enter "0" in column 2.														
APPLICATION AS AMENDED – PART II														
(Column 1)			(Column 2)		(Column 3)			SMALL ENTITY OR			OTHER THAN SMALL ENTITY			
AMENDMENT	06/30/2008		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)			
	Total (37 CFR 1.16(i))		* 27		Minus ** 20		= 7		X \$25 =		175			
	Independent (37 CFR 1.16(h))		* 7		Minus *** 3		= 4		X \$105 =		420			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))													
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))													
	TOTAL ADD'L FEE													
(Column 1) (Column 2) (Column 3)											SMALL ENTITY OR		OTHER THAN SMALL ENTITY	
AMENDMENT	Total (37 CFR 1.16(i))		* 27		Minus ** 20		= 7		X \$25 =		175			
	Independent (37 CFR 1.16(h))		* 7		Minus *** 3		= 4		X \$105 =		420			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))													
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))													
	TOTAL ADD'L FEE													
	TOTAL ADD'L FEE													

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/DALE A. HALL/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/098,030	04/01/2005	Dieter Manstein	036213/US/2-475387-00230	6055

30873 7590 10/31/2008
DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3769

MAIL DATE	DELIVERY MODE
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10/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/098,030	Applicant(s) MANSTEIN, DIETER	
	Examiner Ahmed M. Farah	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,8,10,11 and 13-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,7,8,10,11, and 13-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, 2, 7, 8, 10, 11, 13-15, 20-28 and 32, drawn to treatment apparatuses comprising plurality of needles, classified in class 606, subclass 41.
- II. Claims 16-19, 29-31, and 33, drawn to methods for treating tissue with optical and/or radiofrequency energy, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the method for treating the tissue can be provided by other and materially different apparatus, such as light delivery optical fiber inserted into the tissue.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;

- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species:

A (claims 2 and 26, see paragraph [0047]);

B (claims 15, 21 and 26, see paragraph [0050]); and

C (claims 14, 22 and 23, see paragraph [0049]).

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or

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employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

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prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

A telephone call was made to the office of the applicant's representative, Steven Marsh (Reg. No. 53,271), on October 24, 2008, to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon, Tue, Thur and Fri between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johnson Henry can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ahmed M Farah/
Primary Examiner, Art Unit 3769

October 27, 2008.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Dieter MANSTEIN
Appln. Serial No. : 11/098,030
Filed : April 1, 2005
Entitled : METHOD AND APPARATUS FOR
DERMATOLOGICAL TREATMENT AND TISSUE
RESHAPING
Group Art Unit : 3769
Confirmation No. : 6055
Examiner : Ahmed M. Farah

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

SIR:

This paper is filed in response to the Office Action and Election/Restriction Requirement dated October 31, 2008 (the "Office Action"). Initially, please amend the above-identified application as set forth below.

In The Claims:

Please withdraw claims 16-19, 29-31 and 33 from consideration, and add new claims 34-37 in the present application, as indicated below in the associated claim listing provided on separate sheets:

1. (Previously presented) An apparatus for tissue treatment, comprising:

a base;
a plurality of needles attached to the base;
an energy source provided in communication with at least one of the
needles;
a spacer arrangement for controlling penetration depths of the needles;
and
a control module configured to vary characteristics of energy supplied by
the energy source.

2. (Previously presented) The apparatus of claim 1 wherein more than one of the
needles are electrically conductive, and wherein the energy source is configured to
supply radio frequency electromagnetic energy to individual ones of the needles.

3. (Canceled)

4. (Canceled)

5. (Canceled)

6. (Canceled)

7. (Previously presented) The apparatus of claim 1, wherein the spacer arrangement
comprises a substrate movably attached to the base, wherein the position of the
substrate is adjustable relative to that of the base to control a distance between distal
ends of the needles and a surface of the substrate.

8. (Previously presented) The apparatus of claim 1, wherein at least one of the base or
the substrate further comprises a cooling arrangement configured to cool a skin surface,
and wherein the cooling arrangement comprises at least one of an embedded conduit
configured to circulate a coolant or a Peltier device.

9. (Canceled)

10. (Previously presented) The apparatus of claim 1, further comprising a vibrating arrangement provided in communication with the base.

11. (Previously presented) The apparatus of claim 1, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

12. (Canceled)

13. (Previously presented) The apparatus of claim 1, wherein at least one of the needles is nonconductive and hollow, and is configured to deliver a local analgesic to tissue proximal to a distal end of the needle.

14. (Previously presented) An apparatus for tissue treatment, comprising:

- a base;

- a plurality of needles attached to the base;

- an energy source provided in communication with at least one of the needles;

- a control module configured to vary characteristics of energy supplied by the energy source; and

- an electronic detection device in electrical communication with at least one of the needles that is configured to detect the presence of a nerve near the tip of the at least one of the needles.

15. (Previously presented) The apparatus of claim 1, further comprising:

a source of optical energy; and

at least one optical needle comprising at least one of a light fiber or a light guide, wherein the distal ends of the needles are configured to penetrate into at least one of the dermis or subdermal tissue, and wherein the apparatus is configured to deliver a controlled amount of optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle.

16. (Withdrawn)

17. (Withdrawn)

18. (Withdrawn)

19. (Withdrawn)

20. (Previously presented) The apparatus of claim 1, wherein the plurality of needles protrude a plurality of distances from the base.

21. (Previously presented) The apparatus of claim 15, wherein a portion of the at least one needle is configured to absorb a portion of the optical energy and convert the optical energy to thermal energy.

22. (Previously presented) The apparatus of claim 14, wherein the control module is configured to prevent the energy source from supplying energy to a particular needle if a nerve has been detected near the particular needle.

23. (Previously presented) The apparatus of claim 14, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between two needles in a pair of needles is less than a distance between each one of the two needles and any other needle, and wherein the energy source and the control module are configured

to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

24. (Previously presented) An apparatus for dermatological treatment, comprising:

a base;

a plurality of needles attached to the base;

an energy source provided in communication with at least one of the needles; and

a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles protrude a plurality of distances from the base.

25. (Previously presented) The apparatus of claim 24, wherein the energy source is a source of electromagnetic energy.

26. (Previously presented) The apparatus of claim 24, wherein a plurality of the needles are electrically conductive, and wherein the energy source is configured to supply radio frequency electromagnetic energy to individual ones of the needles.

27. (Previously presented) The apparatus of claim 24, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

28. (Previously presented) The apparatus of claim 24, further comprising:

at least one optical needle comprising at least one of a light fiber or a light guide,

wherein the apparatus is configured to deliver a controlled amount of optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle,

wherein the energy source comprises a source of optical energy.

29. (Withdrawn)

30. (Withdrawn)

31. (Withdrawn)

32. (Previously presented) An apparatus for tissue treatment, comprising:

a base;

a plurality of needles attached to the base;

an energy source provided in communication with at least one of the needles; and

a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

33. (Withdrawn)

34. (New) The apparatus of claim 1, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region of the tissue.

35. (New) The apparatus of claim 24, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region.

36. (New) The apparatus of claim 32, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region of the tissue.

37. (New) An apparatus for tissue treatment, comprising:

- a base;
- a plurality of needles attached to the base;
- an energy source provided in communication with at least one of the needles;
- a control module configured to vary characteristics of energy supplied by the energy source; and
- an electronic detection device in electrical communication with at least one of the needles that is configured to detect the presence of a nerve near the tip of the at least one of the needles.

Remarks

I. INTRODUCTION

Claims 16-19, 29-31, and 33 have been withdrawn without prejudice in response to the restriction requirement, as described below. Applicant reserves the right to file one or more continuing applications in which the subject matter recited in these claims would be prosecuted. New claims 34-37 have been added. Accordingly, claims 1, 2, 7, 8, 10, 11, 13-15, 20-28, 32 and 34-37 are now under consideration in the present application. Provided above, please find a claim listing indicating the addition of new claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. RESTRICTION REQUIREMENT

A. Inventions

In the Office Action, the Examiner states that certain groups of claims of above-identified application recite inventions that are distinct from one another. (See Office Action, page 2). For such reason, the Examiner believes that the restriction of claims is proper, and now requires Applicants to elect one of the following groups:

Group I: claims 1, 2, 7, 8, 10, 11, 13-15, 20-28 and 32, allegedly drawn to a treatment apparatus comprising a plurality of needles, supposedly classified in class 606, subclass 41; and

Group II: claims 16-19, 29-31, and 33, allegedly drawn to methods for treating tissue with optical and/or radio frequency energy, supposedly classified in class 128, subclass 898.

In response to this restriction requirement, Applicant hereby elects Group I, i.e., claims 1, 2, 7, 8, 10, 11, 13-15, 20-28, 32 (drawn to an apparatus comprising a plurality of needles), without traverse, for prosecution in the present application.

Applicant respectfully submits that new claims 34-37 submitted herewith drawn to an apparatus comprising a plurality of needles, should also be included in Group I, and requests that these new claims also be examined as part of this elected group.

B. Species

The Examiner further asserts that certain claims of the present application in Group I are drawn to patentably distinct species. (See *id.*, page 4). Then, the Examiner identifies the following three allegedly distinct species:

- Species A: Claims 2 and 26, reciting application of radio frequency energy using the needle array;
- Species B: Claims 15, 21 and 26, apparently reciting needles delivering optical energy (Applicant notes that claim 26 does not recite optical energy, and thus Applicant assumes that the Examiner intended to include claim 28 in this allegedly distinct species); and
- Species C: Claims 14, 22 and 23 (together with new claim 37), reciting a needle array which is also used to detect the presence of nerves.

The Examiner alleges that the species are independent or distinct because they recite mutually exclusive characteristics of such species, and that there would be an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics.

Applicant notes that the claims reciting these allegedly distinct species each depend from independent claims 1, 14, 24 or 32, as applicable. Applicant respectfully asserts that each of the alleged species A-C recites an apparatus which includes a plurality of needles configured to provide energy to tissue, and that the features identified by the Examiner are **not** mutually exclusive characteristics and, in fact, may be combined using the same recited structure. (See, e.g., paras. [0048]-[0050] of the present application.) Applicant respectfully asserts that the common characteristics of each of these alleged species, e.g., a needle array configured to deliver energy to tissue, does **not** require separate searches and consideration of different fields of research. Applicant also respectfully asserts that independent claims 1 and 24 are generic to the allegedly distinct species A-C.

Thus, Applicant hereby respectfully traverses this species restriction requirement set forth in the Office Action, and provisionally elects alleged species A, corresponding to claims 2 and 26. Applicant notes that claims 1, 2, 7, 8, 10, 11, 13, 20, 24-27, 32, and new claims 34-36 are part of and/or generic to allegedly distinct Species A.

B. Species

Applicant has elected Group I in response to the present restriction requirement, without traverse, and has withdrawn claims 16-19, 29-31, and 33 from consideration in the present application. Applicant has also traversed the species election requirement provided by the Examiner, and provisionally elected a single alleged species (Species A) for this election requirement, but also believe that this restriction requirement is inappropriate as set forth above.

Applicant notes that 37 C.F.R. 1.146 indicates that the Examiner has discretion in requiring an election of identified species. However, Applicant asserts that the species election requirement contained in the latest Office Action would not require searches of different fields of research, nor would consideration of all alleged species place an undue burden on the Patent Office.

Therefore, for at least these reasons, the Examiner is respectfully requested to withdraw the Restriction Requirement (associated with the species) contained in the Office Action dated October 31, 2008. Upon such withdrawal by the Examiner, Applicant respectfully requests that pending claims 1, 2, 7, 8, 10, 11, 13-15, 20-28, 32 and 34-37 be prosecuted on their merits in the present application. Alternatively, to the extent that such withdrawal is not made by the Examiner, Applicant respectfully requests that the elected species identified herein and, if necessary, further non-elected species be considered on their merits.

Applicant further notes that upon the indication of allowability of any generic claim(s), any claims which are directed to non-elected species which depend from such allowable claim(s) be considered.

III. CONCLUSION

In light of the foregoing, Applicant respectfully submits that the pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited. The Examiner is invited to contact the undersigned to expedite the prosecution of this application if any issues remain outstanding.

Respectfully submitted,

Date: December 1, 2008

By 

Gary Abelev
Patent Office Reg. No. 40,479

DORSEY & WHITNEY, L.L.P.
250 Park Avenue
New York, New York 10177

Attorney for Applicant
(212) 415-9371

Electronic Acknowledgement Receipt

EFS ID:	4375082
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Gary Abelev/Marilyn Alexander-Kuruvilla
Filer Authorized By:	Gary Abelev
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	01-DEC-2008
Filing Date:	01-APR-2005
Time Stamp:	17:51:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	036213AmendmentResponseR estrReq01Dec2008.PDF	368171 71cd36a8c44ddb1a87559211fdb529b07a 9c813	no	11

Warnings:

Information:

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/098,030		Filing Date 04/01/2005		<input type="checkbox"/> To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)		SMALL ENTITY <input checked="" type="checkbox"/> OR			OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=	OR	X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=			
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL				
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)		SMALL ENTITY OR			OTHER THAN SMALL ENTITY		
AMENDMENT	12/01/2008	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 23	Minus	** 27	=	0	OR	X \$	=	
	Independent (37 CFR 1.16(h))	* 5	Minus	*** 7	=	0	OR	X \$	=	
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))										
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE		
(Column 1)			(Column 2)		SMALL ENTITY OR			OTHER THAN SMALL ENTITY		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=		OR	X \$	=	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		OR	X \$	=	
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))										
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		
<p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p>										

Legal Instrument Examiner:
/Halley D. Massey/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/098,030	04/01/2005	Dieter Manstein	036213/US/2-475387-00230	6055

30873 7590 03/06/2009
DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3769

MAIL DATE	DELIVERY MODE
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03/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Notice of Non-Compliant
Amendment (37 CFR 1.121)**

Application No.

11/098,030

Examiner

Ahmed M. Farah

Applicant(s)

MANSTEIN, DIETER

Art Unit

3769

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on _____ is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☐ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☐ E. Other: _____.
- ☒ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):
In response to the Restriction/Election requirement dated October 31, 2008., the applicant elected invention for prosecution. The applicant further traversed the requirement for Election of Species A, B, and C. He further points out a typographical error in the Examiner's listing of the claims in species B. However, the applicant failed to t elected invention the applicant failed to elect between the species. According to 35 USC 121, the applicant is required to elect a single species for prosecution.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

/Ahmed M Farah/ Primary Examiner, Art Unit 3769	
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U.S. Patent and Trademark Office
PTOL-324 (01-06)

Notice of Non-Compliant Amendment (37 CFR 1.121)

Part of Paper No. 20090302

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.
36213/US/2 - 475387-00230

Serial No.
11/098,030

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

(Use several sheets if necessary)

Applicant(s)
Dieter Manstein

Filing Date
April 1, 2005

Confirmation No.
6055

U.S. PATENT DOCUMENTS

*Exam. Init.	Document No.	Date	Name	Class	Subclass	Filing Date if Appropriate
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	5 1 0 2 4 1 0	04/07/1992	Dressel			
	5 3 1 2 3 9 5	05/17/1994	Tan et al.			
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	5 9 5 4 7 1 0	09/21/1999	Paolini et al.			
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Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce
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	2005	0	2	2	2	5	6	5	10/06/2005	Manstein			
	2006	0	0	0	4	3	0	6	01/05/2006	Altshuler et al.			
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	2006	0	0	2	0	3	0	9	01/26/2006	Altshuler et al.			
	2006	0	1	2	2	6	6	8	06/08/2006	Anderson et al.			
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	2007	0	0	7	3	3	6	7	03/29/2007	Jones et al.			
	2007	0	1	9	8	0	0	3	08/23/2007	Domankevitz et al.			
	2007	0	1	7	3	7	9	9	07/26/2007	Hsia			
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		5	9	1	9	2	1	9	07/06/1999	Knowlton			
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		6	3	1	1	0	9	0	10/30/2001	Knowlton			
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		6	7	0	8	0	6	0	03/16/2004	Avrahami et al.			
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		7	1	4	1	0	4	9	11/28/2006	Stern et al.			
		7	1	8	9	2	3	0	03/13/2007	Knowlton			
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	2003	0	2	1	6	7	1	9	11/20/2003	Debenedictis et al.			
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	2005	0	2	2	2	5	5	5	10/06/2005	Manstein et al.			
	2006	0	0	0	4	3	0	6	01/05/2006	Altshuler et al.			
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	2006	0	0	5	8	7	1	2	03/16/2006	Altshuler et al.			
	2006	0	1	2	2	6	6	8	06/08/2006	Anderson et al.			
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	2006	0	2	9	3	7	2	2	12/28/2006	Slatkine et al.			
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	1	9	9	2	9	7	1	3	01/04/2001	Germany				
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Date Considered

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			Medical Fiber Optic Components, Schott, Germany, 20 pages (May 2003).
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4813-1828-7875\1

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* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

⑫

EUROPEAN PATENT APPLICATION

②① Application number: 86308847.2

⑤① Int. Cl.⁴: **A 61 B 17/36**

②② Date of filing: 13.11.86

③① Priority: 13.12.85 GB 8530786

④③ Date of publication of application:
24.06.87 Bulletin 87/26

④④ Designated Contracting States:
AT BE CH DE ES FR GB GR IT LI LU NL SE

④⑧ Date of deferred publication of search report:
23.09.87 Bulletin 87/39

⑦① Applicant: **MICRA Ltd.**
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⑦② Inventor: **Hoskin, William John**
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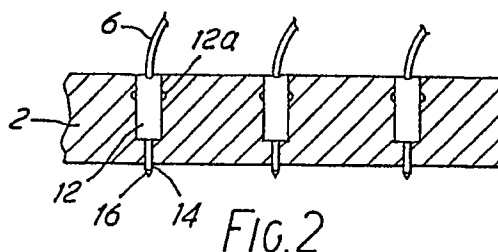
Pierse, Dermot John
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⑤④ **Surgical treatment apparatus and method.**

⑤⑦ Port wine stain treatment apparatus includes a pad 2 supporting a plurality of diamond tipped needles 14. The tip 16 of each needle is supplied with laser radiation and the tip acts to scatter laser radiation sideways. Thus, when the pad 2 is applied to the skin, the tips 16 penetrate the skin and when laser radiation is supplied the tips 16 create a laminar radiation profile located below and spaced from the skin surface.

In this manner, the cause of the port wine stain can be treated without the danger of disfiguring or scarring the skin surface above the stain.





European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT
which under Rule 45 of the European Patent Convention
shall be considered, for the purposes of subsequent
proceedings, as the European search report

Application number

EP 86 30 8847

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	APPLIED OPTICS, vol. 21, no. 19, October 1, 1982, pages 3437-3442; New York, US H. FUJII et al.: "Multispot laser photocoagulation system using a fiber bundle scanner." * Whole article *	1	A 61 B 17/36
A	ENGINEERING, vol. 224, no. 5, May 1984, page XX; Medical Equipment, London, GB MICROSURGICAL ADMINISTRATIVE SERVICES LTD: "Micra diamond knives for microsurgery." * Column 2, lines 26-29; figures *	1	
A	GB-A-2 113 550 (MICROSURGICAL ADMINISTRATIVE SERVICES LTD) * Figures 1,3 *		
			TECHNICAL FIELDS SEARCHED (Int. Cl.4)
			A 61 B A 61 F
INCOMPLETE SEARCH			
<p>The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims.</p> <p>Claims searched completely: 1-10 Claims searched incompletely: 11-14 Claims not searched: 11-14 Reason for the limitation of the search:</p> <p>Method for treatment of the human or animal body by surgery or therapy (see art. 52(4) of the European Patent Convention).</p>			
Place of search The Hague		Date of completion of the search 02-02-1987	Examiner ARGENTINI
CATEGORY OF CITED DOCUMENTS		<p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>	
<p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p>			

EPO Form 1505.1 03/82



CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☐ All claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for all claims.
- ☐ Only part of the claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claims:
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

X LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions,

namely:

- 1) Claims 1-10: Treatment apparatus
- 2) Claims 15-17: Surgical needle

- ☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☒ None of the further search fees has been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims: 1-10



⑮ **BUNDESREPUBLIK
DEUTSCHLAND**



**DEUTSCHES
PATENT- UND
MARKENAMT**

⑫ **Offenlegungsschrift**
⑩ **DE 199 29 713 A 1**

⑤① Int. Cl.⁷:
A 61 N 5/06

⑳ Aktenzeichen: 199 29 713.4
㉔ Anmeldetag: 24. 6. 1999
㉕ Offenlegungstag: 4. 1. 2001

DE 199 29 713 A 1

㉑ **Anmelder:**
Radchenko, Sergey, 13053 Berlin, DE

㉒ **Vertreter:**
Kietzmann, Vosseberg, Röhnicke Patentanwälte
Rechtsanwalt Partnerschaft, 10117 Berlin

㉓ **Erfinder:**
gleich Anmelder

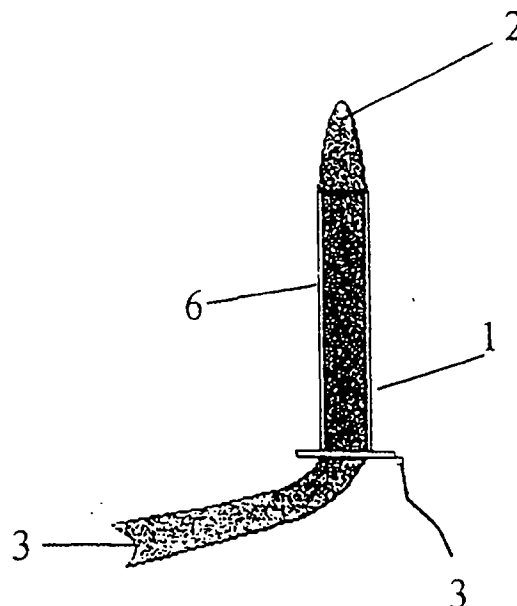
Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

Prüfungsantrag gem. § 44 PatG ist gestellt

⑤④ **Physiotherapiematte**

⑤⑦ Die Erfindung betrifft eine Physiotherapiematte, die zur Hautreizung und Durchblutungsförderung der Muskulatur angewendet wird und sich gut den Körperformen anpasst.

Die Physiotherapiematte besteht aus einer elastischen Matte, in die in definiertem Abstand Nadeln (1) kraftschlüssig angeordnet sind, die mit einem Reizstrom beaufschlagt sein können und/oder die Nadeln (1) weisen eine lichtdurchlässige Nadelspitze (2) auf und sind mit einem Lichtleiter (3) verbunden, der UV-Licht und/oder Laserlicht und/oder Infrarotlicht in die Nadelspitze (2) und damit zum menschlichen Körper transportiert.



E 199 29 713 A 1

Die Erfindung betrifft eine Physiotherapiematte, die zur Hautreizung und Durchblutungsförderung der Muskulatur angewendet wird.

Im DE-Gbm 298 210 62.2 wird eine Physiotherapiematte beschrieben, die aus einem elastischen Material besteht, in das in definiertem Abstand Nadeln kraftschlüssig eingearbeitet sind. Die Nadeln sind in ihrer Oberflächenbeschaffenheit und ihrem Abstand derart ausgebildet, daß keine Verletzungen beim Patienten auftreten können. Sie weisen bevorzugt eine konische Spitze auf, wobei die Mantelfläche nach außen gewölbt ist.

Für die Anwendung zur Reizstromtherapie besteht die elastische Matte aus elektrisch isolierendem Material. An der Unterseite der Matte ist eine erste und eine zweite elektrisch leitfähige Schicht angeordnet. Zwischen diesen leitfähigen und elastischen Schichten befindet sich eine ebenfalls elastische Isolationsschicht. In jeweils abwechselnder Reihenfolge ist eine Nadel mit der ersten elektrisch leitfähigen Schicht und die daneben liegende Nadel durch eine in der ersten leitfähigen Schicht befindlichen kreisförmige Öffnung mit der zweiten elektrisch leitfähigen Schicht verbunden.

Es hat sich nun gezeigt, daß diese Physiotherapiematte schwer an bestimmte Körperzonen anzupassen ist. Das betrifft z. B. das Kniegelenk oder auch den Nacken- und Halsbereich. Weiterhin nutzt diese Physiotherapiematte nicht alle Möglichkeiten der Hautreizung und Durchblutungsförderung der Muskulatur.

Aufgabe der Erfindung ist es, die Anwendungsbereiche der Physiotherapiematte zu erhöhen. Gelöst wird diese Aufgabe mit den kennzeichnenden Merkmalen des Anspruchs 1, vorteilhafte Ausgestaltungen sind Gegenstand der Unteransprüche.

Die erfindungsgemäße Physiotherapiematte besteht aus einer elastischen Matte, in die in definiertem Abstand Nadeln kraftschlüssig angeordnet sind, die mit einem Reizstrom beaufschlagt sein können und/oder die Nadeln weisen eine lichtdurchlässige Nadelspitze auf und sind mit einem Lichtleiter verbunden, der UV-Licht und/oder Laserlicht und/oder Infrarotlicht in die Nadelspitze und damit zum menschlichen Körper transportiert.

In einer bevorzugten Ausführung wechseln sich Nadeln mit lichtdurchlässiger Nadelspitze mit einfachen Metallnadeln und/oder mit reizstrombeaufschlagten Nadeln ab.

Um eine gute Anpassung an den Körper zu gewährleisten, sieht die Erfindung vor, daß auf einer dünnen elastischen Fläche Blöcke von Nadelträgern mit einem Abstand zu einander angeordnet sind, wobei jeder Block über eine oder mehrere Zuleitungen für Reizstrom und/oder Licht verfügt. Die Blöcke können dabei eine ebene und/oder konkave und/oder konvexe Oberfläche aufweisen, aus der die Nadeln herausragen.

In einer weiteren Ausgestaltung der Erfindung ist vorgesehen, daß Reizstrom und Licht über eine gemeinsame Nadel zum Körper geleitet werden. Dazu ist in einer bevorzugten Ausführung die eine lichtdurchlässige Nadelspitze aufweisende Nadel im Bereich des Nadelschaftes mit einem reizstromleitenden Metallmantel versehen, derart, daß die lichtdurchlässige Nadelspitze sich in die menschliche Haut eindrückt und ein Kontakt der Haut zu dem reizstromleitenden Metallmantel hergestellt wird.

Die Erfindung soll an einem Ausführungsbeispiel erläutert werden. Es zeigen:

Fig. 1 Schnitt durch eine Physiotherapiematte und

Fig. 2 eine lichtdurchlässige Nadel, die mit Reizstrom beaufschlagt werden kann.

Fig. 1 zeigt einen Ausschnitt aus der Physiotherapiematte, bei der auf einer dünnen elastischen Fläche 4 Blöcke von Nadelträgern 5 angeordnet sind, die einen Abstand zu einander aufweisen, wobei jeder Block über eine oder mehrere Zuleitungen 3 für Reizstrom und/oder Licht verfügt. Durch die Blockanordnung ist eine gute Anpassung an die jeweilige Körperform gewährleistet.

Jeder dieser Blöcke von Nadelträgern 5 weist einfache Nadeln und/oder mit einem Reizstrom beaufschlagbare Nadeln und/oder Nadeln 1 auf, die eine lichtdurchlässige Nadelspitze 2 haben und mit einem Lichtleiter 3 verbunden sind, der UV-Licht und/oder Laserlicht und/oder Infrarotlicht in die Nadelspitze 2 transportiert.

In der dargestellten Ausführung sind die als Blöcke ausgebildeten Nadelträger 5 mehrschichtig ausgeführt wobei mindestens eine Schicht 7 reizstromleitend ist.

Mit dieser Schicht 7 wird der Bereich des Nadelschaftes, der mit einem reizstromleitenden Metallmantel 6 versehen ist, verbunden. Dies zeigt **Fig. 2**, in der eine lichtdurchlässige Nadel 1, die mit Reizstrom beaufschlagt werden kann, dargestellt ist. Die lichtdurchlässige Nadelspitze 2, die sich in die menschliche Haut eindrückt, weist in einer bevorzugten Ausführung eine Höhe von 0,5–1,0 mm auf. Danach stellt sich bereits der Hautkontakt zu dem reizstromleitenden Metallmantel 6 her.

Die erfindungsgemäße Physiotherapiematte ist ausgesprochen körperfreundlich durch ihre hohe Elastizität und sie gestattet den Einsatz unterschiedlichster Reizmittel auf der Haut, wobei hier optimal Reizkombinationen zusammengestellt werden können, innerhalb einer Behandlung die Reizeinwirkung wechseln kann oder auch in ihrer Intensität veränderbar ist. Dies erfolgt durch eine entsprechende Ansteuerung der mit Licht und/oder Reizstrom beaufschlagbaren Nadeln.

Patentansprüche

1. Physiotherapiematte, insbesondere zur Hautreizung und Durchblutungsförderung, bei der in einer elastischen Matte in definiertem Abstand Nadeln kraftschlüssig angeordnet sind, die mit einem Reizstrom beaufschlagt sein können, **dadurch gekennzeichnet**, daß alle oder ein Teil Nadeln (1) eine lichtdurchlässige Nadelspitze (2) aufweisen und mit einem Lichtleiter (3) verbunden sind, der UV-Licht und/oder Laserlicht und/oder Infrarotlicht in die Nadelspitze (2) transportiert.
2. Physiotherapiematte nach Anspruch 1, dadurch gekennzeichnet, daß die Nadeln (1) mit lichtdurchlässige Nadelspitze (2) sich auf der Physiotherapiematte abwechseln mit einfachen Metallnadeln und/oder mit reizstrombeaufschlagten Nadeln.
3. Physiotherapiematte nach Anspruch 1, dadurch gekennzeichnet, daß auf einer dünnen elastischen Fläche (4) Blöcke von Nadelträgern (5) mit einem Abstand zu einander angeordnet sind, wobei jeder Block über eine oder mehrere Zuleitungen (3) für Reizstrom und/oder Licht verfügt.
4. Physiotherapiematte nach Anspruch 1 und 3, dadurch gekennzeichnet, daß die Blöcke eine ebene und/oder konkave und/oder konvexe Oberfläche aufweisen, aus der die Nadeln herausragen.
5. Physiotherapiematte nach Anspruch 1, dadurch gekennzeichnet, daß die eine lichtdurchlässige Nadelspitze (2) aufweisenden Nadeln (1) im Bereich des Nadelschaftes mit einem reizstromleitenden Metallmantel (6) versehen sind, derart, daß die lichtdurchlässige Nadelspitze (2) sich in die menschliche Haut eindrückt

und ein Kontakt zu dem reizstromleitenden Metallmantel (6) hergestellt wird.

6. Physiotherapiematte nach Anspruch 1 oder 3, dadurch gekennzeichnet, daß die Matte oder die als Blöcke ausgebildeten Nadelträger (5) mehrschichtig ausgeführt sind und mindestens eine Schicht (7) reizstromleitend ist. 5

7. Physiotherapiematte nach Anspruch 3, dadurch gekennzeichnet, daß die dünne elastische Fläche (4) und die als Blöcke ausgebildeten Nadelträger (5) aus einem Stück bestehen. 10

Hierzu 2 Seite(n) Zeichnungen

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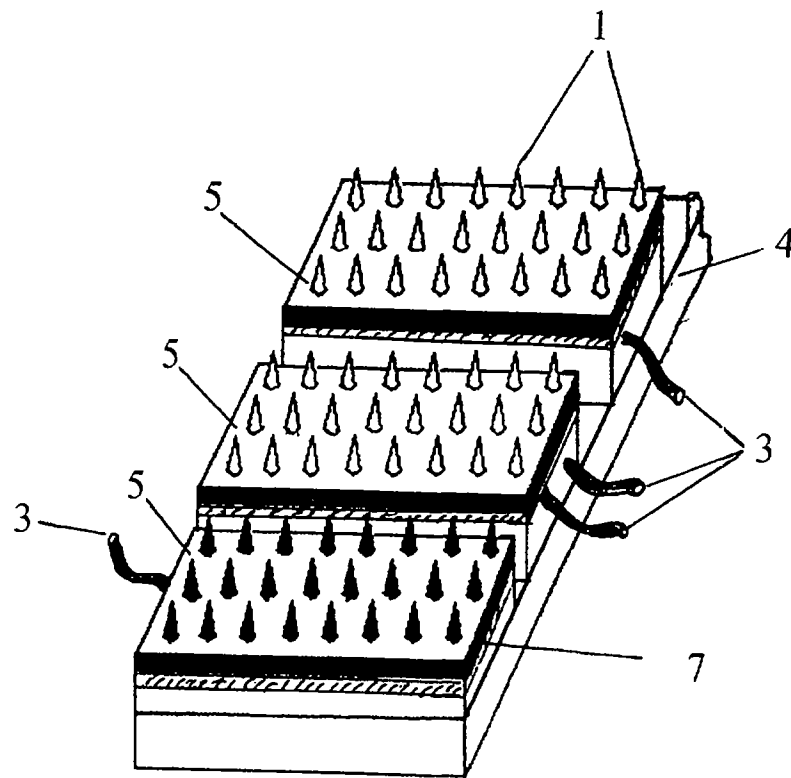


Fig. 1

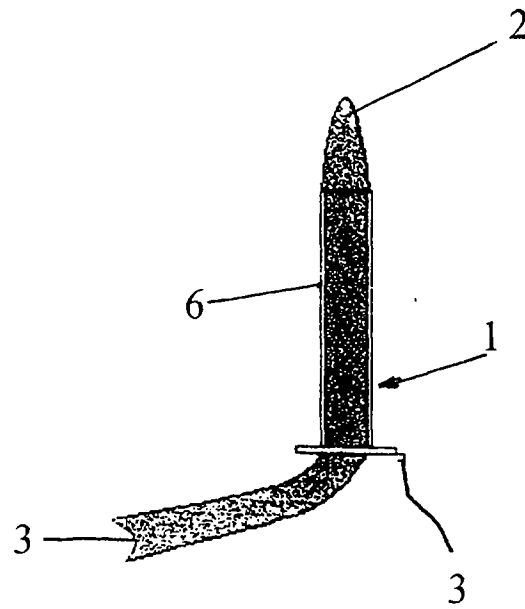


Fig. 2



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(54) Title: SYSTEMS AND METHODS FOR SHRINKING COLLAGEN IN THE DERMIS (57) Abstract <p>Devices are specially configured to apply electromagnetic energy to skin. Each device comprising a carrier and an array of electrodes on the carrier, which are connectable to a source of electromagnetic energy. The carrier, in use, contacts epidermal tissue. The electrodes either rest on the epidermal surface or, alternatively, are sized to extend into tissue beneath the epidermal tissue, e.g., into dermal tissue or into subdermal tissue. The carrier can be differently shaped to match different skin region topographies.</p>		

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**SYSTEMS AND METHODS FOR
SHRINKING COLLAGEN IN THE DERMIS**

FIELD OF THE INVENTION

5 In a general sense, the invention is directed to systems and methods for treating cosmetic conditions in the human body. In a more particular sense, the invention is directed to systems and methods for treating cosmetic conditions affecting the skin of the face and neck, as
10 evidenced by the appearance of lines and wrinkles in the face, or neck, or both.

BACKGROUND OF THE INVENTION

The skin is the principal seat of the sense of touch. The skin also provides protection against
15 the physical forces of the environment, such as heat, cold, sun rays, friction, pressure, and chemicals.

Exposure of the skin to these environmental forces can, over time, cause the skin to sag or
20 wrinkle. Hyperfunctional nervous disorders and normal contraction of facial and neck muscles, e.g. by frowning or squinting, can also over time form furrows or bands in the face and neck region. These and other effects of the normal aging process can
25 present an aesthetically unpleasing cosmetic appearance.

Accordingly, there is a large demand for systems and methods which serve to "tighten" the skin to remove sags and wrinkles in the face and
30 neck.

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One prior method surgically resurfaces facial skin by ablating the outer layer of the skin (from 200 μm to 600 μm), using laser or chemicals. In time, a new skin surface develops. The laser and chemicals used to resurface the skin also irritate or heat collagen tissue, which is widely present in the dermis. When irritated or heated in prescribed ways, the collagen tissue partially dissociates and, in doing so, shrinks. The shrinkage of collagen also leads to a desirable "tightened" look. Still, laser or chemical resurfacing leads to prolonged redness of the skin, infection risk, increased or decreased pigmentation, and scarring.

Lax et al. US 5,458,596 describes the use of radio frequency energy to shrink collagen tissue. This cosmetically beneficial effect can be achieved in facial and neck areas of the body in a minimally intrusive manner, without requiring the surgical removal of the outer layers of skin and the attendant problems just listed.

SUMMARY OF THE INVENTION

The invention provides improved systems and methods of systems and methods of achieving the cosmetically beneficial effects of shrinking collagen tissue in the dermis in an effective, non-invasive manner, which leaves the outer layer of skin intact and undamaged.

One aspect of the invention provides systems and methods for applying electromagnetic energy to skin. The systems and methods include a carrier and an array of electrodes on the carrier, which are connectable to a source of electromagnetic energy to apply the electromagnetic energy. According to this aspect of the invention, a microporous pad on the carrier overlays the array of

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electrodes, forming an interior chamber to contain an electrically conductive material. The microporous pad is adapted, in use, to contact an epidermal skin region and ionically transport the applied electromagnetic energy to ohmically heat dermal tissue beneath the epidermal skin region.

5 In one embodiment, the shape of the carrier can differ to match different skin region topographies.

10 Another aspect of the invention provides systems and methods for applying electromagnetic energy to skin, in which the array of electrodes on the carrier are sized so that, while the carrier contacts an epidermal skin region, the electrodes extend into tissue beneath the epidermal skin region to ohmically heat dermal tissue.

15 In one embodiment, the electrodes are sized to extend into dermal tissue. In another embodiment, the electrodes are sized to extend into subdermal tissue.

20 In one embodiment, the shape of the carrier can differ to match different skin region topographies.

25 Another aspect of the invention provides systems and methods for applying electromagnetic energy to a facelift flap. The systems and methods include a carrier and at least one electrode on the carrier connectable to a source of electromagnetic energy to apply the electromagnetic energy. The electrode is sized so that, while the carrier contacts a backside of the flap, the electrode ohmically heats the dermal tissue.

30 In one embodiment, the electrode, in use, rests on a surface on the backside of the flap.

35 In another embodiment, the electrode is

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sized to extend into dermal tissue within the flap.

Another aspect of the invention provides a family of devices for applying electromagnetic energy to skin. Each device comprising a carrier having a shape and an array of electrodes on the carrier connectable to a source of electromagnetic energy to apply the electromagnetic energy. According to this aspect of the invention, the shapes of the carriers differ to match different skin region topographies.

In one embodiment, the carrier is adapted, in use, to contact epidermal tissue. In this embodiment, the electrodes are sized to extend into tissue beneath the epidermal tissue. The electrodes can be sized to extend into dermal tissue. Alternatively, the electrodes are sized to extend into subdermal tissue.

Features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended Claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a representative side section view of skin and underlying subcutaneous tissue;

Fig. 2 is a schematic view of a system that, in use, heats collagen tissue in the dermis for the purpose of treating cosmetic conditions affecting the skin;

Fig. 3 is an exploded perspective view of one category of an energy applicator, usable in association with the system shown in Fig. 2, to transmit energy into the dermis externally through the epidermis;

Fig. 4 is a side section view of the energy applicator shown in Fig. 3 in use to heat collagen tissue in the dermis;

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Fig. 5 is a front view of the facial and neck region showing various energy applicator, like that shown in Fig. 3, specially shaped to match the topography of a skin region under the eye, below the ear, under the chin, around the lips, and on the forehead above the eyebrows;

Fig. 6 is an exploded perspective view of another category of an energy applicator, usable in association with the system shown in Fig. 2, to transmit energy internally directly into the dermis;

Fig. 7 is a side section view of the energy applicator shown in Fig. 6 in use to heat collagen tissue in the dermis;

Fig. 8 is an exploded perspective view, with portions in section, of another category of an energy applicator, usable in association with the system shown in Fig. 2, to transmit energy into the dermis internally through subcutaneous tissue;

Fig. 9 is a side section view of the energy applicator shown in Fig. 8 in use to heat collagen tissue in the dermis;

Fig. 10 is an exploded, perspective view of another category of an energy applicator, usable in association with the system shown in Fig. 2, to transmit energy into the dermis from the backside of a surgically created facelift flap.

Fig. 11 is a side section view of the energy applicator shown in Fig. 10 in use to heat collagen tissue in the dermis from the backside of a facelift flap;

Fig. 12 is a perspective view of an energy applicator of the type shown in Fig. 3, with associated probes for sensing temperature in the dermis;

Fig. 13 is a side section view of an energy

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applicator shown in Fig. 3, with the sensors deployed in the dermis to sense temperature conditions;

5 Fig. 14 is a side section view of an energy applicator of the type shown in Fig. 6, with associated sensors located in the dermis to sense temperature conditions; and

10 Fig. 15 is a side section view of a penetration tissue temperature sensing probe of the type shown in Figs. 12 to 14, with multiple sensors deployed in a stacked arrangement to sense a temperature gradient in the dermis.

15 The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

20 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention provides systems and methods of treating cosmetic conditions affecting the skin. The system and methods are applicable for use throughout the body. However, the systems and methods are particularly well suited for treating cosmetic conditions in the facial or neck area of the body. For this reason, the systems and methods will be described in this context.

30 I. Anatomy of the Skin

As Fig. 1 shows, the skin 10 overlies and protects subcutaneous tissue 12 and muscle tissue 14 of the body. In the face and neck areas, the skin 10 measures about 2mm in cross section.

35 The skin 10 includes an external, non-

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vascular covering of epithelial cells, called the epidermis 16. In the face and neck regions, the epidermis measures about 100 μm in cross section.

5 The skin 10 also includes a layer of vascular tissue, named the dermis 18. In the face and neck regions, the dermis 18 measures about 1900 μm in cross section.

10 The dermis 18 is tough, flexible, and highly elastic. It is divided into a papillary (upper) layer 20 and a reticular (lower) layer 22. The most numerous fibers in the papillary and reticular layers 20 and 22 are collagen fibers, which in large part account for the strength and physical properties of the dermis 18. Hair bulbs, 15 sweat ducts, and other glands also occupy the reticular layer 22.

The fibrous structure of collagen tissue is observed to dissociate and contract along its length when heated to a defined temperature condition, 20 i.e., about 65 $^{\circ}\text{C}$. The contraction of collagen tissue causes the dermis 18 to reduce in size, which has an observable tightening effect. As collagen contracts, wrinkles and sag lines in the skin are ameliorated. As a result, the outward cosmetic 25 appearance of the skin 10 improves.

The temperature conditions conducive to the beneficial results of collagen shrinkage lay well above the temperature conditions at which irreversible thermal damage to epithelial cells 30 begins to occur, i.e., above about 47 $^{\circ}\text{C}$.

II. Systems for Renovating the Dermis

A. System Overview

Fig. 2 shows a system 24 for renovating and reconstituting the dermis. The system 24 applies 35 energy to the dermis to elevate and maintain its

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temperature at a predetermined temperature condition, at or about 65° C, without increasing the temperature of the epidermis beyond 47° C. In this way, the system applies energy to the dermis in a targeted, selective fashion, to dissociate and contract collagen tissue, while preserving and protecting epithelial cells against thermal damage.

The system 24 includes a treatment device 26. The device 26 includes a handle 28 made, e.g., from molded plastic. The handle 28 carries at its distal end a treatment energy applicator 30, which, in use, contacts the epidermis. The handle 28 is sized to be conveniently grasped like a pencil or paint brush by a physician, to thereby manipulate the applicator 30 on the epidermis 16.

The system 24 further includes a device 32 to generate treatment energy. In the illustrated embodiment, the generator 32 generates radio frequency energy, e.g., having a frequency in the range of about 400 kHz to about 10 MHz.

A cable 34 extending from the proximal end of the handle 28 terminates with an electrical connector 36. The cable 34 is electrically coupled to the applicator 30, e.g., by wires that extend through the interior of the handle 28. When connector 36 plugs into the generator 32, to convey the generated energy to the applicator 30 for transmission to the skin.

The system 24 also includes certain auxiliary processing equipment 38 and 40. In the illustrated embodiment, the processing equipment 38 comprises an external fluid delivery apparatus, and the processing equipment 40 comprises an external aspirating apparatus.

The handle 28 of the treatment device 26

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includes one or more interior lumens 42. The lumens terminate in fittings 44 and 46, located at the proximal end of the handle 28. One fitting 44 connects to the fluid delivery apparatus 38, to convey processing fluid to the distal end of the handle 28 for discharge. The other fitting 46 connects to the aspirating apparatus 40, to convey aspirated material from the distal end of the handle 28 for discharge.

The system 24 also includes a controller 48. The controller 48, which preferably includes a central processing unit (CPU), is linked to the generator 32, the fluid delivery apparatus 38, and the aspirating apparatus 40. The controller 48 governs the power levels, cycles, and duration that the radio frequency energy is distributed to the applicator 30, to achieve and maintain power levels appropriate to achieve the desired treatment objectives. In tandem, the controller 48 also governs the delivery of processing fluid to the applicator 30 and the removal of aspirated material from the applicator 30.

The controller 48 includes an input/output (I/O) device 50. The I/O device 50 allows the physician to input control and processing variables, to enable the controller 48 to generate appropriate command signals. The I/O device 50 also receives real time processing feedback information from one or more sensors 52 associated with the applicator, for processing by the controller 48, e.g., to govern the application of energy and the delivery of processing fluid. The I/O device 50 also includes a display 54, to graphically present processing information to the physician for viewing or analysis.

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B. The Treatment Device

The structure of the treatment device 26 and associated electrical energy applicator 30 can vary.

5 The illustrated embodiments describe and show four representative categories of energy applicators 30, as follows:

 (i) a first category applicator 30(1) (shown in Figs. 3 and 4) transmits energy into the
10 dermis externally through the epidermis.

 (ii) a second category applicator 30(2) (shown in Figs. 6 and 7) transmits energy internally directly into the dermis.

 (iii) a third category applicator
15 30(3) (shown in Figs. 8 and 9) transmits energy into the dermis internally through subcutaneous tissue.

 (iv) a fourth category applicator
20 30(4) (shown in Figs. 10 and 11) transmits energy into the dermis from the backside of a surgically created facelift flap.

The various categories of energy applicators 30(1), 30(2), 30(3), and 30(4) will now be discussed in greater detail.

(i). **Epidermal Energy Applicator**

25 In this category, as shown in Fig. 3, the energy applicator 30(1) includes a carrier grid 56, which is mounted on the distal end of the handle 28. The carrier grid 56 is made from an electrically non-conducting material, e.g., plastic or ceramic.

30 The carrier grid 56 carries a pattern of multiple, spaced apart electrodes 58. Each electrode 58 comprises a discrete transmission source of radio frequency energy. The electrodes 58 can be made, e.g., from stainless steel, platinum, and other
35 noble metals, or combinations thereof. The

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electrodes 58 may be fastened to the grid by various means, e.g., by adhesives, by painting, or by other coating or deposition techniques.

5 In the illustrated embodiment, the carrier grid 56 is formed by an outside frame 60 with crossing interior spacers 62. Together, the frame 60 and spacers 62 define an open lattice of cells 64. In the illustrated embodiment, the grid 56 defines sixteen cells 64. It should be appreciated that the
10 cells 64 could number more or less than sixteen.

In the illustrated embodiment, the electrodes 58 are located on the grid 56 at the four corners of each cell 64. This arrangement provides a symmetric pattern of twenty-five electrodes 58 on
15 the grid 56. Still, it should be appreciated that the electrodes 58 could be arranged in other symmetric or non-symmetric patterns in the grid.

In the embodiment shown in Fig. 3, the energy applicator 30(1) includes an external pad 66, which is attached peripherally about the carrier
20 grid 56. The pad 66 is made from a resilient microporous membrane. As Fig. 4 shows, the pad 66, in use, makes surface contact with the epidermis 16. The resilience of the pad 66 makes it well suited to conform to a variable surface topography of the
25 epidermis 16.

The attachment of the pad about the carrier grid 56 creates an interior chamber 68, which encloses the grid 56. The applicator 30(1) further
30 includes a fluid manifold 70 inside the chamber 68. The fluid manifold 70 communicates with the fluid delivery apparatus 38, via the handle lumens 42. The manifold 70 uniformly introduces processing fluid through the grid 56 and into the interior
35 chamber 68.

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In this arrangement, the processing fluid comprises an electrically conductive liquid, such as saline (about 0.9% to 3.0%). The apparatus 38 includes a pump 72 to convey the electrically conductive liquid through the manifold 70 at a prescribed rate.

The flow of the electrically conductive liquid into the through the grid 56 and into interior chamber 68 contacts the interior surface of the microporous membrane of the pad 66. As Fig. 4 shows, the microporous membrane of the pad 66 has pores 74 sized to permit passage of the electrically conductive fluid in the chamber 68 through the membrane and into contact with the epidermis 16 the membrane contacts.

The diffusion of electrically conductive liquid through the membrane pores 74 serves two purposes. First, it creates conductive cooling at the interface between the membrane pad 66 and the epidermis 16. Second, it serves to ionically transport radio frequency energy transmitted by the grid electrodes 58 through the membrane pores 74, for return (in a unipolar arrangement) through exterior patch electrode 76 coupled to patient ground.

The ionically conducted radio frequency energy transported through the membrane pore 74 will, in turn, cause localized ohmic heating of skin tissue. The application of radio frequency energy by ionic transport to the epidermis surface, simultaneously combined with the conductive surface cooling effects that the ionic transport also provides, places the tissue region where maximum temperature conditions exist (designated TMAX in Fig. 4) at a location below the epidermis 16, into

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the papillary dermis 20 and, preferably, into the reticular dermis 22 as well.

5 The applicator 30(1) thereby makes possible selective heating of the interior dermis 18 to a maximum tissue temperature TMAX of about 65°C, while maintaining the temperature of the epidermis 16 at or about 20°C to 30°C, thereby avoiding thermal damage to the epidermis 16.

10 Alternatively, an electrically conductive jelly can occupy the interior chamber 68. The jelly causes ionic transport of radio frequency energy through the membrane pores 74. In this arrangement, a manifold 78 distributes fluid about the periphery of the pad 66, but not into the chamber 68 itself, 15 to nevertheless cause convective surface cooling effects. In this arrangement, the fluid distributed by the manifold 78 need not be electrically conductive, but it can be to provide uniform distribution of the radio frequency energy at the pad 66. 20

In use, the physician places the pad 66 upon a targeted region of tissue. The controller 48 governs the application of radio frequency energy to the electrodes 58 in concert with the delivery of fluid to the manifold 70 (or 78), to control the 25 desired epidermal and dermal tissue temperature conditions. The controller 48 can also govern the withdrawal of fluid from the vicinity of the pad 66 through the aspirating apparatus 40 for this purpose. 30 The controller 48 can alter the distribution of the radio frequency energy among selected sets or subsets of one or more grid electrodes 58. In this way, the controller 48 can focus the application of radio frequency in selected 35 patterns.

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In maintaining control of the process, the controller 48 can depend upon empirically determined or modeled relationships among selected processing variables, including, e.g., tissue temperature, time, power, and fluid delivery rate, without actual temperature sensing. Preferably, however, localized tissue temperature conditions are sensed to provide direct feedback control, as will be described in greater detail later.

In the illustrated embodiment, the handle 28 and grid 56 can comprise reusable components. In this arrangement, the energy applicator pad 66 can comprise a single use component that is temporarily fastened to the handle 28 at time of use, e.g., by a conventional snap-fit, and then removed after use for disposal.

The pad 66 need not be sized to cover a targeted facial or neck region in its entirety. Instead, the physician can locate the pad 66 in contact with a localized area of epidermal tissue within a targeted region. After applying the desired amount of radio frequency energy, the physician can relocate the pad 66 to an adjacent tissue area in the targeted region and again apply radio frequency energy. The physician can repeat this successive process, until the entire targeted region has been subject to treatment by exposure to radio frequency energy.

The energy applicator pads 66 can be specially shaped and contoured to provide different geometries, selected to match the topography of the targeted facial or neck region, e.g., under the eye (as pad 66(1) in Fig. 5 shows); or below the ear (as pad 66(2) in Fig. 5 shows); or under the chin (as pad 66(3) in Fig. 5 shows); or around the lips (as

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pad 66(4) in Fig. 5 shows); or on the forehead above the eyebrows (as pad 66(5) in Fig. 5 shows).

(ii). Intradermal Energy Applicator

5 As shown in Fig. 6, the second category of energy applicator 30(2) includes a carrier 80 on the distal end of the handle 28. The carrier 80 supports an array of spaced-apart needle electrodes 82. The electrodes 82 are metallic, being made,
10 e.g., from stainless steel, platinum, other noble metals, or combinations thereof. Each electrode 82 comprises a discrete transmission source of radio frequency energy, which the controller 48 governs.

 The carrier 80 can provide physical
15 connections between control wires and each electrode 82, e.g., by solder or adhesive. Alternatively, the carrier 80 can have painted, coated, or otherwise deposited solid state circuitry to provide the electrical paths. The solid state circuitry can
20 include a fuse element that interrupts electrical contact after a specified period of use, to thereby discourage reuse of the carrier 80.

 In use (as Fig. 7 shows), the electrodes 82 are intended to be inserted as a unit on the carrier
25 80 through the epidermis 16 and into the dermis 18. After insertion, the controller 48 conditions the electrodes 82 for operation in a unipolar mode. In this mode, energy transmitted by one or more of the electrodes 82 is returned by an indifferent patch
30 electrode 84, which is coupled to patient ground.

 Alternatively, the controller 48 can condition pairs of electrodes 82 to operate in a bipolar mode, with one electrode serving to transmit radio frequency energy, and the other electrode
35 serving as the return path.

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The size and spacing of the electrodes 82 shown in Figs. 10 and 11 are purposely set to penetrate the skin to a depth sufficient to pass entirely through the epidermis 16 and penetrate the papillary and, preferable, extend into the reticular dermis (e.g., about 200 μm to 300 μm). When used for this purpose, the electrodes 82 each possesses a total length of about 0.5 to about 3.0 mm. The electrodes are mutually spaced apart by about 0.5 mm to 10.0 mm.

An electrical insulating material 86 surrounds the proximal end of each electrode 82 by at least 0.5 mm. This leaves an exposed, non-insulated length at the distal end of about 0.5 mm to 2.5 mm. The insulating material 82 insulates the epidermis 16 and a portion of the dermis 18 from direct exposure to radio frequency energy transmitted by the exposed distal end.

The ratio between exposed and insulated regions on the electrodes 82 affects the impedance of the electrodes 82 during use. Generally speaking, the larger the exposed region is compared to the insulated region, a larger impedance value can be expected.

In use, the physician places the carrier 80 upon a desired region of tissue. The physician applies light pressure on the handle 28 to insert the needle electrodes 82 through the epidermis 16 and into the dermis 18. The controller 48 governs the application of radio frequency energy to the electrodes 82 to ohmically heat adjacent dermal tissue. The electrodes 82 can be operated individually or in groups to form defined energy application patterns. As before described, the controller 48 can depend upon the empirically

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determined or modeled relationships among processing variables to affect process control, with or without actual temperature sensing.

5 In this arrangement, the handle 28 can comprise a reusable component, and the carrier 80 with electrodes 82 can comprise a single use component, which is temporarily fastened to the distal end of the handle 28 for use and then removed after use for disposal.

10 As with the pad 66, the carrier 80 need not be sized to cover a targeted facial or neck region in its entirety. Instead, the physician can successively locate the carrier 80 in a localized areas within a targeted region, and apply radio
15 frequency energy to each localized area.

Like the pad 66, the carrier 80 can also be specially shaped and contoured to provide different geometries, selected to match the topography of the targeted facial or neck region, as shown in Fig. 5.

20 (iii) Subdermal Energy Applicator

As shown in Fig. 8, the third category of energy applicator 30(3) includes a carrier 88 mounted on the distal end of the handle 28. Like the carrier 80 shown in Fig. 6, the carrier 88 shown in
25 Fig. 8 holds an array of spaced-apart, metallic needle electrodes 90. Each electrode 90 comprises a discrete transmission source of radio frequency energy, which the controller 48 governs.

As before explained, the carrier 88 can
30 provide physical connections between control wires and each electrode 90, or carry painted, coated, or otherwise deposited solid state circuitry to provide the electrical paths.

As Fig. 9 best shows, the needle electrodes
35 90 shown in Fig. 8 differ from the electrode 82 in

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Fig. 6 in that they are longer than the needle electrodes 82. The longer electrodes 90 are intended to be inserted as a unit through both the epidermis 16 and the dermis 18, and extend into the subcutaneous tissue region 12 a short distance beyond the reticular dermis 22.

For this purpose, the electrodes 90 each possesses a total length of about 3.0 mm to 10.0 mm. The electrodes 90 are mutually spaced apart by about 0.5 mm to 3.0 mm. An electrical insulating material 92 surrounds the proximal end of each electrode 90 by at least 2.0 mm. This leaves an exposed, non-insulated length at the distal end of each electrode 90 of about 3.0 mm to 4.0 mm. The insulating material 92 insulates the epidermis 16 and dermis 18 from direct exposure to radio frequency energy transmitted by the exposed distal ends of the electrodes 90.

In the illustrated embodiment, at least some, and preferably all, of the needle electrodes 90 include interior fluid passages 94 (see Fig. 8). A manifold 96 couples a select number of the passages 94 in communication with the fluid delivery apparatus 38. This way, processing fluid can be introduced through the electrodes 90 and into the subcutaneous tissue surrounding the distal ends of the electrodes 90. The manifold 96 couples other passages 94 in communication with the aspirating device 40, to evacuate material through the distal ends of the electrodes 90.

In this embodiment, the processing fluid comprises an electrically conductive liquid, such as saline. The apparatus 38 includes a pump 72 (see Fig. 1) to convey the electrically conductive liquid to the manifold 96 at a prescribed rate. The

- 19 -

manifold 96 disperses the electrically conductive liquid through the selected passages 94.

5 The controller conditions the electrodes 90 to operate in a unipolar mode. Energy transmitted by one or more of the electrodes 90 is returned by an indifferent patch electrode 100, which is coupled to patient ground (see Fig. 9). At the same time, electrically conductive liquid flows through the selected passages 94 into the surrounding
10 subcutaneous tissue region 12 (shown by arrows 122 in Fig. 9), while liquid and other material is evacuated through the other passages 94 by the aspirating device 40 (as shown by arrows 124 in Fig. 9).

15 The radio frequency energy transmitted by the exposed, distal ends of the electrodes 90 will cause localized ohmic heating of subcutaneous tissue. The conduction of the electrically conductive fluid ionically distributes the radio
20 frequency energy in a uniform manner, while also providing a localized cooling effect. The cooling effect places the tissue region where maximum temperature conditions exist at a location (designated TMAX in Fig. 9) spaced from the distal
25 ends of the electrodes 90, which includes the reticular dermis 22.

The localized heating effects will all cause fat tissue 102 in the subcutaneous tissue 12 to flow (see Fig. 9). Suction applied by the
30 aspirating device 40 through the passages 94 can be used to evacuate flowing fat tissue from subcutaneous tissue 12 (as arrows 124 in Fig. 9 show). This provides localized liposuction effects in the subcutaneous region 12, in tandem with
35 collagen heating effects in the dermis 18.

- 20 -

In use, the physician places the carrier 88 upon a desired region of tissue. The physician applies light pressure on the handle 18 to insert the needle electrodes 90 through the epidermis 16 and dermis 18 and into a subcutaneous tissue region 12. The controller 48 governs the application of radio frequency energy to the electrodes 90, which can be operated individually or in defined patterns.

The carrier 88 need not be sized to cover an entire targeted region. The physician can locate the carrier 88 in successive local areas within a targeted region, and apply radio frequency energy to each localized area. Like the pad 66, the carrier 88 can also be specially shaped and contoured to provide different geometries, selected to match the topography of the targeted facial or neck region, as shown in Fig. 5.

As before described, the controller 48 can depend upon the empirically determined or modeled relationships among processing variables to affect process control, with or without actual temperature sensing.

In this embodiment, as in the preceding embodiment, the handle 28 can comprise a reusable component, and the carrier 88 and needle electrodes 90 can comprise a single use component that is temporarily fastened to the handle 28 for use and then removed after use for disposal.

(iv) **Facelift Flap Energy
Applicator**

As shown in Fig. 10, the fourth category of energy applicator 30(4) likewise includes a carrier 104 on the distal end of the handle 28. The carrier 104 holds a pair of bipolar metallic electrodes 106. In use, energy transmitted by one of the electrodes

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106 is returned by the other electrode 106 to patient ground. Alternatively, the carrier 104 can hold an array of several needle electrodes, which are operated in either a bipolar or unipolar mode.

5 In use (see Fig. 11), the physician surgically creates a facelift flap 108 in the targeted tissue region. The flap 108 extends well into the dermis 18 (e.g., 200 μm to 300 μm). The physician inserts the needle electrodes 106 into the
10 backside of the flap 108 and applies radio frequency energy.

 The size and spacing of the electrodes 106 are purposely set to penetrate into the backside of the skin flap 108 to a depth sufficient to locate
15 the distal ends of the electrodes 106 in dermal tissue.

 When used for this purpose, the electrodes 106 each possesses a total length of about 3.0 mm to 8.0 mm. The electrodes 106 are mutually spaced apart
20 by about 0.5 mm to 10.0 mm.

 Alternatively, in this embodiment, the applicator 30(4) can comprise an array of surface electrodes 106 that do not penetrate the skin flap 108, but which rest on the surface of the backside
25 of the skin flap.

 As before described, the controller 48 governs application of radio frequency energy to achieve the desired tissue effects.

 In this embodiment, as in preceding
30 embodiments, the handle 28 can comprise a reusable component, and the carrier 104 and electrodes 106 can comprise a single use component that is temporarily fastened to the handle for use and then removed after use for disposal.

35 **C. Dermal Temperature Sensing**

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In all of the preceding embodiments, the controller 48 preferable relies upon sensing tissue temperature conditions as a form of active process feedback control.

5 For this purpose, the energy applicator carries at least one sensor 112 (see Fig. 12), which senses tissue temperature conditions. In the illustrated embodiment, the at least one sensor 112 is located beneath the epidermis 16 and into the
10 dermis 18 (see Fig. 13), to sense actual tissue temperature conditions in the dermis 18.

 When used in association with the applicator pad 66 of the category (i) applicator 30(1) (as Fig. 12 shows), an array of probes 114 is
15 arranged in a spaced-apart relationship along the periphery of the pad 66. Each probe 114 carries at least one temperature sensor 112. In use, the probes 114 extend through the epidermis 16 and into the dermis 18, as Fig. 13 shows.

20 When use in association with a penetrating needle electrode 82, 90, or 106, (see Fig. 14) each needle electrode 82, 90, or 106 can carry at least one temperature sensor 112. Alternatively, of course, probes could be used to carry the sensors
25 112, in the manner shown in Figs. 12 and 13. In any event, the sensors 112 are located so that, in use, they are positioned in the region of the dermis 118 where radio frequency heating is targeted, as Fig. 14 shows.

30 In the embodiment shown in Fig. 15, a tissue penetrating probe 116 (or needle electrode, as the case may be) may support a vertically stacked array 118 of temperature sensors 120. The temperature sensors 120 are arranged at known, fixed
35 intervals along the probe 116. The stacked sensors

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120 sense a dermal tissue temperature gradient along the length of the probe 116.

5 The sensing of a temperature gradient within dermal tissue targeted for radio frequency heating permits the controller 48 to identify along the gradient the location of the maximum tissue temperature region TMAX. For control purposes, the controller 48 can include an algorithm that selects the maximum tissue temperature TMAX and also
10 identifies the depth D(TMAX) at which the maximum tissue temperature occurs. By varying the power of radio frequency energy applied and the rate of surface cooling (when appropriate), the controller 48 can adjust the maximum tissue temperature TMAX to
15 achieve the desired control point temperature, which for collagen shrinkage is 65° C. The controller 48 can also establish and maintain a control depth (D(TMAX) at which the desired control point temperature occurs, e.g., at a skin depth of 200 μ m
20 to 300 μ m (pre-set or set by the physician), to achieve optimal collagen shrinkage.

Various features of the invention are set forth in the following claims.

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We Claim:

1. A device for applying electromagnetic energy to skin comprising
a carrier,
an array of electrodes on the carrier connectable to a source of electromagnetic energy to apply the electromagnetic energy, and
a microporous pad on the carrier overlying the array of electrodes forming an interior chamber to contain an electrically conductive material, the microporous pad adapted, in use, to contact an epidermal skin region and ionically transport the applied electromagnetic energy to ohmically heat dermal tissue beneath the epidermal skin region.
2. A device according to claim 1
wherein the carrier is shaped to match a targeted skin region topography.
3. A device according to claim 1
wherein the microporous pad is made from a resilient material to conform to a variable epidermal skin region topography.
4. A device according to claim 1
wherein the electrically conductive material comprises an electrically conductive liquid.
5. A device according to claim 1
wherein the electrically conductive material comprises an electrically conductive jelly.
6. A device according to claim 5
further including a manifold on the carrier to distribute liquid about the microporous pad.
7. A device according to claim 1
further including at least one temperature sensing probe on the carrier.
8. A device according to claim 7

wherein the temperature sensing probe is located outside the microporous pad .

9. A device according to claim 7

wherein the temperature sensing probe is sized to extend into dermal tissue when the microporous pad contacts the epidermal tissue region.

10. A device according to claim 7

wherein the temperature sensing probe carries more than one temperature sensor.

11. A device according to claim 1

wherein the array of electrodes is arranged to create a pattern for applying the electromagnetic energy.

12. A family of devices for applying electromagnetic energy to skin, each device comprising a carrier having a shape, an array of electrodes on the carrier connectable to a source of electromagnetic energy to apply the electromagnetic energy, and a microporous pad on the carrier overlying the array of electrodes forming an interior chamber to contain an electrically conductive material, the microporous pad adapted, in use, to contact an epidermal skin region and ionically transport the applied electromagnetic energy to ohmically heat dermal tissue beneath the epidermal skin region, and the shape of the carriers differing to match different skin region topographies.

13. A method for applying electromagnetic energy to skin comprising the steps of

providing a carrier, an array of electrodes on the carrier connectable to a source of electromagnetic energy to apply the electromagnetic energy, and a microporous pad on the carrier

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overlying the array of electrodes forming an interior chamber to contain an electrically conductive material, and

placing the microporous pad in contact with an epidermal skin region while applying the electromagnetic energy with the electrodes to ionically transport the applied electromagnetic energy through the microporous pad to ohmically heat dermal tissue beneath the epidermal skin region.

14. A method according to claim 13

further including the step of circulating the electrically conductive material in the interior chamber while applying the electromagnetic energy.

15. A method according to claim 13

further including the step of distributing liquid about the microporous pad while applying the electromagnetic energy.

16. A method according to claim 13

further including the step of sensing temperature while applying the electromagnetic energy.

17. A method according to claim 16

wherein the temperature sensing step includes sensing temperature of dermal tissue beneath the epidermal tissue region.

18. A device for applying electromagnetic energy to skin comprising

a carrier, and

an array of electrodes on the carrier connectable to a source of electromagnetic energy to apply the electromagnetic energy, the electrodes being sized so that, while the carrier contacts an epidermal skin region, the electrodes extend into tissue beneath the epidermal skin region to

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ohmically heat dermal tissue.

19. A device according to claim 18
wherein the electrodes are sized to extend
into dermal tissue.

20. A device according to claim 18
wherein the electrodes are sized to extend
into subdermal tissue.

21. A device according to claim 18
wherein each electrode has a distal end,
and

further including an electrical insulating
material on at least some of the electrodes while
leaving the respective distal end free of the
electrical insulating material.

22. A device according to claim 18
wherein at least some of the electrodes
include an interior passage for conveying fluid.

23. A device according to claim 18
wherein the carrier is shaped to match a
topography of the epidermal skin region.

24. A device according to claim 18
further including at least one temperature
sensing probe on the carrier.

25. A device according to claim 24
wherein the temperature sensing probe is
sized to extend into tissue beneath the epidermal
tissue region.

26. A device according to claim 18
further including a temperature sensor
carried by at least one of the electrodes.

27. A device according to claim 18
further including more than one temperature
sensor carried by at least one of the electrodes.

28. A device according to claim 18

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wherein the array of electrodes is arranged to create a pattern for applying the electromagnetic energy.

29. A family of devices for applying electromagnetic energy to skin, each device comprising a carrier having a shape, an array of electrodes on the carrier connectable to a source of electromagnetic energy to apply the electromagnetic energy, the electrodes being sized so that, while the carrier contacts an epidermal skin region, the electrodes extend into tissue beneath the epidermal skin region to ohmically heat dermal tissue, and the shape of the carriers differing to match different skin region topographies.

30. A method for applying electromagnetic energy to skin comprising the steps of

providing a carrier, an array of electrodes on the carrier connectable to a source of electromagnetic energy to apply the electromagnetic energy, the electrodes being sized so that, while the carrier contacts an epidermal skin region, the electrodes extend into tissue beneath the epidermal skin region, and

placing the carrier in contact with an epidermal skin region while applying the electromagnetic energy with the electrodes to ohmically heat tissue beneath the epidermal skin region.

31. A method according to claim 30

further including the step of conveying a liquid through an interior passage in at least some of the electrodes while applying the electromagnetic energy.

32. A method according to claim 30

further including the step of sensing

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temperature while applying the electromagnetic energy.

33. A method according to claim 32 wherein the temperature sensing step includes sensing temperature of dermal tissue beneath the epidermal tissue region.

34. A method according to claim 30 wherein the electrodes ohmically heat dermal tissue.

35. A method according to claim 30 wherein the electrodes ohmically heat dermal and subdermal tissue.

36. A device for applying electromagnetic energy to a facelift flap comprising a carrier, and at least one electrode on the carrier connectable to a source of electromagnetic energy to apply the electromagnetic energy, the electrode being sized so that, while the carrier contacts a backside of the flap, the electrode ohmically heat the dermal tissue.

37. A device according to claim 36 wherein the electrode, in use, rests on a surface on the backside of the flap.

38. A device according to claim 36 wherein the electrode is sized to, in use, extend into dermal tissue within the flap.

39. A family of devices for applying electromagnetic energy to skin, each device comprising a carrier having a shape, an array of electrodes on the carrier connectable to a source of electromagnetic energy to apply the electromagnetic energy, and the shape of the carriers differing to match different skin region topographies.

40. A family according to claim 39

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wherein the carrier is adapted, in use, to contact epidermal tissue, and

wherein the electrodes are sized to extend into tissue beneath the epidermal tissue.

41. A family according to claim 39

wherein the electrodes are sized to extend into dermal tissue.

42. A family according to claim 39

wherein the electrodes are sized to extend into subdermal tissue.

43. A family according to claim 39

further including a pad overlying the electrodes that, in use, contacts epidermal tissue.

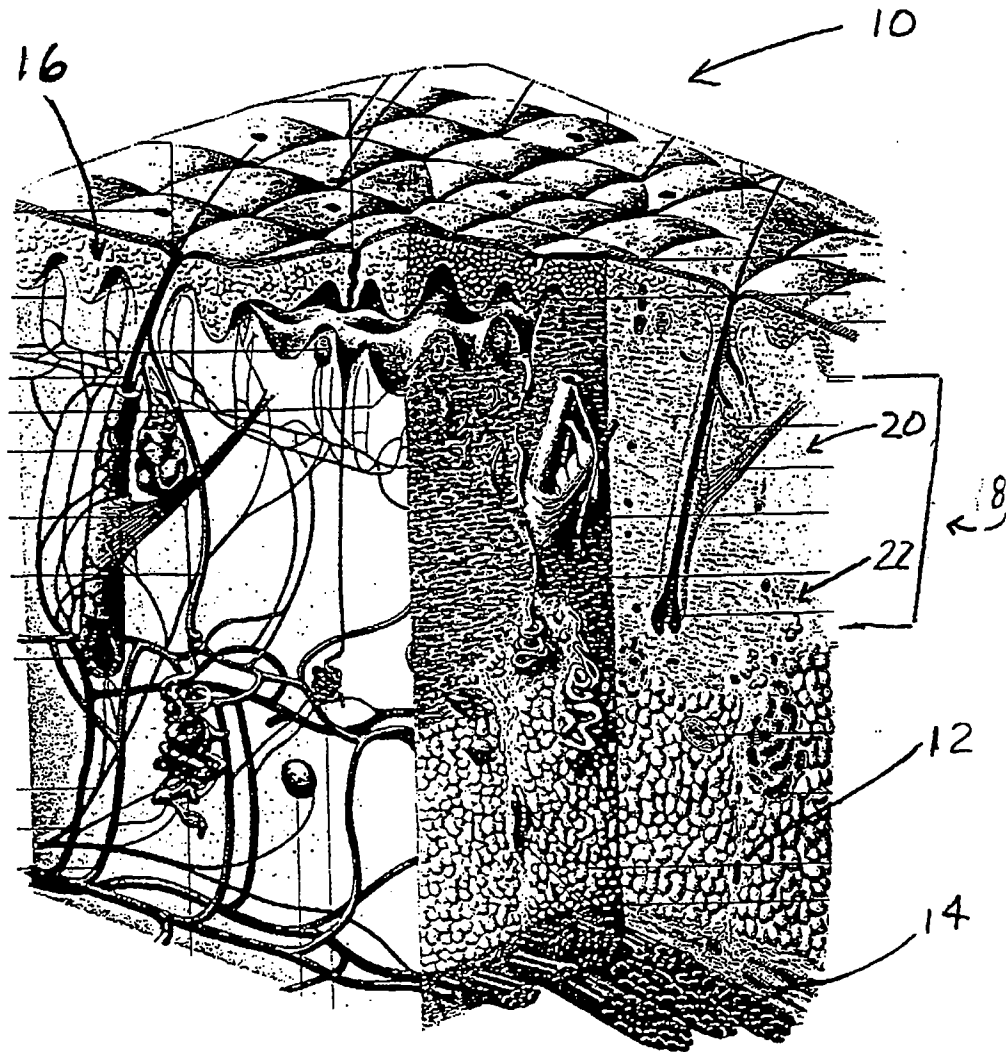
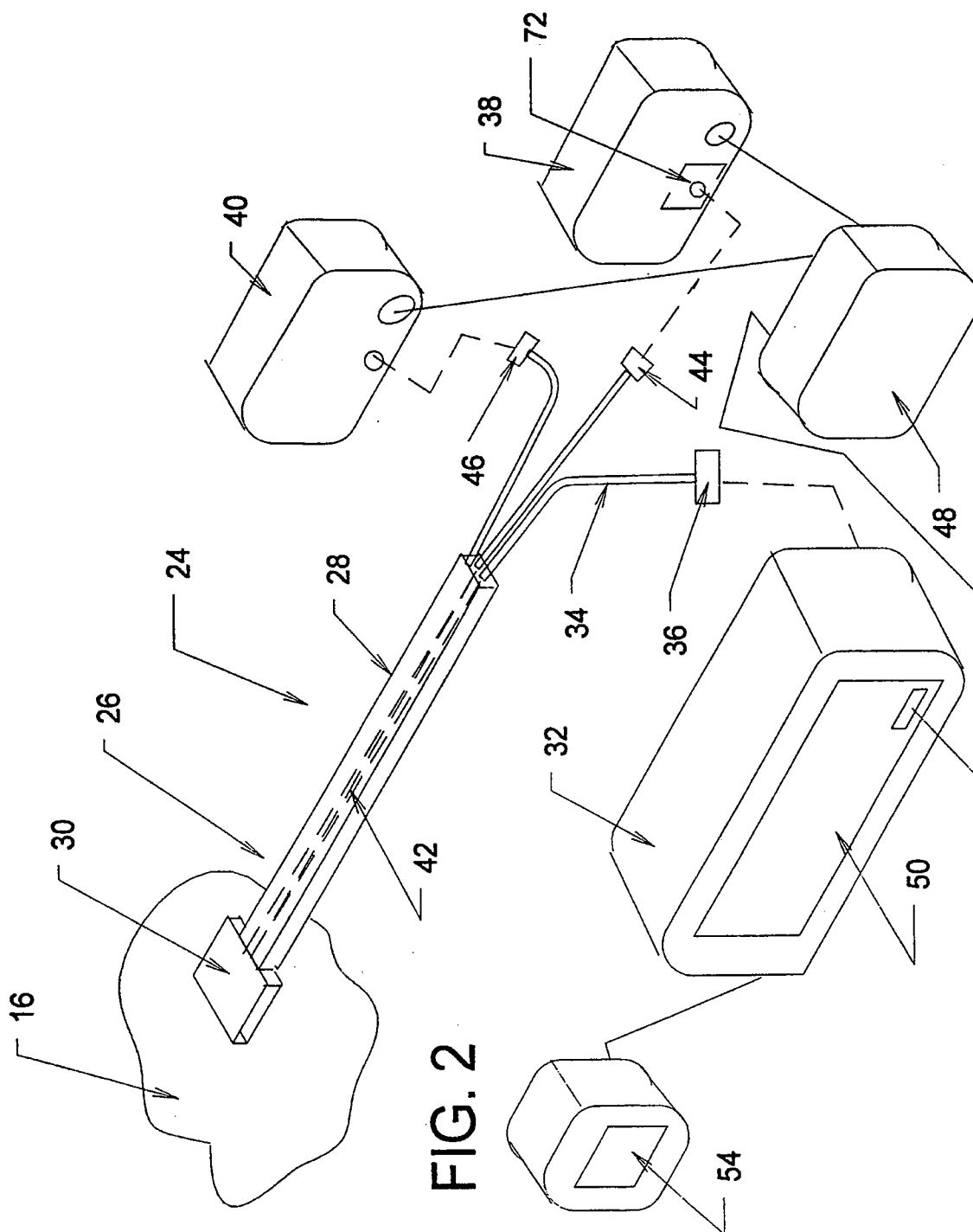


FIG. 1



F/G.3

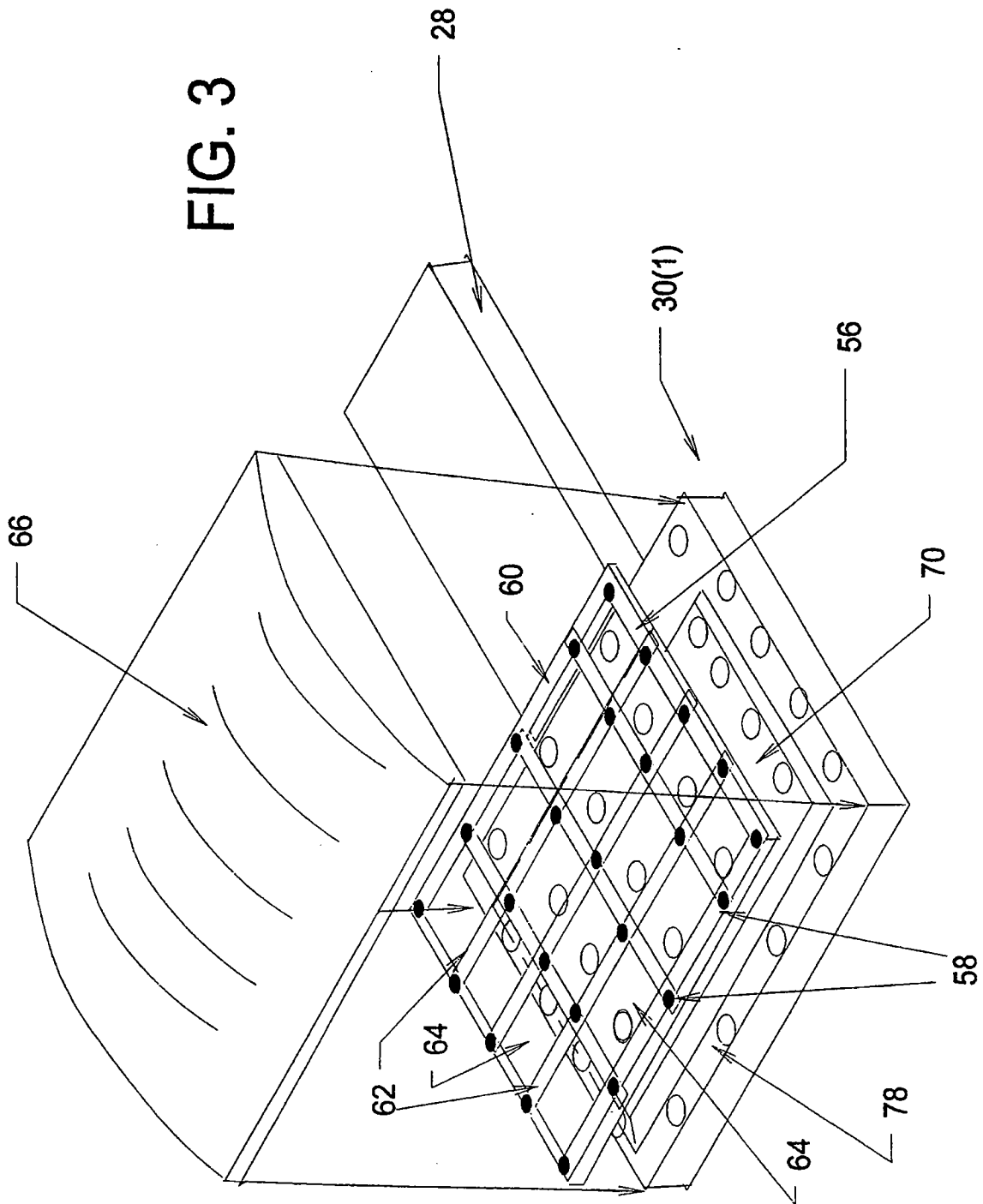


FIG. 4

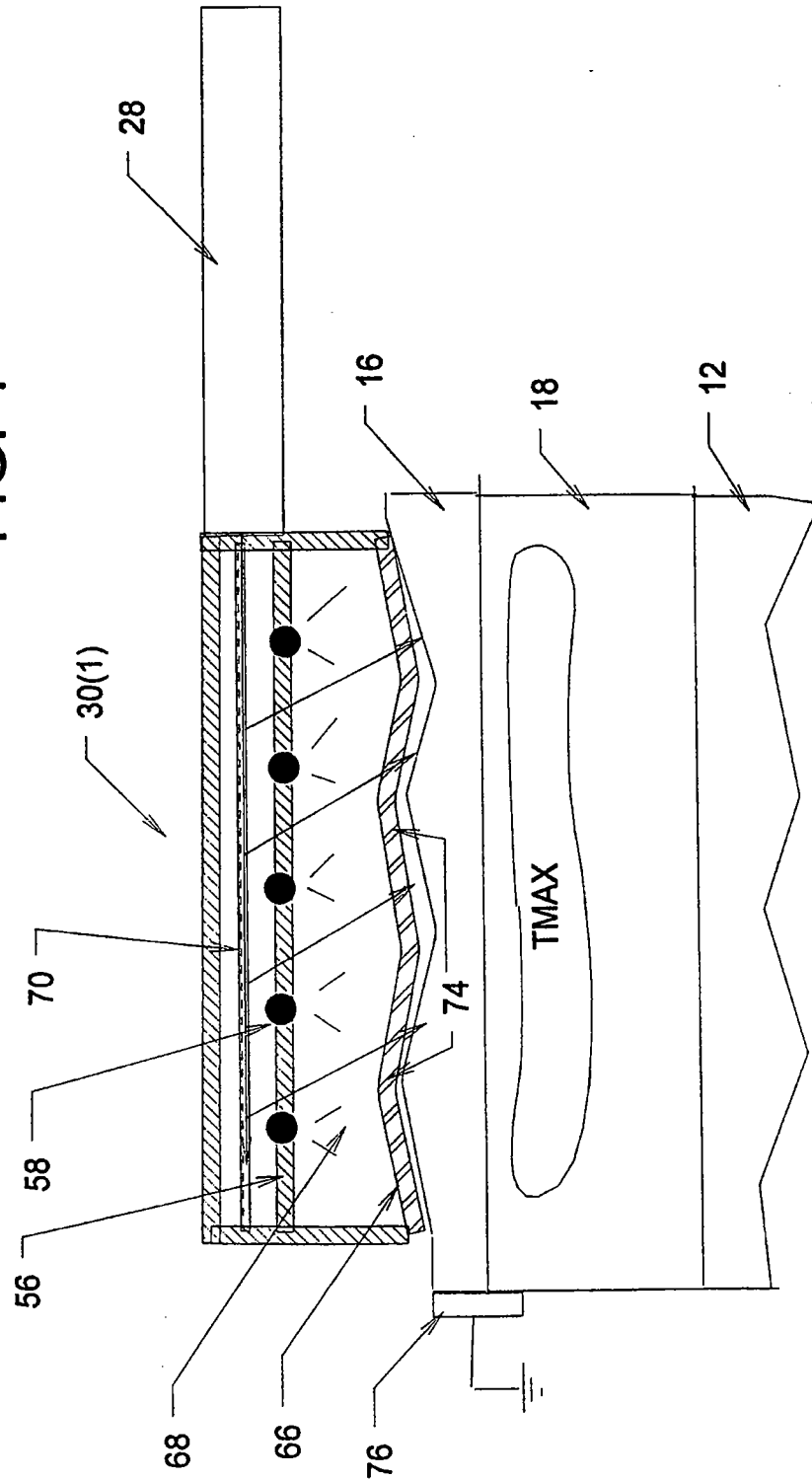


FIG. 5

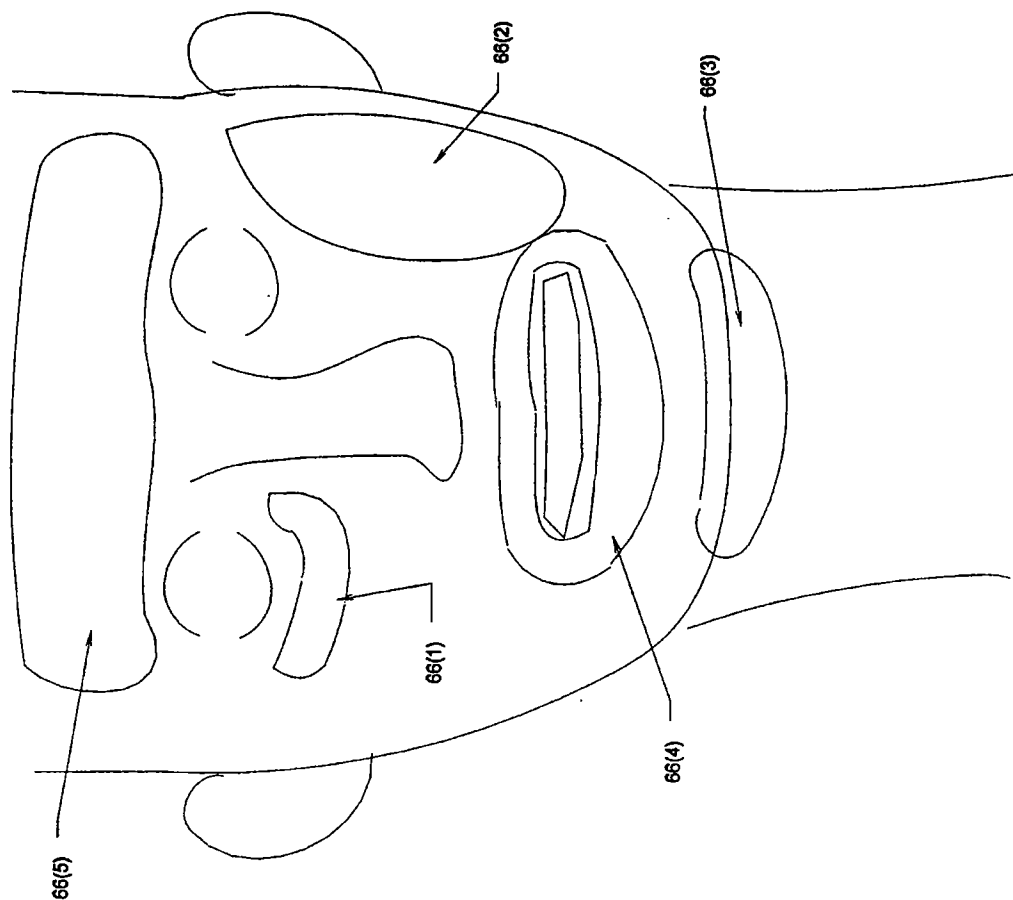


FIG. 6

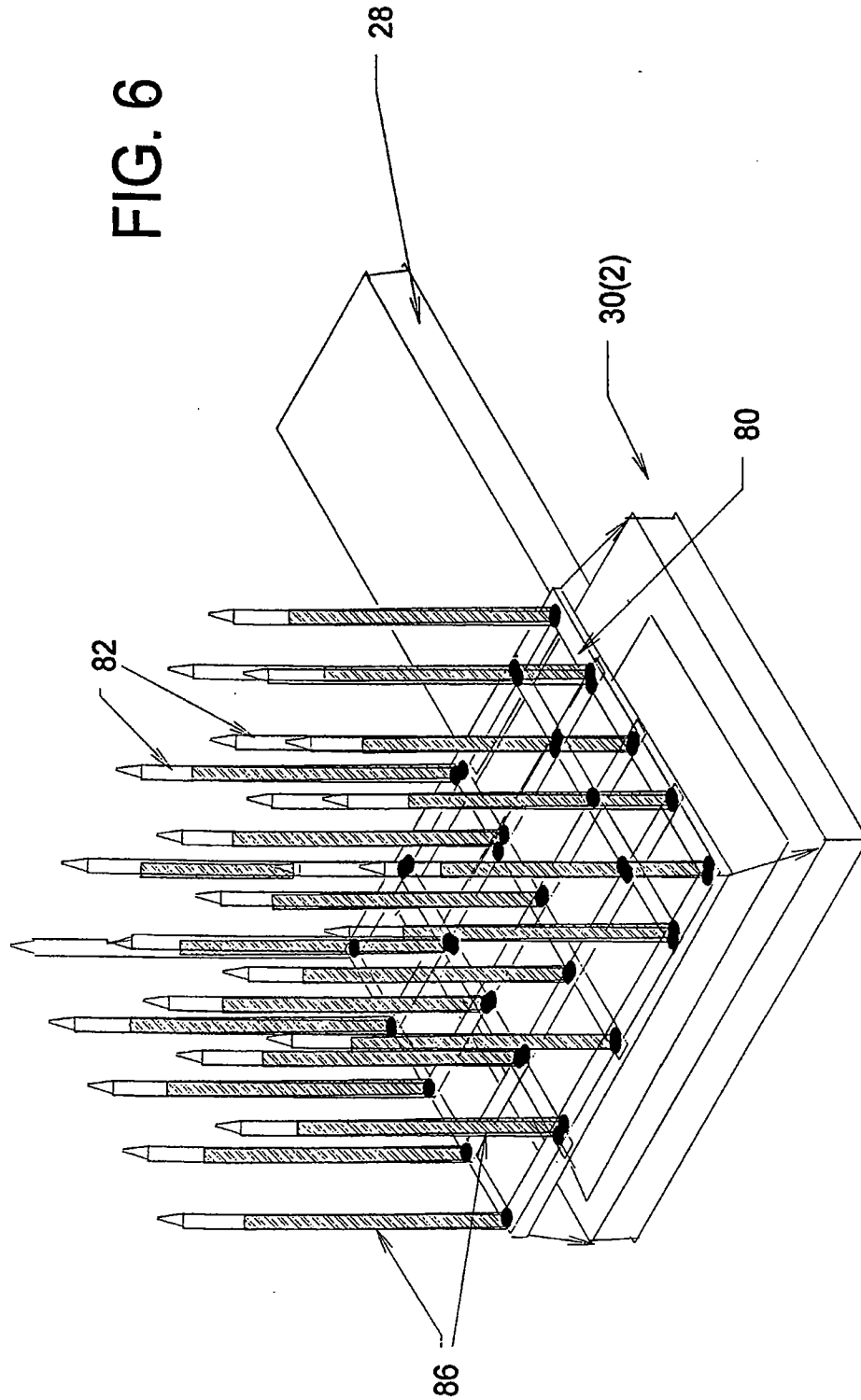


FIG. 7

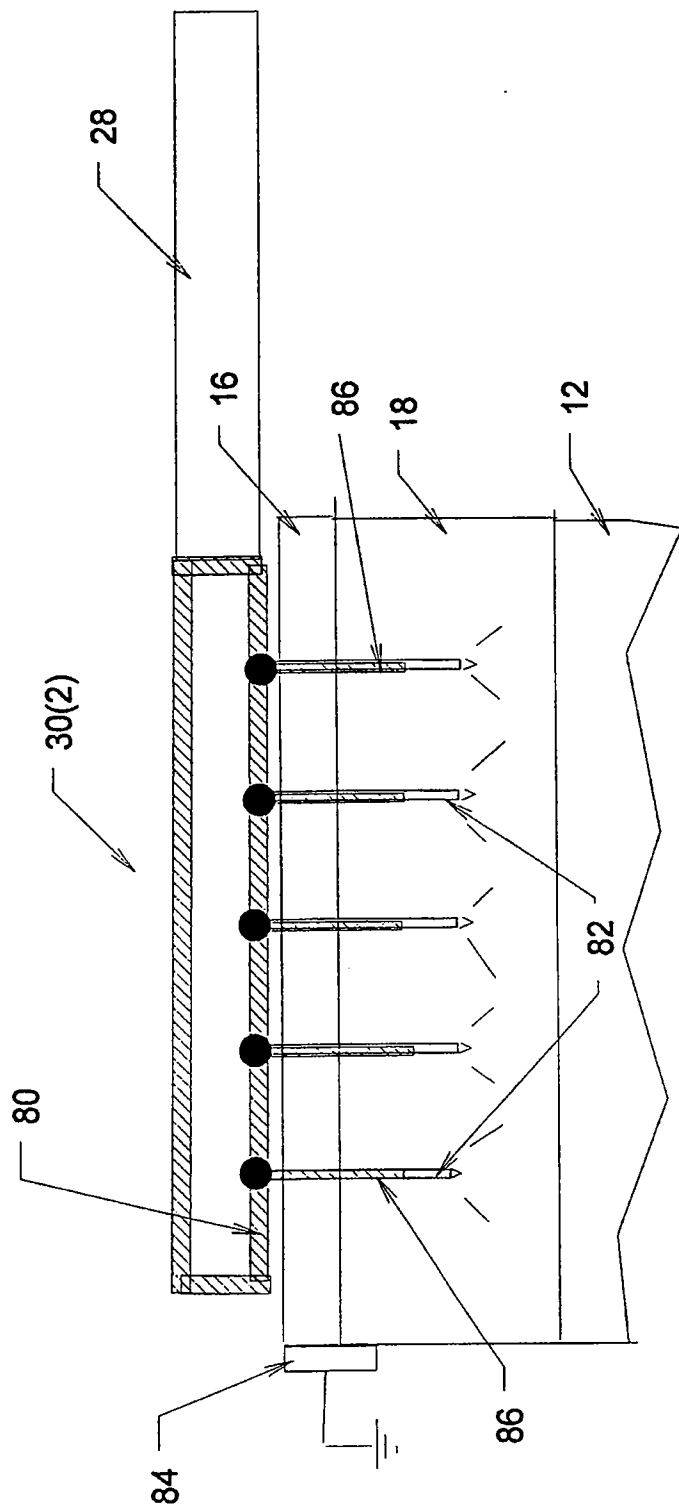


FIG. 8

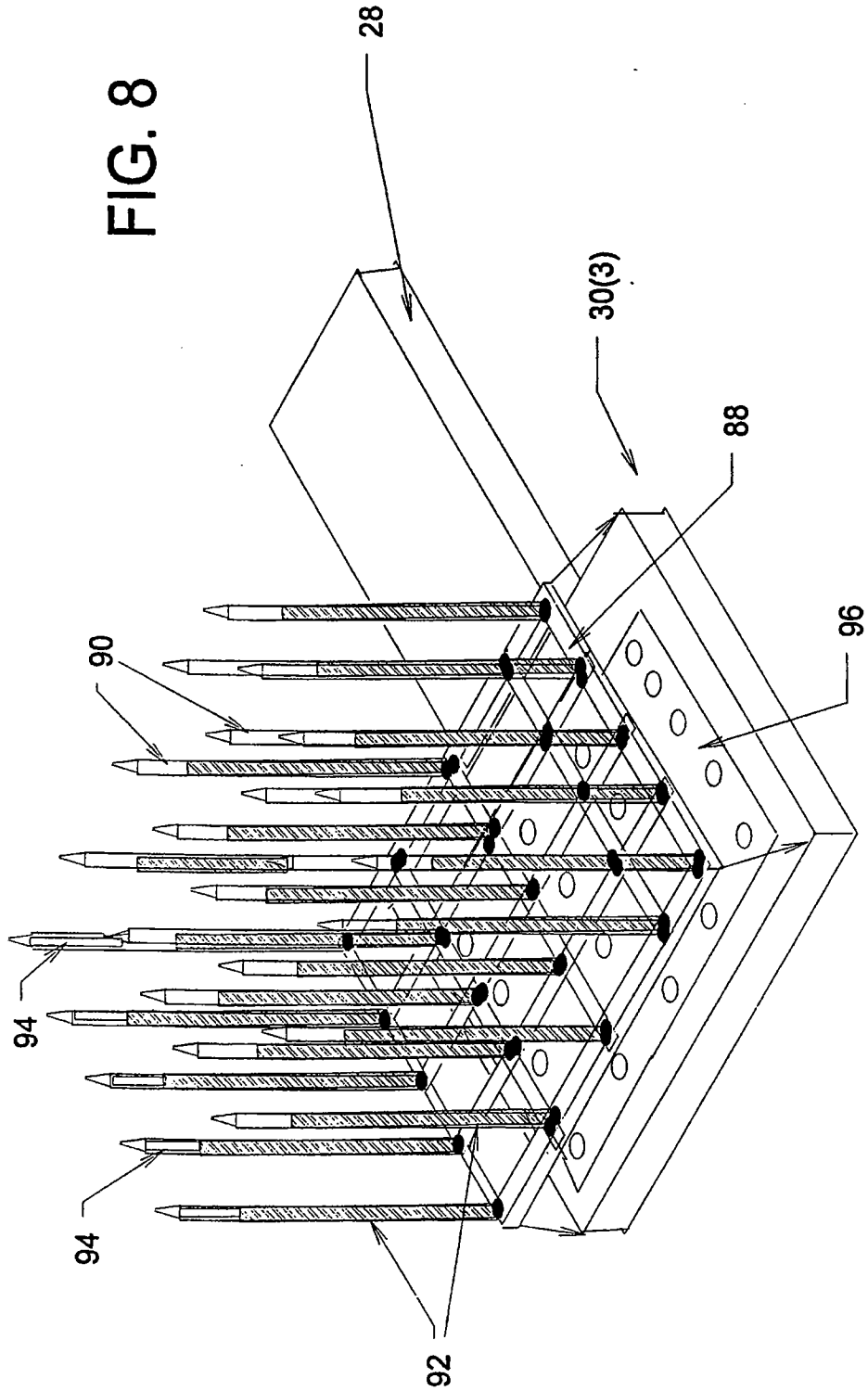


FIG. 9

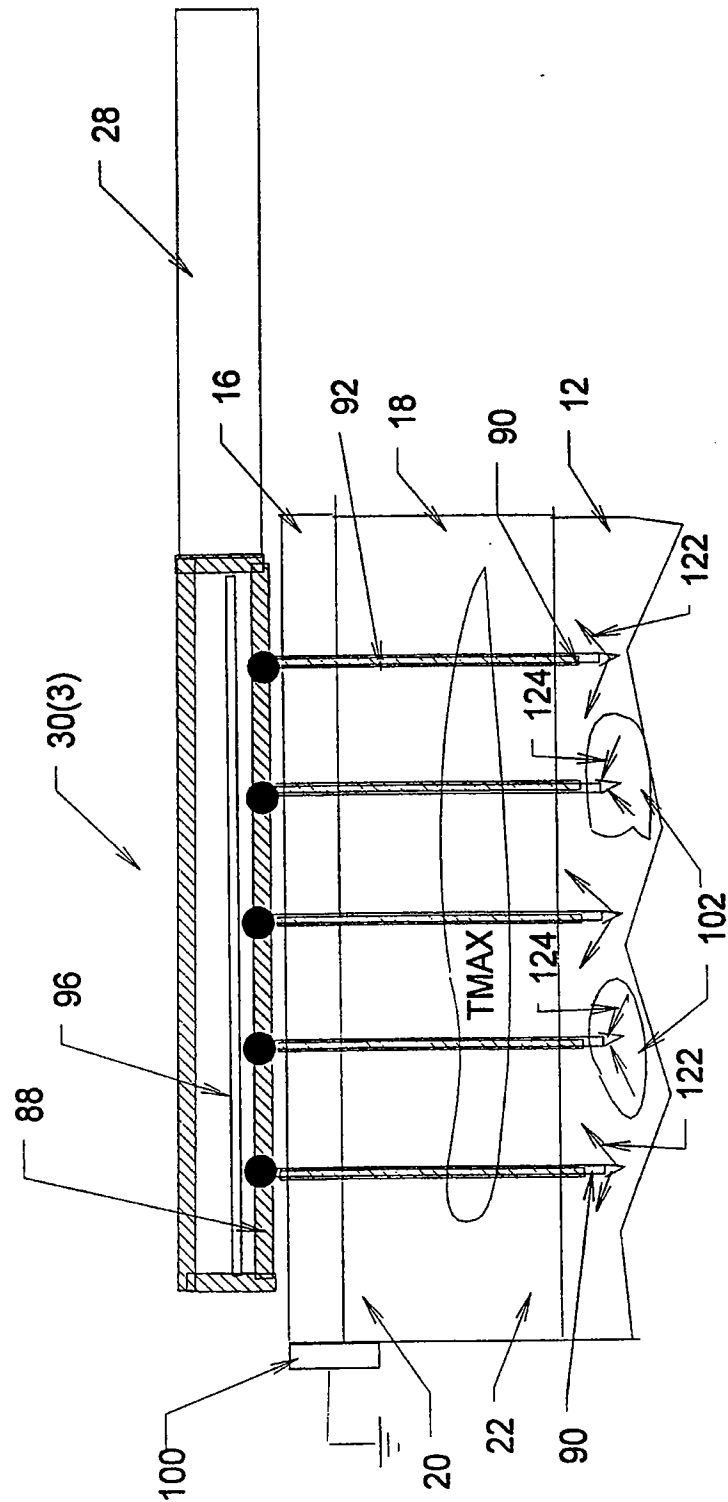
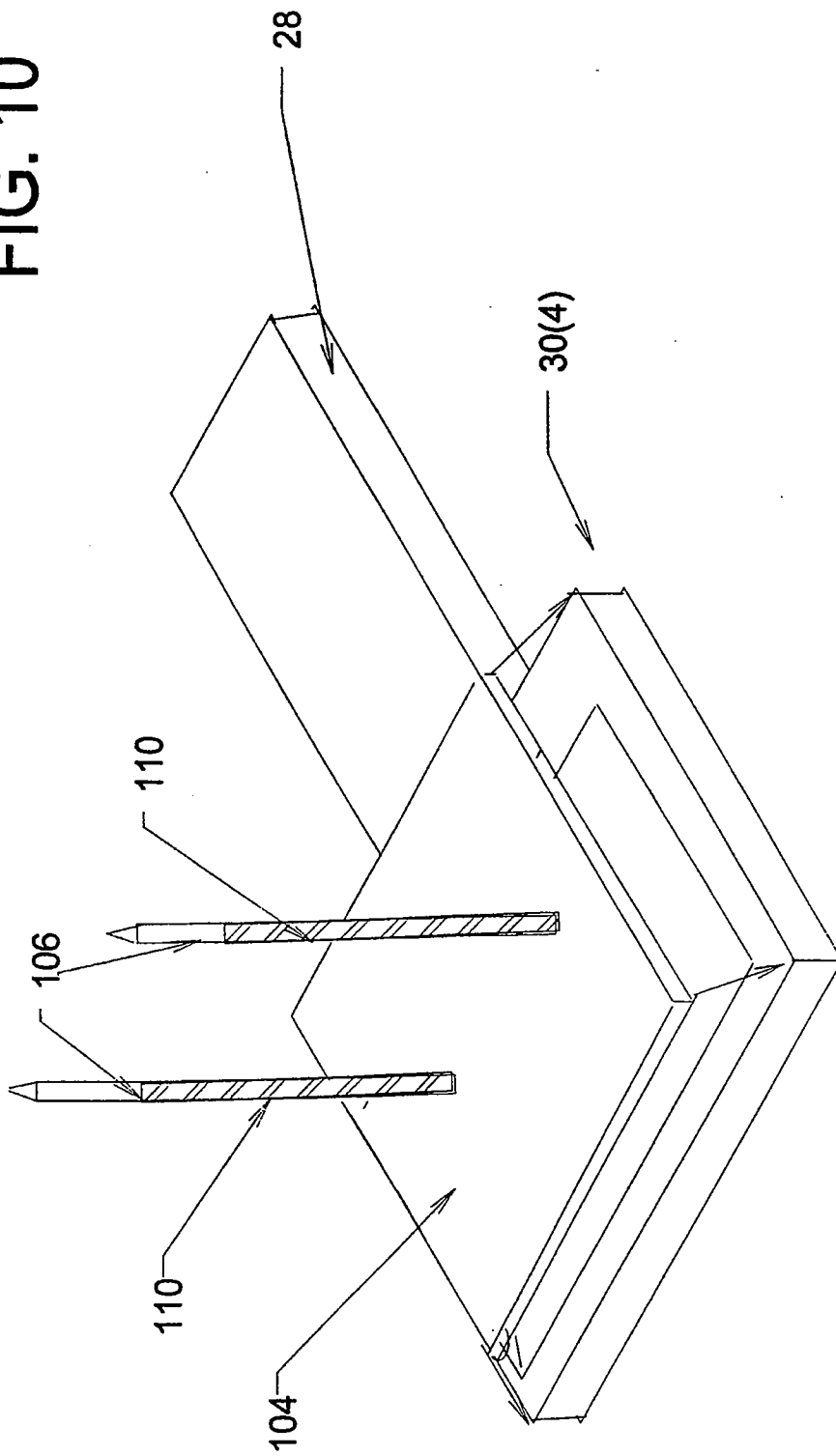


FIG. 10



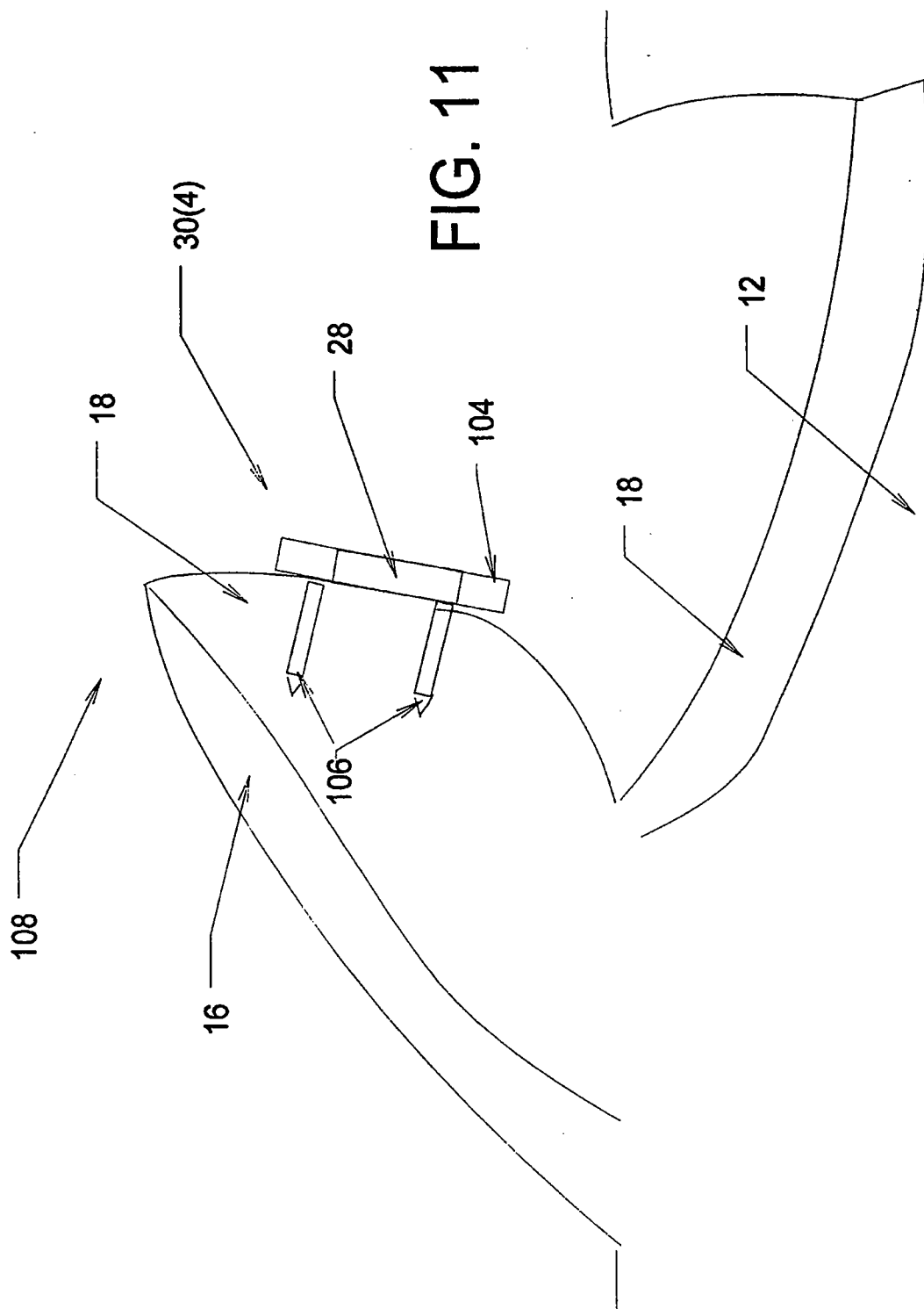


FIG. 12

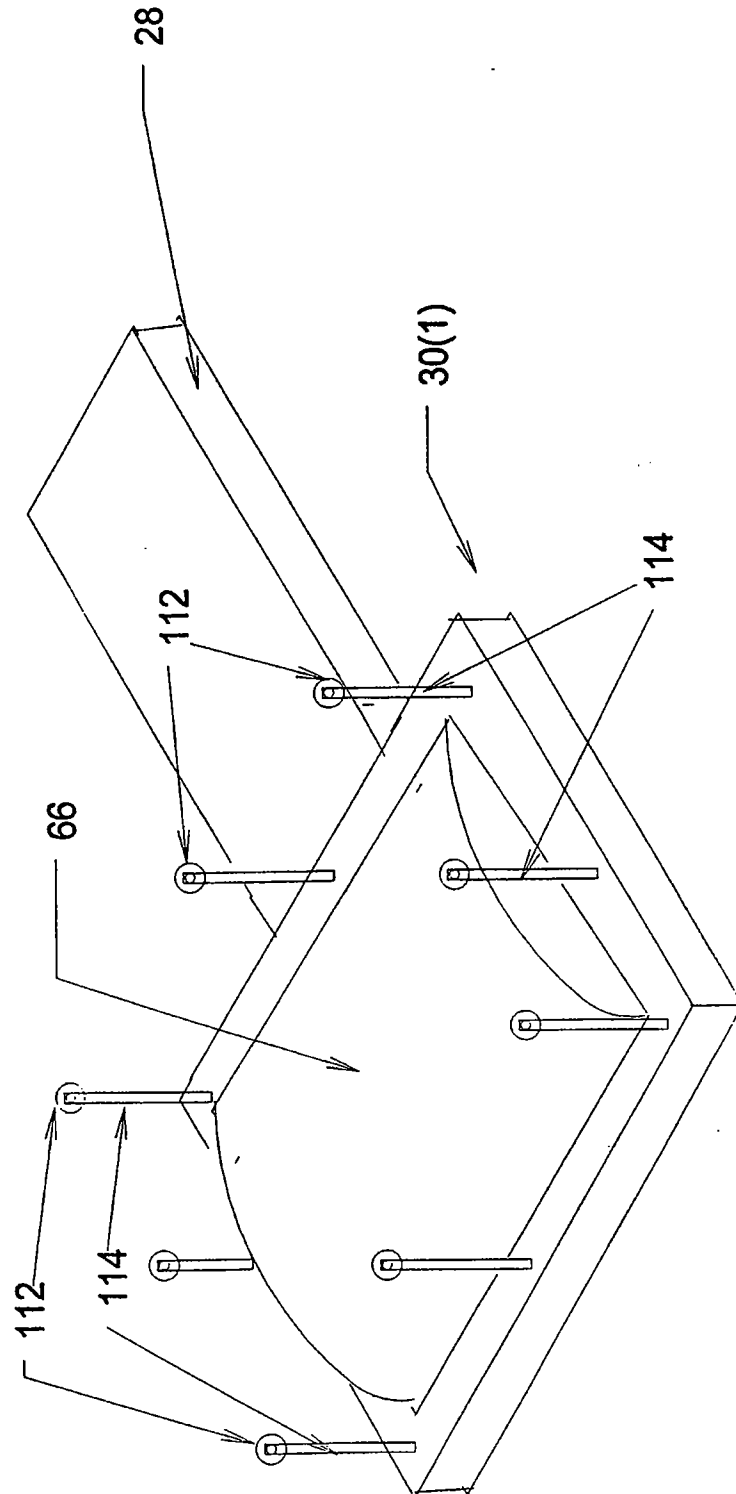


FIG. 13

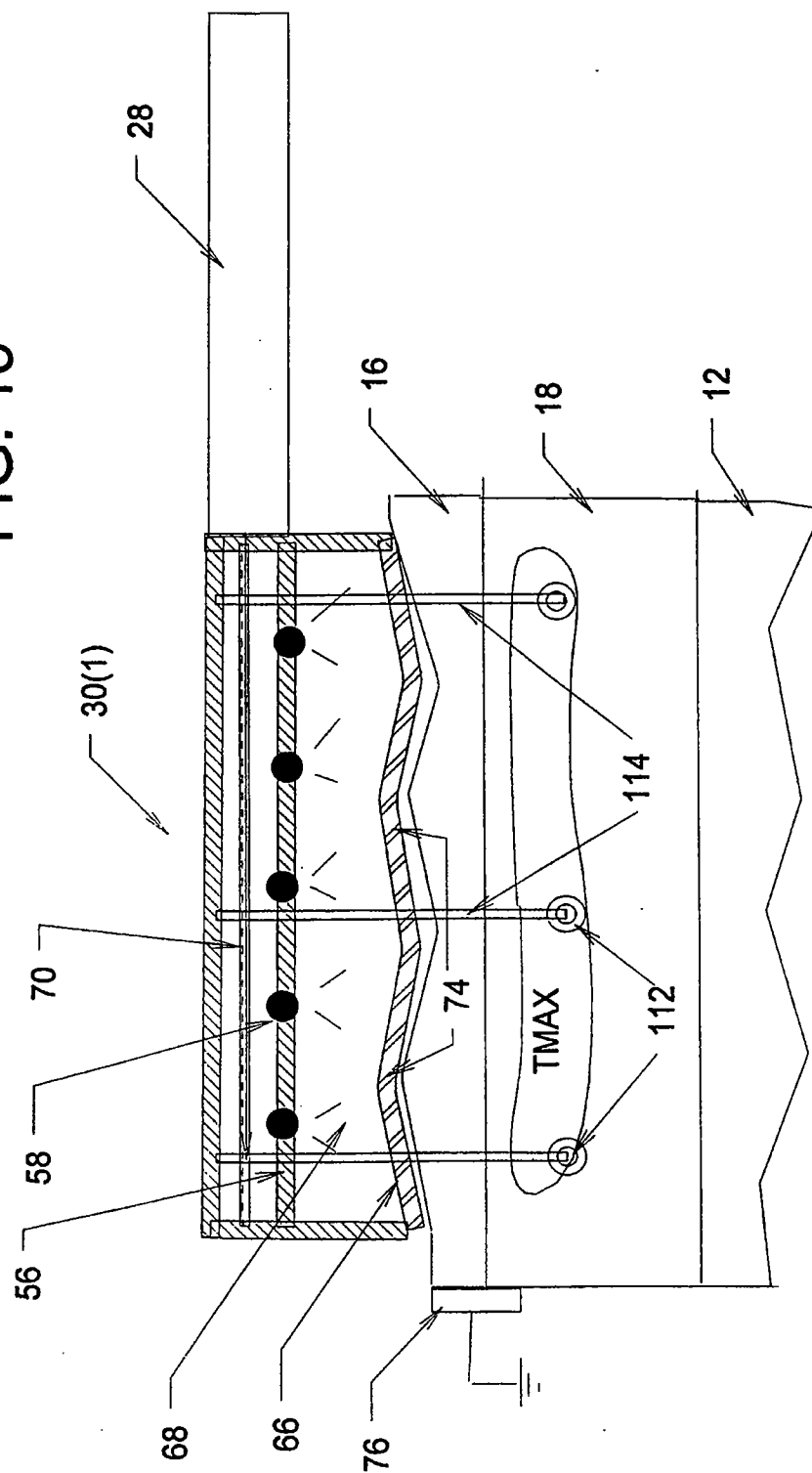


FIG. 14

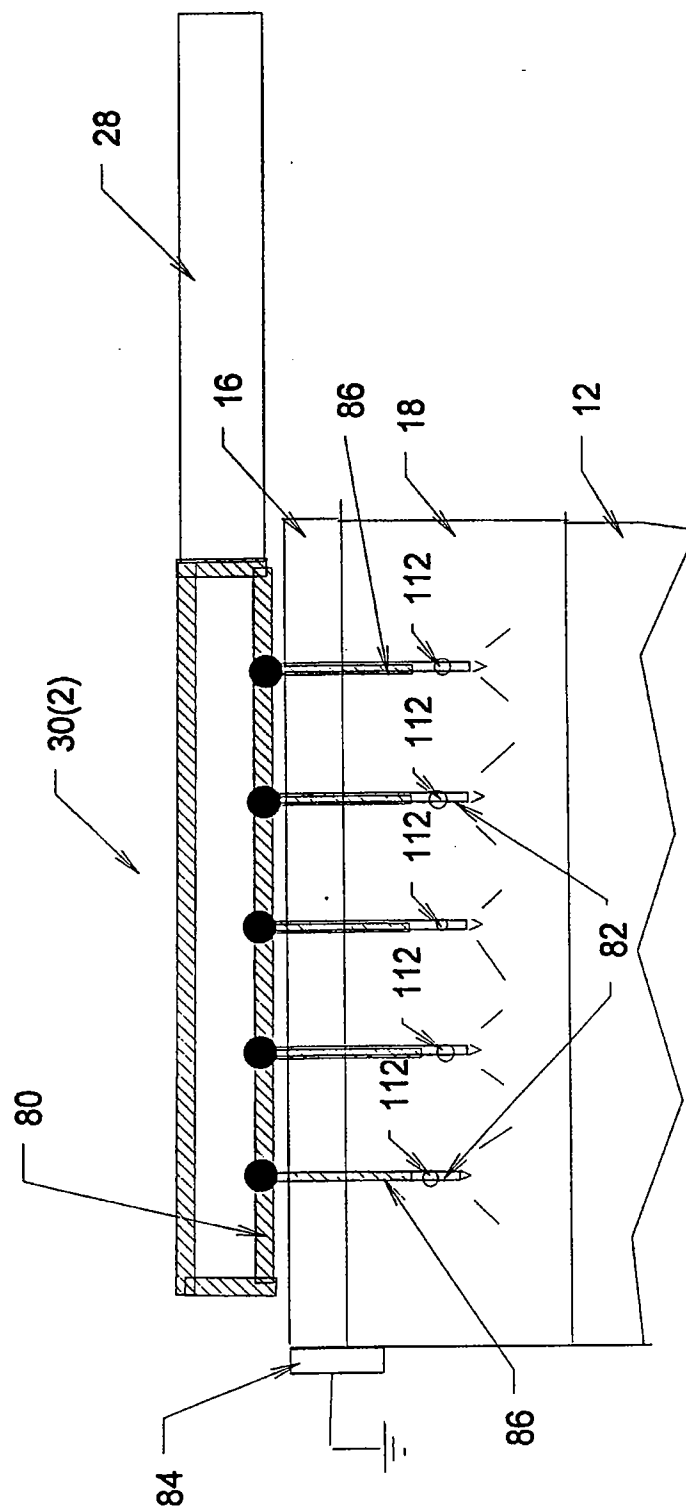
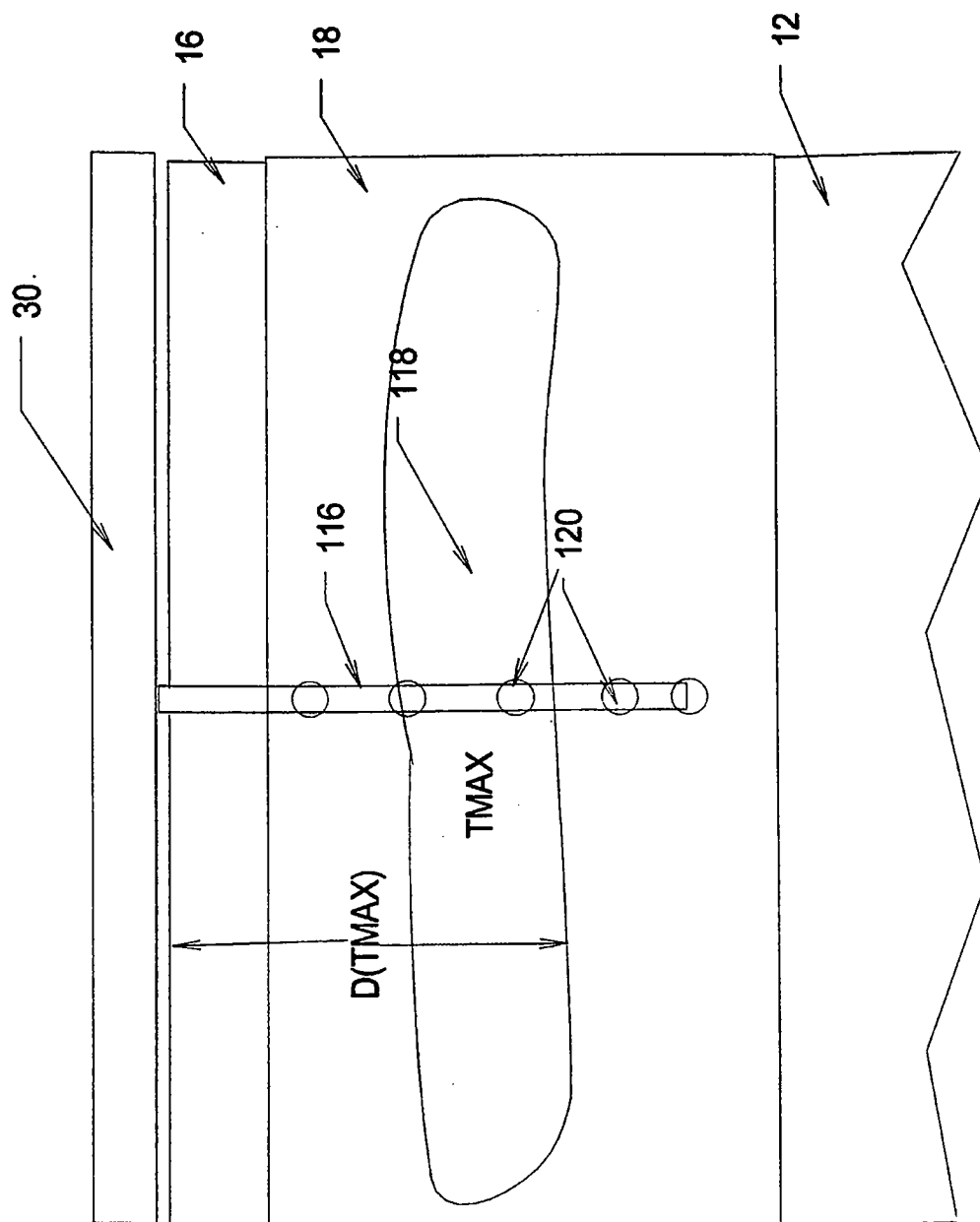


FIG. 15



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International Bureau



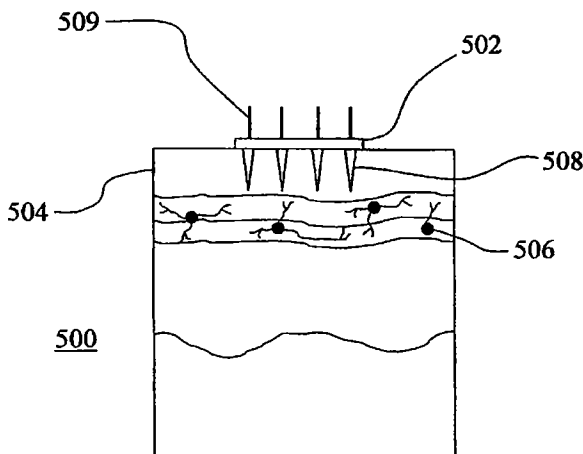
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- (71) Applicant: CERAMOPTEC INDUSTRIES, INC. [US/US]; 515 Shaker Road, East Longmeadow, MA 01028 (US). For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
- (72) Inventor: NEUBERGER, Wolfgang; 22 Taman Jasa, Jalan Tun Mustapha, 87000 F.T. Labuan (MY).

(54) Title: LASER SYSTEM FOR IMPROVED TRANSBARRIER THERAPEUTIC RADIATION DELIVERY



(57) Abstract: The present invention describes a system and method to improve radiation delivery through a barrier that may be encountered during therapeutic laser procedures, particularly where the objective of treatment is to produce thermal damage or alterations to subsurface tissue constituents without destroying or altering the overlying barrier. To achieve this result, a bio-compatible fluid is preoperatively administered to the tissue. The bio-compatible fluid is a light-scattering fluid that will scatter light primarily at the desired site thereby achieving a more uniform, enhanced heating over a relatively large treatment area. In addition, a second fluid, a dispersion fluid, can be added to the tissue to function in distributing the light scattering fluid throughout the treatment site. Laser radiation is then administered, through micro pores created for example by a device such as a micro-needle patch, into the treatment site. When a micro-needle patch is employed to deliver the fluid and the radiation, it can be a single patch for both functions, or a separate patch for each function.

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LASER SYSTEM FOR IMPROVED TRANSBARRIER THERAPEUTIC RADIATION DELIVERY

The present invention describes a method to enhance radiation delivery through a barrier that may be encountered during therapeutic laser procedures, particularly where the objective of treatment is to obtain uniform sub-barrier heating and to effect thermal damage to subsurface tissue constituents without
5 destroying or altering the overlying barrier.

Since its invention in 1960, the laser has found niches in both diagnostic and therapeutic medical applications. Lasers have become widely accepted for treating vascular lesions, comprising enlarged or ectatic blood vessels, pigmented lesions, and tattoos. More recent additions to the list of aesthetic
10 laser treatments include abatement of wrinkles, scars and other blemishes, removal of unwanted hair, creation of skin pockets during hair transplantation surgery and shrinkage of varicose veins. In the above-stated procedures it is necessary to use a sufficient dose of light to irradiate subsurface tissue constituents to achieve the desired clinical effects. However, the delivery of
15 radiation to the appropriate treatment site can be problematic because excessive absorption at the stratum corneum often results in epidermal damage and scattering in the dermal region often results in inadequate heat generation at the treatment site.

Various solutions have been proposed to eliminate the above-stated
20 complications. Generally, the solutions concentrate on increasing the absorption at the treatment site or facilitating transmission through the epidermis.

For example, U.S. Patent No. 5,226,907 describes a device and method for light-induced hair removal that involves placing an absorptive substance at the
25 treatment site and exposing that substance to the proper wavelength of light. The light-absorbing substance is allowed to migrate at least part-way into the follicle or treatment site. The excess light-absorbing substance is then removed and the area is irradiated to destroy, modify or stimulate the treatment site. The excess light-absorbing substance is then removed and the
30 area is irradiated to destroy, modify or stimulate the treatment site. However,

it is difficult to get the light-absorbing substance or chromophore deep enough into the treatment site to effect destruction, modification, or stimulation of subsurface tissue constituents. Further, this technique results in substantial energy being applied to and absorbed by the epidermis and other skin layers in the region being treated, with significantly reduced energy reaching the treatment area. Therefore, it is difficult to achieve and sustain the critical core temperature that is necessary to destroy, modify or stimulate without damaging the surrounding tissue and without causing pain and injury to the patient.

Whereas, U.S. Patent No. 5,454,807 describes a device that can facilitate transmission of light through the epidermis. Specifically, a conduit is constructed to deliver a flow of coolant to the surface of a treatment site. Generally cryogen has been used as a coolant to protect the epidermis because the liquid-vapor phase transition of cryogen has been shown to provide a mechanism for selectively cooling the skin. Specifically, the liquid-phase transition of cryogen creates a boundary layer which creates a heat sink below the surface of the skin that can rapidly remove trapped heat before, during, and after laser exposure to protect the epidermis from thermal damage. However, this technique can be counterproductive if a heating effect is desired in the epidermal or upper dermal region because the treatment site will also be cooled and as a result may remain resistant to photothermolysis.

U.S. Patent No. 5,749,868 describes another method to facilitate transmission of light through the epidermis by using light in the near infrared region to effect a decrease in the ration of melanin to hemoglobin absorption in the treatment of blood vessels. The method described is, however, limited. First, the method does not provide a way to get through the epidermis. What the invention provides is merely a way to decrease the negative skin-surface side effects (such as hyper-pigmentation) resulting from the treatment. It is evident from the patent description that melanin absorption still occurs at the described treatment wavelengths therefore, some amount of surface damage will still be present, only minimized. The described invention combines the commonly accepted idea that increased penetration can be obtained by using longer wavelengths of light with the use of light in the specific near-IR

wavelengths that increase hemoglobin absorption. Second, the invention described addresses exclusively the ratio of melanin to hemoglobin absorption and is therefore limited to blood vessel treatment and is limited in its application.

5 U.S. Patent No. 5,000,752 describes a method for transdermal laser delivery through the insertion of an array of surgical needles into a treatment tissue, preventing damage to the skin surface. The needles are attached in a fixed pattern on a flexible pad that allows the entire array to be inserted at one time. However, there are a couple of drawbacks to this invention. First,
10 treatment with the device is painful for the patient. The stratum corneum, or the outermost 10-15 μm of skin, has no nerve endings. Penetration below that layer, however, causes pain. The device is described as having delivery needles greater in length than the depth of the stratum corneum. Second, the needles employed in the invention are intrusive and increase the chance of
15 infection. The larger the bore of the delivery needle, the larger the entry hole and the greater the chance that microorganisms might be introduced into the site. Third, the invention describes an array of very detailed delivery needles with adjustable, specialized tips. The device must therefore be expensive to manufacture and purchase. Practical application of the invention can be
20 hindered by its cost.

In another example, U.S. Patent No. 5,735,844 describes a method of improving laser delivery by inserting a needle-like element into the follicle to facilitate light energy reaching the appropriate treatment site. However, this procedure is very painful. On the other hand, if the irradiation source is not
25 inserted into the follicle, it is difficult to get sufficient energy to achieve and sustain the critical core temperature that is necessary to destroy, modify or stimulate without also causing significant damage to the surrounding tissue and thus causing pain and injury to the patient.

An ideal device would enable the irradiation source to be inserted into the
30 treatment site without pain to the patient to improve heat generation at the treatment site and to facilitate the transmission of light energy through the epidermis. Thus, a device and method are needed that will improve

transdermal laser delivery without the complications associated with the prior art.

It is an object of the present invention to provide a system and method for improved transbarrier laser delivery to the appropriate treatment site without the complications associated with the prior art.

It is another aim of the present invention to insert the irradiation source, transbarrierly, into the treatment site without pain to the patient to facilitate radiation delivery through the epidermis.

It is a further aim of the present invention to employ pre-treatment methods to further enhance heat generation at the treatment site.

Briefly stated, the present invention describes a system and method to improve radiation delivery through a barrier that may be encountered during therapeutic laser procedures, particularly where the objective of treatment is to produce thermal damage or alterations to subsurface tissue constituents without destroying or altering the overlying barrier. To achieve this result, a bio-compatible fluid is preoperatively administered to the tissue. The bio-compatible fluid is a light-scattering fluid that will scatter light primarily at the desired site thereby achieving a more uniform, enhanced heating over a relatively large treatment area. In addition, a second fluid, a dispersion fluid, can be added to the tissue to function in distributing the light scattering fluid throughout the treatment site. Laser radiation is then administered, through micro pores created for example by a device such as a micro-needle patch, into the treatment site. When a micro-needle patch is employed to deliver the fluid and the radiation, it can be a single patch for both functions, or a separate patch for each function.

The above and other objects, features, and advantages of the present invention will become apparent from the following detailed description read in conjunction with the accompanying drawings.

Fig. 1 illustrates the various laser-tissue interactions that can occur during laser therapy.

Fig. 2 illustrates the inverse relationship between optical scattering and wavelength.

Fig. 3 is a diagram of the laser radiation delivery system.

Fig. 4 is an electron microscope image of a micro-needle array.

Fig. 5 is a schematic illustration of the laser radiation delivery system being employed on a cross-section of tissue.

5 Fig. 6 illustrates a micro-needle array incorporating both laser energy and fluid delivering needles on the same patch.

Fig. 7 illustrates a system for coupling laser energy from an optical fiber into a micro-needle patch.

10 The present invention describes a system and method of use that controls the degree and spatial distribution of heating in the epidermis and dermis to achieve and sustain the critical core temperature that is necessary to ablate or stimulate the treatment site. The invention relates to therapeutic procedures where the objective of treatment is to produce irreversible thermal damage to subsurface tissue constituents without destroying or altering the outer barrier.
15 Although most examples refer to an epidermal barrier that must be penetrated, this should not be taken to imply that the present invention is limited to enhancing radiation delivery only through the epidermis. The present invention may be used to enhance radiation delivery through any barrier that is encountered. Other suitable variations of the present invention may include,
20 but are not limited to delivering laser energy through soft tissue in the oral cavity or through arterial or venal walls.

Fig. 1 illustrates the various laser-tissue interactions that can occur during laser therapy. At near-normal (nearly perpendicular) incidence, a small
25 fraction of an incident radiation is reflected due to the change in refractive index between air ($N_D = 1.0$) and stratum corneum ($N_D \cong 1.55$). For normally incident radiation, this regular reflectance of an incident beam from normal skin is typically between 4% and 7% over the entire spectrum from 250-3000 nm. This same air-tissue optical interface also causes internal reflection of
30 diffuse, back-scattered radiation. Within any of the layers of skin, the 93% to 96% of the incident radiation not returned by regular reflectance may be absorbed or scattered.

The stratum corneum and epidermis provide an optical barrier primarily by absorption of radiation and to a lesser degree, by optical scattering. The dermis has distinctly different optical properties than the epidermis, reflecting differences in structure and composition. The dermal region may be
5 considered a turbid tissue matrix in which optical scattering is an inverse function of wavelength and largely defines the depth of optical penetration for a non-absorptive wavelength. Fig. 2 illustrates the inverse relationship between optical scattering and wavelength.

Scattering results from inhomogeneities in a medium's refractive index,
10 corresponding to physical inhomogeneities. The spatial distribution and intensity of scattered light depends upon the size and shape of the inhomogeneities relative to the wavelength, and upon the difference in refractive index between the medium and inhomogeneities. Thus, microstructures (e.g. collagen fibrils) in the dermis largely determine the
15 penetration depth at various wavelengths. For example, at shorter wavelengths, the wavelength has dimensions of the same order as the collagen fibers. As a result, scattering is strong and the penetration depth is correspondingly reduced.

The present invention employs lasers with wavelengths in the near-infrared
20 portion of the electro-magnetic spectrum (700 to 1400 nm) to limit scattering in the dermal region so that the radiation can reach the treatment site.

Heat generation at the treatment site is enhanced through micro-poration techniques wherein micro pores are created in the stratum corneum. Such micro pores serve as channels for any fluid media needing to be introduced
25 into the site. Micro poration can be achieved using a micro-needle patch. Fig. 3 illustrates a sectional view 400 of micro-needle 404 on micro-needle patch 402 enlarged by an electron microscope. Micro-needles 404 on micro-needle patch 402 can be placed onto the treatment area and the bio-compatible fluid passed through micro-needles 404 directly into the tissue. Conversely, micro-
30 needles 404 on micro-needle patch 402 can be placed onto the treatment area to form micro pores in the tissue. Micro-needles 404 on micro-needle patch 402 are then removed from the area. The micro pores remain for a period. Fluids can be administered by capillary action and preferably along a pressure

gradient through the micro pores and into the treatment tissue. As a result, the user will be able to achieve more uniform, enhanced heating over a relatively large treatment area.

Micro-needles on a single patch generally have the same dimensions.

- 5 Typically, each needle is approximately 40-50 μm in length and has a diameter (at the base of the needle – where the needle is attached to the patch) of approximately 12-15 μm .

Radiation is then applied to the treatment site. In turn, micro-needles can be employed to enhance heat generation at the treatment site during irradiation
10 to achieve and sustain a critical core temperature necessary to ablate or stimulate the treatment area. Illustrated in Fig. 4 is laser radiation delivery system 300 where the proximate end of multiple fibers 302 is connected to laser 306 via fiber bundle 308. Multiple fibers 302 are inserted into micro-needles 304 that are arranged in an array on micro-needle patch 312. Micro-
15 needles 304 facilitate radiation delivery through the epidermis by providing a painless way for the optical fibers to cross the stratum corneum and to facilitate the transmission of radiation through the epidermis.

In an example and preferred embodiment, the present invention may be used to treat vascular lesions. According to Fig. 2, a 980 nm diode laser
20 would be preferable to limit scattering in the dermal region so that the radiation can reach the treatment site. Additionally, Patent Ser. No. 5,749,868 teaches that near infrared light achieves enhanced selectivity in the treatment of vascular lesions. While 980 nm light limits scattering in the dermal region to achieve an increased penetration depth, heat generation at the treatment site
25 is not uniform over large treatment areas and may be inadequate to achieve and maintain the critical core temperature that is necessary to ablate or stimulate. Therefore, a micro-needle patch is applied prior to laser therapy to enhance heat generation at the treatment site and to provide for uniform heating over a relatively large surface area. For example, Fig. 5 illustrates
30 application of a device to treatment area 500. Micro-needles 508 on micro-needle patch 502 cross stratum corneum 504, but do not strike nerve endings 506 therefore the procedure is painless because nerve endings 506 are not pierced. Micro-needles 508 act like little tunnels that go through stratum

corneum 504, through which optical fibers 509 may be passed. A scattering fluid is injected into the tissue. The scattering fluid can be followed by a dispersion fluid to aid in pushing the scattering fluid to the treatment site. The dispersion fluid is optically transparent to the treatment wavelength involved
5 to prevent any interference with the radiation delivery.

A micro-needle patch enhances heat generation at the treatment site by injecting a bio-compatible, medium-viscous to highly-viscous fluid into the tissue that will essentially scatter light only at the treatment site to achieve and sustain the critical core temperature that is necessary to ablate the vessels.
10 Alternatively, another micro-poration technique may be used to introduce the fluid.

In an embodiment, the optically transparent fluid is composed of 80% glycerine and 20% water and the light-scattering fluid is composed of oil and water with 1 to 5 parts oil in a 100-part mixture. One of ordinary skill in the
15 art, in light of the teachings herein, can readily use various scattering material and diluents without exceeding the scope of the present invention. For example, fat emulsions that contain soybean oil, egg, phospholipids and glycerol such as Intralipid, Nutralipid, or Liposyn can be used without departing from the scope of the invention.

20 As another example, isotonic phosphate buffer saline may be used as the diluent instead of deionized H₂O without departing from the scope of the invention.

The laser may then be employed to stimulate or ablate the treatment site. The laser's light penetrates the epidermis then travels to the treatment site
25 where the photons of the laser radiation are scattered in the quasi absorption-free scattering fluid and then deposited into the tissue to enhance heat generation at the treatment site and to obtain a uniform heating result across a relatively large treatment site.

One of ordinary skill in the art, in light of the teachings herein, can readily
30 use this method in the treatment of varicose veins or other vascular lesions without departing from the scope of the present invention. For example in varicose vein therapy, longer wavelengths are useful to penetrate more deeply to reach the treatment site. A micro-needle patch then may be employed to

enhance heat generation at the treatment site and to obtain heating uniformity over a large surface area.

Fig. 6 illustrates a top view of micro-needle patch **600**. This particular version of the present invention incorporates both laser delivery 'needles' **604** and scattering-fluid delivery 'needles' **602** on the same patch. This embodiment allows users to administer a complete treatment using the same patch, thereby reducing treatment time and complexity. The practitioner simply applies a single micro-needle patch, administers the scattering fluid, and then the laser radiation. Further, this variation ensures that scattering fluid is administered precisely at the site of laser delivery.

Fig. 7 illustrates a variation of the present invention wherein micro-needle patch **710** containing micro-needles **712** is manufactured out of an optically transparent material such as quartz glass. Within needles **712** is a region with a variant refractive index that comprises 'core' **708**. Fibers **702** are properly oriented and attached **706** to needles **712** such that fiber core **704** aligns with needle 'core' **708**. Laser energy can then be administered transdermally from optical fiber **702**, through needles **712**, and into the treatment site. Conversely, a radiation source may be placed directly onto the micro-needle patch for delivery into the tissue, wherein the needle 'core' **708** captures and transmits light across the stratum corneum.

In another example and preferred embodiment, the present invention may be used in non-ablative facial rhytide treatment. A 1.32 μm laser may be employed to selectively injure the lower papillary/upper reticular dermis to stimulate the skin to produce new collagen and "remodel" itself, thereby de-emphasizing wrinkles. According to Fig. 2, scattering in the dermis is minimal at the 1.32 μm wavelength.

A micro-needle patch may then be employed to inject a scattering fluid into the tissue to scatter the radiation only at the treatment site to achieve a uniform heating effect. A uniform heating effect is especially advantageous in facial rhytide therapy where the treatment area is particularly large. Additionally, the scattering fluid enhances heat generation at the treatment site, therefore an increase in power is not necessary to stimulate the lower papillary/upper reticular dermal region and the risk of injury to the epidermal barrier is

significantly reduced. The holes that are created in the stratum corneum by the micro-needles may provide an additional means to reduce the risk of thermal injury because the holes may release some of the residual heat that has built up within the tissue underlying the stratum corneum in the course of laser therapy.

Certain changes may be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings be considered as illustrative and not in a limiting sense. For example, a desired energy choice may include, but is not limited to non-coherent radiation, radiation from flash lamps, diodes, frequency doubled laser diodes, laser diode pumped lasers, or photo luminescent diodes without departing from the scope of this invention.

As another example, although most references cite to an epidermal barrier that must be penetrated, the use of stratum corneum in the above-stated examples should not be taken to imply that the present invention is limited to enhancing radiation delivery through the epidermis. The present invention may be used to enhance radiation delivery through any inner or outer barrier that is encountered. Other suitable variations of the present invention may include, but are not limited to delivering laser energy through soft tissue in the oral cavity or through arterial walls.

Having described the preferred embodiments of the invention with reference to the accompanying drawings, the invention is not limited to these precise embodiments, and changes and modifications may be effected by one skilled in the art without departing from the scope of the invention as defined in the appended claims.

What is claimed is:

1. A therapeutic laser delivery system for the improved transbarrier delivery and improved uniformity of dispersion of laser radiation comprising:
 - a radiation source;
 - means for painlessly generating a multitude of micro pores in a biological barrier layer protecting a treatment site;
 - means for delivering a bio-compatible, light-scattering fluid to said treatment site;
 - wherein said radiation source is optically connected to said micro pores; and
 - wherein said micro pores provide access to said treatment site for radiation from said radiation source.
2. A transbarrier, therapeutic laser delivery system according to claim 1, wherein said means for painlessly generating a multitude of micro pores is a micro-needle patch.
3. A transbarrier, therapeutic laser delivery system according to claim 1, wherein said radiation source is coupled to said micro pores by an optical fiber bundle such that individual fibers are associated with at least one micro pore.
4. A transbarrier, therapeutic laser delivery system according to claim 1, wherein said radiation source is coupled to said micro pores by an optical fiber bundle such that individual fibers are associated with at least one micro pore.
5. A transbarrier, therapeutic laser delivery system according to claim 2, wherein said radiation source coupled to said micro pores by an optical fiber bundle such that individual fibers are associated with at least one micro pore.

6. A transbarrier, therapeutic laser delivery system according to claim 1, wherein said radiation source is placed over said multitude of micro pores such that radiation from said source is transmitted through said micro pores to said treatment site.
7. A transbarrier, therapeutic laser delivery system according to claim 1, wherein an optically transparent, bio-compatible, dispersion fluid composed of 80% glycine and 20% water is utilized to distribute said light-scattering fluid.
8. A transbarrier, therapeutic laser delivery system according to claim 1, wherein said bio-compatible light-scattering fluid is composed of 1 to 5 parts oil to water in a 100-part mixture.
9. A transbarrier, therapeutic laser delivery system according to claim 2, wherein said bio-compatible fluids are administered to said treatment site through a separate pre-treatment micro-needle patch, prior to commencement of laser treatment.
10. A transbarrier, therapeutic laser delivery system according to claim 2, wherein a single micro-needle patch, containing an array of micro-needles, is attached to both said radiation source and fluid sources to deliver said fluids and said radiation in a simultaneous manner.
11. A transbarrier, therapeutic laser delivery system according to claim 2, wherein said micro-needle patch is optically transparent to laser radiation such that said optical fibers or said radiation source may be optically coupled to said micro-needle patch at the base of each needle.
12. A method for improving the delivery of laser radiation for transbarrier therapeutic treatments comprising the steps of:

applying a micro poration technique to painlessly create a multitude of micro pores in a barrier protecting a treatment site;

injecting a bio-compatible, light-scattering fluid, capable of dispersing therapeutic radiation, through said multitude of micro pores into tissue around said treatment site;

delivering said therapeutic radiation from a source to said treatment site through a suitable means and said multitude of micro pores; and

scattering said therapeutic radiation at said treatment site to promote improved uniformity and enhanced density of said radiation at said treatment site.

13. A method for improved delivery of laser radiation for transbarrier therapeutic treatments according to claim 12, wherein said applied micro poration technique is application of a micro-needle patch.

14. A method for improved delivery of laser radiation for transbarrier therapeutic treatments according to claim 12, wherein said suitable means for delivery of therapeutic radiation is an optical fiber bundle optically connecting said radiation source to said micro pores.

15. A method for improved delivery of laser radiation for transbarrier therapeutic treatments according to claim 12, wherein said bio-compatible light-scattering fluid is composed of 1 to 5 parts oil to water in a 100-part mixture.

16. A method for improved delivery of laser radiation for transbarrier therapeutic treatments according to claim 12, wherein said light-scattering, bio-compatible fluid is injected into said tissue through a micro-needle patch.

17. A method for improved delivery of laser radiation for transbarrier therapeutic treatments according to claim 12, wherein an optically transparent, bio-compatible dispersion fluid is administered after said light-scattering, bio-compatible fluid to disperse said light-scattering, bio-compatible fluid evenly throughout said treatment site.

18. A method for improved delivery of laser radiation for transbarrier therapeutic treatments according to claim 12, wherein said radiation is administered to said treatment site through a second micro-needle patch.

19. A method for improved delivery of laser radiation for transbarrier therapeutic treatments according to claim 12, wherein said radiation and said light-scattering, bio-compatible fluid are delivered through same said micro-needle patch.

FIG. 1

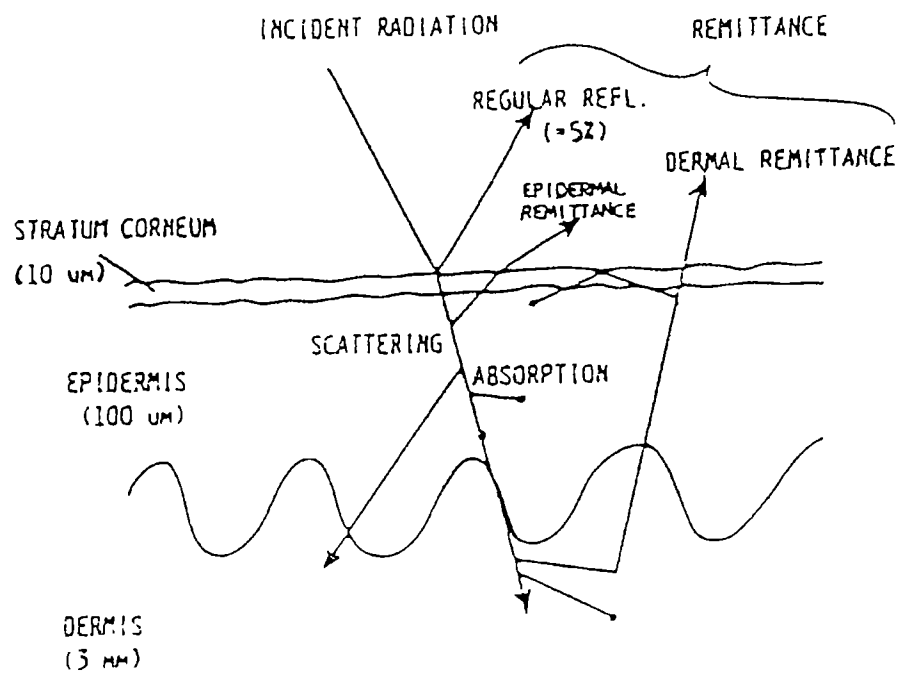


FIG. 2

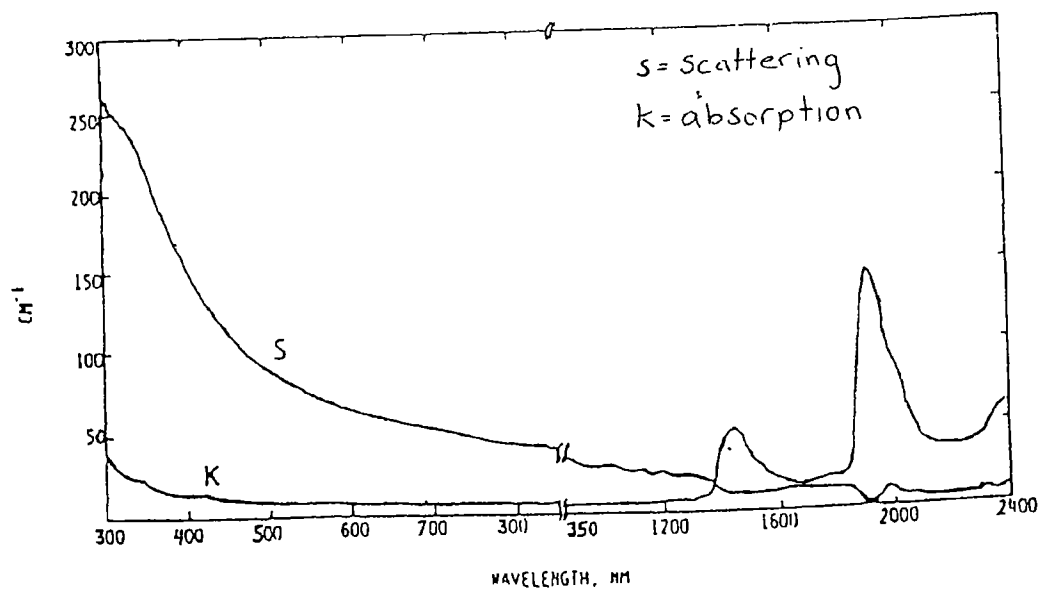


FIG. 3

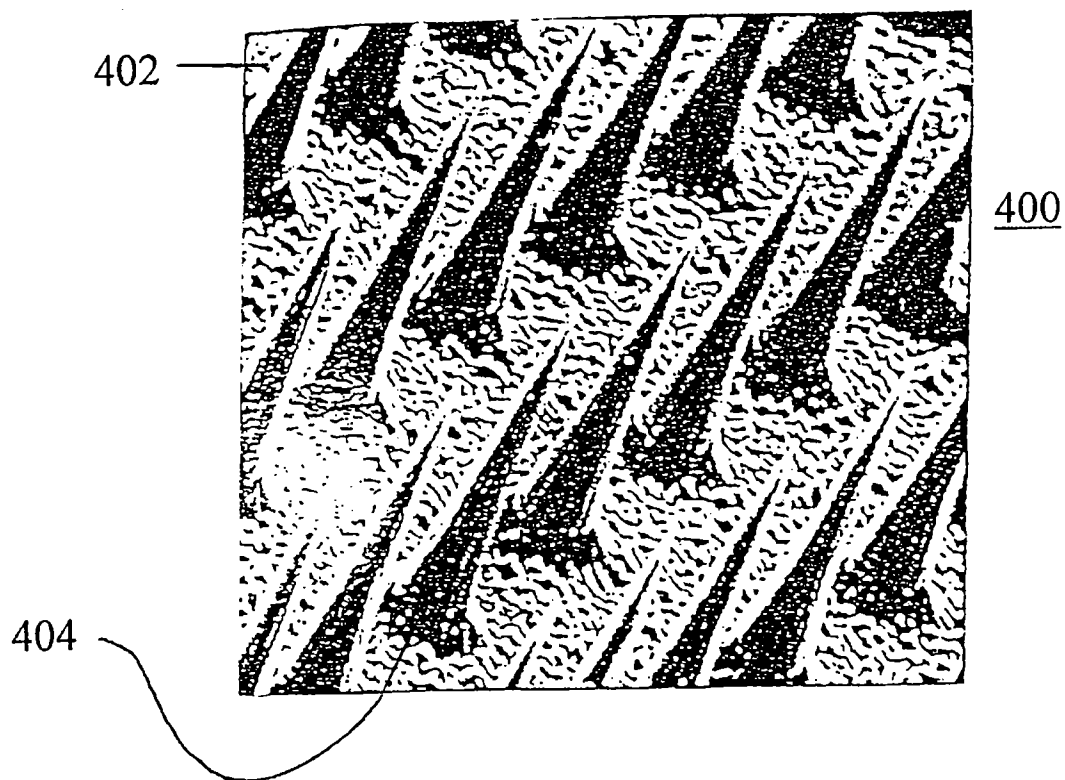


FIG. 4

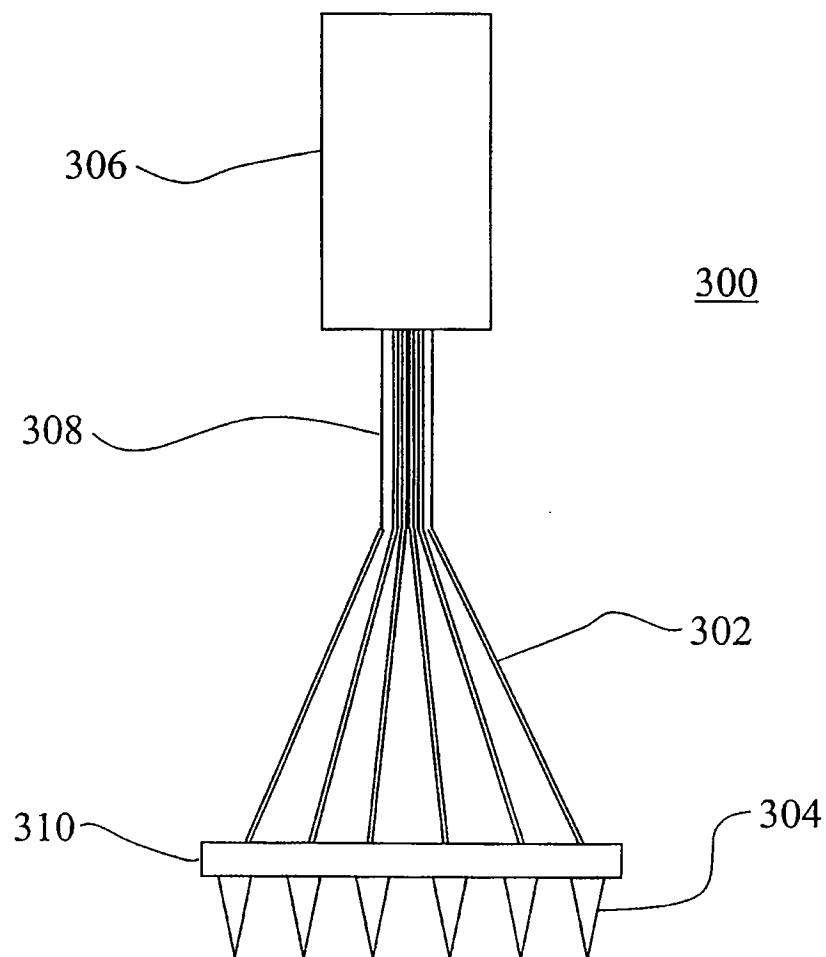


FIG. 5

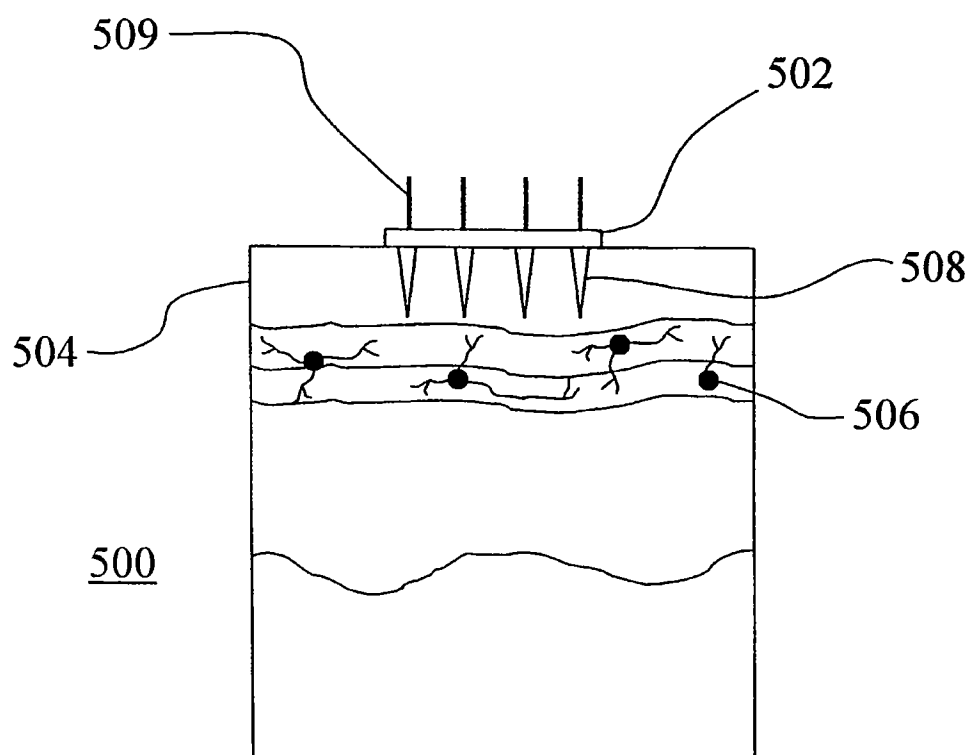


FIG. 6

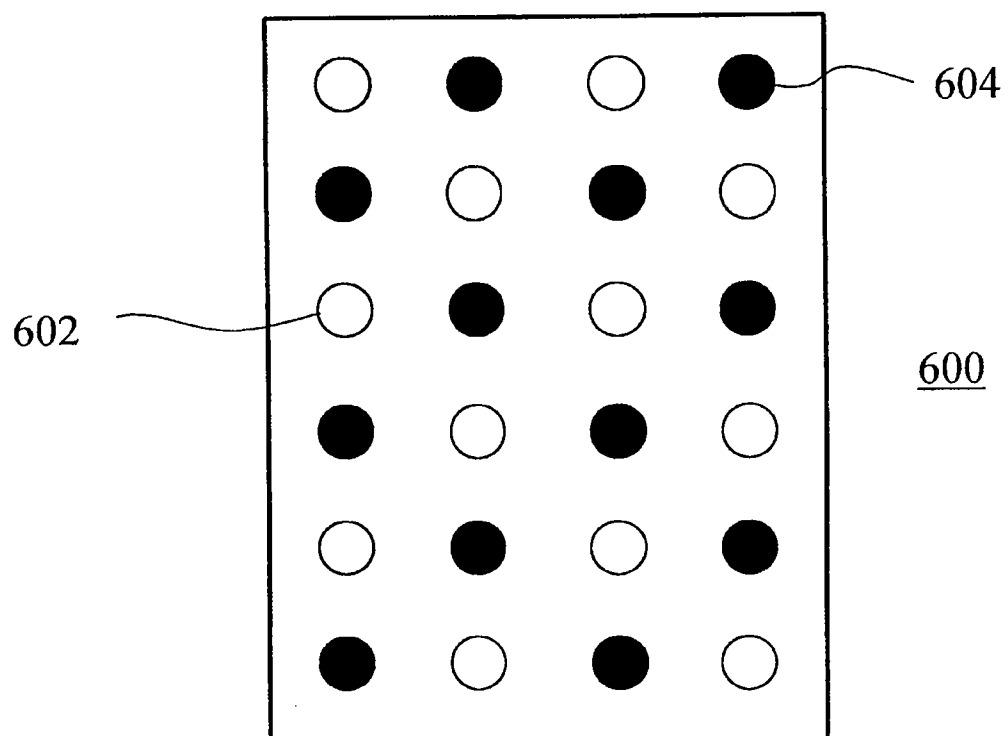
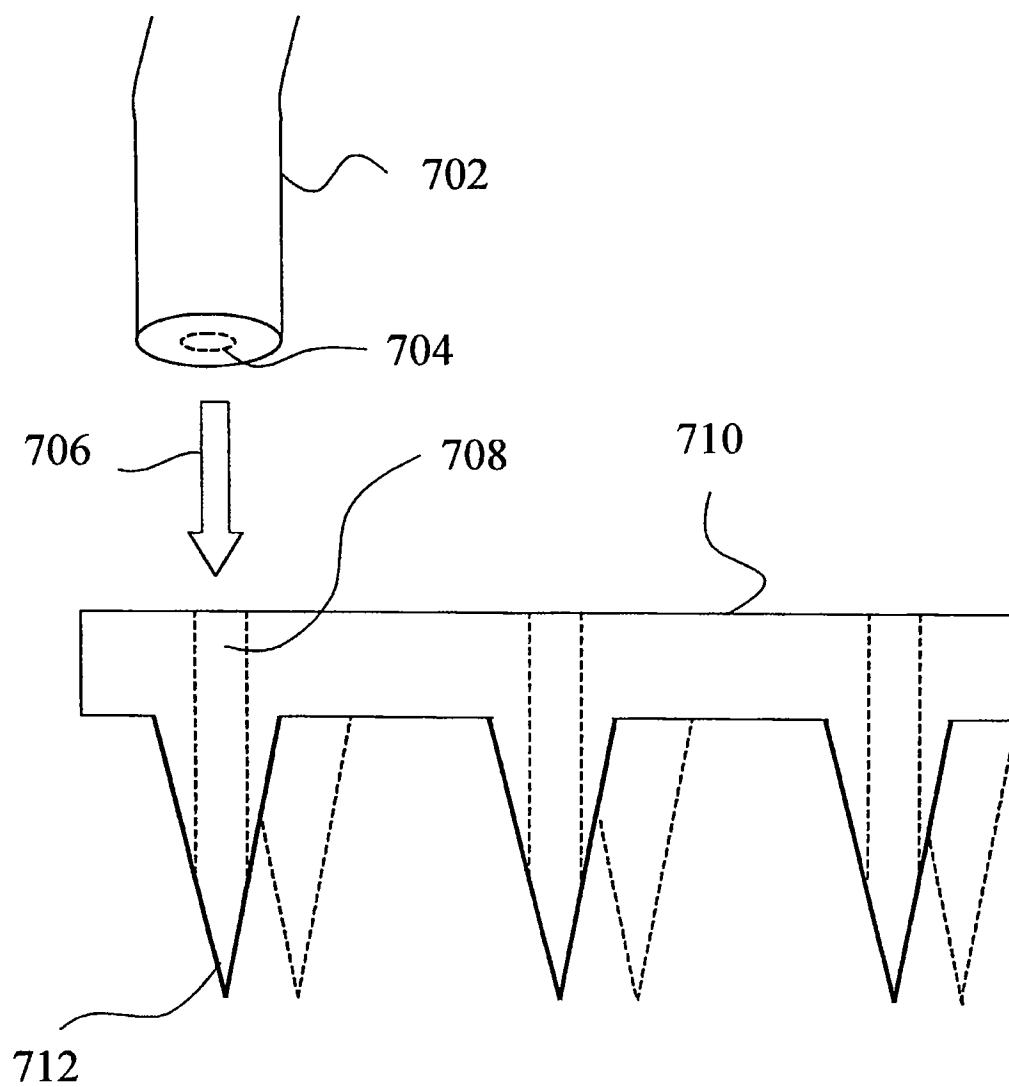


FIG. 7



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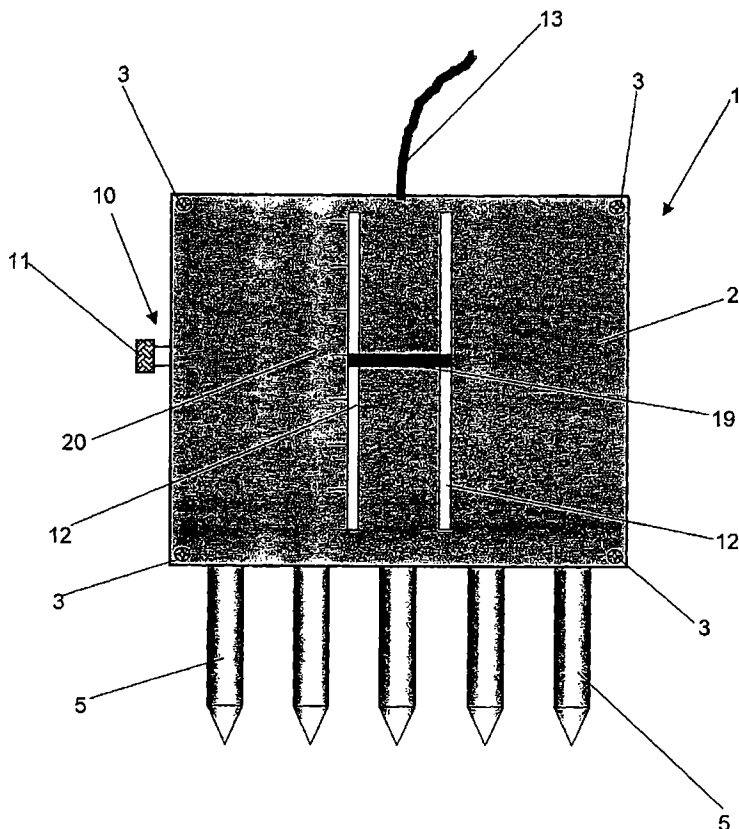
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[Continued on next page]

(54) Title: APPARATUS FOR TREATING ORGANIC TISSUES



(57) Abstract: An apparatus for treating organic tissue (16) to be subjected to surgical resection comprises a body (1) with which the resection means (5) of said organic tissue (16) is associated, said resection means comprising a plurality of resection elements (5) arranged in an aligned configuration.

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- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent*

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Apparatus for treating organic tissues

This invention concerns an apparatus for treating organic tissues such as, for example, hepatic tissue, prostatic
5 tissue, pulmonary tissue, etc. that are to be subjected to both intraoperating and laparoscopic surgical resection.

From prior art, different types of surgical instruments are known for the resection of tissues, such as, for example, metal scalpels, electric scalpels, electric scalpels powered
10 by radio frequency, laser scalpels.

All these instruments require the operation of resection of the tissue to be periodically interrupted to enable coagulation in the resection zone in order to stop bleeding in said zone. With electric scalpels, the function of coagulation
15 and the function of resection can be carried out by the same apparatus by varying the power supply to the apparatus and anyway alternating the two functions.

The need to alternate resection with coagulation of the blood inevitably lengthens the duration of the operation and
20 increases the risk of blood entering the cavity.

The aim of this invention is to provide an apparatus for treating organic tissues to be subjected to both intraoperating and laparoscopic surgical resection that enables maximum flexibility of use, and, in particular,
25 enables all the zone affected by the resection to be covered, whatever its form and/or location.

According to a first aspect of this invention an apparatus is provided for treating organic tissue to be subjected to surgical resection, comprising a body with which treatment
30 means of said organic tissue is associated, characterised in that said treatment means comprises a plurality of treating elements arranged in an aligned configuration.

The treating elements may consist of electrode needles supplied with radio frequency electric power, by appropriate electrical supply means.

5 The use of a plurality of electrode needles that can be inserted along a resection line in the area of organic tissue in which the resection has to be carried out makes it possible, when the needles are powered by electric power means with a radio frequency voltage, to cause the necrotisation of the organic tissue along said resection line and the
10 cauterisation of the blood vessels along said resection line, thereby making the resection operation much more rapid and eliminating the risk of blood entering the cavity.

According to a further aspect of this invention, the treatment means comprises a plurality of hollow needle means, arranged
15 in an aligned configuration, a laser optic fibre being arranged inside each hollow needle means, each laser optic fibre being supplied by an appropriate supply means.

Also in this case the aligned arrangement of the needle elements with the laser optic fibre inside simultaneously
20 enables necrotisation of the organic tissue and cauterisation of the blood vessels along the resection line identified by the aligned needles.

In order that the invention may be clearly and completely disclosed, reference will now be made, by way of examples that
25 do not limit the scope of the invention, to the accompanying drawings, wherein:

Fig. 1 is a front view of an apparatus according to the invention, in a non-operational configuration;

Fig. 2 is a view like the one in Fig. 1, partially sectioned;

30 Fig. 3 is a view like the one in Fig. 2, with the apparatus according to the invention in an operational configuration;

Fig. 4 is a cross-section of the apparatus in Fig. 1;

Fig. 5 is a view of a portion of organic tissue subjected to treatment with an apparatus according to the invention;

Fig. 6 is a view like the one in Fig. 3, showing a variation of the apparatus according to the invention;

Fig. 7 is a view like the one in Fig. 3, showing a further variation of the apparatus according to the invention.

5 The apparatus according to the invention shown in Figs. 1 to 3 comprises a body 1 that is substantially box-shaped, provided with a removable front wall 2 that is fixed to the body 1 by, for example, screws 3. Inside the body 1 (Fig. 2) a support plate 4 is housed that supports a plurality of needle elements
10 5, each one of which has an end 6 fixed in a removable manner to the support plate 4, for example with a Luer connection. The support plate 4 is provided, at its opposite ends, with a slide means 7, coupled in a sliding manner with relative slide guides 8 fixed the side walls 9 of the body 1. To one of the
15 slide means 7 a manoeuvring element 10 is connected, which protrudes outside the body 1, with a knob-shaped element 11 that is used to control shifts in a vertical direction of the support plate 4 to vary the length of the portion of each needle 5 that protrudes from the bottom of the body 1. The
20 manoeuvring element 10 is also used to lock the support plate 4 after said support plate 4 has been positioned in the required position, the slide 7 being connected to the respective slide guide 8 by means of rotation of the knob 11. An indicator means 19 is further connected to the slide 7, the
25 indicator means 19 emerging from a pair vertical slits 12 made in the body 1 of the apparatus, to which a graded scale 20 is associated, which, for example, indicates by how much the needle elements 5 protrude from the body 1.

In a first embodiment of the invention, each needle element 5
30 consists of electrode needle in a conductive material, the top end of which 6 is connected by a supply connector 13 and a conductor of electricity 24 to a source of electrical energy that supplies all the electrode needles 5 with radio frequency voltage, for example at a frequency of several hundred KHz,

preferably about 460 KHz. Each needle element 5 can be provided with a cooling means to increase the area of necrotisation along the resection lines.

In a variation of the invention, the needle elements 5 are constituted by hollow needles within each of which an optic
5 fibre is arranged via which a beam of laser light can be sent to the needle 5, which beam of laser light emerges from the end of the optic fibre arranged at the tip 14 of the hollow needle 5.

10 In a first version of the invention shown in Figs. 1 to 4, the needle elements 5 are of essentially the same length and the support plate 4 has an essentially uniform height, in such a manner that when the needle elements 5 are fixed to the support plate 4, their tips 14 are substantially aligned along
15 a line that is substantially parallel to one side 23 of the body 1.

Fig. 6 shows a variation of the first version of the apparatus shown in Figs. 1 to 4, wherein needle elements 5a of differing lengths are provided that have been chosen to fix the needle
20 elements 5a to the support plate 4, their tips 14 being substantially aligned along a line that is not parallel to said side 23 of the body 1. Said line along which the tips 14 are aligned may be a straight line, but also a curved line.

Obviously, an apparatus according to said first version of the invention can be provided with two series of needle elements:
25 a first series of needle elements 5, to create resections in tissues with a substantially constant depth and a second series of needle elements 5a, to create resections in tissues with a depth that increases or decreases along the selected
30 resection line.

The needle elements 5 and 5a of the first and the second versions of the apparatus are interchangeable. In this way an apparatus according to the invention can be provided with both series of needle elements 5, 5a.

Replacing a series of needle elements 5, 5a, with the other series of needle elements 5, 5a, is simple and rapid to achieve thanks to the "Luer lock" connections between the needle elements 5, 5a and the support plate 4.

5 Fig. 7 shows a second version of an apparatus according to the invention, wherein the support plate 4a has a height that varies in a substantially linear manner. In this way, by fixing a series of needle elements 5 of the same length to the support plate 4a the relative tips 14 are aligned along a
10 straight line that is tilted in relation to the side 23 of the body 1. On the other hand, if a series of needle elements 5 of differing lengths is fitted to the support plate 4a the tips 14 can be aligned along a line that is parallel to the side 23 of the body 1, or along a curved line.

15 An apparatus according to the invention can be provided with just one series of needle elements 5, or 5a, and with two interchangeable support plates 4 and 4a, in such a way as to be able to obtain all the alignments of the tips 14 of the needle elements described above by simple replacement of the
20 support plate 4 with the support plate 4a, or vice versa.

To carry out a resection of organic tissue, for example to remove tumour metastasis 15 from hepatic tissue 16 (see Fig. 5), the needle elements 5, 5a are positioned along a first resection line 17 and are inserted into the tissue 16, whilst
25 the electrode needles or the optic fibres are simultaneously supplied with electric power. The needles are positioned beforehand by moving the support element 4, 4a in such a manner that they protrude from the body 1 of the apparatus by a sufficient amount to penetrate the entire depth of the
30 tissue 16, along the entire resection line 17. If the needle elements 5, 5a consist of electrode needles supplied by radio frequency, when they come into contact with the tissue 16, inside the body tissue, between the tip 14 of each needle and the tips of the adjacent needles, radio frequency currents are

established which cause progressive necrotisation of the tissue along the resection line 17 and simultaneous cauterisation of the blood vessels along said resection line 17 whilst the needles 5, 5a are penetrating the tissue 16. The operation can be repeated along a second resection line 18 to completely insulate the metastasis 15 from the rest of the tissue 16. Finally, using a prior-art scalpel, or also only manually, the portion of tissue with the metastasis 15 is detached from the rest of the tissue 16, along the two resection lines 17, 18 along which the tissue 16 is necrotised and therefore easily separable from the surrounding tissue. There is furthermore no loss of blood because, as already mentioned, the blood vessels along the resection line were cauterised when the needles 5, 5a were inserted into the tissue 16.

In the version of the apparatus that is provided with hollow needle elements 5, 5a containing optic fibres, the described operations do not vary. In this case, necrotisation of the tissue 16 along the resection lines 17, 18 and simultaneous cauterisation of the blood vessels are caused by heating the tissue by means of the laser light transmitted via the optic fibres inserted into each hollow needle 5, 5a.

In the practical embodiment the materials, dimensions and the implemented details may be different from those described but be technically equivalent, and still fall within the legal scope of this invention.

CLAIMS

1. Apparatus for treating organic tissue (16) to be subjected to surgical resection, comprising a body (1) with which treatment means of said organic tissue (16) is associated (5; 5a), characterized in that said treatment means comprises a plurality of treating elements (5; 5a) arranged in an aligned configuration.
2. Apparatus according to claim 1, wherein each of said treating elements consists of a needle element (5, 5a), one end (14) of which may protrude from said body (1).
3. Apparatus according to claim 2, wherein said needle elements (5, 5a) are of essentially the same length.
4. Apparatus according to claim 2, wherein said needle elements (5, 5a) have lengths that vary from one other.
5. Apparatus according to claim 3, wherein said needle elements (5; 5a) are arranged in such a way that their tips (14) are substantially aligned along a line that is parallel to one side (23) of said body (1).
6. Apparatus according to claim 3, wherein said needle elements (5; 5a) are arranged in such a way that their tips (14) are substantially aligned along a straight line that is tilted in relation to one side (23) of said body (1).
7. Apparatus according to claim 4, wherein said needle elements (5; 5a) are arranged in such a way that their tips (14) are substantially aligned along a line that is parallel to one side (23) of said body (1).

8. Apparatus according to claim 4, wherein said needle elements (5; 5a) are arranged in such a way that their tips (14) are substantially aligned along a straight line that is tilted in relation to one side (23) of said body (1).
9. Apparatus according to claim 4, wherein said needle elements (5; 5a) are arranged in such a way that their tips (14) are substantially aligned along a curved line.
10. Apparatus according to any one of claims 2 to 9, wherein said needle elements are electro-needle elements (5, 5a) connected to respective electric-power supply means.
11. Apparatus according to claim 10, wherein said electric-power supply means supply said electrode-needles (5; 5a) with a radio frequency voltage.
12. Apparatus according to any one of claims 2 to 9, wherein each of said needle elements comprises a hollow needle (5; 5a) inside which a laser optic fibre is inserted.
13. Apparatus according to claim 12, wherein each of said laser optic fibres is supplied with a laser light by appropriate supply means .
14. Apparatus according to any one of claims 2 to 13, wherein each of said needle elements (5; 5a) is fixed in a removable manner to a support element (4; 4a).

15. Apparatus according to claim 14, wherein each of said needle elements (5; 5a) is fixed at its own end (6), opposite said end (14), to said support element (4; 4a).
- 5 16. Apparatus according to claim 15, wherein each of said needle elements (5; 5a) is fixed to said support element (4; 4a) by means of a Luer-lock fixing element.
- 10 17. Apparatus according to any one of claims 14 to 16, wherein said support element (4; 4a) is coupled with said body (1) in a sliding manner.
- 15 18. Apparatus according to claim 17, wherein said support element (4; 4a) is associated with sliding means (7) running along a guide means (8) fixed to said body (1).
- 20 19. Apparatus according to claim 18, wherein said sliding means (7) is associated with manoeuvring means (10, 11).
- 25 20. Apparatus according to claim 19, wherein said manoeuvring means (10) comprises the locking means (11) of said slide means (7).
- 30 21. Apparatus according to any one of claims 14 to 20, wherein said support element (4; 4a) is associated with an indicator means (19).
22. Apparatus according to claim 21, wherein said indicator means (19) emerges through a pair of slits (12) made in a front wall (2) of said body (1).

23. Apparatus according to claim 22, wherein at least one of said slits (12) is associated with a graded scale (20).

5 24. Apparatus according to claim 22, or 23, wherein said front wall (2) is connected to said body (1) in a removable manner.

10 25. Apparatus according to any one of claims 14 to 24, wherein said support element (4, 4a) has a substantially constant height.

15 26. Apparatus according to any one of claims 14 to 24, wherein said support element (4; 4a) has a height that varies in a substantially linear manner.

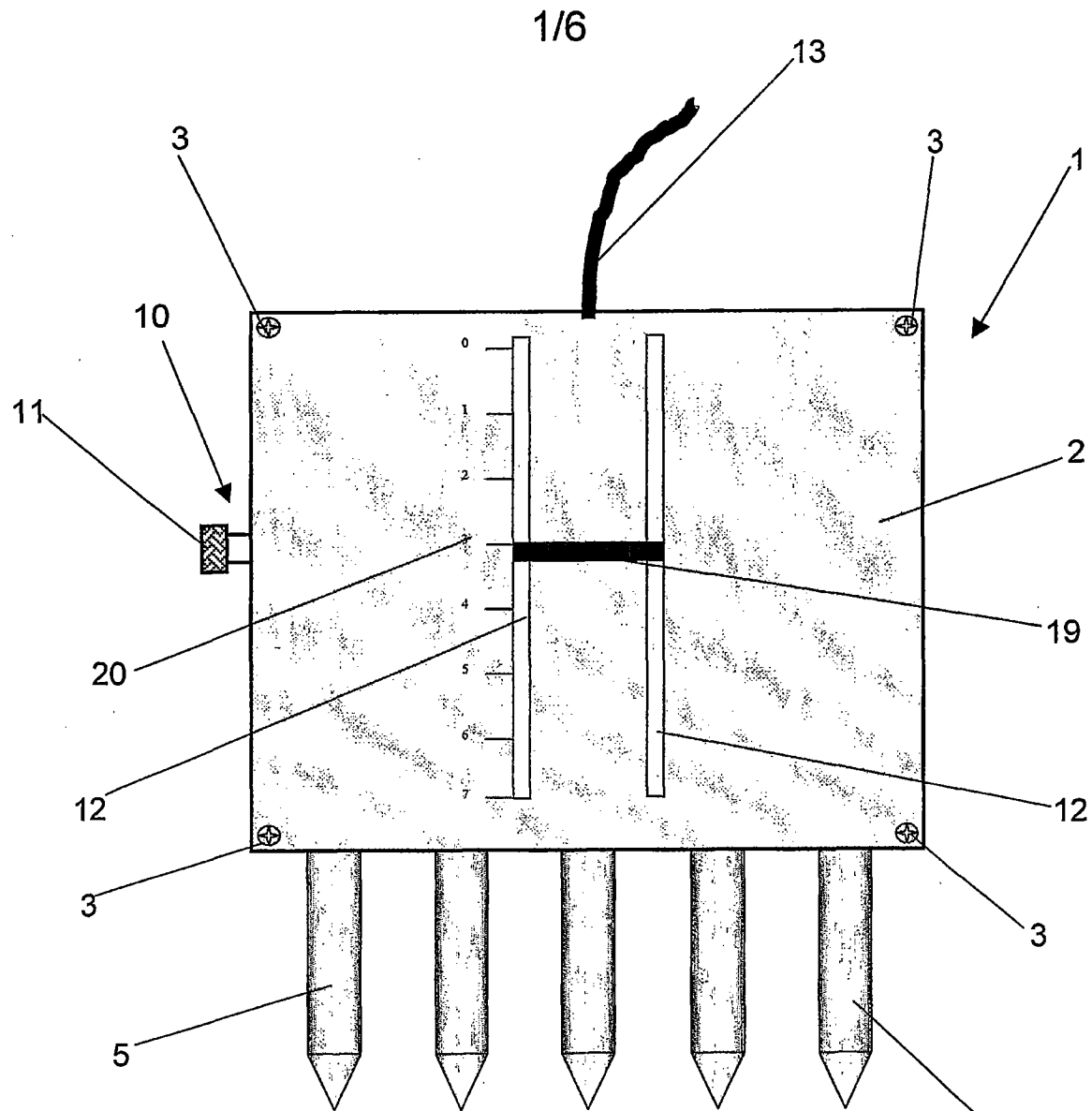


Fig. 1

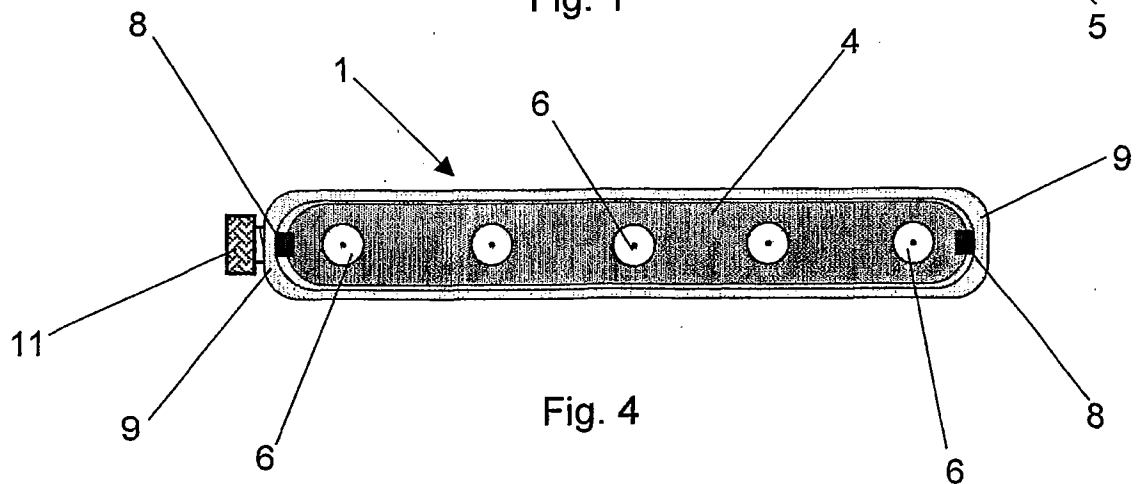


Fig. 4

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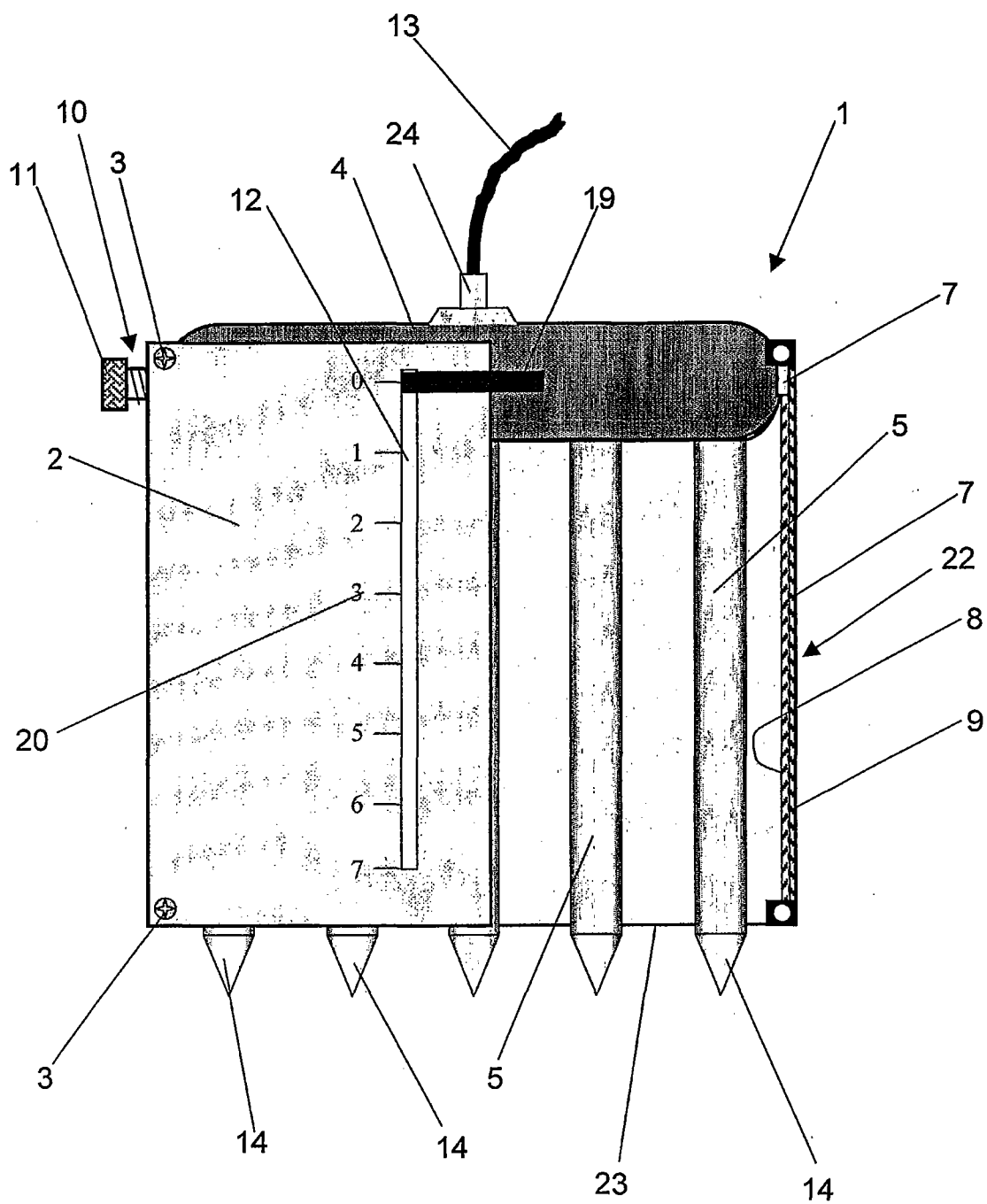
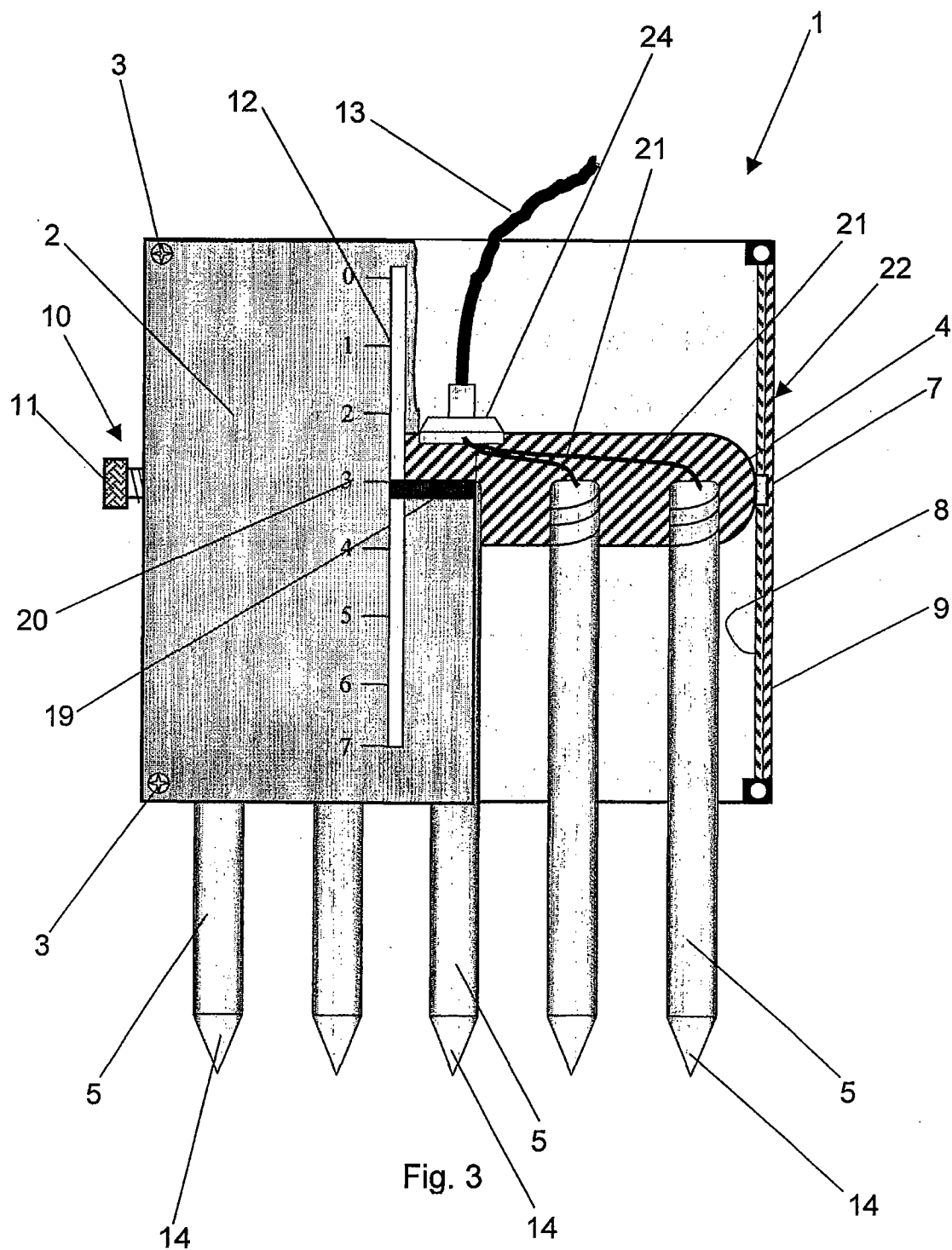


Fig. 2



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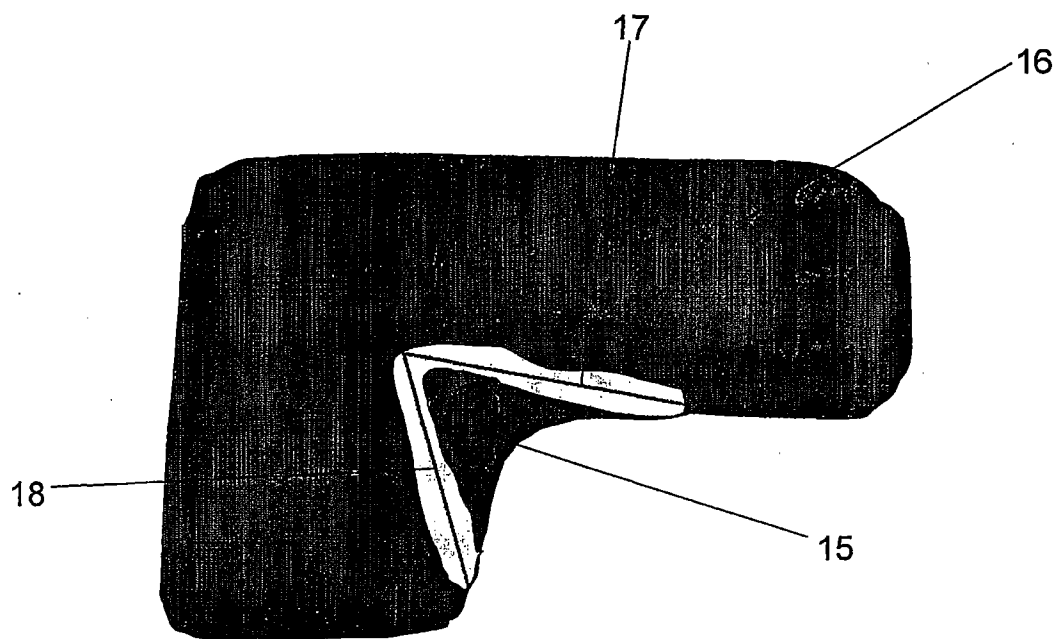
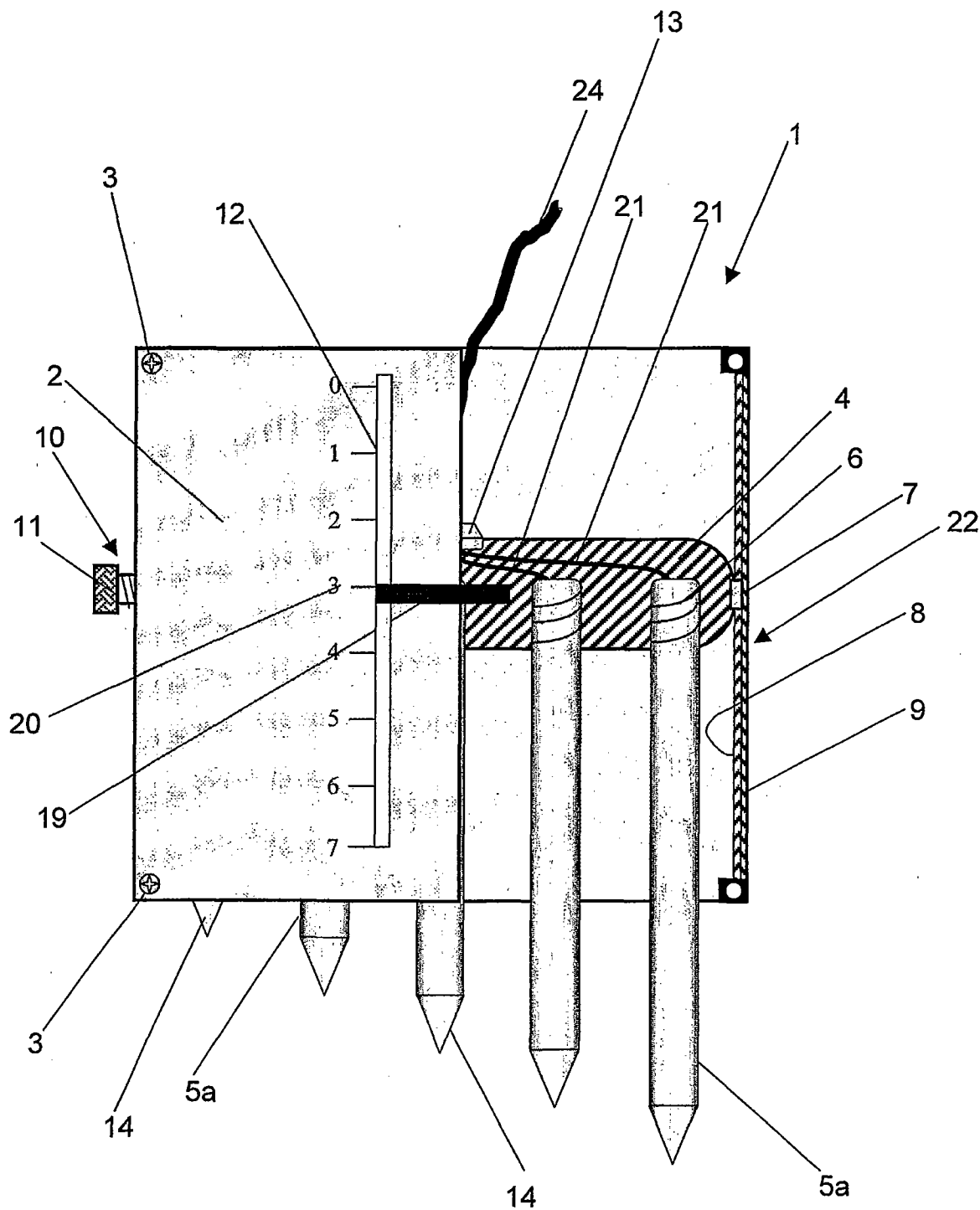


Fig. 5



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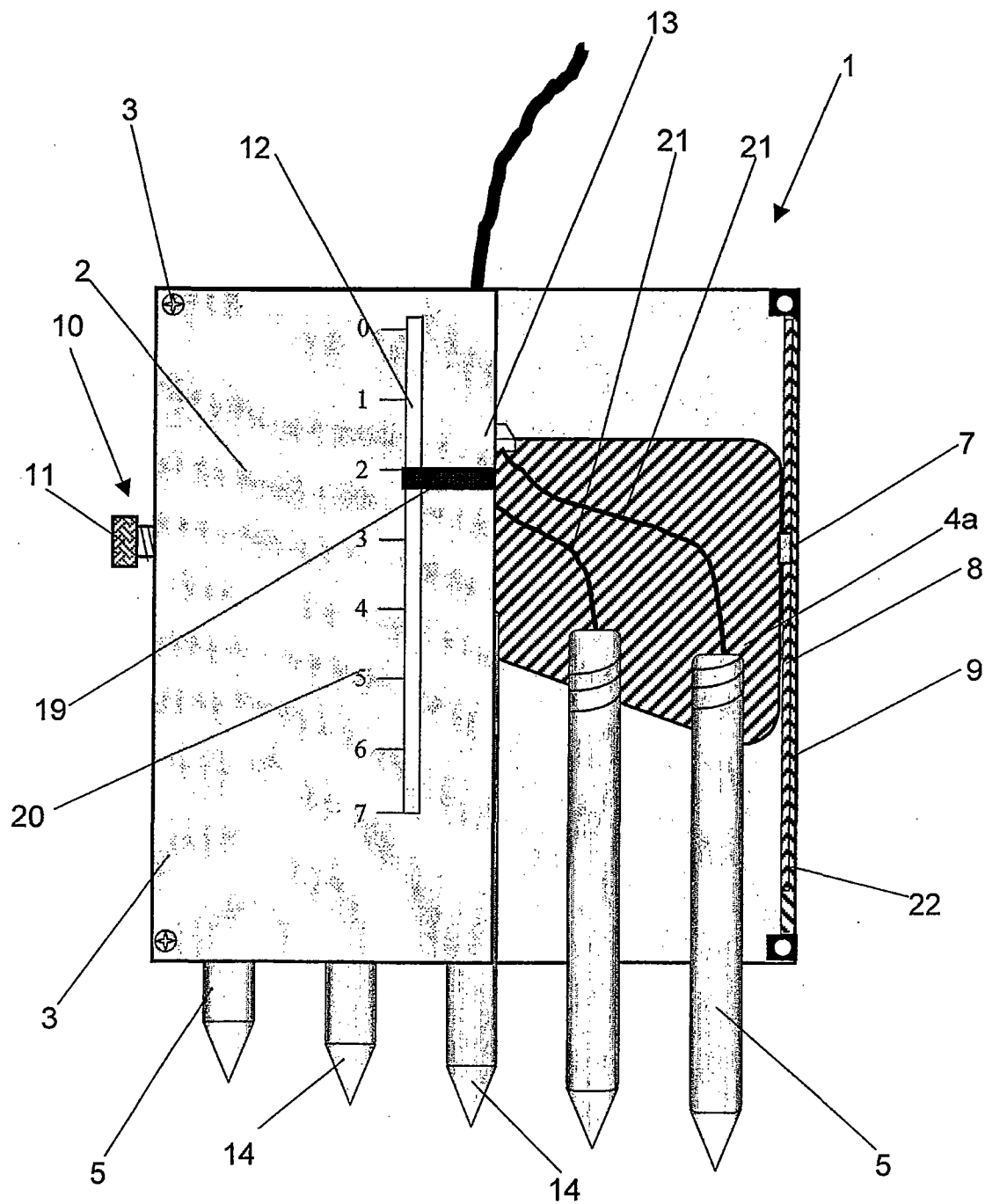


Fig. 7

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International Application No.
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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B18/14		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
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X	US 6 126 657 A (LAX RONALD G ET AL) 3 October 2000 (2000-10-03) column 4, line 50 -column 5, line 40; figure 2	1-13
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<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
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Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Mayer, E

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(74) Agent: **ABELEV, Gary**; Baker Botts L.L.P., 30 Rockefeller Plaza, New York, NY 10112-4498 (US).

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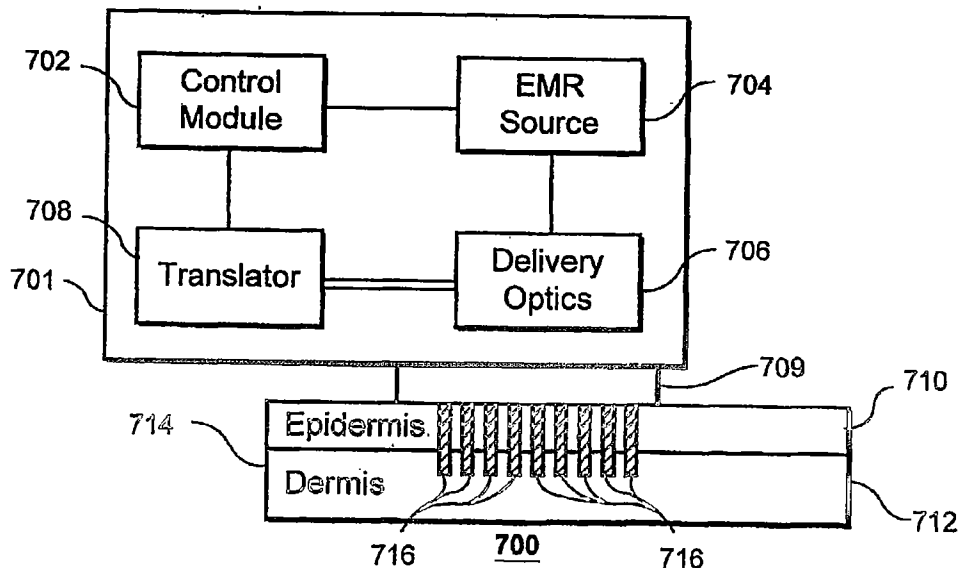
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(54) Title: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND FRACTIONAL SKIN RESURFACING



(57) Abstract: A system and method for performing fractional resurfacing of a target area of skin using electromagnetic radiation are provided. An electromagnetic radiation is generated by an electromagnetic radiation source. The electromagnetic radiation is caused to be applied to a particular portion of a target area of skin. The electromagnetic radiation can be impeded from affecting another portion of the target area of the skin by a mask. Alternatively, the electromagnetic radiation may be applied to portions of the target area of the skin, other than the particular portion.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND FRACTIONAL SKIN RESURFACING

SPECIFICATION

5 CROSS REFERENCE TO RELATED APPLICATIONS

The present application claims priority from U.S. Provisional Patent Application Serial No. 60/458,770 filed March 27, 2003, the entire disclosure of which is incorporated herein by reference.

10 BACKGROUND OF THE INVENTION

1. Field Of The Invention

The present invention relates to methods and apparatus that use electromagnetic radiation for dermatological treatment and, more particularly to a method and apparatus that use optical radiation to ablate or damage a target area of skin surface for dermatological treatment, which skin surface includes the epidermis and parts of the dermis as the objective or side effect of the desired treatment.

2. Background Art

There is an increasing demand for repair of or improvement to skin defects, which can be induced by aging, sun exposure, dermatological diseases, traumatic effects, and the like. Many treatments which use electromagnetic radiation have been used to improve skin defects by inducing a thermal injury to the skin, which results in a complex wound healing response of the skin. This leads to a biological repair of the injured skin.

Various techniques providing this objective have been introduced in recent years. The different techniques can be generally categorized in two groups of treatment modalities: ablative laser skin resurfacing ("LSR") and non-ablative collagen remodeling ("NCR"). The first group of treatment modalities, i.e., LSR, includes causing thermal damage to the epidermis and/or dermis, while the second group, i.e., NCR, is designed to spare thermal damage of the epidermis.

LSR with pulsed CO₂ or Er:YAG lasers, which may be referred to in the art as laser resurfacing or ablative resurfacing, is considered to be an effective treatment option for signs of photo aged skin, chronically aged skin, scars, superficial

pigmented lesions, stretch marks, and superficial skin lesions. However, patients may experience major drawbacks after each LSR treatment, including edema, oozing, and burning discomfort during first fourteen (14) days after treatment. These major drawbacks can be unacceptable for many patients. A further problem with LSR procedures is that the procedures are relatively painful and therefore generally require an application of a significant amount of analgesia. While LSR of relatively small areas can be performed under local anesthesia provided by injection of an anesthetic, LSR of relatively large areas is frequently performed under general anesthesia or after nerve blockade by multiple injections of anesthetic.

Any LSR treatment results in thermal skin damage to the treatment area of the skin surface, including the epidermis and/or the dermis. LSR treatment with pulsed CO₂ lasers is particularly aggressive, causing thermal skin damage to the epidermis and at least to the superficial dermis. Following LSR treatment using CO₂ lasers, a high incidence of complications can occur, including persistent erythema, hyperpigmentation, hypopigmentation, scarring, and infection (e.g., infection with Herpes simplex virus). LSR treatment with the Er:YAG laser has been introduced as a more gentle alternative to the CO₂ laser, due to the lesser penetration depth of the Er:YAG pulsed laser. Using the Er:YAG laser results in a thinner zone of thermal injury within the residual tissue of the target area of the skin. However, LSR that uses the Er:YAG laser produces side effects similar to those made by LSR that uses the CO₂ laser within the first days after treatment.

A limitation of LSR using CO₂ or Er:YAG lasers is that ablative laser resurfacing generally can not be performed on the patients with dark complexions. The removal of pigmented epidermis tissue can cause severe cosmetic disfigurement to patients with a dark complexion, which may last from several weeks up to years, which is considered by most patients and physicians to be unacceptable. Another limitation of LSR is that ablative resurfacing in areas other than the face generally have a greater risk of scarring. LSR procedures in areas other than the face result in an increased incidence of an unacceptable scar formation because the recovery from skin injury within these areas is not very effective.

In an attempt to overcome the problems associated with LSR procedures, a group of NCR techniques has emerged. These techniques are variously referred to in the art as non-ablative resurfacing, non-ablative subsurfacing, or non-ablative skin remodeling. NCR techniques generally utilize non-ablative lasers,

flashlamps, or radio frequency current to damage dermal tissue while sparing damage to the epidermal tissue. The concept behind NCR techniques is that the thermal damage of only the dermal tissues is thought to induce wound healing which results in a biological repair and a formation of new dermal collagen. This type of wound healing can result in a decrease of photoaging related structural damage. Avoiding epidermal damage in NCR techniques decreases the severity and duration of treatment related side effects. In particular, post procedural oozing, crusting, pigmentary changes and incidence of infections due to prolonged loss of the epidermal barrier function can usually be avoided by using the NCR techniques.

Various strategies are presently applied using nonablative lasers to achieve damage to the dermis while sparing the epidermis. Nonablative lasers used in NCR procedures have a deeper dermal penetration depth as compared to ablative lasers used in LSR procedures. Wavelengths in the near infrared spectrum can be used. These wavelengths cause the non-ablative laser to have a deeper penetration depth than the very superficially-absorbed ablative Er:YAG and CO₂ lasers. The dermal damage is achieved by a combination of proper wavelength and superficial skin cooling, or by focusing a laser into the dermis with a high numerical aperture optic in combination with superficial skin cooling. While it has been demonstrated that these techniques can assist in avoiding epidermal damage, one of the major drawbacks of these techniques is their limited efficacies. The improvement of photoaged skin or scars after the treatment with NCR techniques is significantly smaller than the improvements found when LSR ablative techniques are utilized. Even after multiple treatments, the clinical improvement is often far below the patient's expectations. In addition, clinical improvement is usually several months delayed after a series of treatment procedures.

Another limitation of NCR procedures relates to the breadth of acceptable treatment parameters for safe and effective treatment of dermatological disorders. The NCR procedures generally rely on an optimum coordination of laser energy and cooling parameters, which can result in an unwanted temperature profile within the skin leading to either no therapeutic effect or scar formation due to the overheating of a relatively large volume of the tissue.

Yet another problem of non-ablative procedures relates to the sparing of the epidermis. While sparing the epidermis is advantageous in order to decrease the side effects related to complete removal of the epidermis, several applications of

NCR procedures may benefit from at least partial removal of epidermal structures. For example, photoinduced skin aging manifests not only by the dermal alterations, but also by epidermal alterations.

A further problem of both ablative and nonablative resurfacing is that
5 the role of keratinocytes in the wound healing response is not capitalized upon. Keratinocyte plays an active role in the wound healing response by releasing cytokines when the keratinocyte is damaged. During traditional ablative resurfacing procedures, the keratinocytes are removed from the skin along with the epidermis, thereby removing them from the healing process altogether. On the other hand, in
10 traditional non-ablative procedures, the keratinocytes, which are located in the epidermis, are not damaged, therefore they do not release cytokines to aid in the healing process.

Another major problem with all LSR and NCR techniques now used is the appearance of visible spots and/or edges after treatment due to inflammation,
15 pigmentation, or texture changes, corresponding to the sites of treatment. Devices for LSR and NCR produce macroscopic (easily seen) sexposure areas. For example, laser exposure spot diameters typically vary from about 1 to 10 mm, and NCR exposure spot diameters from about 3 to 50 mm. Some devices, such as indense pulsed light devices, leave "boxes" of skin response due to rectangular output patterns on the skin.
20 Patients do not like such spot or box patterns, easily seen as red, brown or white areas ranging from on the order of millimeters to centimeters in size, which remain for days or even years after treatment.

Therefore, there is a need to provide a procedure and apparatus that combine safe and effective treatment for improvement of dermatological disorders
25 with minimum side effects, such as intra procedural discomfort, post procedural discomfort, lengthy healing time, and post procedural infection.

SUMMARY OF THE INVENTION

It is therefore one of the objects of the present invention to provide an
30 apparatus and method that combines safe and effective treatment for an improvement of dermatological disorders with minimum side effects. Another object of the present invention is to provide an apparatus and method that cause thermal skin damage to only a fraction of a target area of skin.

These and other objects can be achieved with the exemplary embodiment of the apparatus and method according to the present invention, in which portions of a target area to be subjected to irradiation are masked. The exemplary apparatus can include at least one shielding member configured to mask at least one
5 portion of a target area of skin from electromagnetic radiation, in which the shielding members are formed such that a minimal amount of electromagnetic radiation is reflected back towards an electromagnetic radiation source.

In another advantageous embodiment of the present invention, electromagnetic radiation can be generated by an electromagnetic radiation source,
10 thus causing the electromagnetic radiation to be applied to a target area of the skin. At least one portion of the target area of the skin is then masked from the electromagnetic radiation using a mask.

In yet another advantageous embodiment of the present invention, an apparatus and method for treating dermatological conditions is provided. In
15 particular, a delivery module and translator are utilized. The delivery module is configured to direct electromagnetic radiation generated by an electromagnetic radiation source to a predetermined area within a target area of skin, wherein the predetermined area is located in a location relative to the delivery module, and wherein the electromagnetic radiation is adapted to cause thermal damage to
20 epidermal tissue and dermal tissue of the predetermined area within the target area of the skin. The translator is capable of moving the delivery module, such that the delivery module targets a plurality of spatially separated individual exposure areas of the predetermined area.

In a further advantageous embodiment of the present invention, the
25 electromagnetic radiation can be applied to a first individual exposure area of the target area of the skin. The electromagnetic radiation can then be applied to a second individual exposure area of the target area of the skin, which is separated from the first individual exposure area by a non-irradiated skin section.

30 BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention and its advantages, reference is now made to the following description, taken in conjunction with the accompanying drawings, in which:

Figs. 1A – 1C show progressive illustrations of a first exemplary embodiment of a fractional resurfacing system for conducting various dermatological treatments at various stages of use according to the present invention;

Fig. 2 shows a top view of a first exemplary embodiment of a mask
5 according to the present invention;

Fig. 3 shows a cross-sectional view of the mask of Fig. 2;

Fig. 4 shows a top view of a second exemplary embodiment of the mask according to the present invention;

Fig. 5 shows a cross-sectional view of the mask of Fig. 4;

10 Fig. 6 shows a cross-sectional view of another variant of the mask of Fig. 4;

Figs. 7A and 7B show progressive illustrations of a second exemplary embodiment of the fractional resurfacing system for conducting various dermatological treatments at various stages of use according to the present invention;

15 Fig. 8 shows a top view of small individual exposure areas created by the fractional resurfacing system of Figs. 7A and 7B; and

Fig. 9 shows an exemplary embodiment of a system for monitoring the location of the fractional resurfacing system of Figs. 7A and 7B.

Throughout the drawings, the same reference numerals and characters,
20 unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present invention will now be described in detail with reference to the Figures, it is done so in connection with the illustrative embodiments.

25 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figs. 1A – 9 illustrate various embodiments of a method and apparatus for fractional resurfacing of a target area of skin. Generally, the exemplary methods and apparatus deliver an electromagnetic radiation to the patient's skin defined by various patterns, so as to induce thermal injury of the skin surface corresponding to
30 such patterns and involving only a fraction of the targeted surface area of the skin. Such technique combines the efficacy of ablative resurfacing procedures with the minimal side effects of non-ablative procedures. The delivery of the electromagnetic radiation to the skin in a predetermined pattern is achieved by either masking parts of the target area of the skin surface in order to protect the masked parts of the skin

surface from the electromagnetic radiation, or by utilizing a light beam of relatively small diameter which is scanned across the skin surface by various means in order to generate a specific pattern for affecting superficial thermal skin injury.

Fractional resurfacing is defined as the controlled ablation, removal,
5 destruction, damage or stimulation of multiple small (generally less than 1 mm) individual exposure areas of skin tissue with intervening spared areas of skin tissue, performed as a treatment to improve the skin. The individual exposure areas may be oval, circular, arced and/or linear in shape. The spatial scale of fractional resurfacing is chosen to avoid the appearance of various spots or boxes on a macroscopic scale,
10 while still providing effective treatment because the multiple small areas can be exposed to greater than a minimal stimulus. For example, removal or photothermal destruction of thousands of 0.1 mm diameter individual exposure areas, spaced 0.2 mm apart, and extending into the skin up to a depth of 0.5 mm, is well tolerated and produces effective improvement of photoaging, without apparent spots and with rapid
15 healing. Spared skin between the individual exposure areas rapidly initiates a wound healing response, which is better tolerated than conventional LSR.

During the exemplary fractional resurfacing procedure of the present invention, certain portions of the target area remain undamaged, thereby preserving keratinocytes and melanocytes, which serve as a pool of undamaged cells to promote
20 reepithelialization. This procedure differs from the traditional resurfacing procedures, such that the entirety of the target area is damaged. In traditional resurfacing procedures, reepithelialization is generally initiated from the depth of an undamaged follicular epithelium. Because the traditional procedures remove the entire epithelium, an important factor for the time of reepithelialization is the density of
25 follicles. The vellus hair density of the face (439 hairs/cm^2) of the subject is significantly higher than on the back of the subject (85 hairs/cm^2). Therefore, the face of the subject, generally experiences better and faster reepithelialization in comparison to other body areas with a lower hair density.

The resurfacing of the dark pigmented skin is currently not very
30 frequently performed because of the prolonged repigmentation process. The fractional resurfacing technique improves the repigmentation process but, melanocytes do not migrate well. By sparing certain portions of the target area of the skin, the travel distance of melanocytes can be decreased, thereby reducing the repigmentation time and allowing the resurfacing of all skin types.

Figs. 1A – 1C illustrate a progressive use of a first exemplary embodiment of a fractional resurfacing system 100 for conducting various dermatological treatments using electromagnetic radiation (“EMR”) and generating a superficial pattern of skin damage of a target area by using a mask according to the present invention. The system 100 may be used for collagen remodeling, removal of unwanted pigment or tattoo, and/or other dermatological applications. As shown in Figs. 1A-1C, the system 100 includes a case 101, a control module 102, an EMR source 104, delivery optics 106 and a mask 108. The case 101 contains the control module 102, the EMR source 104, and the delivery optics 106. An aperture is provided through a sidewall of the case 101. The mask 108 is placed in registration with the aperture formed through the sidewall of the case 101. By placing the mask 108 in registration with the aperture of the case 101, the focal length of the EMR emitted by the delivery optics 106 is fixed, and can be configured such that it does not impact the side of the mask 108, so as to cause injuries to the operator of the fractional ablation system 100. The control module 102 is in communication with the EMR source 104, which in turn is operatively connected to the delivery optics 106.

In one exemplary variant of the present invention, the control module 102 can be in wireless communication with the EMR source 104. In another variant, the control module 102 may be in wired communication with the EMR source 104. In another exemplary variant of the present invention, the control module 102 can be located outside of the case 101. In another variant, the EMR source 104 is located outside of the case 101. In still another variant, the control module 102 and the EMR source 104 are located outside of the case 101. It is also possible that the mask 108 is not connected to the case 101.

The control module 102 provides application specific settings to the EMR source 104. The EMR source 104 receives these settings, and generates EMR based on these settings. The settings can control the wavelength of the EMR, the energy delivered to the skin, the power delivered to the skin, the pulse duration for each EMR pulse, the fluence of the EMR delivered to the skin, the number of EMR pulses, the delay between individual EMR pulses, the beam profile of the EMR, and the size of the area within the mask exposed to EMR. The energy produced by the EMR source 104 can be an optical radiation, which is focused, collimated and/or directed by the delivery optics 106 to the mask 108. The mask 108 can be placed on a target area of a patient’s skin, and may provide a damage pattern on the target area of

the skin with a fill factor in the range from 0.1% to 90%. The fill factor is the percentage of the target area exposed to the EMR that is emitted by the EMR source 106.

In one exemplary embodiment, the EMR source 106 is one of a laser, a flashlamp, a tungsten lamp, a diode, a diode array, and the like. In another exemplary embodiment, the EMR source 106 is one of a CO₂ laser and a Er:YAG laser.

Prior to being used in a dermatological treatment, the system 100 shown in Fig. 1A can be configured by a user. For example, the user may interface with the control module 102 in order to specify the specific settings usable for a particular procedure. The user may specify the wavelength of the EMR, the energy delivered to the skin, the power delivered to the skin, the pulse duration for each EMR pulse, the fluence of the EMR delivered to the skin, the number of EMR pulses, the delay between individual EMR pulses, the beam profile of the EMR, and the size of the area within the mask exposed to EMR. The EMR source 104 may be set to produce a collimated pulsed EMR irradiation with a wavelength ranging from 400 to 11,000 nm, and preferably near 3.0 μm when using an Er:YAG laser and near 10.6 μm when using a CO₂ laser as the EMR source. The collimated pulsed EMR irradiation may be applied which has a pulse duration in the range of 1 μs to 10 s, preferably in the range of 100 μs to 100 ms, and more preferably in the range of 0.1 ms to 10 ms, and fluence in the range from 0.01 to 100 J/cm², and preferably in the range from 1 to 10 J/cm². The applied EMR should be able to achieve at least a temperature rise within the exposed areas of the skin that is sufficient to cause thermal damage to the epidermis 110 and/or the dermis 112. The peak temperature sufficient to cause thermal damage in the exposed tissues is time dependant and at least in the range of 45° C to 100° C. For exposure times in the range of 0.1 ms to 10 ms the minimum temperature rise required to cause thermal damage is in the range of approximately 60° C to 100° C. The depth of thermal damage can be adjusted by proper choice of wavelength, fluence per pulse and number of pulses.

During the dermatological treatment, the system 100 produces EMR 120 which is directed to the target area of the skin 114, as shown in Fig. 1B. The EMR 120 may be pulsed multiple times to create the appropriate affect and irradiation in the target area of the skin 114.

After the dermatological treatment is completed, the target area of the skin 114 is likely damaged in specific places. The application of the EMR 120 creates a prearranged thermal skin damage 130 in an epidermal tissue 110 and the dermal tissue 112. It should be noted that the thermal skin damage 130 extends through the epidermal tissue 110 and into the dermal tissue 112 only to a predetermined depth. The mask 108 controls in a location where the thermal skin damage 130 is created. The thermal skin damage 130 generally accounts for only 0.1% to 90% of the skin surface area in the target area. A fill factor is defined as the ratio of surface area of the target area of skin thermally damaged by EMR to surface area of the target area of the skin.

In an exemplary embodiment of the present invention, the thermal skin damage 130 may extend through the epidermal tissue 110 and through the entirety of the dermal tissue 112. In another exemplary embodiment of the present invention, the thermal skin damage 130 may occur principally in the dermal tissue 112 and minor skin damage may occur in the epidermal tissue 110. It should be noted that it is possible that the penetration depths of each of the micro areas of the thermal skin damage 130 may be different from one another or same as one another. This may be because pigment removal or dermal removal can be separately regulated by varying the density of the micro-damaged areas for either the deeper or superficial damages, e.g., dermal remodeling and pigment adjustment, respectively.

Fig. 2 illustrates a top view of a first exemplary embodiment of the mask 108 according to the present invention. The mask 108 includes shielding structured 202. The diameter of the mask 108 should preferably be matched to greater than the size of the diameter of the target area. The target area is defined as the area targeted by the collimated EMR emitted by the EMR source 104, which can be in the range 1 - 100 mm in diameter, preferably within the range of 5 to 20 mm. This diameter of most of the currently commercially available CO₂ and Er:YAG laser systems can match the diameter of the exposed area. The width of shielding structures 202 within the mask 108 should be in the range of 50 to 300 μ m. The width of the apertures of the mask 108 that are formed by the shielding structures should be in the range of 10 - 1000 μ m, and preferably in the range of 50 to 300 μ m. The shielding-exposure ratio surface area covered by the of shielding structures 202 to the surface area exposed by the apertures effects the clinical efficacy and provides

side effects of the dermatological treatment. This also determines the fill factor and the pattern of the thermal damage of the skin. The depth of thermal damage is determined by the number of pulses, the fluence of the EMR and the wavelength of the EMR. The shielding-exposure ratio of the mask 108 will vary for different
5 dermatological treatments, particular patient needs, particular patient indications, skin types and body areas.

The mask 108 may have a large shielding-exposure ratio at the edge of the mask 108 to generate a transition zone at the edge of resurfaced area. This technique is called "feathering." It avoids a sharp macroscopically visible
10 demarcation between treated and untreated areas. In another preferred embodiment, a mask may be used that has a large shielding-exposure ratio at the edge of a conventionally resurfaced area to generate a transition zone.

The surface of the mask 108 should preferably have a minimal absorption at the wavelength generated by the EMR source 104 for the particular
15 dermatological process. Such absorption can decrease the undesirable heating of the mask 108. The mask 108 may be coated by a metal material for affectuating a minimal absorption of the EMR. The design of the shielding structures 202 of the mask 108, a cross-section A-A of which is shown in Fig. 3; generally takes into consideration safety aspects, including a back-reflected EMR in order to avoid EMR
20 inflicted accidents. The shielding structures 202 are shaped in a peaked manner to minimize the amount of back reflected EMR. Also, with the mask 108 being connected to the case 101 the distance between the delivery optics 106 and the mask 108 is fixed, thereby minimizing the chances that EMR would be reflected back towards the user by hitting the edge of the mask 108. Additionally, the microstructure
25 of the mask 108 can have a periodicity preferably in the range of the wavelength of the EMR emitted by the delivery optics 106. This configuration can diffuse the collimated EMR emitted by the delivery optics 106 into a highly scattered beam so as to decrease the risk of EMR-related accidents.

In one exemplary embodiment, the metal coating of the mask 108 may
30 be composed of gold, silver, or copper materials, or the like. In another exemplary embodiment, the microstructure of the surface of the mask 108 may have a periodicity in the range of the wavelength of the EMR emitted by the delivery optics 106.

The mask 108 may also have a configuration so as to provide effective skin cooling during the exposure thereof with the EMR radiation. Skin cooling

provides significant anesthetic effects, and has other advantages related to the pattern induced by the EMR radiation. The mask 108 can be cooled prior to the beginning of the dermatological procedure, during the procedure by spraying an evaporative agent or a precooled liquid onto the mask 108 between the successive EMR pulses, or
5 during the procedure by introducing a cool or cold liquid into microchannels 302 (shown in Fig. 3) running through the mask 108. The cooling of the mask 108 has a secondary advantage in that such cooling of the mask 108 decreases the rate of the EMR absorption by the mask 108, as the rate of the EMR absorption by the metals increases with the increasing temperature.

10 In order to provide skin cooling as described above, the temperature of the mask 108 should be in the range of 37° C to -20° C, and preferably 10° C to -4° C. The mask 108 can both protect and cool the portions of the skin surface that are not exposed to EMR emitted by the EMR source 104. In addition to cooling and shielding portions of the skin surface, the mask 108 allows the debris ejected during
15 ablative procedures to escape, and thereby not interfere with the beam delivery for successive pulses. For example, the areas that are not exposed to the laser are being cooled by the mask 108, i.e., the areas that are provided between the affected areas. In another exemplary embodiment, all areas (i.e., both the affected and nonaffected areas) are cooled to provide anesthesia, and to reduce over-damaging the superficial
20 levels of the damaged areas.

Fig. 3 illustrates a cross-section A-A of the mask 108 of Fig. 2. The cross-section A-A shows the microchannels 302 that run through at least the shielding structures 202 of the mask 108. A cooling agent, e.g., either a liquid or gas, may circulate through these microchannels 302 during a dermatological procedure, thereby
25 removing heat from the protected skin and the mask 108 itself.

Fig. 4 illustrates a top view of a second embodiment of the mask 400 according to the present invention. The mask 400 differs from the mask 108 only in the layout and design of the shielding structures 402. The details of the mask 400 are in all other respects substantially similar to those of the mask 108. The shielding
30 structures 402 are cylindrical in shape, as indicated in cut-away cross-sections B-B and C-C, shown in Figs. 5 and 6, respectively. The shielding structures 402 of the mask 400 contain microchannels 502 and 602, which are capable of carrying a cooled liquid or gas so as to cool the mask 400 and the masked portions of the target area of

the skin. The microchannels 502, 602 intersect at the intersection of the shielding structures 402.

In an exemplary embodiment of the present invention, the microstructures 502, 602 are not required to intersect at the intersection of the shielding structures 402.

In an exemplary embodiment of the present invention, the mask 108 is an ablative mask. An ablative mask includes multiple sections having various thicknesses. Prior to a procedure, the ablative mask is attached to the skin with an adhesive. During the procedure having multiple EMR pulses, the ablative mask is ablated, such that the thickness of each of the multiple sections is diminished, potentially gradually exposing different areas of the skin to the EMR pulses. The ablative mask can be composed of various materials including polymer materials. The ablative mask can be easily produced by imprinting a pattern therein.

A particular dermatological treatment, i.e., the removal of tattoos, shall be described in further detail. Tattoo removal may be performed with a combination of an ablative EMR and the mask 108. In particular, utilizing the CO₂ laser and/or the Er:YAG laser may be appropriate for this application. During this dermatological procedure, the tattoo can be exposed to ablative EMR radiation with the mask 108 providing a fill factor of the target area in the range of 10 to 90%, and preferably in the range of 25 to 70%. Preferably, the mask 108 is applied under pressure to the skin, which minimizes the blood flow during the procedure. Limiting the blood flow during the procedure allows a deeper ablation of the skin surface before blood can interfere with the EMR radiation, thereby limiting the ablation depth. Multiple pulses of ablative EMR radiation can be applied to the individual areas of the tattoo until the desired ablation depth is reached. The desired ablation depth can be in the range of 100 μ m to 5 mm. This exemplary procedure can cause a specific fraction of the tattoo that is controlled by the mask 108 to be immediately ablated. Wound healing may be enhanced because only a fraction of the surface is ablated.

The removal of tattoos utilizing fractional resurfacing may be augmented using a short pulsed EMR, preferentially absorbed by the tattoo particles either before or after the application of the fractional resurfacing. In a short pulsed-laser application, the laser may be pulsed for short periods of time, preferably for less than 1 μ s in duration. The EMR source used in this type of procedure can preferably be a Q-switched ruby laser, a Nd:YAG laser, a KTP laser and/or an Alexandrite laser.

The objective of this procedure is to release the pigment within areas that are not exposed to fractional resurfacing ablation. The released pigment particles may drain in the ablated channels, and can be flushed from the area after the procedure by the blood resident in the target area and/or an external rinsing agent, e.g., saline. Several
5 such procedures may be utilized until the desired clearance of the tattoo has occurred.

As an alternative to the fractional resurfacing using a mask, a second embodiment of a fractional resurfacing system 700, as shown as the progressive use thereof in Figs. 7A – 7B, can be used. The system 700 can include a case 701, a control module 702, an electromagnetic radiation (“EMR”) source 704, delivery
10 optics 706, an x-y translator 708 and an optically transparent plate 709. The case 701 may contain the control module 702, the EMR source 704, the delivery optics 706 and the translator 708. As with the system 100, an aperture may be formed through a sidewall of the case 701. The optically transparent plate 709 may be placed in registration with the aperture that is formed through the sidewall of the case 701.
15 Placing the plate 709 in registration with the aperture formed through the sidewall of the case 701 seals the system 700, which contains sophisticated translation mechanisms, e.g., the delivery optics 706 and the translator 708. The control module 702 is in communication with the translator 708 and the EMR source 704, and the EMR source 704 is operatively connected to the delivery optics 706.

20 In one exemplary variant of the present invention, the control module 702 can be located outside of the case 701. In another exemplary variant, the EMR source 704 is located outside of the case 701. In still another variant, the control module 702 and the EMR source 704 are located outside of the case 701.

The control module 702 provides application specific settings to the
25 EMR source 704, and controls the x-y translator 708. The EMR source 704 receives these settings, and generates EMR based on these settings. The settings can control the wavelength of the energy produced, the intensity of the energy produced, the fluence of the energy produced, the duration of the dermatological procedure, the pulse length of each of the EMR pulses administered during the procedure, the spatial
30 distance between individual exposure areas 716 (shown in Fig. 8), the shape of individual exposure areas 716, the pattern defined by individual exposure areas 716, and the fill factor of the target area. It should be noted that the thermal skin damage caused to individual exposure areas 716 extends through the epidermal tissue 710 and into the dermal tissue 712 only to a predetermined depth. The EMR source 704 can

be a laser or other light source. The EMR produced by the EMR source 704 can be delivered through a fiber, waveguide or mirrors if the source is located outside the delivery optics 706. Alternatively, if the EMR source 704 is located in a close vicinity to the skin 714, the EMR source 704 produces the EMR directly to the delivery optics 706. The energy produced by the EMR source 704 may be focused and/or directed by focusing optics in the delivery optics 706 to one of the an individual exposure areas 716, shown in Fig. 8. Each of the individual exposure areas 716 are located within the target area of the skin 714, and are relatively small compared to the target area of the skin 714. The target area of the skin 714 can generally be 1 cm² in size and each of the individual exposure areas 716 may be 100 μm in diameter.

In an exemplary embodiment of the present invention, the optics of the delivery optics 706 may contain a beam collimator or focusing optics. In another exemplary embodiment of the present invention, the thermal skin damage caused to individual exposure areas 716 may extend through the epidermal tissue 710 and through the entirety of the dermal tissue 712. In another exemplary embodiment of the present invention, the thermal skin damage caused to individual exposure areas 716 may principally occur in the dermal tissue 712 and only minor thermal damage may occur in the epidermal tissue 710. It should be noted that it is possible that the penetration depths of each of the micro areas of the thermal skin damage caused to individual exposure areas 716 may be different from one another or same as one another. This may be because pigment removal or dermal removal can be separately regulated by varying the density of the micro-damaged areas for either the deeper or superficial damages, e.g., dermal remodeling and pigment adjustment, respectively. In a further exemplary embodiment of the present invention, the predetermined depth of the thermal skin damage caused to individual exposure areas 716 is approximately 300 μm.

Prior to use in a dermatological treatment and similarly to the use of system 100, the system 700, as shown in Fig. 7A, can be configured by a user. In particular, the user interfaces with the control module 702 in order to specify the specific settings to be used for a particular procedure. The user may specify the desired damage pattern, the wavelength of the energy produced by the EMR source 704, the intensity of the energy produced, the fluence of the energy produced, the length of time the treatment will take and the pulse duration of the EMR source 704.

During the treatment, the translator 708 moves the delivery optics 706 across sequential portions of the target area of the skin 714 in order to treat the entire target area. The target area is treated when the system 700 delivers EMR to individual exposure areas 716 of the target area. The individual exposure areas 716 may be
5 targeted serially and/or in parallel. When one of the portions of the target area has been completely treated, the system 700 is moved to the next portion of the target area. For example, the system 700 is moved at the completion of irradiation of each portion of the target area until the desired skin surface damage pattern is achieved for the entire area. The system 700 can be moved using discrete movements from one
10 sequential portion to the next, i.e., stamping mode, or using continuous movement across the skin surface, i.e., continuous scanning mode. In either case, the movement of the delivery optics 706, driven by the translator 708, is controlled by the control unit 702 and likely matched with the movement of the system 700 by the operator (or the user) in order to provide the desired surface damage pattern to the target area of
15 the skin 714.

In an exemplary embodiment of the present invention, the system 700, while operating in the continuous scanning mode, can deliver EMR to a particular individual exposure area 716, then, after exposure of such area 716, translate along the skin of the target area, and thereafter deliver a further EMR to another individual
20 exposure area 716 separated from the previous particular individual exposure area 716 by non-irradiated region. In another exemplary embodiment of the present invention, the system 700, while operating in the continuous scanning mode, can deliver EMR to a particular group of individual exposure areas 716, for example the top row of individual exposure areas 716 (shown in Fig. 8), then, after exposure of such areas
25 716, translate along the skin of the target area, and deliver a further EMR to another group of individual exposure areas 716, for example the second row of individual exposure areas 716 (shown in Fig. 8), separated from the particular group of individual exposure areas 716 by non-irradiated areas.

In an exemplary embodiment of the present invention, the system 700
30 includes a position sensor, which is in communication with the control module 702. The position sensor is capable of sensing the relative velocity as between the skin 114 and the case 701. The position sensor can be an optical mouse, wheels, track ball, conventional mouse, and the like.

In another exemplary embodiment of the present invention, the system 700 targets individual exposure areas 716 one at a time. Administering EMR to the individual exposure areas 716 one at a time decreases the amount of pain experienced by the subject. A time period of 50 milliseconds may be provided between each administration of EMR to each of the individual exposure areas 716. Thereby controlling the amount of pain experienced by the subject and avoiding bulk heating of the tissue targeted by the system 700. In still another exemplary embodiment of the present invention, the system 700 targets a predetermined number of individual exposure areas 716 at a time. Limiting the number of predetermined target areas 716 targeted at one time limits the amount of pain experienced by a patient. Targeting a large number of individual exposure areas 716 at one time requires targeting a collectively large area of skin, which excites many nerve endings simultaneously, therefore causing the subject a proportionally large amount of pain. Targeting fewer individual exposure areas 716 causes a subject less pain, but causes a procedure to take longer.

In a further exemplary embodiment of the present invention, the system 700 creates individual exposure areas 716 having a separation distance between each of the individual exposure areas 716 of approximately at least 125 μm and at most 500 μm , preferably, the separation distance is approximately at least 250 μm .

Before the initiation of a dermatological procedure, the optically transparent plate 709 can be brought in a direct contact with the skin surface covering the target area. The optically transparent plate 709 can be composed out of any material having good thermal conductivity, and being transparent over a broad range of the visible and near infrared spectrum. The plate 709 seals the system 700, which contains sophisticated translation mechanisms, and provides cooling to the target area of the skin 714. The plate 709 can provide cooling to the target area of the skin 714 in two ways: heat conduction and heat convection. Heat conduction transfers heat through the optically transparent plate 709 to the case 701, which provides cooling by circulating a coolant agent through the case 701 of the system 700. The entire optically transparent place 709 can also be cooled prior to application to the target area of the skin 714. Alternatively, heat convection can be utilized for this procedure. An evaporating agent sprayed onto the optical window or onto a compartment in good thermal contact with the window may also be utilized. The delivery of the

evaporating agent can be administered during the procedure between EMR pulses through a valve, which can be controlled by a thermostat with a temperature sensor at the optical plate.

5 In one embodiment, of the present invention the optically transparent plate 709 can be composed of sapphire or quartz. In another embodiment of the present invention, the system 700 can be moved multiple times over the same portion of the skin 714 until the desired fill factor is achieved. In yet another embodiment, multiple procedures can be performed to achieve the desired effect.

10 During the dermatological procedure, the EMR source 704 emits EMR having a wavelength in the range of 400 - 12,000 nm. Preferably the EMR has a wavelength in one of the following ranges: 1,300 to 1,600 nm, 1,850 to 2,100 nm, 2,300 to 3,100 nm and around 10,640 nm. Depending on the application, a single wavelength or a combination of different wavelengths may be utilized. The EMR source 704 can be a diode laser, a fiber laser, a solid state laser, a gas laser, and the
15 like. The pulse duration can range from 100 μ s to 100 ms, and preferably in the range from 500 μ s to 15 ms, and more preferably in the range from 1.5 ms to 5 ms. The energy density per pulse within an individual exposure area 716 may be in the range of 0.1 to 100 J/cm², preferably 1 to 32 J/cm², and more preferably 1.5 to 3 J/cm². The energy per pulse within an individual exposure area 716 may be in the range of 1 mJ
20 and 10 mJ, and preferably 5 mJ.

In an exemplary embodiment of the present invention, the EMR source 704 is a 1.5 μ m laser system, preferably a Reliant FSR prototype, manufactured by Reliant Technologies, Palo Alto, CA, is used.

25 After the dermatological treatment is completed, the target area of the skin 714 is damaged in a specific pattern. The application of EMR creates the thermal skin damage in an epidermis 710 and a dermis 712 of the skin 714. The radiation provided by the EMR source 704 is delivered to the skin 714 within multiple small individual exposure areas 716, shown in Fig. 7B, through the delivery optics 706. The delivery optics 706 can deliver multiple individual beams across the target area of
30 the skin surface.

Fig. 8 illustrates a top view of the small individual exposure areas 716 of the epidermis. The shape of the individual exposure areas 716 may be circular (shown in Fig. 8), elliptical, rectangular, linear or irregular with a lateral diameter of

the smallest dimension in the range of 1 – 500 μm . The fill factor of the target area can be approximately 20 – 40%.

The system 700 can create multiple individual exposure areas 716 through heating, ablation, removal, photothermal coagulation, thermal necrosis and/or stimulation. The multiple areas can be exposed sequentially or simultaneously. Sequential exposure may be achieved by scanning or moving an energy source which may be either pulsed, shuttered or continuous. Simultaneous exposure can be achieved, for example, by an array of sources or a multi-array of lenses. The array of sources may be a uni-dimensional array, a bi-dimensional array or the like. The array can be moved relative to the skin, and one or multiple passes of treatment can be performed in a target area.

Fig. 9 illustrates an exemplary embodiment of a monitoring system 900 according to the present invention. The monitoring system 900 tracks the movement of the system 700, and feeds such positional information to the control module 702. The control module 702 utilizes this information to appropriately instruct the translator 708 to position the delivery optics 706, such that the appropriate damage pattern is achieved across the target area of the skin 714. The monitoring system 900 may use a computer 902, a mouse 904, and a charge coupled device (“CCD”) camera 906. In particular, the computer 902 receives the positional information about the system 700 from the CCD camera 906. The computer then updates the control module 702 based on this positional information as to the current position of the system 700. The control module 702 utilizes this information to cause the system 700 to create the appropriate damage pattern on the skin 714 within the target area. In addition, the monitoring system can utilize additional motion detecting devices, including, wheels or any other motion sensor.

The shape of the individual exposure areas 716 and the relative pattern represented by all of the individual exposure areas 716 may vary. The individual exposure areas 716 can have a circular, elliptical, rectangular, linear or irregular shape. The average distance between individual regions of unexposed skin surface may be in the range between 10 to 2000 μm , and preferably in the range of 100 to 500 μm . The macroscopic pattern of the individual exposure areas 716 may be a field of uniformly distributed individual exposure areas 716 with constant spacing throughout the target area, randomly distributed individual exposure areas 716 within the target area, and/or regularly distributed individual exposure areas 716 with constant average

spacing with randomly shifted location. In particular, having regularly distributed individual exposure areas 716 with constant average spacing with randomly shifted location may be useful to minimize undesirable effects, which may occur during multiple treatments. Such multiple treatments are utilized to cover the entire area as
5 homogeneously as possible by the individual exposure areas 716 during the course of multiple treatments. However, uniformly distributed individual exposure areas 716 with constant spacing throughout the target area may create unwanted spatial distributions similar to moiré patterns, resulting in spatial interference macroscopic patterns generated with a distance in between the areas of exposure which have a
10 significant spatial period. In order to minimize the occurrence of moiré patterns, a randomized shift within the range of 10 to 50% of the average distance between individual exposure areas 716 during a single scan may be utilized.

The treatment can be performed in by a single treatment covering the skin surface with a specific surface damage pattern, or by multiple treatments either
15 performed at the same visit or during different treatment visits. Individual or multiple exposures can be used to achieve the appropriate thermal damage in particular individual exposure areas 716.

Fractional resurfacing may cause portions of the epidermis to be thermally damaged or ablated, thereby reducing the efficacy of the barrier function of
20 the epidermis and in particular decreasing the stratum corneum. This facilitates the delivery of drugs or specific substances to the dermis and epidermis which can either enhance the effects of the treatment, or decrease the side effects caused by partial damage of the epidermis and/or dermis. Groups of drugs and substances, which may enhance the efficacy of skin remodeling include growth factors, collagen byproducts,
25 collagen precursors, hyaluronic acid, vitamins, antioxidants, amino acids and supplemental minerals among others. Groups of drugs and substances, which may decrease side effects, can be steroidal anti-inflammatory drugs, non-steroidal anti-inflammatory drugs, antioxidants, antibiotics, antiviral drugs, antiyeast drugs and antifungal drugs.

30 In an exemplary embodiment of the present invention, the vitamins that are used may be vitamin C and/or vitamin E. The supplemental minerals used are copper and zinc. The antioxidants can be vitamin C and/or vitamin E.

In a clinical observation, enhanced wound healing was observed for fractional resurfacing as compared to conventional resurfacing. The forearm skin of a

white, male Caucasian was exposed to pulsed CO₂ laser radiation with identical settings of the illuminating laser beam with a beam diameter of approximately 3 mm, a Coherent Ultra Pulse Laser, CPG handpiece, at approximately 300mJ/pulse. One area was exposed to the laser beam without benefit of a mask while another area was partially shielded by a cooled mask. More pronounced erythema was evident at the conventionally resurfaced test site as compared to the fractionally resurfaced test site.

The fill factor of the target area may be monitored by sensing the electrical impedance of the skin from a location on the skin within the target area to a remote location on the skin outside of the target area during or after treatment. An indicator capable of staining the defects in the stratum corneum (for example, trypan glue) or transdermal waterloss are effective indicators of the fill factor of the target area.

The foregoing merely illustrates the principles of the invention. Various modifications and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. It will thus be appreciated that those skilled in the art will be able to devise numerous techniques which, although not explicitly described herein, embody the principles of the invention and are thus within the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An apparatus, comprising:
at least one member configured to mask at least one portion of a target area of skin from an electromagnetic radiation provided by an electromagnetic radiation
5 source, wherein at least one member is configured such that a particular amount of the electromagnetic radiation that impacts the at least one member is reflected in a direction of the electromagnetic radiation source.
2. The apparatus of claim 1, wherein the target area is a predetermined area of the skin.
- 10 3. The apparatus of claim 1, wherein each of the at least one shielding member is configured to reflect the impacted electromagnetic radiation away from the apparatus.
4. The apparatus of claim 1, wherein each of the at least one shielding member is configured to absorb a minimal amount of electromagnetic radiation.
5. The apparatus of claim 1, wherein the electromagnetic radiation is optical
15 radiation.
6. The apparatus of claim 1, wherein the electromagnetic radiation source is an ablative laser.
7. The apparatus of claim 1, wherein the electromagnetic radiation source is generated by a carbon dioxide laser.
- 20 8. The filtering apparatus of claim 1, wherein the electromagnetic radiation source is an Er:YAG laser.
9. The apparatus of claim 1, wherein the at least one shielding member masks at least 0.1% of the target area from the electromagnetic radiation.
10. The apparatus of claim 1, wherein the at least one member masks at most 90%
25 of the target area from the electromagnetic radiation.
11. The apparatus of claim 1, wherein the at least one member masks the at least one portion of the target area such that the electromagnetic radiation is prevented

from affecting the at least one portion of the target area.

12. The apparatus of claim 1, wherein the at least one member is at least 50 μm in width and at most 300 μm .
13. The apparatus of claim 1, wherein the at least one member is configured to
5 define at least one aperture.
14. The apparatus of claim 13, wherein the at least one aperture has a width of at least 50 μm and at most 1000 μm .
15. The apparatus of claim 1, wherein the at least one member is cooled.
16. The apparatus of claim 1, wherein the at least one member is adapted to be
10 cooled to at least 37°C and at most negative 20°C .
17. The apparatus of claim 1, wherein the at least one member includes at least one channel extending therethrough.
18. The apparatus of claim 17, wherein the at least one channel is configured to facilitate a cooling agent.
- 15 19. A method for treating dermatological conditions, comprising:
controlling an electromagnetic radiation source to generate an electromagnetic radiation;
causing the electromagnetic radiation to be applied to a target area of skin; and
masking at least one portion of the target area of the skin from the
20 electromagnetic radiation.
20. The method of claim 19, wherein the masking step is performed using a mask which includes at least one member.
21. The method of claim 20, wherein the at least one shielding member masks at least 0.1% of the target area from the electromagnetic radiation.
- 25 22. The method of claim 20, wherein the at least one member masks at most 90% of the target area from the electromagnetic radiation.
23. The method of claim 20, wherein the at least one member masks the at least

one portion of the target area such that the electromagnetic radiation is prevented from affecting the at least one portion of the target area.

24. The method of claim 20, wherein the at least one member masks the at least one portion of the target area such that the electromagnetic radiation has an affect on
5 the at least one portion than an affect to other portions of the target area.

25. The method of claim 20, wherein the at least one member is at least 50 μm in width and at most 300 μm .

26. The method of claim 20, wherein the at least one member is configured to define at least one aperture.

10 27. The method of claim 26, wherein the at least one aperture has a width of at least 50 μm and at most 1000 μm .

28. The method of claim 20, wherein the at least one member is cooled.

29. The method of claim 20, wherein the at least one member is adapted to be cooled to at least 37°C and at most negative 20°C .

15 30. The method of claim 20, wherein the at least one member includes at least one channel extending therethrough.

31. The method of claim 30, wherein the at least one channel is configured to facilitate a cooling agent.

20 32. The method of claim 19, wherein the mask is configured to reflect a predetermined amount of the electromagnetic radiation in a direction of the electromagnetic radiation source.

33. The method of claim 19, wherein the mask is configured to reflect the electromagnetic radiation away from the electromagnetic radiation source.

25 34. The method of claim 19, wherein the mask is configured to diffuse the electromagnetic radiation.

35. The method of claim 19, wherein the electromagnetic radiation has a particular wavelength.

36. The method of claim 35, wherein a surface of the mask has a microstructure having a periodicity approximately in the range of the particular wavelength.
37. The method of claim 19, wherein the mask is configured to absorb a predetermined amount of the electromagnetic radiation.
- 5 38. The method of claim 19, wherein the electromagnetic radiation source is an ablative laser.
39. The method of claim 19, wherein the electromagnetic radiation source is a carbon dioxide laser.
40. The method of claim 19, wherein the electromagnetic radiation source is a
10 Er:YAG laser.
41. The method of claim 19, further comprising the steps of:
controlling a further electromagnetic radiation source to generate a further electromagnetic radiation; and
applying the further electromagnetic radiation to the target area of the skin.
- 15 42. The method of claim 41, wherein the further electromagnetic radiation source is substantially the same as the electromagnetic radiation source.
43. The method of claim 41, wherein the further electromagnetic radiation source is different than the electromagnetic radiation source.
44. The method of claim 41, wherein the further electromagnetic radiation source
20 is one of a Q-switched ruby laser, a Nd:YAG laser, a KTP laser and an Alexandrite laser.
45. The method of claim 19, further comprising the step of introducing a substance to the target area, wherein the substance is one of growth factors, collagen byproducts, collagen precursors, hyaluronic acid, vitamins, antioxidants, amino acids
25 and supplemental minerals.
46. An apparatus for treating dermatological conditions, comprising:
a delivery module configured to direct an electromagnetic radiation generated by an electromagnetic radiation source to a target area of skin; and

a mask including at least one member configured to mask at least one portion of the target area of the skin from the electromagnetic radiation.

47. The apparatus of claim 46, wherein the at least one member is configured to reflect a predetermined amount of the electromagnetic radiation in the direction of the
5 electromagnetic radiation source.

48. The apparatus of claim 46, wherein each of the at least one member is configured to reflect the electromagnetic radiation away from the electromagnetic radiation source.

49. The apparatus of claim 46, wherein each of the at least one member is
10 configured to diffuse the electromagnetic radiation.

50. The apparatus of claim 46, wherein the electromagnetic radiation has a particular wavelength.

51. The apparatus of claim 50, wherein each of the at least one member includes a microstructure having a periodicity in the range of the particular wavelength.

15 52. The apparatus of claim 46, wherein each of the at least one member is configured to absorb a minimal amount of the electromagnetic radiation.

53. The apparatus of claim 46, wherein the electromagnetic radiation source is an ablative laser.

54. The apparatus of claim 46, wherein the electromagnetic radiation source is a
20 carbon dioxide laser.

55. The apparatus of claim 46, wherein the electromagnetic radiation source is a Er:YAG laser.

56. The apparatus of claim 46, wherein the at least one shielding member masks at least 0.1% of the target area from the electromagnetic radiation.

25 57. The apparatus of claim 46, wherein the at least one member masks at most 90% of the target area from the electromagnetic radiation.

58. The apparatus of claim 46, wherein the at least one member masks the at least

one portion of the target area such that the electromagnetic radiation is prevented from affecting the at least one portion of the target area.

59. The apparatus of claim 46, wherein the at least one member masks the at least one portion of the target area such that the electromagnetic radiation is prevented
5 from affecting the at least one portion of the target area.

60. The apparatus of claim 46, further comprising a case having an aperture formed in a sidewall of the case, wherein the case contains the electromagnetic radiation source and the delivery module, and wherein the at least one member is in registration with the aperture.

10 61. The apparatus of claim 46, wherein the delivery module includes a beam collimator.

62. The apparatus of claim 46, wherein the delivery module includes optical components.

63. An apparatus for treating dermatological conditions, comprising:
15 a delivery module configured to direct electromagnetic radiation generated by an electromagnetic radiation source to a predetermined area within a target area of skin, wherein the predetermined area is located in a location relative to the delivery module, and wherein the electromagnetic radiation is adapted to cause thermal damage to epidermal tissue and dermal tissue of the predetermined area within the
20 target area of the skin; and

a translator capable of moving the delivery module, such that the delivery module targets a plurality of spatially separated individual exposure areas of the predetermined area.

64. The apparatus of claim 63, wherein the electromagnetic radiation source is an
25 ablative laser.

65. The apparatus of claim 63, wherein the electromagnetic radiation source is one of a diode laser, a fiber laser, a solid state laser and a gas laser.

66. The apparatus of claim 63, further comprising a case having an aperture formed in a sidewall of the case, wherein the case contains the electromagnetic

radiation source, the delivery module and the translator.

67. The apparatus of claim 66, further comprising a transparent plate in registration with the aperture, wherein the transparent plate seals the case.

68. The apparatus of claim 67, wherein the electromagnetic radiation has a particular wavelength.

69. The apparatus of claim 68, wherein the transparent plate absorbs a predetermined amount of the electromagnetic radiation at the particular wavelength.

70. The apparatus of claim 67, wherein the transparent plate is cooled to provide an aesthetic affect to the target area of the skin.

71. The apparatus of claim 67, wherein the transparent plate is configured to be cooled to at least 37°C and at most negative 20°C.

72. The apparatus of claim 63, wherein the delivery module includes a beam collimator.

73. The apparatus of claim 63, wherein the delivery module includes optical components.

74. The apparatus of claim 63, wherein the dermal tissue of the skin of the plurality of spatially separated individual exposure areas is damaged down to a predetermined depth thereof.

75. The apparatus of claim 63, wherein the plurality of spatially separated individual exposure areas cover at least five percent of the target area and at most sixty percent of the target area.

76. The apparatus of claim 63, wherein an average distance between each of the plurality of spatially separated individual exposure areas is at least 10 μm and at most 2000 μm .

77. The apparatus of claim 63, wherein each of the plurality of spatially separated individual exposure areas have a diameter of approximately 0.1 mm.

78. The apparatus of claim 63, wherein each of the plurality of spatially separated

individual exposure areas have a lateral diameter of a smallest dimension of at least 1 μm and at most 500 μm .

79. The apparatus of claim 63, further comprising an optically transparent plate disposed between delivery module and the target area of the skin.

5 80. The apparatus of claim 79, wherein the optically transparent plate is cooled.

81. The apparatus of claim 79, wherein the optically transparent plate cooled to at least 37°C and at most negative 20°C .

82. The apparatus of claim 63, wherein a first one of the plurality of spatially separated individual exposure areas is separated from a second one of the plurality of spatially separated individual exposure areas.
10

83. The apparatus of claim 82, wherein the first one of the plurality of spatially separated individual exposure areas is separated from the second one of the plurality of spatially separated individual exposure areas by non-irradiated skin section.

84. The apparatus of claim 63, wherein a first one of the plurality of spatially separated individual exposure areas is exposed to electromagnetic radiation associated with a first set of parameters and a second one of the plurality of spatially separated individual exposure areas is exposed to electromagnetic radiation associated with a second set of parameters.
15

85. The apparatus of claim 63, wherein at least two of the individual exposure areas are separated from one another by an unaffected area.
20

86. The apparatus of claim 85, wherein the at least two of the individual exposure areas are separated from one another by at least approximately 125 μm .

87. The apparatus of claim 85, wherein the at least two of the individual exposure areas are separated from one another by at most approximately 500 μm .

88. The apparatus of claim 63, wherein one of at least one hundred of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one hundred of the individual exposure areas by an unaffected area.
25

89. The apparatus of claim 63, wherein one of at least one thousand of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one thousand of the individual exposure areas by an unaffected area.
- 5 90. A method for treating dermatological conditions, comprising the steps of:
- (a) controlling an electromagnetic radiation source to generate first and second electromagnetic radiation;
 - (b) causing a first electromagnetic radiation to be applied to a first individual exposure area of a plurality of spatially separated individual exposure areas of a target
 - 10 area of skin, wherein epidermal tissue and dermal tissue of the first individual exposure area are thermally damaged; and
 - (c) causing a second electromagnetic radiation to be applied to a second individual exposure area of a plurality of spatially separated individual exposure areas of the target area of the skin, wherein epidermal tissue and dermal tissue of the second
 - 15 individual exposure area are thermally damaged, wherein the first electromagnetic radiation is one of the same as and different from the second electromagnetic radiation, and wherein the first and second individual exposure areas are separated from one another by an unaffected area.
91. The method of claim 90, wherein the target area has a surface area of
- 20 approximately 1 cm².
92. The method of claim 90, wherein the electromagnetic radiation source is an ablative laser.
93. The method of claim 90, wherein the electromagnetic radiation source is one of a diode laser, a fiber laser, a solid state laser and a gas laser.
- 25 94. The method of claim 90, wherein the dermal tissue of the skin of the plurality of spatially separated individual exposure areas is damaged down to a predetermined depth thereof.
95. The method of claim 90, wherein the plurality of spatially separated individual exposure areas cover at least twenty percent of the target area and at most forty
- 30 percent of the target area.

96. The method of claim 90, wherein an average distance between each of the plurality of spatially separated individual exposure areas is at least approximately 10 μm and at most approximately 2000 μm .
97. The method of claim 90, wherein each of the plurality of spatially separated individual exposure areas have a diameter of approximately 0.1 mm.
98. The method of claim 90, wherein each of the plurality of spatially separated individual exposure areas have a lateral diameter of a smallest dimension of at least approximately 1 μm and at most approximately 500 μm .
99. The method of claim 90, further comprising the step of:
- (d) placing an optically transparent plate in registration with the target area.
100. The method of claim 99, wherein the optically transparent plate is cooled.
101. The method of claim 99, wherein the optically transparent plate cooled to at least approximately 37°C and at most approximately negative 20°C .
102. The method of claim 90, wherein the first individual exposure area is separated from a second individual exposure area.
103. The method of claim 90, wherein the first individual exposure area is separated from the second individual exposure area by non-irradiated skin.
104. The method of claim 90, wherein the first electromagnetic radiation is associated with a first set of parameters, and wherein the second electromagnetic radiation is associated with a second set of parameters.
105. The method of claim 90, wherein at least two of the individual exposure areas are separated from one another by an unaffected area.
106. The method of claim 105, wherein the at least two of the individual exposure areas are separated from one another by at least approximately 125 μm .
107. The method of claim 105, wherein the at least two of the individual exposure areas are separated from one another by at most approximately 500 μm .

108. The method of claim 90, wherein one of at least one hundred of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one hundred of the individual exposure areas by an unaffected area.

109. The method of claim 90, wherein one of at least one thousand of the individual
5 exposure areas within an area of a square centimeter is separated from another one of the at least one thousand of the individual exposure areas by an unaffected area.

1 / 5

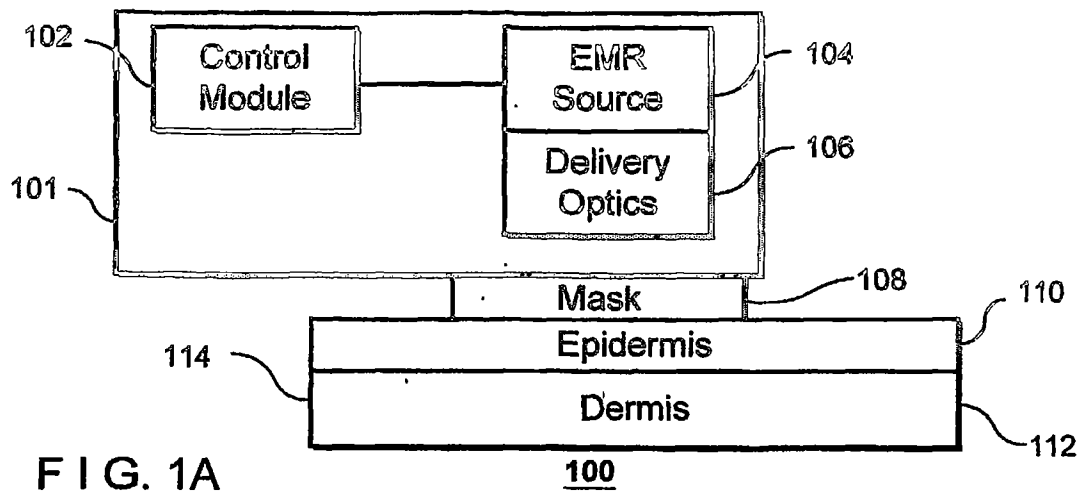


FIG. 1A

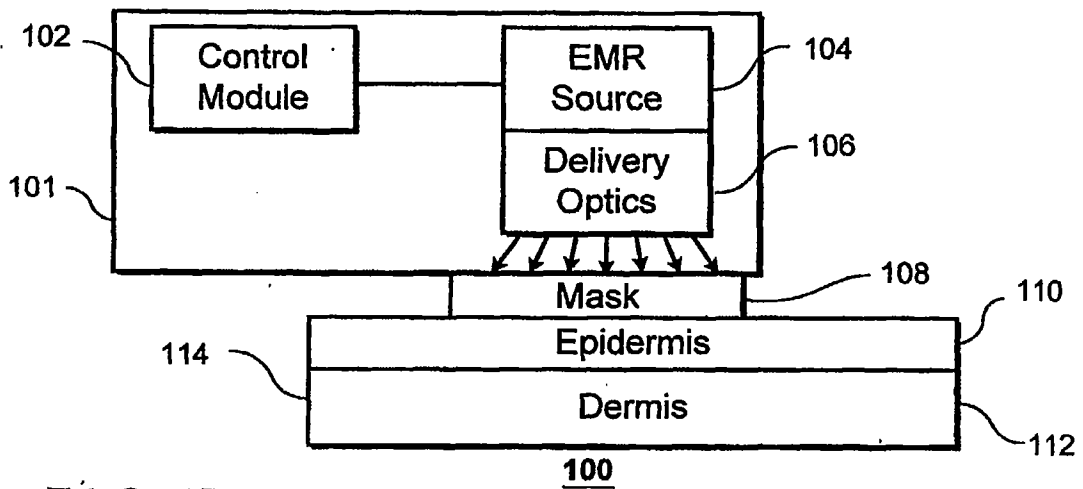


FIG. 1B

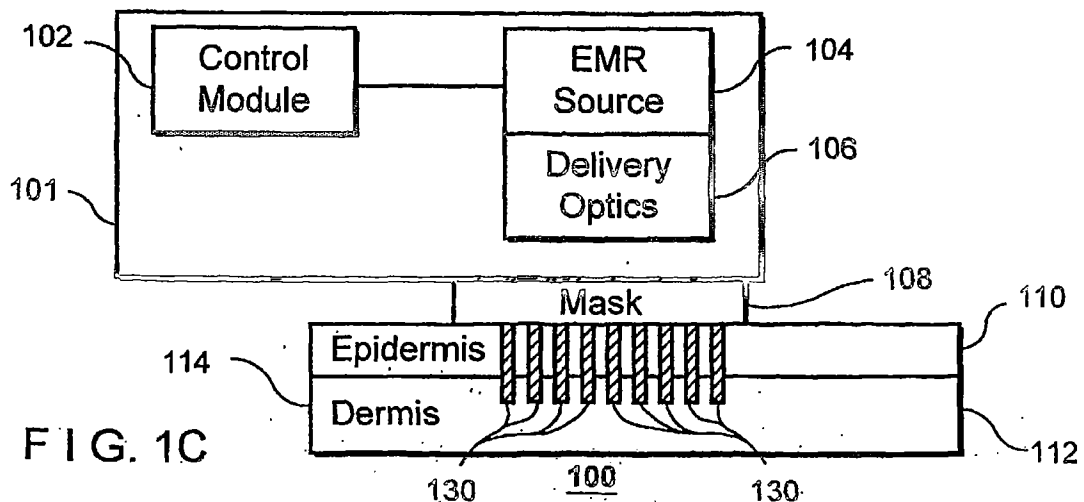


FIG. 1C

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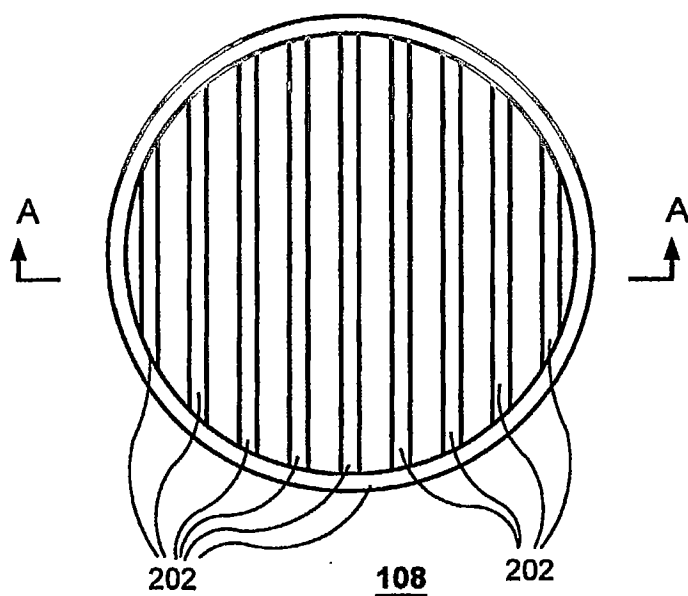


FIG. 2

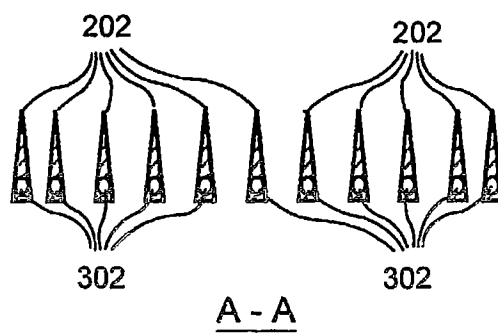


FIG. 3

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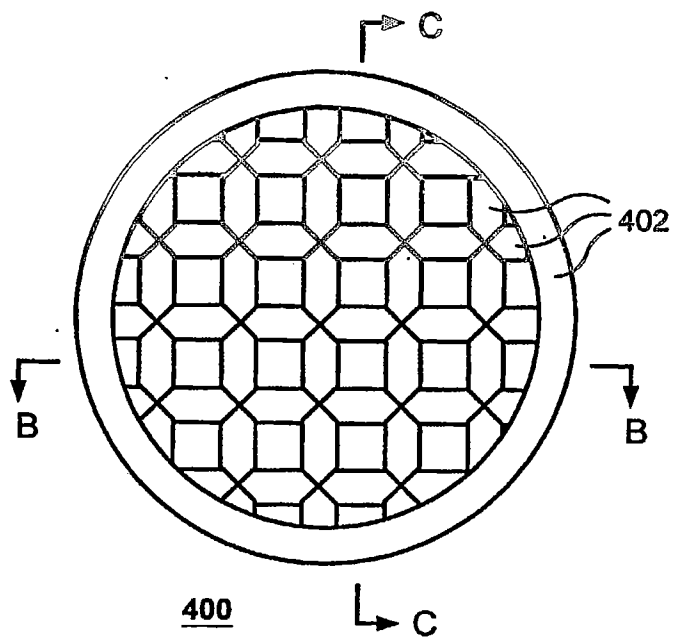


FIG. 4

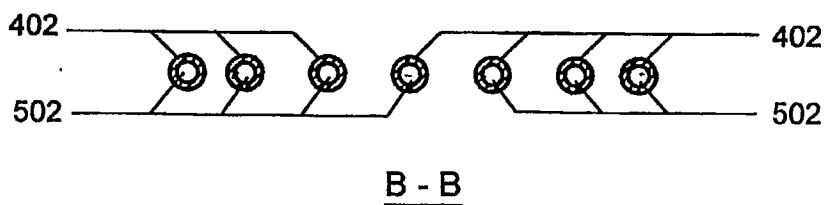


FIG. 5

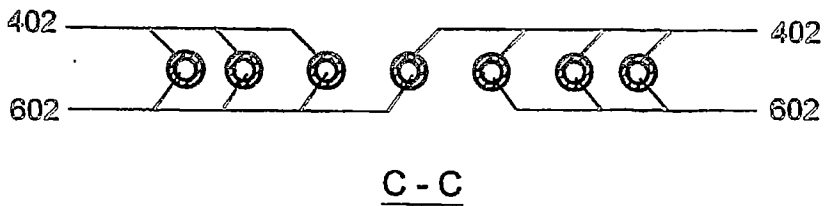


FIG. 6

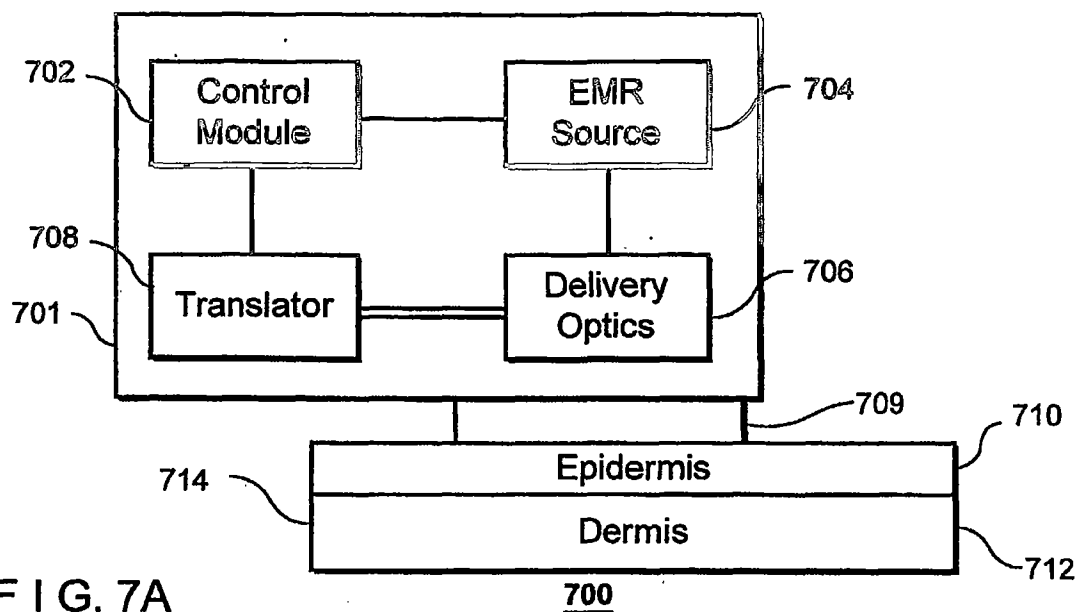


FIG. 7A

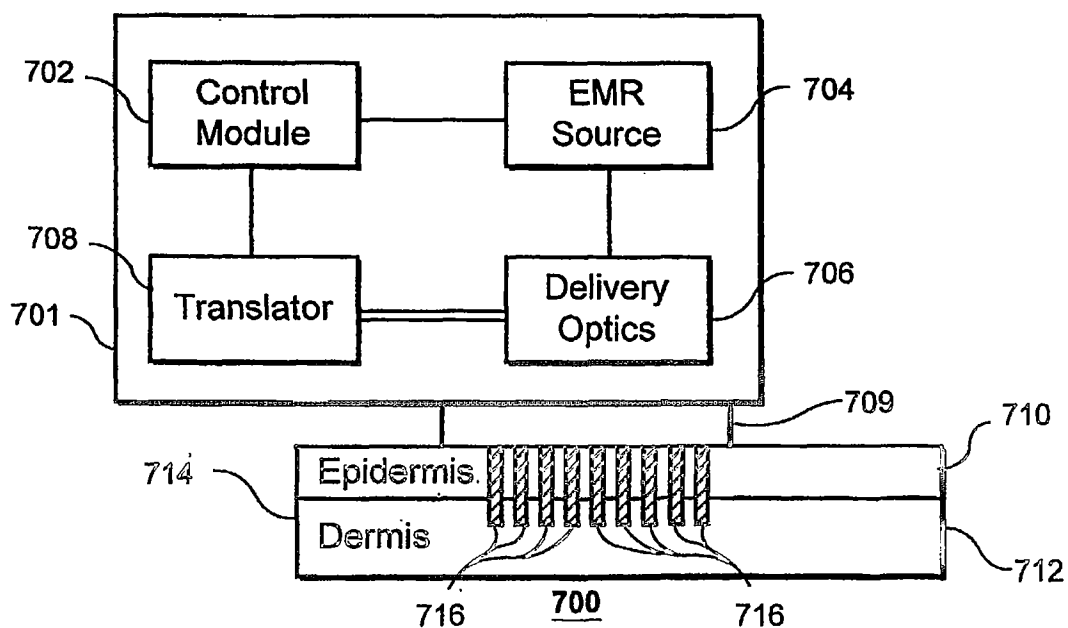


FIG. 7B

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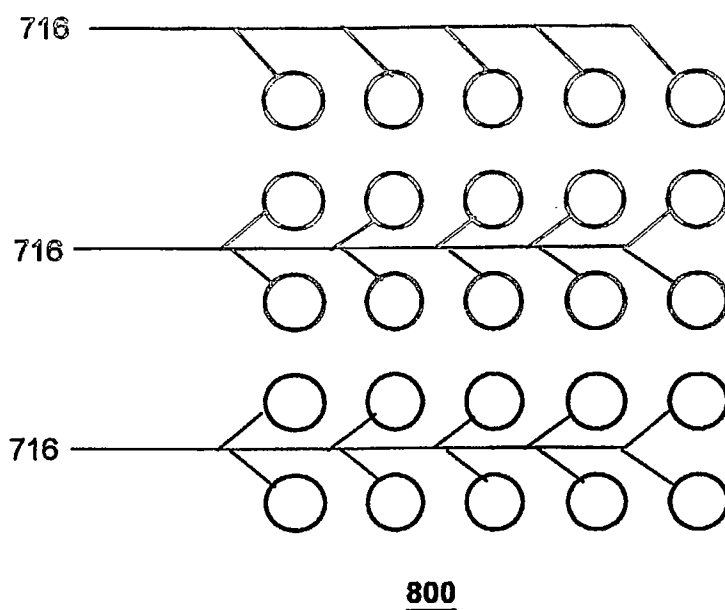


FIG. 8

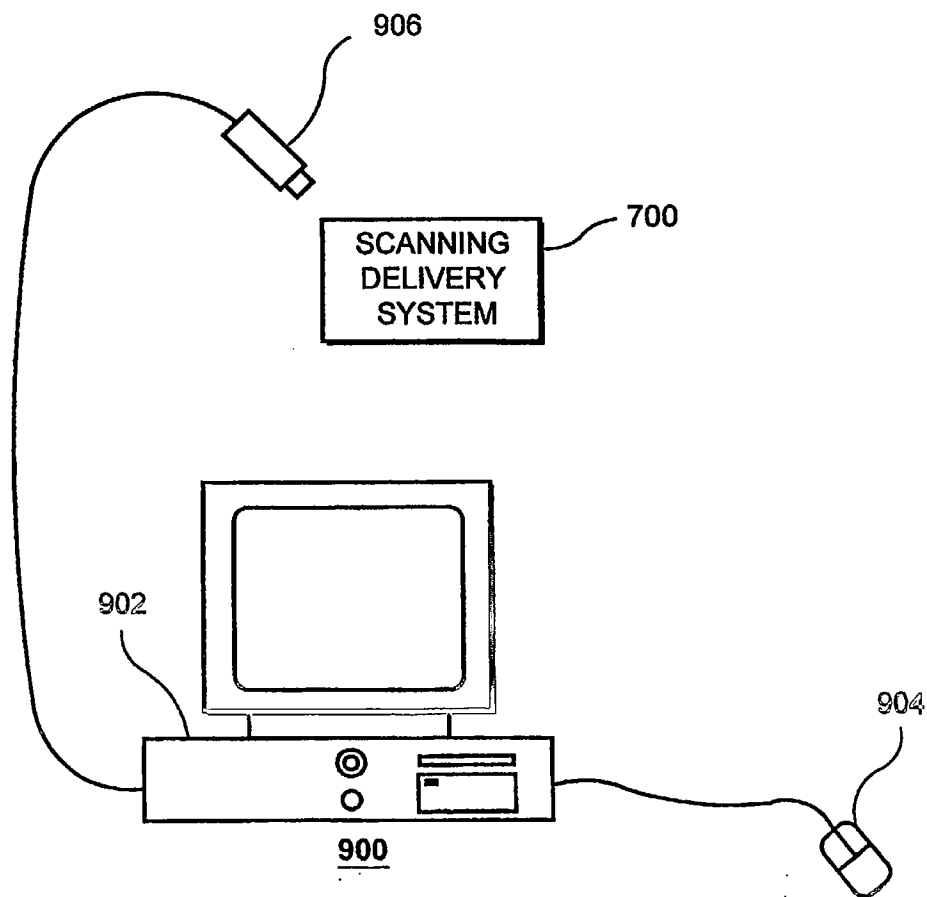


FIG. 9

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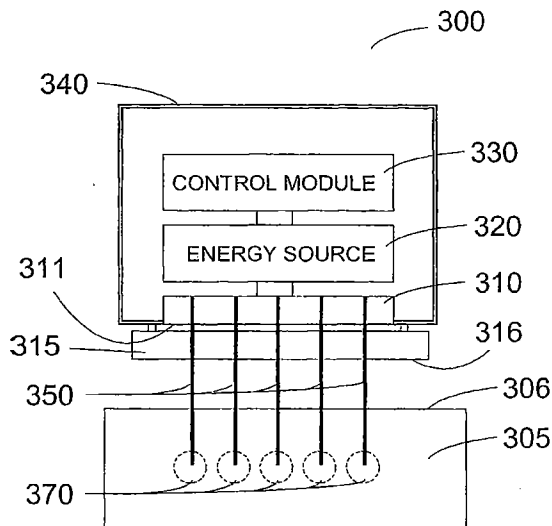
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ning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING



(57) Abstract: The present invention provides improved methods and apparatus for skin treatment and tissue remodeling. The apparatus includes an array of needles that penetrate the skin and serve as electrodes to deliver radio frequency current or other electrical or optical energy into the tissue being treated, causing thermal damage in controlled patterns. The damaged regions promote beneficial results such as uniform skin tightening by stimulation of wound healing and collagen growth.

WO 2005/096979 A1

TITLE OF THE INVENTION

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE
RESHAPING

RELATED APPLICATION

5 This application claims priority to U.S. Provisional Application Serial No.
60/558,476, filed on April 1, 2004.

INCORPORATION BY REFERENCE

 The foregoing applications, and all documents cited therein or during their
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manufacturer's instructions, descriptions, product specifications, and product sheets for any
products mentioned herein or in any document incorporated by reference herein, are hereby
incorporated herein by reference, and may be employed in the practice of the invention.

15 FIELD OF THE INVENTION

 The present invention is directed to an improved method for treatment of skin and
other tissues. More specifically, it is directed to a method of fractional wounding using
arrays of needles to damage selected regions of the skin or subdermal tissue and thereby
promote beneficial results including skin tightening and tissue remodeling.

20 BACKGROUND OF THE INVENTION

 Skin is primarily made of two layers. The outer layer, or epidermis, has a depth of
approximately 100 μm . The inner layer, or dermis, has depth of approximately 3000 μm from
the outer surface of the skin and is primarily composed of a network of fibrous protein known
as collagen.

25 There is an increasing demand for repair of skin defects, which can be induced by
aging, sun exposure, dermatological diseases, traumatic effects, and the like. Aging skin
tends to lose its elasticity, leading to increased formation of wrinkles and sagging. Other
causes of undesirable wrinkles in skin include excessive weight loss and pregnancy. There
are several well-known surgical approaches to improving the appearance of skin that involve
30 incisions being made in the skin followed by the removal of some tissue and rejoining of the
remaining tissue. These surgical approaches include facelifts, brow lifts, breast lifts, and
"tummy tucks." Such approaches have many negative side effects including scar formation,
long healing times, displacement of skin from its original location relative to the underlying
bone structure, and nonuniform skin tightening.

Many treatments have been developed that use electromagnetic radiation to improve skin defects by inducing a thermal injury to the skin, which results in a complex wound healing response of the skin. This leads to a biological repair of the injured skin and may be accompanied by other desirable effects. Various techniques providing this objective have been introduced in recent years. The different techniques can be generally categorized in two groups of treatment modalities: ablative laser skin resurfacing ("LSR") and non-ablative collagen remodeling ("NCR"). The first group of treatment modalities, LSR, includes causing fairly extensive thermal damage to the epidermis and/or dermis, while the second group, NCR, is designed to avoid thermal damage of the epidermis.

LSR is considered to be an effective laser treatment for repairing skin. In a typical LSR procedure, shown schematically in Fig. 1, a region of the epidermis 100 and a corresponding region of the dermis 110 beneath it are thermally damaged to promote wound healing. Electromagnetic energy 120 is directed towards a region of skin, ablating the skin and removing both epidermal and dermal tissue in region 130. LSR with pulsed CO₂ or Er:YAG lasers, which may be referred to in the art as laser resurfacing or ablative resurfacing, is considered to be an effective treatment option for signs of photo aged skin, chronically aged skin, scars, superficial pigmented lesions, stretch marks, and superficial skin lesions. However, patients may experience major drawbacks after each LSR treatment, including edema, oozing, and burning discomfort during first fourteen (14) days after treatment. These major drawbacks can be unacceptable for many patients. A further problem with LSR procedures is that the procedures are relatively painful and therefore generally require an application of a significant amount of analgesia. While LSR of relatively small areas can be performed under local anesthesia provided by injection of an anestheticum, LSR of relatively large areas is frequently performed under general anesthesia or after nerve blockade by multiple injections of anesthetic.

A limitation of LSR is that ablative resurfacing in areas other than the face generally have a greater risk of scarring because the recovery from skin injury within these areas is not very effective. Further, LSR techniques are better suited for correction of pigmentation defects and small lesions than for reducing or eliminating wrinkles.

In an attempt to overcome the problems associated with LSR procedures, several types of NCR techniques has emerged. These techniques are variously referred to in the art as non-ablative resurfacing, non-ablative subsurfacing, or non-ablative skin remodeling. NCR techniques generally utilize non-ablative lasers, flashlamps, or radio frequency current to damage dermal tissue while sparing damage to the epidermal tissue. The concept behind

NCR techniques is that thermal damage of the dermal tissue is thought to induce collagen shrinkage, leading to tightening of the skin above, and stimulation of wound healing which results in biological repair and formation of new dermal collagen. This type of wound healing can result in a decrease of structural damage related to photoaging. Avoidance of epidermal damage in NCR techniques decreases the severity and duration of treatment-related side effects. In particular, post-procedural oozing, crusting, pigmentary changes and incidence of infections due to prolonged loss of the epidermal barrier function can usually be avoided by using NCR techniques.

In the NCR method of skin treatment, illustrated schematically in Fig. 2, selective portions of dermal tissue 135 within the dermal layer 110 are heated to induce wound healing without damaging the epidermis 100 above. Selective dermal damage that leaves the epidermis undamaged can be achieved by cooling the surface of the skin and focusing electromagnetic energy 120, which may be a laser beam, onto dermal region 135 using lens 125. Other strategies are also applied using nonablative lasers to achieve damage to the dermis while sparing the epidermis in NCR treatment methods. Nonablative lasers used in NCR procedures generally have a deeper dermal penetration depth as compared to ablative lasers used in LSR procedures. Wavelengths in the near infrared spectrum can be used. These wavelengths cause the non-ablative laser to have a deeper penetration depth than the very superficially-absorbed ablative Er:YAG and CO₂ lasers. Examples of NCR techniques and apparatus are disclosed by Anderson et al. in U.S. Patent Publication No. 2002/0161357.

While it has been demonstrated that these NCR techniques can assist in avoiding epidermal damage, one of the major drawbacks of these techniques is their limited efficacies. The improvement of photoaged skin or scars after the treatment with NCR techniques is significantly smaller than the improvements found when LSR ablative techniques are utilized. Even after multiple treatments, the clinical improvement is often far below the patient's expectations. In addition, clinical improvement is usually several months delayed after a series of treatment procedures. NCR is moderately effective for wrinkle removal and is generally not effective for dyschromia. One advantage of NCR is that it does not have the undesirable side effects that are characteristic of the LSR treatment, such as the risk of scarring or infection.

Another limitation of NCR procedures relates to the breadth of acceptable treatment parameters for safe and effective treatment of dermatological disorders. The NCR procedures generally rely on an optimum coordination of laser energy and cooling parameters, which can result in an unwanted temperature profile within the skin leading to

either no therapeutic effect or scar formation due to the overheating of a relatively large volume of the tissue.

Another approach to skin tightening and wrinkle removal involves the application of radio frequency ("RF") electrical current to dermal tissue via a cooled electrode at the surface of the skin. Application of RF current in this noninvasive manner results in a heated region developed below the electrode that damages a relatively large volume of the dermis, and epidermal damage is minimized by the active cooling of the surface electrode during treatment. This treatment approach can be painful, and can lead to short-term swelling of the treated area. Also, because of the relatively large volume of tissue treated and the need to balance application of RF current with surface cooling, this RF tissue remodeling approach does not permit fine control of damage patterns and subsequent skin tightening. This type of RF technique is monopolar, relying on a remote grounding of the patient to complete the current flow from the single electrode. The current in monopolar applications must flow through the patient's body to the remote ground, which can lead to unwanted electrical stimulation of other parts of the body. In contrast, bipolar instruments conduct the current between two relatively nearby electrodes through a more localized pathway.

In view of the shortcomings of the above methods of dermatological treatment and tissue remodeling, there is a need to provide a procedure and apparatus that combine safe and effective treatment for tissue remodeling, skin tightening, and wrinkle removal with minimal side effects, such as intra-procedural discomfort, post-procedural discomfort, lengthy healing time, and post-procedural infection.

Citation or identification of any document in this application is not an admission that such document is available as prior art to the present invention.

SUMMARY OF THE INVENTION

It is therefore one of the objects of the present invention to provide an apparatus and method that combines safe and effective treatment for an improvement of dermatological disorders with minimum side effects. Another object of the present invention is to provide an apparatus and method that promotes skin tightening and wrinkle removal by creation of a pattern of small localized regions of thermal damage within the dermis. Still another object of the present invention is to provide a method and apparatus for skin tightening or other forms of tissue remodeling by using an array of electrode needles to controllably deliver electrical or thermal energy to predetermined locations within the dermis or other tissue.

These and other objects can be achieved with an exemplary embodiment of the apparatus and method according to the present invention, in which portions of a target area of

tissue are be subjected electromagnetic radiation, such as radio frequency pulses, or thermal energy. Electromagnetic radiation is directed to portions of a target area within the skin or deeper tissue using minimally invasive methods, causing fractional wounding of the portions of the target area. The electromagnetic radiation may be generated by an electromagnetic radiation source, which is configured to deliver heat, radio frequency pulses, electrical current, or the like to a plurality of target areas.

In yet another exemplary embodiment according to the present invention, an electromagnetic radiation source is configured to generate electromagnetic radiation, and a delivery device comprising an array of needles, coupled to the electromagnetic radiation source, is configured to penetrate the skin to a desired depth to deliver the electromagnetic radiation directly to a plurality of target areas.

One method in accordance with the present invention comprises inserting an array of needles into a region of skin to a predetermined depth. Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles.

In an alternate aspect of the invention, one or more of the needles in the array may be hollow and used to deliver small amounts of analgesic or anesthetic into the region of skin being treated. These hollow needles may be interspersed among the electrode needles in the array, and they may also function as electrodes.

In another embodiment of the invention, the electrode needles may also be connected to a second source of electrical current in the milliampere range. Detection of a nerve close to any of the inserted needles of the array is achieved by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, the nearby needle or needles can be deactivated during the subsequent application of RF current to other electrode needles in the array to avoid damaging the nerve.

In yet another embodiment of the invention, the methods and apparatus described herein can be used to heat portions of cartilage, such as that located in the nose, using a minimally invasive technique, allowing reshaping of the pliant heated cartilage to a desired form.

A further understanding of the nature and advantages of the present invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The following detailed description, given by way of example, but not intended to limit the invention solely to the specific embodiments described, may best be understood in conjunction with the accompanying drawings, in which:

5 Fig. 1 is a schematic drawing of a cross section of a tissue treated using the ASR method.

Fig. 2 is a schematic drawing of a cross section of a tissue treated using the NSR method.

10 Fig. 3 is a schematic illustration of an apparatus for conducting tissue reshaping using electromagnetic energy according to one embodiment of the present invention.

Fig. 4 is a schematic illustration of portions of an apparatus for conducting tissue reshaping according to one embodiment of the present invention.

Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present invention will now be described in
15 detail with reference to the Figures, it is done so in connection with the illustrative embodiments and is not limited by the particular embodiments illustrated in the Figures.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to methods and apparatus for improvement of skin defects
20 including, but not limited to, wrinkles, stretch marks, and cellulite. In one embodiment, skin tightening or tissue remodeling is accomplished by creating a distribution of regions of necrosis, fibrosis, or other damage in the tissue being treated. The tissue damage is achieved by
30 delivering localized concentrations of electrical current that is converted into heat in the vicinity of the tips of the electrode needles. Inducing regions of local thermal damage within the dermis
25 results in an immediate shrinking of collagen, leading to beneficial skin tightening response. Additionally, the thermal damage tends to stimulate the formation of new collagen, which makes the local skin tissue fuller and gradually leads to additional skin tightening and reduction of wrinkles.

In an exemplary embodiment of the present invention, tissue treatment apparatus 300
30 shown in Fig. 3 may be used to create regions of damage within the tissue being treated. The tissue reshaping apparatus may comprise a plurality of needles 350 attached to a base 310. The base is attached to housing 340 or formed as a part of the housing. A source of RF current 320 is electrically connected to each of the needles 350. A control module 330 permits variation of the characteristics of the RF electrical current, which can be supplied

individually to one or more of the needles. Optionally, energy source 320 and/or control module 330 may be located outside of the housing.

In one exemplary embodiment, the energy source 320 is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range. In another exemplary embodiment, the energy source is capable of outputting an AC or DC electric current. The control module 330 provides application-specific settings to the energy source 320. The energy source 320 receives these settings, and generates a current directed to and from specified needles for selectable or predetermined durations, intensities, and sequences based on these settings.

In yet another embodiment of the present invention, a spacer substrate 315 containing a pattern of small holes through which the array of needles protrudes may optionally be provided between the base 310 and the surface of the skin 306. This spacer substrate may be used to provide mechanical stability to the needles. Optionally, this substrate may be movably attached to the base 310 or housing 340 and adjustable with respect to base 310, supporting the array of needles to control the depth of the needles protruding from the lower surface 316 of spacer substrate 315, and thus controlling the depth to which the needles are inserted into the skin.

In practicing a method in accordance with the present invention, the sharp distal ends of needles 350 pierce the surface 306 of skin tissue 305 and are inserted into the tissue until the bottom surface 316 of spacer substrate 315 (or the bottom surface 311 of base 310 if a spacer substrate 315 is not used) contacts the surface 306 of the skin 305. This configuration permits reliable insertion of the array of needles to a predetermined depth within the tissue being treated. Control module 330 is then configured to deliver controlled amounts of RF current to one or more needles 350.

Base 310 and/or spacer substrate 315, if used, can be planar or they may have a bottom surface that is contoured to follow the shape of the region of tissue being treated. This permits penetration of the needle array to a uniform depth within the targeted tissue even if the surface of the skin is not planar, e.g., along the eye sockets.

In another embodiment, base 310 and/or a spacer substrate 315, if used, may be cooled by any suitable means (such as by embedded conduits containing circulating coolant or by a Peltier device) to cool the surface of the skin when the needle array penetrates the skin to reduce or eliminate pain. The surface region of the skin being treated and/or the needles themselves may also be precooled by separate means, including convective or conductive means, prior to penetration of the skin by the array of needles.

In a preferred embodiment of the present invention, the shafts of conductive needles 350 are electrically insulated except for the portion of the needle near the tip. In the apparatus of Fig. 3, application of RF current to the needles 350 causes heating in the exposed tip region, inducing thermal damage regions 370 around the tip of each needle.

5 Thermal damage regions 370 result from operation of the apparatus in monopolar configuration, in which a remote grounding electrode, not shown in Fig. 3, is attached to a remote part of the patient's body to complete the circuit of electricity conveyed to needles 350 by energy source 320. In this monopolar configuration, RF current causes heating of the tip regions of the needles 350, generating thermal damage in tissue regions 370 adjacent to
10 the needle tips that are approximately spherical or slightly elongated in shape.

In one embodiment of the invention, current may be delivered simultaneously to all needles in the array to produce a pattern of thermal damage around the tip of each needle. In alternative embodiments, control module 330 and energy source 320 can be configured to supply electrical current to individual needles, to specific groups of needles within the array,
15 or to any combination of individual needles in any desired temporal sequence. Providing current to different needles at different times during treatment (instead of heating all needles in the array at once) may help to avoid potential local electrical or thermal interactions among needles that can lead to excessive local damage.

In yet another embodiment of the present invention one or more vibrating means, such
20 as a piezoelectric transducer or a small motor with an eccentric weight fixed to the shaft, may be mechanically coupled to housing 340 and/or base 310 that supports the array of needles 350. Vibrations conductively induced in needles 350 by such vibrating means can facilitate the piercing of the skin by the needle tips and subsequent insertion of the needles into the tissue. The vibrating means can have an amplitude of vibration in the range of about 50-500
25 μm or, more preferably, between about 100-200 μm . The frequency of the induced vibrations can be from about 10 hz to about 10 khz, more preferably from about 500 hz to about 2 khz, and even more preferably about 1 khz. The particular vibration parameters chosen may depend on the size and material of the needles, the number of needles in the array, and the average spacing of the needles. The vibrating means may further comprise an optional
30 controller capable of adjusting the amplitude and/or frequency of the vibrations.

Additional details and embodiments of the present invention are shown in Figure 4. Conductive needles 410 and 415 are shown attached to base 310. Insulation 420 covers the shaft of needles 410 and 415 protruding from base 310 except for the region near the lower tip, and electrically insulates each conductive needle shaft from surrounding tissue 305.

Electrical conductors 430 and 431, which may be wires or the like, extend from an upper portion of needles 410 and 415 respectively, and are connected to the energy source (not shown here). Suitable insulating materials for insulation 420 include, but are not limited to, Teflon®, polymers, glasses, and other nonconductive coatings. A particular material may be
5 chosen as an insulator to facilitate penetration and insertion of needles 410 and 415 into tissue 305.

Needles 410 and 415 are shown operating in bipolar mode in another embodiment of the present invention. Needle 410 is a positive electrode delivering RF or other current to the tip region of the needle from the energy source via conductor 430. Needle 415 functions as a
10 grounding electrode that is connected to the ground of the energy source via conductor 431. In this configuration the applied current will travel through the tissue between the tips of needles 410 and 415, generating an elongated region of thermal damage 425 around and between the tips of the two needles.

An elongated region of damaged tissue 425 can be created between any two adjacent
15 or nearby needles in the array through proper configuration of control module 330 and energy source 320. In an embodiment of the present invention, elongated damage regions 425 are formed between several pairs of needles within the array of needles to form a desired damage pattern in the tissue 305. The regions of thermal damage 425 created in bipolar operation of the apparatus may be formed simultaneously or, alternatively, sequentially, using any
20 combinations of proximate needles in the array to form each region. A wide variety of thermal damage patterns can be created using a single array of needles through appropriate configuration of energy source 320 and control module 330 to deliver predetermined amounts of current between selected pairs of needles. This apparatus thus allows for the creation of complex damage patterns within the tissue 305 that may be macroscopically elongated in
25 preferred directions to produce anisotropic shrinkage and reshaping.

In practicing the methods and apparatus of the present invention, the needles can have a width of about 500-1000 μm or preferably about 700-800 μm . Needles less than 500 μm in diameter may also be used if they are mechanically strong enough. Needles thicker than about 1000 μm in diameter may be undesirable because of the difficulty in forcing larger
30 needles to penetrate the skin and because of the increased propensity for pain and scarring. The length of the needles extending into the skin will depend on the targeted depth for damaging the tissue. A typical depth for targeting collagen in the dermis is about about 1500-2000 μm , although shallower or deeper distances may be preferred for different treatments

and regions of the body being treated. Needles within a single array may protrude by different lengths from the base 310 or spacer substrate 315. This will cause the tips of the needles to be positioned at different depths within the tissue being treated, and allow creation of damaged tissue at more than one depth. This variation in needle depth can achieve
5 formation of damaged tissue over a larger volume within the tissue being treated.

The needle arrays may have any geometry appropriate for the desired treatment being performed. The spacing between adjacent needles is preferably greater than about 1mm apart, and may be as large as about 2 cm. The spacing between needles in an array need not be uniform, and can be closer in areas where a greater amount of damage or more precise
10 control of damage in the target area of tissue is desired. In one embodiment, the array of needles may comprise pairs of needles separated from adjacent pairs by larger distances. This geometry may be well-suited for inducing damage in bipolar mode between pairs of needles. Needles may also be arranged in a regular or near-regular square or triangular array. In any array geometry, the pattern of damage and resultant tissue reshaping may be controlled
15 with some precision by adjusting the intensity and duration of power transmitted to single needles or pairs of needles.

The amount of energy directed to a given needle will vary depending on the tissue being treated and the desired extent of thermal damage to induce. For typical needle spacings noted above, the energy source should be configured to deliver about 1-100 mJ per needle or
20 pair of needles in the array. It may be preferable to initially use lower amounts of energy and perform two or more treatments over the same target area to better control the damage patterns and extent of reshaping.

In yet another embodiment of the present invention, one or more of the needles in the array may be hollow, such as needle 440 in Fig. 4. Center channel 450 may be used to
25 deliver a local analgesic such as lidocaine 2% solution from a source (not shown) located within or above base 310 into the tissue 305 to reduce or eliminate pain caused by the thermal damage process.

In yet another embodiment of the present invention, hollow needle 440 is bifunctional, capable of conducting RF current or other energy via conductor 432 and also
30 capable of delivering a local analgesic or the like through center channel 450. Similar to needles 410 and 415, bifunctional needle 440 has insulation 445 covering the shaft extending from base 310 except for the region near the lower tip. Analgesic may be supplied to the tissue either before or during application of RF or other current to the needle 450.

In one embodiment of the invention, one or more of the needles in the array may be bifunctional like needle 440. Alternatively, one or more needles may be hollow and optionally nonconductive, suitable only for delivering a local analgesic or the like. The array of needles used for a given application may comprise any combination of solid electrodes, bifunctional needles, or hollow nonconductive needles. For example, one type of needle array may comprise pairs of electrode needles operating in bipolar mode, with a hollow needle located between each pair. In this configuration, the hollow needle can deliver analgesic to the tissue between the tips of the electrode needles prior to applying current to the electrodes and causing thermal damage in the numbed tissue.

In yet another embodiment of the present invention, one or more of the needles in the array may be further connected to an electronic detection apparatus and perform the additional function of a probe to detect the presence of a nerve near the tip. The electronic detection apparatus may comprise a source of electrical current in the milliamperage range and control means to send small currents on the order of a milliamp to specific needles in the array. Detection of a nerve close to any of the inserted needles of the array is performed by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, control module 330 can be configured to deactivate the needle or needles close to the nerve during the subsequent treatment to avoid damaging the nerve. A nerve detection method based on principles similar to those described herein is disclosed by Urmei et al. in *Regional Anesthesia and Pain Medicine* 27:3 (May-June) 2002, pp. 261-267.

In still another embodiment, one or more of the needles may be hollow, and a light fiber or light guide is inserted into the hollow needle such that one end of it extends to or slightly protrudes from the needle tip. The other end of the light fiber or light guide in communication with a source of optical energy. Optical energy supplied to the tip of the light guide or light fiber may then be used to heat the tip, which then heats the surrounding tissue, i.e., the target area, to cause fractional wounding at the needle tip. An array of needles used in accordance with the present invention may comprise a mix of electrode needles and light-guide needles. Alternatively, each needle may carry a light guide and all of the energy used to cause thermal damage may be generated by the optical energy source instead of using RF or other electrical current. A portion of the light guide or light fiber, such as the portion at the tip of the needle, may be configured to absorb energy and facilitate conversion of the optical energy to heat. In these embodiments, the optical energy source may comprise, but is not limited to, a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG

laser, an argon-ion laser, a He-Ne laser, a carbon dioxide laser, an excimer laser, or a ruby laser. The optical energy conveyed by a light guide or light fiber may optionally be continuous or pulsed.

5 Treatments performed in accordance with the present invention may be used to target collagen in the dermis. This can lead to immediate tightening of the skin and reduction of wrinkles overlying the damaged tissue arising from contraction of the heated collagen. Over time, the thermal damage also promotes the formation of new collagen, which serves to smooth out the skin even more.

10 An alternative application of the methods of the present invention may be to reduce or eliminate the appearance of cellulite. To achieve this, the arrays of needles are configured to target the dermis and optionally the upper layer of subcutaneous fat directly. Creating dispersed patterns of small thermally-damaged regions in these layers can tighten the networked collagen structure and suppress the protrusion of the subcutaneous fat into the dermal tissue that causes cellulite.

15 Yet another application of the methods and apparatus of the present invention is to reshape cartilage. It is known that cartilage softens upon heating, and heating it to about 70 degrees C can soften the cartilage sufficiently to permit reshaping that persists upon cooling. Currently, specialized lasers are used to heat and soften cartilage in the nasal passages for reshaping. Using the methods and apparatus described herein, cartilage can be targeted by an
20 array of needles and heated in a suitably gradual way, using lower power densities and longer times, to provide relatively uniform heating. Shaping of the cartilage is thus possible using a minimally invasive technique that can be used where laser heating may not be feasible.

Any of the thermal damaging and tissue reshaping methods practiced in accordance with the present invention may be performed in a single treatment, or by multiple treatments
25 performed either consecutively during one session or at longer intervals over multiple sessions. Individual or multiple treatments of a given region of tissue can be used to achieve the appropriate thermal damage and desired cosmetic effects.

Having thus described in detail preferred embodiments of the present invention, it is to be understood that the invention defined by the above paragraphs is not to be limited to
30 particular details set forth in the above description as many apparent variations thereof are possible without departing from the spirit or scope of the present invention.

WHAT IS CLAIMED IS:

1. A tissue reshaping apparatus comprising:
a plurality of needles attached to a base, wherein the base is attached to a housing or part of the housing;
an energy source in communication with one or more of the needles; and
optionally comprising a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.
2. The apparatus of claim 1 wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles.
3. The apparatus of claim 2 wherein the energy source and/or control module is located outside of the housing.
4. The apparatus of any one of claims 1 to 3 wherein the energy source is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range.
5. The apparatus of any one of claims 1 to 4 wherein the energy source is capable of outputting an AC or DC electric current.
6. The apparatus of any one of claims 1 to 5 wherein the control module provides application-specific settings to the energy source, and wherein the energy source receives the settings, and generates a current directed to and optionally from specified needles for selectable or predetermined durations, intensities, and sequences based on the settings.
7. The apparatus of any one of claims 1 to 6 wherein the needles comprise sharp distal ends capable of piercing the surface of skin tissue and penetrating into the tissue until the lower side of the base contacts the surface of the skin.
8. The apparatus of any one of claims 1 to 7 wherein the control module is configured to deliver controlled amounts of RF current to one or more of the needles.
9. The apparatus of any one of claims 1 to 8 further comprising a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes.
10. The apparatus of claim 9 wherein the substrate is movably attached to the base or the housing and wherein the position of the substrate is adjustable relative to that of the base to control the depth of the needles protruding from the lower surface of the spacer substrate.

11. The apparatus of any one of claims 1 to 10 wherein the base and/or optionally, the spacer substrate, is planar or has a lower surface that is contoured to follow the shape of the region of tissue being treated.

12. The apparatus of any one of claims 1 to 11 wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminats pain when the plurality of needles penetrates the skin surface.

13. The apparatus of claim 12 wherein said cooling comprises embedded conduits containing circulating coolant or a Peltier device.

14. The apparatus of any one of claims 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a monopolar configuration.

15. The apparatus of any one of claims 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a bipolar configuration.

16. The apparatus of any one of claims 1 to 15 further comprising a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft.

17. The apparatus claim of 16 wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz.

18. The apparatus claim 17 wherein the vibrational amplitude of said vibrating means is between about 50-500 μm or between about 100-200 μm .

19. The apparatus of any one of claims 1 to 18 wherein the energy source and the control module are configured to deliver energy to a plurality of pairs of needles in bipolar mode..

20. The apparatus of any one of claims 1 to 19 wherein the diameter of the needles is between about 500-1000 μm or between about 700-800 μm .

21. The apparatus of any one of claims 1 to 20 wherein the average spacing of needles is between about 1 mm and 2 cm, and wherein the needles optionally are not uniformly spaced.

22. The apparatus of any one of claims 1 to 21 wherein one or more of the needles are hollow and are configured to deliver a local analgesic to the tissue surrounding the tip of the needle.

23. The apparatus of any of claims 1 to 22 further comprising an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles.

24. The apparatus of claim 23 wherein the detection device is in communication with the control module and the control module is configured to prevent the energy source from supplying energy to any needle if a nerve has been detected near that needle.

25. The apparatus of any of claims 1 to 24 further comprising a source of optical energy and one or more hollow needles containing light fibers or light guides, wherein the apparatus is configured to deliver a controlled amount of electromagnetic energy through the light fiber or light guide and into the tissue surrounding the tip of the hollow needle.

26. The apparatus of claim 25 wherein the optical energy source comprises a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG laser, an argon-ion laser, a He-Ne laser, a carbon dioxide laser, an excimer laser, or a ruby laser, and wherein the electromagnetic energy conveyed by the light guide or light fiber is continuous or pulsed.

27. A method of treating skin comprising the steps of:
providing a plurality of needles attached to a base;
providing an energy source in communication with one or more of the needles;
inserting the needles into the skin to a predetermined depth; and
supplying energy to more than one of the needles to induce a pattern of damage in the tissue surrounding the needles.

28. The method of claim 27 further comprising:
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

29. The method of claim 28 further comprising:
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin.

30. The method of claim 29 wherein the energy is RF current and the needles are insulated except near their tips.

31. The method of claim 30 further comprising:
providing a detection device in communication with one or more of the needles;
supplying low current to one or more of the needles sequentially to detect the presence of a nerve near the needles; and

preventing the energy source from supplying energy to any needle if a nerve has been detected near that needle.

32. The method of claim 27 further comprising:

providing one or more hollow needles attached to the base and injecting an analgesic through the hollow needles into the surrounding tissue after the needles are inserting into the skin.

33. The method of claim 29 further comprising:

providing hollow needles containing light fibers or light guides in communication with the energy source, wherein the energy source is a source of optical energy;

supplying energy to the light fibers or light guides to induce thermal damage in a portion of the tissue surrounding the hollow needles.

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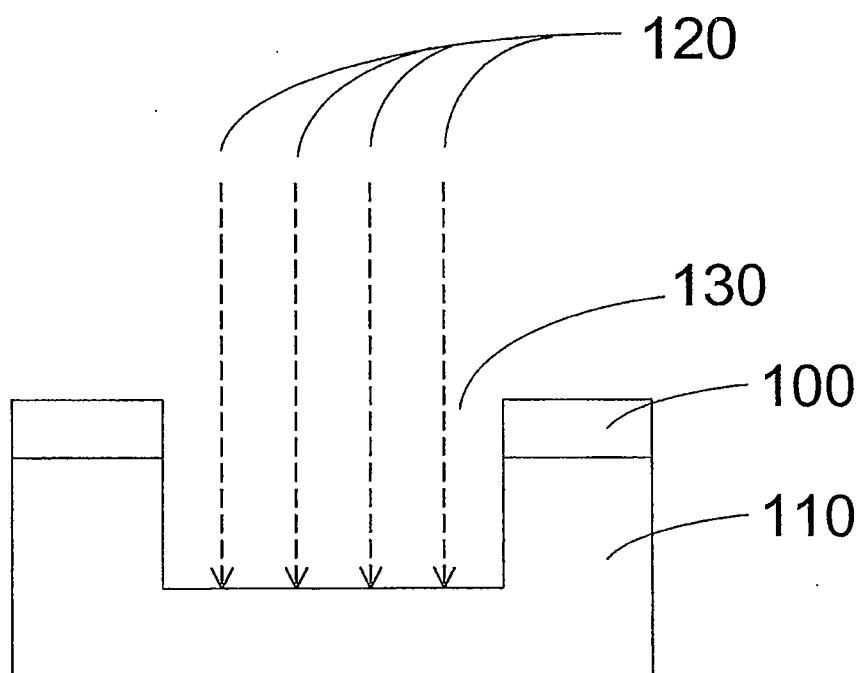


FIG. 1

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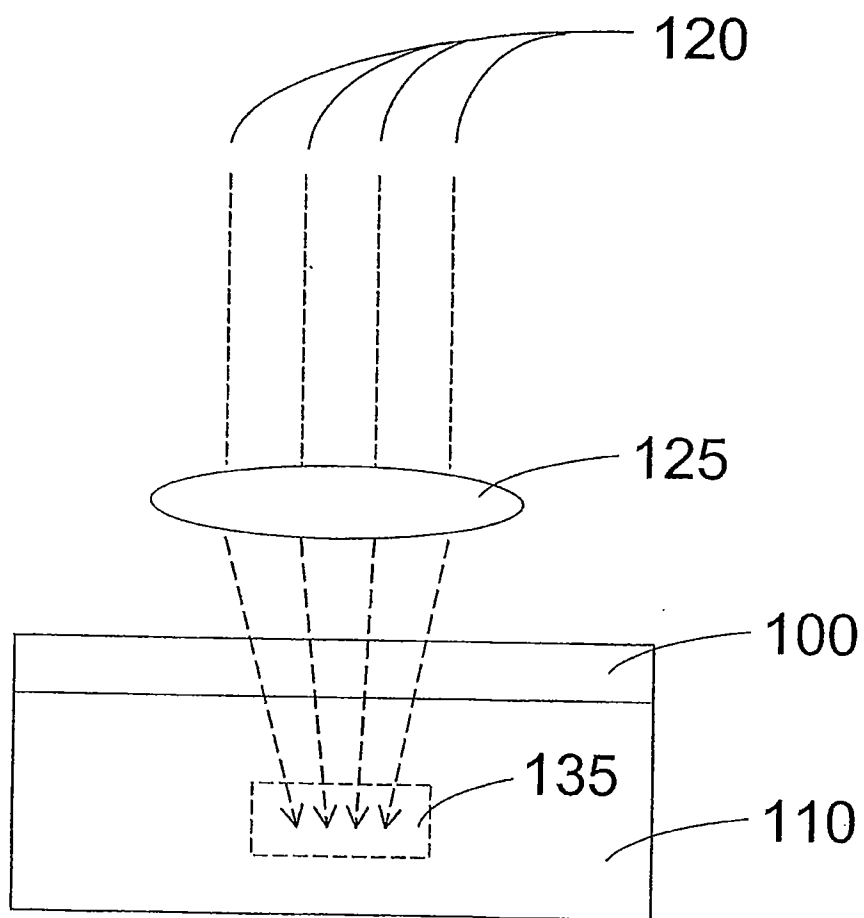


FIG. 2

3/4

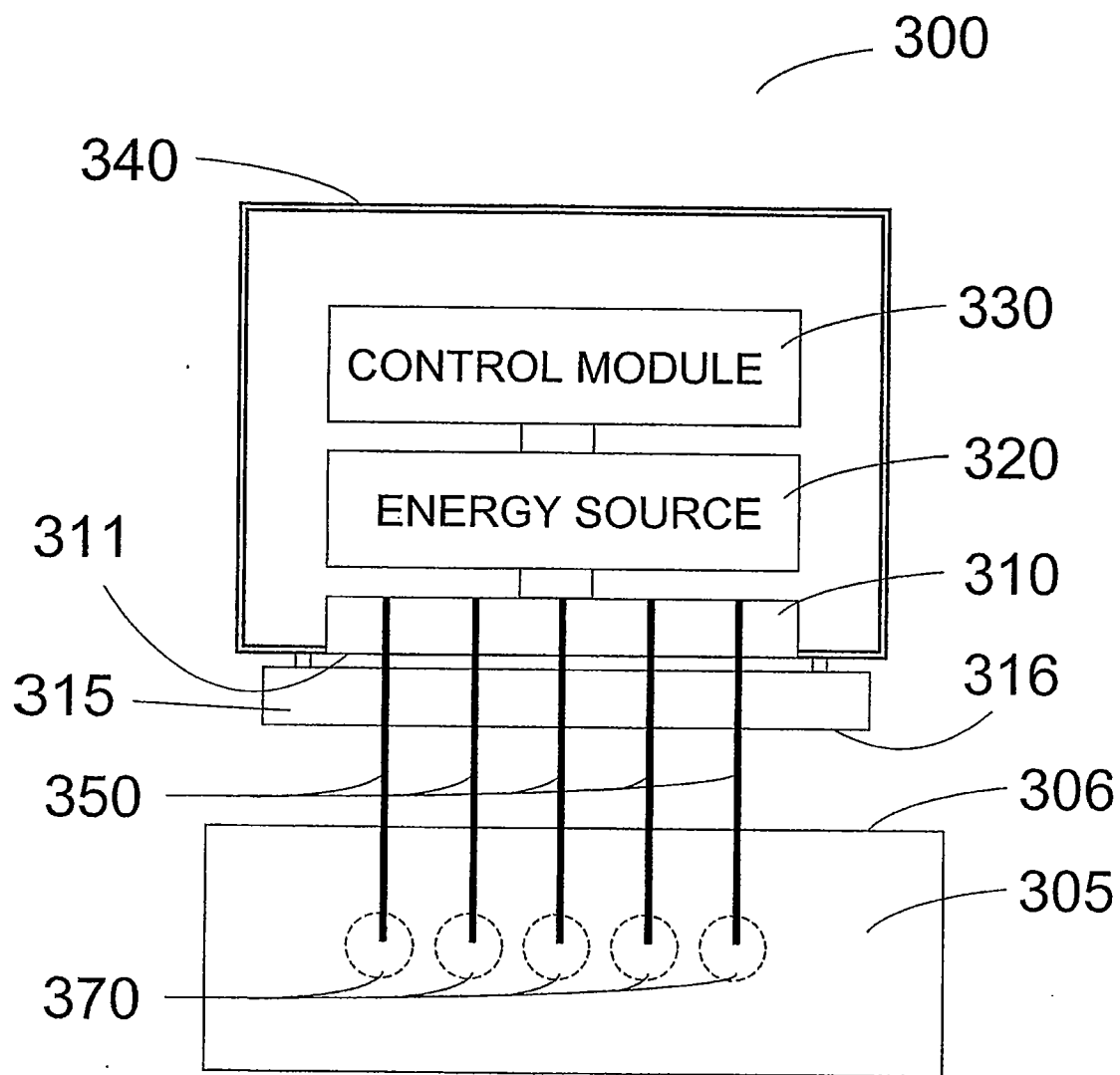


FIG. 3

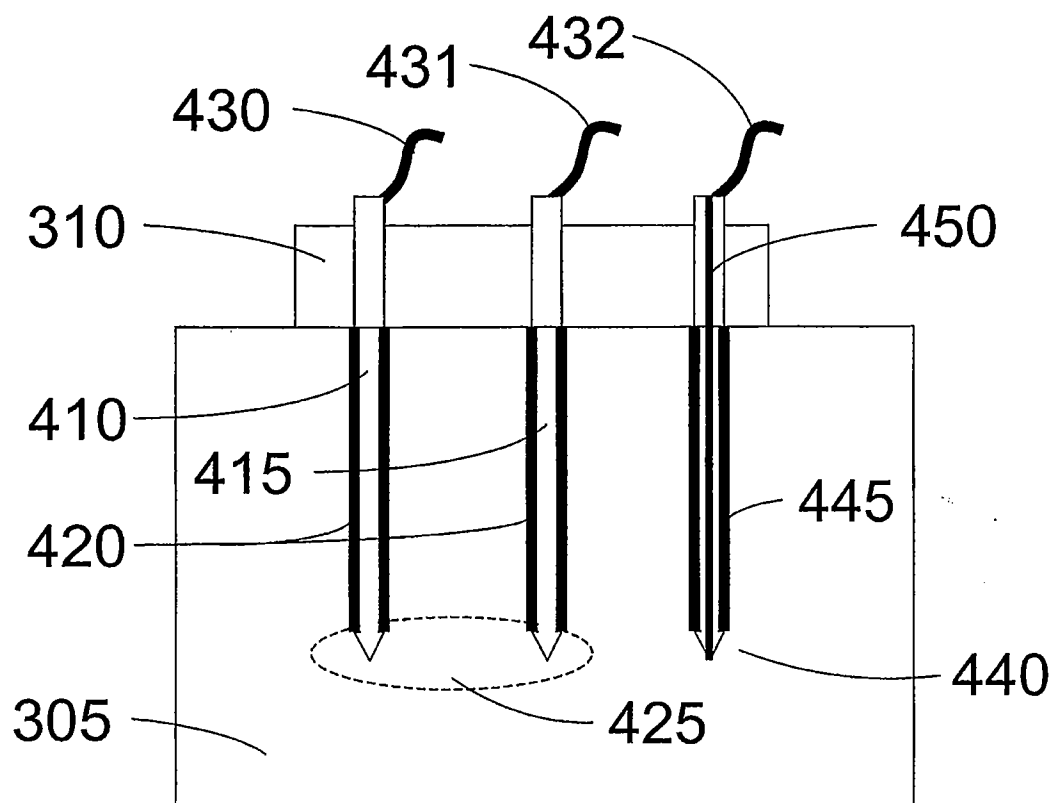


FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/011096

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14 A61N1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 277 116 B1 (UTELY DAVID ET AL) 21 August 2001 (2001-08-21) abstract; figures 6-9	1-15, 19-22
Y	column 3, line 49 - column 5, line 30 column 7, line 38 - column 10, line 9	16-18, 23-26
X	US 2002/128641 A1 (UNDERWOOD RONALD A ET AL) 12 September 2002 (2002-09-12) abstract; figures 5-8 paragraph '0032! - paragraph '0040! paragraph '0051! - paragraph '0056!	1-10, 12-15, 19-21
Y	WO 02/060523 A (BROWN, TONY, R; NGUYEN, HEIN; WADHWANI, SURESH; ADAME, OCTAVIO, V; LAU) 8 August 2002 (2002-08-08) paragraph '0063!; claims 19,20	16-18
-/-		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

5 July 2005

Date of mailing of the international search report

15/07/2005

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/011096

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	W.F. URMEY: "Percutaneous electrode guidance: A noninvasive technique for prelocation of peripheral nerves to facilitate peripheral plexus or nerve block" REGIONAL ANESTHESIA AND PAIN MEDICINE, vol. 27, no. 3, 2002, pages 261-267, XP002334726 cited in the application abstract page 262 - page 263	23,24
Y	US 5 861 002 A (DESAI ET AL) 19 January 1999 (1999-01-19) column 16, line 51 - column 17, line 20	25,26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/011096

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 27-33
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery, Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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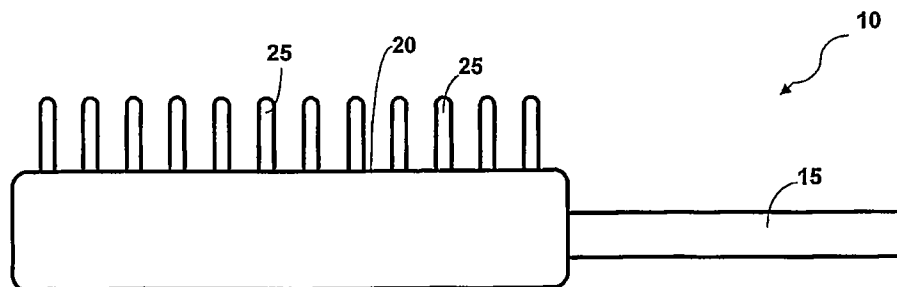
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(54) Title: DEVICE AND METHOD FOR TREATING TISSUE



(57) Abstract: A device for creating a pattern of perforations in a tissue, comprising a treating surface coupled to a distal end of the elongated member and configured to be positioned adjacent one or more tissue planes, a plurality of electrodes extending outwardly from at least one surface of the treating surface and adapted for creating simultaneous perforations in one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers. Methods of using the device and methods of creating perforations in one or more layers of tissues are also provided.

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DEVICE AND METHOD FOR TREATING TISSUE

FIELD OF THE INVENTION

The invention relates to a device and method for treating one or more
5 layers of tissue, for example by simultaneously imparting perforations into the one
or more layers. In particular, the invention relates to a device and method for
treating one or more layers of the skin to elicit a healing response which produces
a more desirable skin appearance.

10 BACKGROUND OF THE INVENTION

Several undesirable conditions of the skin are commonly seen in
dermatologic practice, which may be caused by age, exposure to the sun's
ultraviolet rays, and other influences. For example, acne scars, burn scars,
erythema, fine lines, wrinkles or other irregular conditions are undesirable. There
15 are currently several ways to treat these conditions. For example, many topical
medications are available such as retinoic acid, hydroxyquinones, alpha hydroxy
acids and chemicals peels. These offer some improvement in skin texture and
coloration, yet they are irritating to use and only offer mild improvement. More
aggressive measures using dermabrasion, lasers and surgical scar revisions have
20 also been used.

All of these methods are generally used to horizontally treat or remove one
or more layers of tissue, so that entire layers of tissue are seared, cauterized or
otherwise removed. Thus, all of these methods remove entire layers of skin or
tissue, so that new layers form during healing. Cosmetic improvement is seen
25 when the skin containing wrinkles or another undesirable mark is replaced by a
new layer of skin.

However, all of these methods disrupt and completely remove the
epidermis. The resulting open wounds require daily care to optimize wound
healing. The open wounds also increase the risk of infection, which can lead to
30 prolonged healing time and scarring. Procedures involving the complete removal
of the epidermis are also painful and require general anesthesia. Also, due to the
amount and type of tissue removal, one or two weeks of healing time and constant

skin care are needed. Also, patients often experiences two to four months of having red sensitive skin.

Epidermal destruction and subsequent healing may also cause side effects including prolonged hypopigmentation, hyperpigmentation, erythema and edema.

- 5 Hyperpigmentation occurs frequently in darker skin types as a result of an inflammatory response of the skin. Hyperpigmentation results in the treated area of the subject's skin turning darker than the surrounding untreated skin. Hyperpigmentation can be slow to clear, sometimes taking up to a year to disappear. Hypopigmentation is attributable to damage to the melanin-producing
- 10 cells in the skin. While generally transient, hypopigmentation can be permanent, and is cosmetically undesirable while it persists. Also, erythema or redness of the skin may be significant for weeks to months after the procedure, requiring the patients to wear conspicuous amounts of make-up.

- Certain methods have been developed to treat one or more layers of skin
- 15 without removing entire layers of tissue. One example of device which treats tissue in this manner is the FRAXEL infrared scanning laser. This device uses a scanner to direct a small 10-70 micron diameter laser beam across the tissue surface in order to create small vertical zones of coagulated tissue. One drawback with the FRAXEL laser is that the laser does not create perforations or vertical
- 20 holes in the tissue, but only causes zones of coagulation. Applicant has discovered that it is desirable to create vertical perforations or ablation holes in tissue, as this prompts an even more aggressive wound healing response than is currently seen. When perforations are created, tissue layers surrounding the perforations are left untreated and contribute to tissue regeneration. Thus, the
- 25 treated tissue can heal and regenerate from all edges of the perforation wound, not just from the tissue areas underneath the wound. Perforations allow for a faster regeneration and healing time. The use of perforations are also advantageous in that by leaving zones of untreated tissue in between the perforations, less scarring and/or pigmentations are visible. Thus, there is a need
- 30 for a device and method which imparts actual perforations into the skin, thereby promoting more aggressive healing.

Another drawback with the FRAXEL laser and other devices is that they are manually operated by the medical provider. The quality of the treatment depends

largely on the medical provider's skill in operating the device. With the FRAXEL laser, the precise number of coagulations in the tissue is entirely dependant upon the speed and number of passes the laser is moved along the skin by the operator. Thus, there is a lot of room for operator error and it is difficult to control
5 or otherwise standardize the treatment. Control circuits have also been developed to monitor and track the speed of treatment. However, such circuits are often complicated and expensive. Therefore, there is a need for a device which allows for more standardized treatment and which reduces the chance of operator error. There is also a need for a device which is more simplified and less expensive than
10 current devices.

Additionally, even if a simple knife, needle or other device is used to cause perforations in tissue, this would be a cumbersome process and would require that perforations be made one at a time. Again, the depth, width, and pattern of perforations would be subjected to the skill of the operator and would not be
15 standardized. Thus, there is a need for a more standardized device which can impart perforations into tissue in a simultaneous and standardized manner. Also, when perforations are made mechanically rather than with the use of energy, excess bleeding takes place. Thus, there is also a need for a device which creates perforations without causing undue bleeding.

20 A yet another drawback to lasers and other prior devices is that they use deep penetrating laser light or other harmful energies which can cause ocular injury if used too close to the eyes. There are often many skin conditions which are present near the eyes which would benefit from aggressive treatments. Thus, it is desirable for a device which uses a form of energy that is safe when used
25 close to the eyes and other delicate body parts.

BRIEF SUMMARY OF THE INVENTION

In some embodiments, the invention provides a device for creating a pattern of perforations in a tissue. The device comprises a treating surface
30 configured to be positioned in contact with tissue adjacent one or more tissue planes and a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding

pattern of perforations in the one or more tissue layers. The electrode pattern can be selected to create perforations which are between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns. The electrode pattern can also be
5 selected to create a zone of coagulative tissue surrounding each perforation. In some cases, the zone of coagulative tissue has a length of between about about 5 microns to about 100 microns. The electrodes can also have a depth and width for providing perforations being no more than about 2 mm in depth and about 0.5 mm in width. Likewise, the electrodes can have a spacing for providing
10 perforations spaced apart by no more than about 5 mm or less.

The device also includes an energy source coupled to the plurality of electrodes, the energy source configured to deliver energy selected from the group consisting of radio frequency, non-ionizing ultraviolet radiation, or microwave radiation. A control device may also be coupled to the energy source.
15 In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy. The electrodes can be provided as a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are monopolar electrodes whereas in other cases the electrodes are bipolar electrodes. The electrodes can also be configured to provide power in the range
20 of about 50 to about 200 watts per square centimeter and also configured to provide an energy of at least about 1 joule per square centimeter. In many cases, one or more sensors are coupled to the plurality of electrodes.

The treating surface of the treatment device can be selected from the group consisting of a flexible surface, contoured surface, rigid surface, horizontal
25 surface, rolling surface, expandable surface and three-dimensional surface. In some cases, the treating surface is an expandable surface and is sized in an expanded state to conform to a surface of a tissue. In other cases, the treating surface is a horizontal surface and is applied to the one or more tissue planes in a stamping motion. In yet other cases, the treating surface is a rolling surface and is
30 applied to the one or more tissue planes in a rolling motion.

In certain embodiments, a device is provided for creating a pattern of perforations in a tissue. The device includes an elongated member, a treating surface coupled to a distal end of the elongated member and configured to be

positioned adjacent one or more tissue planes, and a plurality of monopolar RF electrodes extending outwardly from at least one surface of the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding
5 pattern of perforations in the one or more tissue layers.

A method for creating a pattern of perforations in tissue is also provided. The method includes the steps of providing a device having a treating surface which includes a plurality of electrodes extending outwardly from the treating surface, wherein the plurality of electrodes are arranged in a desired pattern,
10 placing the treating surface in contact with tissue adjacent to one or more tissue planes, and delivering energy to the electrodes to simultaneously impart perforations into one or more layers of the tissue, wherein the perforations correspond to the electrode pattern.

A kit for creating a pattern of perforations in tissue is also provided. The kit
15 includes two or more devices, wherein each of the devices have either a differently sized treating surface, a differently shaped treating surface, a different treating surface type, a different electrode pattern, a different electrode width, a different electrode length or a different electrode spacing.

A method for treating human skin is also provided. The method includes
20 identifying a target area of skin, providing a device adapted to simultaneously create a desired pattern of perforations into one or more layers of the target area of skin, and simultaneously perforating the target area to provide the desired pattern of perforations which elicit a healing response that produces a revitalized skin surface.

25

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of the distal end of a treatment device in accordance with one embodiment of the invention.

Figure 2 is a side view of the distal end of a treatment device in accordance with
30 another embodiment of the invention.

Figure 3 is a side view of the distal end of a treatment device in accordance with yet another embodiment of the invention.

Figure 4 is a front view of the distal end of a treatment device showing an electrode pattern in accordance with one embodiment of the invention.

Figure 5 is a front view of the distal end of a treatment device showing an electrode pattern in accordance with another embodiment of the invention.

5 Figure 6 is a front view of the distal end of a treatment device showing an electrode pattern in accordance with another embodiment of the invention.

Figure 7 is a front view of the distal end of a treatment device showing an electrode pattern in accordance with another embodiment of the invention.

10 Figure 8 is a cross-sectional view of a treated skin surface according to a prior art method.

Figure 9 is a cross-sectional view of a treated skin surface according to an embodiment of the invention.

Figure 10 is a top view of a treated skin surface according to an embodiment of the invention.

15

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A device and method are provided for treating one or more tissue layers by providing a plurality of vertical perforations in a simultaneous fashion. The device does not remove entire layers of tissue, but rather creates perforations in one or
20 more layers. These perforations create holes, which extend vertically into the tissue and across one or more layers. In some cases, the holes extend deep into the tissue across several layers. In other cases, the holes are shallow, and extend across only one or two superficial layers of tissue. As used herein, the term "perforation" means vertical areas of thermal damage or ablation to the tissue
25 causing tissue necrosis.

Figure 8 illustrates a skin area treated in accordance with a prior method. The skin area in Figure 8 has been treated using a FRAXEL infrared scanning laser. The laser causes coagulation, indicated at reference number 2. A perforation is not created at area 2, which is treated by the laser. On the other
30 hand, Figure 9 illustrates a skin area treated in accordance with the invention. The treated area 4 is clearly a perforation, which extends vertically into the skin. Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation 4. Likewise, with reference to Figure 10, zones of coagulation are seen

on areas of the skin surface surrounding the perforation 4. Generally, these zones extend into the tissue in all directions originating from the perforation site. These zones of coagulation are beneficial as coagulation leads to tissue regeneration.

The device and method also allow for controlled placement of perforations
5 having a predetermined depth, width and degree of separation. Such perforations are so small that they cannot be seen with the naked eye. The treatment device is advantageous because it creates several perforations simultaneously with one or a few discharges of energy.

Many conditions can be treated by imparting a plurality of vertical
10 perforations into tissue. In most cases, skin conditions are treated by creating perforations into the skin. For example, the device can be used on skin areas suffering from photo-aging or sun-damage. The device can also be used on skin areas exhibiting acne scars, burn scars, erythema, fine lines, wrinkles, irregular pigmentations, precancerous or cancerous lesions or other irregular conditions.
15 The creation of perforations in the skin helps to revitalize or rejuvenate these irregular areas to make them more desirable in appearance. The zones of coagulation created in the tissue area surrounding each perforation also help to revitalize and rejuvenate skin.

In other cases, the device and method are used to treat the uterus lining for
20 excess menometorrhagia. In yet other cases, the device and method are used to treat conductive abnormalities of the heart. The heart could also be treated to treat conductive abnormalities by ablating multiple foci of aberrant electrical paths.

The treatment device and method provide several advantages. For example, the treatment allows for a more standardized and controlled method of
25 treating tissue, since the perforations are provided in a pre-selected pattern. An operator uses the device to impart the pre-selected pattern of perforations into the skin and does not create each perforation individually, thereby reducing chances of operator error. The device also imparts perforations into the skin, rather than merely imparting coagulations into the skin. The creation of actual perforations
30 leads to more aggressive healing responses. Additionally, the use of perforations into skin rather than removal of entire skin layers reduces the chances of scarring and promotes a faster healing time.

The treatment device includes a treating surface, which is adapted to be placed in direct contact with a tissue adjacent a tissue plane to be treated. The treating surface is generally positioned adjacent to a tissue plane of the tissue to be treated. One or more layers of the tissue in the tissue plane can be treated. In some cases, it is desirable to only treat the outermost layer of tissue, while leaving the deeper layers untreated. In other cases, it is desirable to treat the deeper layers of tissue as well. The tissue to be treated can include almost any tissue. In some cases, the tissue includes one or more layers of organ tissue. In other cases, the tissue includes one or more layers of skin.

In many tissues and/or organs, natural layers are present. Typically, organ layers include an inner mucosal layer, a submucosal layer, a muscularis layer and an outer serosal layer. For example, an esophagus includes a mucosal layer, a submucosal layer, and a muscularis layer. A uterus wall includes a mucosal layer (known as the endometrium), a fibromuscular layer (known as the myometrium) and an outer serosal layer. In some cases, it is desirable to treat an innermost mucosal layer, while leaving the intermediate submucosal layer intact. In other cases, it is desirable to treat both mucosal and submucosal layers, while leaving the muscularis layer intact. Again, any type and number of layers can be treated with the invention.

Similarly, the skin includes natural layers. Human skin consists mainly of two layers: the top layer of skin known as the epidermis; and the layer beneath the epidermis known as the dermis. The dermis is primarily acellular and is composed of water, the protein collagen, and glycosaminoglycans. Collagen and glycosaminoglycans are constantly produced by fibroblasts, a type of connective tissue cell, degraded by enzymes. With aging, the amount of dermal collagen decreases and is replaced by the protein elastin. In addition, the remaining collagen tends to be chaotically oriented as compared to the more organized patterns found in youthful skin.

Glycosaminoglycans are very hydrophilic, and increased amounts of these carbohydrates are associated with the increased skin vigor found in youthful skin. One major difference between the smooth, supple skin of newborns and the drier, thinned skin of older individuals is the far greater relative amount of glycosaminoglycans found in newborn skin. The glycosaminoglycans found in

newborns can bind up to 1000 times their weight in water. As the skin ages and the amount of glycosaminoglycans decreases, the skin may become less hydrated and lose some of the suppleness found in youth. The treatment device can be used to create perforations and zones of coagulation across both the epidermis and dermis to activate fibroblasts which deposit increased amounts of extracellular matrix constituents (i.e., collagen and glycosaminoglycans). These increases in extracellular matrix constituents are responsible for dermal skin rejuvenation.

The treating surface of the treatment device can be provided in any desired shape or configuration. In most cases, the treatment device is used to treat layers of the skin, and a treating surface is provided having a surface which conforms to the external part of the body wherein the skin is treated. However, the size and shape of the treating surface is variable and often depends on the surface area of tissue to be treated. For example, the treating surface can be provided as a horizontal surface, three-dimensional surface, rigid surface, curved surface, contoured surface, expandable surface or the like.

In certain embodiments, the treating surface is an expandable surface, e.g., an expandable balloon. Suitable expandable treating surfaces include but are not limited to a balloon, compliant balloon, balloon with a tapered geometry, basket, plurality of struts, an expandable member with a furled and an unfurled state, one or more springs, foam, bladder, backing material that expands to an expanded configuration when unrestrained, and the like. The expandable surface can be made of a variety of different materials, including but not limited to an electroconductive elastomer such as a mixture of polymer, elastomer, and electroconductive particles

The expandable surface can be made to expand to a fixed size or a variable size. In particular cases, the expandable surface in its expanded state has a diameter in the range of between about 0.5 mm to about 5 cm. In cases where the treatment device is placed inside of a hollow organ, it may be desirable to provide a treating surface which has a shape and size which expands to conform to the interior shape of an organ. The expandable surface can also be configured to stretch the hollow interior of an organ. This stretching of tissue often impedes blood flow into the treatment area.

In certain cases, especially wherein the treatment device is used inside of the body, the treating surface can be provided as a three-dimensional surface, which corresponds to the surface of a particular body organ. For example, the surface can conform to the interior space of an organ to treat a layer of tissue lining the interior space. The surface can also conform to an exterior surface of an organ to treat the exterior layer of tissue lining the exterior surface of the organ.

In some cases, the treatment device includes an elongated member or shaft that has a proximal end and a distal end. The elongated member is especially desirable when using the treatment device inside of the body. The treating surface is generally provided about the distal end and in some cases, the treating surface may be the distal end of the elongated member itself. In such cases, the distal end is configured as a surface adapted for contacting a desired tissue plane. In most cases, however, the distal end will be coupled to a separately provided treating surface. The treating surface can be bonded or otherwise attached to an area along the distal end. In cases where the treatment device is placed inside of the body to treat menometorrhagia, conductive abnormalities of the heart or other internal conditions, an operator manipulates the proximal end to cause the distal end to be inserted into a desired place in the body. The distal end can be inserted and positioned into the body in any of various ways known in the art and selected by the operator, including using endoscopic methods, surgical methods and other methods. The treatment device can also include steerable and directional control devices to aid the operator in positioning the distal end within the body.

When the treating surface is expandable and desired to be expanded inside of the body, it may be desirable to provide the member in a folded positioned and placed within a sheath during positioning of the distal end within the body. This prevents the treating surface from taking up too much space, so the distal end can be guided through narrower channels in the body. Once the distal end is positioned at a desired site in the body, the sheath can be removed, for example by retracting it along the shaft to expose the treating surface.

The treating surface generally includes a plurality of electrodes positioned about at least a portion of its circumference so that the electrodes come into contact with the tissue. The electrodes can be provided about the entire surface of

the treating surface or about a portion of the surface. The areas of tissue in contact with the electrodes are those areas which are perforated.

The electrodes are arranged in a pattern to create the desired pattern of perforation in tissue. The electrodes are preferably configured as spikes or pins which extend outwardly from the treating surface. For example, Figure 1 illustrates a treatment device 10 having a treating surface 20 connected to a distal end or shaft 15. A plurality of electrode pins 25 are positioned about a portion of the treating surface. When it is desired to apply the treating surface 20 of Figure 1, one uses a stamping motion and stamps the tissue layers with the treating surface 20.

Likewise, Figure 2 also illustrates a treatment device 10 having a plurality of electrode pins 25 positioned about a treating surface 20. However, the electrode pins in Figure 2 are positioned about substantially the entire surface of the treating surface whereas in Figure 1, the electrode pins are positioned only about one surface of the treating surface. Whereas the treating surfaces in the illustrated Figures have a flat or sheet-like shape, it should be understood that they can provided in any suitable shape and/or adapted to be expanded into any suitable shape.

Figure 3 illustrates a treatment device 10 having a rolling treating surface 20. Here the treating surface 20 can be rolled along a tissue plane, creating perforations along the way. When it is desired to apply the treating surface 20 of Figure 3, one uses a rolling motion and creates the perforations by rolling.

The electrodes are positioned on the treating surface in any manner to provide a desired pattern of perforations into the one or more tissue planes. Generally, the electrodes come into direct contact with the one or more tissue planes. So, the pattern of electrodes directly correspond to the pattern of perforations desired in the tissue. Any desired pattern or electrode arrangement is within the scope of the invention. In certain cases, the electrodes are patterned in order to create perforations being between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns. In other preferred cases, the electrodes have a depth and width for providing perforations being no more than about 2 mm in depth and about 0.5 mm in width. In yet other cases, the electrodes have a spacing for

providing perforations spaced apart by no more than about 5 mm or less and more preferably no more than about 2 mm or less.

Zones of coagulation are also created in areas of tissue surrounding each perforation. The zones can extend from the perforation site into the tissue for a
5 length ranging from about 5 microns to about 100 microns. The zone of coagulation can be varied by changes in energy and power levels .

It should be understood that not all of the electrodes present on a treating surface need to be of the same size. Also, the spacing between electrodes can be varied along the treating surface, to create certain desired affects. In some cases,
10 the electrodes in the center of the treating surface are spaced more closely than the electrodes on the edges of the treating surface. This provides for a feathered effect, so that no sharp lines are seen at the areas where the treated skin meet the untreated skin.

In some cases, the electrodes are arranged in an orderly pattern. Figures
15 4-7 illustrate electrodes 25 provided in various electrode patterns and positioned on a portion of the treating surface 20. Each of the Figures 4-7 illustrate an orderly pattern of electrodes. However, in some cases, a random electrode pattern may be desired. In further cases, a feathered pattern may be desired to reduce the lines seen between the treated tissue and untreated tissue. The length of the
20 electrode arrangement on the treating surface can also be varied. In certain embodiments, the length of the plurality of electrodes is in the range of about 0.5 mm to about 5 cm.

The outer tips of each electrode are designed to be placed into contact with a tissue plane. Energy is delivered to the tip to provide the perforation of tissue. In
25 some cases, when it is desirable to provide a deeper perforation, the electrode pins are placed all the way into the tissue, so that more than one layers of tissue are treated. When it is desirable to provide an even deeper perforation, the electrode pins can be providing having longer lengths, so that the tips are placed even deeper into the tissue layers. The length and width of the electrode pins are
30 variable and can be chosen based on the desired treatment. Again, in preferred embodiments, the electrodes are provided having a length and width which creates perforations having a depth of no more than about 2 mm and a width of no more than about 0.5 mm.

The electrodes can also be spaced apart at a desired length so that the perforations in tissue will also be spaced apart at that length. Any length between electrodes is within the scope of the invention. In some cases, each of the electrodes on a treating surface are spaced apart evenly whereas in other cases, some electrodes on a treating surface are spaced apart at a smaller length than other electrodes. The spacing of the electrodes can be adjusted in order to provide any desired spacing of perforations. With reference to the Figures, the electrodes of Figure 3 have a larger spacing than the electrodes of Figure 4. In certain embodiments, electrodes are provided on a treating surface have a spacing of less than about 5 mm, and preferably less than about 2 mm.

The width or diameter of each electrode pin can also be varied to provide a perforation having a desired width. For example, the electrodes of Figure 5 and 6 have a larger width than the electrodes of Figures 3 and 4. In most cases, the width of each electrode pin on a particular treating surface will be the same, although this is not necessary. Electrode pins having different widths can be provided. The width of the perforation created will be at least the width of the electrode, and in many cases larger. The width of the perforation created depends not only on the width of the electrode, but also the level of energy discharged from the electrode. When more energy is discharged from the electrode, a larger perforation width and depth is created. Additionally, the width of perforation may be tapered with depth.

The electrodes can also be arranged as an array of electrodes. In some cases, the electrode pairs are arranged as a contiguous sequence of arrays. In particular embodiments, the electrodes are provided as a contiguous sequence of arrays with a single common RF electrode along an entire length of the arrays. The electrodes can be also provided as a pattern of electrode pairs rather than as a pattern of individual electrodes. The electrodes in some cases are provided as an array of electrode pairs. In other cases, each electrode pair has an electrode which is divided into a sequence of selectable lengths. In further cases, each electrode in an electrode pair is parallel to an adjacent electrode. Figure 6 illustrates a pattern of electrode pairs. Doctors can choose a particular pattern based on the desired treatment needed for a tissue.

The electrodes can be either monopolar or bipolar electrodes. In some embodiments, the electrodes are monopolar electrodes. In a monopolar electrode arrangement, one electrode serves as a treating electrode and another electrode is provided as a return electrode. The return electrode generally has a much
5 larger area than the treating electrode and is placed out of the treated area. In certain cases, the treating device of the invention is provided having a monopolar electrode arrangement, wherein the electrode pins extending outwardly from the treating surface serve as treating electrodes and a grounding pad is placed within the treating surface to serve as the return electrode. In embodiments wherein the
10 electrodes are provided as individual electrodes rather than in pairs, monopolar electrodes are desirable.

In other embodiments, the electrodes are provided as a bipolar electrode arrangement. In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are
15 bipolar axial interlaced finger electrodes. In embodiments wherein the electrodes are provided as electrode pairs, bipolar electrodes are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode. The electrodes can be shaped in such a way that the middle portion of distal portion is enlarged in order to create a zone of injury that is
20 greater at the distal end compared to the proximal end. The base of the treatment pad or treating surface and various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well.

The treatment device also includes an energy source coupled to the
25 electrodes for delivering energy to the electrodes. The energy delivery device can deliver a variety of different types of energy including but not limited to, radio frequency energy, non- ionizing ultraviolet radiation and microwave radiation. In some cases, the electrodes are configured to provide power in the range of about 50 to about 200 watts per square centimeter. In other cases, the electrodes are
30 configured to provide an energy of at least about 1 joules per square centimeter.

In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes. RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue

being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use
5 on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes.

The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue. The energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a
10 controlled depth and/or width of perforation. The energy source can also be coupled to a controller, which may be a digital or analog controller for use with the energy source, including but not limited to an RF source, or a computer with software. When the computer controller is used it can include a CPU coupled through a system bus. The system may include a keyboard, a disk drive, or other
15 non-volatile memory system, a display and other peripherals known in the art. A program memory and a data memory can also be coupled to the bus. The energy source can be positioned at different positions in proximity to the treatment device.

For those treatment devices employing a variably shaped expandable member (e.g., that conforms to an oddly shaped organ or external body part), the
20 desired power and energy settings can be scaled as needed so that each electrode delivers the same power and energy per unit area. These changes can be made either automatically or from user input to the RF power source. If different treatment depths are desired for one or more electrodes on the expandable member, the geometry of the some of the electrodes can be modified
25 to create either a deeper or more superficial treatment region than other electrodes.

In some embodiments, one or more sensors can be positioned upon one or more electrode pins in order to monitor the temperature, depth or diameter of perforation, and the like. For example, in some cases, a temperature sensor is
30 coupled to the electrodes. In other cases, a multiplexer is coupled to the electrodes. In yet other cases, a multiple-pin electrical connector is coupled to the electrodes.

In some embodiments, a surgical kit including differently sized treatment devices is provided, each device having a differently sized or shaped treating surface, different treating surface type, different electrode pattern, a different electrode size, diameter or length, and/or a different level of energy delivery. An operator can select various treatment devices which are best suited for a given application. Furthermore, when treating areas of the skin, the use of different devices can aid an operator in feathering the edges of the treatment zone, so that no sharp lines are seen at the areas where the treated skin meet the untreated skin. For example, the number of the perforations can be gradually decreased when moving from the treated skin to the untreated skin. This can be accomplished by using a device having a greater number of perforations on the treatment skin and then by supplementing this device with those having less perforations when moving from the treatment areas to the non-treated areas.

Methods for vertically treating one or more layers of tissue in a tissue plane are also provided. The method generally includes simultaneously imparting perforations into one or more tissue layers in a tissue plane. In a preferred embodiment, a method is provided for simultaneously imparting perforations into one or more layers of skin. In many cases, skin areas along the face, neck, chest and hands will be treated. The treatment area of the skin is first cleansed using a cleanser, for example a mild, gently abrasive skin cleanser. A topical may then be applied to the treatment area to numb the skin so that a patient will not feel and prickling or heat sensation during treatment. In some cases, the topical will be a lipid based topical anesthetic ointment. A treatment device according to any of the embodiments already described is provided and the treating surface is placed in contact with a desired area of the skin. The device is activated to create a plurality of perforations in the skin. In many cases, the same area of skin will be treated several times and usually at different time intervals.

In another embodiment, methods are provided for treating tissue inside of a body. The operator may first determine the length of the portion of the tissue needing treatment inside of the body by visual observation through an endoscope. The provider then selects a treatment device having an electrode pattern which is best suited for treating that portion of tissue. For example, when the tissue is a small patch of tissue on an esophagus, a treatment device having electrodes only

on one surface may be desirable. On the other hand, when the issue is the interior lining of a hollow organ, the treatment device may include an expandable member which in an expanded state, conforms to and/or stretches the interior wall of the organ. Once the desired treatment device is in place, the energy source is
5 activated to deliver energy to the electrodes. Following treatment, the medical provider may do an endoscopic evaluation of the treated areas.

Example

A freshly exercised pig skin was obtained. A monopolar electrode array was placed upon the skin. The array consisted of two 0.3 mm length needles
10 placed in a row 500 microns apart. The array was hooked up to an electrical generator. A power of 50 watts and an energy of 1 joule were delivered to the electrode array. A 4 mm punch biopsy was taken and process for routine light microscopy. Upon examination of the tissue, both the epidermis and dermis were perforated by two equivalent vertical perforations. The perforations were widest at
15 the top (50 to 100 microns in diameter) and tapered to a point at a depth of 250-300 microns. Throughout the edge of the injury, a 10-50 micron zone of coagulation was also seen.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be
20 exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

WHAT IS CLAIMED IS:

1. A device for creating a pattern of perforations in a tissue, comprising
a treating surface configured to be positioned in contact with tissue
adjacent one or more tissue planes;
5 a plurality of electrodes extending outwardly from the treating surface and
adapted for imparting simultaneous perforations into one or more tissue layers,
wherein the electrodes are provided in a pattern to impart a corresponding pattern
of perforations in the one or more tissue layers.
2. The device of claim 1 wherein the electrode pattern also selected to create
10 a zone of coagulative tissue surrounding each perforation.
3. The device of claim 1 wherein the electrode pattern also selected to create
a zone of coagulative tissue surrounding each perforation, wherein the zone of
coagulative tissue has a length of between about 5 microns to about 100 microns.
4. The device of claim 1 wherein the electrode pattern is selected to create
15 perforations which are between about 30 to about 100 microns in diameter, up to
about 1000 microns deep and spaced apart by between about 50 to about 400
microns.
5. The device of claim 1 wherein the plurality of electrodes have a depth and
width for providing perforations being no more than about 2 mm in depth and
20 about 0.5 mm in width.
6. The device of claim 1 wherein the plurality of electrodes have a spacing for
providing perforations spaced apart by no more than about 5 mm or less.
7. The device of claim 1 further comprising an energy source coupled to the
plurality of electrodes, the energy source configured to deliver energy selected
25 from the group consisting of radio frequency, non-ionizing ultraviolet radiation, or
microwave radiation.
8. The device of claim 7 further comprising a control device coupled to the
energy source.
9. The device of claim 1 wherein the plurality of electrodes are RF electrodes
30 and are configured for receiving RF energy.
10. The device of claim 1 wherein the plurality of electrodes are provided as a
plurality of electrode pairs.

11. The device of claim 1 wherein the plurality of electrodes are provided as an array of electrodes.
12. The device of claim 1 wherein the plurality of electrodes are monopolar electrodes.
- 5 13. The device of claim 1 wherein the plurality of electrodes are bipolar electrodes.
14. The device of claim 1 wherein the treating surface is selected from the group consisting of a flexible surface, contoured surface, rigid surface, horizontal surface, rolling surface, expandable surface and three-dimensional surface.
- 10 15. The device of claim 14 wherein the treating surface is an expandable surface and is sized in an expanded state to conform to a surface of a tissue.
16. The device of claim 14 wherein the treating surface is a horizontal surface and is applied to the one or more tissue planes in a stamping motion.
17. The device of claim 14 wherein the treating surface is a rolling surface and
15 is applied to the one or more tissue planes in a rolling motion.
18. The device of claim 1 wherein the electrodes are configured to provide power in the range of about 50 to about 200 watts per square centimeter.
19. The device of claim 1 wherein the electrodes are configured to provide an energy of at least about 1 joule per square centimeter.
- 20 20. The device of claim 1 further comprising one or more sensors coupled to the plurality of electrodes.
21. A device for creating a pattern of perforations in a tissue, comprising
an elongated member;
a treating surface coupled to a distal end of the elongated member and
25 configured to be positioned adjacent one or more tissue planes;
a plurality of monopolar RF electrodes extending outwardly from at least one surface of the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more
30 tissue layers and also a zone of coagulative tissue around each perforation.
22. A method for creating a pattern of perforations in tissue, comprising the steps of:

providing a device having a treating surface which includes a plurality of electrodes extending outwardly from the treating surface, wherein the plurality of electrodes are arranged in a desired pattern;

5 placing the treating surface in contact with tissue adjacent to one or more tissue planes:

delivering energy to the electrodes to simultaneously impart perforations into one or more layers of the tissue, wherein the perforations correspond to the electrode pattern.

23. A kit for creating a pattern of perforations in tissue, the kit comprising two or
10 more devices as in claim 1, wherein each of the devices have either a differently sized treating surface, a differently shaped treating surface, a different treating surface type, a different electrode pattern, a different electrode width, a different electrode length or a different electrode spacing.

24. A method for treating human skin, comprising:
15 identifying a target area of skin;

providing a device adapted to simultaneously create a desired pattern of perforations into one or more layers of the target area of skin;

simultaneously perforating the target area to provide the desired pattern of perforations which elicit a healing response that produces a revitalized skin
20 surface.

Figure 1

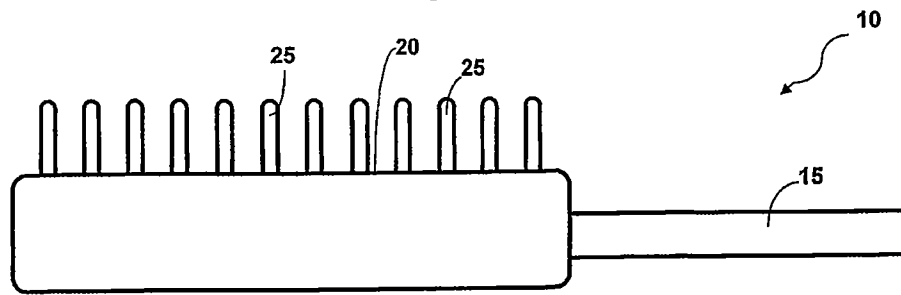


Figure 2

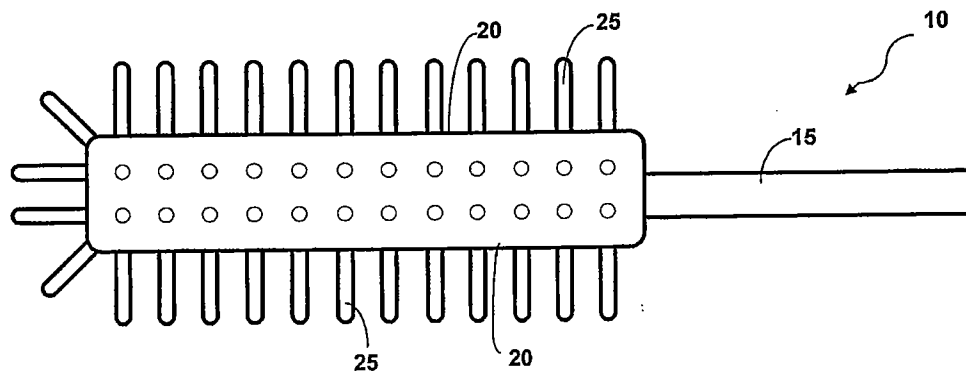


Figure 3

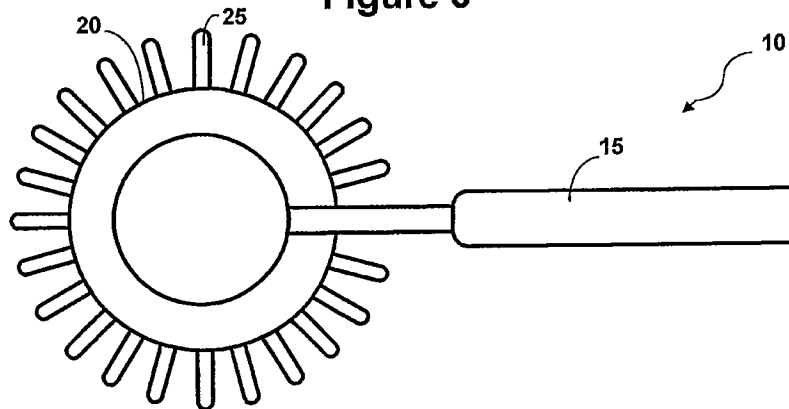


Figure 4

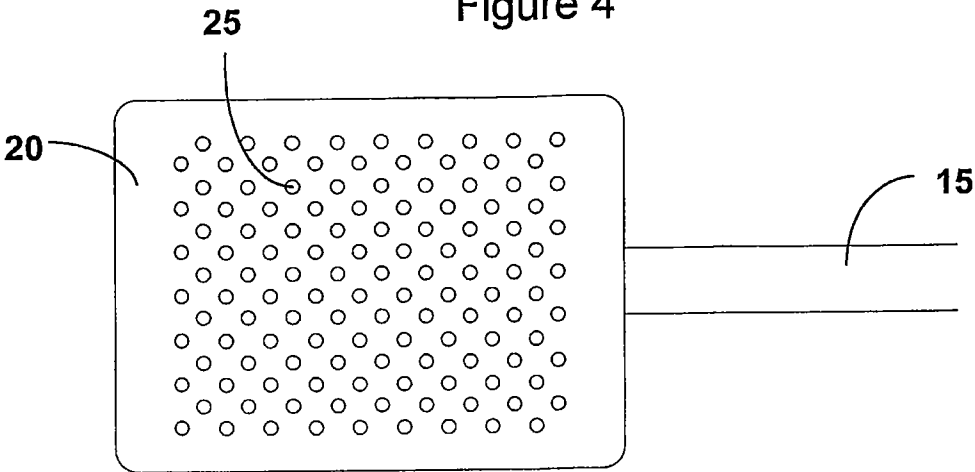


Figure 5

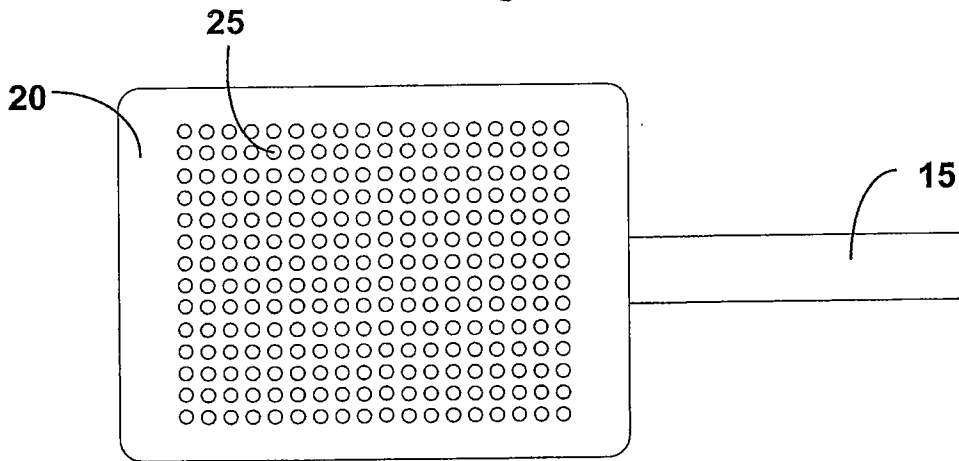


Figure 6

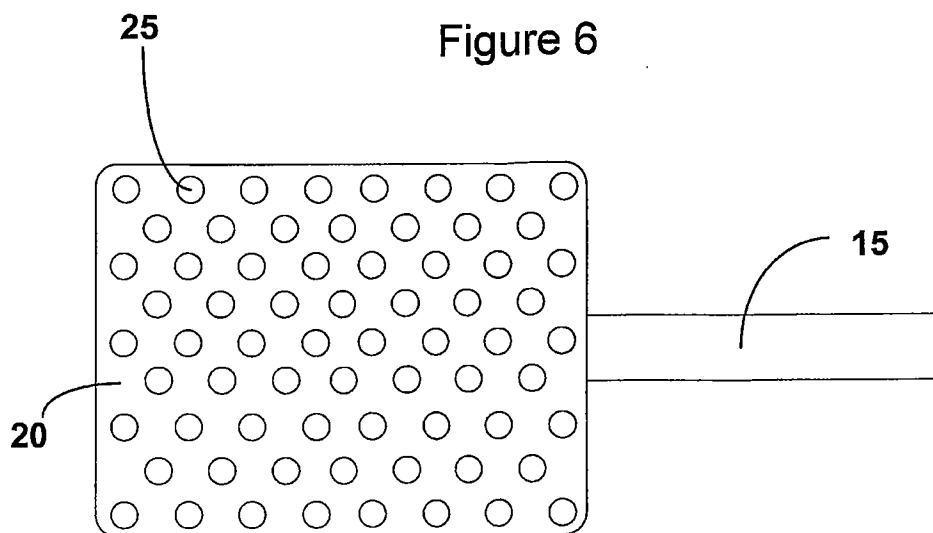


Figure 7

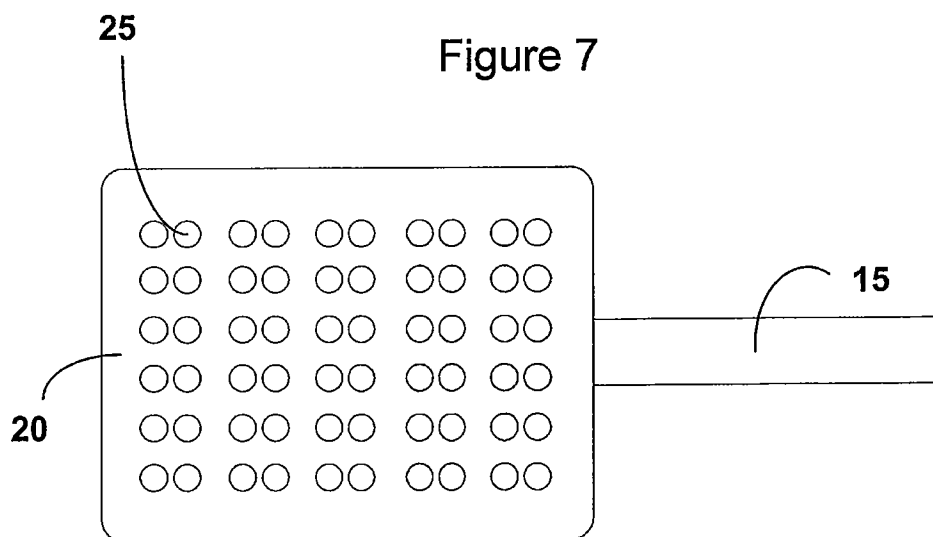


Figure 8
Prior Art

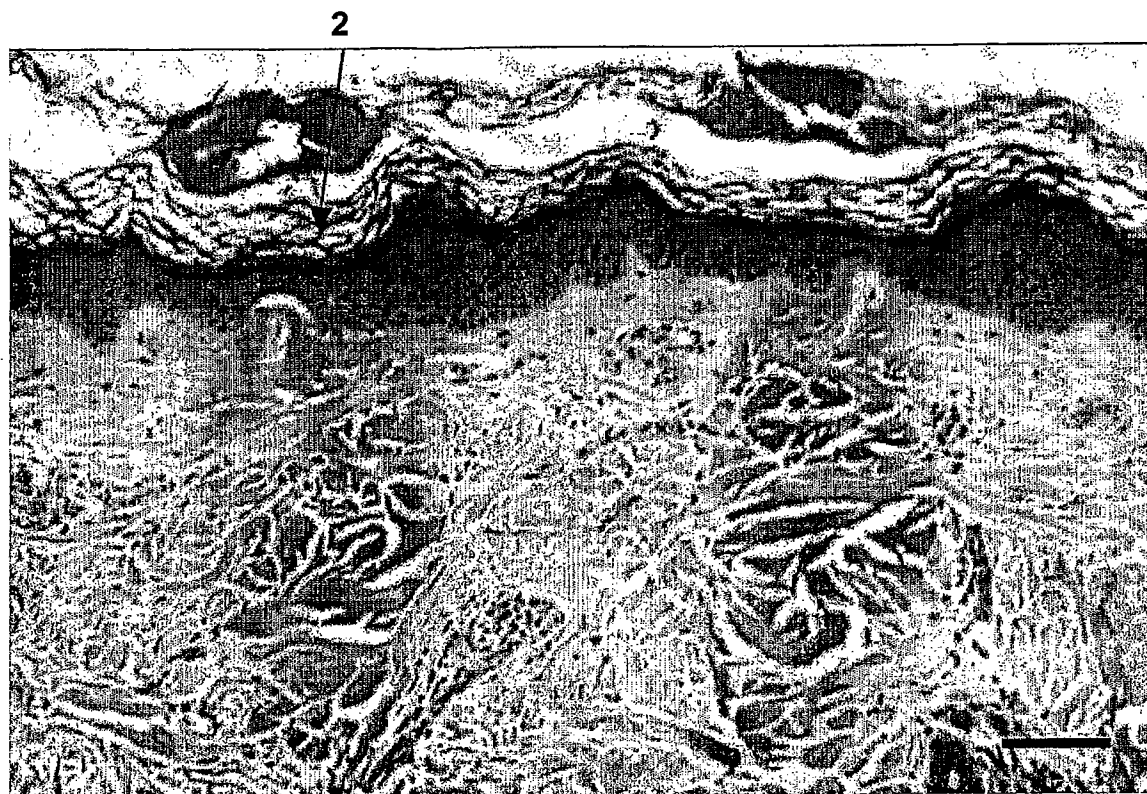


Figure 9

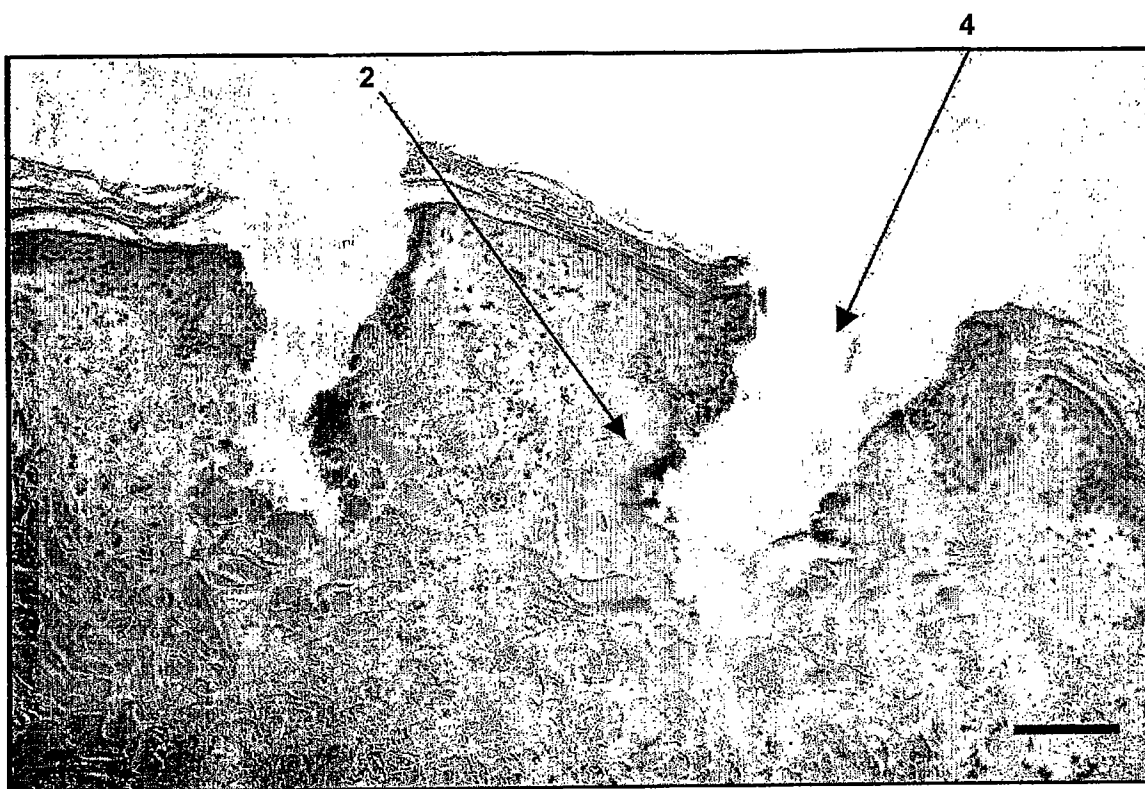
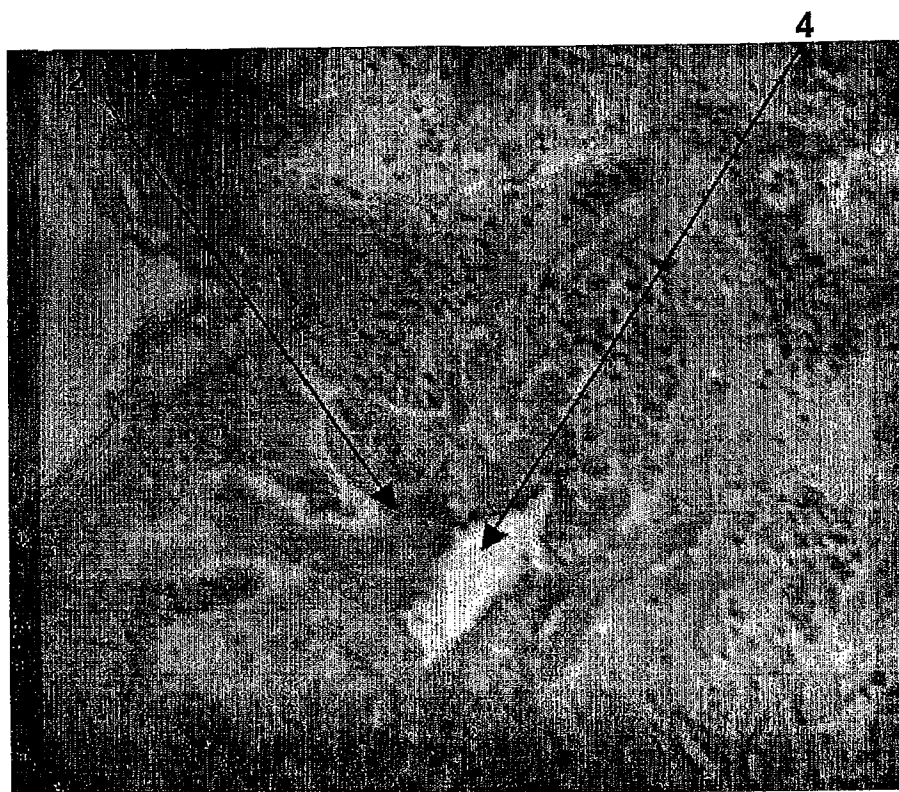


Figure 10



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/11683

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 18/18

US CL : 606/049

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/41, 45-50; 607/101-102

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,277,116 B1 (Utely et al) 21 August 2001, whole document	1-14, 16, 18-22, 24 ----- 23
X --- Y	US 2002/0120260 A1 (Morris et al) 29 August 2002, whole document	1-16, 18-24 ----- 3-6
A	US 6,416,514 B1 (Ein-Gal) 09 July 2002, whole document	1-24

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

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Date of the actual completion of the international search

10 August 2005 (10.08.2005)

Date of mailing of the international search report

08 SEP 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/061682

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B18/22 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC:

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/096979 A (GEN HOSPITAL CORP [US]) 20 October 2005 (2005-10-20)	1-4, 6-13, 15-26, 28-47
Y	page 11, line 22 - page 12, line 14 figures 3,4 page 7, line 29 - line 34	14,27, 48,49
X	EP 0 226 336 A (MICRA LTD [GB]) 24 June 1987 (1987-06-24) figures 1,2 column 1, line 36 - column 4, line 8 ----- -/--	1-13, 17-26, 30-47,50

☒ Further documents are listed in the continuation of Box C

☒ See patent family annex.

* Special categories of cited documents:

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P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

& document member of the same patent family

Date of the actual completion of the international search

9 September 2008

Date of mailing of the international search report

17/09/2008

Name and mailing address of the ISA/

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Authorized officer:

Cornelissen, P

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/061682

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 199 29 713 A1 (RADCHENKO SERGEY [DE]) 4 January 2001 (2001-01-04) figures 1,2 column 1, line 1 - column 2, line 34 -----	1-3,6,7, 9-13, 18-22, 25,30, 35-43, 46,50
X	WO 01/32073 A (CERAMOPTEC IND INC [US]) 10 May 2001 (2001-05-10) figures 4-6 paragraph [0030] - paragraph [0033] -----	1-3,6,7, 9-13, 19-22, 25-27, 30, 35-43, 46,50
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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/061682

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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WO 03005919	A	23-01-2003	IT M020010146 A1	13-01-2003

Form: PCT/ISA/210 (patent family annex) (April 2005)

Electronic Acknowledgement Receipt

EFS ID:	5105888
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Gary Abelev/Marilyn Alexander-Kuruvilla
Filer Authorized By:	Gary Abelev
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	06-APR-2009
Filing Date:	01-APR-2005
Time Stamp:	18:10:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		036213IDS06Apr2009.PDF	289651 1ba00656bc6b891751b0fc580c5e64156ac d09d0	yes	8

	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Transmittal Letter		1	2	
	Information Disclosure Statement (IDS) Filed (SB/08)		3	8	
Warnings:					
Information:					
2	Foreign Reference	036213ForRef106Apr2009.pdf	103276 5e0058d25b992de3a8023a05e9eabcdfc3ec887	no	3
Warnings:					
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3	Foreign Reference	036213ForRef206Apr2009.pdf	178742 8f2eaa9bb419a6df002bd17dc6fa8979369273dc	no	6
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7	Foreign Reference	036213ForRef606Apr2009.pdf	1698946 bc679d53aba9935a9d7e6c416f16919551fecfd	no	39
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9	Foreign Reference	036213ForRef806Apr2009.pdf	1629529	no	28
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Total Files Size (in bytes):			23569458		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter MANSTEIN
Serial No. : 11/098,030
Filed : April 1, 2005
Entitled : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Group Art Unit : 3769
Examiner : Ahmed M. Farah
Confirmation No. : 6055

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant brings to the attention of the Examiner the documents listed on the attached Form PTO-1449, and respectfully request that the listed documents be considered by the Examiner and made of record in the above-captioned application. Copies of the U.S. Patent and patent publications are not enclosed but copies of the PCT, foreign and other references are enclosed.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute “prior art.” If the Examiner applies the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute “prior art” under

United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

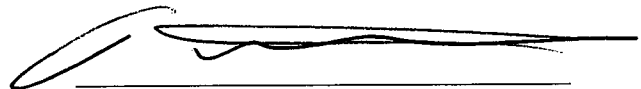
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

This submission is being filed before any substantive action by the U.S. Patent and Trademark Office on the merits. Therefore, applicants do not believe that any fee is due in connection with the submission of this paper. However, if any fee is due, or if any overpayment has been made, the Commissioner is authorized to charge any such fee or credit any overpayment, to our Deposit Account No. 50-2054.

Respectfully submitted,

DORSEY & WHITNEY, LLP

Date: April 6, 2009

A handwritten signature in black ink, appearing to read 'Gary Abelev', is written over a horizontal line.

Gary Abelev, Esq.
PTO Reg. No. 40,479
Attorney for Applicants
(212) 415-9371

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Dieter MANSTEIN
Appln. Serial No. : 11/098,030
Filed : April 1, 2005
Entitled : METHOD AND APPARATUS FOR
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RESHAPING
Group Art Unit : 3769
Confirmation No. : 6055
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**AMENDMENT AND RESPONSE TO RESTRICTION
REQUIREMENT AND NOTICE OF NON-COMPLIANT AMENDMENT**

SIR:

This paper is filed in response to the Office Action and Election/Restriction Requirement dated October 31, 2008 (the "Office Action") and to the Notice of Non-Compliant Amendment ("Notice") dated March 6, 2009 for the above-identified application. Initially, please amend the above-identified application as set forth below.

In The Claims:

Please withdraw claims 16-19, 29-31 and 33 from consideration, and add new claims 34-37 in the present application, as indicated below in the associated claim listing provided on separate sheets:

1. (Previously presented) An apparatus for tissue treatment, comprising:

a base;
a plurality of needles attached to the base;
an energy source provided in communication with at least one of the
needles;
a spacer arrangement for controlling penetration depths of the needles;
and
a control module configured to vary characteristics of energy supplied by
the energy source.

2. (Previously presented) The apparatus of claim 1 wherein more than one of the
needles are electrically conductive, and wherein the energy source is configured to
supply radio frequency electromagnetic energy to individual ones of the needles.

3. (Canceled)

4. (Canceled)

5. (Canceled)

6. (Canceled)

7. (Previously presented) The apparatus of claim 1, wherein the spacer arrangement
comprises a substrate movably attached to the base, wherein the position of the
substrate is adjustable relative to that of the base to control a distance between distal
ends of the needles and a surface of the substrate.

8. (Previously presented) The apparatus of claim 1, wherein at least one of the base or
the substrate further comprises a cooling arrangement configured to cool a skin surface,
and wherein the cooling arrangement comprises at least one of an embedded conduit
configured to circulate a coolant or a Peltier device.

9. (Canceled)

10. (Previously presented) The apparatus of claim 1, further comprising a vibrating arrangement provided in communication with the base.

11. (Previously presented) The apparatus of claim 1, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

12. (Canceled)

13. (Previously presented) The apparatus of claim 1, wherein at least one of the needles is nonconductive and hollow, and is configured to deliver a local analgesic to tissue proximal to a distal end of the needle.

14. (Previously presented) An apparatus for tissue treatment, comprising:

- a base;

- a plurality of needles attached to the base;

- an energy source provided in communication with at least one of the needles;

- a control module configured to vary characteristics of energy supplied by the energy source; and

- an electronic detection device in electrical communication with at least one of the needles that is configured to detect the presence of a nerve near the tip of the at least one of the needles.

15. (Previously presented) The apparatus of claim 1, further comprising:

a source of optical energy; and

at least one optical needle comprising at least one of a light fiber or a light guide, wherein the distal ends of the needles are configured to penetrate into at least one of the dermis or subdermal tissue, and wherein the apparatus is configured to deliver a controlled amount of optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle.

16. (Withdrawn)

17. (Withdrawn)

18. (Withdrawn)

19. (Withdrawn)

20. (Previously presented) The apparatus of claim 1, wherein the plurality of needles protrude a plurality of distances from the base.

21. (Previously presented) The apparatus of claim 15, wherein a portion of the at least one needle is configured to absorb a portion of the optical energy and convert the optical energy to thermal energy.

22. (Previously presented) The apparatus of claim 14, wherein the control module is configured to prevent the energy source from supplying energy to a particular needle if a nerve has been detected near the particular needle.

23. (Previously presented) The apparatus of claim 14, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between two needles in a pair of needles is less than a distance between each one of the two needles and any other needle, and wherein the energy source and the control module are configured

to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

24. (Previously presented) An apparatus for dermatological treatment, comprising:

a base;

a plurality of needles attached to the base;

an energy source provided in communication with at least one of the needles; and

a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles protrude a plurality of distances from the base.

25. (Previously presented) The apparatus of claim 24, wherein the energy source is a source of electromagnetic energy.

26. (Previously presented) The apparatus of claim 24, wherein a plurality of the needles are electrically conductive, and wherein the energy source is configured to supply radio frequency electromagnetic energy to individual ones of the needles.

27. (Previously presented) The apparatus of claim 24, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

28. (Previously presented) The apparatus of claim 24, further comprising:

at least one optical needle comprising at least one of a light fiber or a light guide,

wherein the apparatus is configured to deliver a controlled amount of optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle,

wherein the energy source comprises a source of optical energy.

29. (Withdrawn)

30. (Withdrawn)

31. (Withdrawn)

32. (Previously presented) An apparatus for tissue treatment, comprising:

a base;

a plurality of needles attached to the base;

an energy source provided in communication with at least one of the needles; and

a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

33. (Withdrawn)

34. (New) The apparatus of claim 1, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region of the tissue.

35. (New) The apparatus of claim 24, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region.

36. (New) The apparatus of claim 32, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region of the tissue.

37. (New) An apparatus for tissue treatment, comprising:

- a base;

- a plurality of needles attached to the base;

- an energy source provided in communication with at least one of the needles;

- a control module configured to vary characteristics of energy supplied by the energy source; and

- an electronic detection device in electrical communication with at least one of the needles that is configured to detect the presence of a nerve near the tip of the at least one of the needles.

Remarks

I. INTRODUCTION

Claims 16-19, 29-31, and 33 have been withdrawn without prejudice in response to the restriction requirement, as described below. Applicant reserves the right to file one or more continuing applications in which the subject matter recited in these claims would be prosecuted. New claims 34-37 have been added. Accordingly, claims 1, 2, 7, 8, 10, 11, 13-15, 20-28, 32 and 34-37 are now under consideration in the present application. Provided above, please find a claim listing indicating the addition of new claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

Additionally, in the Notice, it was alleged that the species election was not made in the prior Response dated December 1, 2008 (the "Response"). Applicants respectfully disagree, and confirm that Species A was indeed elected, with traverse, in the Response. This explicit election last is shown in the present document (which includes the same language as provided in the prior Response) and provided in **bold, underlined and italic text**.

II. RESTRICTION REQUIREMENT

A. *Inventions*

In the Office Action, the Examiner states that certain groups of claims of above-identified application recite inventions that are distinct from one another. (See Office Action, page 2). For such reason, the Examiner believes that the restriction of claims is proper, and now requires Applicants to elect one of the following groups:

Group I: claims 1, 2, 7, 8, 10, 11, 13-15, 20-28 and 32, allegedly drawn to a treatment apparatus comprising a plurality of

needles, supposedly classified in class 606, subclass 41;
and

Group II: claims 16-19, 29-31, and 33, allegedly drawn to methods for treating tissue with optical and/or radio frequency energy, supposedly classified in class 128, subclass 898.

In response to this restriction requirement, Applicant hereby elects Group I, i.e., claims 1, 2, 7, 8, 10, 11, 13-15, 20-28, 32 (drawn to an apparatus comprising a plurality of needles), without traverse, for prosecution in the present application.

Applicant respectfully submits that new claims 34-37 submitted herewith drawn to an apparatus comprising a plurality of needles, should also be included in Group I, and requests that these new claims also be examined as part of this elected group.

B. Species

The Examiner further asserts that certain claims of the present application in Group I are drawn to patentably distinct species. (See *id.*, page 4). Then, the Examiner identifies the following three allegedly distinct species:

Species A: Claims 2 and 26, reciting application of radio frequency energy using the needle array;

Species B: Claims 15, 21 and 26, apparently reciting needles delivering optical energy (Applicant notes that claim 26 does not recite optical energy, and thus Applicant assumes that the Examiner intended to include claim 28 in this allegedly distinct species); and

Species C: Claims 14, 22 and 23 (together with new claim 37), reciting a needle array which is also used to detect the presence of nerves.

The Examiner alleges that the species are independent or distinct because they recite mutually exclusive characteristics of such species, and that there would be an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics.

Applicant notes that the claims reciting these allegedly distinct species each depend from independent claims 1, 14, 24 or 32, as applicable. Applicant respectfully asserts that each of the alleged species A-C recites an apparatus which includes a plurality of needles configured to provide energy to tissue, and that the features identified by the Examiner are **not** mutually exclusive characteristics and, in fact, may be combined using the same recited structure. (See, e.g., paras. [0048]-[0050] of the present application.) Applicant respectfully asserts that the common characteristics of each of these alleged species, e.g., a needle array configured to deliver energy to tissue, does **not** require separate searches and consideration of different fields of research. Applicant also respectfully asserts that independent claims 1 and 24 are generic to the allegedly distinct species A-C.

Thus, **Applicant hereby respectfully traverses this species restriction requirement set forth in the Office Action, and provisionally elects alleged species A, corresponding to claims 2 and 26.** Applicant notes that claims 1, 2, 7, 8, 10, 11, 13, 20, 24-27, 32, and new claims 34-36 are part of and/or generic to allegedly distinct Species A.

C. *Species*

Applicant has elected Group I in response to the present restriction requirement, without traverse, and has withdrawn claims 16-19, 29-31, and 33 from consideration in the present application. **Applicant has also traversed the species election requirement provided by the Examiner, and provisionally elected a single alleged species (Species A) for this election requirement, but also believe that this restriction requirement is inappropriate as set forth above.**

Applicant notes that 37 C.F.R. 1.146 indicates that the Examiner has discretion in requiring an election of identified species. However, Applicant asserts that the species election requirement contained in the latest Office Action would not require searches of different fields of research, nor would consideration of all alleged species place an undue burden on the Patent Office.

Therefore, for at least these reasons, the Examiner is respectfully requested to withdraw the Restriction Requirement (associated with the species) contained in the Office Action dated October 31, 2008. Upon such withdrawal by the Examiner, Applicant respectfully requests that pending claims 1, 2, 7, 8, 10, 11, 13-15, 20-28, 32 and 34-37 be prosecuted on their merits in the present application. Alternatively, to the extent that such withdrawal is not made by the Examiner, Applicant respectfully requests that the elected species identified herein and, if necessary, further non-elected species be considered on their merits.

Applicant further notes that upon the indication of allowability of any generic claim(s), any claims which are directed to non-elected species which depend from such allowable claim(s) be considered.

III. CONCLUSION

In light of the foregoing, Applicant respectfully submits that the pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited. The Examiner is invited to contact the undersigned to expedite the prosecution of this application if any issues remain outstanding.

Respectfully submitted,

Date: April 6, 2009

By: 

Gary Abelev
Patent Office Reg. No. 40,479

DORSEY & WHITNEY, L.L.P.
250 Park Avenue
New York, New York 10177

Attorney for Applicant
(212) 415-9371

4823-8209-2547\1

Electronic Acknowledgement Receipt

EFS ID:	5106034
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Gary Abelev/Marilyn Alexander-Kuruvilla
Filer Authorized By:	Gary Abelev
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	06-APR-2009
Filing Date:	01-APR-2005
Time Stamp:	18:23:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	036213Amendment06Apr2009. PDF	385234 <small>9caa01199f889754411c2afac2b0c44539443128</small>	no	12

Warnings:

Information:

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/098,030

04/01/2005

Dieter Manstein

036213/US/2-475387-00230

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09/18/2009

DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

EXAMINER

FARAH, AHMED M

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

09/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/098,030	Applicant(s) MANSTEIN, DIETER	
	Examiner Ahmed M. Farah	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,8,10,11,13-15,20-28,32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,8,10,11,13-15,20-28,32 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/6/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the invention of Group I in the reply filed on April 6, 2009 is acknowledged.

Claims 16-19, 29-31 and 33 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 6, 2009.

The elected invention of Group I contains a patentably distinct species A, B, and C. However, the applicant failed to elect a single species for prosecution on the merits. Hence, in order to expedite prosecution of the application, invention I, species A is selected for examination in this Office Action.

Newly submitted claim 37 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claim recites an electronic detection system in communication with the micro-needles, which is directed to independent distinct species.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 37 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 7, 8, 10, 11, 13, 20, 24-27, 32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Utely et al. US Patent No. 6,277,116 in view of Prausnitz et al. US Patent No. 6,743,211 (herein after *Prausnitz '211*).

Utely et al. discloses a system and methods of use for shrinking collagen tissue, the apparatus comprising: a plurality of needles 82, 90, attached to a base 80,88, wherein the base is attached to a housing or part of the housing (see Figs. 6 and 8); energy source in communication with one or more of the needles (see Fig. 2); and a control module 48 configured to permit variation of the characteristics of the energy supplied by the energy source as claimed (see col. 6, line 59 through col. 7, line 3).

With respect to claim 2, the source is a radiofrequency source, which is capable of outputting a desired RF signals.

As to claim 7, the spacer substrate comprises a pattern of small holes through which the plurality of the needles protrude (see Figs. 7-9).

As to claim 11, the energy source is configured to deliver energy to a plurality of pairs of needles in bipolar mode (see col. 7, lines 64-67).

As to claim 13, the needles are hollow and are configured to deliver therapeutic fluid to the tissue surrounding the tip of the needles (see col. 9, lines 11-17).

With respect to the newly submitted claims 34-36, the recited claims languages is directed to intended use of the claimed device. Moreover, the system of Utely et al. would provide thermal damage to the skin tissue as claimed.

Utely et al. fails to teach the use of “spacer arrangement for controlling [the] penetration depth of the needles” as recited in the amended claims. However, the use of depth stop to control the penetration depth of the needles into the tissue is known in the art. *Prausnitz '211* discloses an alternative micro-needle device and method of use for penetration of biological tissue, the micro-needles comprising extensions adapted for penetration stop to limit the depth of micro-needle penetration into the tissue. Therefore, at the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the device of Utely et al. in view of *Prausnitz '211* and use penetration depth control means in order to limit or control the depth of micro-needles penetration into the tissue.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Utely et al. in view of *Prausnitz '211* as applied to claims 1, 2, 7, 8, 10, 11, 13, 20, 24-27, 32 and 34-36 above, and further in view of Prausnitz et al. US Patent No. 6,503,231 (herein-after *Prausnitz '231*).

Utely et al., described above, does not teach the use of optical energy and delivery means as claimed. However, the use of optical energy as alternative treatment energy is well known in the art. *Prausnitz '231* discloses an alternative micro-needle apparatus and delivery waveguides adapted to be incorporated into the micro-needles

Art Unit: 3769

to deliver optical energy to a desired treatment site. *Prausnitz '231* further teaches the equivalence of different forms of energy for tissue treatment (see col. 5, lines 34-38).

Therefore, at the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify Utely et al. in view of Prausnitz et al. and use optical energy and delivery fibers as an equivalent alternative means to provide the treatment energy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon, Tue, Thur and Fri between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johnson Henry can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 11/098,030

Page 6

Art Unit: 3769

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ahmed M Farah/
Primary Examiner, Art Unit 3769

June 22, 2009.

Notice of References Cited	Application/Control No. 11/098,030		Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER	
	Examiner Ahmed M. Farah		Art Unit 3769	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
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*	B	US-6,743,211	06-2004	Prausnitz et al.	604/239
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	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark OfficeAtty. Docket No.
36213/US/2 - 475387-00230Serial No.
11/098,030**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

(Use several sheets if necessary)

Applicant(s)
Dieter MansteinFiling Date
April 1, 2005Confirmation No.
6055**U.S. PATENT DOCUMENTS**

*Exam. Init.	Document No.	Date	Name	Class	Subclass	Filing Date if Appropriate
	4 9 8 5 0 2 7	01/15/1991	Dressel			
	5 1 0 2 4 1 0	04/07/1992	Dressel			
	5 3 1 2 3 9 5	05/17/1994	Tan et al.			
	5 5 9 9 3 4 2	02/04/1997	Hsia et al.			
	5 8 0 7 3 8 5	09/15/1998	Keller			
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	5 9 5 4 7 1 0	09/21/1999	Paolini et al.			
	6 1 0 6 5 1 6	08/22/2000	Massengill			
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	6 9 9 7 9 2 3	02/14/2006	Anderson et al.			
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200	4 0 4 8 8 4 2	03/11/2004	McMillan			
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Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AF/

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.
36213/US/2 – 475387-00230

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11/098,030

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(Use several sheets if necessary)

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Filing Date
April 1, 2005

Confirmation No.
6055

	2005	0	2	2	2	5	6	5	10/06/2005	Manstein			
	2006	0	0	0	4	3	0	6	01/05/2006	Altshuler et al.			
	2006	0	0	0	9	7	5	0	01/12/2006	Altshuler et al.			
	2006	0	0	2	0	3	0	9	01/26/2006	Altshuler et al.			
	2006	0	1	2	2	6	6	8	06/08/2006	Anderson et al.			
	2006	0	2	2	4	1	4	8	10/05/2006	Cho et al.			
	2006	0	2	5	3	1	1	2	11/09/2006	Suarez et al.			
	2007	0	0	7	3	3	6	7	03/29/2007	Jones et al.			
	2007	0	1	9	8	0	0	3	08/23/2007	Domankevitz et al.			
	2007	0	1	7	3	7	9	9	07/26/2007	Hsia			
	6	0	7	0	7	7	7	8	08/12/2005	Rylander et al.			
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		5	4	5	8	5	9	6	10/17/1995	Lax et al.			
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		5	8	7	1	5	2	4	02/16/1999	Knowlton			
		5	9	1	9	2	1	9	07/06/1999	Knowlton			
		5	9	4	8	0	1	1	09/07/1999	Knowlton			

Examiner

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6055

		6	4	1	8	2	3	2	11/14/2000	Avrahami			
		6	2	4	1	7	5	3	06/05/2001	Knowlton			
		6	2	7	7	1	1	6	08/21/2001	Utely et al.			
		6	3	1	1	0	9	0	10/30/2001	Knowlton			
		6	3	3	4	8	5	6	01/01/2002	Allen et al.			
		6	3	5	0	2	7	6	02/26/2002	Knowlton			
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		6	4	1	3	2	5	5	07/02/2002	Stern			
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(REV. 2-82) Patent and Trademark OfficeAtty. Docket No.
36213/US/2 - 475387-00230Serial No.
11/098,030**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**
(Use several sheets if necessary)Applicant(s)
Dieter MansteinFiling Date
April 1, 2005Confirmation No.
6055

		6	4	8	2	2	0	4	11/19/2002	Lax et al.			
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		6	5	9	7	9	4	6	07/22/2003	Avrahami et al.			
		6	6	1	1	7	0	6	08/26/2003	Avrahami et al.			
		6	6	1	5	0	7	9	09/02/2003	Avrahami			
		6	7	0	8	0	6	0	03/16/2004	Avrahami et al.			
		6	7	1	1	4	3	5	03/24/2004	Avrahami et al.			
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		7	0	0	8	4	2	1	03/07/2006	Daniel et al.			
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Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark OfficeAtty. Docket No.
36213/US/2 - 475387-00230Serial No.
11/098,030**INFORMATION DISCLOSURE STATEMENT
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(Use several sheets if necessary)

Applicant(s)
Dieter MansteinFiling Date
April 1, 2005Confirmation No.
6055

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	2005	0	0	4	9	5	8	2	03/03/2005	Debenedictis et al.			
	2005	0	1	3	7	6	6	2	06/23/2005	Morris et al.			
	2005	0	2	2	2	5	5	5	10/06/2005	Manstein et al.			
	2006	0	0	0	4	3	0	6	01/05/2006	Altshuler et al.			
	2006	0	0	0	4	3	4	7	01/05/2006	Altshuler et al.			
	2006	0	0	2	0	3	0	9	01/26/2006	Altshuler et al.			
	2006	0	0	5	8	7	1	2	03/16/2006	Altshuler et al.			
	2006	0	1	2	2	6	6	8	06/08/2006	Anderson et al.			
	2006	0	2	0	6	1	1	0	09/14/2006	Knowlton et al.			
	2006	0	2	9	3	7	2	2	12/28/2006	Slatkine et al.			
	2007	0	0	1	0	8	1	1	01/11/2007	Stern et al.			
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	2008	0	1	2	5	7	7	5	05/29/2008	Morris			

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		Document No.							Date	Country	Class	SubClass	Translator Yes No	
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	1	9	9	2	9	7	1	3	01/04/2001	Germany				
		0	0	4	8	6	4	4	08/24/2000	WIPO				

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* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.
36213/US/2 - 475387-00230

Serial No.
11/098,030

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

(Use several sheets if necessary)

Applicant(s)
Dieter Manstein

Filing Date
April 1, 2005

Confirmation No.
6055

		0	1	3	2	0	7	3	05/10/2001	WIPO				
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4813-1828-7875\1

Examiner

/Ahmed Farah/ (07/05/2009)

Date Considered

07/05/2009

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter Manstein
Serial No. : 11/098,030
Filed : April 1, 2005
Entitled : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Group Art Unit : 3769
Examiner : Ahmed M. Farah
Confirmation No. : 6055

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), applicants bring to the attention of the Examiner the documents listed on the attached Form PTO/SB/08A, and respectfully request that the listed documents be considered by the Examiner and made of record in the above-captioned application. Copies of the United States patent references listed on the Form PTO/SB/08A are not enclosed, but the PCT, foreign and non-patent references are enclosed.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute "prior art." If the Examiner applies the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute "prior art" under

United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.


If the Examiner applies the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

As an Office Action on the merits, but before any final Office Action or Notice of Allowance was generated for this application, the requisite fee of \$180.00 pursuant to these sections and 37 C.F.R. § 1.17(p) is enclosed herewith. The Commissioner is hereby further authorized to charge any deficiencies and credit any over payments for the submission of this Information Disclosure Statement to the Dorsey & Whitney's Deposit Account 50-2054.

Respectfully submitted,

DORSEY & WHITNEY, LLP

Date: November 13, 2009



Gary Abelev
USPTO Reg. No. 40,479
Attorney for Applicants
(212) 415-9371

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	11/098,030
				Filing Date	Apr 1, 2005
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	Ahmed M. Farah
Sheet	1	of	1	Attorney Docket No: P036213.US.02-475387-230	

US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2002/0115991	Aug 22, 2002	Edwards, Stuart D.	
		2002/0120263	Aug 29, 2002	Brown, Tony R., et al.	
		2002/0128641	Sep 12, 2002	Underwood, Ronald A., et al.	
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		7217265	May 15, 2007	Hennings, David R., et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		WO-2002/060523	Aug 8, 2002	Brown, R. T., et al.	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
8 August 2002 (08.08.2002)

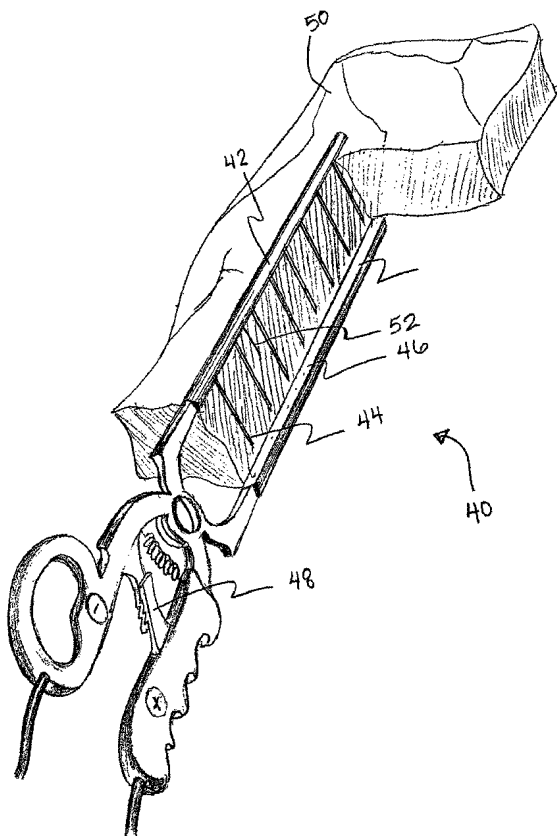
PCT

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- (21) International Application Number: PCT/US01/48776
- (22) International Filing Date:
17 December 2001 (17.12.2001)
- (25) Filing Language: English
- (26) Publication Language: English
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60/256,245 15 December 2000 (15.12.2000) US
60/287,798 30 April 2001 (30.04.2001) US
- (63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 60/256,245 (CIP)
Filed on 15 December 2000 (15.12.2000)
- (71) Applicant and
(72) Inventor: **BROWN, Tony, R.** [US/US]; 6605 East Canyon Hills Road, Anaheim Hills, CA 92807 (US).
- (72) Inventors; and
(75) Inventors/Applicants (for US only): **NGUYEN, Hein** [US/US]; 3106 West Borchard Avenue, Santa Ana, CA 92704 (US). **WADHWANI, Suresh** [US/US]; 23672 Via Astorga, Mission Viejo, CA 92691 (US). **ADAME, Octavio, V.** [MX/MX]; Tarascos 3469, 2do. Piso C.P., 44670 Guadalajara (MX). **LAUFER, Michael, D.** [US/US]; 1259 El Camino Real, #21, Menlo Park, CA 94025 (US).
- (74) Agent: **LYNCH, Cindy, A.**; BURNS, DOANE, SWECKER & MATHIS, LLP, P.O. BOX 1404, Alexandria, VA 22313 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,

[Continued on next page]

(54) Title: ATRIAL FIBRILLATION RF TREATMENT DEVICE AND METHOD



(57) Abstract: An RF treatment device according to the present invention includes one or two radio frequency electrode holders each having multiple electrodes arranged to create a transmural lesion through tissue. The treatment device is placed with one holder placed on the endocardial surface of the heart and the other optional holder placed on the epicardial surface of the heart to form a bipolar arrangement of equally spaced parallel tissue penetrating electrodes. The invention creates a transmural lesion in heart tissue to treat atrial fibrillation by blocking passage of abnormal electrical currents through the heart and may also be used to create continuous transmural lesions in heart tissue and other body organs and tissues to treat other conditions. The devices may also be used to apply other types of energy, including cryo, ultrasound, microwave, heat, or other electrical means of providing an interruption in abnormal electrical circuits.



WO 02/060523 A2



GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ATRIAL FIBRILLATION RF TREATMENT DEVICE AND METHOD

Cross Reference to Related Applications

[0001] This application claims priority under 35 U.S.C. §119(e) to U.S.
5 Provisional Application Serial No. 60/256,245 filed on December 15, 2000 and
U.S. Provisional Application Serial No. 60/287,798 filed on April 30, 2001, both
of which are incorporated herein by reference in their entirety.

Field of the Invention

[0002] The invention relates to an atrial fibrillation RF treatment device and
10 method, and more particularly, the invention relates to a device and method for
creating a narrow transmural lesion or discontinuity in tissue, such as heart tissue
or other body organs or tissues.

Description of the Related Art

[0003] Atrial fibrillation is a condition of the heart in which abnormal electrical
15 signals are generated in the myocardial tissue causing irregular beating of the
heart. One method used to treat atrial fibrillation is called the Maze procedure.
The Maze procedure involves forming barriers in the heart tissue to prevent the
abnormal electrical signals from passing through the heart. The barriers are
created by forming several long (i.e., approximately 2-10cm) scars. The scars are

formed by cutting through the heart wall and sewing the wall back together to create the scars which are intended to stop the irregular beating of the heart by preventing the passage of abnormal currents. This procedure is referred to as the Maze procedure because it creates a maze of scars blocking the passage of abnormal electrical currents through the heart. These scars may be formed by cutting or by application of energy.

[0004] Procedures for forming the linear scars involve opening the patients chest cavity and forming linear incisions or cuts through the heart wall in specific locations described as the Maze III and other similar atrial fibrillation treatments.

[0005] The Maze III procedure using conventional surgical incisions has a success rate of up to 90%. A new technique of cryo-ablation has also been used to create the lesions in the heart wall. This approach has the benefit of reducing the cardiopulmonary bypass pump time and allowing more time for correcting the valvular disease and CABG if needed.

[0006] Although catheter techniques have been attempted for minimally invasive treatment of atrial fibrillation, these techniques have not been successful to date. Known catheter devices for forming these lesions include flexible catheters which form lesions from an interior surface of the heart. Examples of these ablation catheters are described in U.S. Patent Nos. 5,895,417; 5,941,845; and 6,129,724 which are incorporated herein by reference in their entirety.

[0007] One drawback with the catheter techniques and devices used on the epicardial surface of the heart is that it is difficult to impossible to assure a transmural lesion or the complete blockage of unwanted electrical signals. In addition, RF energy will not go through fat with currently available devices because of the high impedance of the fat compared to the low impedance of tissue. In addition, current devices have difficulty dealing with varying thickness of tissue through which a transmural lesion is desired. Accordingly, it would be desirable

to provide a system for precisely creating transmural lesions on a beating heart or non-beating heart with a minimum of trauma to the patient.

Summary of the Invention

[0008] The present invention relates to a device and method for creating a
5 transmural lesion.

[0009] In accordance with one aspect of the present invention, an RF treatment device for creating transmural lesions in tissue includes an electrode holder; a plurality of tissue penetrating RF needle electrodes arranged in a single linear array to create a continuous transmural lesion, each of the RF needle electrodes
10 having a length of at least 4 mm; and an RF energy source connected to each of the RF needle electrodes with alternating electrodes connected to opposite polarities of the RF energy source.

[0010] In accordance with an additional aspect of the present invention, an RF treatment device for creating transmural lesions in heart tissue includes an
15 electrode holder; a plurality of tissue penetrating RF needle electrodes arranged in a single linear array to create a continuous transmural lesion, each of the RF needle electrodes having a length sufficient to create a transmural lesion through the entire thickness of the tissue of the heart wall; and an RF energy source connected to each of the RF needle electrodes.

[0011] In accordance with a further aspect of the invention, a method of treating atrial fibrillations includes the steps of: penetrating heart tissue to be treated with an RF treatment device comprising a plurality of tissue penetrating RF needle electrodes arranged in a single linear array; and applying radio frequency energy to form a transmural lesion which provides a barrier across an entire thickness of
20 the heart tissue to prevent the passage of abnormal electrical currents through the heart tissue.

[0012] In accordance with another aspect of the invention, a method of treating atrial fibrillations includes the steps of: positioning a first electrode of a radio frequency forceps on an endocardial surface of a heart at a location to be treated; positioning a second electrode of the radio frequency forceps on an epicardial surface of the heart opposite the first electrode; and applying radio frequency with the first and second electrodes to form a transmural lesion which provides a barrier to the passage of abnormal electrical currents through the heart tissue.

5 [0013] In accordance with another additional aspect of the present invention, a medical device for creating transmural lesions in tissue includes an electrode holder; a plurality of tissue penetrating needle electrodes arranged in a single linear array to create a continuous narrow lesion, each of the needle electrodes having a length sufficient to create a transmural lesion through the tissue of the heart wall; and an energy source connected to each of the needle electrodes.

Brief Description of the Drawing Figures

15 [0014] The invention will now be described in greater detail with reference to the preferred embodiments illustrated in the accompanying drawings, in which like elements bear like reference numerals, and wherein:

[0015] FIG. 1 is a perspective view of a RF treatment device with two RF electrode holders and multiple electrodes.

20 [0016] FIG. 2 is a perspective view of an alternative embodiment of a treatment device with two electrode holders and multiple electrodes.

[0017] FIG. 3 is a perspective view of a treatment device with a single electrode holder having multiple electrodes and an anvil opposite the electrode holder.

[0018] FIG. 4 is a perspective view of a treatment device with a single electrode holder having multiple electrodes for application from an epicardial side of the heart.

[0019] FIG. 5 is a perspective view of a treatment device with a single hinged electrode holder having multiple electrodes.

[0020] FIG. 5A is an enlarged view of the device of FIG. 5 with the electrode is a rotated position.

[0021] FIG. 6 is a perspective view of a treatment device with a single curved electrode holder having multiple electrodes.

[0022] FIG. 7 is a perspective view of a treatment device with a thermocouple and electrodes for measuring temperature and electrical potential.

[0023] FIG. 8 is a partial cross sectional perspective view of a treatment device with retractable electrodes in a retracted position.

[0024] FIG. 9 is a partial cross sectional perspective view of the device of FIG. 8 with the electrodes in an extended position.

[0025] FIG. 10 is a partial cross sectional perspective view of a treatment device with retractable electrodes in an extended position.

[0026] FIG. 11 is an enlarged perspective view of a portion of the device of FIG. 10.

[0027] FIG. 12 is a partial cross sectional perspective view of a treatment catheter device with electrodes in a retracted position.

[0028] FIG. 13 is a partial cross sectional perspective view of the device of FIG. 12 with the electrodes in an extended position.

[0029] FIG. 14 is a perspective view of a treatment device with hollow needle electrodes for sealing holes created in the tissue.

[0030] FIG. 15 is a partial cross sectional perspective view of a treatment device with electrodes having holes for sealing holes created in the tissue.

[0031] FIG. 16 is a perspective view of a forceps type RF treatment device without tissue penetrating electrodes.

Detailed Description of the Invention

[0032] FIG. 1 shows a first embodiment of an RF treatment device 10 with two
5 radio frequency electrode holders 12, 14 each having multiple electrodes 16
arranged to create a transmural lesion through tissue. The treatment device 10 is
placed with one electrode holder 12 placed on the endocardial surface of the heart
wall with the electrodes 16 protruding towards the epicardial surface of the heart
and the other electrode holder 14 placed on the epicardial surface of the heart with
10 the electrodes protruding towards the endocardial surface of the heart forming a
bipolar arrangement of equally spaced electrodes. The electrodes 16 are of an RF
conducting material, such as, stainless steel.

[0033] A handle 18 of the device 10 is provided to position the electrodes 16
with a minimal force through any fat on the surfaces of the tissue and into the
15 heart tissue. Preferably, the handle 18 provides a mechanism to hold the positive
electrode holder 14 parallel to the negative electrode holder 12 and assure the
electrodes 16 are parallel and equally spaced apart in a linear array. As will be
discussed below, the linear array of electrodes may form a straight line, a curved
line, a zig zag shape or other desired shape to form a continuous narrow lesion.
20 Radio frequency energy is applied between the positive electrodes 16 on a positive
electrode holder 14 and the negative electrodes 16 on the negative electrode holder
12 so that a transmural lesion is formed between each positive and negative
electrode.

[0034] The embodiments of the present invention will be described below for use in creating a transmural lesion in heart tissue to treat atrial fibrillation by blocking the passage of abnormal electrical currents through the heart. However, it should be understood that the devices and methods described herein may also be used to create continuous transmural lesions in heart tissue and other body organs and tissues to treat other conditions. The basic principles discussed herein apply to the creation of a narrow transmural lesion through any conductive layer of material or tissue of varying thicknesses.

[0035] As used herein the term "transmural lesion" means a tissue lesion which completely transverses the tissue of a heart wall, an organ, or other tissue and causes a complete blockage of unwanted electrical signals through the tissue.

[0036] The RF treatment device 10 of FIG. 1 includes a controller 20 which may be positioned within the handle 18 or otherwise attached to the treatment device 10. Preferably, a thermocouple or temperature sensing member 24 is arranged on one of the electrode holders 12, 14 and is connected to the controller 20 to provide feedback to the controller of the temperature of the tissue. The temperature sensing member 24 is preferably arranged equal distance between the two center most electrodes (one positive and one negative), but can be between any two electrodes to measure the temperature of the tissue. The controller 20 controls the power delivered to the tissue to attain and maintain a preferred temperature of about 65 degrees Centigrade with a range of about 60-95 degrees Centigrade.

[0037] Since fat has significantly higher impedance than tissue, RF energy goes uniformly through tissue and not fat. The RF treatment devices of the present invention provide an advantage over known devices which deliver RF energy to the surface of the heart or penetrate a small distance into the heart tissue but not through the fat. By penetrating through the fat and delivering the RF energy

directly to the tissue, the present invention is able to create a continuous transmural where other devices create a discontinuous lesion or a lesion which does not extend all the way through the tissue.

[0038] In addition, blood has about the same impedance as the tissue and blood is a tremendous dissipater of heat energy. Thus, the flow of blood within the heart does not coagulate during formation of the lesion even if exposed to RF energy.

[0039] The RF treatment device of FIG. 1 includes electrodes 16 having a preferred diameter of about 0.022 inches (0.56 mm), but can have a range of diameters 50% greater or smaller. The preferred length of the electrodes is at least 4 mm to ensure that the electrodes 16 pass through any fat lying on a surface of the heart tissue and into the heart tissue itself. Preferably, the electrodes have a length of about 5 mm to about 15 mm, and more preferably about 8 mm. The electrodes in both electrode holders 12, 14 are spaced at a preferred distance of about 8 mm, but can range from about 6 mm to about 10 mm such that when both electrode holders are in position the distance between the adjacent positive and negative electrodes is preferably about 4 mm, with a range of about 3 mm to about 5 mm. The electrodes 16 are preferably sharpened like a hypodermic needle for easy penetration through the heart wall.

[0040] FIG. 2 shows a heat treatment device 30 which operates in a manner similar to the RF treatment device of FIG. 1. The heat treatment device 30 includes two electrode holders 32, 34 with multiple electrodes 36 arranged in an alternating linear fashion as in the embodiment of FIG. 1. The lesions are formed by applying heat energy including either cryo-ablation, thermoelectric cooling, heating with heat pipes, or other known heating or cooling techniques or RF energy. The electrode holders 32, 34 may be arranged on the legs of a forceps device as described above with respect to FIG. 1. Alternatively, the electrode holders 32, 34 may be positioned on the ends of catheters or other medical devices

in which case a controller will be used to accurately locate the electrodes on opposite sides of the heart tissue.

[0041] FIG. 3 shows an alternative embodiment of a treatment device 40 with all of the electrodes 44 (positive and negative) mounted in a single electrode holder 42 placed on the epicardial surface of the heart 50 with the electrodes protruding towards the endocardial surface. The electrodes 44 are arranged in a bipolar arrangement of equally spaced electrodes with alternating polarities. The treatment device 40 includes an anvil 46 that is placed inside the heart. The anvil 46 supports the tissue for penetration of the radio frequency, cryo-ablation, thermoelectric, or other electrodes 44 and assures that the electrodes easily penetrate all the way through the heart wall. The electrodes 44 may touch the anvil 46, protrude into the anvil, or be spaced slightly from the anvil. Preferably, the electrodes completely transverse the tissue. A handle 48 is provided to hold the electrode holder 42 parallel to the anvil 44. In addition, a temperature sensing member 52 is provided to provide feedback to a controller to control the application of energy.

[0042] FIG. 4 illustrates a treatment device 60 with a single electrode holder 62 and a single array of electrodes 64 similar to the device of FIG. 3, except there is no anvil. The electrodes 64 are sharpened adequately to allow penetration through the heart wall without the use of an anvil and there is no need for the anvil mechanism shown in FIG. 3. As in the embodiments above, a temperature sensing member 76 is provided between electrodes. At the proximal end of the electrode holder 62 the electrode holder is connected to a handle 66 by a stem 68 of sufficient length and formability to allow transthoracic procedures. The handle 66 contains a power control switch 70, a power indicator light 72, and a cable 74 for connection to an energy source.

[0043] The electrodes 44 in the embodiment of FIG. 4 and in other embodiments with a single electrode holder are preferably of sufficient length to completely transverse the tissue and even protrude out an opposite side. The electrodes are preferably at least 4 mm long.

5 [0044] FIGS. 5 and 5A show a treatment device 80 including an electrode holder 82 and a plurality of electrodes 84 arranged in an array on the electrode holder. The electrode holder 82 is connected to a handle 86 by a stem 88. The stem 68 is pivotally connected to the electrode holder 82 to improve maneuverability for transthoracic procedures. As shown in FIG. 5A, the electrode
10 holder 82 can be pivoted 90 degrees in two directions to achieve a desired orientation of the parallel electrode array.

[0045] FIG. 6 illustrates a treatment device 100 having an electrode holder 102 with a curved shape. The electrode holder 102 supports an array of electrodes 104 in a curved linear array. As in previous embodiments, the electrode holder 102 is
15 supported on a handle 106 by a stem 108 which is preferably a flexible shaft. The electrode holder 102 is configured to fit the anatomical need to stop atrial fibrillation in specific locations of the heart, such as around the pulmonary veins. The electrodes 102, their length, diameter, and spacing are the same as in previous embodiments. The different shapes may also be provided with different curvatures
20 and in different sizes.

[0046] FIG. 7 is a probe or catheter type treatment device 110 with an electrode holder 112 at the distal end containing a plurality of positive and negative electrodes 114. The treatment device 110 of FIG. 7 also includes a temperature sensing member 116, such as a thermocouple, and two additional diagnostic
25 electrodes 118. The diagnostic electrodes 118 are located about 1 mm to about 2 mm on each side of a line through a centerline of the electrodes 114. The diagnostic electrodes 118 may be used to measure the potential across the lesion to

assure the electrodes 114 are properly placed across an atrial fibrillation pathway and/or to assure total blockage of the atrial fibrillation pathway before the electrodes are removed from the heart wall. FIG. 7 also shows the pattern of holes formed in the heart tissue 120 by the electrodes 114 (holes 1-8), the temperature sensing member 116 (hole 11), and the diagnostic electrodes 118 (holes 9 and 10). The electrical potential is preferably measured between the diagnostic electrodes. In addition, the electrical potential may be measured between electrodes 114, 118 and sensing member 116, for example, measured between holes 4-9, 4-11, 5-9, 5-10, 9-11, and 10-11 to gain electrical signal vector information.

[0047] FIGS. 8 and 9 illustrate a probe or catheter type treatment device 130 having electrode holder 132 at a distal end with a plurality of positive and negative electrodes 134. A mechanical pusher arm 136 within the catheter device 130 acts as a cam to cause the electrodes to extend from or retract into the catheter device. As shown in FIG. 8, when the mechanical pusher arm 136 is in a proximal position the electrodes 134 are retracted entirely within the distal end of the treatment device 130. When the mechanical pusher arm 136 is advanced to the distal position illustrated in FIG. 9, a ramp 138 on the pusher arm moves the electrodes 134 and the temperature sensor 140 to extended positions at which the electrodes and temperature sensor project through openings 142 in the device. The openings 142 may be one or more holes, as shown, or may be slots.

[0048] FIGS. 10 and 11 illustrate another probe or catheter type treatment device 150 having an electrode holder 152 at a distal end with a plurality of positive and negative electrodes 154 and a temperature sensor 156. The electrode holder 152 includes a circular track 158. As the catheter device 150 is advanced along the heart wall tissue, the electrodes 154 rotate out to 90 degrees with respect to the catheter and sequentially enter the heart wall tissue. At a proximal end of

the track 158 the electrodes 154 are pulled out of the tissue, retracted into the catheter, and lay flat on the track. FIG. 11 is an enlarged view of a portion of the distal end of the device 150 showing more clearly the track 158 and a wheel 160 for supporting the track.

5 [0049] FIGS. 12 and 13 show an alternative catheter treatment device 170 in which a plurality of positive and negative electrodes 172 and a temperature sensor 180 are advanced out of a distal end of the catheter or through openings in the catheter. The electrodes 172 are advanced out the end of a catheter sheath from a retracted delivery position (FIG. 12) to an extended treatment position (FIG. 13) by a pusher mechanism 174. The electrodes 172 are advanced in a circular
10 manner to create a circular lesion, such as around a pulmonary vein. A center lumen of the catheter device 170 is used to advance a guidewire 176 upon which is mounted a distal tip locator and/or balloon 178 to position the center of the catheter in the center of the pulmonary vein opening. Preferably, the electrodes
15 172 are flared to a desired diameter by a conical member 182 on the guidewire 176.

[0050] FIGS. 14 and 15 illustrate alternative embodiments of treatment devices including ways to add an FDA approved glue, sealant, hemostat, mechanical plug, or other material around the electrodes to seal or encourage sealing of the holes
20 created by the electrodes. A treatment device 190 of FIG. 14 includes hollow electrodes 192 for delivery of a liquid or paste into the holes created by the electrodes. The electrodes may be partially or fully hollow. In addition, or in place of the hollow electrodes, a mechanical plug 194 or disk may be positioned on the electrode holder 196 around each of the electrodes to seal the holes after
25 removal of the electrodes. Alternatively, a strip of plug material may be used in place of the disks 194.

[0051] FIG. 15 shows a treatment device 200 in which the electrodes 202 (and possibly temperature sensing member) include side holes 204, a partially hollow central portion 206, and a plugged distal end 208 for delivery of one of the sealants described above to the holes in the tissue. The sealant delivered through a hollow body 210 of the device 200 to stop the potential leakage of blood from the heart wall.

[0052] Another method of sealing the holes in the heart tissue is to continue delivery of RF energy or other energy at full or partial power during extraction of the electrodes from the tissue. Further, the RF energy or other energy may be used to aid in delivery of a sealant or glue by melting the material. The holes may also be sealed naturally by coagulation caused by residual warmth in the tissue after application of the energy.

[0053] One example of the parameters used to create a transmural lesion with the devices described above is about 10-25 watts of power applied for about 20-40 seconds to achieve a temperature of about 65-75 degrees Centigrade. This system achieves a very narrow and complete transmural scar in heart tissue. The lesion has a narrow width which is preferably about 1 to about 3 mm.

[0054] In use of the forceps type treatment devices described above, one of the electrode holders 12 or legs of the forceps is inserted into the heart through an incision and is positioned on the endocardial surface of the heart at the location identified for treatment. The other electrode holder 14 or leg of the forceps is positioned on the epicardial surface of the heart. The legs of the forceps are brought together on opposite sides of the heart wall and bi-polar RF energy is applied to create a burn or lesion that is transmural or extends completely through the heart tissue.

[0055] The forceps of FIG. 1 are designed to create a lesion in a straight line. Other forceps may be curved to form a transmural lesion with a curved or semicircular pattern. The semicircular lesion pattern may be used to create a lesion pattern that includes the four pulmonary veins. The straight forceps may be used to create an ablation at the vena cava intersection and for the right ventricle in the area of the tricuspid valve. In addition, the curved forceps of may be used for treatment at the base of the atrial appendix. The forceps shapes and uses illustrated and described are merely examples of some of the shapes which may be used to reach different parts of the heart. It should be understood that other shapes may also be used to reach other parts of the heart tissue to be treated.

[0056] The treatment according to the present invention can be done with or without extracorporeal circulation. The treatment may be performed on a beating or stopped heart. When beating heart surgery is performed the leg of the forceps which enters the heart is preferably provided with a seal, gasket, or suture to prevent blood leakage at the incision.

[0057] A hinge 26 of the forceps shown in FIG. 1 and in other embodiments of the invention is preferably an adjustable hinge to keep an even pressure along the entire length of the electrodes provided on the legs of the forceps. The hinge preferably provides a means of keeping the legs of the forceps parallel and to accommodate tissue thicknesses from about 1-15mm.

[0058] A length of the electrode holders in the various embodiments of the invention may vary depending on the length of the lesion desired. For example the length of the electrode holders may be about 1 cm to about 10 cm.

[0059] The embodiment of FIG. 16 is a treatment device 220 with flat electrodes 222 positioned on opposite surfaces of the heart tissue without tissue penetrating electrodes. The tissue contacting faces of the electrodes 222 preferably have a flat tissue contacting surface with radius corners to best minimize the width of the

treatment zone and prevent current concentration at the corners. The electrodes may be sandwiched between insulating layers and measuring electrodes. The measuring electrodes are provided upon opposite sides of the RF electrodes and are used for measuring the potential across the lesion. The measurement of the potential across the lesion is used to determine whether treatment is complete. It may be desirable to roughen the tissue contacting surface of the electrode to allow the electrode to break or cut through the thin film of insulating tissue which forms a barrier on the endocardial and epicardial surfaces of the heart.

[0060] Although the present invention has been described with respect to the application of RF bi-polar energy, it should be understood that the forceps device according to the present invention may also be used to apply other types of energies, such as cryo, ultrasound, microwave, heat, or other electrical means of providing an interruption to the abnormal electrical circuits at given regions. These types of energy would be able to create a transmural barrier having a minimal width to block electrical currents. The length and curvature of the electrode and the corresponding lesion created can be designed to meet requirements of a particular treatment site.

[0061] Although electrodes having circular cross sections have been described as the preferred embodiments, other electrode cross sections may be used. Methods for attaching the electrodes to the electrode holders include molding, welding, the use of adhesive to attach electrodes to existing instruments, or the use of sleeves containing the electrodes which slide over the legs of the exiting forceps instruments.

[0062] The electrodes positioned on the electrode holders of the forceps type devices have been illustrated as brought together by manual force applied by the operator. However, the electrodes may be brought together by other means such as by magnets, springs, or the like.

[0063] One or more methods may be employed in any of the foregoing embodiments of the invention to facilitate electrode insertion. These methods include vibration, such as ultrasonic vibration, oscillation in any plane, rotation of the electrodes, sequential electrode insertion, coatings or lubricants on the electrodes, and tip geometries which aid in penetration. In addition, a holding device, such as a vacuum device, may be used to hold the treatment device to the tissue before and during penetration with the electrodes.

[0064] While the invention has been described in detail with reference to the preferred embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention.

WHAT IS CLAIMED IS:

1. An RF treatment device for creating transmural lesions in tissue,
the device comprising:
an electrode holder;
5 a plurality of tissue penetrating RF needle electrodes arranged in
a single linear array to create a continuous transmural lesion, each of the RF
needle electrodes having a length of at least 4 mm; and
an RF energy source connected to each of the RF needle
electrodes with alternating electrodes connected to opposite polarities of the RF
10 energy source.
2. The device of Claim 1, wherein the linear array of RF needle
electrodes forms a straight line.
3. The device of Claim 1, wherein the linear array of RF needle
electrodes forms a curved line.
- 15 4. The device of Claim 1, wherein each of the RF needle electrodes
has a length of about 5 mm to about 15 mm to completely transverse the tissue.
5. The device of Claim 1, wherein each of the RF needle electrodes
has a sharp tissue penetrating tip.
- 20 6. The device of Claim 1, wherein the electrode holder is mounted
on a catheter.

7. The device of Claim 1, wherein the electrode holder is mounted on a non-catheter medical device.

8. The device of Claim 1, further comprising an anvil movable with respect to the electrode holder to trap tissue between the electrode holder and the anvil.

9. The device of Claim 8, further comprising a plurality of RF needle electrodes positioned on the anvil.

10. The device of Claim 1, wherein the RF needle electrodes are retractable.

11. The device of Claim 10, further comprising a cam element within the electrode holder for moving the RF needle electrodes from a retracted position to an extended position.

12. The device of Claim 10, wherein the RF needle electrodes are rotatable within the electrode holder from a retracted position to an extended position.

13. The device of Claim 10, wherein the needle holder is a tubular member and the RF needle electrodes are contained within the tubular member in a retracted position and are pushed out of a distal end of the tubular member to an extended position.

14. The device of Claim 1, wherein the RF needle electrodes include holes for delivery of a sealant.

15. The device of Claim 1, further comprising a temperature sensing member positioned between two of the RF needle electrodes.

5 16. The device of Claim 16, wherein the temperature sensing member is mounted on a tissue penetrating needle.

17. The device of Claim 1, further comprising diagnostic electrodes positioned on tissue penetrating needles arranged on opposite sides of the linear array of RF needle electrodes.

10 18. The device of Claim 1, wherein the RF needle electrodes are parallel.

19. The device of Claim 1, further comprising means for aiding penetration of the tissue with the RF needle electrodes.

15 20. The device of Claim 19, wherein the means for aiding penetration is vibration, oscillation, or impact.

21. The device of Claim 19, wherein the means for aiding penetration includes coatings or lubricants.

22. An RF treatment device for creating transmural lesions in heart tissue, the device comprising:

an electrode holder;

5 a plurality of tissue penetrating RF needle electrodes arranged in a single linear array to create a continuous transmural lesion, each of the RF needle electrodes having a length sufficient to create a transmural lesion through the entire thickness of the tissue of the heart wall; and

an RF energy source connected to each of the RF needle electrodes.

10 23. The device of Claim 22, wherein the RF needle electrodes having a length of at least 4 mm.

24. The device of Claim 22, wherein the linear array of RF needle electrodes forms a straight line.

15 25. The device of Claim 22, wherein the linear array of RF needle electrodes forms a curved line.

26. The device of Claim 22, wherein the RF needle electrodes are parallel.

27. A method of treating atrial fibrillations comprising:
penetrating heart tissue to be treated with an RF treatment device
20 comprising a plurality of tissue penetrating RF needle electrodes arranged in a single linear array; and

applying radio frequency energy to form a transmural lesion which provides a barrier across an entire thickness of the heart tissue to prevent the passage of abnormal electrical currents through the heart tissue.

5 28. The method of Claim 27, wherein the heart tissue is penetrated from an endocardial surface of the heart.

 29. The method of Claim 27, wherein the heart tissue is penetrated from an epicardial surface of the heart.

10 30. The method of Claim 27, wherein the heart tissue is penetrated with RF needle electrodes having a length sufficient to create a transmural lesion through the tissue of the heart wall.

 31. The method of Claim 27, wherein the heart tissue is penetrated with RF needle electrodes having a length sufficient to penetrate at least 2/3 of the way through the heart wall.

15 32. The method of Claim 27, further comprising a step of controlling the power delivered to the RF treatment device based on a temperature sensed within the heart tissue.

 33. The method of Claim 27, wherein the step of applying radio frequency energy forms a narrow transmural lesion with a width of about 1 mm to about 3 mm.

34. The method of Claim 27, further comprising a step of applying a glue, sealant, hemostat or mechanical plug to prevent bleeding from the holes created by the RF needle electrodes.

5 35. The method of Claim 27, further comprising retracting the RF needle electrodes from the heart tissue while applying radio frequency energy to assist in sealing the holes created by the RF needle electrodes.

36. The method of Claim 27, further comprising controlling the application of radio frequency energy based on feedback from a temperature sensor and diagnostic electrodes.

10 37. A method of treating atrial fibrillations comprising:
positioning a first electrode of a radio frequency forceps on an endocardial surface of a heart at a location to be treated;
positioning a second electrode of the radio frequency forceps on an epicardial surface of the heart opposite the first electrode; and
15 applying radio frequency with the first and second electrodes to form a transmural lesion which provides a barrier to the passage of abnormal electrical currents through the heart tissue.

38. A medical device for creating transmural lesions in tissue, the device comprising:
20 an electrode holder;
a plurality of tissue penetrating needle electrodes arranged in a single linear array to create a continuous transmural lesion, each of the needle

electrodes having a length sufficient to create a transmural lesion through the tissue of the heart wall; and

an energy source connected to each of the needle electrodes.

39. The device of Claim 38, wherein the electrodes are one of
5 unipolar RF electrodes, bipolar RF electrodes, cryo-ablation electrodes, thermoelectric electrodes, heat pipe electrodes, and ultrasonic electrodes.

40. The device of Claim 38, wherein the electrodes have a length of at least 4 mm to create the transmural lesion.

FIG. 1

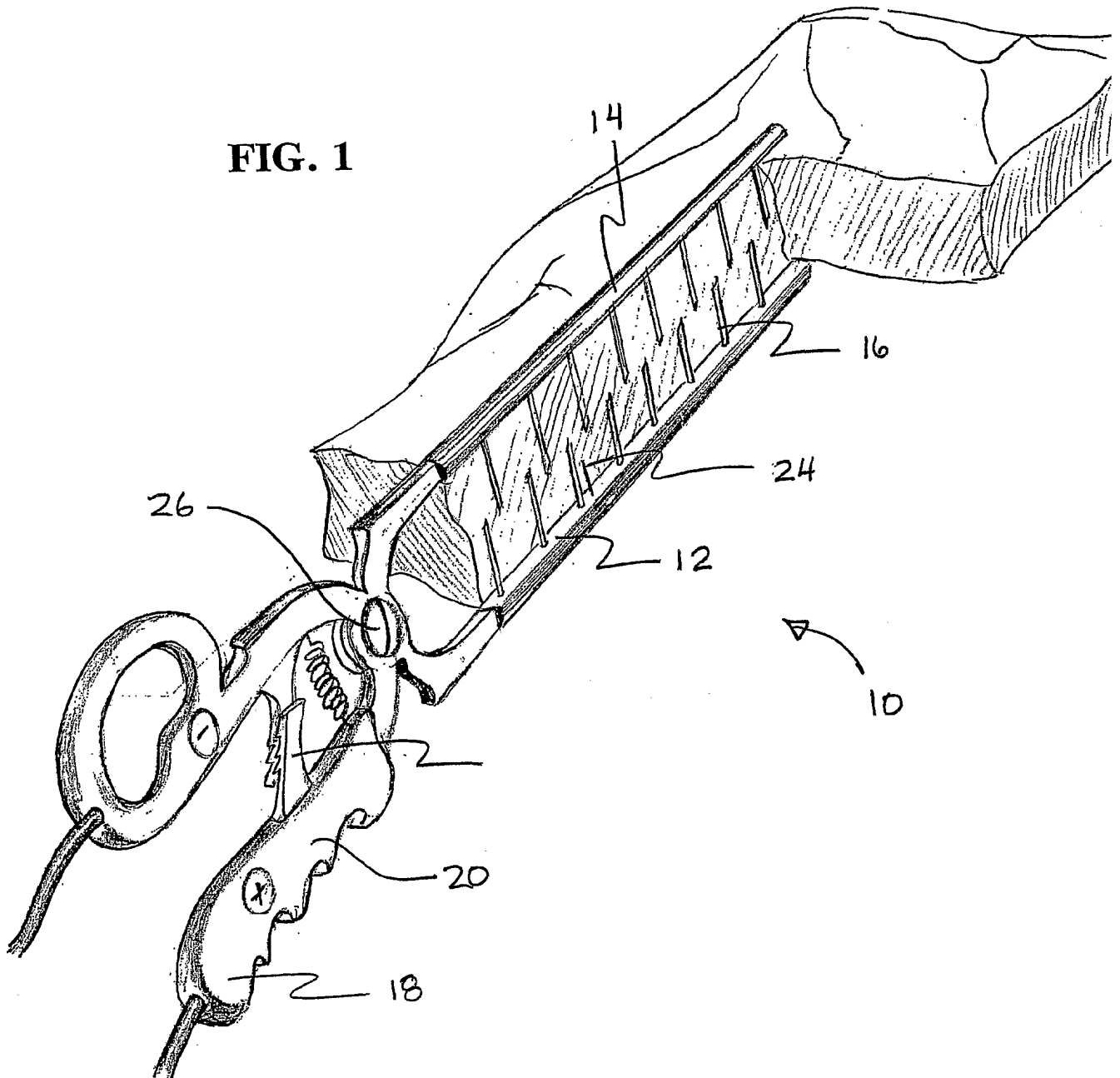


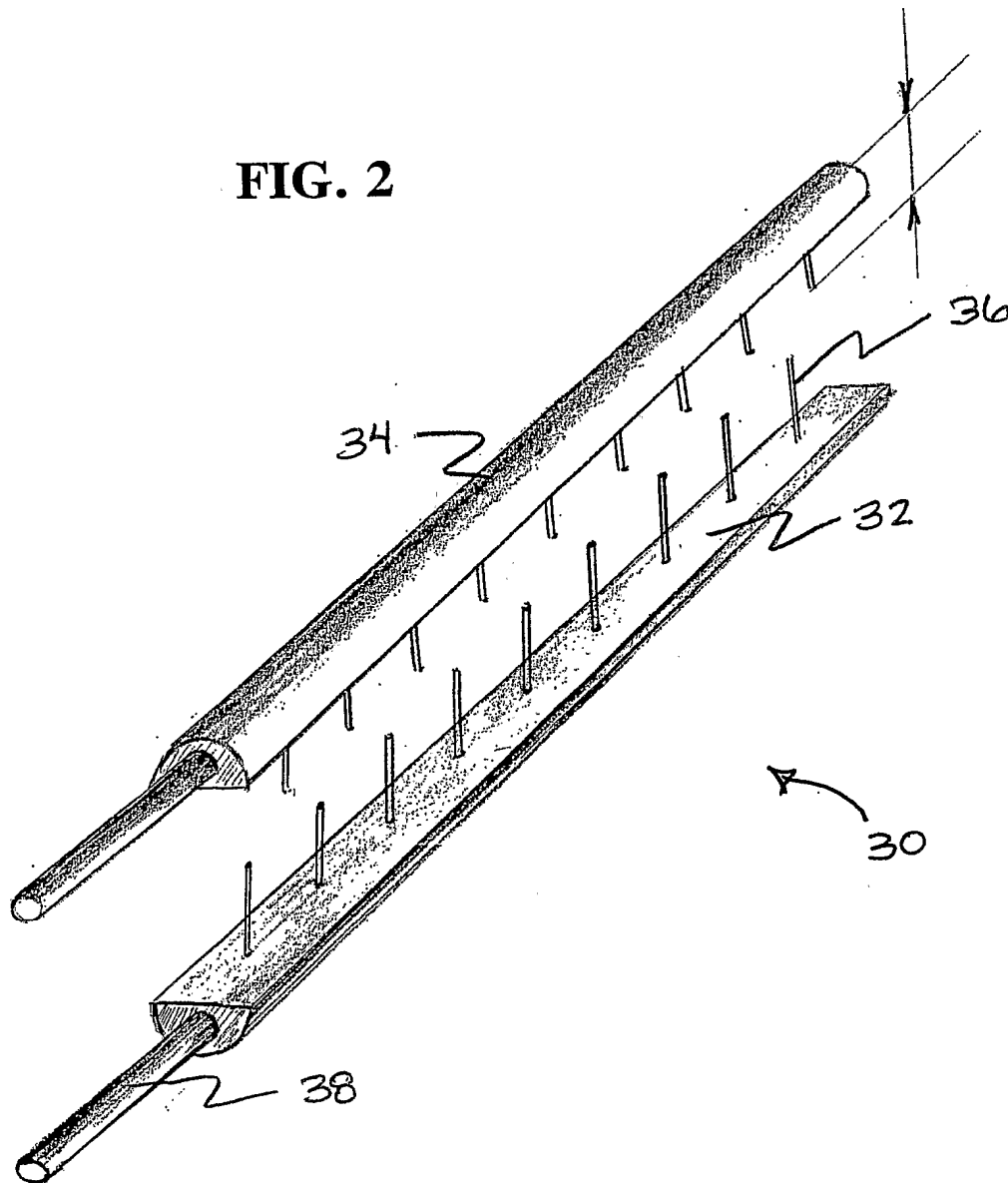
FIG. 2

FIG. 3

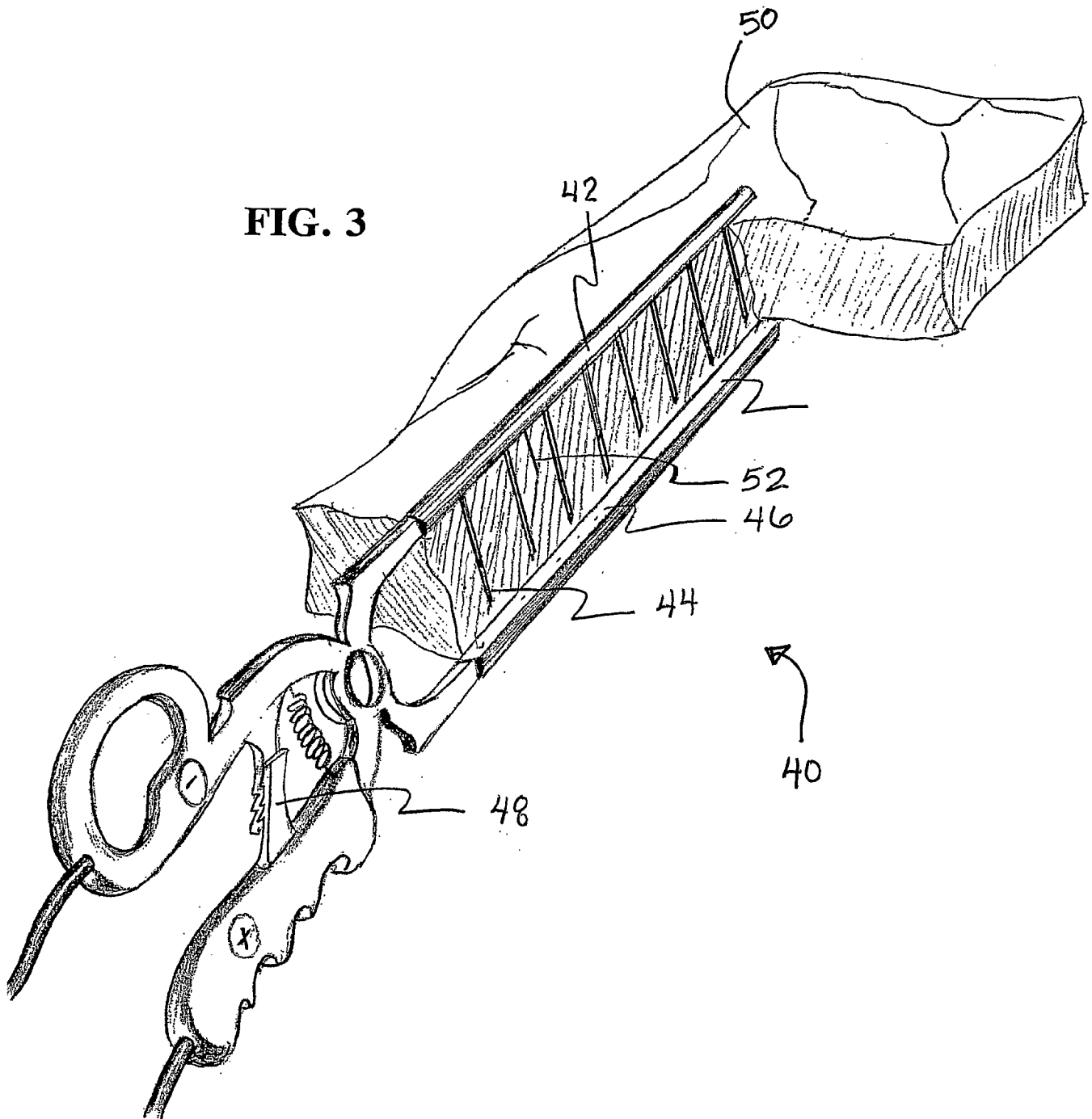


FIG. 4

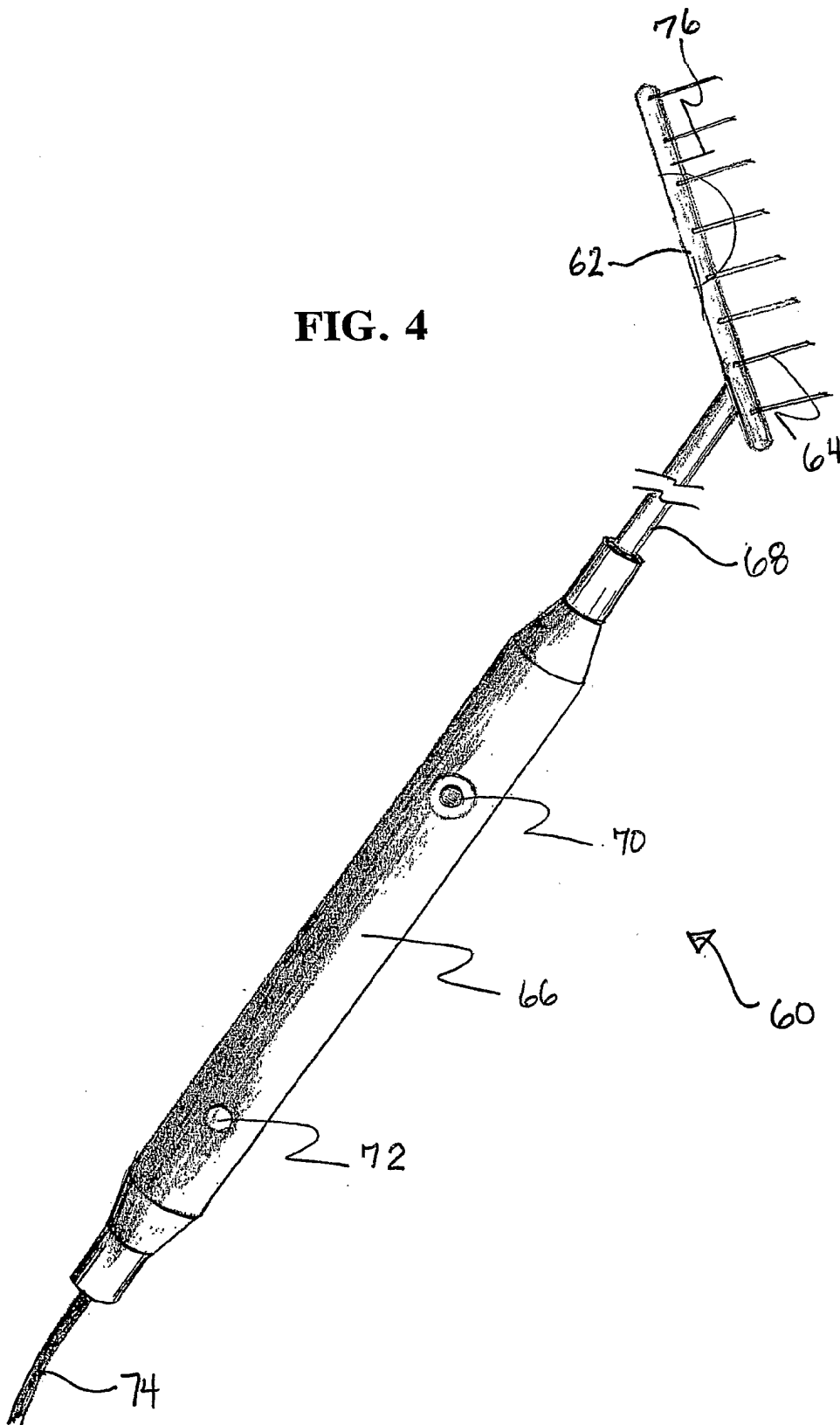
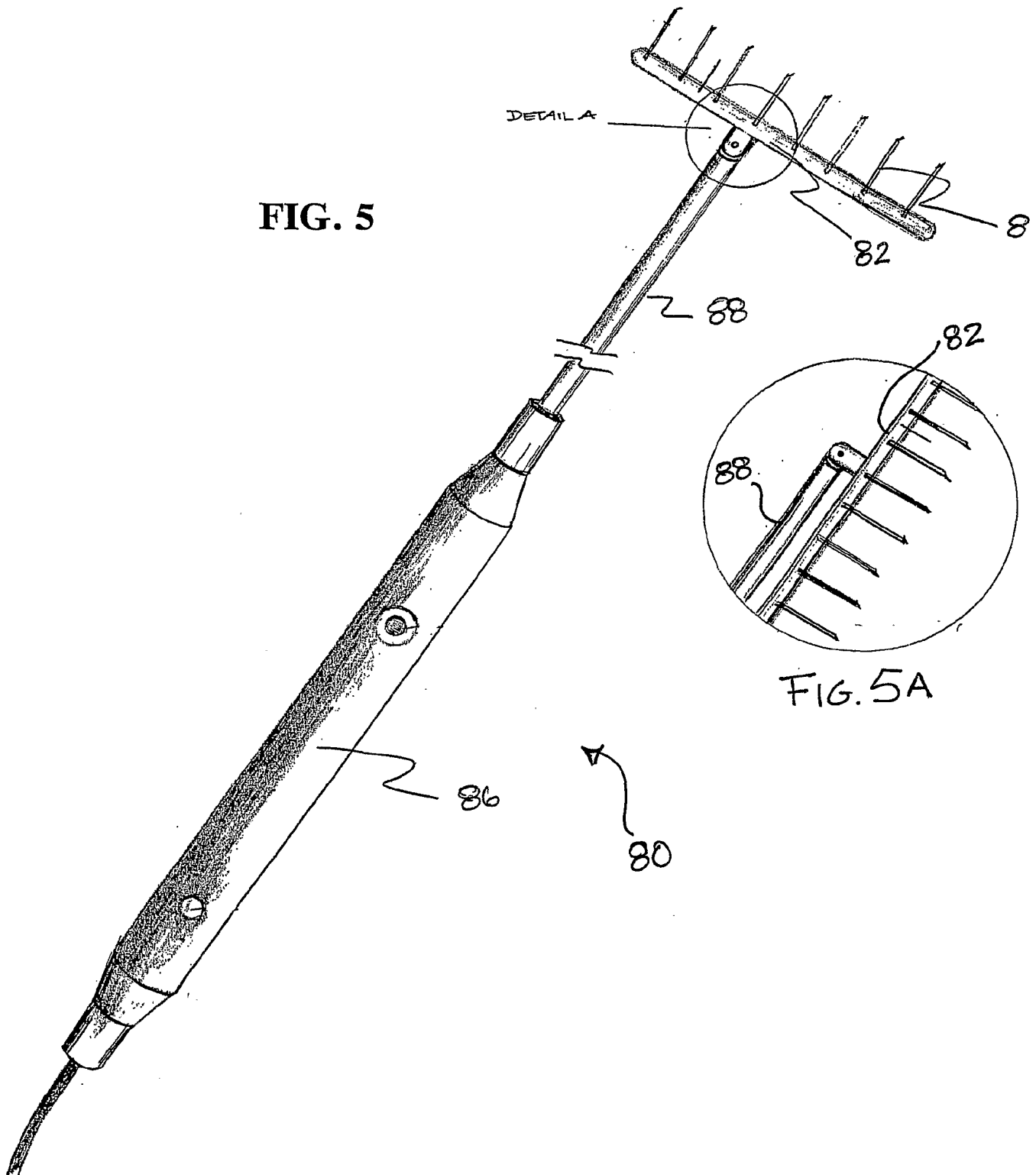


FIG. 5



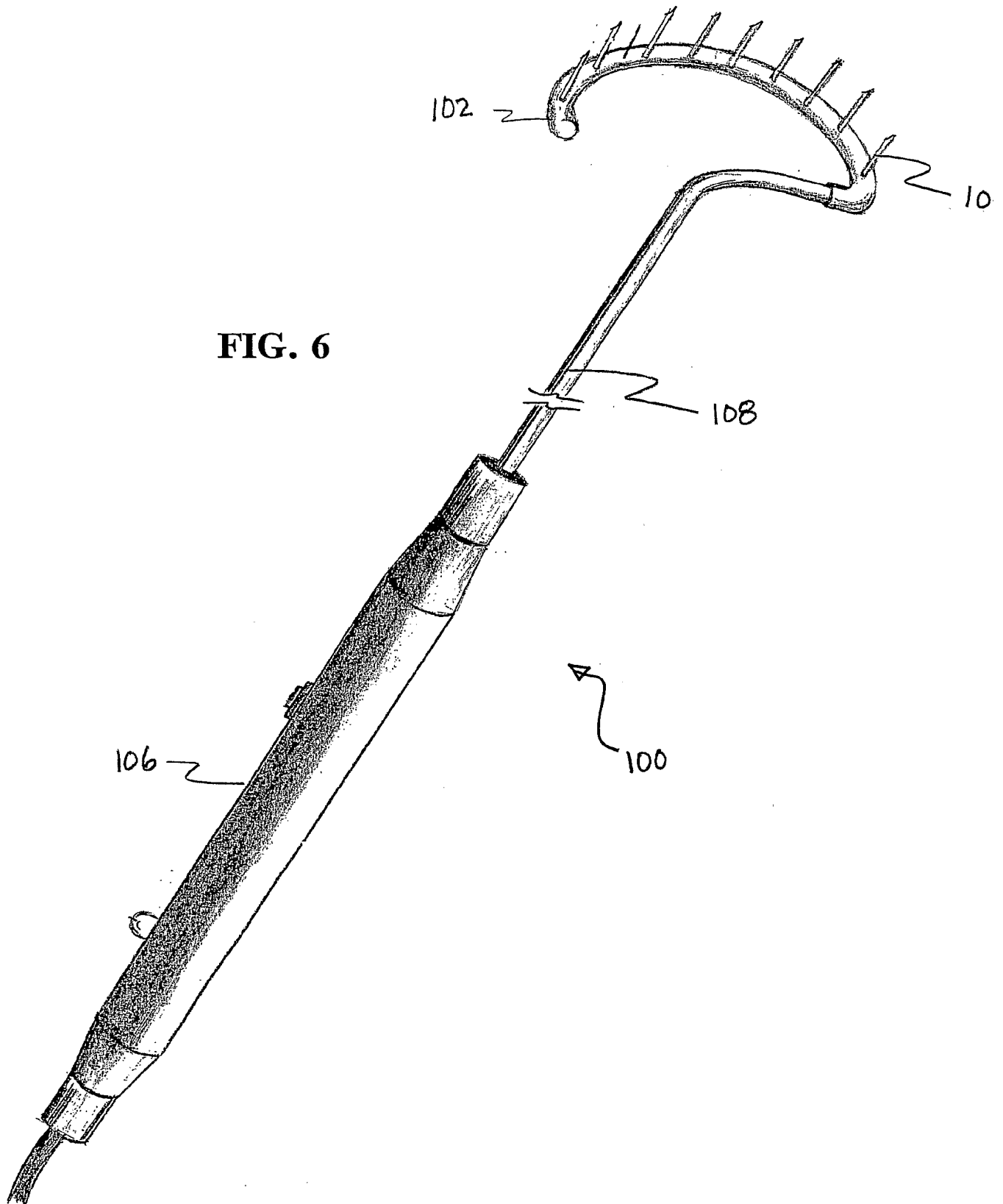


FIG. 7

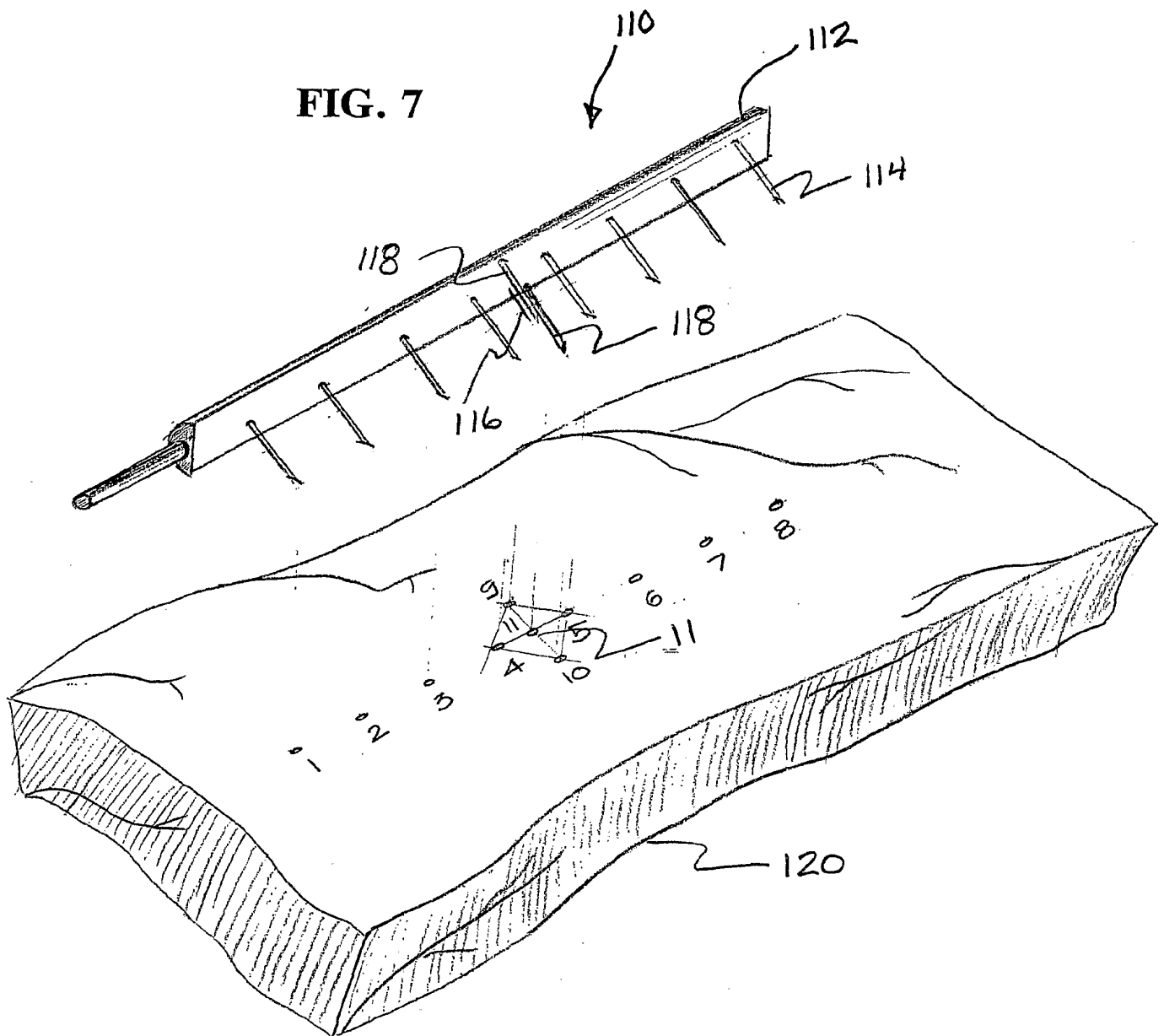


FIG. 8

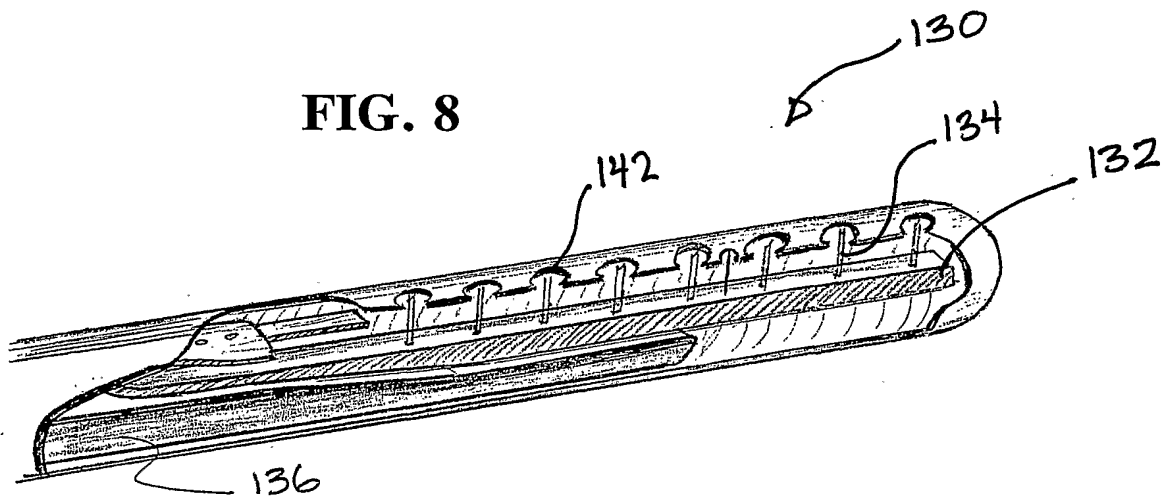
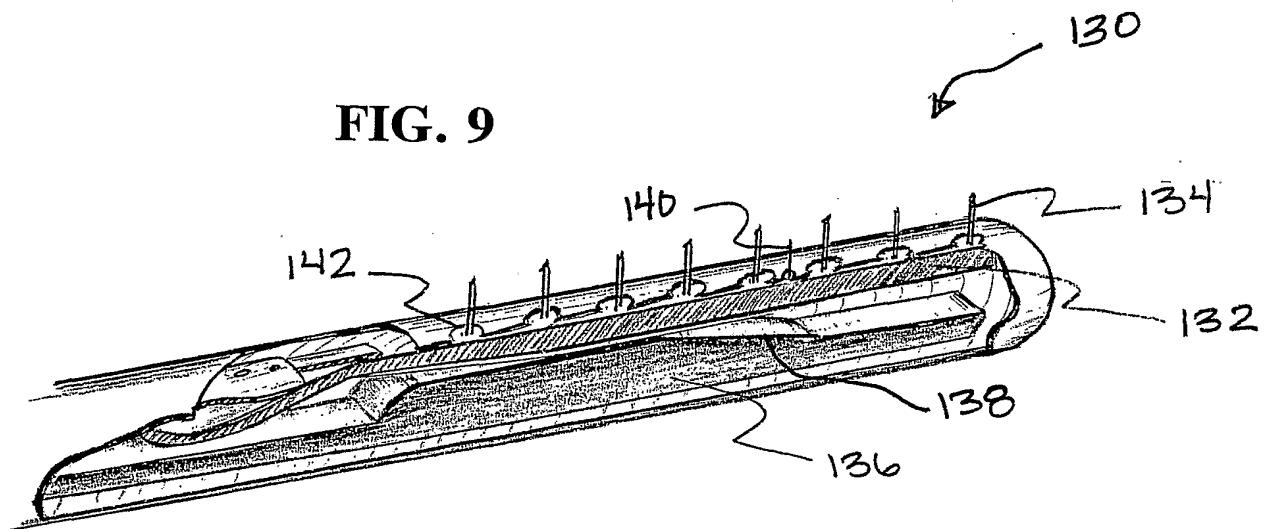


FIG. 9



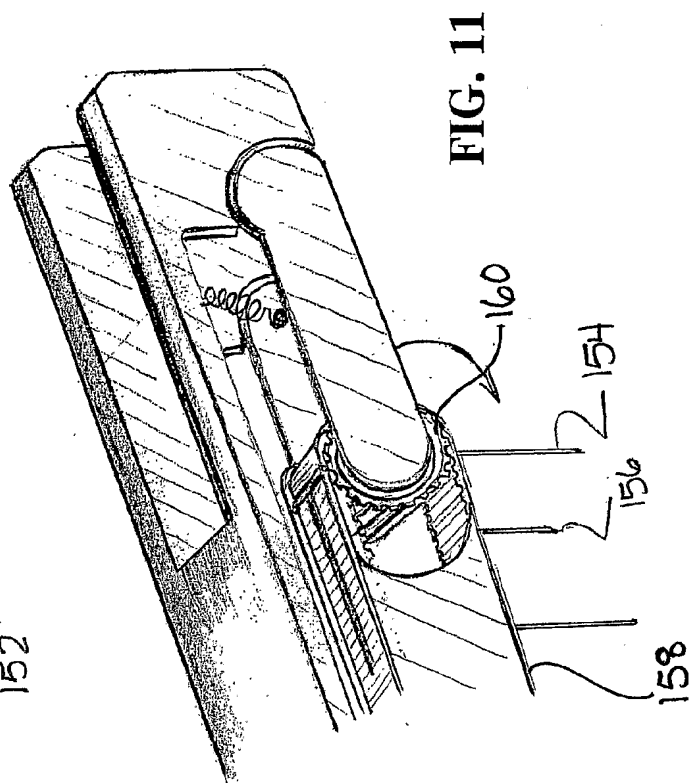
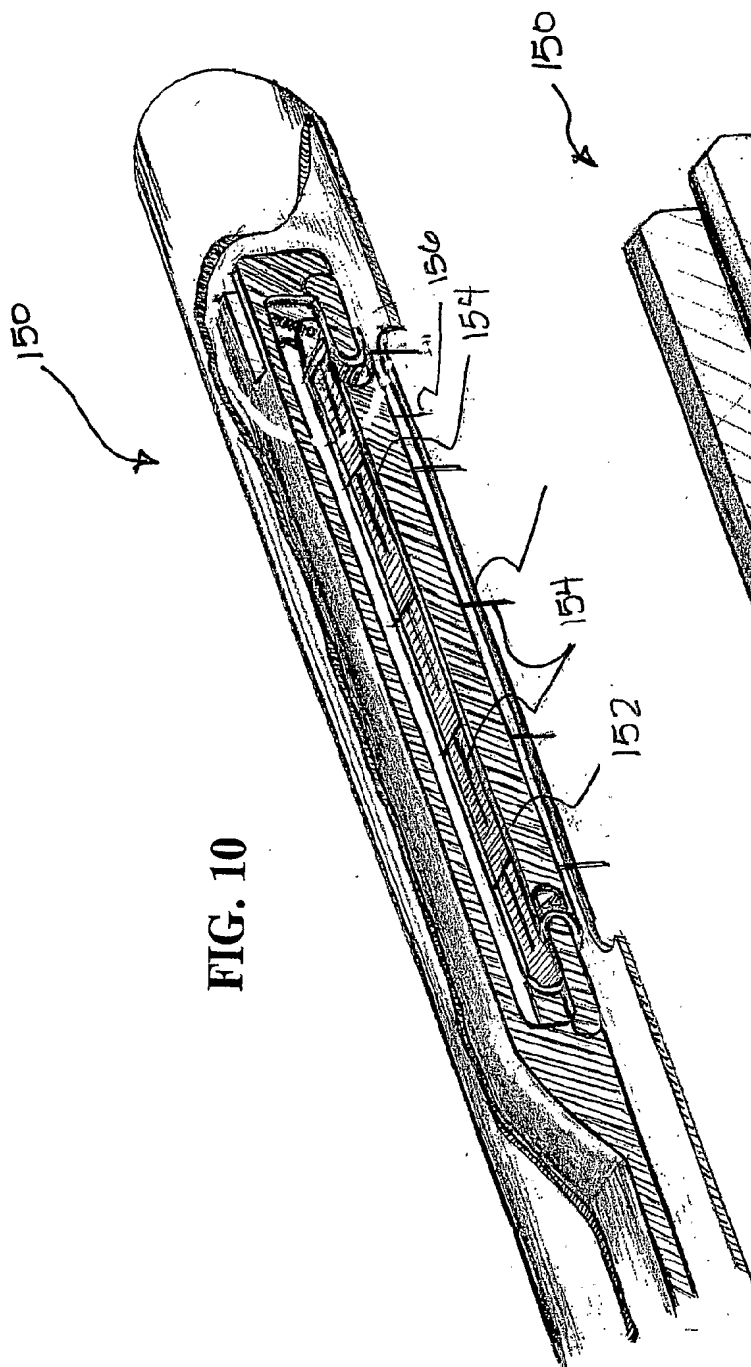


FIG. 12

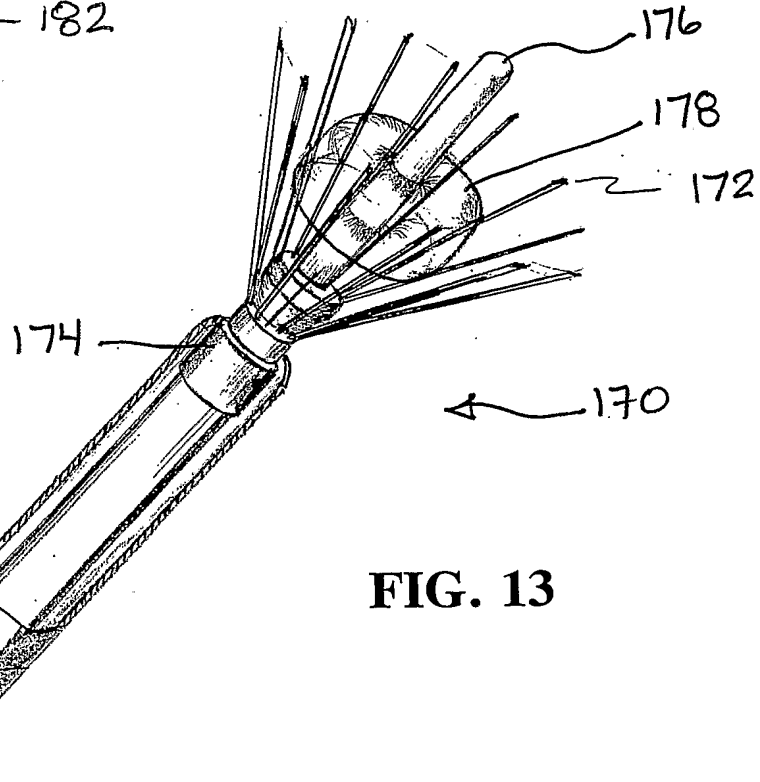
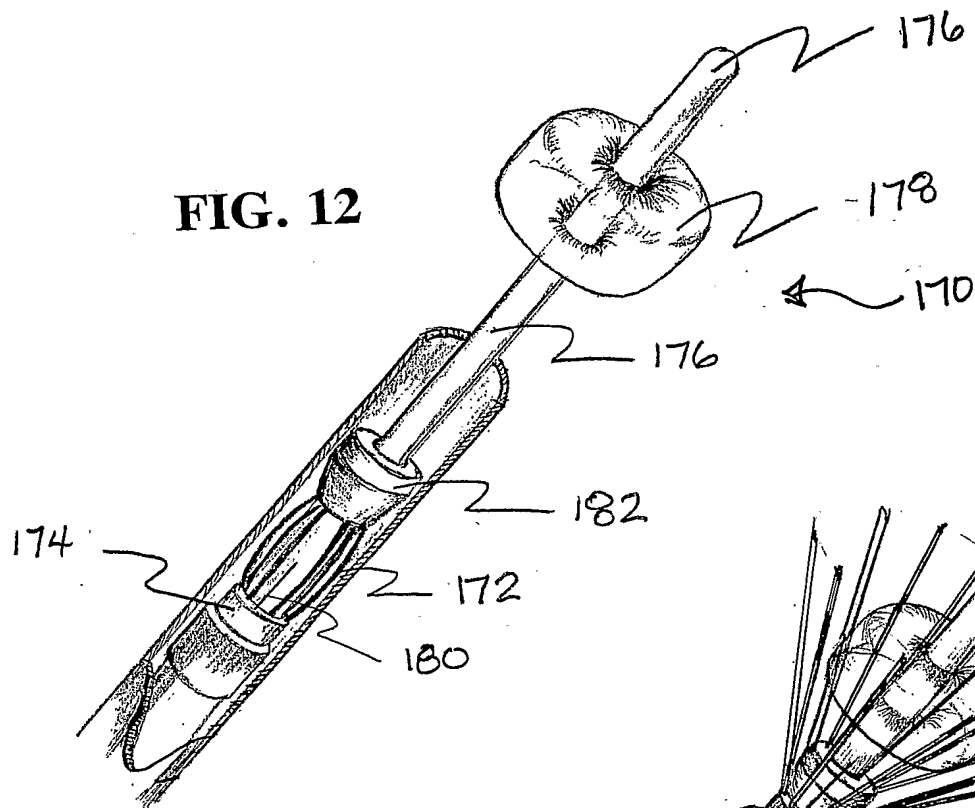


FIG. 13

FIG. 14

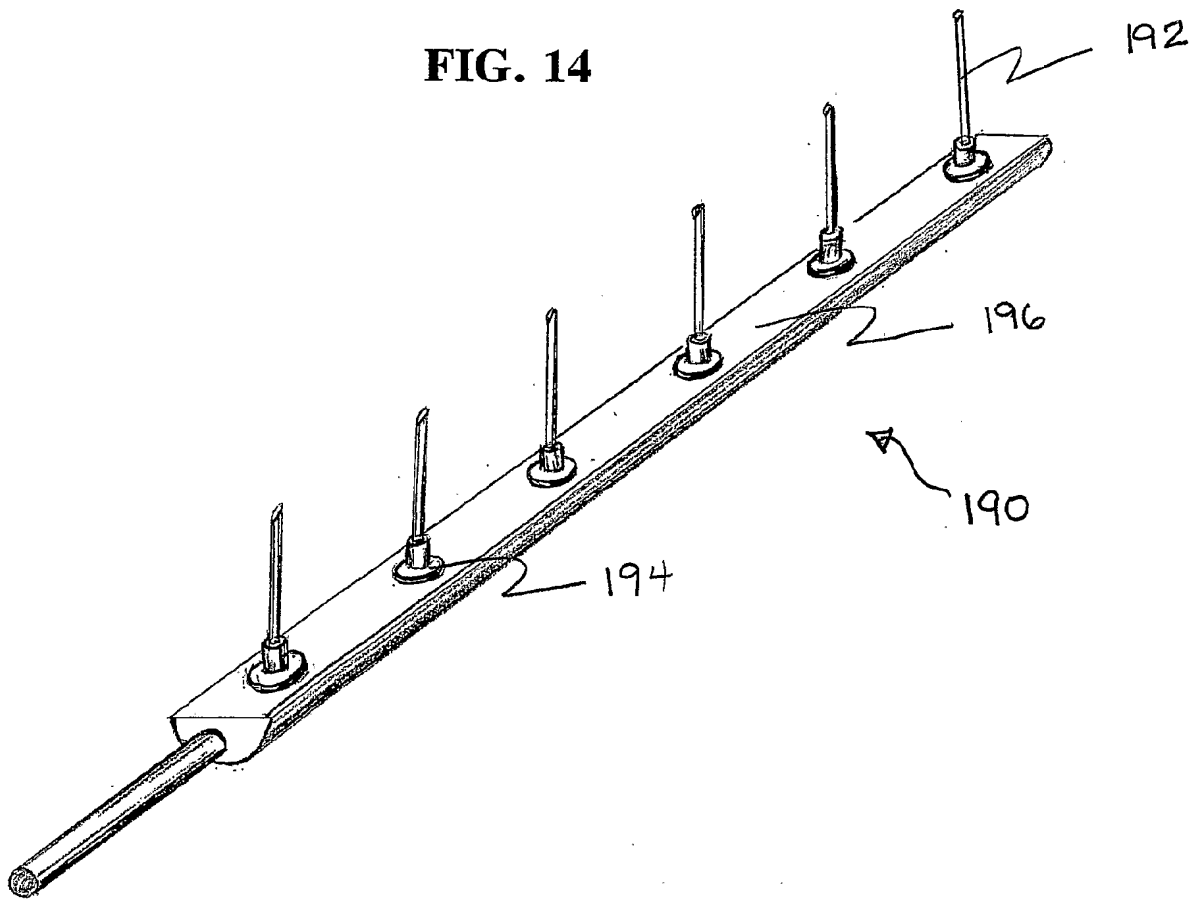


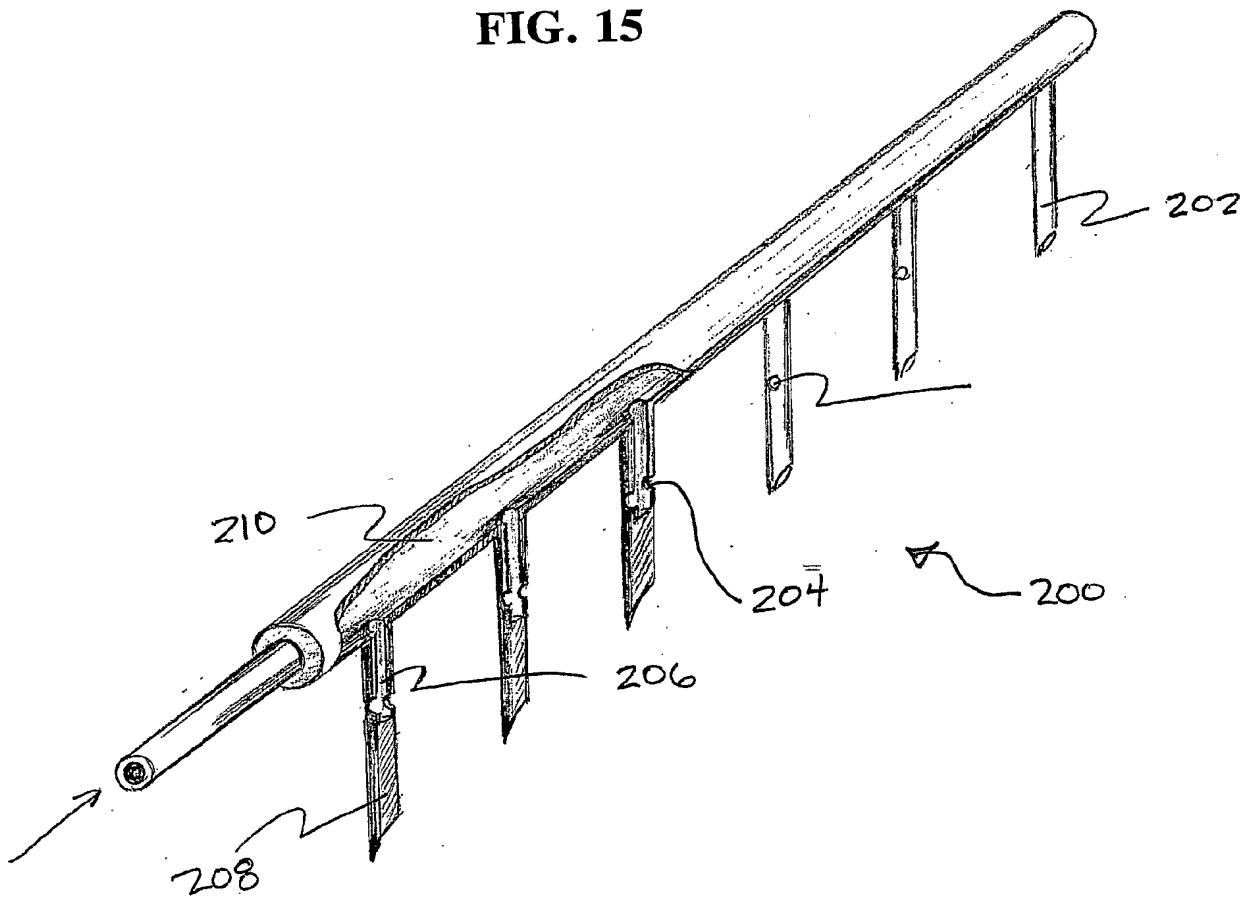
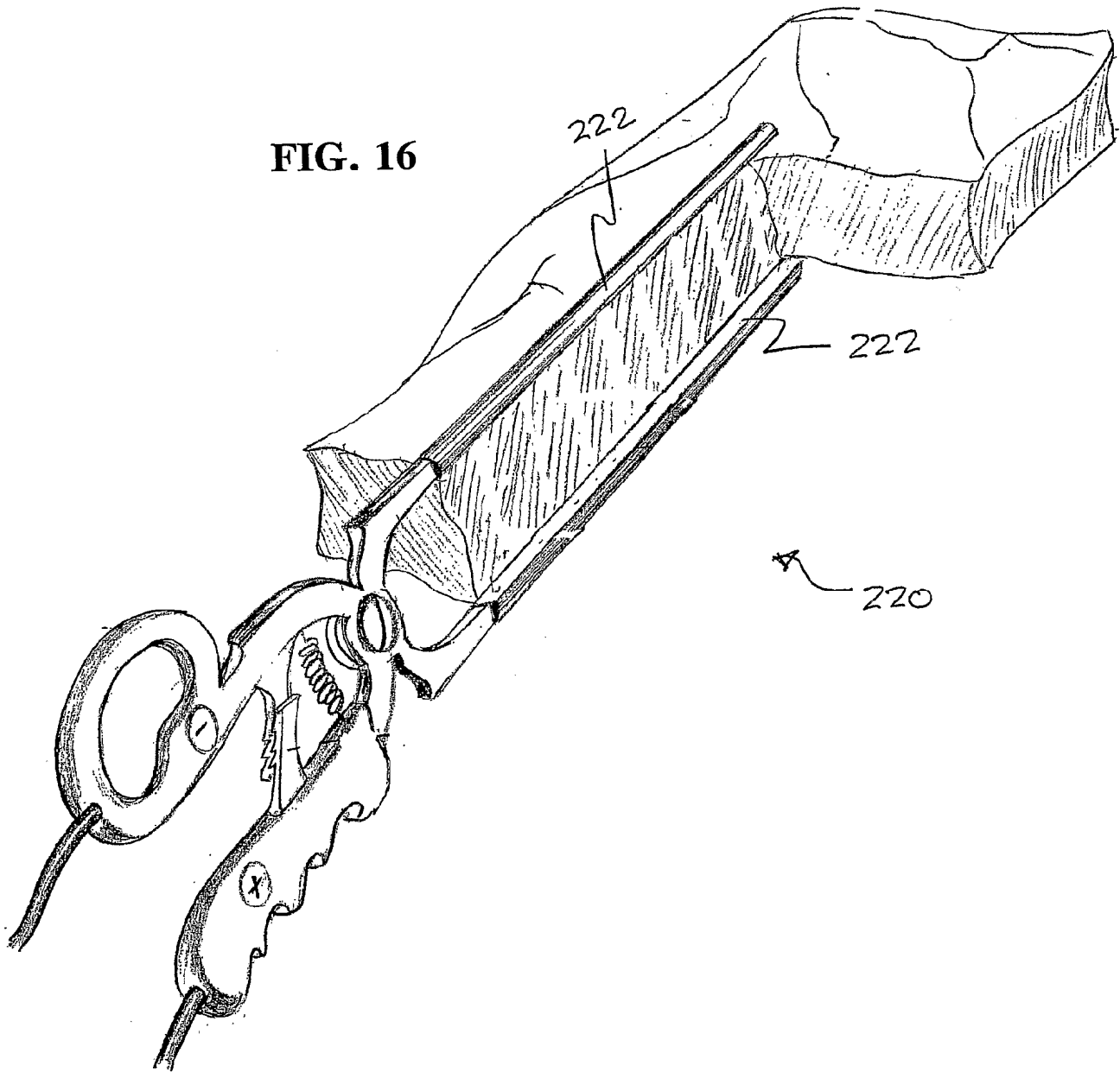
FIG. 15

FIG. 16



Electronic Patent Application Fee Transmittal

Application Number:	11098030			
Filing Date:	01-Apr-2005			
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping			
First Named Inventor/Applicant Name:	Dieter Manstein			
Filer:	Emil Bradley Gould/Miesha Hollingsworth			
Attorney Docket Number:	036213/US/2-475387-00230			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

Electronic Acknowledgement Receipt

EFS ID:	6451860
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Emil Bradley Gould/Miesha Hollingsworth
Filer Authorized By:	Emil Bradley Gould
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	13-NOV-2009
Filing Date:	01-APR-2005
Time Stamp:	16:18:35
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 180
RAM confirmation Number	2455
Deposit Account	502054
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		p036213ids.pdf	111699 170912178b73c0287946e07fe5e811b5efc533b8	yes	3
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Information Disclosure Statement (IDS) Filed (SB/08)		1	2	
	Information Disclosure Statement (IDS) Filed (SB/08)		3	3	
Warnings:					
Information:					
2	Foreign Reference	02060523.pdf	1426004 d88eadd02cc661da4e0b5033b04c5dd80a82bd70	no	38
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	30132 b717e5508cb35f49a7b5974e50ba138e739643b6	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1567835		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Dieter MANSTEIN
Appln. Serial No. : 11/098,030
Filed : April 1, 2005
Entitled : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Group Art Unit : 3769
Confirmation No. : 6055
Examiner : Ahmed M. Farah

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO NON-FINAL OFFICE ACTION

SIR:

This paper is filed in response to a non-final Office Action dated September 18, 2009 (the "Office Action"). Prior to further examination, please amend the application, and consider the remarks as set forth herein below.

IN THE CLAIMS:

Please amend claims 1, 7, 24, and 32 as provided below, and add new claims 38 and 39. A complete listing of all claims and their current status is provided on separate sheets.

1. (Currently amended) An apparatus for tissue treatment, comprising:

a base;

a plurality of needles attached to the base;

an energy source provided in communication with at least one of the needles;

a spacer arrangement that is movably attached to the base for controlling penetration depths of the needles; and

a control module configured to vary characteristics of energy supplied by the energy source.

2. (Previously presented) The apparatus of claim 1 wherein more than one of the needles are electrically conductive, and wherein the energy source is configured to supply radio frequency electromagnetic energy to individual ones of the needles.

3-6. (Canceled)

7. (Currently amended) The apparatus of claim 1, wherein the spacer arrangement comprises a substrate ~~movably attached to the base~~, wherein the position of the substrate is adjustable relative to that of the base to control a distance between distal ends of the needles and a surface of the substrate.

8. (Previously presented) The apparatus of claim 1, wherein at least one of the base or the substrate further comprises a cooling arrangement configured to cool a skin surface, and wherein the cooling arrangement comprises at least one of an embedded conduit configured to circulate a coolant or a Peltier device.

9. (Canceled)

10. (Previously presented) The apparatus of claim 1, further comprising a vibrating arrangement provided in communication with the base.

11. (Previously presented) The apparatus of claim 1, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair

of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

12. (Canceled)

13. (Previously presented) The apparatus of claim 1, wherein at least one of the needles is nonconductive and hollow, and is configured to deliver a local analgesic to tissue proximal to a distal end of the needle.

14. (Previously presented) An apparatus for tissue treatment, comprising:

- a base;

- a plurality of needles attached to the base;

- an energy source provided in communication with at least one of the needles;

- a control module configured to vary characteristics of energy supplied by the energy source; and

- an electronic detection device in electrical communication with at least one of the needles that is configured to detect the presence of a nerve near the tip of the at least one of the needles.

15. (Previously presented) The apparatus of claim 1, further comprising:

- a source of optical energy; and

- at least one optical needle comprising at least one of a light fiber or a light guide, wherein the distal ends of the needles are configured to penetrate into at least one of the dermis or subdermal tissue, and wherein the apparatus is configured to deliver a controlled amount of optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle.

16-19. (Withdrawn)

20. (Previously presented) The apparatus of claim 1, wherein the plurality of needles protrude a plurality of distances from the base.

21. (Previously presented) The apparatus of claim 15, wherein a portion of the at least one needle is configured to absorb a portion of the optical energy and convert the optical energy to thermal energy.

22. (Previously presented) The apparatus of claim 14, wherein the control module is configured to prevent the energy source from supplying energy to a particular needle if a nerve has been detected near the particular needle.

23. (Previously presented) The apparatus of claim 14, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between two needles in a pair of needles is less than a distance between each one of the two needles and any other needle, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

24. (Currently amended) An apparatus for dermatological treatment, comprising:

a base;

a plurality of needles attached to the base;

a spacer arrangement that is movably attached to the base for controlling penetration depths of the needles;

an energy source provided in communication with at least one of the needles; and

a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles protrude a plurality of distances from the base.

25. (Previously presented) The apparatus of claim 24, wherein the energy source is a source of electromagnetic energy.

26. (Previously presented) The apparatus of claim 24, wherein a plurality of the needles are electrically conductive, and wherein the energy source is configured to supply radio frequency electromagnetic energy to individual ones of the needles.

27. (Previously presented) The apparatus of claim 24, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

28. (Previously presented) The apparatus of claim 24, further comprising:

at least one optical needle comprising at least one of a light fiber or a light guide,
wherein the apparatus is configured to deliver a controlled amount of optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle,

wherein the energy source comprises a source of optical energy.

29-31. (Withdrawn)

32. (Currently amended) An apparatus for tissue treatment, comprising:

a base;

a plurality of needles attached to the base;

a spacer arrangement that is movably attached to the base for controlling penetration depths of the needles;

an energy source provided in communication with at least one of the needles; and

a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

33. (Withdrawn)

34. (Previously presented) The apparatus of claim 1, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region of the tissue.

35. (Previously presented) The apparatus of claim 24, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region.

36. (Previously presented) The apparatus of claim 32, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region of the tissue.

37. (Previously presented) An apparatus for tissue treatment, comprising:

- a base;

- a plurality of needles attached to the base;

- an energy source provided in communication with at least one of the needles;

- a control module configured to vary characteristics of energy supplied by the energy source; and

- an electronic detection device in electrical communication with at least one of the needles that is configured to detect the presence of a nerve near the tip of the at least one of the needles.

38. (New) The apparatus of claim 24, wherein the spacer arrangement comprises a substrate, and wherein a position of the substrate relative to a position of the base is adjustable to control a distance between distal ends of the needles and a surface of the substrate.

39. (New) The apparatus of claim 32, wherein the spacer arrangement comprises a substrate, and wherein a position of the substrate relative to a position of the base is adjustable to control a distance between distal ends of the needles and a surface of the substrate.

REMARKS

I. INTRODUCTION

Claims 3-6, 9, and 12 have previously been canceled, without prejudice. Claims 16-19, 29-31 and 33 have previously been withdrawn in response to the restriction requirement issued on October 31, 2008. Applicant reserves the right to file one or more continuing applications in which the subject matter recited in these canceled or withdrawn claims would be prosecuted. Claims 1, 7, 24, and 32 have been amended as indicated in the claim listing above, and new claims 38 and 39 have been added. Accordingly, claims 1, 2, 7, 8, 10, 11, 13-15, 20-28, 32 and 34-39 are now under consideration in the present application. Provided above, please find a claim listing indicating the current amendments to the previously-pending claims and the addition of new claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. ELECTION/RESTRICTIONS

In the Office Action, the Examiner correctly notes that Applicant has elected Group I, without traverse, as identified by the Examiner in the restriction requirement issued on October 31, 2008 (the "Restriction Requirement").

However, Applicant respectfully disagrees with the Examiner's contention that Applicant has failed to elect one of the allegedly patentably distinct species A, B, or C identified by the Examiner. (See Office Action, p. 2, Ins. 10-12). Applicant respectfully notes, and the Examiner may readily ascertain, that **Species A has been previously provisionally elected, with traverse, in both** the response to the Restriction Requirement filed on December 1, 2008, and in the response submitted on April 6, 2009 to the Notice of Non-Compliant Amendment issued on March 6, 2009.

In the Restriction Requirement, the Examiner asserted that certain claims of the present application in elected Group I are drawn to patentably distinct species. (See Restriction Requirement, page 4). Then, the Examiner identified the following three allegedly distinct species:

Species A: Claims 2 and 26, reciting application of radio frequency energy using the needle array;

- Species B: Claims 15, 21 and 26, apparently reciting needles delivering optical energy (Applicant notes that claim 26 does not recite optical energy, and thus Applicant assumes that the Examiner intended to include claim 28 in this allegedly distinct species); and
- Species C: Claims 14, 22 and 23 (together with new claim 37), reciting a needle array which is also used to detect the presence of nerves.

The Examiner alleged that the species are independent or distinct because they recite mutually exclusive characteristics of such species, and that there would be an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics.

Applicant notes that 37 C.F.R. § 1.146 allows the Examiner discretion in requiring an election of identified species. However, Applicant asserts that the species election requirement contained in the Restriction Requirement contained in the prior Office Action and in the latest Office Action would not require searches of different fields of research, nor would consideration of all alleged species place an undue burden on the U.S. Patent and Trademark Office.

Applicant further notes that the claims reciting these allegedly distinct species each depend from independent claims 1, 14, 24 or 32, as applicable. Applicant respectfully asserts that each of the alleged species A–C recites an apparatus which includes a plurality of needles configured to provide energy to tissue, and that the features identified by the Examiner are **not** mutually exclusive characteristics and, in fact, may be combined using the same recited structure. (*See*, e.g., paras. [0048]-[0050] of the present application.) Applicant respectfully asserts that the common characteristics of each of these alleged species, e.g., a needle array configured to deliver energy to tissue, and optionally to further detect presence of nearby nerves using these same needles, does **not** require separate searches and consideration of different fields of research. Applicant also respectfully asserts that independent claims 1 and 24 are generic to the allegedly distinct species A-C.

Therefore, for at least these reasons, the Examiner is respectfully requested to withdraw the Restriction Requirement (associated with the species) contained in the Office Action dated October 31, 2008. Upon such withdrawal by the Examiner, Applicant respectfully

requests that pending claims 1, 2, 7, 8, 10, 11, 13-15, 20-28, 32 and 34-37 be prosecuted on their merits in the present application. Alternatively, to the extent that such withdrawal is not made by the Examiner, Applicant respectfully requests that the elected species identified herein and, if necessary, further non-elected species be considered on their merits.

Applicant further notes that upon the indication of allowability of any generic claim(s), any claims which are directed to non-elected species which depend from such allowable claim(s) be considered.

Thus, Applicant again respectfully **traverses** this species Restriction Requirement as set forth in the latest Office Action, and **provisionally elects alleged species A**, corresponding to claims 2 and 26. Applicant notes that claims 1, 2, 7, 8, 10, 11, 13, 20, 24-27, 32, and new claims 34-36 are part of and/or generic to allegedly distinct Species A.

III. REJECTIONS UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN

A. Rejection Based on the Utely and Prausnitz '211 Patents

Claims 1, 2, 7, 8, 10, 11, 13, 20, 24-27, 32, and 34-36 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,277,116 issued to Utely et al. (the “Utely Patent”) in view of U.S. Patent No. 6,743,211 issued to Prausnitz et al. (the “Prausnitz '211 Patent”). (See Office Action, p. 3).

The Utely Patent describes methods and apparatus for shrinking collagen tissue by applying energy to tissue using an array of electrodes configured to penetrate beneath the epidermal skin region. The Prausnitz '211 Patent describes methods and apparatus for transport of therapeutic materials and/or energy across tissue barriers using microneedles.

Independent claim 1, as amended herein, recites an apparatus that comprises, *inter alia*, a plurality of needles attached to a base, and **a spacer arrangement that is movably attached to the base** for controlling penetration depths of the needles. Even if the cited references were combinable, which Applicant believes likely not to be the case, the alleged combination of the Utely Patent and the Prausnitz '211 Patent fails to teach or suggest the subject matter recited in amended independent claim 1 and the claims that depend therefrom.

In the latest Office Action, the Examiner acknowledges that the Utely Patent fails to disclose a spacer arrangement for controlling the penetration depth of the needles, but alleges that the Prausnitz '211 cures such deficiency. (See Office Action, p. 4). However, Applicant believes that the Prausnitz '211 Patent fails to cure the deficiencies of the Utely Patent to teach or suggest the subject matter recited in amended independent claim 1. In particular, the Prausnitz '211 Patent describes the use of **fixed** extensions that consist of relatively wide bases provided between the substrate and the microneedles that are “typically made integrally with the substrate and microneedles.” (See Prausnitz '211 Patent, col. 10, lns. 33-62; and FIGS. 10a-10c). Thus, the alleged combination of the Utely Patent and the Prausnitz '211 Patent fails to teach, suggest or disclose any device that includes a plurality of needles attached to a base, and **a spacer arrangement that is movably attached to the base** for controlling penetration depths of the needles, as explicitly recited in amended independent claim 1. Indeed, the Prausnitz '211 Patent *teaches away* from such recited subject matter.

Accordingly, for at least these reasons provided above, Applicant respectfully requests that the rejection of amended independent claim 1 and the claims that depend therefrom (i.e., claims 2, 7, 8, 10, 11, 13, 20, and 34) under 35 U.S.C. §103(a) based on the alleged combination of the Utely Patent with the Prausnitz '211 Patent be withdrawn.

Independent claim 24 has been amended above to recite an apparatus that comprises, *inter alia*, a plurality of needles attached to a base and **a spacer arrangement that is movably attached to the base** for controlling penetration depths of the needles, where the needles protrude a plurality of distances from the base. Applicant respectfully asserts that the alleged combination of the Utely Patent with the Prausnitz '211 Patent fails to teach, suggest or disclose such a movably attached spacer arrangement, for at least the same reasons as discussed in detail above with respect to amended independent claim 1.

Accordingly, for at least these reasons provided above, Applicant respectfully requests that the rejection of amended independent claim 24 and the claims that depend therefrom (i.e., claims 25-27, 35, and new claim 38) under 35 U.S.C. §103(a) based on the alleged combination of the Utely Patent with the Prausnitz '211 Patent be withdrawn.

Independent claim 32 has been amended above to recite an apparatus which comprises, *inter alia*, a plurality of needles attached to a base and **a spacer arrangement that is movably attached to the base** for controlling penetration depths of the needles, where the needles are configured in pairs to deliver radio frequency electromagnetic energy in a bipolar mode. Applicant respectfully asserts that the alleged combination of the Utely Patent with the Prausnitz '211 Patent fails to teach, suggest or disclose such a movably attached spacer arrangement, for at least the same reasons as discussed in detail above with respect to amended independent claim 1.

Accordingly, for at least these reasons provided above, Applicant respectfully requests that the rejection of amended independent claim 32 and the claims that depend therefrom (i.e., claims 25-27, 35, and new claim 39) under 35 U.S.C. §103(a) based on the alleged combination of the Utely Patent with the Prausnitz '211 Patent be withdrawn.

B. Rejection Based on the Utely, Prausnitz '211 and Prausnitz '231 Patents

Claim 28 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Utely Patent in view of the Prausnitz '211 Patent and further in view of U.S. Patent No. 6,503,231 to Prausnitz et al. (the "Prausnitz '231 Patent"). (*See* Office Action, p. 4). The Prausnitz '231 Patent describes methods and apparatus for transport of therapeutic materials and/or energy across tissue barriers using microneedle arrays which penetrate into the epidermal layer of skin.

Even if the cited references are combinable, the alleged combination of the Utely Patent, the Prausnitz '211 Patent and the Prausnitz '231 Patent fails to teach or suggest the subject matter recited in claim 28 which depends from independent claim 24, as amended herein. Indeed, none of the Utely Patent, the Prausnitz '211 Patent or the Prausnitz '231 Patent, considered individually or in combination, teach or suggest an apparatus that comprises, *inter alia*, a plurality of needles attached to a base and **a spacer arrangement that is movably attached to the base** for controlling penetration depths of the needles, for at least the same reasons as described above with respect to amended independent claim 24 from which claim 28 depends. Applicant respectfully asserts that the Prausnitz '231 Patent fails to cure this

deficiencies of the Utely Patent and the Prausnitz '211 Patent, and the Examiner does not contend that it does.

Accordingly, Applicant respectfully submits that the alleged combination of the Utely Patent with the Prausnitz '211 Patent and the Prausnitz '231 Patent, even if combinable, fails to teach, suggest or disclose the subject matter recited in claim 28. Thus, withdrawal of the rejection of this claim under 35 U.S.C. § 103(a) is respectfully requested.

IV. INDEPENDENT CLAIMS 15 AND 37

In the latest Office Action, the Examiner does not reject independent claims 15 and 37 as being anticipated or obvious over any prior art of record. To that end, Applicant believes that the Examiner appears to acknowledge that these independent claims 15 and 37 are allowable. Thus, Applicant respectfully request that the Examiner confirm that independent claims 15 and 37 are allowable over the art of record in the next communication.

V. CONCLUSION

In light of the foregoing, Applicant respectfully submits that the pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited. The Examiner is invited to contact the undersigned to expedite the prosecution of this application if any issues remain outstanding.

Respectfully submitted,

Date: December 18, 2009

By:



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Patent Office Reg. No. 40,479

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New York, New York 10177

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4850-2967-2197\2

Electronic Patent Application Fee Transmittal

Application Number:	11098030			
Filing Date:	01-Apr-2005			
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping			
First Named Inventor/Applicant Name:	Dieter Manstein			
Filer:	Gary Abelev/Marilyn Alexander-Kuruvilla			
Attorney Docket Number:	036213/US/2-475387-00230			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1202	2	52	104
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				104

Electronic Acknowledgement Receipt

EFS ID:	6672403
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Gary Abelev/Marilyn Alexander-Kuruvilla
Filer Authorized By:	Gary Abelev
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	18-DEC-2009
Filing Date:	01-APR-2005
Time Stamp:	17:26:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 104
RAM confirmation Number	4002
Deposit Account	502054
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	36213Amendment18Dec2009.PDF	534228 3169d30c044d991beee53472096cf13a9c6a0c4c	no	13
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	30043 a76f0a5a5c450888792f23fdb3d37be93e199c07	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			564271		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/098,030		Filing Date 04/01/2005		<input type="checkbox"/> To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=		X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=			
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	12/18/2009	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 26	Minus	** 27	= 0	X \$26 =	0	OR	X \$ =	
	Independent (37 CFR 1.16(h))	* 5	Minus	*** 7	= 0	X \$110 =	0	OR	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))									
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE		
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =		X \$ =		
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =		X \$ =		
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))									
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		
<p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p>										

Legal Instrument Examiner:
/VENICE M. WILLIAMS/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/098,030	04/01/2005	Dieter Manstein	036213/US/2-475387-00230	6055

30873 7590 03/16/2010
DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3769

MAIL DATE	DELIVERY MODE
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03/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/098,030	Applicant(s) MANSTEIN, DIETER	
	Examiner Ahmed M. Farah	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,8,10,11,13-15,20-28,32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) 14,22,23 and 37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,7,8,10,11,13,15,20,21,24-28,32,34-36,38 and 39 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/13/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application is in condition for allowance except for the presence of claims 14, 22, 23, and 37 directed to an invention non-elected with traverse in the reply filed on April 6, 2009. Applicant is given ONE MONTH or THIRTY DAYS from the date of this letter, whichever is longer, to cancel the noted claims or take other appropriate action (37 CFR 1.144). Failure to take action during this period will be treated as authorization to cancel the noted claims by Examiner's Amendment and pass the case to issue. Extensions of time under 37 CFR 1.136(a) will not be permitted since this application will be passed to issue.

The prosecution of this case is closed except for consideration of the above matter.

Claims 15, 21, and 26 are allowable. The restriction requirement between species A (claims 2, 26) and B (claims 15, 26), as set forth in the Office action mailed on October 10, 2008, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 15 and 21, directed to needles comprising at least one optical fiber/light-guide no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim. However, claims 14, 22, 23, and 37, directed to apparatus comprising a plurality of needles and an electronic detection device in

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communication with at least one of the needles, said electronic detection device configured to detect the presence of a nerve near the tip of the at least one of said needles are withdrawn from consideration because they do not require all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Allowable Subject Matter

Claims 1, 2, 7, 8, 10, 11, 13, 15, 20, 21, 24-28, 32, 34-36, 38 and 39 are allowed.

The following is an examiner's statement of reasons for allowance: the prior art of record fails to disclose, teach or suggest an apparatus comprising: a base, a plurality of needles attached to said base, energy source in communication with at least one of said needles, a control means configured to vary parameters of the energy of said source, and a spacer mechanism movably attached to said base and configured to control penetration depth of said needles as claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following references:

Erickson et al., US Patent No. 5,582,184, teach an apparatus comprising at least one needle 214' attached to base 215', and a spacer element 202' configured to control the penetration depth of said at least one needle 214' (see Fig. 20). However, the spacer is not movably attached to control the penetration depth of the needle as presently claimed.

Giusti et al., WO 03/005919 A1, disclose apparatus comprising a plurality of needles and an adjustable mechanism configured to control the penetration depth of said needles (see Figs. 1-4, 6, and 7). However, the penetration control mechanism is not attached to the base of the apparatus as claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon, Tue, Thur and Fri between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johnson Henry can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 11/098,030

Page 6

Art Unit: 3769

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ahmed M Farah/
Primary Examiner, Art Unit 3769

March 12, 2010.

Notice of References Cited	Application/Control No. 11/098,030		Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER	
	Examiner Ahmed M. Farah		Art Unit 3769	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,582,184	12-1996	Erickson et al.	600/576
*	B	US-5,000,752	03-1991	Hoskin et al.	606/9
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N	WO 03/005919 A1	01-2003	WO	Giusti et al.	A61B 18/14
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	2	((Dario near2 Giusti) (Crisiano near2 Huscher)).in.	US-PGPUB; USPAT	OR	OFF	2010/03/12 22:13
L3	5	((Dario near2 Giusti) (Crisiano near2 Huscher)).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/12 22:14
L4	3	((("6077257") or ("6126657") or ("5599294")).PN.	USPAT; USOCR	OR	OFF	2010/03/12 22:16
L5	19060	((606/3,9-12,35- 46,131,167-187,189) or (607/88-91)).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/12 22:17
L6	21704	((606/3,9-12,27- 50,131,167-187,189) or (607/88-91)).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/12 22:18
L7	6626	6 and (needle microneedle (micro adj needle))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/03/12 22:21
L8	327	7 and (control with penetration with depth)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/03/12 22:22
L9	8	7 and (spacer same (control with penetration with depth))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/03/12 22:22

L10	8	7 and (spacer same control same penetration same depth)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/03/12 22:55
S1	10571	((606/3,9-12,131,167-187,189) or (607/88-91)).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2007/03/13 18:05
S2	1	S1 and (micro adj blade)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:06
S3	15	S1 and microblade	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:06
S4	59	("5879326").URPN.	USPAT	OR	OFF	2007/03/13 18:27
S5	25	S4 and laser	USPAT	OR	OFF	2007/03/13 18:38
S6	3487	S1 and laser	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2007/03/13 18:38
S7	1049	S6 and (cut\$3 same (skin tissue body))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2007/03/13 18:40
S8	488	S7 and (knife blade)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:40

S9	6	S7 and (micro adj (knife blade needle))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:42
S10	671	S7 and (knife blade needle)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:42
S11	216	S7 and ((plurality multiple) same (knife blade needle))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:43
S12	178	S11 and control\$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:44
S13	78	S12 and (sensor detector)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:44
S14	54	S13 and housing	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:55
S15	24	S13 not S14	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:57
S16	29	((MANSTEIN near DIETER) (ANDERSON near "R.")).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:58

S17	13	S1 and S16	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:59
S18	16	S16 not S17	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/03/13 18:59
S20	14	("2397757" "4653495" "5103073" "5303722" "5306143" "5569368" "5569929" "5616140" "5803093" "5814078" "6022345" "6129748" "6187029").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2007/03/13 19:04
S21	3	("6497719").URPN.	USPAT	OR	OFF	2007/03/13 19:06
S22	29	(US-20050222555-\$ or US-20050049625-\$ or US-20020177839-\$ or US-20020123675-\$ or US-20020111600-\$ or US-20070038181-\$ or US-20060079919-\$ or US-20050222565-\$). did. or (US-7186235-\$ or US-7182747-\$ or US- 6497719-\$ or US- 6607513-\$ or US- 6855131-\$ or US- 6835184-\$ or US- 6790372-\$ or US- 6743211-\$ or US- 6689100-\$ or US- 6611707-\$ or US- 6591124-\$ or US- 6503231-\$ or US- 5879326-\$ or US- 6440096-\$ or US- 6083196-\$ or US- 6168590-\$ or US- 6048352-\$ or US- 5803093-\$ or US- 2397757-\$ or US- 5569368-\$ or US- 5306143-\$).did.	US-PGPUB; USPAT	OR	OFF	2008/03/27 20:55

S23	3	S22 and ('rf radiofrequenc\$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/03/27 20:56
S24	19	(micro adj (knife blade needle)) same ('rf' radiofrequency)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/03/27 20:57
S25	2	((("6149644") or ("7090670")).PN.	USPAT; USOCR	OR	OFF	2008/03/27 21:14
S26	1	("7331953").PN.	USPAT; USOCR	OR	OFF	2008/03/27 21:19
S27	29	("20030032950" "20030216719" "20050222565" "20070038181" "2397757" "5306143" "5569242" "5643252" "5755753" "5879326" "5919219" "5948011" "6048352" "6083196" "6273884" "6277116" "6377855" "6405090" "6440096" "6497719" "6511475" "6591124" "6656147" "6749624" "6766202" "6835184" "6855131" "7186235").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2008/03/27 21:21
S28	36	(US-20050222555-\$ or US-20050049625-\$ or US-20020177839-\$ or US-20020123675-\$ or US-20020111600-\$ or US-20070038181-\$ or US-20060079919-\$ or US-20050222565-\$ or US-20070088348-\$ or US-20070010810-\$ or US-20040068256-\$ or US-20030216719-\$). did. or (US-7186235-\$ or US-7182747-\$ or US- 6497719-\$ or US- 6607513-\$ or US- 6855131-\$ or US-	US-PGPUB; USPAT	OR	OFF	2009/09/16 03:18

		6835184-\$ or US- 6790372-\$ or US- 6743211-\$ or US- 6689100-\$ or US- 6611707-\$ or US- 6591124-\$ or US- 6503231-\$ or US- 5879326-\$ or US- 6440096-\$ or US- 6083196-\$ or US- 6168590-\$ or US- 6048352-\$ or US- 5803093-\$ or US- 2397757-\$ or US- 5569368-\$ or US- 5306143-\$ or US- 6669685-\$ or US- 6656147-\$ or US- 6277116-\$).did.				
S29	2	S28 and (depth with (contrl stop))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/09/16 03:18
S30	2	S28 and (depth with (contrl stop))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/16 03:18

EAST Search History (Interference)

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	11/098,030
				Filing Date	Apr 1, 2005
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	Ahmed M. Farah
Sheet	1	of	1	Attorney Docket No: P036213.US.02-475387-230	

US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2002/0115991	Aug 22, 2002	Edwards, Stuart D.	
		2002/0120263	Aug 29, 2002	Brown, Tony R., et al.	
		2002/0128641	Sep 12, 2002	Underwood, Ronald A., et al.	
		2003/0216719	Nov 20, 2003	Debenedictis et al.	
		2004/0267335	Dec 30, 2004	Tulip, John et al.	
		2005/0087198	Apr 28, 2005	Bruno-Raimondi, Alfredo E., et al.	
		3505993	Apr 14, 1970	Lewes, D. S., et al.	
		5697909	Dec 16, 1997	Eggers, Philip E., et al.	
		5976129	Nov 2, 1999	Desai, Ashvin H.	
		6355054	Mar 12, 2002	Neuberger, Wolfgang	
		6416531	Jul 9, 2002	Chen, James C.	
		6503231	Jan 7, 2003	Prausnitz, Mark R., et al.	
		7025765	Apr 11, 2006	Balbierz, Daniel J.	
		7217265	May 15, 2007	Hennings, David R., et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		WO-2002/060523	Aug 8, 2002	Brown, R. T., et al.	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²

EXAMINER

/Ahmed Farah/ (03/13/2010)

DATE CONSIDERED

03/13/2010

Substitute Disclosure Statement Form (PTO-1449)
 * EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AF/



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/098,030	04/01/2005	Dieter Manstein	036213/US/2-475387-00230	6055

30873 7590 04/16/2010
DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3769

MAIL DATE	DELIVERY MODE
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04/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/098,030	Applicant(s) MANSTEIN, DIETER	
	Examiner Ahmed M. Farah	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,8,10,11,13-15,20-28,32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) 14,22,23 and 37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,7,8,10,11,13-15,20-28,32 and 34-39 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>4/6/2010</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

Interview Summary	Application No. 11/098,030	Applicant(s) MANSTEIN, DIETER	
	Examiner Ahmed M. Farah	Art Unit 3769	

All participants (applicant, applicant's representative, PTO personnel):

(1) Ahmed M. Farah. (3) ____.

(2) Gary Abelev (Reg. No. 40,479). (4) ____.

Date of Interview: 06 April 2010.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.
If Yes, brief description: ____.

Claim(s) discussed: N/A.

Identification of prior art discussed: N/A.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The applicant's representative, Gary Abelev (Reg. No. 40,479), contacted the examiner to correct informality in the Office Action (OA) mailed March 16, 2010. In the written OA, the examiner gave the applicant 1 month or thirty days of response time. However, in the PTOL-326 form, the examiner inadvertently gave the applicant 3 months of response time. This error caused the applicant uncertainty and not knowing what the correct response period is. Hence, the examiner agreed to issue a supplemental Action to correct the deficiency of the prior OA and to restart the response period.

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DETAILED ACTION

Election/Restrictions

This application is in condition for allowance except for the presence of claims 14, 22, 23, and 37 directed to an invention non-elected with traverse in the reply filed on April 6, 2009. Applicant is given ONE MONTH or THIRTY DAYS from the date of this letter, whichever is longer, to cancel the noted claims or take other appropriate action (37 CFR 1.144). Failure to take action during this period will be treated as authorization to cancel the noted claims by Examiner's Amendment and pass the case to issue. Extensions of time under 37 CFR 1.136(a) will not be permitted since this application will be passed to issue.

The prosecution of this case is closed except for consideration of the above matter.

Claims 15, 21, and 26 are allowable. The restriction requirement between species A (claims 2, 26) and B (claims 15, 26), as set forth in the Office action mailed on October 10, 2008, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 15 and 21, directed to needles comprising at least one optical fiber/light-guide no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim. However, claims 14, 22, 23, and 37, directed to apparatus comprising a plurality of needles and an electronic detection device in

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communication with at least one of the needles, said electronic detection device configured to detect the presence of a nerve near the tip of the at least one of said needles are withdrawn from consideration because they do not require all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Allowable Subject Matter

Claims 1, 2, 7, 8, 10, 11, 13, 15, 20, 21, 24-28, 32, 34-36, 38 and 39 are allowed.

The following is an examiner's statement of reasons for allowance: the prior art of record fails to disclose, teach or suggest an apparatus comprising: a base, a plurality of needles attached to said base, energy source in communication with at least one of said needles, a control means configured to vary parameters of the energy of said source, and a spacer mechanism movably attached to said base and configured to control penetration depth of said needles as claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following references:

Erickson et al., US Patent No. 5,582,184, teach an apparatus comprising at least one needle 214' attached to base 215', and a spacer element 202' configured to control the penetration depth of said at least one needle 214' (see Fig. 20). However, the spacer is not movably attached to control the penetration depth of the needle as presently claimed.

Giusti et al., WO 03/005919 A1, disclose apparatus comprising a plurality of needles and an adjustable mechanism configured to control the penetration depth of said needles (see Figs. 1-4, 6, and 7). However, the penetration control mechanism is not attached to the base of the apparatus as claimed.

Hoskin et al. US Patent No. 5,000,752, disclose apparatus comprising: a laser assembly 10, plurality of optical fibers 6, a base unit 2, support elements 12 fixedly attached to the base by annular flange 12a, and plurality of hollow needles 14 adapted to guide the optical fibers, wherein the needles 14 are screwed/ attached with the support element 12. Although Hoskin et al. teach that the distance/depth of the needles

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tips can be adjusted by rotating the support body 12 or by a cam mechanism (note: the reference fails to show or describe the structure of the cam mechanism), the adjustment mechanism is within the base unit. Hence, Hoskin et al. fail to teach an adjustment mechanism that is moveably attached to the base unit for controlling the penetration depth of the needles as claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon, Tue, Thur and Fri between 9:30 AM 7:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johnson Henry can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ahmed M Farah/
Primary Examiner, Art Unit 3769

April 7, 2010.

Notice of References Cited	Application/Control No. 11/098,030		Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER	
	Examiner Ahmed M. Farah		Art Unit 3769	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,582,184	12-1996	Erickson et al.	600/576
*	B	US-5,000,752	03-1991	Hoskin et al.	606/9
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N	WO 03/005919 A1	01-2003	WO	Guisti et al.	A61B 18/14
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Dieter MANSTEIN
Appln. Serial No. : 11/098,030
Filed : April 1, 2005
Entitled : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Group Art Unit : 3769
Confirmation No. : 6055
Examiner : Ahmed M. Farah

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

SIR:

This paper is filed in response to a Restriction Requirement dated April 16, 2010 (the "Office Action"). Prior to further examination, please amend the application, and consider the remarks as set forth herein below.

IN THE CLAIMS:

Please cancel claims 14, 16-19, 22, 23, 29-31, 33 and 37, without prejudice. A complete listing of all claims and their current status is provided on separate sheets.

1. (Previously presented) An apparatus for tissue treatment, comprising:
 - a base;
 - a plurality of needles attached to the base;
 - an energy source provided in communication with at least one of the needles;
 - a spacer arrangement that is movably attached to the base for controlling penetration depths of the needles; and
 - a control module configured to vary characteristics of energy supplied by the energy source.
2. (Previously presented) The apparatus of claim 1 wherein more than one of the needles are electrically conductive, and wherein the energy source is configured to supply radio frequency electromagnetic energy to individual ones of the needles.
- Claims 3-6 (Canceled).
7. (Previously presented) The apparatus of claim 1, wherein the spacer arrangement comprises a substrate, wherein the position of the substrate is adjustable relative to that of the base to control a distance between distal ends of the needles and a surface of the substrate.
8. (Previously presented) The apparatus of claim 1, wherein at least one of the base or the substrate further comprises a cooling arrangement configured to cool a skin surface, and wherein the cooling arrangement comprises at least one of an embedded conduit configured to circulate a coolant or a Peltier device.
9. (Canceled)
10. (Previously presented) The apparatus of claim 1, further comprising a vibrating arrangement provided in communication with the base.
11. (Previously presented) The apparatus of claim 1, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair

of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

12. (Canceled)

13. (Previously presented) The apparatus of claim 1, wherein at least one of the needles is nonconductive and hollow, and is configured to deliver a local analgesic to tissue proximal to a distal end of the needle.

14. (Cancelled)

15. (Previously presented) The apparatus of claim 1, further comprising:

a source of optical energy; and

at least one optical needle comprising at least one of a light fiber or a light guide, wherein the distal ends of the needles are configured to penetrate into at least one of the dermis or subdermal tissue, and wherein the apparatus is configured to deliver a controlled amount of optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle.

Claims 16-19 (Cancelled).

20. (Previously presented) The apparatus of claim 1, wherein the plurality of needles protrude a plurality of distances from the base.

21. (Previously presented) The apparatus of claim 15, wherein a portion of the at least one needle is configured to absorb a portion of the optical energy and convert the optical energy to thermal energy.

Claims 22 and 23 (Cancelled).

24. (Previously presented) An apparatus for dermatological treatment, comprising:

a base;

a plurality of needles attached to the base;

a spacer arrangement that is movably attached to the base for controlling penetration depths of the needles;

an energy source provided in communication with at least one of the needles; and

a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles protrude a plurality of distances from the base.

25. (Previously presented) The apparatus of claim 24, wherein the energy source is a source of electromagnetic energy.

26. (Previously presented) The apparatus of claim 24, wherein a plurality of the needles are electrically conductive, and wherein the energy source is configured to supply radio frequency electromagnetic energy to individual ones of the needles.

27. (Previously presented) The apparatus of claim 24, wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

28. (Previously presented) The apparatus of claim 24, further comprising:

at least one optical needle comprising at least one of a light fiber or a light guide,

wherein the apparatus is configured to deliver a controlled amount of optical energy through the at least one optical needle and into tissue proximal to a portion of the at least one optical needle,

wherein the energy source comprises a source of optical energy.

Claims 29-31 (Cancelled).

32. (Previously presented) An apparatus for tissue treatment, comprising:

- a base;
- a plurality of needles attached to the base;
- a spacer arrangement that is movably attached to the base for controlling penetration depths of the needles;
- an energy source provided in communication with at least one of the needles; and
- a control module configured to vary characteristics of energy supplied by the energy source,

wherein the plurality of needles are provided as a plurality of pairs of needles such that a distance between the two needles in a pair of needles is less than a distance between each of the two needles and any other needle in the array, and wherein the energy source and the control module are configured to deliver radio frequency electromagnetic energy to the pairs of needles in bipolar mode.

Claim 33 (Cancelled).

34. (Previously presented) The apparatus of claim 1, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region of the tissue.

35. (Previously presented) The apparatus of claim 24, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region.

36. (Previously presented) The apparatus of claim 32, wherein the plurality of needles are configured to provide a pattern of localized regions of thermal damage within a dermal region of the tissue.

37. (Cancelled)

38. (Previously presented) The apparatus of claim 24, wherein the spacer arrangement comprises a substrate, and wherein a position of the substrate relative to a position of the base is adjustable to control a distance between distal ends of the needles and a surface of the substrate.

39. (Previously presented) The apparatus of claim 32, wherein the spacer arrangement comprises a substrate, and wherein a position of the substrate relative to a position of the base is adjustable to control a distance between distal ends of the needles and a surface of the substrate.

REMARKS

In this Amendment, originally-filed claims 14, 16-19, 22, 23, 39-31, 33 and 37 have been cancelled, without prejudice. Accordingly, claims 1, 2, 7, 8, 10, 11, 13, 15, 20, 21, 24-28, 32, 34-36, 38 and 39 are now under consideration in the above-identified application, and which the Examiner indicated as being allowed. Applicant reserves the right to file one or more continuing applications in which the subject matter recited in these canceled or withdrawn claims would be prosecuted. Provided above, please find a claim listing indicating the current cancellation to claims 14, 16-19, 22, 23, 39-31, 33 and 37 and the status of other claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

Applicants assert that the pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited. The Examiner is invited to contact the undersigned to expedite the prosecution of this application if any issues remain outstanding.

Respectfully submitted,

Date: May 17, 2010

By: 

Gary Abelev
Patent Office Reg. No. 40,479

DORSEY & WHITNEY, L.L.P.
250 Park Avenue
New York, New York 10177

Attorney(s) for Applicant(s)
(212) 415-9371

Electronic Acknowledgement Receipt

EFS ID:	7622147
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Gary Abelev/Marilyn Alexander-Kuruvilla
Filer Authorized By:	Gary Abelev
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	17-MAY-2010
Filing Date:	01-APR-2005
Time Stamp:	12:45:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	036213Amendment17May2010.pdf	219615 8de94fd6c6446e63c119135e9f3686064770c3e0	no	7

Warnings:

Information:

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number		11/098,030		
				Filing Date		April 1, 2005		
				First Named Inventor		Dieter Manstein		
				Art Unit		3769		
				Examiner Name		Ahmed M. Farah		
Sheet	1	of	1	Attorney Docket Number		036213/US/2-475387-230		
U.S. PATENT DOCUMENTS								
*Examiner Initials	Cite No.	DOCUMENT NUMBER Number - Kind Code (if known)		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		2005/0209564		09-22-2005	Bonner et al.			
		2005/0209565		09-22-2005	Yuzhakov et al.			
FOREIGN PATENT DOCUMENTS								
*Examiner Initial	Cite No.	FOREIGN PATENT DOCUMENT		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	TRANSLATION YES	TRANSLATION NO	
		Country Code:	Number - Kind Code (if known)					
						<input type="checkbox"/>	<input type="checkbox"/>	
OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS								
*Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published					TRANSLATION YES NO	
							<input type="checkbox"/>	<input type="checkbox"/>
EXAMINER SIGNATURE				DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

Sent completed form to: **Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

Electronic Patent Application Fee Transmittal

Application Number:	11098030			
Filing Date:	01-Apr-2005			
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping			
First Named Inventor/Applicant Name:	Dieter Manstein			
Filer:	Emil Bradley Gould/Miesha Hollingsworth			
Attorney Docket Number:	036213/US/2-475387-00230			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

Electronic Acknowledgement Receipt

EFS ID:	7625791
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Emil Bradley Gould/Miesha Hollingsworth
Filer Authorized By:	Emil Bradley Gould
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	17-MAY-2010
Filing Date:	01-APR-2005
Time Stamp:	16:05:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 180
RAM confirmation Number	2779
Deposit Account	502054
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		036213idsc.pdf	101165 12d08000d56cfd33423c0cfc65b992e52e029bdd	yes	3				
	Multipart Description/PDF files in .zip description								
	Document Description		Start	End					
	Transmittal Letter		1	2					
	Information Disclosure Statement (IDS) Filed (SB/08)		3	3					
Warnings:									
Information:									
2	Fee Worksheet (PTO-875)	fee-info.pdf	30133 3011adf9badef1ace5ca76b9d27fe07bd2a0f97d	no	2				
Warnings:									
Information:									
Total Files Size (in bytes):			131298						
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>									

Electronic Acknowledgement Receipt

EFS ID:	7625791
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	Method and apparatus for dermatological treatment and tissue reshaping
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Emil Bradley Gould/Miesha Hollingsworth
Filer Authorized By:	Emil Bradley Gould
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	17-MAY-2010
Filing Date:	01-APR-2005
Time Stamp:	16:05:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 180
RAM confirmation Number	2779
Deposit Account	502054
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		036213idsc.pdf	101165 12d08000d56cfd33423c0cfc65b992e52e029bdd	yes	3				
	Multipart Description/PDF files in .zip description								
	Document Description		Start	End					
	Transmittal Letter		1	2					
	Information Disclosure Statement (IDS) Filed (SB/08)		3	3					
Warnings:									
Information:									
2	Fee Worksheet (PTO-875)	fee-info.pdf	30133 3011adf9badef1ace5ca76b9d27fe07bd2a0f97d	no	2				
Warnings:									
Information:									
Total Files Size (in bytes):			131298						
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>									

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter Manstein et al.
Serial No. : 11/098,030
Filed : April 1, 2005
Entitled : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Group Art Unit : 3769
Examiner : Ahmed M. Farah
Confirmation No. : 6055

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), applicants bring to the attention of the Examiner the documents listed on the attached Form PTO/SB/08a, and respectfully request that the listed documents be considered by the Examiner and made of record in the above-captioned application. Copies of the United States patent references listed on the Form PTO/SB/08a are not enclosed, but the PCT, foreign and non-patent references are enclosed.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute “prior art.” If the Examiner applies the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute “prior art” under

United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

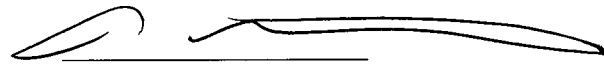
If the Examiner applies the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute “prior art” under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

As an Office Action on the merits, but before any final Office Action or Notice of Allowance was generated for this application, the requisite fee of \$180.00 pursuant to these sections and 37 C.F.R. § 1.17(p) is enclosed herewith. The Commissioner is hereby further authorized to charge any deficiencies and credit any over payments for the submission of this Information Disclosure Statement to the Dorsey & Whitney’s Deposit Account 50-2054.

Respectfully submitted,

DORSEY & WHITNEY, LLP

Date: May 17, 2010



Gary Abelev
USPTO Reg. No. 40,479
Attorney for Applicants
(212) 415-9371

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/098,030		Filing Date 04/01/2005		<input type="checkbox"/> To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=		X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=			
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	05/17/2010	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 21	Minus	** 27	= 0	X \$26 =	0	OR	X \$ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 7	= 0	X \$110 =	0	OR	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))									
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE		
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =		X \$ =		
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =		X \$ =		
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))									
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		
<p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p>										

Legal Instrument Examiner:
/POLIN ANG/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

30873 7590 06/28/2010

DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

EXAMINER

FARAH, AHMED M

ART UNIT

PAPER NUMBER

3769

DATE MAILED: 06/28/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

11/098,030

04/01/2005

Dieter Manstein

036213/US/2-475387-00230

6055

TITLE OF INVENTION: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	09/28/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

30873 7590 06/28/2010

DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

11/098,030 04/01/2005 Dieter Manstein 036213/US/2-475387-00230 6055

TITLE OF INVENTION: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional YES \$755 \$300 \$0 \$1055 09/28/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
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FARAH, AHMED M 3769 606-009000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/098,030

04/01/2005

Dieter Manstein

036213/US/2-475387-00230

6055

30873

7590

06/28/2010

EXAMINER

FARAH, AHMED M

ART UNIT

PAPER NUMBER

3769

DATE MAILED: 06/28/2010

DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 587 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 587 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	11/098,030	MANSTEIN, DIETER	
	Examiner	Art Unit	
	Ahmed M. Farah	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 5/17/2010.
2. ☒ The allowed claim(s) is/are 1,2,7,8,10,11,13,15,20,21,24-28,32,34-36,38,39.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.


4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>5/17/2010</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|---|

/Ahmed M Farah/
Primary Examiner, Art Unit 3769

Search Notes 	Application/Control No. 11098030	Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER
	Examiner Ahmed M Farah	Art Unit 3769

SEARCHED			
Class	Subclass	Date	Examiner
606	3,9-12,35-46,131,167-187,189	6/15/2010	AF
607	88-93,96-101	6/15/2010	AF

SEARCH NOTES		
Search Notes	Date	Examiner
See the attached "Search History."	6/15/2010	AF

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
606	3,9-12,35-46,131,167-187,189	6/15/2010	AF
607	88-93,96-101	6/15/2010	AF

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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BIB DATA SHEET

CONFIRMATION NO. 6055

SERIAL NUMBER 11/098,030	FILING or 371(c) DATE 04/01/2005 RULE	CLASS 606	GROUP ART UNIT 3769 036213/US/2-475387-00230	ATTORNEY DOCKET NO.		
APPLICANTS Dieter Manstein, Boston, MA; ** CONTINUING DATA ***** This appln claims benefit of 60/558,476 04/01/2004 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** ** SMALL ENTITY ** 04/25/2005						
Foreign Priority claimed <input type="checkbox"/> Yes <input type="checkbox"/> No 35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Verified and Acknowledged <u>/AHMED M FARAH/</u> Examiner's Signature		<input type="checkbox"/> Met after Allowance AF Initials	STATE OR COUNTRY MA	SHEETS DRAWINGS 4	TOTAL CLAIMS 21	INDEPENDENT CLAIMS 3
ADDRESS DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT 250 PARK AVENUE NEW YORK, NY 10177 UNITED STATES						
TITLE Method and apparatus for dermatological treatment and tissue reshaping						
FILING FEE RECEIVED 1264	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit			

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	22553	((606/3,9-12,35-50,131,167-187,189) or (607/88-93,96-101)).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/06/16 20:40
L2	50	(MANSTEIN near DIETER).IN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/06/16 20:40
L3	26	1 and 2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/06/16 20:40
L4	0	((apparatus device system) AND treat\$5 AND tissue AND base AND plurality AND needle AND source AND communication AND spacer AND arrangement AND movably AND attach \$3 AND control\$5 AND penetration AND depth AND vary AND characteristic AND energy).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/06/16 20:41

L6	0	((apparatus device system) AND treat\$5 AND tissue AND base AND plurality AND needle AND source AND communication AND spacer AND arrangement AND movably AND attach \$3 AND control\$5 AND penetration AND depth AND vary AND characteristic AND energy AND protrude AND distance).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/06/16 20:42
L8	0	((apparatus device system) AND treat\$5 AND tissue AND base AND plurality AND needle AND source AND communication AND spacer AND arrangement AND movably AND attach \$3 AND control\$5 AND penetration AND depth AND vary AND characteristic AND energy AND pairs AND distance AND radiofrequency AND bipolar AND mode).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/06/16 20:42

EAST Search History (I nterference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L5	0	((apparatus device system) AND treat\$5 AND tissue AND base AND plurality AND needle AND source AND communication AND spacer AND arrangement AND movably AND attach\$3 AND control\$5 AND penetration AND depth AND vary AND characteristic AND energy).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2010/06/16 20:42

L7	0	((apparatus device system) AND treat\$5 AND tissue AND base AND plurality AND needle AND source AND communication AND spacer AND arrangement AND movably AND attach\$3 AND control\$5 AND penetration AND depth AND vary AND characteristic AND energy AND protrude AND distance).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2010/06/16 20:42
L9	0	((apparatus device system) AND treat\$5 AND tissue AND base AND plurality AND needle AND source AND communication AND spacer AND arrangement AND movably AND attach\$3 AND control\$5 AND penetration AND depth AND vary AND characteristic AND energy AND pairs AND distance AND radiofrequency AND bipolar AND mode). clm.	US-PGPUB; USPAT; UPAD	OR	ON	2010/06/16 20:43

6/16/2010 8:43:42 PM

C:\Documents and Settings\afarah\My Documents\EastWorkFolders\11098030.wsp

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Dieter MANSTEIN
Appln. Serial No. : 11/098,030
Filed : April 1, 2005
Entitled : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Group Art Unit : 3769
Confirmation No. : 6055
Examiner : Ahmed M. Farah

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

SIR:

This paper is filed in response to a Restriction Requirement dated April 16, 2010 (the "Office Action"). Prior to further examination, please amend the application, and consider the remarks as set forth herein below.

IN THE CLAIMS:

Please cancel claims 14, 16-19, 22, 23, 29-31, 33 and 37, without prejudice. A complete listing of all claims and their current status is provided on separate sheets.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number		11/098,030		
				Filing Date		April 1, 2005		
				First Named Inventor		Dieter Manstein		
				Art Unit		3769		
				Examiner Name		Ahmed M. Farah		
Sheet	1	of	1	Attorney Docket Number		036213/US/2-475387-230		
U.S. PATENT DOCUMENTS								
*Examiner Initials	Cite No.	DOCUMENT NUMBER Number - Kind Code (if known)		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
/AF/		2005/0209564		09-22-2005	Bonner et al.			
/AF/		2005/0209565		09-22-2005	Yuzhakov et al.			
FOREIGN PATENT DOCUMENTS								
*Examiner Initial	Cite No.	FOREIGN PATENT DOCUMENT		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	TRANSLATION YES	TRANSLATION NO	
		Country Code:	Number - Kind Code (if known)					
						<input type="checkbox"/>	<input type="checkbox"/>	
OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS								
*Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published					TRANSLATION YES	TRANSLATION NO
							<input type="checkbox"/>	<input type="checkbox"/>
EXAMINER SIGNATURE /Ahmed Farah/ (06/16/2010)				DATE CONSIDERED 06/16/2010				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

Sent completed form to: **Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

Sheet 1 of 1

Based on Form PTO-1449
(3/90)

NOV 02 2005

ATTY. DOCKET NO.

910000-3080.1

SERIAL NO.

11/098,030

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT

Manstein

FILING DATE

April 1, 2005

GROUP

3739

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
/AF/	AA	5,569,242	10/29/96	Lax et al.			
	AB	5,697,281	12/16/97	Eggers et al.			
	AC	5,755,753	05/26/98	Knowlton			
	AD	5,861,002	01/19/99	Desai			
	AE	5,919,219	07/06/99	Knowlton			
	AF	5,948,011	07/07/99	Knowlton			
	AG	6,277,116	08/21/01	Uteley et al.			
	AH	6,377,855	04/23/02	Knowlton			
	AI	6,405,090	06/11/02	Knowlton			
	AJ	6,723,092	04/20/04	Brown et al.			
	AK	6,749,624	06/15/04	Knowlton			
	AL	6,766,202	07/20/04	Underwood et al.			
	AM	2003/0130655	07/10/03	Woloszko et al.			
	AN	2003/0212394	11/13/03	Pearson et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
	AO	WO 04/086947	10/14/04	PCT			
	AP						

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

/AF/	AQ	Urney et al., "Percutaneous Electrode Guidance: A Noninvasive Technique For Prelocation of Peripheral nerves to Facilitate Peripheral Plexus or Nerve Block," Regional Anesthesia and Pain Medicine, vol. 27, no. 3, 2002, pp. 261-267.
/AF/	AR	Tschopp et al., "Comparison of Various Methods of Electromyographic Monitoring of the Recurrent Laryngeal Nerve in Thyroid Surgery," Ann. Otol. Rhinol. Laryngol., 111:2002, pp. 811-816.

EXAMINER

/Ahmed Farah/ (03/27/2008)

DATE CONSIDERED

03/27/2008

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

30873 7590 06/28/2010

DORSEY & WHITNEY LLP
 INTELLECTUAL PROPERTY DEPARTMENT
 250 PARK AVENUE
 NEW YORK, NY 10177

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

11/098,030 04/01/2005 Dieter Manstein 036213/US/2-475387-00230 6055

TITLE OF INVENTION: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional YES \$755 \$300 \$0 \$1055 09/28/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
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FARAH, AHMED M 3769 606-009000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
 2 Dorsey & Whitney LLP
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

The General Hospital Corporation

(B) RESIDENCE: (CITY AND STATE OR COUNTRY)

55 Fruit Street, Boston, MA 02114

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

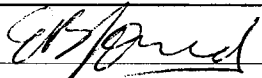
- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 502054 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☒ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature



Date September 28, 2010

Typed or printed name E. Bradley Gould, Esq.

Registration No. 41,792

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal

Application Number:	11098030			
Filing Date:	01-Apr-2005			
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING			
First Named Inventor/Applicant Name:	Dieter Manstein			
Filer:	Emil Bradley Gould/Miesha Hollingsworth			
Attorney Docket Number:	036213/US/2-475387-00230			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	1501	1	1510	1510
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1810

Electronic Acknowledgement Receipt

EFS ID:	8515661
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Emil Bradley Gould/Miesha Hollingsworth
Filer Authorized By:	Emil Bradley Gould
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	28-SEP-2010
Filing Date:	01-APR-2005
Time Stamp:	15:33:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 1810
RAM confirmation Number	2032
Deposit Account	502054
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Issue Fee Payment (PTO-85B)	36213issuefee.pdf	95826 187572b107cd2bf6974ac815c1a360f14ed2624d	no	1
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	32111 4cad61c4c1c0b336295ffc1711dbef646b4a1c45	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			127937		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



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Bib Data Sheet

CONFIRMATION NO. 6055

SERIAL NUMBER 11/098,030	FILING OR 371(c) DATE 04/01/2005 RULE	CLASS 606	GROUP ART UNIT 3769	ATTORNEY DOCKET NO. 036213/US/2- 475387-00230	
APPLICANTS Dieter Manstein, Boston, MA; ** CONTINUING DATA ***** This appln claims benefit of 60/558,476 04/01/2004 ** FOREIGN APPLICATIONS ***** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 04/25/2005					
Foreign Priority claimed <input type="checkbox"/> yes <input type="checkbox"/> no 35 USC 119 (a-d) conditions <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after met Allowance Verified and Acknowledged		STATE OR COUNTRY MA	SHEETS DRAWING 4	TOTAL CLAIMS 19	INDEPENDENT CLAIMS 2
ADDRESS 30873					
TITLE METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING					
FILING FEE RECEIVED 1564	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit		



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/098,030	11/02/2010	7824394	036213/US/2-475387-00230	6055

30873 7590 10/13/2010

DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 1488 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Dieter Manstein, Boston, MA;

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:



Practitioners associated with Customer Number:

26710

OR

Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number

Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:



The address associated with Customer Number:

26710

OR


Firm or Individual Name		
Address		
City		
Country		
Telephone		Email

Assignee Name and Address: The General Hospital Corporation
55 Fruit Street
Boston, MA 02114

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	9/10/14
Name	Irene Abrams	Telephone	
Title	Executive Director of Innovation, for the General Hospital Corporation		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Electronic Acknowledgement Receipt

EFS ID:	22526358
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Jack M. Cook/Sara Kerstein
Filer Authorized By:	Jack M. Cook
Attorney Docket Number:	036213/US/2-475387-00230
Receipt Date:	03-JUN-2015
Filing Date:	01-APR-2005
Time Stamp:	15:49:19
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Assignee showing of ownership per 37 CFR 3.73	mgh_1002_373.pdf	73245 4c878bf6c03a0719a9664c7057c427bde07fba99	no	2

Warnings:

Information:

2	Power of Attorney	POA_MGH.pdf	107274	no	1
			f9b356bde9cb6a6db65c7c93bfbdb06bf56df fe7c		
Warnings:					
Information:					
Total Files Size (in bytes):				180519	
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)Applicant/Patent Owner: The General Hospital CorporationApplication No./Patent No.: 11/098,030 Filed/Issue Date: April 1, 2005Titled: Method and Apparatus for Dermatological Treatment and Tissue ReshapingThe General Hospital Corporation, a corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.
2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):
- ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.
- ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 017526, Frame 0473, or for which a copy thereof is attached.
- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

[Page 1 of 2]

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.☐ Additional documents in the chain of title are listed on a supplemental sheet(s).☐ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Jack M. Cook/

Signature

Jack M. Cook

Printed or Typed Name

June 3, 2015

Date

Reg. No. 56,098

Title or Registration Number



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/098,030	04/01/2005	Dieter Manstein	036213/US/2-475387-00230

CONFIRMATION NO. 6055

POWER OF ATTORNEY NOTICE

30873
DORSEY & WHITNEY LLP - NEW YORK
ATTENTION: INTELLECTUAL PROPERTY - PATENT DOCKET
51 WEST 52ND STREET
NEW YORK, NY 10019-6119



Date Mailed: 06/09/2015

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/03/2015.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/dtdinh/



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/098,030	04/01/2005	Dieter Manstein	036213/US/2-475387-00230

CONFIRMATION NO. 6055

POA ACCEPTANCE LETTER



26710
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

Date Mailed: 06/09/2015

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/03/2015.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/dtdinh/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1st Named Inventor: Dieter Manstein
Application No.: 11/098,030
Filed: April 1, 2005
Art Unit: 3769
Confirmation No.: 6055
Docket No.: 125141.01002
Title: Method and Apparatus for Dermatological Treatment and
Tissue Reshaping

**PAYMENT OF FEES PURSUANT TO 37 C.F.R. §1.27(g) RELATED TO CHANGE
FROM SMALL ENTITY STATUS TO LARGE ENTITY STATUS**

Commissioner:

In the above-identified application, erroneously and without deceptive intent, back fees made at the small entity rate were not paid up to the large entity rate. Accordingly, please charge the deficiency in payments listed below to Deposit Account No. 17-0055.

Date paid	Fee Code Paid	Amount Paid	Large Entity Fee Code	Amount	Deficiency Due
6/13/2005	2051	65	1051	160	95
6/13/2005	2011	150	1011	300	150
6/13/2005	2111	250	1111	660	410
6/13/2005	2311	100	1311	760	660
7/1/2008	2202	175	1202	700	525
7/1/2008	2201	420	1201	1840	1420
				Total	\$3260

Again, the present application was filed with small entity status. However, this was done in error and without deceptive intent. Thus, Applicant hereby takes steps to correct the error and therefore requests the deficiencies to be paid. Should any additional fees or credit be due for the above-identified patent, the Commissioner is hereby authorized to charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Dated: November 16, 2018

/Thomas J. Keating/
Thomas J. Keating, Reg. No. 59,110
Quarles & Brady LLP
Attorney for Applicant
411 East Wisconsin Avenue
Milwaukee, WI 53202-4497
(414) 277-5000

Electronic Acknowledgement Receipt

EFS ID:	34338337
Application Number:	11098030
International Application Number:	
Confirmation Number:	6055
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	26710
Filer:	Thomas J. Keating
Filer Authorized By:	
Attorney Docket Number:	125141.01002
Receipt Date:	16-NOV-2018
Filing Date:	01-APR-2005
Time Stamp:	18:07:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	mgh-1002-request.pdf	99380	no	2
			3ed36a6402c3252ffd20721f8b70c4b714bf59a7		

Warnings:

Information:	
Total Files Size (in bytes):	99380
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>	