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NOTICE OF ALLOWANCE AND FEE(S) DUE

490

7590

02/14/2005

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

JIMENEZ, MARC QUEMUEL

ART UNIT

PAPER NUMBER

3726

DATE MAILED: 02/14/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/444,807	05/23/2003	Michael Austin	S63.2-7405-US03	8997

TITLE OF INVENTION: APPARATUS FOR CONTRACTING, LOADING OR CRIMPING SELF-EXPANDING AND BALLOON EXPANDABLE STENT DEVICES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$300	\$1700	05/16/2005

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 REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

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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.

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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 should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. 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.

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.

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Complete and send this form, together with applicable fee(s), to: **Mail**

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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.

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(Depositor's name)
(Signature)
(Date)

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nonprovisional	NO	\$1400	\$300	\$1700	05/16/2005

EXAMINER	ART UNIT	CLASS-SUBCLASS
JIMENEZ, MARC QUEMUEL	3726	072-402000

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,
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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.

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Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

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- ☐ Issue Fee
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- ☐ A check in the amount of the fee(s) is enclosed.
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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).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above. 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.

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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 0 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 0 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 (703) 305-8283.

Notice of Allowability

Application No.

10/444,807

Examiner

Marc Jimenez

Applicant(s)

AUSTIN, MICHAEL

Art Unit

3726

-- 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 1/7/05.
2. ☒ The allowed claim(s) is/are 27-64,66 and 67.
3. ☒ The drawings filed on 23 May 2003 are accepted by the Examiner.
4. ☐ 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.

5. ☐ 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.
 6. ☐ 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).
7. ☐ 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)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Marc Jimenez
Primary Examiner
Art Unit 3726
February 9, 2005

Application No. 10/444807
Page 2

Amendment
Attorney Docket No. S63.2Q-7405-US03

Amendments To The Claims:

Claims 1-26. (Canceled)

Claim 27. (Currently Amended) A stent crimper comprising:

a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture of a substantially regular polygonal shape, the dies disposed about the aperture and between stationary end-walls which are disposed about the longitudinal axis, at least one of the stationary end-walls operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same;

each die having a first straight side and a second straight side, the first straight side and the second straight side converging to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die.

Claim 28. (Previously presented) The stent crimper of claim 27 having a rotatable actuation device coupled to the dies, rotation of the actuation device causing the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Claim 29. (Previously presented) The stent crimper of claim 27 the dies are cooled below ambient temperature.

Claim 30. (Previously presented) The stent crimper of claim 29 including a stent within the aperture.

Claim 31. (Previously presented) The stent crimper of claim 30 wherein the stent is made of nitinol.

Claim 32. (Previously presented) The stent crimper of claim 27 wherein at least 8 dies are provided.

Claim 33. (Previously presented) The stent crimper of claim 27 wherein at least 16 dies are provided.

Claim 34. (Previously presented) The stent crimper of claim 27 wherein the dies are moved cooperatively inward during the moving step.

Claim 35. (Previously presented) The stent crimper of claim 27 wherein the dies are wedge-shaped.

Application No. 10/444807
Page 3

Amendment
Attorney Docket No. S63.2Q-7405-US03

Claim 36. (Previously presented) A stent crimper comprising:

a plurality of movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a longitudinal axis and a substantially regular polygonal shape, each of the dies having an inward facing straight side which faces the longitudinal axis of the aperture, both when the dies move to maximize the aperture and when the dies move to minimize the aperture, the dies between two stationary end-walls disposed about the longitudinal axis, the longitudinal axis passing through a point substantially centered on the end-walls,

a rotatable actuation device coupled to the dies, rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Claim 37. (Previously presented) The stent crimper of claim 36 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.

Claim 38. (Previously presented) The stent crimper of claim 36 wherein a stent is cooled below ambient temperature prior to reducing the size of the aperture.

Claim 39. (Previously presented) The stent crimper of claim 37 having a stent, wherein the stent is made of nitinol.

Claim 40. (Previously presented) The stent crimper of claim 36 wherein the dies are wedge-shaped.

Claim 41. (Previously presented) The stent crimper of claim 36 wherein at least 8 dies are provided.

Claim 42. (Previously presented) The stent crimper of claim 36 wherein at least 16 wedge-shaped dies are provided.

Claim 43. (Previously presented) The stent crimper of claim 36 wherein an entire stent is disposed in the aperture.

Claim 44. (Previously presented) A stent crimper comprising:

eight or more movable dies arranged to form an iris, the iris defining an aperture of a substantially regular polygonal shape, the aperture having a longitudinal axis, each die having an inward facing flat portion which faces the longitudinal axis of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture, the dies between stationary end walls and operatively engaged to at least one of the stationary end-walls,

Application No. 10/444807
Page 4

Amendment
Attorney Docket No. S63.2Q-7405-US03

the stationary end-walls disposed about the longitudinal axis,

the iris comprising at least eight of the inward facing flat portions, the aperture being reducible in size by moving the inward facing flat portions toward the longitudinal axis of the aperture,

a rotatable actuation device coupled to the dies, rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Claim 45. (Previously presented) The stent crimper of claim 44 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.

Claim 46. (Previously presented) The stent crimper of claim 44 wherein the dies are cooled below ambient temperature.

Claim 47. (Previously presented) The stent crimper of claim 46 including a stent in the aperture, wherein the stent is made of nitinol.

Claim 48. (Previously presented) The stent crimper of claim 44 wherein the dies are wedge-shaped.

Claim 49. (Previously presented) The stent crimper of claim 44 wherein at least 16 dies are provided.

Claim 50. (Previously presented) The stent crimper of claim 44 wherein the dies are moved cooperatively inward during the moving step.

Claim 51. (Previously presented) The stent crimper of claim 44 wherein an entire stent is disposed in the aperture.

Claim 52. (Previously presented) A stent crimper comprising:

an aperture with a plurality of movable blades disposed thereabout, the aperture having a longitudinal axis and being substantially polygonal, the blades between stationary end-walls substantially centered about the longitudinal axis, the blades coupled to one another so as to be movable inward or outward simultaneously, movement of the blades outward increasing the size of the aperture, movement of the blades inward decreasing the size of the aperture, the aperture remaining substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture.

Application No. 10/444807
Page 5

Amendment
Attorney Docket No. S63.2Q-7405-US03

Claim 53. (Previously presented) The stent crimper of claim 52 further comprising a rotatable actuation device coupled to the blades, rotation of the actuation device causing the blades to move inward or outward.

Claim 54. (Previously presented) A stent crimper comprising:
an aperture with a plurality of movable blades disposed thereabout, the aperture being substantially polygonal, the blades coupled to one another so as to be movable inward or outward simultaneously, movement of the blades outward increasing the size of the aperture, movement of the blades inward decreasing the size of the aperture, the aperture remaining substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture;

a cryogenic source, the cryogenic source in fluid communication with the stent crimper so as to cool the blades.

Claim 55. (Previously presented) A stent crimping assembly comprising a stent crimper as in claim 46 and a loading device for loading a stent in the aperture.

Claim 56. (Previously presented) The stent crimper of claim 52 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.

Claim 57. (Previously presented) The stent crimper of claim 53 wherein the dies are cooled below ambient temperature.

Claim 58. (Previously presented) The stent crimper of claim 57 including a stent, wherein the stent is made of nitinol.

Claim 59. (Previously presented) The stent crimper of claim 53 wherein the dies are wedge-shaped.

Claim 60. (Previously presented) The stent crimper of claim 53 wherein at least 16 dies are provided.

Claim 61. (Previously presented) The stent crimper of claim 53 wherein the dies are moved cooperatively inward during the moving step.

Claim 62. (Previously presented) The stent crimper of claim 53 wherein an entire stent is disposed in the aperture.

Claim 63. (Currently Amended) A stent crimper comprising:
a plurality of overlapping movable dies arranged to form an iris, the dies disposed about

Application No. 10/444807
Page 6

Amendment
Attorney Docket No. S63.2Q-7405-US03

an aperture, the aperture having a longitudinal axis, the dies between stationary end-walls disposed about the longitudinal axis, the dies operatively engaged to at least one of the stationary end-walls;

each die having a first straight side and a second straight side, the first straight side and the second straight side converging to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die.

Claim 64. (Currently Amended) A stent crimper comprising:

a plurality of movable dies and a thermal cooling unit for cooling the dies, the plurality of movable dies arranged to form an iris disposed about an aperture, the aperture having a longitudinal axis, the plurality of movable dies between stationary end-walls substantially centered about the longitudinal axis, at least one stationary end-wall operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same, each die in communication with an actuation device, the actuation device constructed and arranged such that rotational motion of the actuation device opens or closes the aperture.

Claim 65. (Canceled)

Claim 66. (Currently Amended) A stent crimper comprising:

a plurality of movable dies arranged to form an iris disposed about an aperture, the aperture having a center and a first opening and a second opening, the dies constructed and arranged to have a length exceeding the length of a stent with a longitudinal axis passing through both the first opening and the second opening, each die in communication with an actuation device, the actuation device constructed and arranged such that rotational motion of the actuation device opens or closes the aperture;

each die having a first straight side and a second straight side, the first straight side and the second straight side converging to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die.

Claim 67. (Currently Amended) A stent crimper comprising:

a plurality of movable dies arranged to form an iris disposed about an aperture, the aperture having a longitudinal axis, the plurality of movable dies between stationary plates disposed about the longitudinal axis, each die in communication with an actuation device, the

Application No. 10/444807
Page 7

Amendment
Attorney Docket No. S63.2Q-7405-US03

actuation device constructed and arranged such that rotational motion of the actuation device opens or closes the aperture, the dies operatively engaged to at least one of the stationary plates; each die having a first straight side and a second straight side, the first straight side and the second straight side converging to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die.

Application No. 10/444807
Page 8

Amendment
Attorney Docket No. S63.2Q-7405-US03

Remarks

This Amendment is in response to the Final Office Action dated **October 19, 2004**. In the Office Action claims 36-62 were allowed and claim 65 was found to contain allowable subject matter. Claims 27, 28, 34, 35, 63, 64, 66, and 67 were rejected under 35 USC 102(b) as being anticipated by Whitesell (5,261,263). Claims 29-33 were rejected under 35 USC 103(a) as being unpatentable over Whitesell (5,261,263). These objections and rejections are addressed under headings consistent with the paragraph numbering of the Office Action. Claim 65 has been canceled without prejudice or disclaimer. Claims 27, 63, 64, 66, and 67 have been amended. No new matter has been added.

3

In the Office Action, claims 27, 28, 34, 35, 63, 64, 66, and 67 were rejected under 35 USC 102(b) as being anticipated by Whitesell (5,261,263). Claims 27, 63, 66, and 67 have been amended to recite "each die having a first straight side and a second straight side, the first straight side and the second straight side converging to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die." Whitesell does not teach this limitation. First, Whitesell teaches two straight sides that intersect a curved portion of the die. Furthermore, Whitesell does not teach each first straight side parallel to the second side of an adjacent die, instead each first side is oblique to the second side of an adjacent die. For at least these reasons, Applicant believes amended claim 27, 63, 66, and 67 are in condition for allowance. Claims 34 and 35 are believed to be in condition for allowance for at least the reason that they claim dependence on an allowable base claim.

Claim 64 has been amended to include the allowable subject matter of claim 65 and is believed to be in condition for allowance.

Applicant respectfully requests that the anticipation rejection of claims 27, 28, 34, 35, 63, 64, 66, and 67 were rejected under 35 USC 102(b) as being anticipated by Whitesell (5,261,263) be withdrawn.

Application No. 10/444807
Page 9

Amendment
Attorney Docket No. S63.2Q-7405-US03

5

In the Final Office Action, claims 29-33 were rejected under 35 USC 103(a) as being unpatentable over Whitesell (5,261,263). Claim 27 has been amended to recite "each die having a first straight side and a second straight side, the first straight side and the second straight side converging to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die." Whitesell does not teach or suggest this limitation; thus claim 27 is believed to be in condition for allowance. Claims 29-33 are dependent upon independent claim 27. For at least this reason claims 29-33 are believed to be in condition for allowance.

Applicant respectfully requests that the 35 USC 103(a) rejection of claims 29-33 as being unpatentable over Whitesell be withdrawn.

CONCLUSION

In view of the foregoing it is believed that the present application, with pending claims 27-64 and 66-67, is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: January 7, 2005

By: Brendan C. Babcock
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Austin
Application No.:	10/444,807
Filed:	May 23, 2003
For:	A Method and Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices
Examiner:	Marc Jimenez
Group Art Unit:	3726

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

Docket No.: S63.2-7405-US03

FACSIMILE TRANSMITTAL LETTER

TO: Examiner Jimenez

DATE: January 7, 2005

FACSIMILE NO.: 703-872-9306

TIME: 1:00 p.m.

GROUP ART UNIT: 3726

TOTAL NUMBER OF PAGES (including cover letter): 10

Following please find a 9 page Amendment in addition to this 1 page Facsimile Transmittal Letter.

If a fee is required, Commissioner of Patents is hereby authorized to charge Deposit Account No. 22-0350 for any required fees. To the extent that any petition is required to consider this communication, please treat this as such a petition.

Respectfully Submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

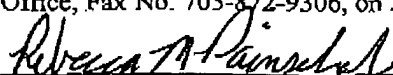
Date: January 7, 2005

By: 
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In re Application of:	Austin
Application No.:	10/444807
Filed:	May 23, 2003
For:	A Method and Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices
Examiner:	Marc Jimenez
Group Art Unit:	3726

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

Docket No.: S63.2Q-7405-US03

AMENDMENT

This Amendment is in response to the Office Action dated **October 19, 2004**.

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicant hereby petitions for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

Please amend the application as follows:



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
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
10/444,807	05/23/2003	Michael Austin	S63.2-7405-US03	8997

490 7590 10/19/2004

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER	
JIMENEZ, MARC QUEMUEL	
ART UNIT	PAPER NUMBER
3726	

DATE MAILED: 10/19/2004

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

Office Action Summary	Application No. 10/444,807	Applicant(s) AUSTIN, MICHAEL	
	Examiner Marc Jimenez	Art Unit 3726	

-- 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) 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 the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- 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 22 September 2004.
- 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) 27-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-62 is/are allowed.
- 6) ☒ Claim(s) 27-35, 63, 64, 66 and 67 is/are rejected.
- 7) ☒ Claim(s) 65 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) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/04 has been entered.

Claim Rejections - 35 USC § 102

2. 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.

3. **Claims 27, 28, 34, 35, 63, 64, 66, and 67** are rejected under 35 U.S.C. 102(b) as being anticipated by Whitesell (5,261,263).

Regarding claims 27 and 64, Whitesell teaches a plurality of movable dies **18** arranged to form an iris **30** having a longitudinal axis (see figure 2), the iris **30** defining an aperture of a substantially polygonal shape, the dies **18** disposed about the aperture and between stationary end-walls (see figure 8) which are disposed about the longitudinal axis, at least one of the stationary end-walls operatively engaged to the dies **18** at distinct connection locations such that

Art Unit: 3726

the number of distinct connection locations and the number of dies **18** are the same. Whitesell is considered to meet the "substantially polygonal shape" limitation because as shown in figure 2, the straight edges of the dies **18** which bound the aperture **30** create a substantially polygonal shape around the aperture **30**.

Regarding claim 28, note the rotatable actuation device **28**.

Regarding claims 34 and 35, the dies **18** are moved inward and are wedge shaped.

Regarding claim 63, note the overlapping dies **18**.

Regarding claims 66 and 67, note that stents come in different sizes and therefore the limitation "arranged to have a length of a stent" is considered met by the dies of Whitesell. Note the actuation device **28**.

Claim Rejections - 35 USC § 103

4. 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.

5. **Claim 29-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitesell.

Regarding claim 29, note that the dies being cooled below ambient temperature or the stent being cooled below ambient temperature prior to reducing the size of the aperture does not further limit the structural features of the crimper and therefore has not been given patentable weight. Also, official notice is taken that it was well known to a person of ordinary skill in the

Art Unit: 3726

art, at the time of the invention, to have provided the invention of Whitesell with cooling the dies to below ambient temperature, in order to work on workpieces that need to remain cool while performing a crimping operation. Regarding claims 30 and 31, a stent being within the aperture does not further limit the structural features of the claimed crimper and therefore has not been given patentable weight. Regarding the limitations that the crimper is used for a stent, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Regarding claims 32 and 33, at the time of the invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art, to have used 8 or 16 dies because applicant has not disclosed that using 8 or 16 dies provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the number of dies taught by Whitesell or the claimed number of dies because either number of dies perform the same function of crimping equally well. Therefore, it would have been an obvious matter of design choice to modify Whitesell in order to obtain the invention as specified in claims 32 and 33. Furthermore, Whitesell suggests that any number and shape of dies could be used (col. 3, lines 34-35).

Art Unit: 3726

Allowable Subject Matter

6. **Claims 36-62** are allowed.
7. **Claim 65** 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.

Response to Arguments

8. Applicant's arguments with respect to claims 27, 28, 29-35, 63, 64, 66, and 67 have been considered but are moot in view of the new ground(s) of rejection.

Contact Information

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Jimenez whose telephone number is (703) 306-5965. The examiner can normally be reached on Monday-Friday between 5:30 a.m.-2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Vo can be reached on (703) 308-1789. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3726

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).



Marc Jimenez
Patent Examiner
AU 3726

MJ

October 15, 2004

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SEP 22 2004

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Michael Austin
Application No.:	10/444,807
Filed:	May 23, 2003
For:	A Method and Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices
Examiner:	Marc Jimenez
Group Art Unit:	3726

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

Docket No.: S63.2-7405-US03

FACSIMILE TRANSMITTAL LETTER**TO: Examiner Jimenez****DATE: September 22, 2004****FACSIMILE NO.: 703-872-9306****TIME: 3:00 p.m.****GROUP ART UNIT: 3726****TOTAL NUMBER OF PAGES (including cover letter): 3**

Following please find a 1 page Request for Continued Examination (RCE) Transmittal and 1 page Petition for an Extension of Time Under 27 CFR §1.136 in addition to this 1 page Facsimile Transmittal Letter.

If a fee is required, Commissioner of Patents is hereby authorized to charge Deposit Account No. 22-0350 for any required fees. To the extent that any petition is required to consider this communication, please treat this as such a petition.

Respectfully Submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

Date: September 22, 2004

By: Brendan C. Babcock
Brendan C. Babcock
Reg. No. 50,705

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

Certificate of Transmission

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. 703-872-9306, on September 22, 2004.

Signature: Rebecca M. Painschab
Rebecca M. Painschab

Request For Continued Examination (RCE) Transmittal Address to: Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number	10/444807	
	Filing Date	May 23, 2003	
	First Names Inventor	Austin	
	Art Unit	3726	
	Examiner Name	Marc Quemuel	
	Attorney Docket Number	S63.2Q-7405-US03	
This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility of plant application filed prior to June 8, 1995, or to any design application.			
1. <u>Submission required under 37 CFR 1.114</u> Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s). a. ☒ Previously submitted. If a final Office Action is outstanding, any amendments filed after the Final Office Action may be considered as a submission even if this box is not checked. i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____ ii. ☐ Other _____ b. ☒ Enclosed i. ☐ Amendment/Reply (Pages _____) iii. ☐ Information Disclosure Statement (IDS) (Pages _____) ii. ☐ Affidavit(s)/ Declaration(s) (Pages _____) iv. ☒ Other: 1 page Petition for an Extension of Time			
2. <u>Miscellaneous</u> a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required) b. ☐ Other _____			
3. <u>Fees</u> The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed. a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 22-0350. i. ☒ RCE fee required under 37 CFR 1.17(e) ii. ☒ Extension of time fee (37 CFR 1.136 and 1.17) iii. ☐ Other _____ b. ☐ Check in the amount of \$ _____ enclosed c. ☐ Payment by credit card (Form PTO-2038 enclosed)			
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.			
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED			
Name (Print/Type)	Brendan C. Babcock	Registration No. (Attorney/Agent)	50705
Signature	<i>Brendan Babcock</i>	Date	September 22, 2004
CERTIFICATE OF MAILING OR TRANSMISSION			
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.			
Name (Print/Type)	Rebecca M. Painschab		
Signature	<i>Rebecca M. Painschab</i>	Date	September 22, 2004

Entered
with RCE of 9/22/04
H. Morgan
10/12/04

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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JUL 22 2004

OFFICIAL

In re Application of: Austin
Application No.: 10/444807
Filed: May 23, 2003
For: A Method and Apparatus for Contracting, Loading
or Crimping Self-Expanding and Balloon
Expandable Stent Devices
Examiner: Marc Jimenez
Group Art Unit: 3726

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

Docket No.: S63.2Q-7405-US03

AMENDMENT

This Amendment is in response to the Final Office Action dated April 22, 2004.

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicant hereby petitions for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

Please amend the application as follows:

7/27/04
L. Morgan
10/12/04
H. Morgan

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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JUL 22 2004

OFFICIAL

In re Application of: Austin
Application No.: 10/444807
Filed: May 23, 2003
For: A Method and Apparatus for Contracting, Loading
or Crimping Self-Expanding and Balloon
Expandable Stent Devices

Examiner: Marc Jimenez
Group Art Unit: 3726

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

Docket No.: S63.2Q-7405-US03

AMENDMENT

This Amendment is in response to the Final Office Action dated April 22, 2004.

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicant hereby petitions for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

Please amend the application as follows:



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/444,807	05/23/2003	Michael Austin	S63.2-7405-US03	8997

490 7590 09/16/2004

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

JIMENEZ, MARC QUEMUEL

ART UNIT PAPER NUMBER

3726

DATE MAILED: 09/16/2004

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

Advisory Action

Application No.

10/444,807

Applicant(s)

AUSTIN, MICHAEL

Examiner

Marc Jimenez

Art Unit

3726

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

THE REPLY FILED 22 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ they raise the issue of new matter (see Note below);
(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: 54.

Claim(s) rejected: 27-53 and 55-66.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


Marc Jimenez
AU 3726
9/13/04

Continuation of 2. NOTE: the amendments to the claims raises new issues that would require further consideration and search.

Application No. 10/444807
Page 2

Amendment
Attorney Docket No. S63.2Q-7405-US03

Amendments To The Claims:

Claims 1-26. (Canceled)

Claim 27. (Currently Amended) A stent crimper comprising:

a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture of a substantially regular polygonal shape, the dies disposed about an the aperture and between stationary end-walls which are disposed about the longitudinal axis, ~~the aperture having a center, each of the dies having a stent contacting surface, each die arranged such that the stent contacting surface extends along a line that intersects the stent contacting surface of an adjacent die and forms an angle, the angle remaining substantially the same when the dies move to open the aperture and when the dies move to close the aperture, at least one of the stationary end-walls operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same.~~

Claim 28. (Previously presented) The stent crimper of claim 27 having a rotatable actuation device coupled to the dies, rotation of the actuation device causing the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Claim 29. (Previously presented) The stent crimper of claim 27 the dies are cooled below ambient temperature.

Claim 30. (Previously presented) The stent crimper of claim 29 including a stent within the aperture.

Claim 31. (Previously presented) The stent crimper of claim 30 wherein the stent is made of nitinol.

Claim 32. (Previously presented) The stent crimper of claim 27 wherein at least 8 dies are provided.

Claim 33. (Previously presented) The stent crimper of claim 27 wherein at least 16 dies are provided.

Claim 34. (Previously presented) The stent crimper of claim 27 wherein the dies are moved cooperatively inward during the moving step.

Claim 35. (Previously presented) The stent crimper of claim 27 wherein the dies are wedge-shaped.

Claim 36. (Currently Amended) A stent crimper comprising:

Application No. 10/444807
Page 3

Amendment
Attorney Docket No. S63.2Q-7405-US03

a plurality of movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a ~~center~~ longitudinal axis and a substantially regular polygonal shape, each of the dies having an inward facing straight side which faces the ~~center~~ longitudinal axis of the aperture, ~~the inward facing straight side facing the center of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture, the dies~~ between two stationary end-walls disposed about the longitudinal axis, the longitudinal axis passing through a point substantially centered on the end-walls.

a rotatable actuation device coupled to the ~~blades~~ dies, rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Claim 37. (Previously presented) The stent crimper of claim 36 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.

Claim 38. (Previously presented) The stent crimper of claim 36 wherein a stent is cooled below ambient temperature prior to reducing the size of the aperture.

Claim 39. (Previously presented) The stent crimper of claim 37 having a stent, wherein the stent is made of nitinol.

Claim 40. (Previously presented) The stent crimper of claim 36 wherein the dies are wedge-shaped.

Claim 41. (Previously presented) The stent crimper of claim 36 wherein at least 8 dies are provided.

Claim 42. (Previously presented) The stent crimper of claim 36 wherein at least 16 wedge-shaped dies are provided.

Claim 43. (Previously presented) The stent crimper of claim 36 wherein an entire stent is disposed in the aperture.

Claim 44. (Currently Amended) A stent crimper comprising:
eight or more movable dies arranged to form an iris, the iris defining an aperture of a substantially regular polygonal shape, the aperture having a ~~center~~ longitudinal axis, each die having an inward facing flat portion which faces the ~~center~~ longitudinal axis of the aperture, ~~the inward facing flat portion faces the center of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture, the dies~~ between stationary end-

Application No. 10/444807
Page 4

Amendment
Attorney Docket No. S63.2Q-7405-US03

walls and operatively engaged to at least one of the stationary end-walls, the stationary end-walls disposed about the longitudinal axis.

the iris comprising at least eight of the inward facing flat portions, the aperture being reducible in size by moving the inward facing flat portions toward the center longitudinal axis of the aperture,

a rotatable actuation device coupled to the ~~blades~~ dies, rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Claim 45. (Previously presented) The stent crimper of claim 44 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.

Claim 46. (Previously presented) The stent crimper of claim 44 wherein the dies are cooled below ambient temperature.

Claim 47. (Previously presented) The stent crimper of claim 46 including a stent in the aperture, wherein the stent is made of nitinol.

Claim 48. (Previously presented) The stent crimper of claim 44 wherein the dies are wedge-shaped.

Claim 49. (Previously presented) The stent crimper of claim 44 wherein at least 16 dies are provided.

Claim 50. (Previously presented) The stent crimper of claim 44 wherein the dies are moved cooperatively inward during the moving step.

Claim 51. (Previously presented) The stent crimper of claim 44 wherein an entire stent is disposed in the aperture.

Claim 52. (Currently Amended) A stent crimper comprising:

an aperture with a plurality of movable blades disposed thereabout, the aperture having a longitudinal axis and being substantially polygonal, the blades between stationary end-walls substantially centered about the longitudinal axis, the blades coupled to one another so as to be movable inward or outward simultaneously, movement of the blades outward increasing the size of the aperture, movement of the blades inward decreasing the size of the aperture, the aperture remaining substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture.

Application No. 10/444807
Page 5

Amendment
Attorney Docket No. S63-2Q-7405-US03

Claim 53. (Previously presented). The stent crimper of claim 52 further comprising a rotatable actuation device coupled to the blades, rotation of the actuation device causing the blades to move inward or outward.

Claim 54. (Currently Amended) A stent ~~crimper crimping assembly comprising a stent crimper as in claim 52 and:~~

an aperture with a plurality of movable blades disposed thereabout, the aperture being substantially polygonal, the blades coupled to one another so as to be movable inward or outward simultaneously, movement of the blades outward increasing the size of the aperture, movement of the blades inward decreasing the size of the aperture, the aperture remaining substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture;

a cryogenic source, the cryogenic source in fluid communication with the stent crimper so as to cool the blades.

Claim 55. (Previously presented) A stent crimping assembly comprising a stent crimper as in claim 46 and a loading device for loading a stent in the aperture.

Claim 56. (Previously presented) The stent crimper of claim 52 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.

Claim 57. (Previously presented) The stent crimper of claim 53 wherein the dies are cooled below ambient temperature.

Claim 58. (Previously presented) The stent crimper of claim 57 including a stent, wherein the stent is made of nitinol.

Claim 59. (Previously presented) The stent crimper of claim 53 wherein the dies are wedge-shaped.

Claim 60. (Previously presented) The stent crimper of claim 53 wherein at least 16 dies are provided.

Claim 61. (Previously presented) The stent crimper of claim 53 wherein the dies are moved cooperatively inward during the moving step.

Claim 62. (Previously presented) The stent crimper of claim 53 wherein an entire stent is disposed in the aperture.

Claim 63. (Currently Amended) A stent crimper comprising:

Application No. 10/444807
Page 6

Amendment
Attorney Docket No. S63.2Q-7405-US03

a plurality of overlapping movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a center longitudinal axis, the dies between stationary end-walls disposed about the longitudinal axis, the dies operatively engaged to at least one of the stationary end-walls, each of the dies having a stent contacting surface which is curved.

Claim 64. (Currently Amended) A stent crimper comprising:

~~a first stationary plate and a second stationary plate,~~ a plurality of movable dies ~~between the stationary plates and~~ arranged to form an iris disposed about an aperture, the aperture having a center longitudinal axis, the plurality of movable dies between stationary end-walls substantially centered about the longitudinal axis, at least one stationary end-wall operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same, each die in communication with an actuation device, the actuation device constructed and arranged such that rotational motion of the actuation device opens or closes the aperture.

Claim 65. (Previously presented) The stent crimper of claim 64 further comprising a thermal cooling unit for cooling the dies.

Claim 66. (Previously presented) A stent crimper comprising:

a plurality of movable dies arranged to form an iris disposed about an aperture, the aperture having a center and a first opening and a second opening, the dies constructed and arranged to have a length exceeding the length of a stent with a longitudinal axis passing through both the first opening and the second opening, each die in communication with an actuation device, the actuation device constructed and arranged such that rotational motion of the actuation device opens or closes the aperture.

Claim 67. (New) A stent crimper comprising:

a plurality of movable dies arranged to form an iris disposed about an aperture, the aperture having a longitudinal axis, the plurality of movable dies between stationary plates disposed about the longitudinal axis, each die in communication with an actuation device, the actuation device constructed and arranged such that rotational motion of the actuation device opens or closes the aperture, the dies operatively engaged to at least one of the stationary plates.

Application No. 10/444807
Page 7

Amendment
Attorney Docket No. S63.2Q-7405-US03

Remarks

This Amendment is in response to the Final Office Action dated April 22, 2004. In the Final Office Action claim 54 was found to contain allowable subject matter. Claim 27 was objected to due to an informality. Claims 36-51 and 55 were rejected under 35 USC 112 for indefiniteness. Claims 27, 32, 34, 35, 52, 56, and 63 were rejected under 35 USC 102(b) as being anticipated by Tuberman (3,695,087). Claims 27, 28, 34-37, 39, 40, 43, 52, 53, 56, 59, 61, 62, 64, and 66 were rejected under 35 USC 102(e) as being anticipated by Wilhelm et al. (6,176,116). Claims 28, 36-51, 53, 55, 57-62, and 64-66 were rejected under 35 USC 103(a) as being unpatentable over Tuberman in view of Latin et al. (2,887,222). Claims 29-31 and 33 were rejected under 35 USC 103(a) as being unpatentable over Tuberman. These objections and rejections are addressed under headings consistent with the paragraph numbering of the Final Office Action. New claim 67 has been added. Claims 27, 36, 44, 52, 54, 63, and 64 have been amended. No new matter has been added.

1

In the Final Office Action, claim 27 was objected to due to an informality. Claim 27 has been amended and the informality has been corrected. Applicant respectfully requests that the objection be withdrawn.

3

In the Final Office Action, claims 36-51 and 55 were rejected under 35 USC 112, second paragraph. The Office Action states that "the blades" lack antecedent basis in claims 36 and 46 (Applicant believes claim 44 was intended rather than claim 46). Applicant has addressed this issue in the amendments of claims 36 and 44 and believes these claims and the claims dependent thereupon are in condition for allowance.

5

In the Final Office Action, claims 27, 32, 34, 35, 52, 56, and 63 were rejected under 35 USC 102(b) as being anticipated by Tuberman (3,695,087). Claim 27 has been amended to recite "the dies disposed about an aperture and between stationary end-walls which

Application No. 10/444807
Page 8

Amendment
Attorney Docket No. S63.2Q-7405-US03

are disposed about the longitudinal axis, at least one of the stationary end-walls operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same". Tuberman does not teach stationary end-walls centered about the longitudinal axis with the end-walls operatively engaged to the dies; rather in as much as Tuberman teaches end-walls, the end-walls are there merely for support purposes and are not operatively engaged to the dies. Thus, claim 27 is believed to be in condition for allowance. Claims 32, 34, and 35 dependent from claim 27 are believed to be in condition for allowance for at least the reason discussed above with respect to claim 27.

Independent claim 52 has been amended to recite blades between stationary end-walls substantially centered about the longitudinal axis. Tuberman does not teach or suggest blades between stationary end-walls centered about the longitudinal axis. In as much as Tuberman teaches end-walls, the end-walls are not centered about the longitudinal axis. For at least this reason amended claim 52 is not anticipated by Tuberman and is believed to be in condition for allowance. Claim 56 dependent from claim 52 is believed to be in condition for allowance for at least the reason that claim 52 is believed to be in condition for allowance.

Independent claim 63 has been amended to recite "the dies between stationary end-walls disposed about the longitudinal axis, the dies operatively engaged to at least one of the stationary end-walls". Tuberman does not teach or suggest dies between stationary end-walls disposed about the longitudinal axis, the dies operatively engaged to at least one of the stationary end-walls. For at least this reason amended claim 63 is not anticipated by Tuberman and is believed to be in condition for allowance.

Applicant respectfully requests that the anticipation rejection of claims 27, 32, 34, 35, 52, 56, and 63 in view of Tuberman be withdrawn.

6

In the Final Office Action, claims 27, 28, 34-37, 39, 40, 43, 52, 53, 56, 59, 61, 62, 64, and 66 were rejected under 35 USC 102(e) as being anticipated by Wilhelm et al. (6,176,116). Independent claims 27 has been amended to recite "the dies disposed about an aperture and between stationary end-walls which are disposed about the longitudinal axis, at least one of the stationary end-walls operatively engaged to the dies at distinct connection locations

Application No. 10/444807
Page 9

Amendment
Attorney Docket No. S63.2Q-7405-US03

such that the number of distinct connection locations and the number of dies are the same". Wilhelm does not teach stationary end-walls as claimed in claim 27; rather Wilhelm teaches an open face apparatus without stationary end-walls centered about a longitudinal axis. For at least this reason amended claim 27 is believed to be in condition for allowance. Claims 32, 34, and 35 dependent from claim 27 are believed to be in condition for allowance for at least the reason that claim 27 is believed to be in condition for allowance.

Independent claims 36, 44, 52, and 64 have been amended to claim dies or blades between stationary end-walls. Wilhelm et al. does not teach or suggest dies or blades between stationary end-walls. Rather, Wilhelm et al teaches an open face apparatus without stationary end-walls. For at least this reason amended claims 36, 44, 52, and 63 are not anticipated by Wilhelm et al. and are believed to be in condition for allowance. Dependent claims 28, 34, 35, 37, 39, 40, 43, 53, 56, 59, 61, 62 are believed to be in condition for allowance at least for the same reasons that the independent claims from which they depend are considered to be allowable.

Regarding claim 64, Applicant asserts that plates 5,17 are not stationary plates as the plates move relative to one another as required in claim 64. Nonetheless Applicant has amended this claim and believes it is in condition for allowance.

Regarding claim 66, Applicant points out that the recitation "the dies constructed and arranged to have a length exceeding the length of a stent with a longitudinal axis passing through both the first opening and the second opening" does result in a structural difference between the claimed invention and the prior art, as the die of claim 66 must be a minimum length. Wilhelm does not teach or suggest dies having this length. Thus, it is believed that claim 66 is in condition for allowance.

Applicant respectfully requests that the anticipation rejection of claims 27, 28, 34-37, 39, 40, 43, 52, 53, 56, 59, 61, 62, 64, and 66 in view of Wilhelm et al. be withdrawn.

8

In the Final Office Action, claims 28, 36-51, 53, 55, 57-62, and 64-66 were rejected under 35 USC 103(a) as being unpatentable over Tuberman in view of Latin et al. (2,887,222). Applicant believes the rejection of claim 64 lacks specificity. Nevertheless,

Application No. 10/444807
Page 10

Amendment
Attorney Docket No. S63.2Q-7405-US03

Applicant has amended the claim and believes it is in condition for allowance.

Claim 66 is mischaracterized in the Final Office Action in that claim 66 does not claim the limitation of a thermal cooling unit in the dies. Claim 65 does contain this limitation. Applicant traverses the Official Notice taken in the Final Office Action in which it is asserted that it was well known to a person of ordinary skill in the art, at the time of the invention, to use a thermal cooling unit in dies. Applicant requests that a reference supporting the position taken in the Office Action regarding that this was well known be cited. If this rejection is based on facts within the personal knowledge of the examiner, Applicant requests that the data be stated as specifically as possible and that the facts be supported by an affidavit from the Examiner.

Claim 28 is dependent upon amended claim 27. Claim 27 is believed to be in condition for allowance as discussed above. Neither Tuberman nor Latin teach dies disposed about an aperture and between stationary end-walls centered about the longitudinal axis and that at least one of the stationary end-walls is operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same. Claim 28 is allowable for at least the reason that claim 27 from which it depends is believed to be allowable.

Regarding amended independent claims 36, 44, 52, 63, and 64, Latin does not provide the missing limitation of the dies between two stationary end-walls disposed about the longitudinal axis. For at least this reason, amended independent claims 36, 44, 52, 63, and 64 and dependent claims 37-43, 45-51, 53, 55, 57-62, and 65 dependent thereof are in condition for allowance.

Furthermore, regarding claims 28, 36-51, 53, 55, 57-62, and 64-66, one skilled in the art would have no motivation to look to the extrusion art of Latin and the point making art of Tuberman to devise an apparatus for crimping a stent as these are very different arts; the apparatuses of both Tuberman and Latin are applied to solid side walled tubes or pipes or the creation of solid side walled tubes or pipes, the stent of the instant invention has a side wall with holes throughout it. The characteristics of these walls are very different and respond differently such that one would not look to pipe and tube art when considering a stent crimper. As such, a finding of obviousness using these two references is inappropriate.

Applicant respectfully requests that the 35 USC 103(a) rejection of claims 28, 36-

Application No. 10/444807
Page 11

Amendment
Attorney Docket No. S63.2Q-7405-US03

51, 53, 55, 57-62, and 64-66 as being unpatentable over Tuberman in view of Latin et al. be withdrawn.

9

In the Final Office Action, claims 29-31 and 33 were rejected under 35 USC 103(a) as being unpatentable over Tuberman. Claims 29-31 and 33 are dependent upon amended claim 27. Claim 27 is believed to be in condition for allowance as discussed above. Tuberman does not teach or suggest dies disposed about an aperture and between stationary end-walls centered about the longitudinal axis and that at least one of the stationary end-walls is operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same. Claims 29-31 and 33 are allowable for at least the reason discussed above with respect to claim 27 from which they depend.

10

In the Final Office Action, claim 54 was found to contain allowable subject matter. Claim 54 has been rewritten into independent form and is believed to be in condition for allowance. Applicant respectfully requests that the objection to this claim be withdrawn.

Application No. 10/444807
Page 12

Amendment
Attorney Docket No. S63.2Q-7405-US03

CONCLUSION

In view of the foregoing it is believed that the present application, with pending claims 27-67, is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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Date: July 21, 2004

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Michael Austin
Application No.: 10/444,807
Filed: May 23, 2003
For: A Method and Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices
Examiner: Marc Jimenez
Group Art Unit: 3726

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Commissioner for Patents
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Alexandria, VA 22313-1450

Docket No.: S63.2-7405-US03

FACSIMILE TRANSMITTAL LETTER

TO: Examiner Jimenez

DATE: July 22, 2004

FACSIMILE NO.: 703-872-9306

TIME: 2:15pm

GROUP ART UNIT: 3726

TOTAL NUMBER OF PAGES (including cover letter): 13

Following please find a 12 page Amendment in addition to this 1 page Facsimile Transmittal Letter.

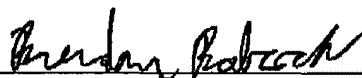
If a fee is required, Commissioner of Patents is hereby authorized to charge Deposit Account No. 22-0350 for any required fees. To the extent that any petition is required to consider this communication, please treat this as such a petition.

Respectfully Submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

Date: July 22, 2004

By:



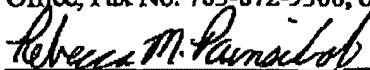
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In re Application of:	Austin
Application No.:	10/444807
Filed:	May 23, 2003
For:	A Method and Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices
Examiner:	Marc Jimenez
Group Art Unit:	3726

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

Docket No.: S63.2Q-7405-US03

AMENDMENT

This Amendment is in response to the Final Office Action dated April 22, 2004.

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicant hereby petitions for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

Please amend the application as follows:



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/444,807	05/23/2003	Michael Austin	S63.2-7405-US03	8997

490 7590 04/22/2004

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EXAMINER

JIMENEZ, MARC QUEMUEL

ART UNIT PAPER NUMBER

3726

DATE MAILED: 04/22/2004

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

Office Action Summary

Application No.

10/444,807

Applicant(s)

AUSTIN, MICHAEL

Examiner

Marc Jimenez

Art Unit

3726

-- 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) 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 the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- 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 22 January 2004.
- 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) 27-66 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) 27-53 and 55-66 is/are rejected.
- 7) ☒ Claim(s) 54 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) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. **Claim 27** is objected to because of the following informalities: claim 27 recites “an aperture” in line 3 which should be - - the aperture - -. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. 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.

3. **Claims 36-51 and 55** 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.

Claim 36 recites “the blades” in line 7 which lacks proper antecedent basis.

Claim 46 recites “the blades” in line 9 which lacks proper antecedent basis.

Claim Rejections - 35 USC § 102

4. 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.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

Art Unit: 3726

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 27, 32, 34, 35, 52, 56, and 63** are rejected under 35 U.S.C. 102(b) as being anticipated by Tuberman (3,695,087).

Tuberman teaches a plurality of movable dies **27** (fig. 23-26) arranged to form an iris, the iris defining an aperture of a substantially regular polygonal shape, the dies **27** disposed about the aperture, the aperture having a center, each of the dies **27** having a contacting surface **27**, each die **27** arranged such that the contacting surface extends along a line that intersects the contacting surface of an adjacent die **27** and forms an angle, the angle remaining substantially the same when the dies **27** move to open the aperture and when the dies move to close the aperture. Regarding the limitations that the crimper is used for a stent, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Regarding claim 32, at least 8 dies **27** are provided.

Regarding claim 34, the dies **27** are moved cooperatively inward during the moving step.

Regarding claim 35, the dies **27** are wedge-shaped.

Regarding claim 63, note the curved dies (fig. 24).

6. **Claims 27, 28, 34-37, 39, 40, 43, 52, 53, 56, 59, 61, 62, 64, and 66** are rejected under 35 U.S.C. 102(e) as being anticipated by Wilhelm et al. (6,176,116).

Wilhelm et al. teach dies **18** arranged to form an iris **32** with angles that remain substantially the same when the dies move to open or close. Note the rotatable actuation device **17** coupled to the dies **18**. The dies **18** are wedge shaped. Note the plates **5, 17**.

Regarding the limitations that the crimper is used for a stent, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 103

7. 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.

8. **Claims 28, 36-51, 53, 55, 57-62, and 64-66** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuberman in view of Latin et al. (2,887,222).

Regarding claims 28, 36, 44, and 66, Tuberman teaches the invention cited, in the rejection of claim 27 above, with the exception of having a rotatable actuation device coupled to the dies, rotation of the actuation device causing the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Latin et al. teach a rotatable actuation device 36 coupled to dies 34, rotation of the actuation device 36 causing the dies 34 to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Tuberman with a rotatable actuation device coupled to the dies, rotation of the actuation device causing the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture, in light of the teachings of Latin et al., in order to symmetrically reduce the size of the aperture by simultaneously moving the dies.

Regarding claims 37, 39, 43, 45, 47, 51, 55, 58, and 62, the limitations that the crimper is used for a stent disposed about a medical balloon which is disposed about a catheter, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Regarding claims 38, 46, and 57, note that the dies being cooled below ambient temperature or the stent being cooled below ambient temperature prior to reducing the size of the

aperture does not further limit the structural features of the crimper and therefore has not been given patentable weight.

Regarding claims 40, 48, and 59, Tuberman teaches that the dies **27** are wedge-shaped.

Regarding claim 41, Tuberman teaches that at least 8 dies **27** are provided.

Regarding claims 42, 49, and 60, at the time of the invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art, to have used more than 16 dies because applicant has not disclosed that more than 16 dies provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the 8 dies taught by Tuberman (and as claimed in claim 32) or the claimed 16 or more dies because either number of dies perform the same function of crimping equally well.

Regarding claim 66, official notice is taken that it was well known to a person of ordinary skill in the art, at the time of the invention, to have used a thermal cooling unit in dies, for the purpose of cooling the dies.

9. **Claims 29-31 and 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuberman.

Note that the dies being cooled below ambient temperature or the stent being cooled below ambient temperature prior to reducing the size of the aperture does not further limit the structural features of the crimper and therefore has not been given patentable weight. Also, official notice is taken that it was well known to a person of ordinary skill in the art, at the time of the invention, to have provided the invention of Tuberman with cooling the dies to below

ambient temperature, in order to work on workpieces that need to remain cool while performing a crimping operation. Regarding claims 30 and 31, a stent being within the aperture does not further limit the structural features of the claimed crimper and therefore has not been given patentable weight. Regarding the limitations that the crimper is used for a stent, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Regarding claim 33, at the time of the invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art, to have used more than 16 dies because applicant has not disclosed that more than 16 dies provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the 8 dies taught by Tuberman (and as claimed in claim 32) or the claimed 16 or more dies because either number of dies perform the same function of crimping equally well.

Allowable Subject Matter

10. **Claim 54** 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.

Response to Arguments

11. Applicant's arguments with respect to claims 27-66 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. 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.

Interviews After Final

13. Applicant note that an interview after a final rejection will not be granted unless the intended purpose and content of the interview is presented briefly, in writing (the agenda of the interview must be in writing) to clarify issues for appeal requiring only nominal further

consideration. Interviews merely to restate arguments of record or to discuss new limitations will be denied. See MPEP 714.13 and 713.09.

Contact Information

14. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information. M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer Service at (703) 306-5648, or fax (703) 872-9301 or by email to CustomerService3700@uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Jimenez whose telephone number is **703-306-5965**. The examiner can normally be reached on **Monday-Friday, between 5:30 am- 2:00 pm**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Vo can be reached on 703-308-1789. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Art Unit: 3726

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication	(703) 308-6789 or (888) 786-0101
Assignment Branch	(703) 308-9723
Certificates of Correction	(703) 305-8309
Drawing Corrections/Draftsman	(703) 305-8404/8335
Petitions/Special Programs	(703) 305-9285
Terminal Disclaimers	(703) 305-8408
PCT Help Desk	(703) 305-3257

If the information desired is not provided above, or a number has been changed, please call the general information help line below.

Information Help line	1-800-786-9199
Internet PTO-Home Page	http://www.uspto.gov/


MJ

April 15, 2004


Am 3726

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Austin
Application No.:	10/444807
Filed:	May 23, 2003
For:	A Method and Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices
Examiner:	Marc Jimenez
Group Art Unit:	3726

10
NOB 2-13-04

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

Docket No.: S63.2Q-7405-US03

**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING
REJECTION OVER A PRIOR PATENT**

The owner, SciMed Life Systems, Inc. of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 and 173, as presently shortened by any terminal disclaimer, of prior patent No. 6,360,577. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it, and the prior patents are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of any of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submission on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf on the organization.

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.

2. ☒ The undersigned is an attorney of record.

January 22, 2004
Date

Brendan Babcock
Signature

Brendan C. Babcock
Typed or printed name

- ☐ Terminal disclaimer fee under 37 CFR 1.20(d) included.
☒ PTO suggested wording for terminal disclaimer was
☒ unchanged ☐ changed (if changed, an explanation should be supplied).

JAN 22 2004

OFFICIAL PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Austin
Application No.:	10/444,807
Filed:	May 23, 2003
For:	Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices
Examiner:	Marc Jimenez
Group Art Unit:	3726

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

Docket No.: S63.2-7405-US03

FACSIMILE TRANSMITTAL LETTER

TO: Examiner Jimenez

DATE: January 22, 2004

FACSIMILE NO.: 703-872-9306

TIME: 4:00 pm

GROUP ART UNIT: 3726

TOTAL NUMBER OF PAGES (including cover letter): 16

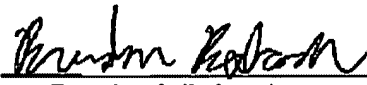
Following please find a 13 page Amendment and 2 page Terminal Disclaimer to Obviate a Double Patenting Rejection Over a Prior Patent in addition to this 1 page Facsimile Transmittal Letter.

If a fee is required, Commissioner of Patents is hereby authorized to charge Deposit Account No. 22-0350 for any required fees. To the extent that any petition is required to consider this communication, please treat this as such a petition.

Respectfully Submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

Date: January 22, 2004

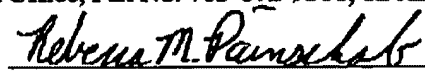
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Certificate of Transmission

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. 703-872-9306, on January 22, 2004.

Signature: 

Rebecca M. Painschab

Application No. 10/444807
Page 2

Amendment
Attorney Docket No. S63.2Q-7405-US03

Amendments To The Specification:

✓
Please amend the title of the application as shown:

~~A METHOD AND APPARATUS FOR CONTRACTING, LOADING OR CRIMPING SELF-EXPANDING AND BALLOON EXPANDABLE STENT DEVICES~~

1 ✓
Please amend the paragraph of the first line of the specification after the heading
"Cross-Reference to related Applications" as shown:

C/ This application is a Continuation application from Application No. 09/966,686
filed October 1, 2001 which is a Continuation application from Application No. 09/401,218 filed
September 22, 1999, now patent no. 6,360,577, the contents of which are hereby incorporated by
reference.

Application No. 10/444807
Page 3

Amendment
Attorney Docket No. S63.2Q-7405-US03

Amendments To The Claims:

Claims 1-26. (Canceled)

Claim 27. (Previously presented) A stent crimper comprising:

a plurality of movable dies arranged to form an iris, the iris defining an aperture of a substantially regular polygonal shape, the dies disposed about an aperture, the aperture having a center, each of the dies having a stent contacting surface, each die arranged such that the stent contacting surface extends along a line that intersects the stent contacting surface of an adjacent die and forms an angle, the angle remaining substantially the same when the dies move to open the aperture and when the dies move to close the aperture longitudinal axis which is tangent to the aperture.

Claim 28. (Previously presented) The stent crimper of claim 27 having a rotatable actuation device coupled to the dies blades, rotation of the actuation device causing the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Claim 29. (Previously presented) The stent crimper of claim 27 the dies are cooled below ambient temperature.

Claim 30. (Previously presented) The stent crimper of claim 29 including a stent within the aperture.

Claim 31. (Previously presented) The stent crimper of claim 30 wherein the stent is made of nitinol.

Claim 32. (Previously presented) The stent crimper of claim 27 wherein at least 8 dies are provided.

Claim 33. (Previously presented) The stent crimper of claim 27 wherein at least 16 dies are provided.

Claim 34. (Previously presented) The stent crimper of claim 27 wherein the dies are moved cooperatively inward during the moving step.

Claim 35. (Previously presented) The stent crimper of claim 27 wherein the dies are wedge-shaped.

Claim 36. (Previously presented) A stent crimper comprising:

a plurality of movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a center and a substantially regular polygonal shape, each of the dies having

Application No. 10/444807
Page 4

Amendment
Attorney Docket No. S63.2Q-7405-US03

an inward facing straight side which faces the center of the aperture, the inward facing straight side facing the center of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture.

a rotatable actuation device coupled to the blades, rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Claim 37. (Previously presented) The stent crimper of claim 36 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.

Claim 38. (Previously presented) The stent crimper of claim 36 wherein a stent is cooled below ambient temperature prior to reducing the size of the aperture.

Claim 39. (Previously presented) The stent crimper of claim 37 having a stent, wherein the stent is made of nitinol.

Claim 40. (Previously presented) The stent crimper of claim 36 wherein the dies are wedge-shaped.

Claim 41. (Previously presented) The stent crimper of claim 36 wherein at least 8 dies are provided.

Claim 42. (Previously presented) The stent crimper of claim 36 wherein at least 16 wedge-shaped dies are provided.

Claim 43. (Previously presented) The stent crimper of claim 36 wherein an entire stent is disposed in the aperture.

Claim 44. (Previously presented) A stent crimper comprising:
eight or more movable dies arranged to form an iris, the iris defining an aperture of a substantially regular polygonal shape, the dies disposed about an aperture having a center, each die having an inward facing flat portion which faces the center of the aperture, the inward facing flat portion faces the center of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture.

the iris comprising at least eight of the inward facing flat portions, the aperture being reducible in size by moving the inward facing flat portions toward the center of the aperture,

a rotatable actuation device coupled to the blades, rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or

Application No. 10/444807
Page 5

Amendment
Attorney Docket No. S63.2Q-7405-US03

outward so as to increase the size of the aperture.

Claim 45. (Previously presented) The stent crimper of claim 44 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.

Claim 46. (Previously presented) The stent crimper of claim 44 wherein the dies are cooled below ambient temperature.

Claim 47. (Previously presented) The stent crimper of claim 46 including a stent in the aperture, wherein the stent is made of nitinol.

Claim 48. (Previously presented) The stent crimper of claim 44 wherein the dies are wedge-shaped.

Claim 49. (Previously presented) The stent crimper of claim 44 wherein at least 16 dies are provided.

Claim 50. (Previously presented) The stent crimper of claim 44 wherein the dies are moved cooperatively inward during the moving step.

Claim 51. (Previously presented) The stent crimper of claim 44 wherein an entire stent is disposed in the aperture.

Claim 52. (Previously presented) A stent crimper comprising:

an aperture with a plurality of movable blades disposed thereabout, the aperture being substantially polygonal, the blades coupled to one another so as to be movable inward or outward simultaneously, movement of the blades outward increasing the size of the aperture, movement of the blades inward decreasing the size of the aperture, the aperture remaining substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture it is subsequently reduced in size.

Claim 53. (Previously presented). The stent crimper of claim 52 further comprising a rotatable actuation device coupled to the blades, rotation of the actuation device causing the blades to move inward or outward.

Claim 54. (Previously presented) A stent crimping assembly comprising a stent crimper as in claim 52 and a cryogenic source, the cryogenic source in fluid communication with the stent crimper so as to cool the blades.

Claim 55. (Previously presented) A stent crimping assembly comprising a stent crimper as in claim 46 and a loading device for loading a stent in the aperture.

Application No. 10/444807
Page 6

Amendment
Attorney Docket No. S63.2Q-7405-US03

- Claim 56. (Previously presented) The stent crimper of claim 52 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.
- Claim 57. (Previously presented) The stent crimper of claim 53 wherein the dies are cooled below ambient temperature.
- Claim 58. (Previously presented) The stent crimper of claim 57 including a stent, wherein the stent is made of nitinol.
- Claim 59. (Previously presented) The stent crimper of claim 53 wherein the dies are wedge-shaped.
- Claim 60. (Previously presented) The stent crimper of claim 53 wherein at least 16 dies are provided.
- Claim 61. (Previously presented) The stent crimper of claim 53 wherein the dies are moved cooperatively inward during the moving step.
- Claim 62. (Previously presented) The stent crimper of claim 53 wherein an entire stent is disposed in the aperture.
- Claim 63. (New) A stent crimper comprising:
a plurality of overlapping movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a center, each of the dies having a stent contacting surface which is curved.
- Claim 64. (new) A stent crimper comprising:
a first stationary plate and a second stationary plate, a plurality of movable dies between the stationary plates and arranged to form an iris disposed about an aperture, the aperture having a center, each die in communication with an actuation device, the actuation device constructed and arranged such that rotational motion of the actuation device opens or closes the aperture.
- Claim 65. (new) The stent crimper of claim 64 further comprising a thermal cooling unit for cooling the dies.
- Claim 66. (new) A stent crimper comprising:
a plurality of movable dies arranged to form an iris disposed about an aperture, the aperture having a center and a first opening and a second opening, the dies constructed and arranged to have a length exceeding the length of a stent with a longitudinal axis passing through both the first opening and the second opening, each die in communication with an actuation device, the actuation device constructed and arranged such that rotational motion of the actuation

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Application No. 10/444807
Page 7

Amendment
Attorney Docket No. S63.2Q-7405-US03

c2
device opens or closes the aperture.

Application No. 10/444807
Page 8

Amendment
Attorney Docket No. S63.2Q-7405-US03

Remarks

This Amendment is in response to the Office Action dated **October 22, 2003**.

Claim 54 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. In the Office Action, Fig. 1 was objected to for not being designated by a legend such as --Prior Art--. The title was also objected to for not being descriptive. The specification was further objected to for not listing the patent number of the Austin reference. Claim 28 was rejected under 35 USC 112, second paragraph. Claims 27, 28, 34-36 40, 52, 53, 59, and 61 were rejected under 35 U.S.C. 102(b) as being anticipated by Whitesell (5,261,263). Claims 32, 33, 41, 42, 44, 48-50, and 60 were rejected under 35 U.S.C. 103(a) as being unpatentable over Whitesell (5,261,263). Claims 27-53 and 55-62 were rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (AAPA). Claims 27-62 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,360,577.

Claims 27, 28, 36, 44, and 52 have been amended. New claims 63-66 have been added. No new matter has been added. Applicant addresses each of the claim objections and claim rejections under paragraph headings which coincide with the paragraph numbering of the Office Action.

1

In a telephonic communication, the Examiner waived the requirement of providing a replacement drawing of Fig. 1 including the legend --Prior Art--. A proposed Fig. 3 including the legend --Prior Art-- was submitted in the Preliminary Amendment mailed May 23, 2003.

2

Applicant has amended the title in accordance with the Examiner's comments. Additionally, Applicant has amended the first line of the specification in that -- now patent no. 6,360,577-- has been inserted after "September 22, 1999".

Application No. 10/444807
Page 9

Amendment
Attorney Docket No. S63.2Q-7405-US03

5

In the Office Action, claim 28 was rejected under 35 USC 112, second paragraph. The Office Action states that "the blades" in line 2 of claim 28 lacks proper antecedent basis. Claim 28 has been amended to recite "the dies" and delete "the blades". In light of this amendment to claim 28, Applicant respectfully requests that the rejection be withdrawn.

7

In the Office Action, claims 27, 28, 34-36 40, 52, 53, 59, and 61 were rejected under 35 U.S.C. 102(b) as being anticipated by Whitesell (5,261,263). Applicant has amended claim 27 to recite "each of the dies having a stent contacting surface, each die arranged such that the stent contacting surface extends along a line that intersects the stent contacting surface of an adjacent die and forms an angle, the angle remaining substantially the same when the dies move to open the aperture and when the dies move to close the aperture." Whitesell does not teach this limitation. In fact, the open configuration of Whitesell in Fig. 2 and the closed configuration of Whitesell in Fig. 4 illustrate that no angle is formed at all between the stent contacting surfaces in the closed configuration of Whitesell.

Independent claim 36 has been amended to recite "each of the dies having an inward facing straight side which faces the center of the aperture, the inward facing straight side facing the center of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture". This limitation is not disclosed in Whitesell. In as much as Whitesell has a straight side, the straight side does not face the center of the aperture in the closed position as shown in Fig. 4 of Whitesell. In fact, in the closed position the straight sides of Whitesell are on the same line as the center of the aperture (i.e. not facing the center of the aperture by definition).

Independent claim 52 has been amended to recite "the aperture remaining substantially polygonal when it is sized to receive a stent therein and when the blades minimize the aperture". This limitation is not disclosed in Whitesell. In as much as Whitesell discloses an aperture that is substantially regular polygonal, Whitesell does not teach that the aperture remains polygonal when the blades minimize the aperture. Again we look to Fig. 4 of Whitesell which shows the closed position. Fig. 4 does not in any way have an aperture that is substantially

Application No. 10/444807
Page 10

Amendment
Attorney Docket No. S63.2Q-7405-US03

regular polygonal in the closed position (minimizing the aperture).

Applicant has amended claims 27, 36, and 52 and believes that these claims and the dependent claims thereof are now in condition for allowance. Applicant respectfully requests that the 35 U.S.C. 102(b) anticipation rejection due to Whitesell be withdrawn.

9

In the Office Action, claims 32, 33, 41, 42, 44, 48-50, and 60 were rejected under 35 U.S.C. 103(a) as being unpatentable over Whitesell (5,261,263). Claims 32, 33, 41, 42, and 60 draw dependence from independent claims 27, 36, and 52. Applicant believes claims 27, 36, and 52 are now in condition for allowance. As such dependent claims 32, 33, 41, 42, and 60 are also now in condition for allowance as they are dependent on an allowable base claim.

Claim 44 has been amended to recite "the inward facing flat portion faces the center of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture". As stated in the second paragraph under heading 7, this limitation is not disclosed in Whitesell. Furthermore, it is not obvious in light of Whitesell in that no suggestion is made in Whitesell that the inward facing flat portion faces the center of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture. In fact, Whitesell teaches quite the opposite as the straight sides of Whitesell are on the same line as the center of the aperture in the closed position. It is believed that amended claim 44 is in condition for allowance and that dependent claims 48-50 dependent thereof are in condition for allowance as they claim dependence on an allowable base claim.

In addition, Whitesell does not teach or suggest the use of either at least 8 or 16 blades. Each figure of Whitesell shows the use of 6 blades.

Applicant request that the 35 U.S.C. 103(a) rejection of claims 32, 33, 41, 42, 44, 48-50, and 60 as being unpatentable over Whitesell be withdrawn.

10

In the Office Action, claims 27-53 and 55-62 were rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (AAPA). The Office Action states that AAPA teaches a plurality of moveable dies arranged to form an iris, the dies disposed

*Application No. 10/444807**Page 11**Amendment**Attorney Docket No. S63.2Q-7405-US03*

about an aperture, the aperture having a center. The Office Action further asserts that AAPA teaches the invention cited with the exception of each of the dies having a longitudinal axis which is tangent to the aperture and that Whitesell provides this limitation.

Independent claims 27, 36, 44, and 52 have been amended, and Applicant has removed from claim 27 the limitation of a longitudinal axis which is tangential to the aperture. Regarding claim 27, AAPA does not teach or suggest forming an iris nor does it teach or suggest "each die arranged such that the stent contacting surface extends along a line that intersects the stent contacting surface of an adjacent die and forms an angle, the angle remaining substantially the same when the dies move to open the aperture and when the dies move to close the aperture".

The AAPA does not form an iris defining an aperture of a substantially regular polygonal shape. Instead the AAPA has members which move radially inward and outward. An iris defining an aperture with a substantially regular polygonal shape acts about an opening or aperture such that the opening or aperture maintains a similar geometric shape while minimizing or maximizing the size of the aperture. The AAPA does not maintain a similar geometric shape while maximizing and minimizing the size of the aperture. Instead, the AAPA manipulates the stent to be crimped by having elongate portions poke radially inward and press portions of the stent in order to minimize the size of the stent. The aperture is not being minimized; elongate members are merely being introduced into the aperture to crimp the stent. As these limitations are not disclosed or suggested in the AAPA and are not found in Whitesell, amended independent claim 27 is in condition for allowance.

Regarding claim 36, AAPA does not teach or suggest forming an iris defining an aperture of a substantially regular polygonal shape as argued above nor does it teach or suggest "the inward facing straight side facing the center of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture, a rotatable actuation device coupled to the blades, rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture." Again, the movements of the AAPA are radial and are not caused by the rotation of the actuation device. As these limitations are not disclosed or suggested in the AAPA and are not found in Whitesell, amended independent claim 36 is in condition for allowance.

Application No. 10/444807
Page 12

Amendment
Attorney Docket No. S63.2Q-7405-US03

Regarding claim 44, AAPA does not teach or suggest forming an iris as argued above. As this limitation is not disclosed or suggested in the AAPA and are not found in Whitesell, amended independent claim 44 is in condition for allowance.

Regarding claim 52, AAPA does not teach or suggest "an aperture with a plurality of movable blades disposed thereabout, the aperture being substantially polygonal, the blades coupled to one another so as to be movable inward or outward simultaneously, movement of the blades outward increasing the size of the aperture, movement of the blades inward decreasing the size of the aperture, the aperture remaining substantially polygonal when it is sized to receive a stent therein and when the blades minimize the aperture." As these limitations are not disclosed or suggested in the AAPA and are not found in Whitesell, amended independent claim 52 is in condition for allowance.

Regarding dependent claims 28-35, 37-43, 45-51, 53 and 55-62, Applicant believes these claims are allowable as they are dependent upon amended independent claims 27, 36, 44, and 52 now believed to be in condition for allowance.

Applicant respectfully request that the 35 U.S.C. 103(a) rejection of claims 27-53 and 55-62 as being unpatentable over Applicant's Admitted Prior Art (AAPA) be withdrawn.

12

In the Office Action, claims 27-62 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,360,577. Applicant herein submits a terminal disclaimer in compliance with 37 CFR 1.321(c) and respectfully request that this rejection be withdrawn.

Application No. 10/444807
Page 13

Amendment
Attorney Docket No. S63.2Q-7405-US03

CONCLUSION

In view of the foregoing it is believed that the present application, with pending claims 27-66, is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: January 22, 2004

By: 
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JAN 22 2004

OFFICIAL

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Austin
Application No.:	10/444807
Filed:	May 23, 2003
For:	An Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices
Examiner:	Marc Jimenez
Group Art Unit:	3726

#9/C
2-13-04
NDB

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

Docket No.: S63.2Q-7405-US03

AMENDMENT

This Amendment is in response to the Office Action dated October 22, 2003.

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicant hereby petitions for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

Please amend the application as follows:



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/444,807	05/23/2003	Michael Austin	S63.2-7405-US03	8997

490 7590 10/22/2003

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

JIMENEZ, MARC QUEMUEL

ART UNIT PAPER NUMBER

3726

DATE MAILED: 10/22/2003

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

Office Action Summary

Application No.

10/444,807

Applicant(s)

AUSTIN, MICHAEL

Examiner

Marc Jimenez

Art Unit

3726

-- 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) 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 the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- 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 09 October 2003.
- 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) 27-62 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) 27-53 and 55-62 is/are rejected.
- 7) ☒ Claim(s) 54 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 23 May 2003 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).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ 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.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed (ie. the apparatus).

3. - - now patent no. 6,360,577 - - should be inserted after "September 22, 1999," in the first line of the specification.

Claim Rejections - 35 USC § 112

4. 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.

5. **Claim 28** is 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.

Claim 28 recites "the blades" in line 2 which lacks proper antecedent basis.

Claim Rejections - 35 USC § 102

6. 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.

7. **Claims 27, 28, 34-36, 40, 52, 53, 59, and 61** are rejected under 35 U.S.C. 102(b) as being anticipated by Whitesell (5,261,263).

Whitesell teaches a crimper (fig. 1 and 2) comprising: a plurality of movable dies 18 arranged to form an iris, the dies 18 disposed about an aperture 30, the aperture 30 having a center, each of the dies 18 having a longitudinal axis which is tangent to the aperture 30. In as much structure claimed, the crimper of Whitesell is considered a stent crimper because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Clearly, the crimper of Whitesell is capable of performing crimping of a stent.

Regarding claim 28, 53, and 61, note the rotatable actuation device **26** coupled to the blades **18**, rotation of the actuation device **26** causing the dies **18** to move inward and reduce the size of the aperture **30** or outward so as to increase the size of the aperture **30**.

Regarding claim 34, the dies **18** are moved cooperatively inward during the moving step.

Regarding claims 35, 40, and 59, the dies **18** are wedge-shaped.

Regarding claim 36, each of the dies **18** have an inward facing straight side which faces the center of the aperture.

Regarding claim 52, the aperture formed by the edges of the dies **18** form a substantially polygonal shape.

Claim Rejections - 35 USC § 103

8. 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.

9. **Claims 32, 33, 41, 42, 44, 48-50, and 60** are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitesell.

Regarding claims 32, 33, 41, 42, 44, 49, and 60, Whitesell teaches the invention cited with the exception of having either at least 8 or 16 dies.

At the time of the invention, it would have been an obvious matter of design choice to a

person of ordinary skill in the art, to have provided at least 8 or 16 dies because applicant has not disclosed that the claimed number of dies provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the number of dies taught by Whitesell or the claimed number of dies because either number of dies perform the same function of crimping equally as well.

Regarding claim 48, the dies **18** are wedge-shaped.

Regarding claim 50, the dies **18** are moved inward during the moving step.

10. **Claims 27-53 and 55-62** are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art [AAPA] (Fig. 1 and page 2, second full paragraph) in view of Whitesell.

[AAPA] teaches a stent crimper comprising: a plurality of movable dies **24** arranged to form an iris, the dies **24** disposed about an aperture **26**, the aperture **26** having a center.

[AAPA] teach the invention cited with the exception of each of the dies having a longitudinal axis which is tangent to the aperture **26**.

Whitesell teaches a crimper with dies **18** having a longitudinal axis which is tangent to an aperture **30**.

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of [AAPA] with dies having a longitudinal axis which is tangent to the aperture, in light of the teachings of Whitesell, in order to provide a symmetric crimping deformation. It is noted that Whitesell recognizes the benefits of using radial applying

Art Unit: 3726

crimping forces over linearly applied forces like the one taught by [AAPA] (see col. 1, lines 14-20 of Whitesell).

Regarding claims 28 and 53, [AAPA] and Whitesell both teach a rotatable actuation device **28 and 26** respectively.

Regarding claims 32 and 41, [AAPA] teaches at least 8 dies **24**.

Regarding claims 34, 50, and 61, the dies are moved inward because they are crimping dies.

Regarding claims 35, 40, 48, and 59, Whitesell teaches that the dies **18** are wedge shaped.

Regarding claims 37, 45, and 56, it is inherent that the stent is disposed about a medical balloon and the medical balloon is disposed about a catheter because stents typically have these features (see also page 1, lines 21-33 of applicant's specification).

Regarding claims 29, 38, 46, and 57, note that the dies being cooled below ambient temperature or the stent being cooled below ambient temperature prior to reducing the size of the aperture does not further limit the structural features of the stent crimper and therefore has not been given patentable weight. Furthermore, if the stent crimper is placed in a cold environment, the dies and stent would also be cold and hence be cooled below ambient temperature.

Regarding claims 30, 43, 51, and 62, [AAPA] teach that the entire stent is disposed in the aperture **26**.

Regarding claims 33, 42, 49, and 60, [AAPA]/Whitesell teaches the invention cited with the exception of having at least 16 dies.

At the time of the invention, it would have been an obvious matter of design choice to a

Art Unit: 3726

person of ordinary skill in the art, to have provided at least 16 dies because applicant has not disclosed that the claimed number of dies provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the number of dies taught by [AAPA]/Whitesell or the claimed number of dies because either number of dies perform the same function of crimping equally as well.

Regarding claims 31, 39, 47, and 58, official notice is taken that it was well known in the art to use stents made of nitinol because of its material properties.

Regarding claim 55, [AAPA] teach a loading device for a stent (see outside of 26).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. **Claims 27-62** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,360,577

Art Unit: 3726

(hereinafter '577) in view of Applicant's Admitted Prior Art [AAPA] (page 1 to page 2, lines 1-24 of applicant's specification).

Although the conflicting claims are not identical, they are not patentably distinct from each other because '577 teaches: a plurality of movable dies (col. 9, line 66 of '577 "dies" correspond to "blades") arranged to form an iris (col. 9, line 67 of '577 "iris" shape is a "circle" shape), the dies disposed about an aperture (col. 9, line 67 of '577), the aperture having a center, each of the dies having a longitudinal axis which is tangent to the aperture (col. 9, lines 8-10, the linear path that the dies move with respect to the circle is a tangent line), a rotatable actuation device coupled to the blades (col. 9, line 65 and col. 10, lines 5-6), rotation of the actuation device causing the dies to move inward and reduce the size of the aperture or outward to increase the size of the aperture (col. 10, line 9), the dies are cooled below ambient temperature (col. 12, lines 12-14), a stent within the aperture (col. 10, line 46), at least 8 dies are provided (col. 10, line 27), at least 16 dies are provided (col. 10, line 24), the dies are wedge shaped (col. 10, lines 43-44), the dies have an inward facing straight side which faces the center of the aperture (col. 10, lines 8-9), the aperture is substantially polygonal (col. 10, lines 19-20), and a cryogenic source (col. 12, lines 9-14).

What is claimed in the instant invention, but not claimed in the '577 is the stent being made of nitinol, the stent is disposed about a medical balloon, with the medical balloon disposed about a catheter, the entire stent is disposed in the aperture, and having a loading device.

Official notice is taken that it is well known in the art to use nitinol stents and disposing the entire stent in an aperture.

Therefore, it would have been obvious to one of ordinary skill in the art, to have used nitinol stents and disposing the entire stent in an aperture, in order to utilize a stent material that has good physical properties and in order to crimp the entire stent symmetrically.

[AAPA] teaches that it is known that a stent is disposed about a medical balloon and the balloon is disposed about a catheter (page 1, lines 24-33 of applicant's specification) and a loading device (see fig. 1 outside of aperture 26).

It would have been obvious to one of ordinary skill in the art, to have used a stent disposed about a medical balloon with the medical balloon disposed about the catheter and a loading device, in light of the teachings of [AAPA] in order to provide a stent that can be used for body vessels and in order to align the stent to the crimper.

Allowable Subject Matter

13. **Claim 54** 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. And if a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) is filed to overcome the rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Contact Information

14. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel. In as much

Art Unit: 3726

as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information. M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer Service at (703) 306-5648, or fax (703) 872-9301 or by email to CustomerService3700@uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Jimenez whose telephone number is **703-306-5965**. The examiner can normally be reached on **Monday-Friday, between 5:30 am- 2:00 pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Vidovich can be reached on 703-308-1513. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication	(703) 308-6789 or (888) 786-0101
Assignment Branch	(703) 308-9723
Certificates of Correction	(703) 305-8309
Drawing Corrections/Draftsman	(703) 305-8404/8335
Petitions/Special Programs	(703) 305-9285
Terminal Disclaimers	(703) 305-8408
PCT Help Desk	(703) 305-3257

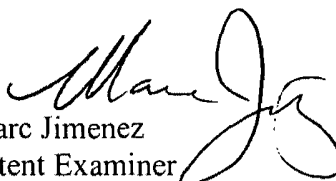
Application/Control Number: 10/444,807
Art Unit: 3726

Page 11

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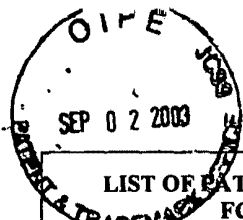

Marc Jimenez
Patent Examiner
AU 3726

MJ
October 18, 2003

UNPUBLISHED US APPLICATIONS NOT RELATED BY PRIORITY (COPIES ENCLOSED)		ATTY DOCKET NO.: S63.2Q-7405-US03		APPLICATION NO. <u>Not yet assigned</u> 10/444,807	
		APPLICANT: Austin			
		FILING DATE: <u>Concurrently herewith</u> 5/23/03		GROUP: <u>Not yet assigned</u> 3720	
UNPUBLISHED US APPLICATIONS NOT RELATED BY PRIORITY					
EXAM'S INIT.		APPLICATION NO.	FILING DATE	INVENTOR(S)	
	DA				
	DB				
	DC				
	DD				
	DE				
EXAMINER				DATE CONSIDERED	
EXAMINER: Initial if application 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.					

US APPLICATIONS RELATED BY PRIORITY (COPIES NOT ENCLOSED)		ATTY DOCKET NO.: S63.2Q-7405-US03		APPLICATION NO. Not yet assigned		
		APPLICANT: Austin				
		FILING DATE: Concurrently herewith		GROUP: Not yet assigned		
US APPLICATIONS REALTED BY PRIORITY						
EXAM'S INIT		APPLICATION NO.	FILING DATE	PATENT NO.	INVENTOR(S)	FORM 1449/892 ENC
<i>mj</i>	EA	09/966,686	10/1/01		Austin	X
<i>mj</i>	EB	09/401,218	9/22/99	6360577	Austin	X
	EC					
	ED					
	EE					
	EF					
EXAMINER <i>Mark Jimenez</i>				DATE CONSIDERED 10/17/03		
EXAMINER: Initial if application 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 application.						

1 of 1



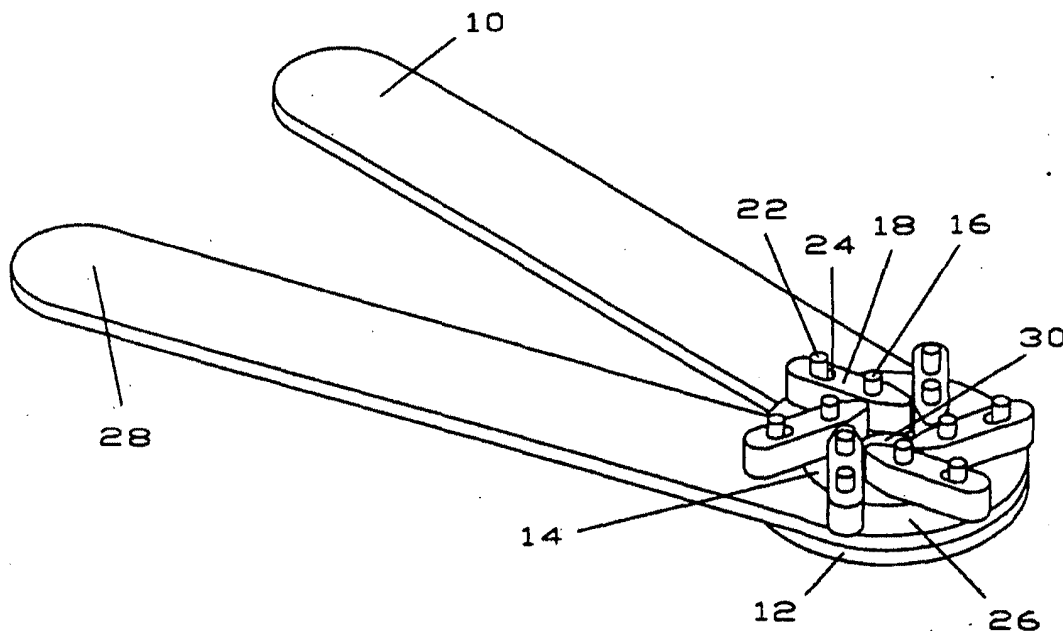
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				ATTY DOCKET NO.: S63.2Q-7405-US03		APPLICATION NO.: 10/444807	
				APPLICANT: Austin			
				FILING DATE: May 23, 2003		GROUP: 3726	
REFERENCE DESIGNATION				U.S. PATENT AND PUBLISHED APPLICATION DOCUMENTS			
EXAM'S INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE IF APPROPRIATE	
<i>mg</i>	AA	565,257	8/4/1896	Boyd	72/402	RECEIVED SEP 04 2003 TECHNOLOGY CENTER R3700	
	AB	758,195	4/26/04	Schweinert et al.	72/402		
	AC	2,986,192	5/30/61	Macleod	153/1		
	AD	3,731,518	5/8/73	Blocher	72/402		
	AE	4,434,645	3/6/84	Svercl et al.	72/402		
	AF	5,715,723	2/10/98	Owens	72/402		
	AG	5,920,975	7/13/99	Morales	29/282		
	AH	5,931,851	8/3/99	Morales	606/194		
	AI	5,951,540	9/14/99	Verbeek	606/1		
	AJ	5,974,652	11/2/99	Kimes et al.	29/516		
	AK	6,018,857	2/1/00	Duffy et al.	29/407.01		
	AL	6,024,737	2/15/00	Morales	606/1		
	AM	6,033,380	3/7/00	Butaric et al.	604/96		
	AN	6,051,002	4/18/00	Morales	606/108		
	AO	6,063,092	5/16/00	Shin	606/108		
	AP	6,063,102	5/16/00	Morales	606/198		
	AQ	6,092,273	7/25/00	Villareal	29/516		
	AR	6,108,886	8/29/00	Kimes et al.	29/280		
	AS	6,125,523	10/3/00	Brown et al.	29/516		
	AT	6,141,855	11/7/00	Morales	29/516		
	AU	6,240,615	6/5/01	Kimes et al.	29/516		
	AV	6,296,655	10/2/01	Gaudoin et al.	606/194		
<i>mg</i>	AW	6,360,577	3/26/02	Austin	72/402		
<i>mg</i>	AX	6,364,870	4/2/02	Pinchasik	606/1		
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY			
<i>mg</i>	BA	90/00098	1/11/90	WO			
EXAMINER <i>Marc Ingram</i>			DATE CONSIDERED <i>10/17/03</i>				
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.							



US005261263A

United States Patent [19]
Whitesell[11] **Patent Number:** **5,261,263**
[45] **Date of Patent:** **Nov. 16, 1993****[54] CRIMPING PLIERS WITH RADially
OPPOSED JAWS****[76] Inventor:** Eric J. Whitesell, 7226 Fargate Ter.,
San Diego, Calif. 92126-2581**[21] Appl. No.:** **994,518****[22] Filed:** **Dec. 21, 1992****[51] Int. Cl.:** **H01R 43/042; B25B 13/28****[52] U.S. Cl.:** **72/410; 72/402;
29/751; 29/237; 81/90.2; 81/90.3; 30/90.1****[58] Field of Search:** **72/402, 410, 409, 450;
29/751, 753, 237; 81/348, 350, 342, 90.2, 90.3;
30/90.1, 95****[56] References Cited****U.S. PATENT DOCUMENTS**3,111,157 11/1963 Henry 72/402
3,199,334 8/1965 Holmes 72/410
3,664,213 5/1972 Anati 81/90.24,578,982 4/1986 Schrock 72/402
4,727,742 3/1988 Weaver 72/402
5,203,197 4/1993 Depperman 72/402**FOREIGN PATENT DOCUMENTS**1042984 9/1983 U.S.S.R. 81/90.2
367221 2/1932 United Kingdom 72/410
2081144 2/1982 United Kingdom 72/402*Primary Examiner*—Daniel C. Crane**[57] ABSTRACT**

An improved crimping tool mechanism with radially opposed jaws that direct and balance compressive forces toward the center of the work, joining cylindrical connectors and cables with more reliable electrical and mechanical contact than that obtainable using linear motion devices.

6 Claims, 6 Drawing Sheets

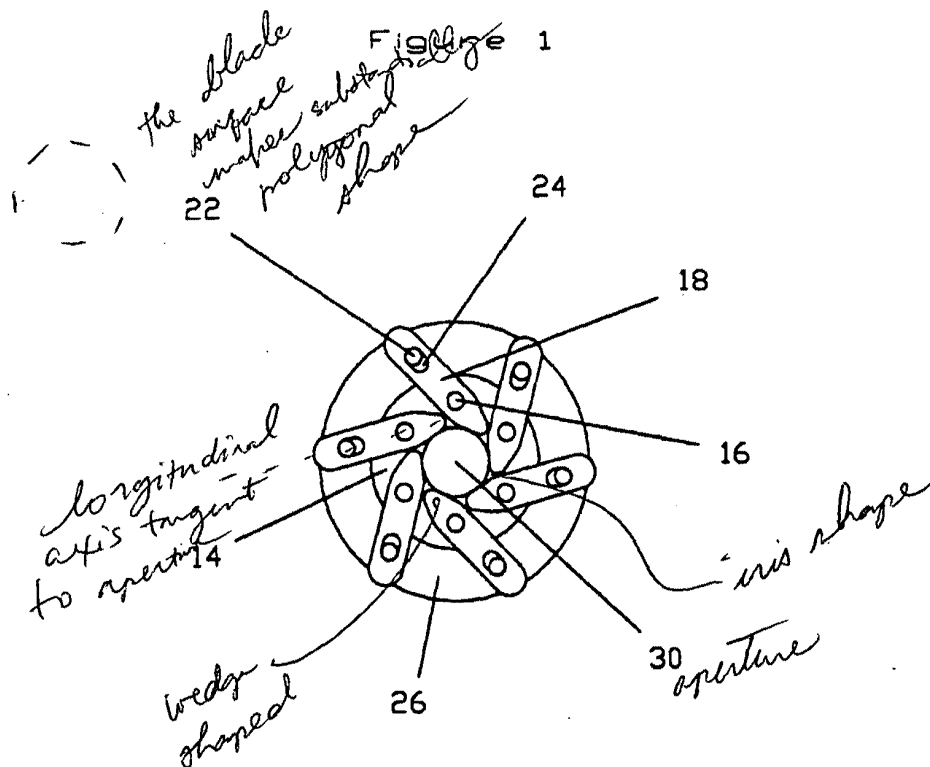
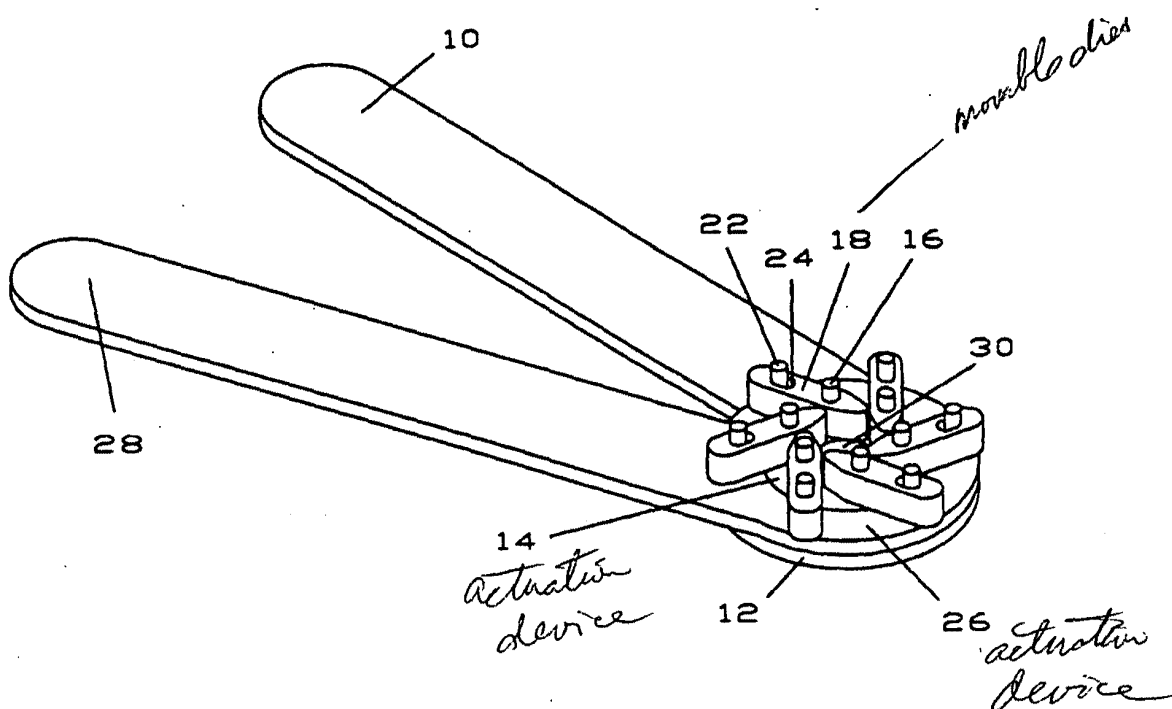


Figure 2

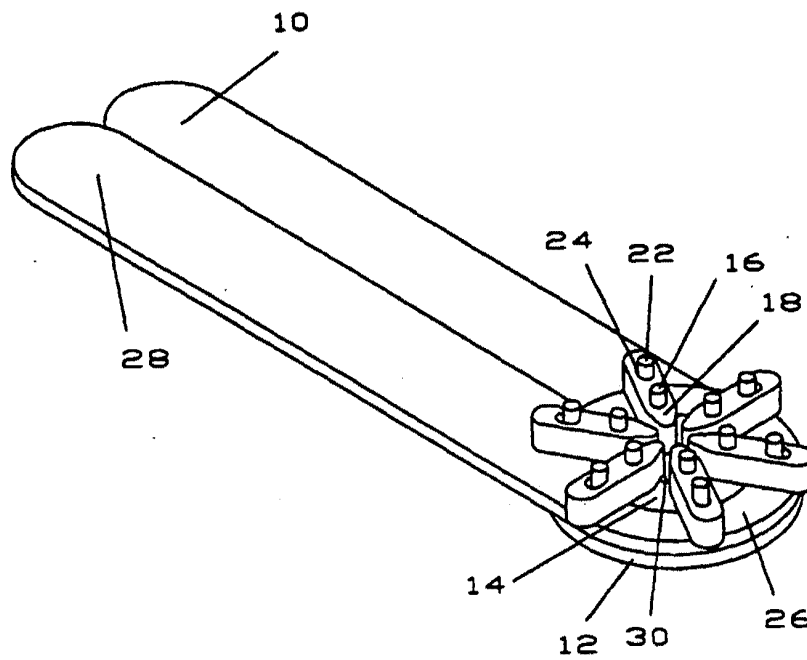


Figure 3

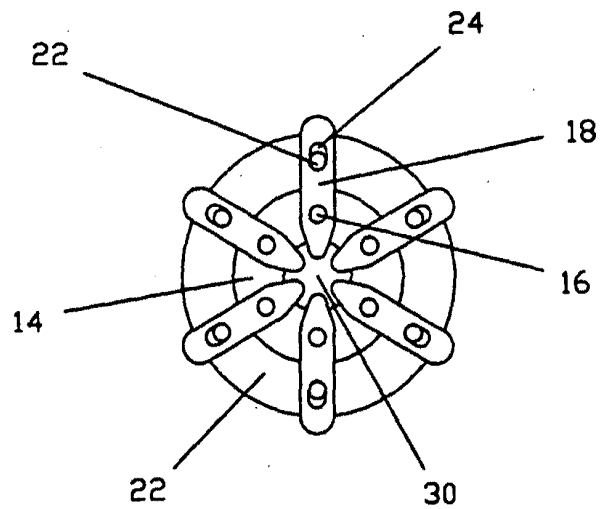


Figure 4

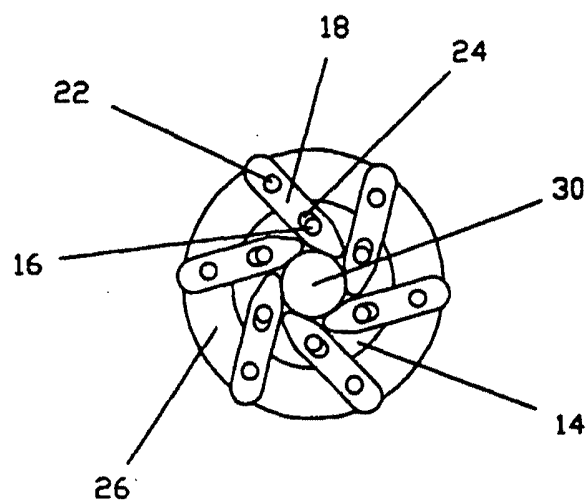


Figure 5

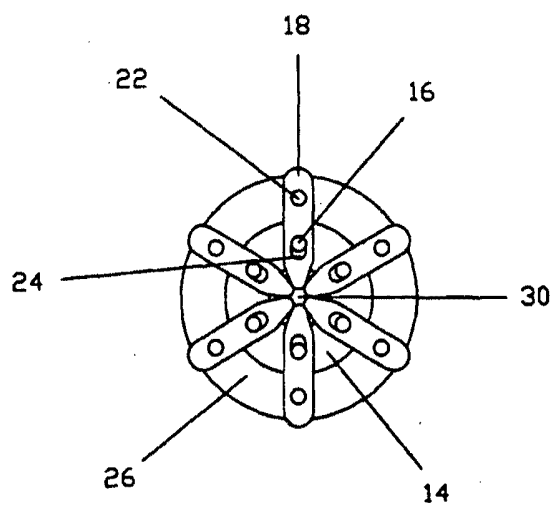


Figure 6

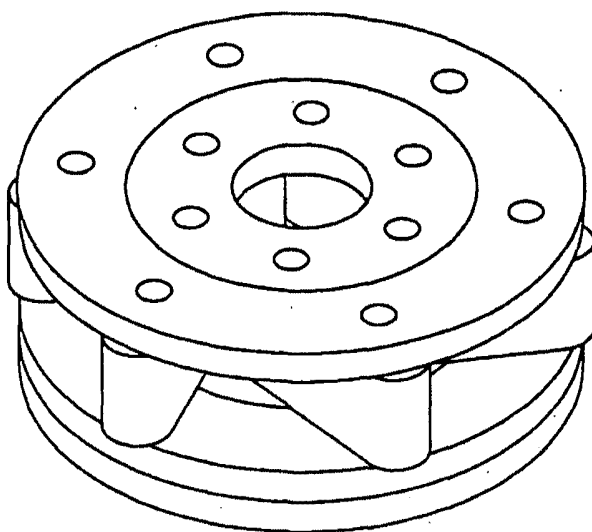


Figure 7

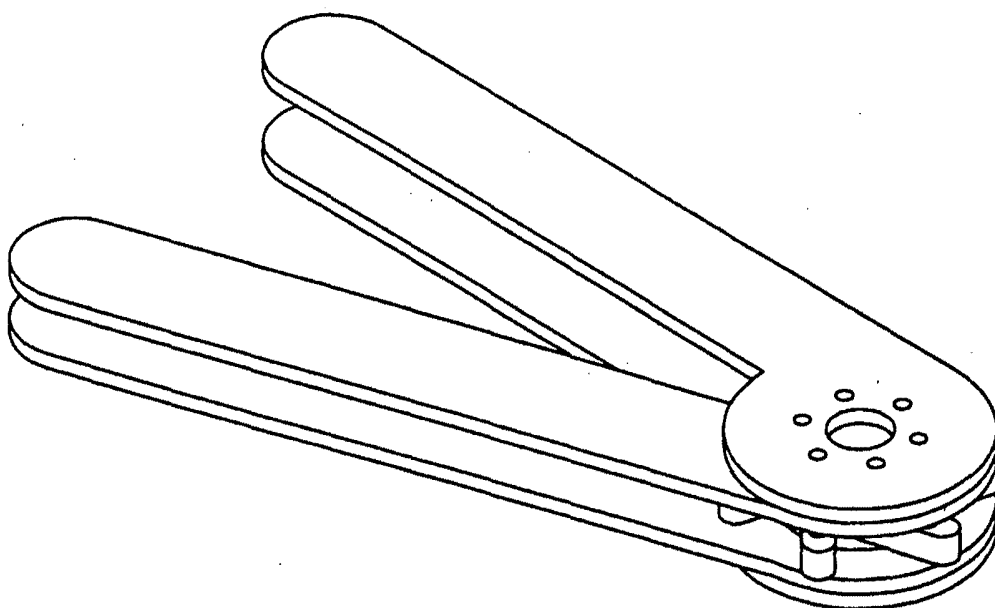


Figure 8

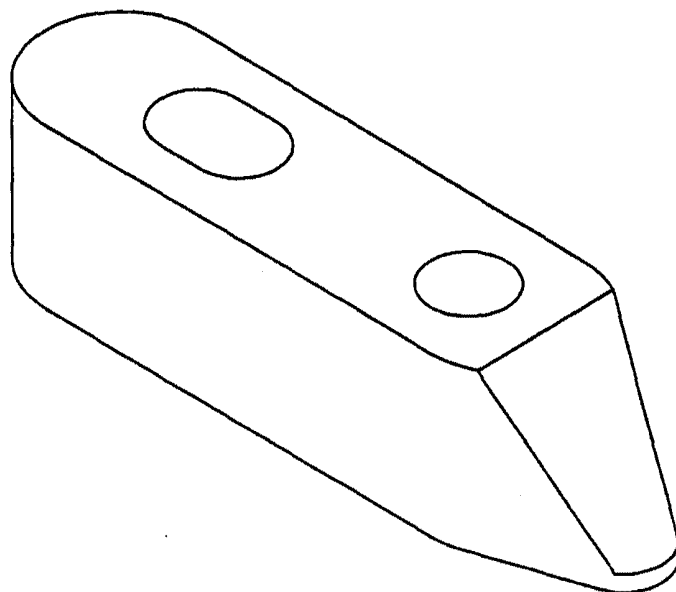


Figure 9

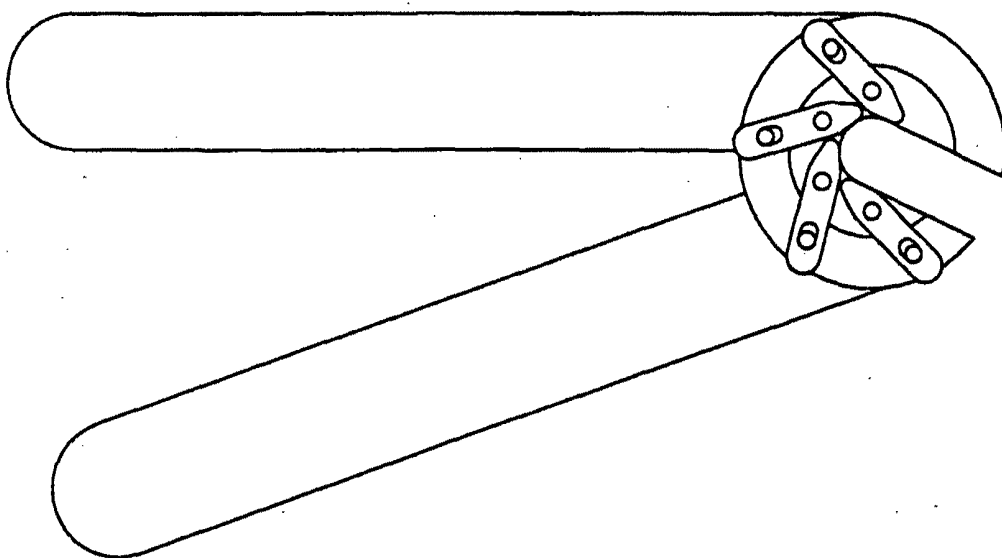


Figure 10

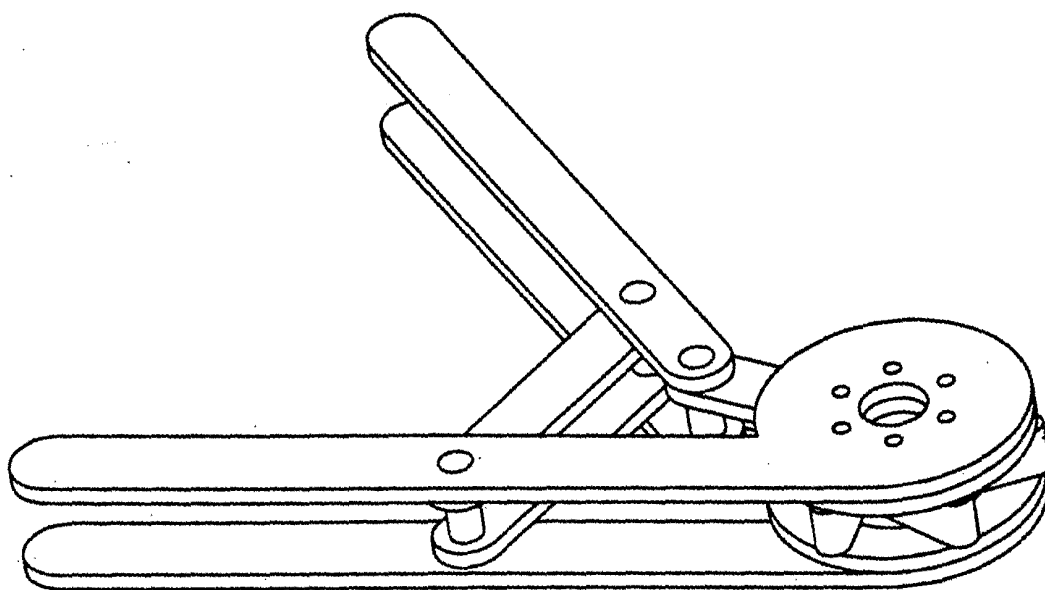


Figure 11

CRIMPING PLIERS WITH RADIALLY OPPOSED JAWS

BACKGROUND

1. Field of Invention

This invention relates to crimping handtools, specifically to an improved mechanism for gripping and crimping cylindrical objects.

2. Discussion of Prior Art

A wide variety of cylindrical electrical connectors are crimped onto wires and coaxial cable. Although the field of crimping tools is a crowded art, most crimping tools invented to date have jaws which apply a linearly opposed force concentrated along the plane where the jaws converge. The resulting deformation of cylindrical connectors is consequently asymmetric, resulting in a crimp which is less than ideal with respect to electrical reliability and mechanical strength. On the other hand, crimping tools designed to apply a radial force are substantially more complex in design and correspondingly more expensive to manufacture than those with linear action.

OBJECTS AND ADVANTAGES

Accordingly, in addition to the objects and advantages described herein, several objects and advantages of the radial pliers of this invention are:

- (a) to provide an improved mechanism for gripping cylindrical workpieces with radially balanced force;
- (b) to provide a method of equally and uniformly deforming electrical connectors whereby optimally reliable electrical and mechanical contact with wires and coaxial cables is achieved;
- (c) to provide a method for increasing leverage as contact increases whereby the effort required by the operator is minimized.

Further objects and advantages of the radial pliers will become apparent from a consideration of the drawings and ensuing description.

DRAWING FIGURES

FIG. 1 shows a perspective view of the radial pliers opened.

FIG. 2 shows a top view detail of the radial pliers opened, handles omitted.

FIG. 3 shows a perspective view of radial pliers closed.

FIG. 4 shows a top view detail of the radial pliers closed, handles omitted.

FIG. 5 shows a top view detail of the radial pliers opened, alternate cam slots, handles omitted.

FIG. 6 shows a top view detail of the radial pliers closed, alternate cam slots, handles omitted.

FIG. 7 shows a perspective view of the radial pliers with added opposing annular bearings, handles omitted.

FIG. 8 shows a perspective view of the radial pliers with added opposing annular bearings and handles.

FIG. 9 shows a magnified perspective view of a lever of the radial pliers modified for cutting.

FIG. 10 shows a top view of the radial pliers with an open-ended aperture.

FIG. 11 shows a perspective view of the radial pliers with added opposing annular bearings and handles arranged with a linkage.

REFERENCE NUMERALS IN DRAWINGS

- 10: upper handle
- 12: annular ring
- 14: inner annular bearing
- 16: inner pivots
- 18: levers
- 22: outer pivots
- 24: cam slots
- 26: outer annular bearing
- 28: lower handle
- 30: common aperture

DESCRIPTION-DRAWINGS 1-6

A typical embodiment of the radial pliers of this invention is illustrated in the perspective view of FIG. 1 and in the top view detail of FIG. 2. To avoid overcrowding the figures with numbers, only one element within a group of identical elements is referenced by a number. The radial pliers has an upper handle 10 terminating in an annular ring 12. Annular ring 12 is fixed to an inner annular bearing 14 to which a plurality of identical inner pivots 16 are radially arranged. A plurality of identical levers 18 are radially arranged and pivotally coupled to inner pivots 16, enclosing a common aperture 30. A plurality of identical cam slots 24 on levers 18 engage a plurality of identical outer pivots 22. Outer pivots 22 are radially arranged on an outer annular bearing 26, which is concentric with inner annular bearing 14. Outer annular bearing 26 is the termination of a lower handle 28.

A second embodiment of the radial pliers of this invention is illustrated in the top view detail of FIG. 5. The description is the same as for the first embodiment, except that cam slots 24 on levers 18 engage inner pivots 16 rather than outer pivots 22.

OPERATION-FIGS. 1-6

Referring to the first embodiment shown in the perspective view of FIG. 1 and in the top view detail of FIG. 2, a cylindrical workpiece (not shown) is inserted into common aperture 30.

The perspective view of FIG. 3 and the top view detail of FIG. 4 show lower handle 28 closed to upper handle 10, causing clockwise rotation of outer annular bearing 26 and outer pivots 22 with respect to inner annular bearing 14 and inner pivots 16. Levers 18 rotate individually in a common clockwise direction on inner pivots 16 as outer pivots 22 slide forward in cam slots 24, thus closing common aperture 30. As contact between levers 18 and cylindrical workpiece (not shown) increases, radial displacement of levers 18 caused by rotation on inner pivots 16 decreases, conversely causing the leverage from displacement of upper handle 10 with respect to lower handle 28 to increase. When lower handle 28 is fully closed to upper handle 10, cylindrical workpiece (not shown) is uniformly deformed by levers 18.

Conversely, as shown in the perspective view of FIG. 1 and in the top view detail of FIG. 2, opening lower handle 28 away from upper handle 10 causes counterclockwise rotation of outer annular bearing 26 and outer pivots 22 with respect to inner annular bearing 14 and inner pivots 16. Levers 18 rotate counterclockwise on inner pivots 16 as outer pivots 22 slide backward in cam slots 24, thus opening common aperture 30 and releasing workpiece (not shown).

3

Referring to the second embodiment illustrated in the top view detail of FIG. 5, cylindrical workpiece (not shown) is inserted into common aperture 30.

The top view detail of FIG. 6 shows the result of clockwise rotation of outer annular bearing 26 and outer pivots 22 with respect to inner annular bearing 14 and inner pivots 16. Levers 18 rotate individually in a common clockwise direction on outer pivots 22 as inner pivots 16 slide backward in cam slots 24, thus closing common aperture 30 and deforming workpiece (not shown).

Conversely, the top view detail of FIG. 5 shows the result of counterclockwise rotation of outer annular bearing 26 and outer pivots 22 with respect to inner annular bearing 14 and inner pivots 16. Levers 18 rotate individually in a common counterclockwise direction on outer pivots 22 as inner pivots 16 slide forward in cam slots 24, thus opening common aperture 30 and releasing workpiece (not shown).

CONCLUSION, RAMIFICATIONS, AND SCOPE OF INVENTION

Accordingly, the reader will see that the radial pliers of this invention is not only a substantial improvement on what is described in the prior art for gripping and crimping cylindrical workpieces, but is also easy to use and economically practical to manufacture, having few unique elements and a simple design.

While the above description contains many specifics, these should not be construed as limitations on the scope of the invention, but rather as an exemplification of preferred embodiments thereof. Other embodiments of the method of the invention are possible, for example: the number, shape, and composition of the levers may be altered; the shape and position of the cam slots may be varied; the common aperture may be modified to provide an open end on the radial pliers, and the handles provided for manual operation may be modified by adding a linkage for increased leverage, or omitted for automated operation. There are other uses for the radial pliers besides crimping, for instance, an adjustable wrench. The radial pliers may be used to cut tubing or to strip cable by modifying the shape of the levers. Accordingly, the scope of the invention should be determined not by the embodiments illustrated, but by the appended claims and their legal equivalents.

I claim:

1. A radial press for cylindrical workpieces, comprising:

- a plurality of levers of predetermined thickness, width, length, and end shape appropriate to engaging a cylindrical workpiece, radially arranged around a common aperture;
- a first outer annular bearing connected to one side of said plurality of said levers by
- a plurality of outer pivots, whereby said plurality of said levers is constrained to move and rotate in a plane parallel to said first outer annular bearing and perpendicular to the axes of rotation of said plurality of said outer pivots and said first outer annular bearing;
- a first inner annular bearing having an outer radius substantially equal to the inner radius of said first

4

outer annular bearing, and having an inner radius enclosing an area substantially equal to the area enclosed by said common aperture, concentrically arranged to said first outer annular bearing and connected to said one side of said plurality of said levers by

a plurality of inner pivots, whereby said plurality of said levers is further constrained to move and rotate in a common direction with respect to the center of said common aperture, at least one of said plurality of inner pivots and said plurality of outer pivots includes elongated cam slots;

a first annular ring having an inner radius substantially equal to the inner radius of said first inner annular bearing and an outer radius substantially equal to the outer radius of said first outer annular bearing, arranged coaxially with said first inner annular bearing and said first outer annular bearing on said one side of said plurality of said inner pivots and said plurality of said outer pivots, fixed to said first inner annular bearing and substantially free to rotate against said first outer annular bearing, whereby the mechanical stability is improved;

a pair of handles arranged with said first outer annular bearing and said first annular ring for causing them to counterrotate by moving said handles towards and away from one another, thus causing said plurality of said levers to open and close said common aperture;

a second inner annular bearing and

a second outer annular bearing arranged to the opposite side of said plurality of said levers by said plurality of said inner pivots and by said plurality of said outer pivots, whereby the mechanical stability is further improved.

2. The radial press recited in claim 1, further comprising a second annular ring having an inner radius substantially equal to the inner radius of said second inner annular bearing and having an outer radius substantially equal to the outer radius of said second outer annular bearing, arranged coaxially with said second inner annular bearing and said second outer annular bearing on the side opposite the inner and outer pivots, fixed to said second inner annular bearing, where said second annular ring is substantially free to rotate against said second outer annular bearing, whereby the mechanical stability is further improved.

3. The radial press recited in claim 2, wherein said pair of handles respectively terminate the annular rings and the outer annular bearings.

4. The radial press recited in claim 3, wherein said pair of handles further comprises a linkage arrangement, whereby the mechanical advantage afforded by said pair of said handles is improved.

5. The radial press recited in claim 1, wherein the predetermined end shape of said plurality of said levers causes said cylindrical workpiece to be crimped when engaged by said plurality of said levers.

6. The radial press recited in claim 1, wherein the predetermined end shape of said plurality of said levers causes said cylindrical workpiece to be cut when engaged by said plurality of said levers.

* * * * *

Application No. 10/444,807
Page 2

Amendment

In the Specification

Please amend the paragraph after the heading "Cross-Reference to Related Applications" as shown:

INS: C1 >
B

~~This application is a Divisional Continuation application from~~
Application No. 09/966,686 filed October 1, 2001 which is a Continuation application
from Application No. 09/401,218 filed September 22, 1999, the contents of which are
hereby incorporated by reference.

Application No. 10/444,807

Amendment

Page 3

In the Claims

Please amend the claims as shown below:

Sub. C2 > Claims 1-26. (Canceled)

Claim 27. (New) A stent crimper comprising:

a plurality of movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a center, each of the dies having a longitudinal axis which is tangent to the aperture.

Claim 28. (New) The stent crimper of claim 27 having a rotatable actuation device coupled to the blades, rotation of the actuation device causing the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Claim 29. (New) The stent crimper of claim 27 the dies are cooled below ambient temperature.

Claim 30. (New) The stent crimper of claim 29 including a stent within the aperture.

Claim 31. (New) The stent crimper of claim 30 wherein the stent is made of nitinol.

Claim 32. (New) The stent crimper of claim 27 wherein at least 8 dies are provided.

Claim 33. (New) The stent crimper of claim 27 wherein at least 16 dies are provided.

Claim 34. (New) The stent crimper of claim 27 wherein the dies are moved cooperatively inward during the moving step.

Claim 35. (New) The stent crimper of claim 27 wherein the dies are wedge-shaped.

Claim 36. (New) A stent crimper comprising:

a plurality of movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a center, each of the dies having an inward facing straight side which faces the center of the aperture,

a rotatable actuation device coupled to the blades, rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.

Claim 37. (New) The stent crimper of claim 36 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.

Claim 38. (New) The stent crimper of claim 36 wherein a stent is cooled below ambient temperature prior to reducing the size of the aperture.

Application No. 10/444,807
Page 4

Amendment

- Sub. C2
- Claim 39. (New) The stent crimper of claim 37 having a stent, wherein the stent is made of nitinol.
- Claim 40. (New) The stent crimper of claim 36 wherein the dies are wedge-shaped.
- Claim 41. (New) The stent crimper of claim 36 wherein at least 8 dies are provided.
- Claim 42. (New) The stent crimper of claim 36 wherein at least 16 wedge-shaped dies are provided.
- Claim 43. (New) The stent crimper of claim 36 wherein an entire stent is disposed in the aperture.
- Claim 44. (New) A stent crimper comprising:
eight or more movable dies arranged to form an iris, the dies disposed about an aperture having a center, each die having an inward facing flat portion which faces the center of the aperture, the iris comprising at least eight of the inward facing flat portions, the aperture being reducible in size by moving the inward facing flat portions toward the center of the aperture,
a rotatable actuation device coupled to the blades, rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.
- Claim 45. (New) The stent crimper of claim 44 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.
- Claim 46. (New) The stent crimper of claim 44 wherein the dies are cooled below ambient temperature.
- Claim 47. (New) The stent crimper of claim 46 including a stent in the aperture, wherein the stent is made of nitinol.
- Claim 48. (New) The stent crimper of claim 44 wherein the dies are wedge-shaped.
- Claim 49. (New) The stent crimper of claim 44 wherein at least 16 dies are provided.
- Claim 50. (New) The stent crimper of claim 44 wherein the dies are moved cooperatively inward during the moving step.
- Claim 51. (New) The stent crimper of claim 44 wherein an entire stent is disposed in the aperture.
- Claim 52. (New) A stent crimper comprising:

Application No. 10/444,807
Page 5

Amendment

Sub. C2

an aperture with a plurality of movable blades disposed thereabout, the aperture being substantially polygonal, the blades coupled to one another so as to be movable inward or outward simultaneously, movement of the blades outward increasing the size of the aperture, movement of the blades inward decreasing the size of the aperture, the aperture remaining substantially polygonal when it is sized to receive a stent therein and when it is subsequently reduced in size.

Claim 53. (New). The stent crimper of claim 52 further comprising a rotatable actuation device coupled to the blades, rotation of the actuation device causing the blades to move inward or outward.

Claim 54. (New) A stent crimping assembly comprising a stent crimper as in claim 52 and a cryogenic source, the cryogenic source in fluid communication with the stent crimper so as to cool the blades.

Claim 55. (New) A stent crimping assembly comprising a stent crimper as in claim 46 and a loading device for loading a stent in the aperture.

Claim 56. (New) The stent crimper of claim 52 wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.

Claim 57. (New) The stent crimper of claim 53 wherein the dies are cooled below ambient temperature.

Claim 58. (New) The stent crimper of claim 57 including a stent, wherein the stent is made of nitinol.

Claim 59. (New) The stent crimper of claim 53 wherein the dies are wedge-shaped.

Claim 60. (New) The stent crimper of claim 53 wherein at least 16 dies are provided.

Claim 61. (New) The stent crimper of claim 53 wherein the dies are moved cooperatively inward during the moving step.

Claim 62. (New) The stent crimper of claim 53 wherein an entire stent is disposed in the aperture.

Application No. 10/444,807
Page 6

Amendment

REMARKS

The Restriction Requirement dated September 9, 2003 defined Group I as claims 1-11 drawn to an apparatus and Group II as claims 16-23 drawn to a method. Applicant elects Group I as drawn to an apparatus. Claims 1-11 and 16-23 have been canceled without prejudice or disclaimer. New claims 27-62 fall within Group I and do not introduce new matter.

The specification has been amended to state that this application is a Continuation application from Application No. 09/966,686 rather than a Divisional.

CONCLUSION

In light of the above, early notification that pending claims 27-62 are in condition for allowance is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: October 9, 2003

By: Brendan C. Babcock
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OCT 10 2003

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Austin
Application No.: 10/444,807
Filed: May 23, 2003
For: A Method and Apparatus for Contracting, Loading or
Crimping Self-Expanding and Balloon Expandable
Stent Devices
Examiner: Marc Jimenez
Group Art Unit: 3726

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

Docket No.: S63.2Q-7405-US03

AMENDMENT

This Amendment is in Response to the Restriction Requirement dated
September 9, 2003. Please amend the application as follows.

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Austin
Application No.:	10/444,807
Filed:	May 23, 2003
For:	A Method and Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices
Examiner:	Marc Jimenez
Group Art Unit:	3726

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

Docket No.: S63.2-7405-US03

FACSIMILE TRANSMITTAL LETTER

TO: Examiner Jimenez

DATE: October 9, 2003

FACSIMILE NO.: 703-872-9302

TIME: 3:00pm

GROUP ART UNIT: 3726

TOTAL NUMBER OF PAGES (including cover letter): 7

Following please find a 6 page Amendment and 1 page Facsimile Transmittal Letter.

If a fee is required, Commissioner of Patents is hereby authorized to charge Deposit Account No. 22-0350 for any required fees. To the extent that any petition is required to consider this communication, please treat this as such a petition.

Respectfully Submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

OFFICIAL

Date: October 9, 2003

By: Brendan C. Babcock
Brendan C. Babcock
Reg. No. 50,705

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Certificate of Transmission

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. 703-872-9302, on October 9, 2003.

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Rebecca M. Painschab



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/444,807	05/23/2003	Michael Austin	S63.2-7405-US03	8997

490 7590 09/09/2003

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MINNETONKA, MN 55343-9185

EXAMINER

JIMENEZ, MARC QUEMUEL

ART UNIT	PAPER NUMBER
----------	--------------

3726

DATE MAILED: 09/09/2003

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

Office Action Summary

Application No.

10/444,807

Applicant(s)

AUSTIN, MICHAEL

Examiner

Marc Jimenez

Art Unit

3726

-- 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) 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 the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- 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) 1-11 and 16-23 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) 1-11 and 16-23 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).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ 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.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, drawn to an apparatus, classified in class 72, subclass 402.
 - II. Claims 16-23, drawn to a method of manipulating a medical device, classified in class 29, subclass 508.

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

2. Inventions Group 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 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 process could be practiced with an apparatus that does not have each blade in communication with an actuation device.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Art Unit: 3726

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Contact Information

7. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information. M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer Service at (703) 306-5648, or fax (703) 872-9301 or by email to CustomerService3700@uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Jimenez whose telephone number is **703-306-5965**. The examiner can normally be reached on **Monday-Friday, between 5:30 am- 2:00 pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

Art Unit: 3726

supervisor, Greg Vidovich can be reached on 703-308-1513. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication	(703) 308-6789 or (888) 786-0101
Assignment Branch	(703) 308-9723
Certificates of Correction	(703) 305-8309
Drawing Corrections/Draftsman	(703) 305-8404/8335
Petitions/Special Programs	(703) 305-9285
Terminal Disclaimers	(703) 305-8408
PCT Help Desk	(703) 305-3257

If the information desired is not provided above, or a number has been changed, please call the general information help line below.

Information Help line	1-800-786-9199
Internet PTO-Home Page	http://www.uspto.gov/



Marc Jimenez
Patent Examiner
AU 3726

MJ
September 5, 2003

*is
any
gas* *S. 10.01* *B. 1* *OK* *OK*
**A METHOD FOR CONTRACTING, LOADING OR CRIMPING SELF-
EXPANDING AND BALLOON EXPANDABLE STENT DEVICES**

BACKGROUND OF THE INVENTION

5 This invention relates to an apparatus and a method for reducing in size a medical device such as a stent, stent-graft, graft, or vena cava filter. The apparatus may be used in particular for fastening a medical device onto a catheter.

Medical devices such as stents, stent-grafts, grafts, or vena cava filters and catheters for their delivery are utilized in a number of medical procedures and
10 situations, and as such their structure and function are well known.

A stent, for example, is a generally cylindrical prosthesis introduced via a catheter into a lumen of a body vessel in a configuration having a generally reduced diameter and then expanded to the diameter of the vessel. In its expanded configuration, the stent supports and reinforces the vessel walls while maintaining the vessel in an
15 open, unobstructed condition.

Stents are typically inflation expandable or self-expanding. Self expanding stents which are constrained by a sheath or other restraining means, must be provided in a reduced diameter.

An example of a stent described in PCT Application No. 960 3092 A1,
20 published 8 February 1996.

In advancing a stent through a body vessel to the deployment site, the stent must be able to securely maintain its axial position on the delivery catheter, without translocating proximally or distally, and especially without becoming separated from the catheter. Stents that are not properly secured or retained to the catheter may
25 slip and either be lost or be deployed in the wrong location. The stent must be crimped in such a way as to minimize or prevent altogether distortion of the stent and to thereby prevent abrasion and/or reduce trauma of the vessel walls.

In the past, this crimping or size reduction has been done by hand often resulting in the application of undesired uneven forces to the stent. Such a stent must
30 either be discarded or re-crimped. Stents which have been crimped or otherwise reduced in size multiple times can suffer from fatigue and may be scored or otherwise marked which can cause thrombosis. A poorly crimped stent can also damage the underlying balloon.

EV342628894US

Recently, stent crimping devices have been disclosed in US 5,546,646 to Williams et al, US 5,183,085 to Timmermans et al., US 5,626,604 to Cottone, Jr., US 5,725,519, US 5,810,873 to Morales, WO 97/20593 and WO 98/19633.

A cam actuated stent crimper, shown in Figure 1, employs a plurality of arc-shaped or curved slots with semi-circular ends, disposed such that each slot or cam engages a cam follower bearing 22. The arc-shaped or curved surfaces of the slots are inclined to be non-concentric relative to the axis of rotation 26, and therefore rotation of the cam plate 28 transmits equal radial displacements to the cam follower bearings 22, to simultaneously actuate a like number of linear bearings 24, which have their corresponding linear tracks or rails mounted on a fixed plate. As shown in Fig.1 the cam plate rotary drive 29 comprises a pneumatic cylinder mounted on a pivot or trunnion, arranged with the cylinder rod connected rotatably to a short arm fixed rigidly to the cam plate. Accordingly, linear motion produced by the pneumatic cylinder translates into controllable arcs of motion of the circular cam plate, which has a projecting V-shaped profile on its outer edge in rolling engagement with three equally spaced rollers with mating inverse V-shaped profiles to provide precise rotatable support to the cam plate. Depending on the direction of rotation, the linear slides which each carry a radially disposed crimping blade, are either moved inwards to apply a crimping force to the stent, or outwards to release the stent. Also when crimping, depending on the degree of rotation of the cam plate, a specific radial crimping displacement may be obtained to match the diametral reduction required for any particular stent.

All US patents and applications and all other published documents mentioned anywhere in this application are incorporated herein by reference in their entirety.

BRIEF SUMMARY OF THE INVENTION

It would be desirable to produce a device capable of crimping a stent uniformly while minimizing the distortion of and scoring and marking of the stent due to the crimping. The present invention is directed to that end.

The present invention is particularly concerned with the crimping and otherwise reducing in size of inflation expandable stents, self-expanding stents and other expandable medical devices. For the purpose of this disclosure, it is understood that the

term 'stent' includes stents, stent-grafts, grafts and vena cava filters. It is also understood that the term 'crimping' refers to a reduction in size or profile of a stent.

In the description that follows it is understood that the invention contemplates crimping a medical device either directly to a catheter tube or to a catheter balloon which is disposed about a catheter tube. When reference is made to crimping a medical device to a catheter, a balloon may be situated between the medical device and the catheter tube or the medical device may be crimped to a region of a catheter tube directly. The invention also contemplates crimping a stent in the absence of a catheter to reduce the stent in size.

The present invention is directed, in one embodiment, to an apparatus for reducing a medical device in size. Desirably, the medical device is a stent, a stent-graft, a graft or a vena cava filter, whether self-expandable, balloon expandable or otherwise expandable, although the inventive apparatus may also be employed with any other suitable, generally tubular medical device which must be reduced in size.

The inventive apparatus comprises at least three coupled movable blades disposed about a reference circle to form an aperture whose size may be varied. Each blade is in communication with an actuation device which is capable of moving the blade to alter the size of the aperture. Each blade includes a single radial point on the surface of the blade which a) lies on the circumference of the reference circle prior to movement of the blade, and b) may be moved only along a radius of the reference circle on movement of the blade.

The apparatus further includes an actuation device which comprises a cam and a plurality of linear slide devices. Each linear slide device is in communication with a blade. Each of the linear slide devices is also in mechanical communication with the cam. Rotation of the cam results in linear translation of the slide device and blade, such that the slide device moves along an axis parallel to the radius on which the radial point of the blade lies or along the radius itself.

The invention is also directed to an apparatus similar to that described above, with blades disposed about a reference tube to form a tubular aperture whose size may be varied. Each blade is in communication with an actuation device which is capable of moving the blade to alter the size of the tubular aperture. Each blade includes a single line which a) lies on the surface of the reference tube prior to

movement of the blade, and b) may be moved only along a radial plane of the reference tube on movement of the blade.

The inventive apparatus finds particular utility in crimping a medical device such as those mentioned above to a catheter or to a balloon disposed about a catheter.

The inventive apparatus also finds utility in reducing the diameter of a medical device such as those mentioned above prior to crimping.

The invention is also directed to a method of manipulating a medical device which comprises the steps of providing the medical device and providing at least three blades capable of applying a radial inward force. The blades are disposed about a reference circle to form a shrinkable aperture. A medical device such as a stent is placed into the shrinkable aperture and the blades simultaneously moved inward to apply a radial inward force to the medical device. The blades are constructed and arranged such that each blade has a single point which a) lies on the circumference of the reference circle prior to movement of the blade, and b) is moved along a radius of the reference circle on movement of the blade.

The inventive apparatus may also be used as a variable size balloon mold. To that end, the invention is further directed to a method of molding a medical balloon. In the practice of the method, a balloon preform prepared through any suitable technique known in the art is provided. The preform is placed in an apparatus which has a shrinkable tubular aperture formed by at least three movable blades disposed about a reference tube. The blades are constructed and arranged such that each blade has a single line which a) lies on the surface of the reference tube prior to movement of the blade, and b) is moved along a radial plane of the reference tube on movement of the blade. The aperture may be set to a predetermined size prior to placement of the preform therein or after placement of the preform therein. An inflation fluid is supplied to the balloon preform to expand the balloon preform until it contacts the blades. The preform may optionally be heated prior to, during or after the blowing step. The thus formed balloon is then pressure relieved and removed from the apparatus.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

Figure 1 shows a perspective view of a stent crimper;

Figure 2a is a schematic front view of an embodiment of the inventive apparatus;

Figure 2b is a schematic front view of the embodiment of Fig. 2a after the stent has been reduced in size;

5 Figures 3a and 3b are schematics of blades;

Figure 3c is a partial schematic front view of an embodiment of the inventive apparatus employing the curved blades of Figure 3b;

Figure 4a is a partial front view of an embodiment of the inventive apparatus;

10 Figure 4b is a partial front view of an embodiment of the inventive apparatus;

Figure 4c shows a side view of the embodiment of Figure 4b taken along lines 4c-4c;

15 Figure 5a shows a partial front view of another embodiment of the inventive apparatus;

Figure 5b shows a link connected to a blade;

Figure 6 is a schematic, perspective view of an embodiment of the inventive apparatus;

Figure 7 shows a partial view of the embodiment of Figure 6;

20 Figures 8a and 8b are partial side elevational views of an embodiment of the inventive apparatus taken along a radial plane during the size reduction process;

Figure 8c is a partial side elevational view of an embodiment of the inventive apparatus taken along a radial plane following crimping of a stent to a catheter;

25 Figure 9 is a diagrammatic side elevational view of an embodiment of the inventive apparatus;

Figure 10 is a partial side elevational view of an embodiment of the inventive apparatus taken along a radial plane of an embodiment of the invention consisting of three individual apparatuses arranged sequentially;

30 Figure 11 is a schematic showing a stent being reduced in size and loaded into a sheath;

Figure 12 is a partial side elevational view of an embodiment of the inventive apparatus taken along a radial plane showing a balloon that has been molded with the inventive device; and

Figure 13 is a partial side elevational view taken along a radial plane showing a stepped balloon that has been molded with the inventive device.

DETAILED DESCRIPTION OF THE INVENTION

While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

As shown generally at 100 in Figures 2a and 2b, the inventive apparatus comprises eight coupled blades 106 disposed about a reference circle 114 to form an aperture 118 whose size may be varied. The apparatus may comprise as few as three blades and as many as sixteen or more blades. Desirably, the apparatus will have four or more blades and more desirably, eight or more blades. The maximum number of blades is limited only by how many blades can physically be coupled together under the relevant size constraints. As the number of blades is increased, the profile of the aperture and hence of the medical device following reduction in size, becomes smoother. Figure 2b shows the apparatus of Figure 2a after the stent has been reduced in size.

Blades 106 as shown in Figure 3a have an inner end 108 which is desirably beveled 111 so as to mesh with adjacent blades and an outer end 110 which is displaced from aperture 118. Aperture 118 is polygonal. Blades 106 may also be shaped with a curved end 112, as shown in Figures 3b and 3c so as to form a substantially circular shaped aperture, when the aperture is fully closed.

Each blade 106 includes a single radial point 122 which lies on a radial line 126 of reference circle 114 prior to movement of blade 106 and which may be moved only along the radius 126 of reference circle 114 on movement of blade 106. Desirably, the single radial point 122 will be disposed at the tip of the blade adjacent to beveled end 111.

In the embodiment shown in Figure 4a, radial point 122 lies at the tip of blade 106. Each blade 106 has a connecting link 130 extending from second end 110.

Connecting link 130 ends in mounting means 134, typically a mounting flange adapted for attachment to a linear bearing block, for interfacing with an actuation device, shown generally at 138. Actuation device 138 is capable of simultaneously moving blades 106 to alter the size of aperture 118.

5 Actuation device 138 includes actuation plate 142 which is coaxial with reference circle 114. Actuation plate 142 has eight equi-spaced radial slots 146. More generally, for every blade there will be a corresponding radial slot on actuation plate 142. Each radial slot 146 overlaps a mounting means 134 for a linear bearing block at the end of a connecting link 130. Each blade 106 is engaged to actuation plate 142 via a
10 cam follower bearing 150 disposed in radial slot 146 and attached to mounting means in slotted end 134.

Each bearing 150 extends from a linear slide 154. Linear slide 154 is mounted on a non-rotating plate 156 (shown in Figure 8). Linear slide 154 is constructed and arranged to slide along a line 158 which is parallel to the radius 126 on
15 which radial point 122 of blade 106 lies.

For the purposes of this disclosure, the term 'cam follower bearing' includes cam follower bearings, low friction rollers, roller bearings, needle roller bearings and a slipper block pivot mounted on a bearing and stub shaft. Figure 4b is a partial front view of an embodiment in which a slipper block is used. A side view of the
20 embodiment of Figure 4b taken along lines 4c-4c is shown in Figure 4c. Slipper block 150 resides in slot 146 of actuation plate 142. Slipper block 150 is mounted on stub shaft 151 which extends from connecting link 130. Desirably, bearings 153 will be present between shaft 151 and slipper block 150. Connecting link 130, in turn, is fastened to linear bearing block 212 via fasteners 214. Bearing block 212 is linearly
25 mounted on linear slide which is mounted on fixed plate 156. Linear motion is facilitated by the presence of bearings 216.

Cam follower bearing 150 may be replaced by any other suitable connecting member which can connect the slide and the link.

In use, as actuation plate 142 is rotated in a clockwise direction, the
30 clockwise motion of the actuation plate is translated into linear motion of each of linear slide 154 and blade 106 via bearing 150. Each blade 106 moves outward in a direction parallel to the radius 126 on which the radial point 122 of the blade 106 lies, resulting in the opening of aperture 118. As actuation plate 142 is rotated in a counterclockwise

direction, each blade 106 moves inward in a direction parallel to the radius 126 on which the radial point 122 of the blade 106 lies, resulting in the closing of aperture 118.

As aperture 118 closes, a radially inward force is applied to a medical device disposed in the aperture. The actuation plate is rotated until the desired size reduction of the aperture and medical device has been achieved. Following the reduction, the actuation plate is rotated in the opposite direction to allow for removal of the medical device from the aperture.

The apparatus may be used to reduce the diameter of a suitable medical device such as those disclosed above or may be used to crimp a medical device to a catheter.

Another embodiment of the invention is shown in Figure 5a. Each blade 106, as shown in Figure 5a, has a connecting link 130 extending therefrom. Connecting link 130 is rigidly attached to blade 106. Connecting link 130 ends in an angled end 134 for interfacing with an actuation device, shown generally at 138. Actuation device 138 is capable of simultaneously moving blades 106 to alter the size of aperture 118.

Actuation device 138 includes a rotatable actuation plate 142 which is co-axial with reference circle 114. Rotatable actuation plate includes cam slots 146 which are not concentric with the axis of rotation, arcing inward. Each connecting link 130 is engaged to actuation plate 146 via a cam follower bearing 150 disposed in slot 146 and attached to both angled end 134 of connecting link 130 and to a linear slide 154. Linear slide 154 is mounted on a non-rotating plate similar to that shown in Figure 8. Linear slide 154 is constructed and arranged to slide along a radial line 158 on which radial point 122 of blade 106 lies.

Connecting link 130 may be bonded adhesively, welded, joined with a fastener or otherwise joined to blade 106. As shown in Figure 5a, a single screw 131 is used to connect link 130 to blade 106. Figure 5b shows a connecting link 130 including a right angle portion which is fastened to a blade 106 using two screws 131. Connecting link 130 and blade 106 may optionally be formed of a single piece of material. Regardless of how the connecting member is joined to the blade, no movement of the blade relative to the connecting link is permitted.

In use, as actuation plate 142 is rotated in a clockwise direction, the clockwise motion of the actuation plate is translated into a linear outward motion of each of linear slides 154 and blades 106 via bearings 150 resulting in the opening of

aperture 118. The outward motion results from the radially outward arcing of cam slot 146. As actuation plate 142 is rotated in a counterclockwise direction, each blade 106, because of the radially inward arc of cam slots 146, moves inward in a direction parallel to the radius 126 on which the radial point 122 of the blade 106 lies, resulting in the closing of aperture 118. As discussed above, as the aperture is decreased in size, a radial inward force is brought to bear against a medical device disposed in the aperture, thereby reducing the size of the medical device.

The embodiment of Figure 5a differs from the embodiment of Figure 4a in that in the embodiment of Figure 5a, the slide moves along the radial line on which the radial point of the attached blade lies whereas in Figure 4a the slide moves parallel to the radial line. In both of the embodiments, each of the blades is constrained with two degrees of freedom to satisfy the condition that the movement of the tip be radial in accordance with the invention.

In the embodiments of Figures 4a and 5a, the slots in the actuation plate are constructed and arranged to allow for a sufficient reduction in size of the aperture so that a medical device can be reduced in size to a desired diameter. Those of ordinary skill in the art will recognize other suitable actuation devices that may be used in the practice of this invention.

Desirably, in the above embodiments, the blades will be as long as or longer than the medical device disposed within so that the medical device is uniformly reduced in size along its entire length.

This is illustrated in the embodiment of Figures 6 and 7 and further in Figures 3a and 3b in which blades 106 are disposed about a reference tube 160 to form a tubular aperture 162 whose size may be varied. Reference circle 114 is seen to lie along reference tube 160. Each blade 106 is in communication with an actuation device such as that shown in Figures 4 or 5. The actuation device is capable of moving blades 106 to alter the size of tubular aperture 162. Each blade 106 includes a single line 166 which a) lies on a radial plane 170 of the reference tube 160 prior to movement of blade 106, and b) may be moved only along a radial plane 170 of reference tube 160 on movement of blade 106. Desirably, reference tube 160 is cylindrical and exceeds the length of the medical device to be reduced in size.

Another embodiment of the invention is illustrated in Figures 8a and 8b. In the embodiment of Figures 8a and 8b, two non-rotating plates 156 are present, one at

each end of the apparatus. Each blade 106 is connected at first end 174 to a linear slide 154a via a connecting link 130a and at second end 178 to a linear slide 154b via a connecting link 130b. Linear slide 154a is mounted on non-rotating plate 156a and linear slide 154b is mounted on non-rotating plate 156b. The presence of the second
5 non-rotating plate 156b, linear slide 154b and connecting link 130b is optional but contributes to providing a rigid frame upon which the connecting links and associated blades may slide without misalignment relative to the reference circle.

Figures 8a and 8b illustrate the use of the inventive apparatus in various stages of the size reduction process. In Figure 8a, stent 180 has been placed in tubular
10 aperture 162 which is characterized by a diameter d_1 . In Figure 8b, the device has been actuated by rotating actuation plate 142 so as to move blades 106 inward. Aperture 162, as shown in Figure 8b is characterized by a diameter d_2 which is reduced relative to diameter d_1 . Stent 180 is seen to be of reduced diameter relative to its previous diameter as shown in Figure 8a.

15 Figure 8c differs from Figure 8b, only in that stent 180 has been crimped onto catheter 184 in Figure 8c.

Blades 106 may be made of any suitable, hard material including hardened steel. Desirably, the blades will be made of a material such as zirconia ceramic. Blades made of zirconia ceramic may be used without lubrication.
20 Furthermore, because of their low thermal conductivity, they may be used to create a highly insulated chamber suitable for cryogenic processing of martensite in nitinol stents.

Such an embodiment is shown in Figure 9. Stent 180 is disposed between blades 106 which can move inward in the direction of the arrows. Blades 106
25 are cooled by a first source of cooling fluid 184 located at first end 174 of blades 106. Although not shown, a second source of cooling fluid may be provided at second end 178 of blades 106 as well. The cooling fluid may be a liquid cryogenic. Exemplary cryogenics include liquid nitrogen, argon or carbon dioxide although other cryogenics may also be used. The cooling fluid may also be a chilled gas such as air. The cooling
30 fluid may also be a cooled inert gas such as nitrogen, argon or other inert gasses.

The aperture formed by the blades is a highly insulated chamber which is suitable for cryogenic processing of martensite in nitinol stents. The chamber is maintained at -80°C and a nitinol stent inserted therein. Upon equilibration of the

temperature of the stent, the blades are moved inward to reduce the diameter of the stent. The stent is thus reduced in diameter while being maintained in the martensitic state.

The embodiment of Figure 9 further has a loading plunger 188 for
5 loading a stent or other suitable medical device into the aperture. A sheath housing 192 which houses sheath 196 is provided at second end 178 of blades 106. Plunger 188 may be further used to transfer the stent after it has been reduced in diameter or size to sheath 196. Desirably, sheath 196 will have a slightly larger diameter than stent 180 following reduction in size of the stent. More desirably, the fit of the stent within the sheath will
10 be within about 1/32" and even more desirably, within about 1/64".

Where lengthy stents or other medical devices are to be reduced in size, the invention contemplates using one of the above described apparatuses with long blades to accommodate the stent. As an alternative, the invention also contemplates disposing two or more of such apparatuses sequentially to form one long aperture. The
15 two or more apertures may then be reduced in size simultaneously or consecutively. The arrangement of Figure 10 shows an embodiment with three devices 100a-c arranged sequentially. A stepped reduction in size may be achieved by placing a stent 180 or similar medical device in the apparatus and independently reducing each aperture 118 a-c to a desired size. To that end, the invention may provide particular utility in
20 manipulating bifurcated stents or other stents whose diameter varies along its length. The embodiment of Figure 10 shows the end portions of the stent being reduced in size prior to the middle portion of the stent. The device may also be operated so as to reduce the middle portion in size prior to the end portions or in any other sequence.

The invention contemplates yet another approach to reducing the
25 diameter of lengthy stents or similar medical devices, namely walking the stent through the apparatus. This may be accomplished by either moving the stent relative to the apparatus or moving the apparatus relative to the stent as shown schematically in Figure 11. To that end, stent 180 is inserted in device 100. Aperture 118a is reduced in size with blades 106a in turn reducing portion 180a of stent 180 in size. Aperture 118a is
30 then opened and aperture 118b reduced in size thereby reducing portion 180b of stent 180. Simultaneously, or shortly thereafter, sheath 196 is pushed by plunger 188 over the portion of the stent that has been reduced in size. Aperture 118b is opened and the stent

advanced in the apparatus. The process is repeated until the entire length, or the desired portion of the stent or medical device is reduced in size.

The reduction in size of the stent or other medical device may occur as part of a precrimping step or it may occur as part of crimping a stent onto a catheter and desirably, onto a balloon disposed about a catheter. In a general sense, it may be used for manipulating a medical device and specifically, for applying a radial inward force to a medical device.

In another embodiment, the invention is directed to a method of manipulating a medical device. As part of the method, a medical device such as those disclosed above is provided. The device has at least three blades capable of applying a radial inward force. The blades are disposed about a reference circle to form a shrinkable aperture. The blades are constructed and arranged such that each blade has only a single point which a) lies on the circumference of the reference circle prior to movement of the blade, and b) is moved along a radius of the reference circle on movement of the blade. The medical device is placed into the shrinkable aperture and the blades simultaneously moved inward to apply a radial inward force to the medical device and thereby reduce the medical device in size, and desirably, in diameter. Following reduction in size of the medical device, the blades are simultaneously moved outward and the medical device removed from the aperture.

The inventive apparatus may also be incorporated into a blow molding tool to provide a variable size balloon mold as shown generally at 100 in Figure 12. The various parts of the apparatus of Figure 12 have been discussed in conjunction with Figures 8a-c and, with exception of balloon 181 and mold cavity ends 193, the reference numerals used in Figure 12 correspond to those used for Figures 8a-c. Mold cavity ends 193 may be provided in a variety of sizes and lengths to contain the balloon at each end. Desirably, the end molds will be adjustably mounted to a portion of the apparatus such as fixed plates 156 to provide for an adjustable length balloon mold.

The invention is also directed to a method for molding a medical balloon using the inventive apparatus described above. A balloon preform prepared through any standard method is provided. The inventive mold, shown generally at 100 is also provided. Balloon 181 is inserted into aperture 162. Aperture 162 is optionally reduced to a predetermined size and the preform expanded using standard techniques. An

inflation fluid, for example, may be supplied to the preform and the preform expanded and heated. The balloon in its expanded state is shown in Figures 12.

More generally, the invention may be practiced by providing at least three movable blades disposed about a reference tube to form a shrinkable tubular aperture. The blades are constructed and arranged such that each blade has a single line which a) lies on the surface of the reference tube prior to movement of the blade, and b) is moved along a radial plane of the reference tube on movement of the blade. A balloon preform is placed into the shrinkable aperture. The aperture may be set at a predetermined size prior to or following insertion of the balloon therein. An inflation fluid is provided and the balloon preform inflated so that the preform expands to the size of the aperture. The preform may be heated during this inflation/blowing step. The inflation fluid is then removed from the thus formed balloon and the balloon removed from the apparatus.

The balloon may be also be molded in accordance with the method described in US 5,163,989, or in accordance with other methods as are known to those of ordinary skill in the art, substituting the instant apparatus for the standard balloon mold. Other patents which discuss balloon molding include US 5,807,520. Other references illustrating the materials and methods of making catheter balloons include: US 4,413,989 and US 4,456,000 to Schjeldahl et al, US 4,490,421, US Re 32,983 and Re 33,561 to Levy, and US 4,906,244, US 5,108,415 and US 5,156,612 to Pinchuck et al.

The use of the inventive apparatus as a mold allows for the blowing of a balloon to a predetermined size using a single adjustable size balloon mold thereby eliminating the need to have multiple molds of different sizes.

The invention further contemplates molding a balloon to a desired shape using a plurality of the inventive devices arranged sequentially. As an example of this, shown in Figure 13, a stepped balloon 181 may be prepared by arranging several devices 100a, 100b and 100c sequentially. A balloon preform is inserted in the aperture formed by the device. The aperture of each device may be preset at a desired size or may be reduced in size to a predetermined size after the balloon preform is inserted therein. The balloon may then be blow molded in accordance with any suitable blow molding technique known in the art.

The invention is also understood to be directed to embodiments employing various combinations of the features disclosed herein.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in
5 this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

Mya Russell
 PATENT
11/21/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Austin
Application No.:	Not yet assigned
Filed:	Concurrently herewith
For:	A Method and Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices
Examiner:	Not yet assigned
Group Art Unit:	Not yet assigned

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

Docket No.: S63.2Q-7405-US03

PRELIMINARY AMENDMENT

Before beginning examination and calculating the fees in this application,
 please amend the above-identified application as indicated below:

In the Title

Please amend the title as follows:

a1
 A METHOD AND APPARATUS FOR CONTRACTING, LOADING OR CRIMPING
 SELF-EXPANDING AND BALLOON EXPANDABLE STENT DEVICES

In the Specification

Insert a new heading after the Title, 1-Cross-Reference to Related Applications--
 and insert as text on the next line thereafter as follows:

a2
 --This application is a Divisional application from Application No. 09/966,686
 filed October 1, 2001 which is a Continuation application from Application No.
 09/401,218 filed September 22, 1999, the contents of which are hereby incorporated by
 reference --

In the Abstract

On page 19, line 3 please amend the Title as follows:

a3
 A METHOD AND APPARATUS FOR CONTRACTING, LOADING OR CRIMPING
 SELF-EXPANDING AND BALLOON EXPANDABLE STENT DEVICES

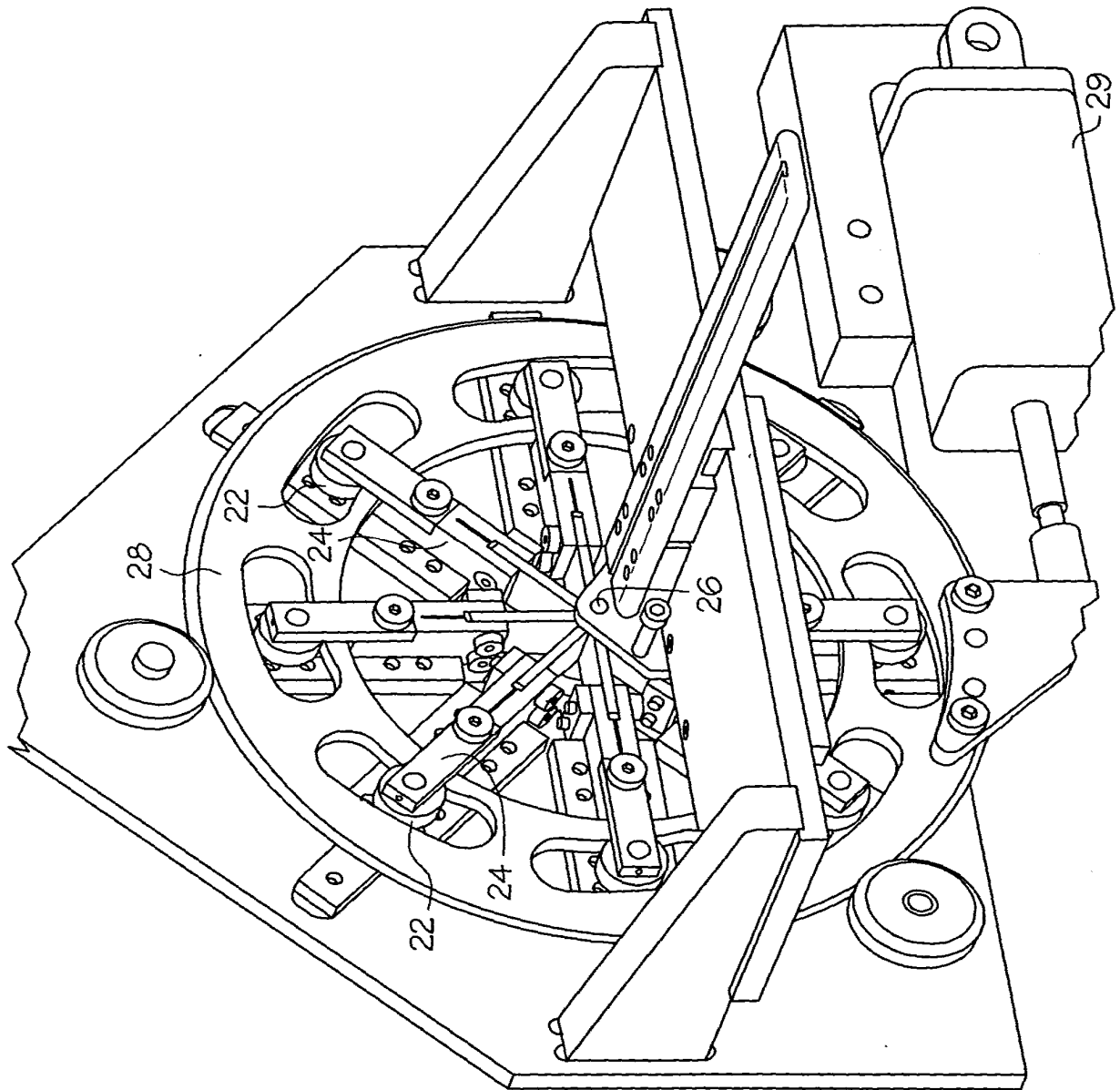


FIG. 1
PRIOR ART

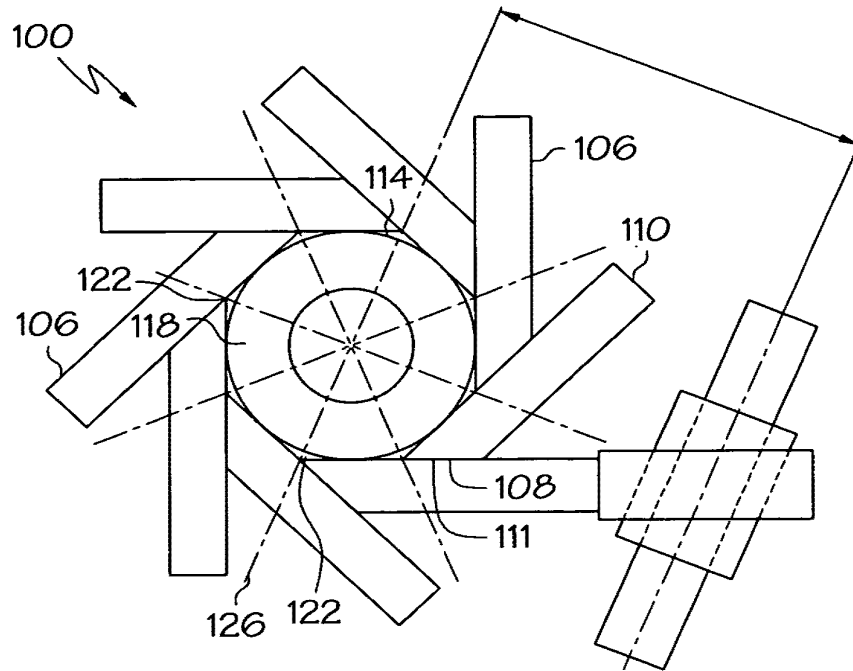


FIG. 2a

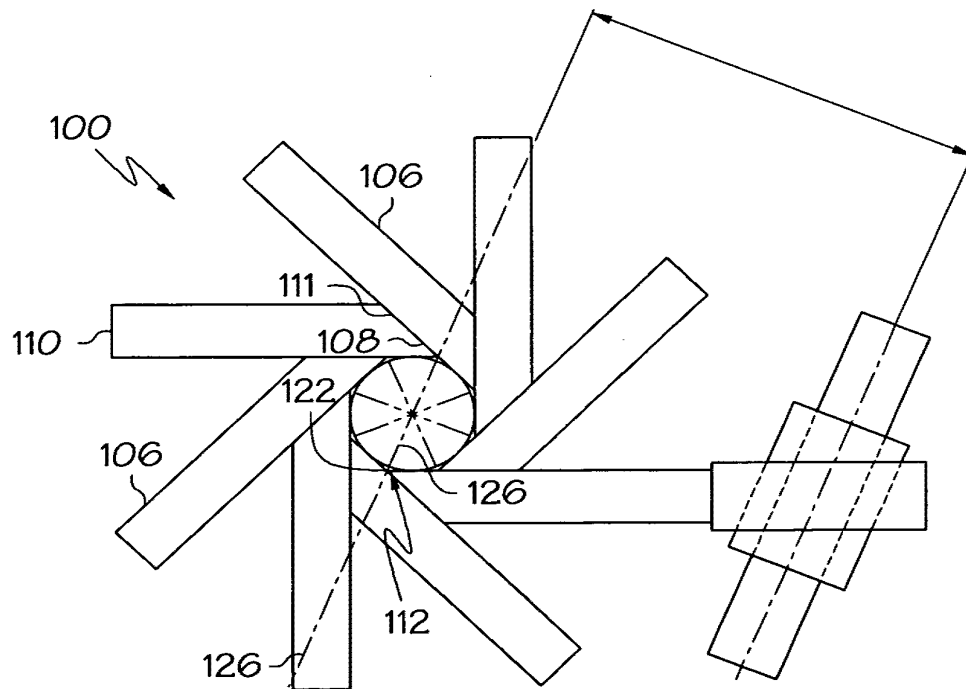


FIG. 2b

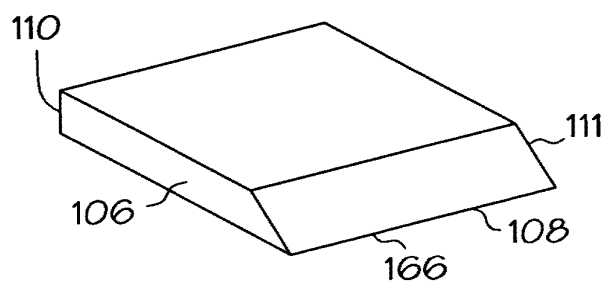


FIG. 3a

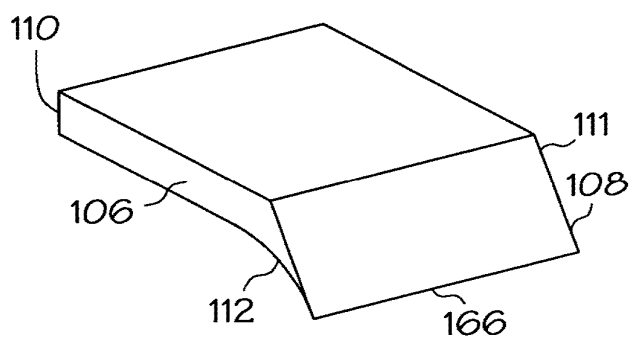


FIG. 3b

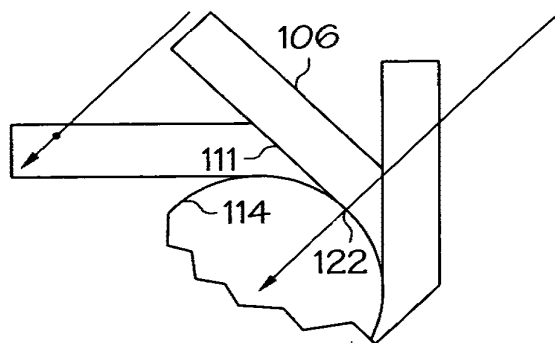


FIG. 3c

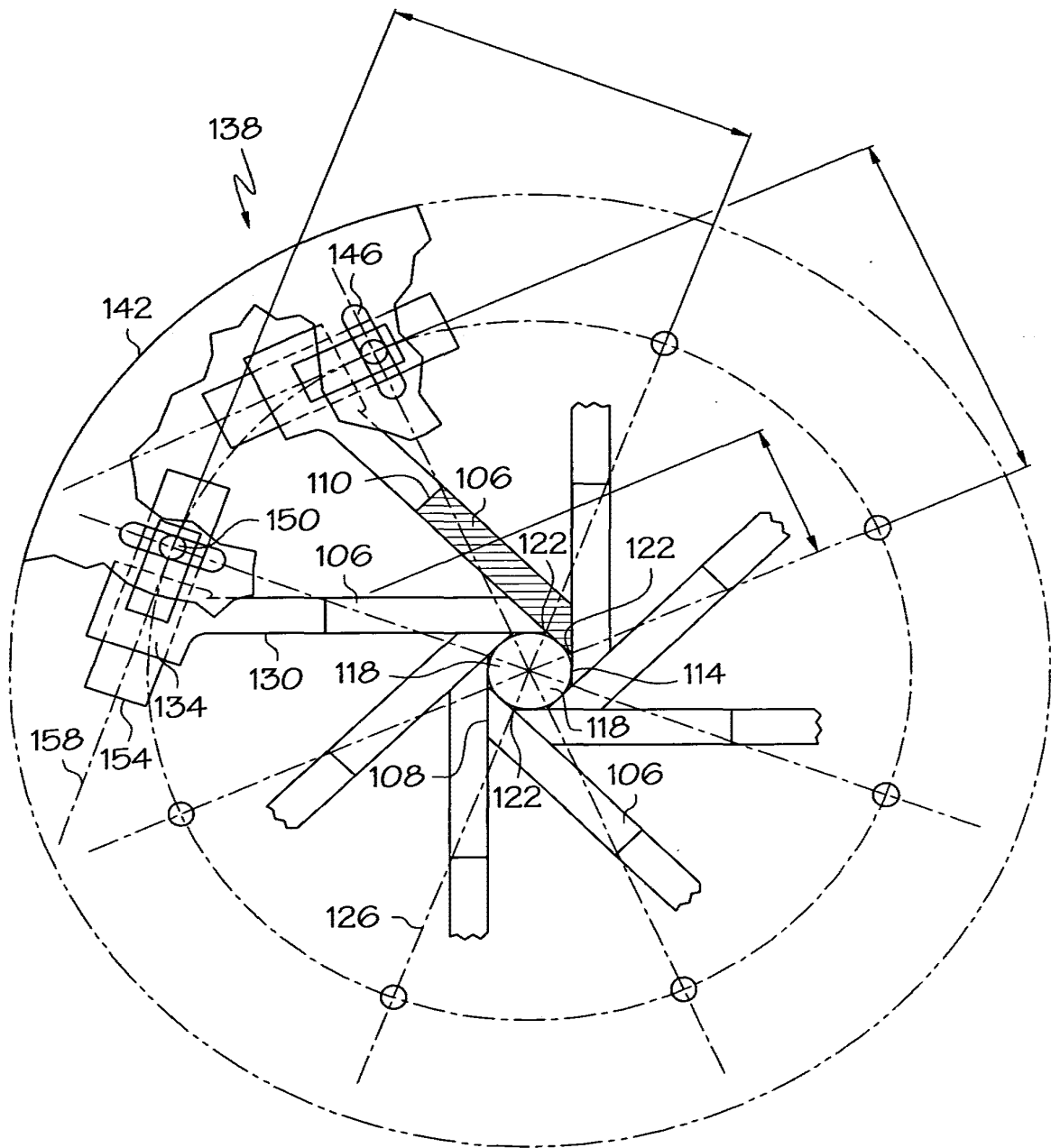


FIG. 4A

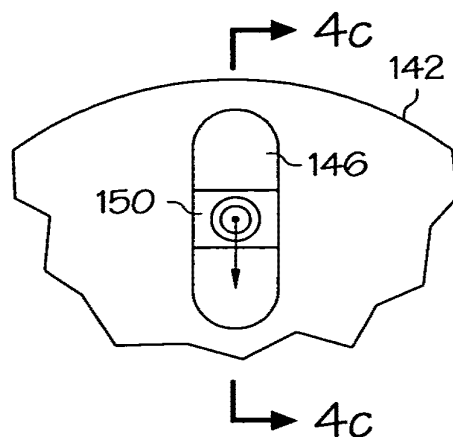


FIG. 4b

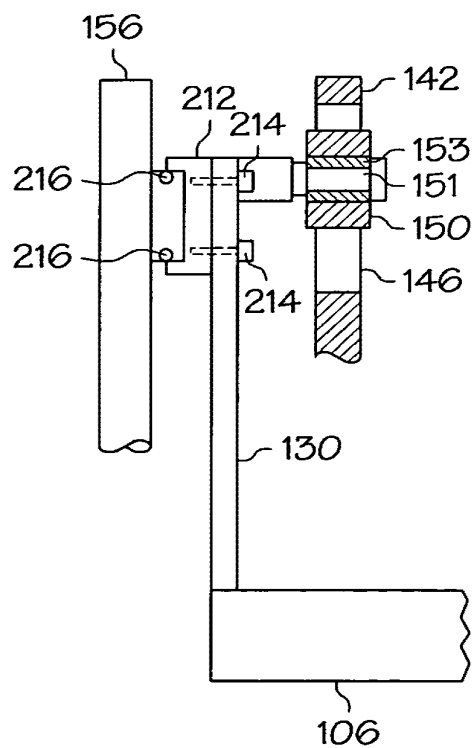


FIG. 4c

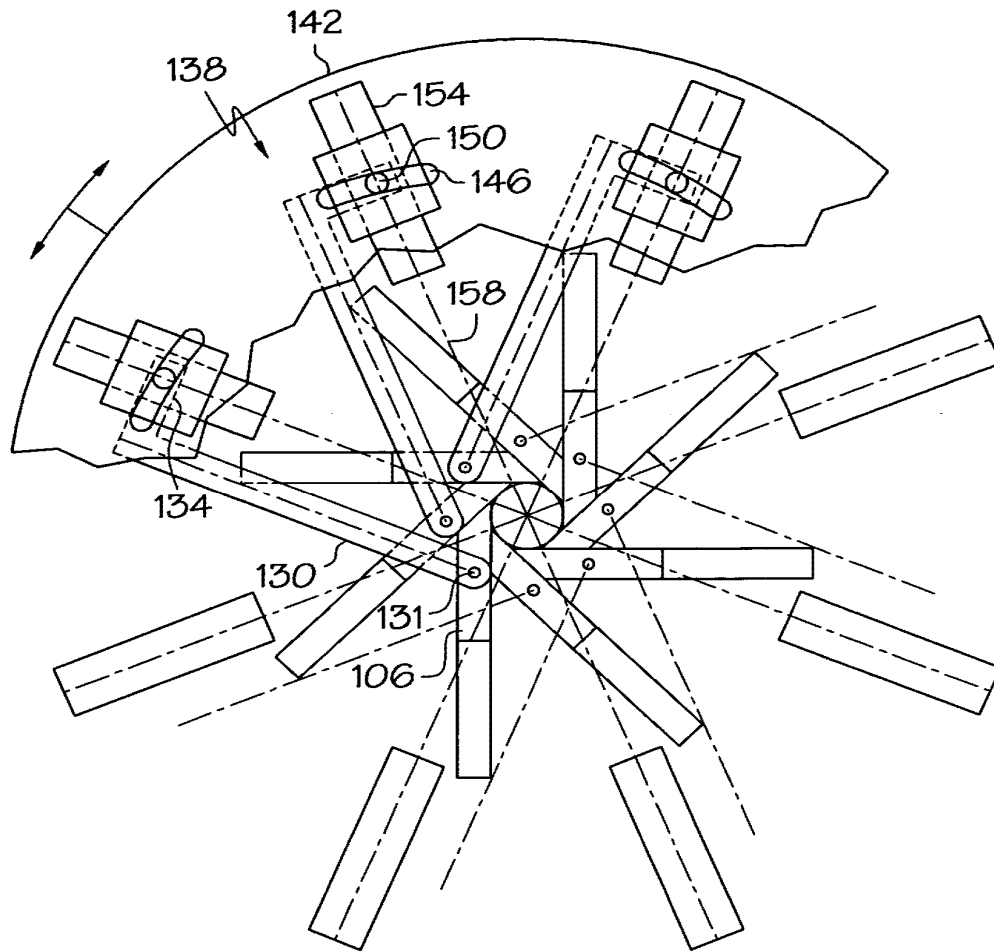


FIG. 5a

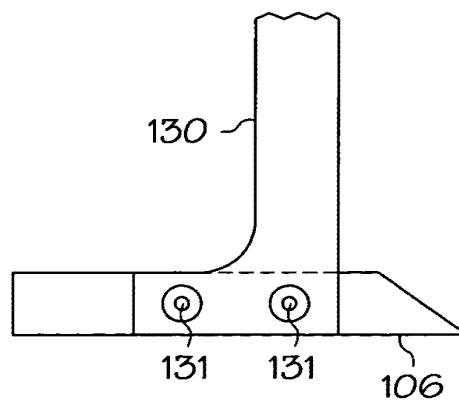


FIG. 5b

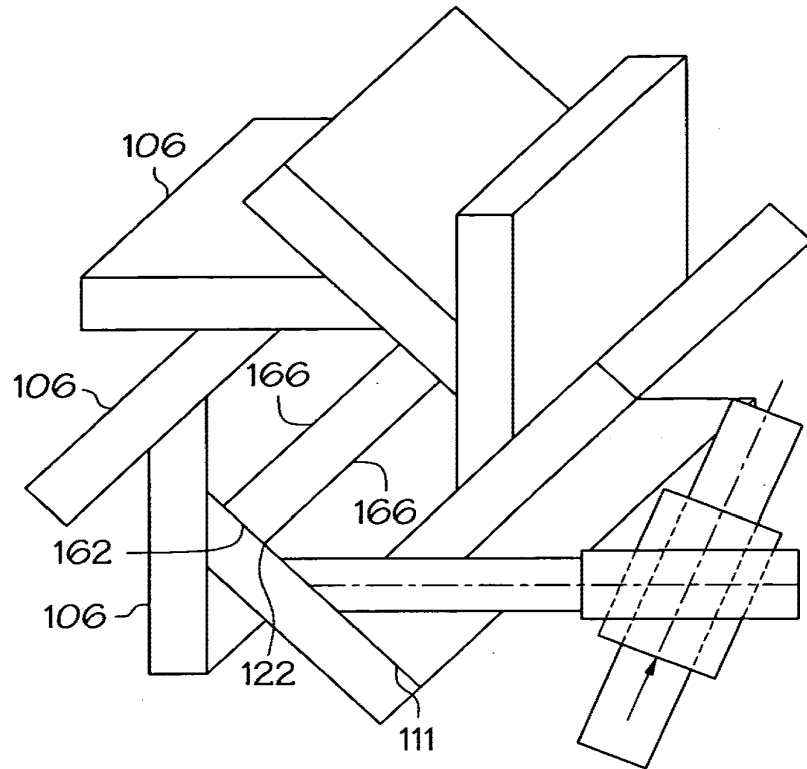


FIG. 6

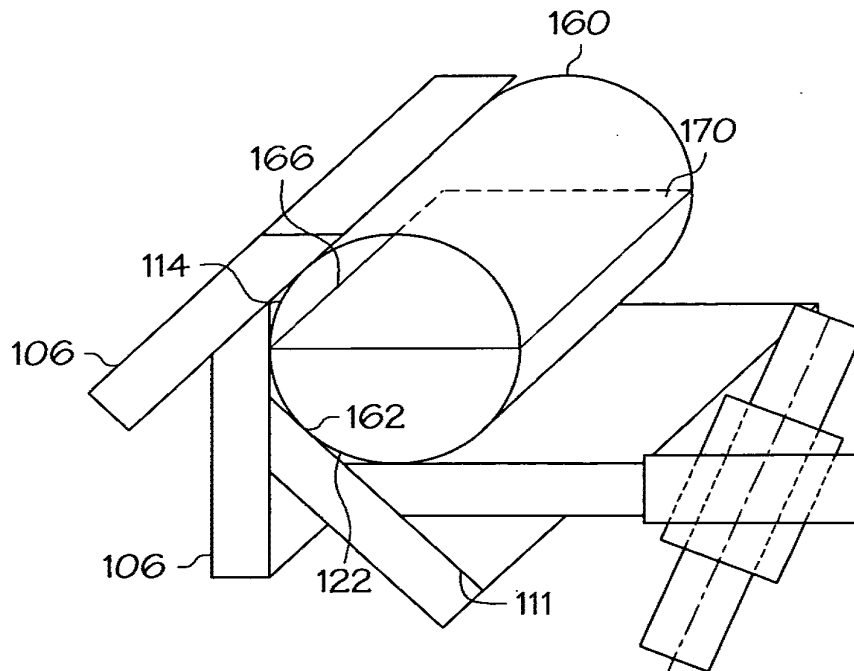


FIG. 7

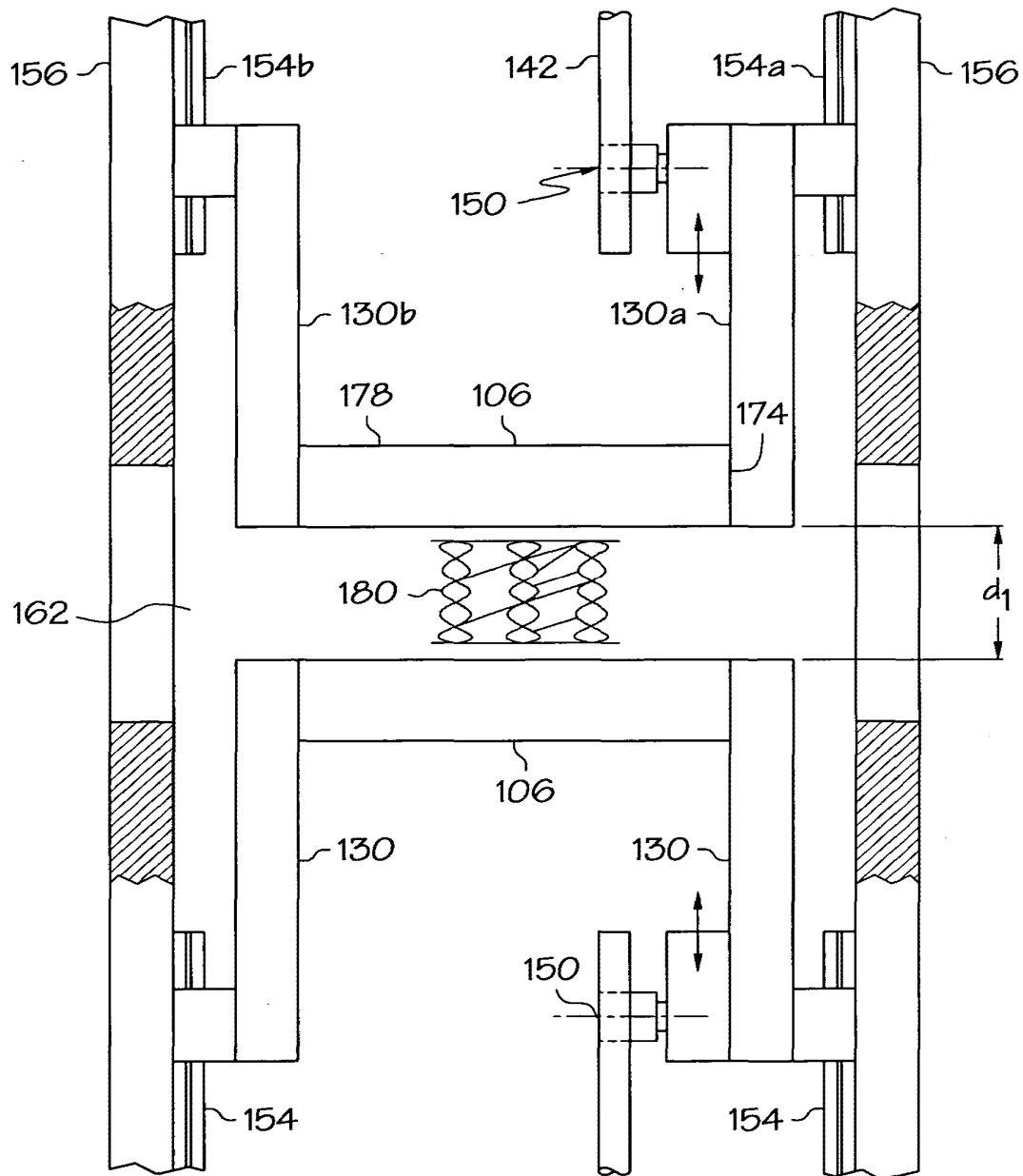


FIG. 8a

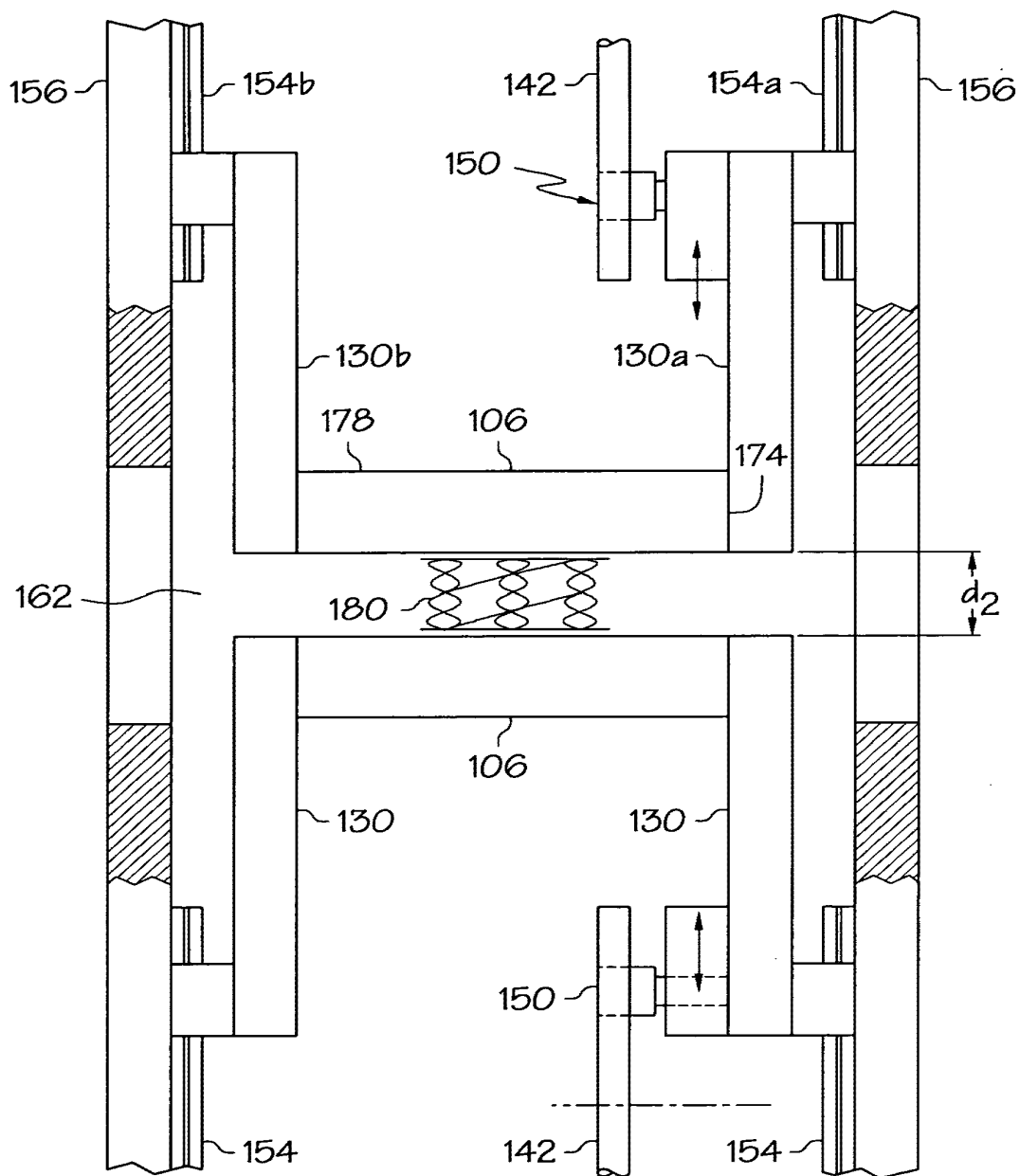


FIG. 8b

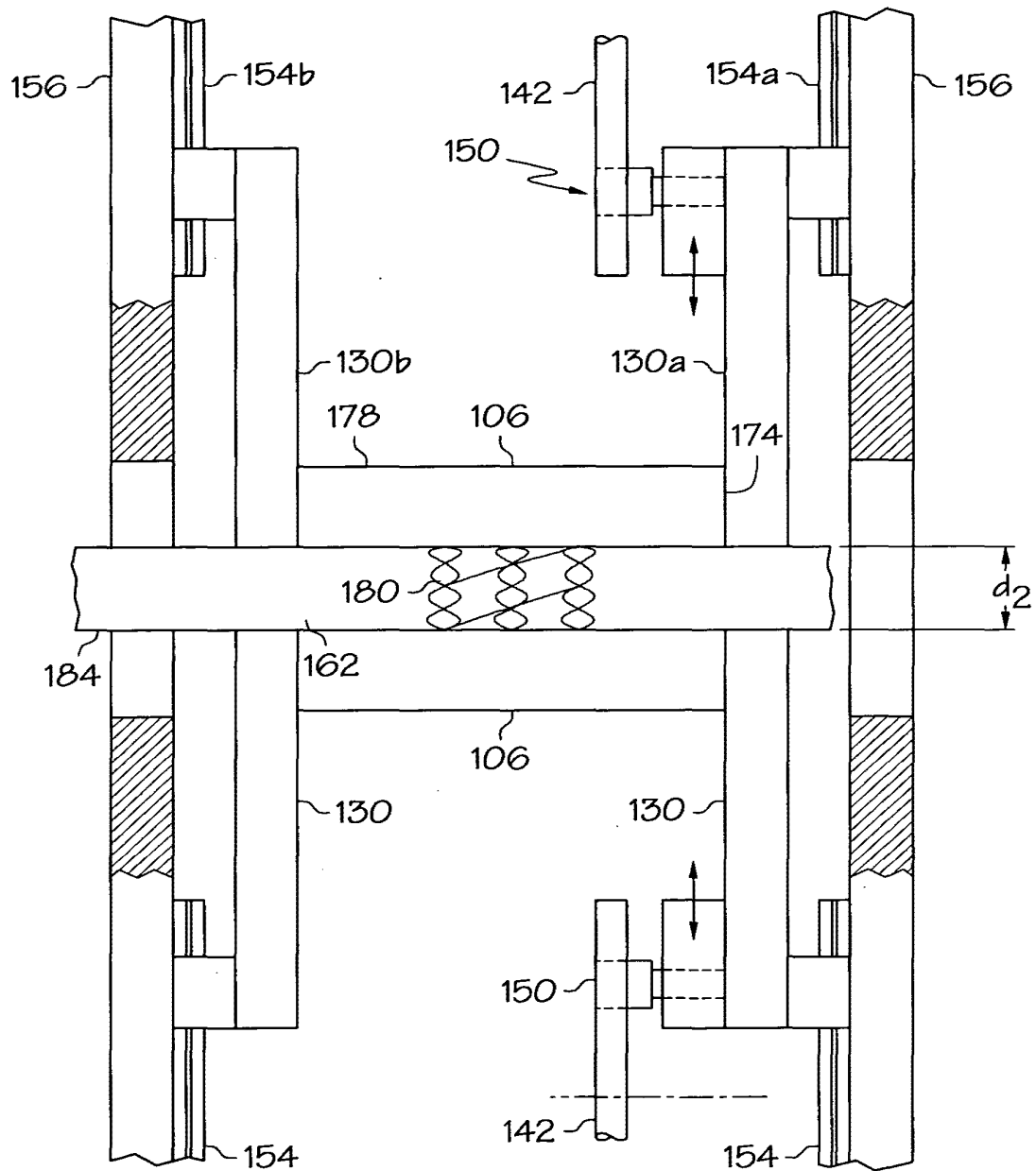


FIG. 8c

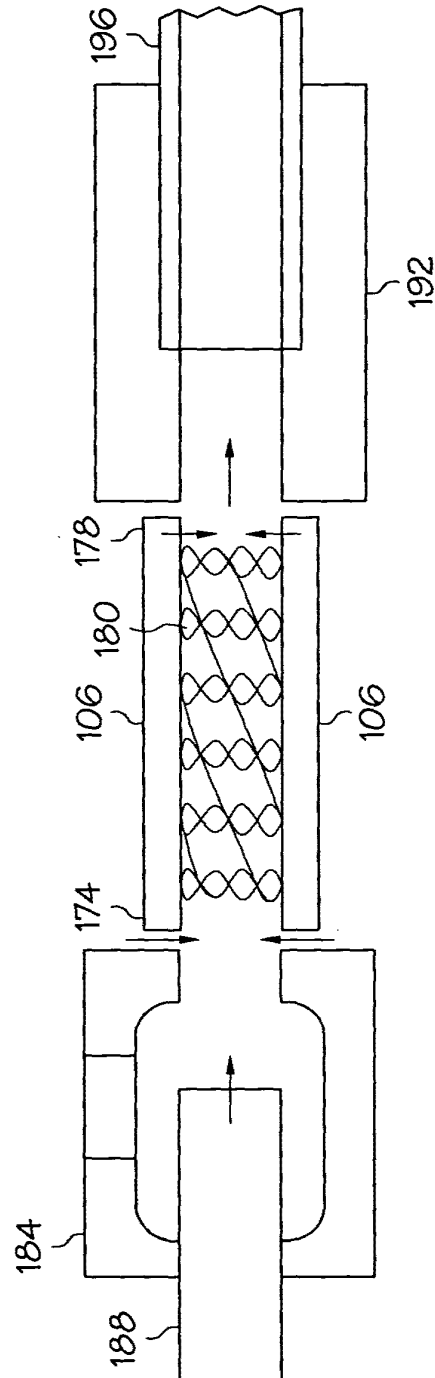


FIG. 9

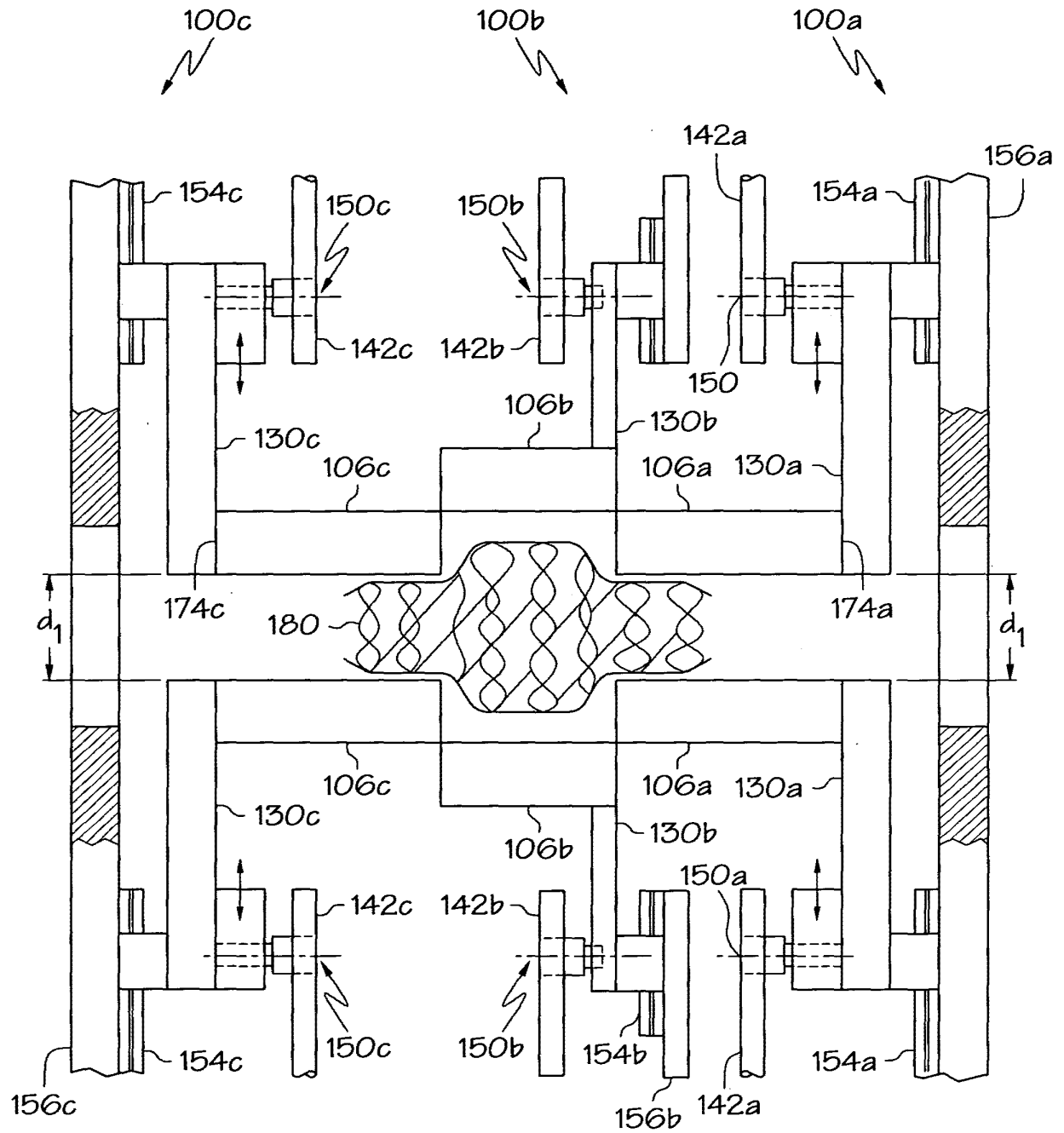


FIG. 10

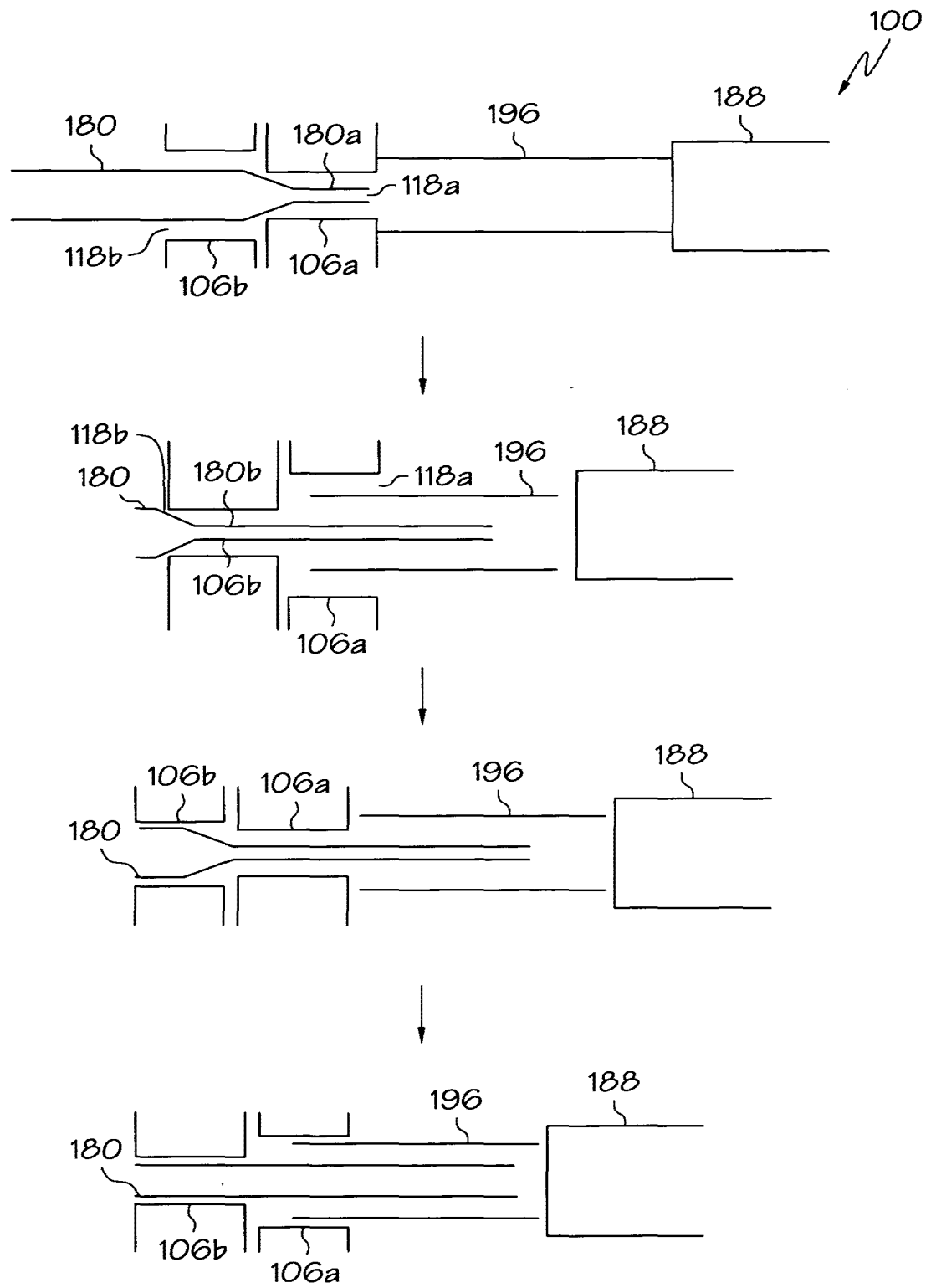


FIG. 11

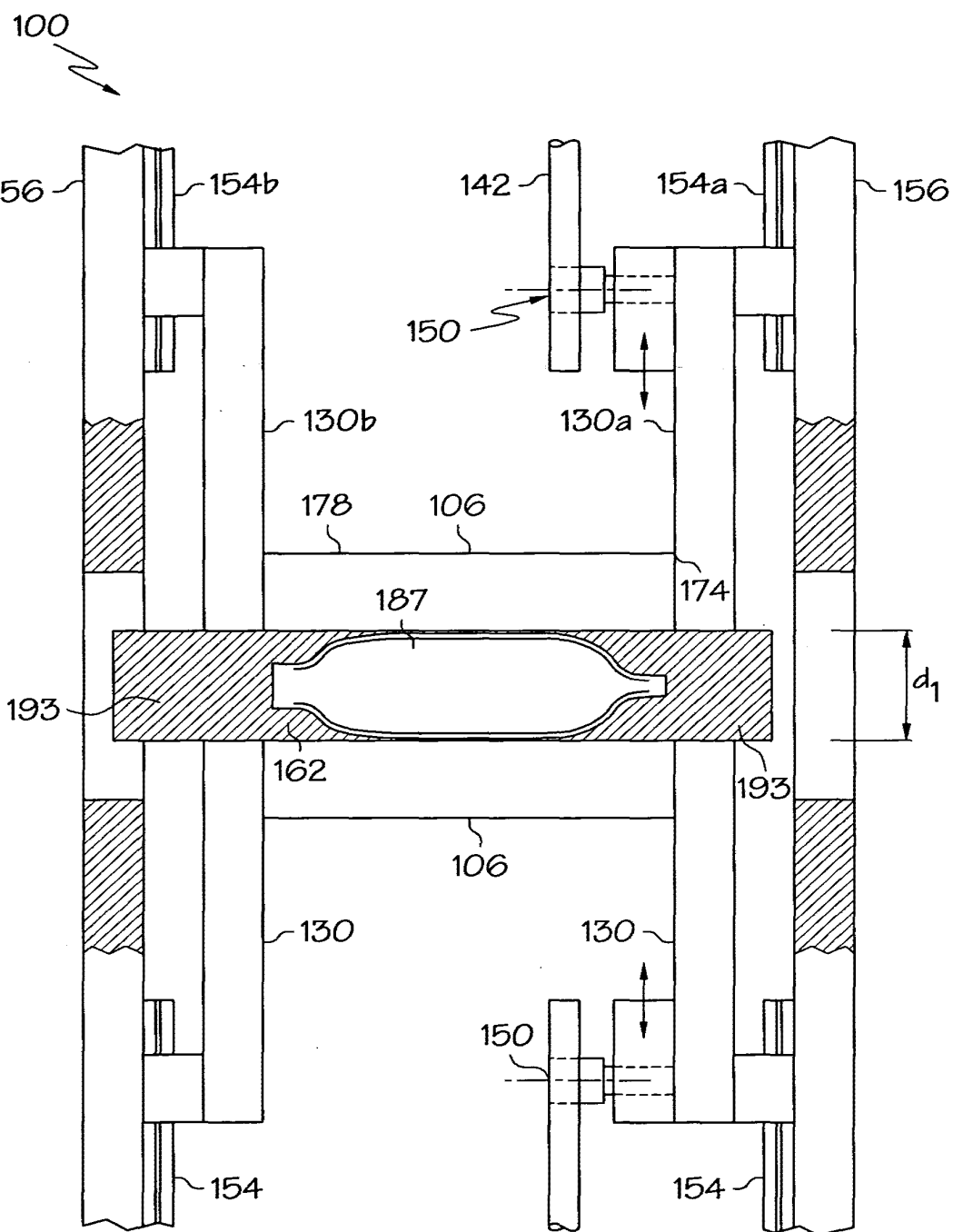


FIG. 12

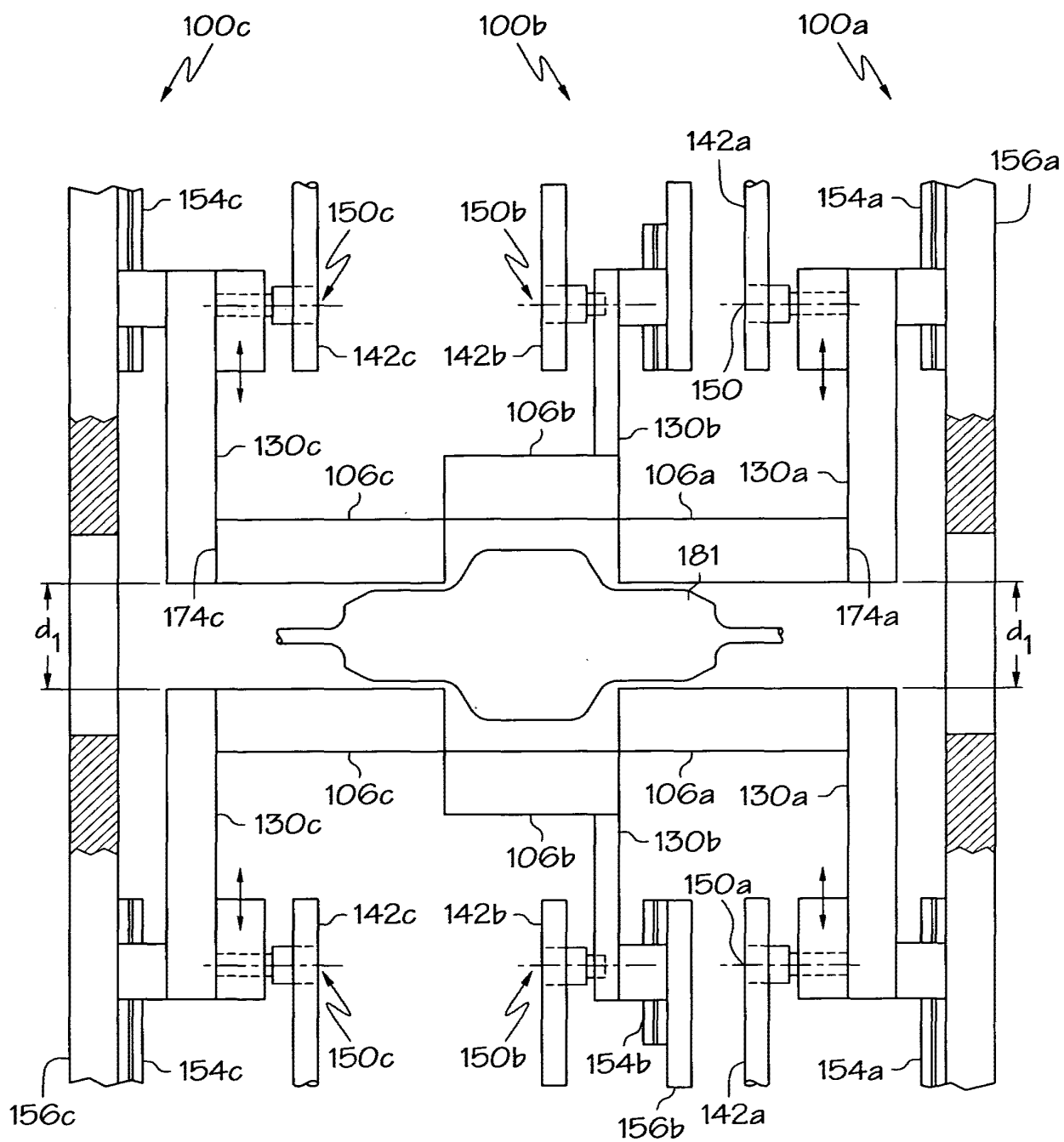


FIG. 13

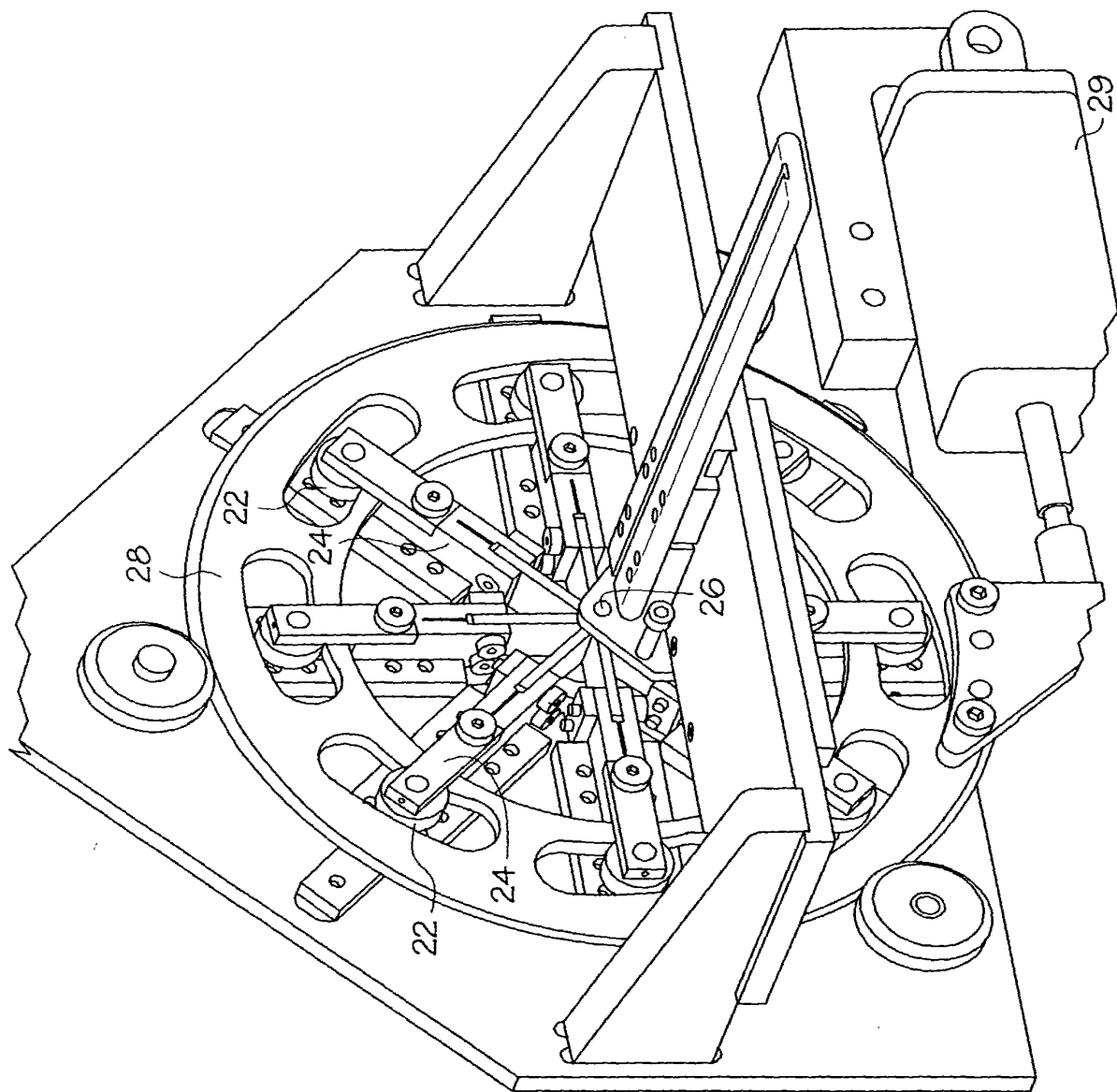


FIG. 1

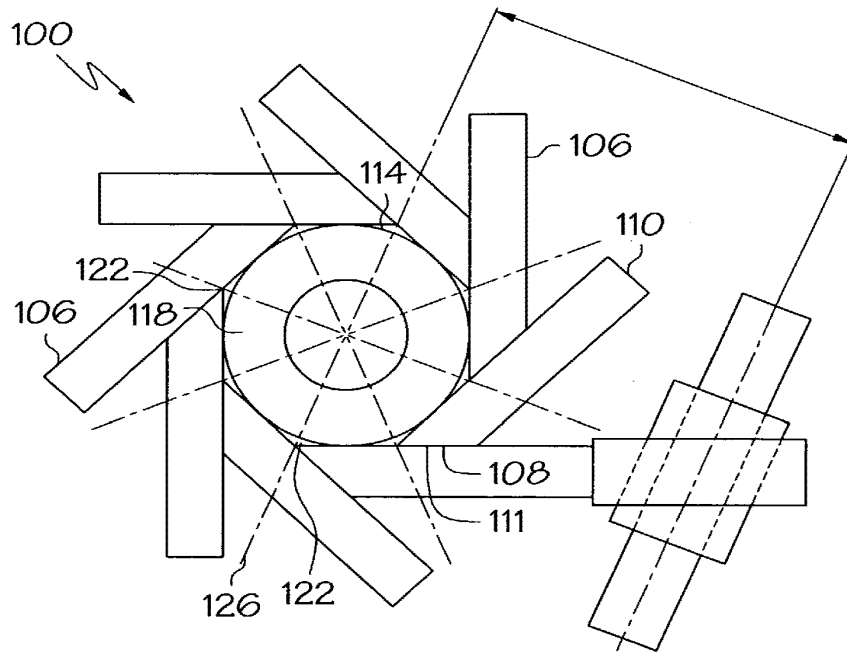


FIG. 2a

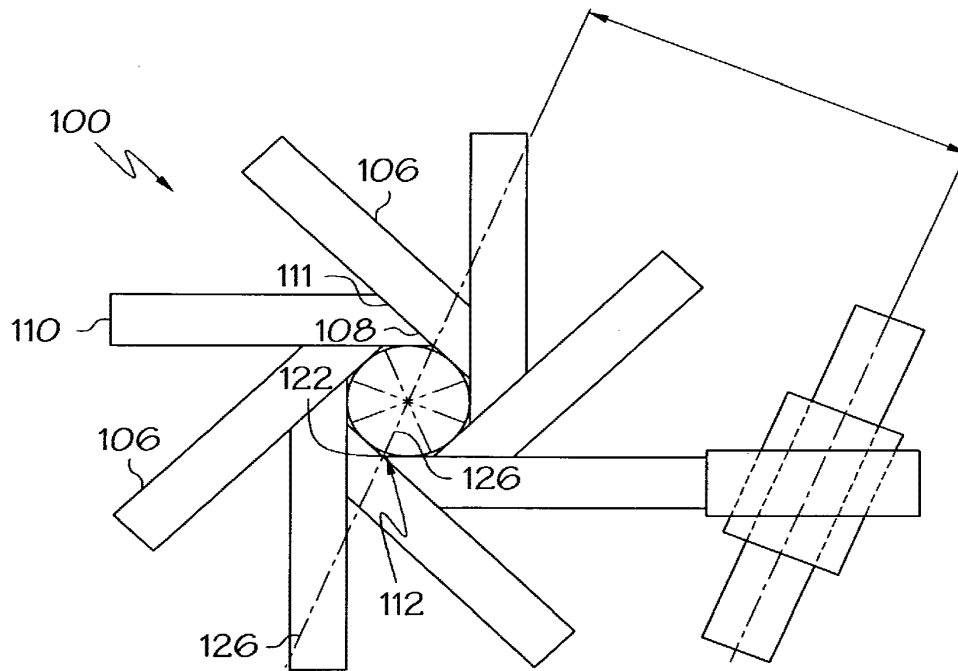


FIG. 2b

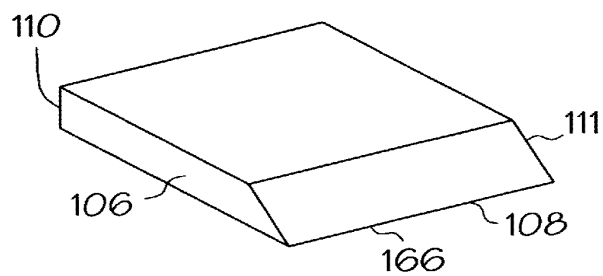


FIG. 3a

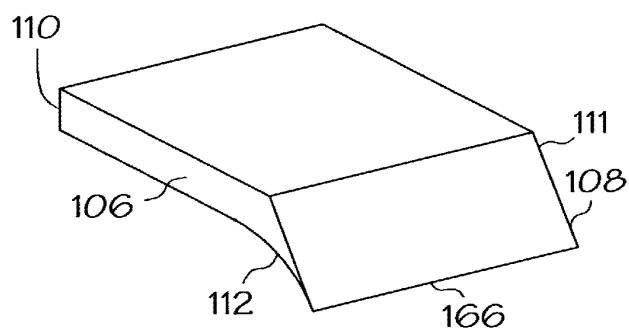


FIG. 3b

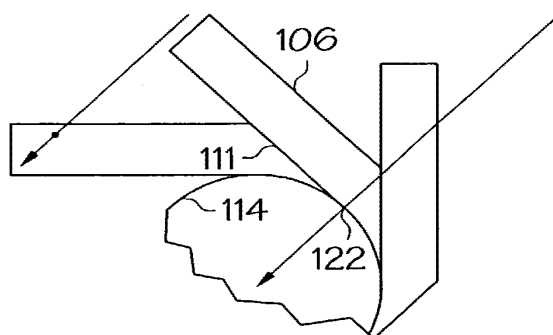


FIG. 3c

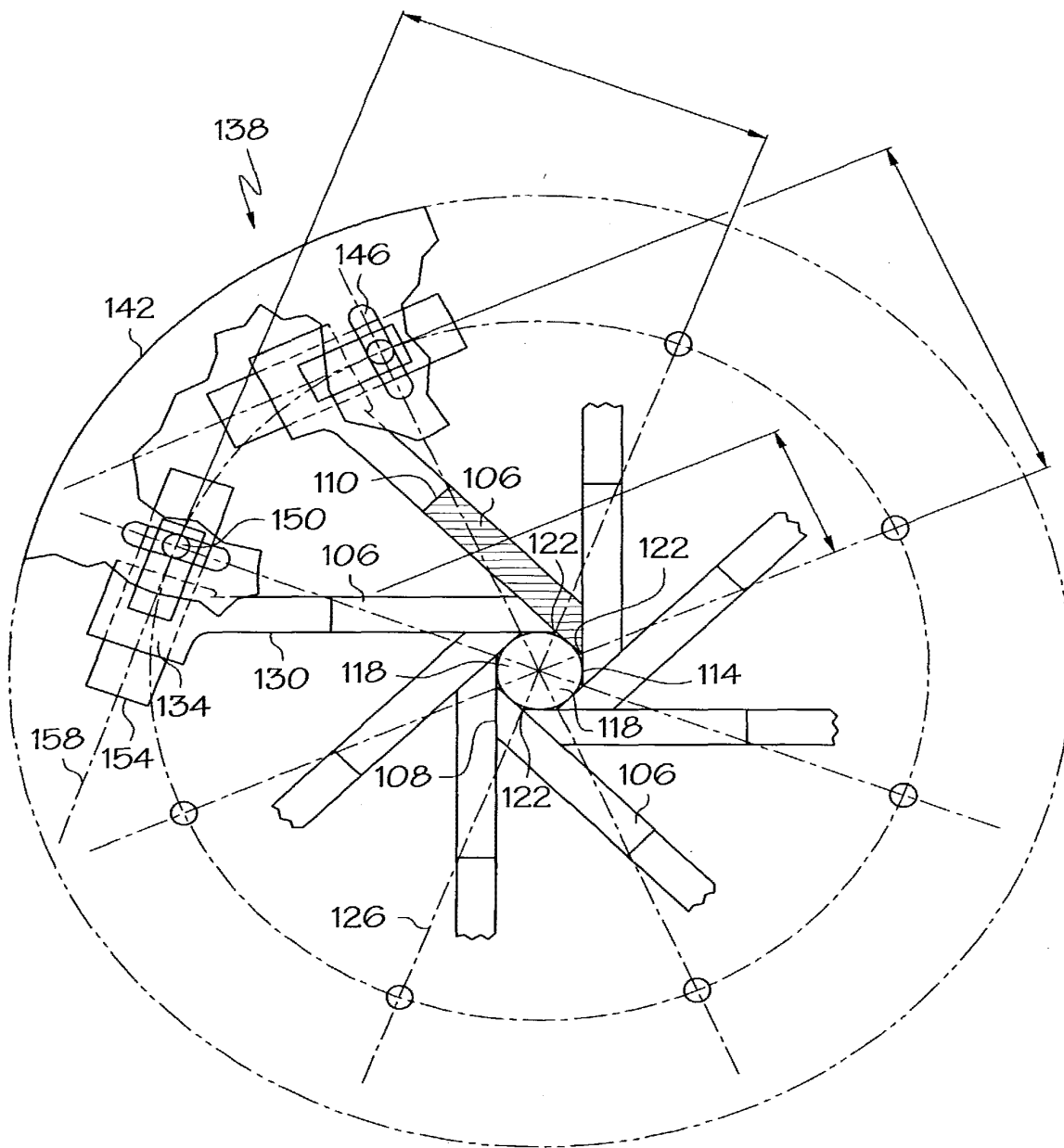


FIG. 4A

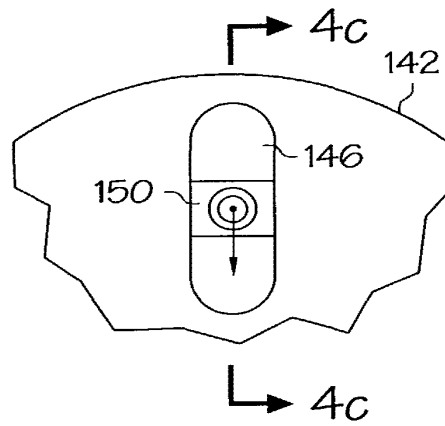


FIG. 4b

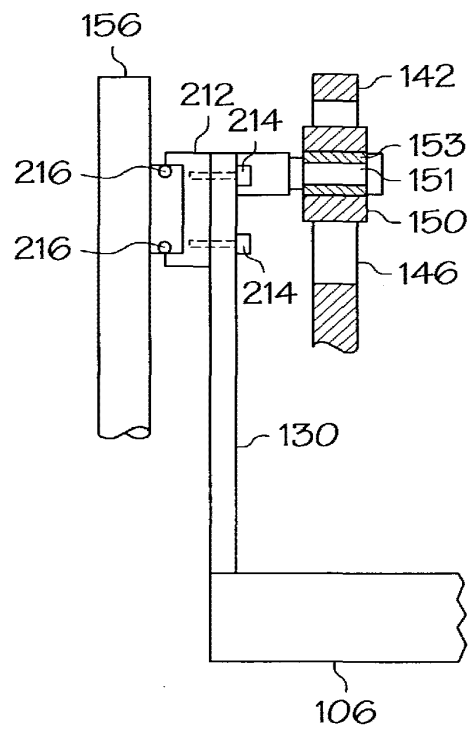


FIG. 4c

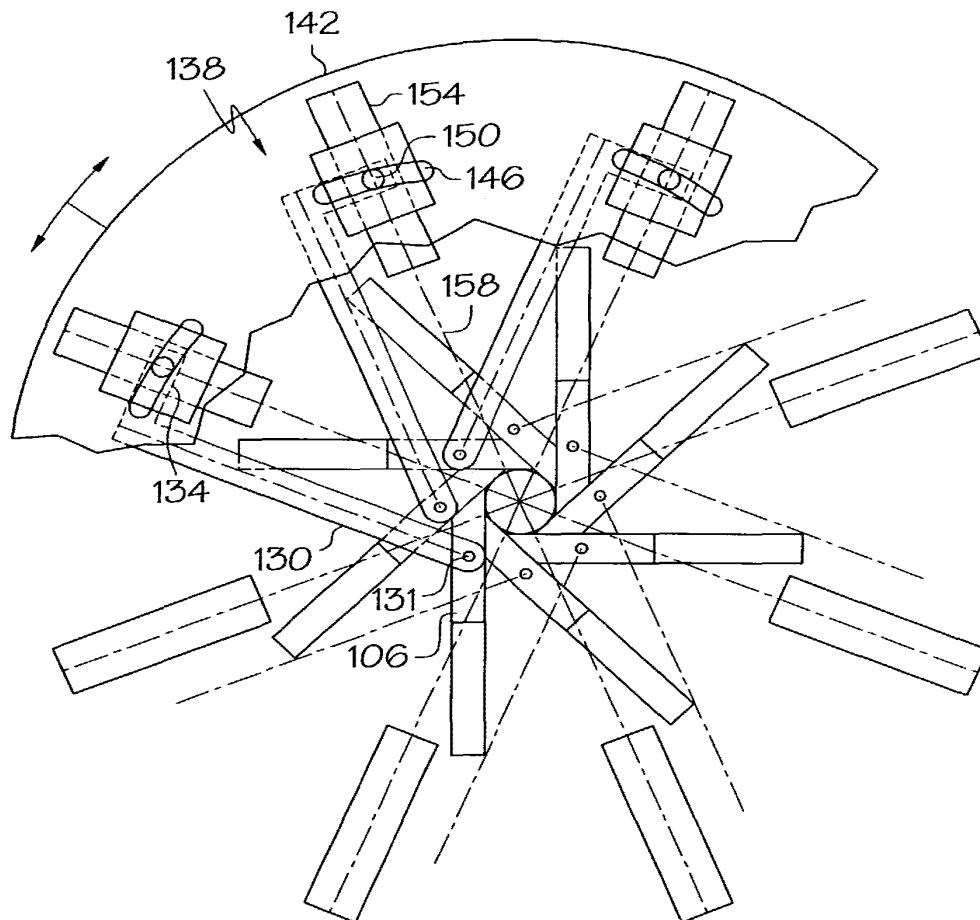


FIG. 5a

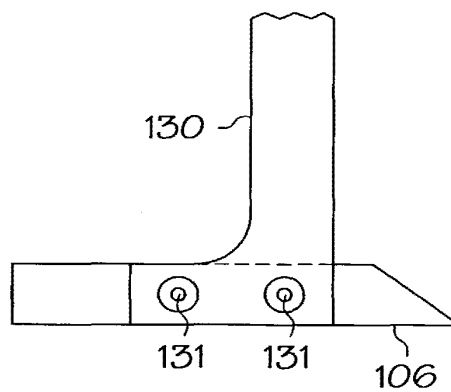


FIG. 5b

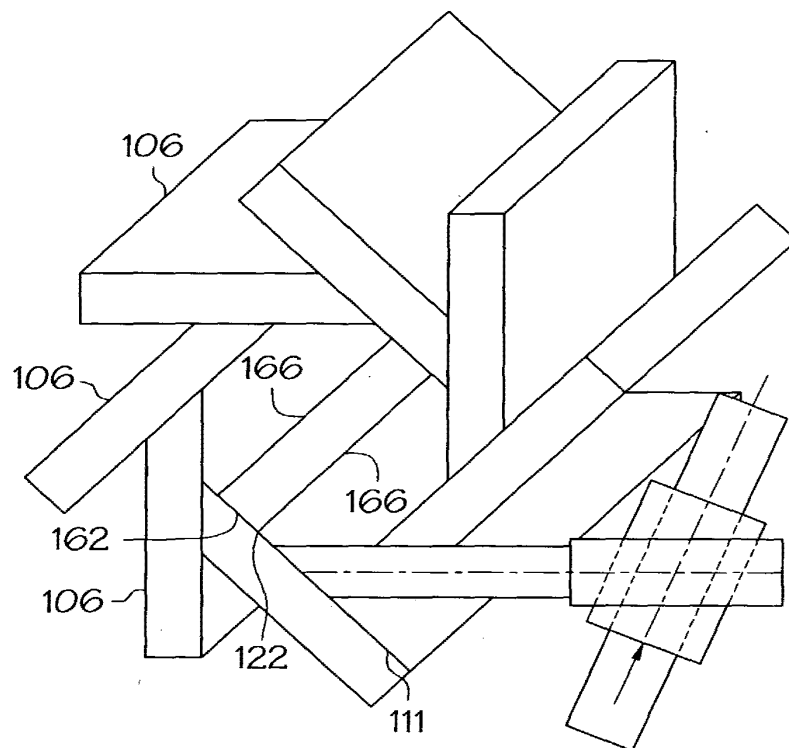


FIG. 6

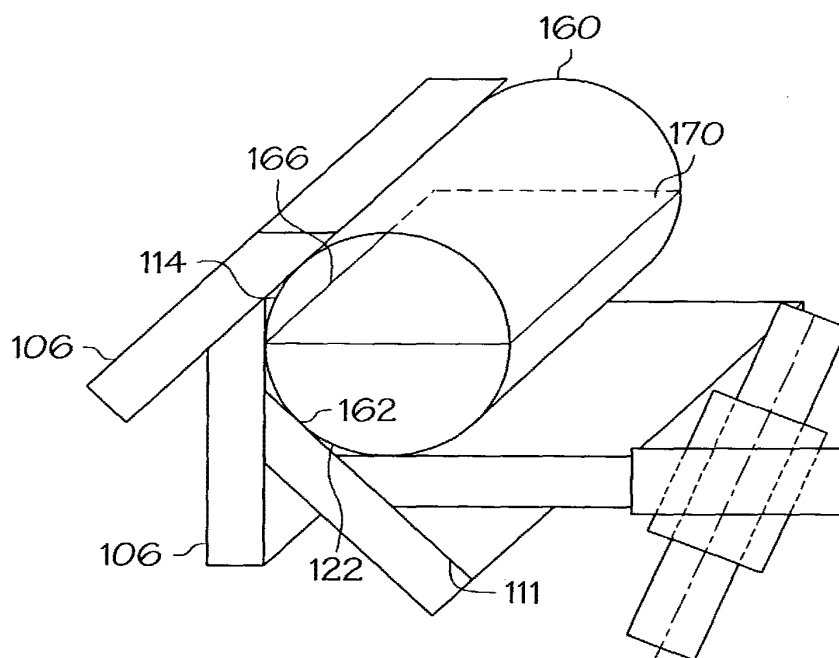


FIG. 7

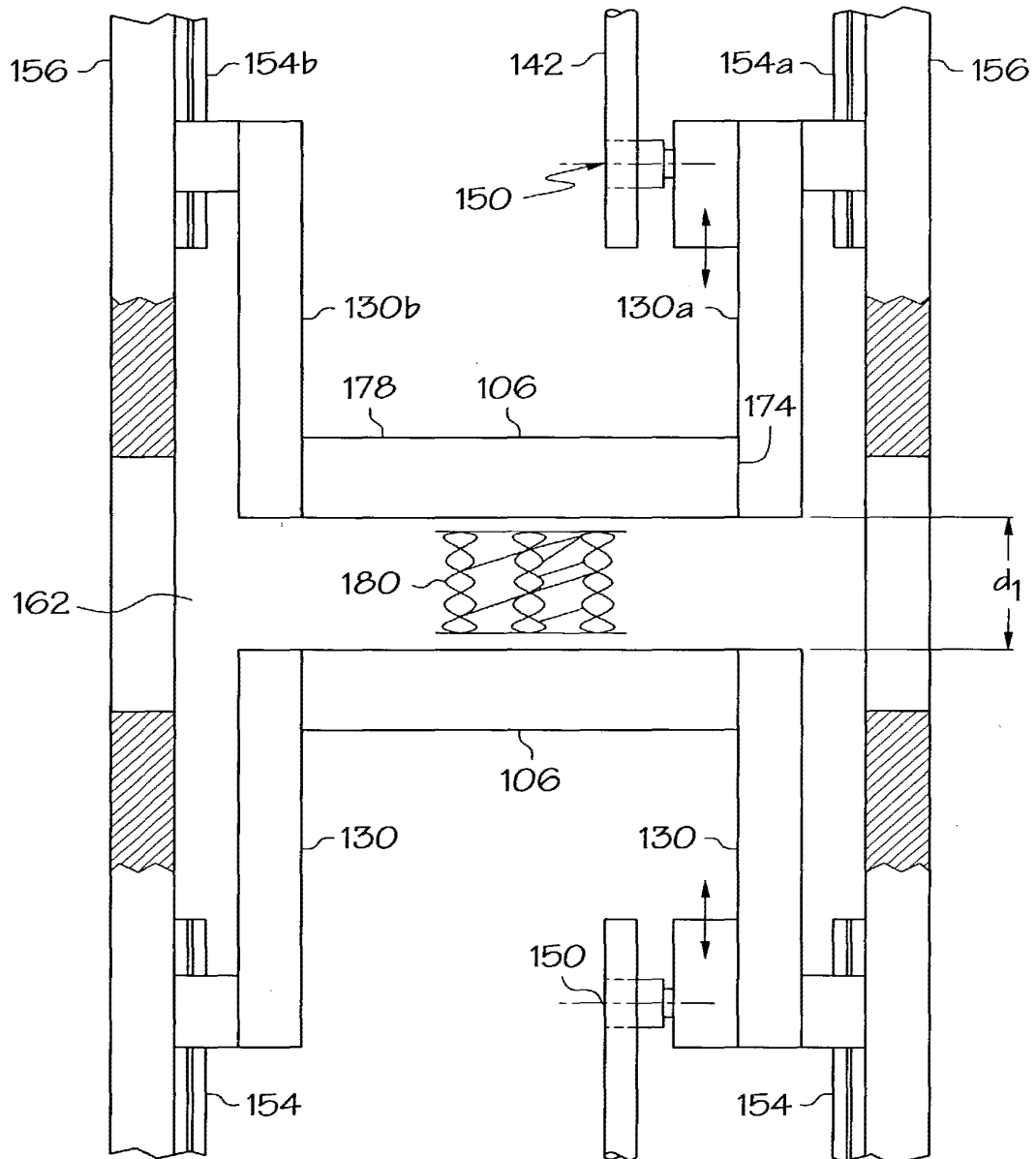


FIG. 8a

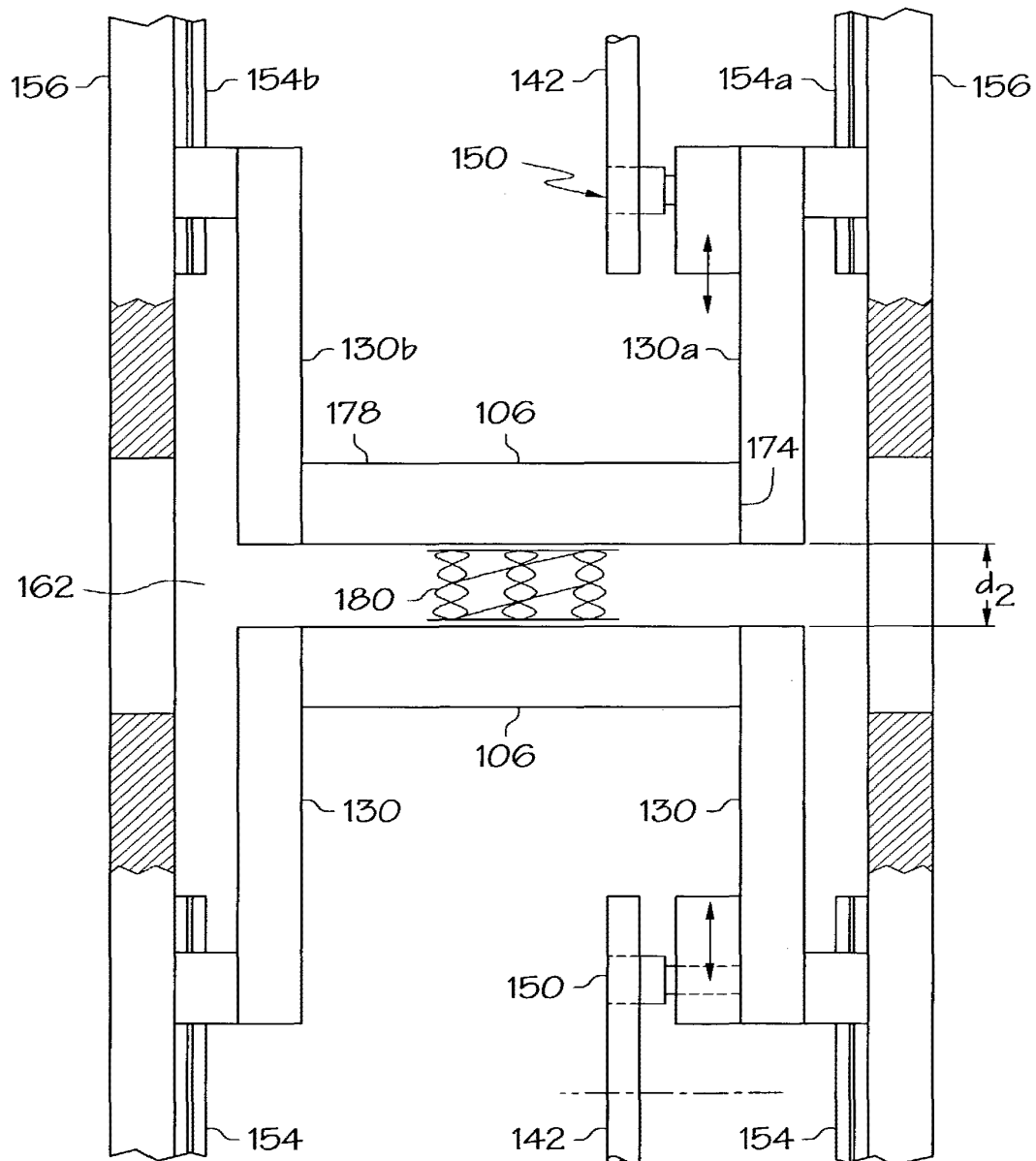


FIG. 8b

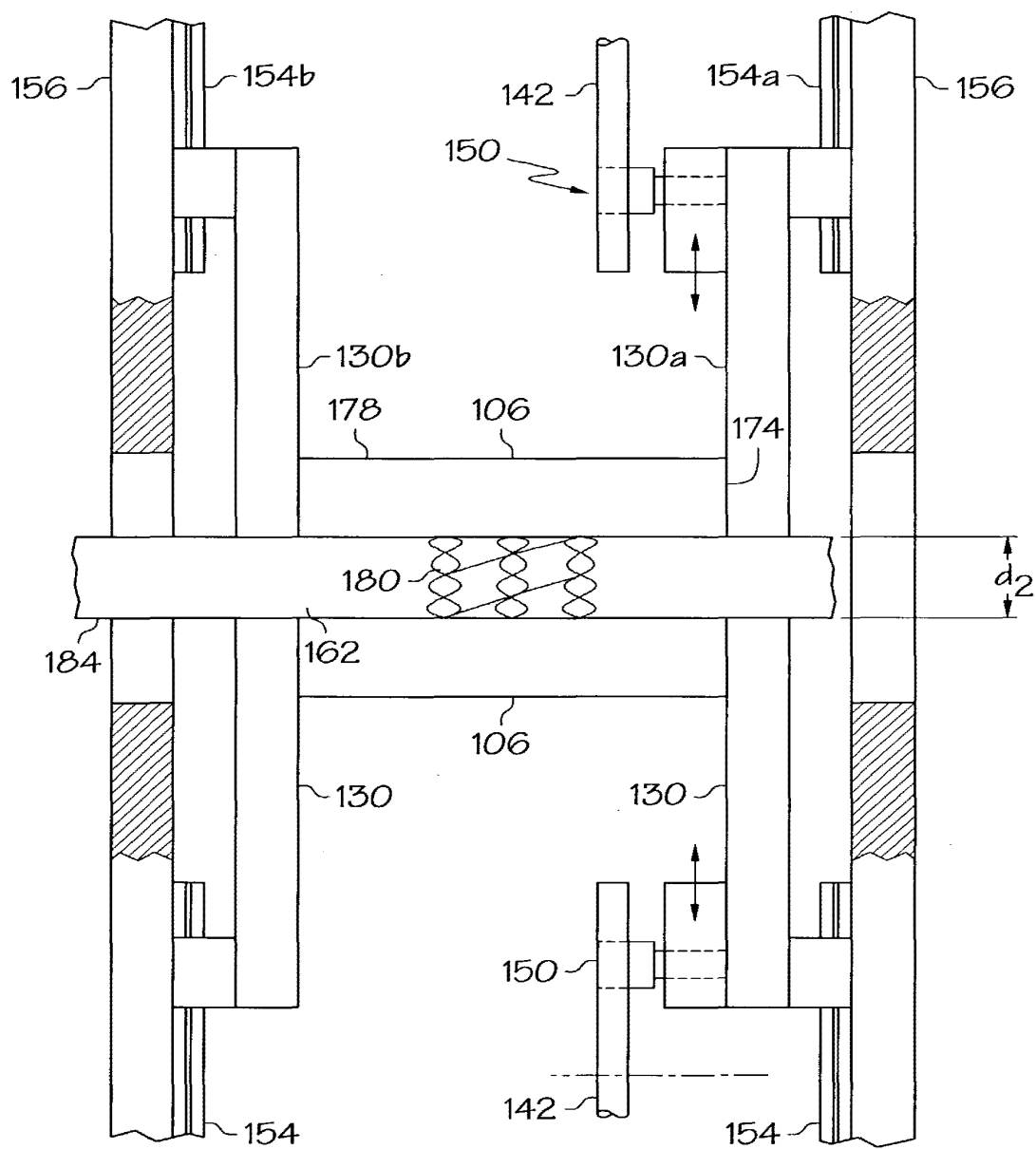


FIG. 8c

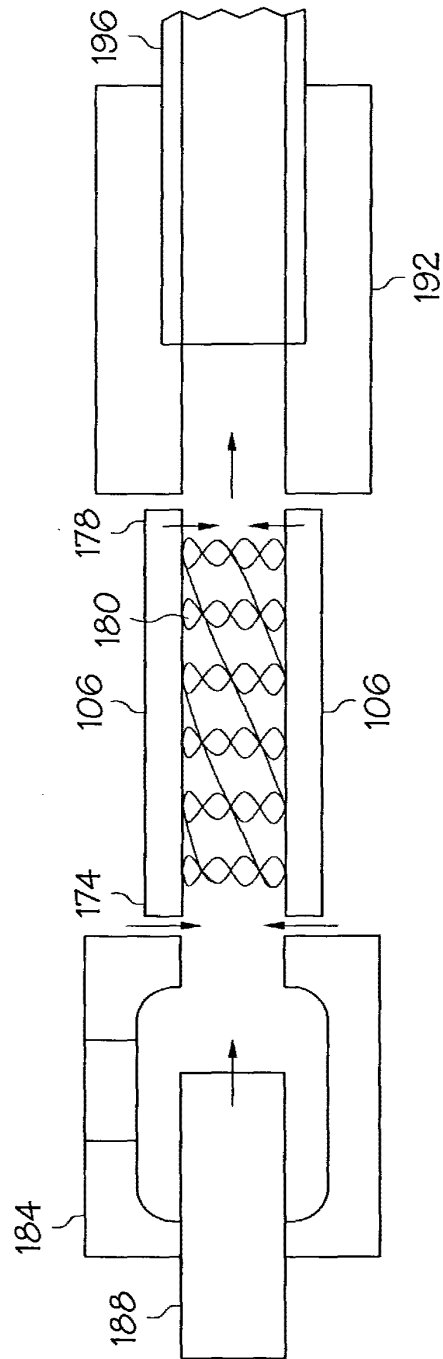


FIG. 9

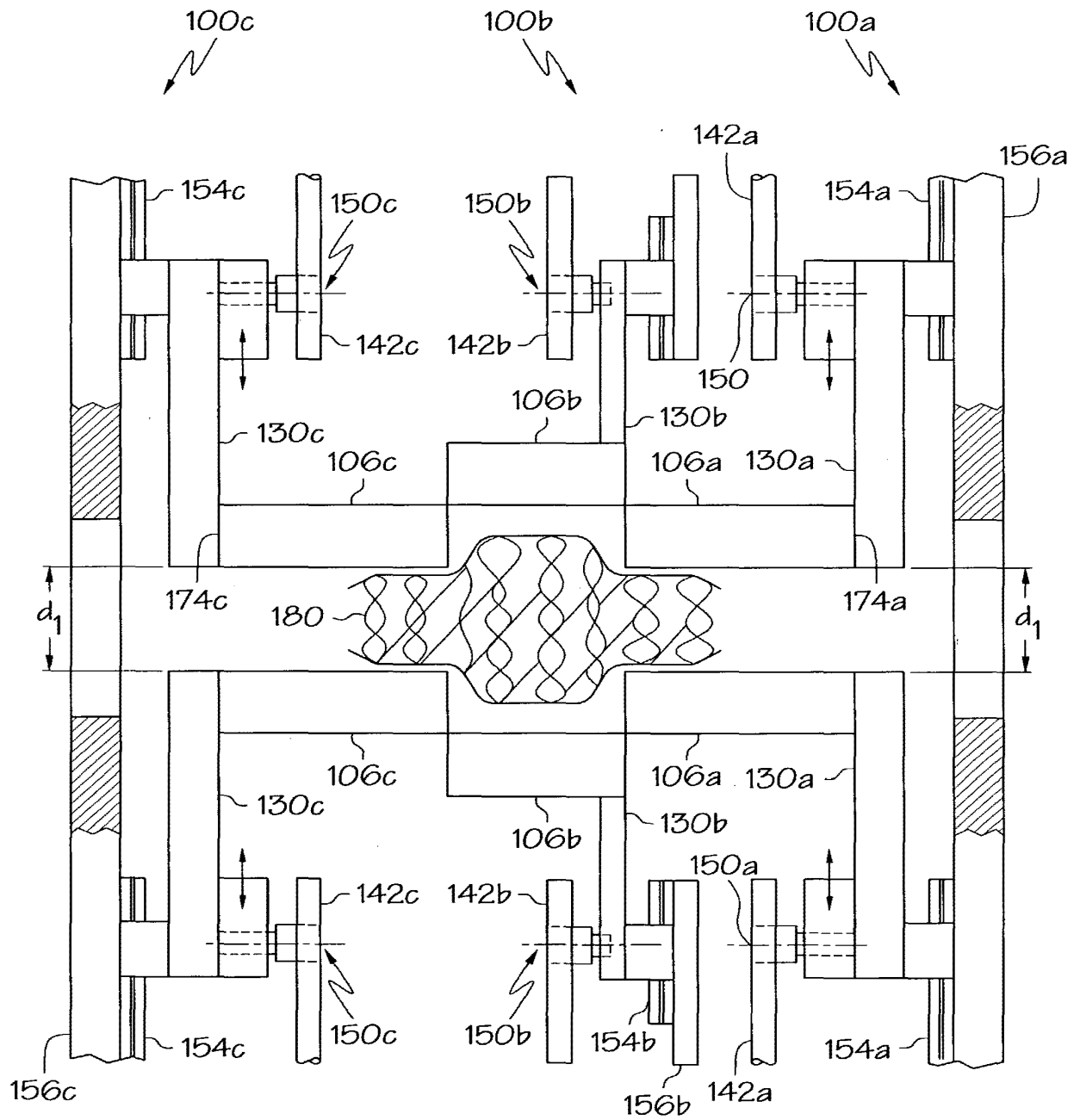


FIG. 10

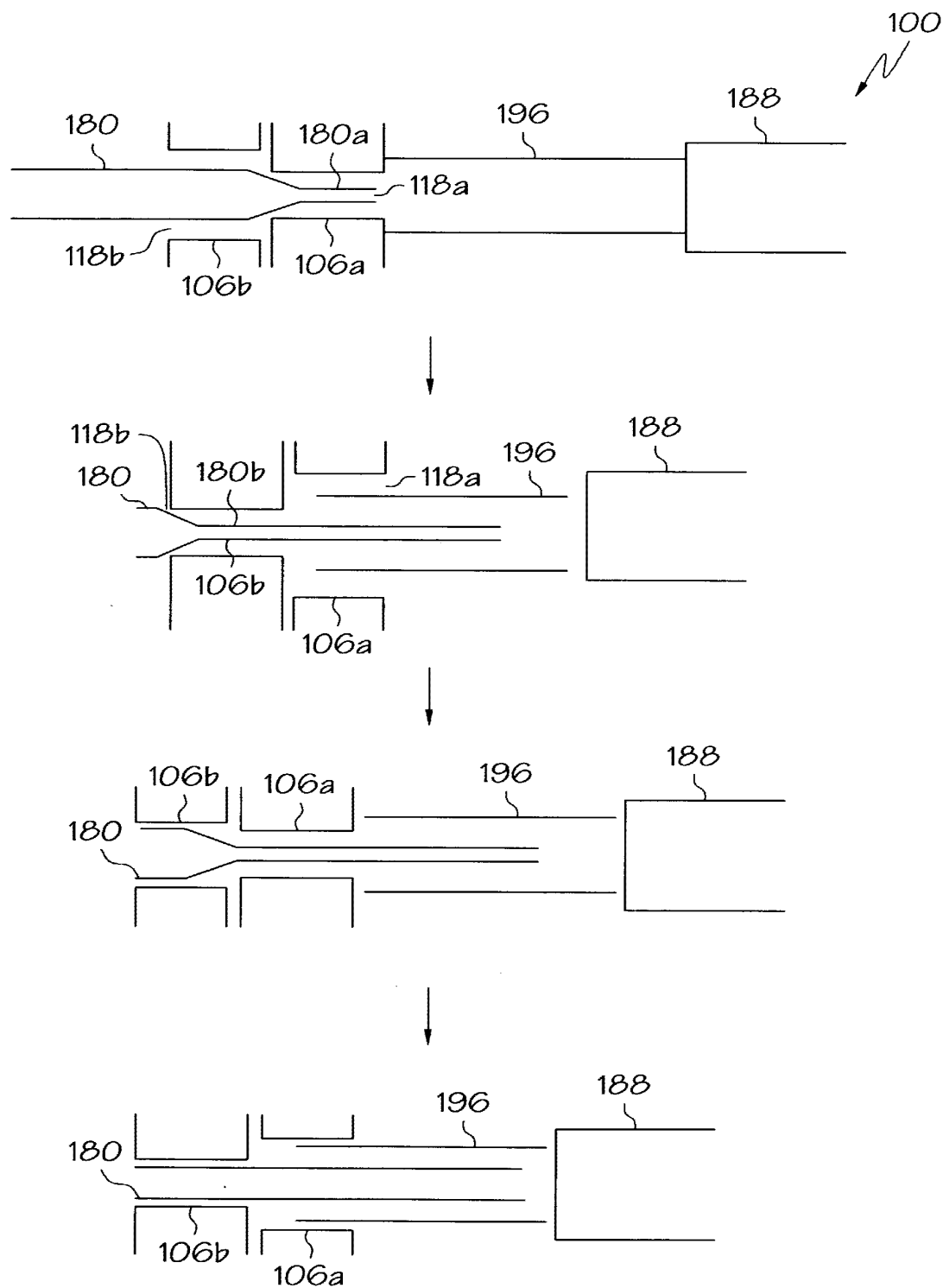


FIG. 11

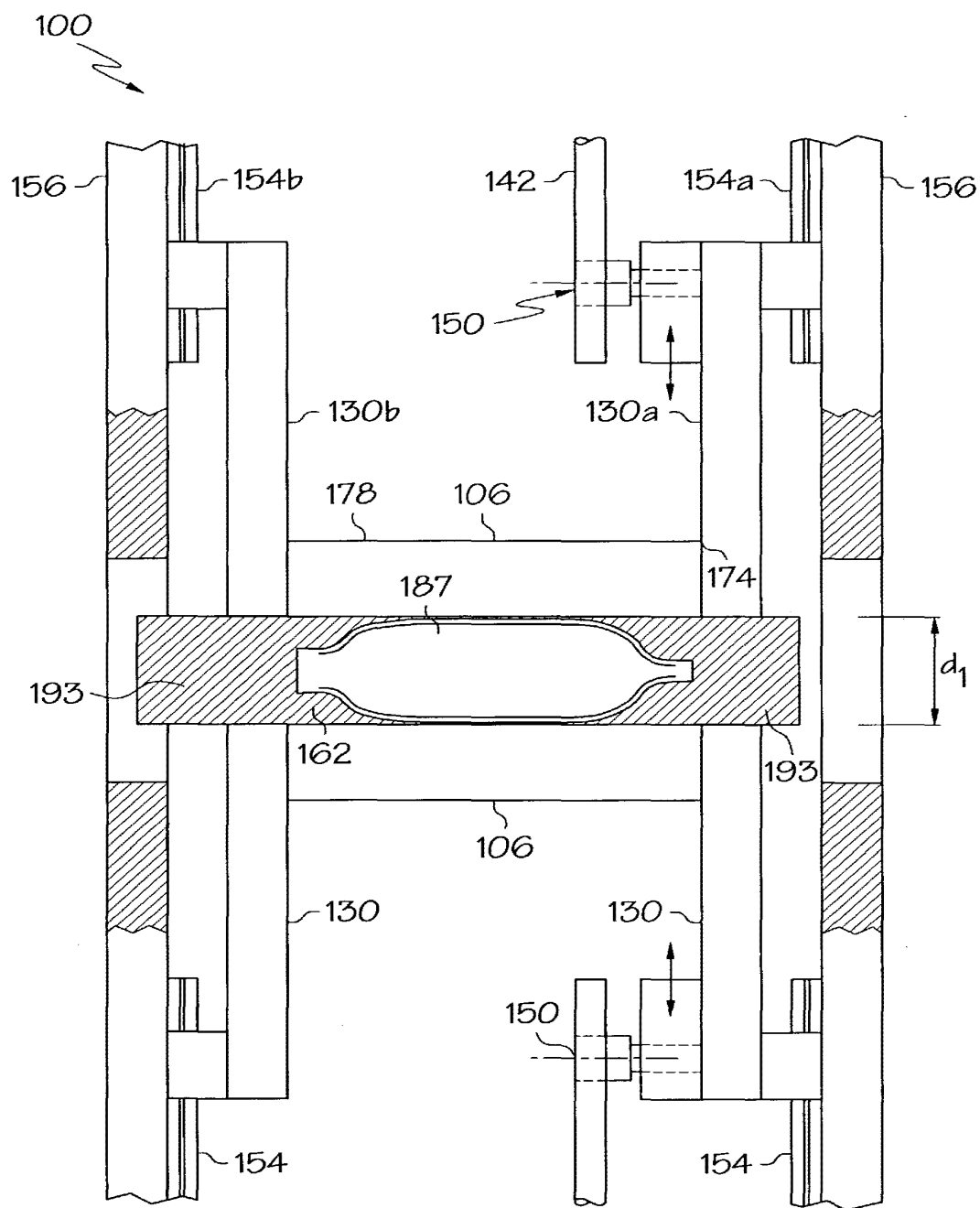


FIG. 12

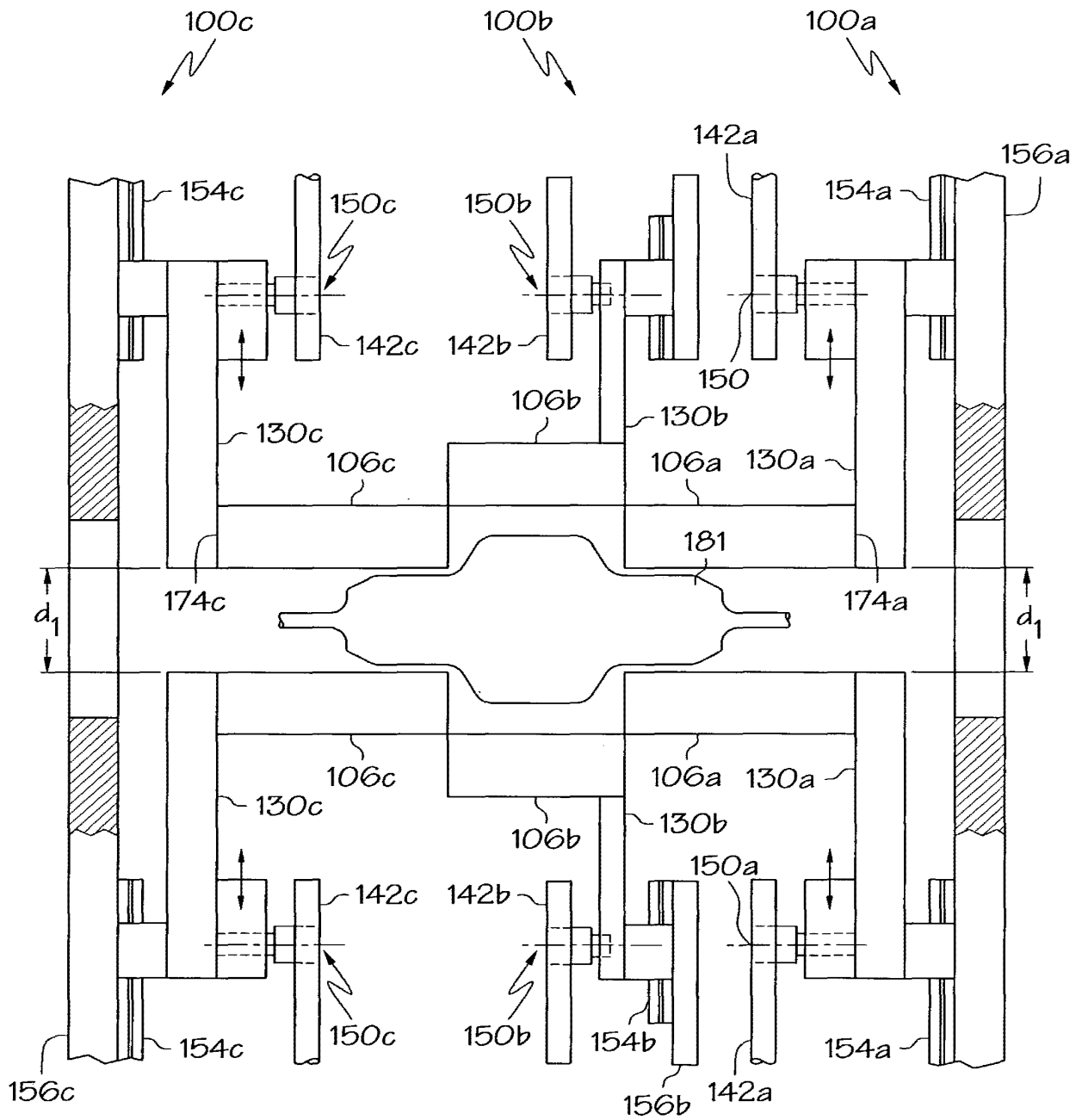


FIG. 13

add 2

CLAIMS:

What is claimed is:

1. An apparatus for reducing in size a medical device comprising:
at least three coupled movable blades disposed about a reference circle to
5 form an aperture whose size may be varied, the aperture capable of being sized to
contain the medical device,
each blade in communication with an actuation device which is capable
of moving the blade to alter the size of the aperture,
wherein each blade includes a single radial point which
10 a) lies on a radial line of the reference circle prior to movement of
the blade, and
b) may be moved only along the radial line of the reference circle
on movement of the blade.
2. The apparatus of claim 1 wherein the blades are constructed and arranged to
15 form a shrinkable polygonal aperture.
3. The apparatus of claim 1 wherein the blades are constructed and arranged to
form a substantially circular aperture.
4. The apparatus of claim 1 wherein the actuation device comprises
20 a cam, and
a plurality of linear slide devices,
each of the linear slide devices in mechanical communication
with the cam,
and each blade is mounted to a linear slide device,
each linear slide device movable along an axis parallel to the radius on which the
25 radial point of the blade lies.
5. The apparatus of claim 1 comprising from 4 to 16 blades.
6. The apparatus of claim 5 comprising 8 blades.
7. The apparatus of claim 1 wherein the blades are disposed about a reference tube
to form a tubular aperture whose size may be varied, the reference circle lying along the
30 reference tube,
each blade in communication with an actuation device which is capable
of moving the blade to alter the size of the tubular aperture,
each blade includes a single line which

- a) lies on the circumference of the reference tube prior to movement of the blade, and
- b) may be moved only along a radial plane of the reference tube on movement of the blade.

5 8. The apparatus of claim 7 wherein the reference tube is a cylinder.

9. The apparatus of claim 1 in combination with a medical device which may be reduced in size, the medical device selected from the group consisting of stents, grafts stent-grafts and vena cava filters.

10 10. The apparatus of claim 1 wherein each blade has an inner end and an outer end, the inner end being beveled to form a tip.

11. The apparatus of claim 13 wherein the single radial point on each blade is at the tip of the blade

12. An apparatus for applying a radial inward force to a medical device comprising:
at least three coupled movable blades disposed about a reference circle to
15 form an aperture whose size may be varied, the aperture capable of being sized to contain the medical device,

each blade in communication with an actuation device which is capable of moving the blade to alter the size of the aperture,

wherein each blade includes a single radial point which

20 a) lies on the circumference of the reference circle prior to movement of the blade, and

b) may be moved only along a radius of the reference circle on movement of the blade.

13. The apparatus of claim 12 with a medical device selected from the group
25 consisting of stents, grafts, stent-grafts and vena cava filters disposed in the aperture.

14. The apparatus of claim 13 wherein the medical device is disposed about a catheter.

15. An apparatus for crimping a medical device comprising:
at least three coupled movable blades disposed about a reference circle to
30 form an aperture whose size may be varied, the aperture capable of being sized to contain the medical device,

each blade in communication with an actuation device which is capable of moving the blade to alter the size of the aperture,

wherein each blade includes a single radial point which

- a) lies on the circumference of the reference circle prior to movement of the blade, and
- b) may be moved only along a radius of the reference circle on movement of the blade.

5

16. A method of manipulating a medical device comprising the steps of:

providing a medical device;

providing at least three blades capable of applying a radial inward force, the

blades disposed about a reference circle to form a shrinkable aperture;

10

placing the medical device into the shrinkable aperture;

simultaneously moving the blades inward to apply a radial inward force to the medical device;

wherein the blades are constructed and arranged such that each blade has a single point which

15

- a) lies on the circumference of the reference circle prior to movement of the blade, and

- b) is moved along a radius of the reference circle on movement of the blade.

20

17. The method of claim 16 wherein the medical device is selected from the group consisting of stents, stent-grafts, grafts and vena cava filters.

18. The method of claim 17 wherein the medical device is reduced in size.

19. The method of claim 17 wherein the medical device is characterized by a diameter and the diameter is reduced in size.

20. The method of claim 17 wherein the medical device is disposed about a catheter.

25

21. The method of claim 17 wherein the medical device is disposed about a balloon which is disposed about a catheter.

22. The method of claim 20 wherein a sufficient radial inward force is applied to crimp the medical device to the catheter.

30

23. The method of claim 21 further comprising the steps of:

simultaneously moving the blades outward; and

removing the medical device from the aperture.

24. A method of molding a balloon comprising the steps of:

providing a balloon preform;

providing at least three movable blades disposed about a reference tube to form a shrinkable tubular aperture, wherein the blades are constructed and arranged such that each blade has a single line which

- 5 a) lies on the surface of the reference tube prior to movement of the blade, and
 b) is moved along a radial plane of the reference tube on movement of the blade;

placing the balloon preform into the shrinkable aperture;

providing an inflation fluid; and

- 10 inflating the balloon preform so that the preform contacts the blades.

25. The method of claim 24 wherein the balloon is heated during the inflating step to form a balloon.

26. The method of claim 25 wherein the inflation fluid is removed from the formed balloon and the balloon is removed from the aperture.

ADD C27

CLAIMS:

What is claimed is:

1. An apparatus for reducing in size a medical device comprising:
at least three coupled movable blades disposed about a reference circle to
5 form an aperture whose size may be varied, the aperture capable of being sized to contain the medical device,
each blade in communication with an actuation device which is capable of moving the blade to alter the size of the aperture,
wherein each blade includes a single radial point which
10 a) lies on a radial line of the reference circle prior to movement of the blade, and
b) may be moved only along the radial line of the reference circle on movement of the blade.
2. The apparatus of claim 1 wherein the blades are constructed and arranged to
15 form a shrinkable polygonal aperture.
3. The apparatus of claim 1 wherein the blades are constructed and arranged to form a substantially circular aperture.
4. The apparatus of claim 1 wherein the actuation device comprises
a cam, and
20 a plurality of linear slide devices,
each of the linear slide devices in mechanical communication with the cam,
and each blade is mounted to a linear slide device,
each linear slide device movable along an axis parallel to the radius on which the
25 radial point of the blade lies.
5. The apparatus of claim 1 comprising from 4 to 16 blades.
6. The apparatus of claim 5 comprising 8 blades.
7. The apparatus of claim 1 wherein the blades are disposed about a reference tube to form a tubular aperture whose size may be varied, the reference circle lying along the
30 reference tube,
each blade in communication with an actuation device which is capable of moving the blade to alter the size of the tubular aperture,
each blade includes a single line which

- a) lies on the circumference of the reference tube prior to movement of the blade, and
- b) may be moved only along a radial plane of the reference tube on movement of the blade.

- 5 8. The apparatus of claim 7 wherein the reference tube is a cylinder.
9. The apparatus of claim 1 in combination with a medical device which may be reduced in size, the medical device selected from the group consisting of stents, grafts stent-grafts and vena cava filters.
10. The apparatus of claim 1 wherein each blade has an inner end and an outer end,
10 the inner end being beveled to form a tip.
11. The apparatus of claim 13 wherein the single radial point on each blade is at the tip of the blade
12. An apparatus for applying a radial inward force to a medical device comprising:
at least three coupled movable blades disposed about a reference circle to
15 form an aperture whose size may be varied, the aperture capable of being sized to contain the medical device,
each blade in communication with an actuation device which is capable of moving the blade to alter the size of the aperture,
wherein each blade includes a single radial point which
20 a) lies on the circumference of the reference circle prior to movement of the blade, and
b) may be moved only along a radius of the reference circle on movement of the blade.
13. The apparatus of claim 12 with a medical device selected from the group
25 consisting of stents, grafts, stent-grafts and vena cava filters disposed in the aperture.
14. The apparatus of claim 13 wherein the medical device is disposed about a catheter.
15. An apparatus for crimping a medical device comprising:
at least three coupled movable blades disposed about a reference circle to
30 form an aperture whose size may be varied, the aperture capable of being sized to contain the medical device,
each blade in communication with an actuation device which is capable of moving the blade to alter the size of the aperture,

wherein each blade includes a single radial point which

- a) lies on the circumference of the reference circle prior to movement of the blade, and
- b) may be moved only along a radius of the reference circle on movement of the blade.

5

16. A method of manipulating a medical device comprising the steps of:

providing a medical device;

providing at least three blades capable of applying a radial inward force, the blades disposed about a reference circle to form a shrinkable aperture;

10 placing the medical device into the shrinkable aperture;

simultaneously moving the blades inward to apply a radial inward force to the medical device;

wherein the blades are constructed and arranged such that each blade has a single point which

15

- a) lies on the circumference of the reference circle prior to movement of the blade, and

- b) is moved along a radius of the reference circle on movement of the blade.

17. The method of claim 16 wherein the medical device is selected from the group consisting of stents, stent-grafts, grafts and vena cava filters.

20

18. The method of claim 17 wherein the medical device is reduced in size.

19. The method of claim 17 wherein the medical device is characterized by a diameter and the diameter is reduced in size.

20. The method of claim 17 wherein the medical device is disposed about a catheter.

25 21. The method of claim 17 wherein the medical device is disposed about a balloon which is disposed about a catheter.

22. The method of claim 20 wherein a sufficient radial inward force is applied to crimp the medical device to the catheter.

23. The method of claim 21 further comprising the steps of:

30

simultaneously moving the blades outward; and
removing the medical device from the aperture.

24. A method of molding a balloon comprising the steps of:
providing a balloon preform;

providing at least three movable blades disposed about a reference tube to form a shrinkable tubular aperture, wherein the blades are constructed and arranged such that each blade has a single line which

- 5 a) lies on the surface of the reference tube prior to movement of the blade, and
- b) is moved along a radial plane of the reference tube on movement of the blade;

placing the balloon preform into the shrinkable aperture;

providing an inflation fluid; and

- 10 inflating the balloon preform so that the preform contacts the blades.

25. The method of claim 24 wherein the balloon is heated during the inflating step to form a balloon.

26. The method of claim 25 wherein the inflation fluid is removed from the formed balloon and the balloon is removed from the aperture.

Application No. Not Signed
Page 2

Preliminary Amendment
Attorney Docket No. S63.2Q-7405-US03

In the Claims

Please cancel claims 12-15 and 24-26 without prejudice or disclaimer.

In the Drawings

Please enter proposed Figure 1.

REMARKS

Claims 12-15 and 24-26 have been cancelled. These claims were prosecuted in the parent application. Also, the Specification has been amended to reflect the chain of priority. The Title has been amended. Finally, figure 1 has been amended by labeling it as prior art.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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f:\wpwork\bcbl07405us03_pre_20030523.doc

ABSTRACT OF THE DISCLOSURE

Sub **A METHOD FOR CONTRACTING, LOADING OR CRIMPING SELF-
EXPANDING AND ~~BALLOON~~ EXPANDABLE STENT DEVICES**

5 An apparatus for manipulating a medical device is formed of at least
three coupled movable blades which are disposed about a reference circle to form an
aperture whose size may be varied. The aperture capable of being sized to contain a
medical device. Each blade is in communication with an actuation device which is
capable of moving the blade to alter the size of the aperture. Each blade includes a
10 single radial point which a) lies on the circumference of the reference circle prior to
movement of the blade, and b) may be moved only along a radius of the reference circle
on movement of the blade.

FORM PTO-1449 (Modified)

LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S INFORMATION DISCLOSURE
STATEMENT

(Use several sheets if necessary)

Atty Docket No.: S63.2-7405

Serial No.: 09/401,218

Applicant: Michael Austin

Filing Date: September 22, 1999

Group: 3726

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAM'S INIT.		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
<i>mj</i>	BA	96/03092	2/8/96	WO				
	BB	0 630 623 A2	12/28/94	EP				
	BC	0 701 800 A1	3/20/96	EP				
	BD	195 32 288 A1	3/6/97	DE			X	
<i>mj</i>	BE	295 06 654.7	7/20/95	DE			X	
	BF							
	BG							
	BH							
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	BK							
	BL							
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	BN							
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	BQ							
	BR							
	BS							
	BT							
	BU							
	BV							
	BW							
	BX							
	BY							
	BZ							

EXAMINER

DATE CONSIDERED

10/17/03

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.

FORM PTO-1449 (Modified) INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				Atty Docket No.: S63.2-7405		Serial No.: 09/401,218	
Applicant: Michael Austin				Filing Date: September 22, 1999		Group: 3726	

REFERENCE DESIGNATION			U.S. PATENT DOCUMENTS				
EXAM'S INIT.	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	5,026,377	6/25/91	Burton et al.			
	AB	5,087,394	2/11/92	Keith			
	AC	5,270,086	12/14/93	Hamlin			
	AD	5,290,305	3/1/94	Inoue			
	AE	5,304,340	4/19/94	Downey			
	AF	5,334,146	8/2/94	Ozasa			
	AG	5,358,486	10/25/94	Saab			
	AH	5,381,686	1/17/95	Thorup			
	AI	5,411,521	5/2/95	Putnam et al.			
	AJ	5,437,083	8/1/95	Williams et al.			
	AK	5,509,184	4/23/96	Herrero			
	AL	5,591,222	1/7/97	Susawa et al.			
	AM	5,628,754	5/13/97	Shevlin et al.			
	AN	5,630,830	5/20/97	Verbeek			
	AO	5,672,169	9/30/97	Verbeek			
	AP	5,700,285	12/23/97	Myers et al.			
	AQ	5,738,674	4/14/98	Williams et al.			
	AR	5,746,644	5/5/98	Cheetham			
	AS	5,746,764	5/5/98	Green et al.			
	AT	5,749,921	5/12/98	Lenker et al.			
	AU	5,766,057	6/16/98	Maack			
	AV	5,766,203	6/16/98	Imran et al.			
	AW	5,810,871	9/22/98	Tuckey et al.			
	AX	5,836,952	11/17/98	Davis et al.			
	AY	5,836,965	11/17/98	Jendersee et al.			
	AZ	5,860,966	1/19/99	Tower			
AAA	5,893,852	4/13/99	Morales				
AAB	5,893,867	4/13/99	Bagaoisan et al.				

EXAMINER:	DATE CONSIDERED: 10/17/03
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EXAMINER: Initial citation considered. Draw line through citation if not 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 (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		ATTY DOCKET NO: S63.2-7405 APPLICANT: Michael Austin FILING DATE: September 22, 1999		Serial No: 09/401,218 Group: 3726	
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REFERENCE DESIGNATION		U.S. PATENT DOCUMENTS					
EXAM'S INIT.	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
MAJ	AA	4,413,989	11/8/83	Schjeldahl et al.	604	96	
	AB	4,456,000	6/26/84	Schjeldahl et al.	128	1	
	AC	4,490,421	12/25/84	Levy	428	35	
	AD	4,906,244	3/6/90	Pinchuk et al.	606	194	
	AE	5,108,415	4/28/92	Pinchuk et al.	606	194	
	AF	5,156,612	10/20/92	Pinchuk et al.	606	194	
	AG	5,163,989	11/17/92	Campbell et al.	65	110	
	AH	5,183,085	2/2/93	Timmermans	140	89	
	AI	5,546,646	8/20/96	Williams et al.	29	407.08	
	AJ	5,626,604	5/6/97	Cottone, Jr.	606	198	
	AK	5,725,519	3/10/98	Penner et al.	606	1	
	AL	5,792,415	8/11/98	Hijkema	264	530	
	AM	5,807,520	9/15/98	Wang et al.	264	520	
	AN	5,810,873	9/22/98	Morales	606	198	
	AO	5,911,752	6/15/99	Dustrude et al.	623	1	
	AP	RE 32,983	7/11/89	Levy	428	36.92	
AQ	RE 33,561	3/26/91	Levy	428	36.92		

FOREIGN PATENT DOCUMENT OR PUBLISHED FOREIGN PATENT APPLICATION								
		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY CODE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
WJ	BA	97/20593	12/6/97	WO				
	BB	98/19633	14/5/98	WO				
	BC							
	BD							
	BE							

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
WJ	CA	Hawley's Condensed Chemical Dictionary, pg 873, 1993.
	CB	

EXAMINER <i>Man</i>	DATE CONSIDERED 10/17/03
---------------------	--------------------------

EXAMINER: Initial citation considered. Draw line through citation if not 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 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				ATTY DOCKET NO.: S63.2-7405		SERIAL NO.: 09/401,218	
APPLICANT: Austin				FILING DATE: September 22, 1999		GROUP: 3726	

REFERENCE DESIGNATION				U.S. PATENT DOCUMENTS			
EXAM'S INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>mg</i>	AA	2,751,077	6/19/56	A. Latin et al.	207	4	
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						

RELATED APPLICATIONS					
		APPLICATION NO.	FILING DATE	INVENTOR(S)	RELATED BY
					SUBJECT PRIORITY (\$120)
	BA				
	BB				

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	CA						
	CB						
	CC						
	CD						

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
	DA	
	DB	
	DC	

EXAMINER: <i>Mac</i>	DATE CONSIDERED: <i>10/17/03</i>
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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.

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				ATTY DOCKET NO.: S63.2-7405		APPLICATION NO.: 09/401,218	
				APPLICANT: Michael Austin			
				FILING DATE: September 22, 1999		GROUP: 3726	

REFERENCE DESIGNATION		U.S. PATENT AND PUBLISHED APPLICATION DOCUMENTS				
EXAMINER'S INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE IF APPROPRIATE	
	AA					
	AB					
	AC					
	AD					
	AE					
	AF					
	AG					
	AH					
	AI					
	AJ					
	AK					
	AL					

FOREIGN PATENT DOCUMENTS				
DOCUMENT NUMBER	DATE	COUNTRY		
BA 935 952 A2	8/18/99	EPO		
BB				
BC				
BD				
BE				

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
CA		
CB		
CC		

EXAMINER <i>Man</i>	DATE CONSIDERED 12/17/03
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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.

Modified Form 1449 UNPUBLISHED US APPLICATIONS NOT RELATED BY PRIORITY (COPIES ENCLOSED)		ATTY DOCKET NO.:		APPLICATION NO.	
		APPLICANT:			
		FILING DATE:		GROUP:	
UNPUBLISHED US APPLICATIONS NOT RELATED BY PRIORITY					
EXAM'S INIT		APPLICATION NO.	FILING DATE	INVENTOR(S)	
	DA				
	DB				
	DC				
	DD				
	DE				
	DF				
EXAMINER			DATE CONSIDERED		
EXAMINER: Initial if application 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.					

Modified Form 1449 US APPLICATIONS RELATED BY PRIORITY (COPIES NOT ENCLOSED)		ATTY DOCKET NO.: S63.2-10142		APPLICATION NO. 09/966,686		
		APPLICANT: Austin				
		FILING DATE: October 1, 2001		GROUP: 3726		
US APPLICATIONS RELATED BY PRIORITY						
EXAM'S INIT		APPLICATION NO.	FILING DATE	PATENT NO.	INVENTOR(S)	FORM 1449/892 ENC
<i>my</i>	EA	09/401,218	9/22/1999		Austin	X
	EB					
	EC					
	ED					
	EE					
	EF					
	EG					
EXAMINER <i>Mark J...</i>			DATE CONSIDERED 10/17/03			
EXAMINER: Initial if application 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.						

Applicant requests that any copies of unpublished US applications submitted herewith be excluded from the file wrapper pursuant to 37 C.F.R. §1.14.

1 of 1