


PATENT NUMBER
6261291



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<p><i>DMF</i> O.I.P.E.</p> <p>SCANNED <u><i>JET</i></u> Q.A. <u><i>mc</i></u></p>	<p>PATENT DATE</p> <p>JUL 17 2001</p>
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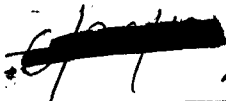
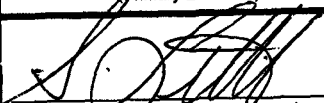
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ISSUING CLASSIFICATION

ORIGINAL		CROSS REFERENCE(S)						
CLASS	SUBCLASS	CLASS	SUBCLASS	CLASS (ONE SUBCLASS PER BLOCK)				
606	69	606	71	73				
INTERNATIONAL CLASSIFICATION								
A61B	17/90							

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03/16/01 Formal Drawings (7 sheets) 1-01/23/01

<input type="checkbox"/> TERMINAL DISCLAIMER	DRAWINGS			CLAIMS ALLOWED	
	Sheets Drwg. 7	Figs. Drwg. 17	Print Fig. 2	Total Claims 28	Print Claim for O.G. 1
<input type="checkbox"/> a) The term of this patent subsequent to _____ (date) has been disclaimed.	 _____ (Assistant Examiner)			NOTICE OF ALLOWANCE MAILED  10/23/00	
<input type="checkbox"/> b) The term of this patent shall not extend beyond the expiration date of U.S Patent. No. _____	_____ MICHAEL BUIZ SUPERVISORY PATENT EXAMINER GROUP 3300 _____ (Primary Examiner)			ISSUE FEE Amount Due 6205 Date Paid 1/23/01	
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PATENT APPLICATION



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INITIALS */*

CONTENTS

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1. Application	papers.		
2.	IDS	2-15-00	
3.	NOA	06/28/00	
4.	PPA	8-21-00	
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FEE DETERMINATION	Smc	71002	7/20/99
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FORMALITY REVIEW		104853	8/15/99

INDEX OF CLAIMS

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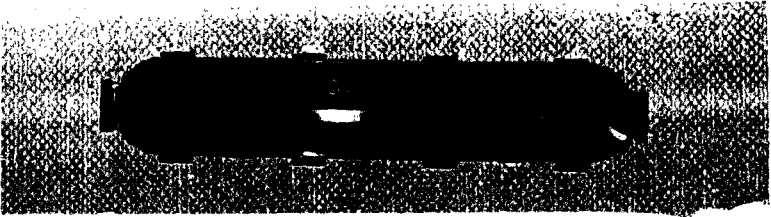
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Class	Sub.	Date	Exmr.
606	60, 63 66, 68 70, 71 72, 73 86	6/16/00	2R
Updated		10/20/00	2R

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
Are Areas SEARCHED		6/16/00	2R
Updated		10/20/00	2R

SEARCH NOTES
(INCLUDING SEARCH STRATEGY)

	Date	Exmr.
None.	6/15/00	3R
Consulted Examiner REP TC 3700		



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(12) **United States Patent**
Talaber et al.

(10) **Patent No.:** **US 6,261,291 B1**
(45) **Date of Patent:** ***Jul. 17, 2001**

(54) **ORTHOPEDIC IMPLANT ASSEMBLY**

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(*) **Notice:** This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(52) **U.S. Cl.** **606/69; 606/71; 606/73**
(58) **Field of Search** **606/60, 63, 66,**
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Primary Examiner—Michael Buiz

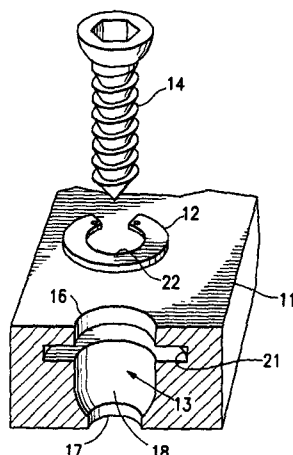
Assistant Examiner—William Lewis

(74) *Attorney, Agent, or Firm*—Heller Ehrman White & McAuliffe LLP

(57) **ABSTRACT**

An orthopedic implant assembly comprising a stabilizing element, a securing element which attaches the stabilizing element to the bone, and a stopping member in the stabilizing element which inhibits the securing element from loosening or backing out of the bone. The stabilizing element has at least one bore with the stopping member therein. In one embodiment, the stopping member has a reversibly expandable inner and outer diameter to allow the securing element to pass posteriorly through the stopping member, but thereafter prevent or inhibit the securing element from anteriorly backing out of the posterior section of the transverse passageway. In another embodiment, the stopping member is secured to an anterior section of the transverse passageway, and the head of the securing element generally has a compressed configuration with a diameter less than the diameter of the stopping member, in which configuration the head can pass through the stopping member, and an uncompressed configuration with a diameter larger than the diameter of the stopping member.

28 Claims, 7 Drawing Sheets



US 6,261,291 B1

Page 2

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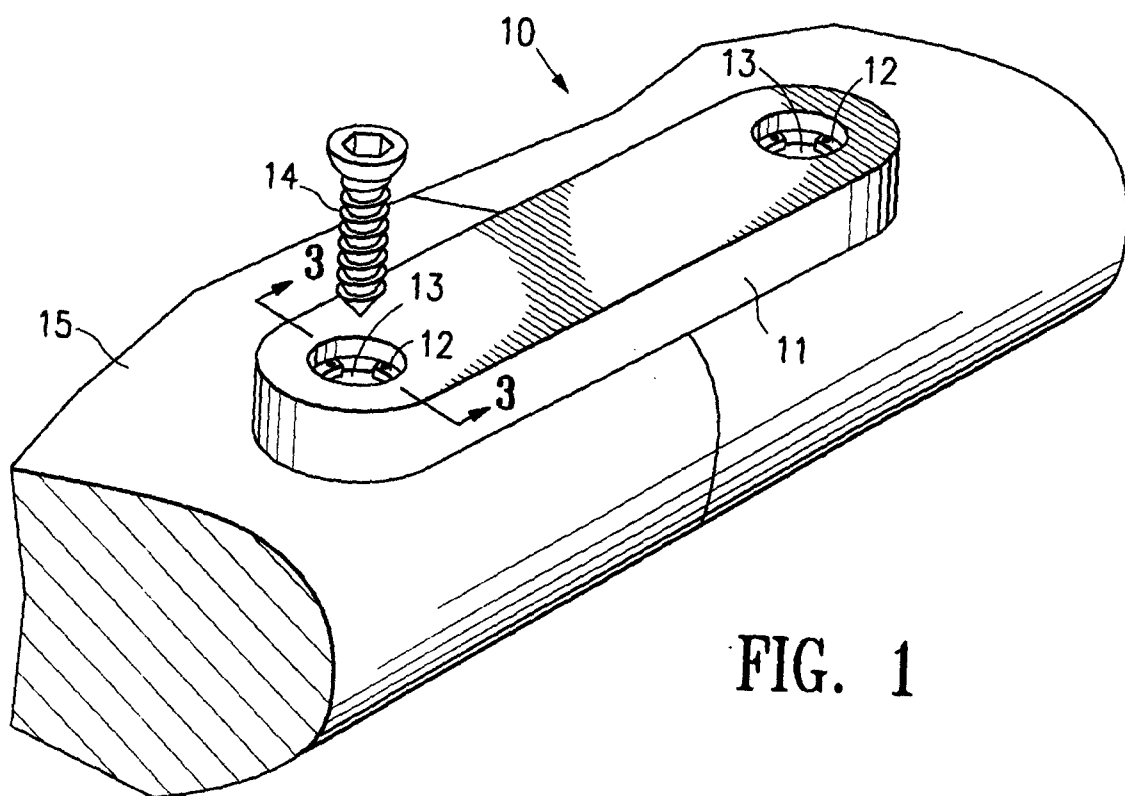
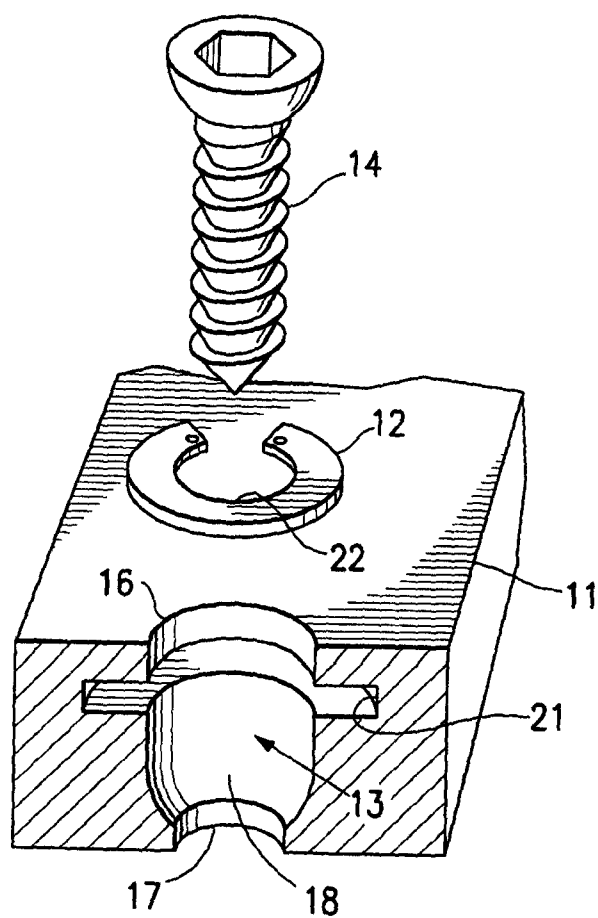


FIG. 1

FIG. 2



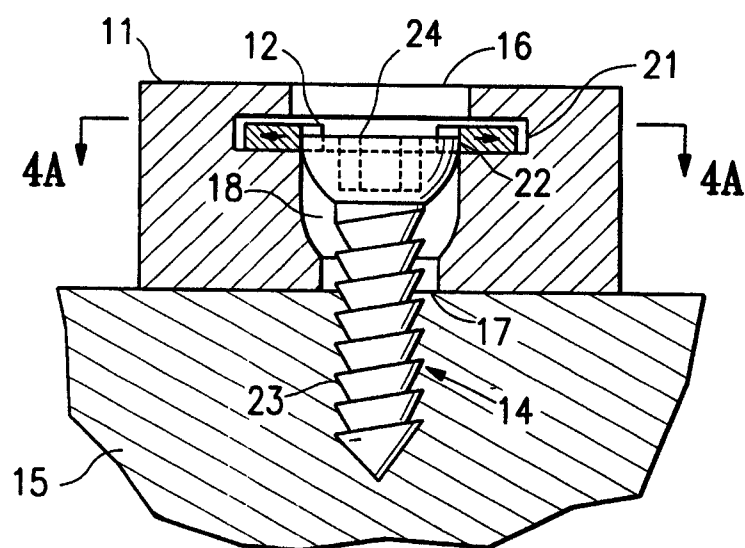


FIG. 4

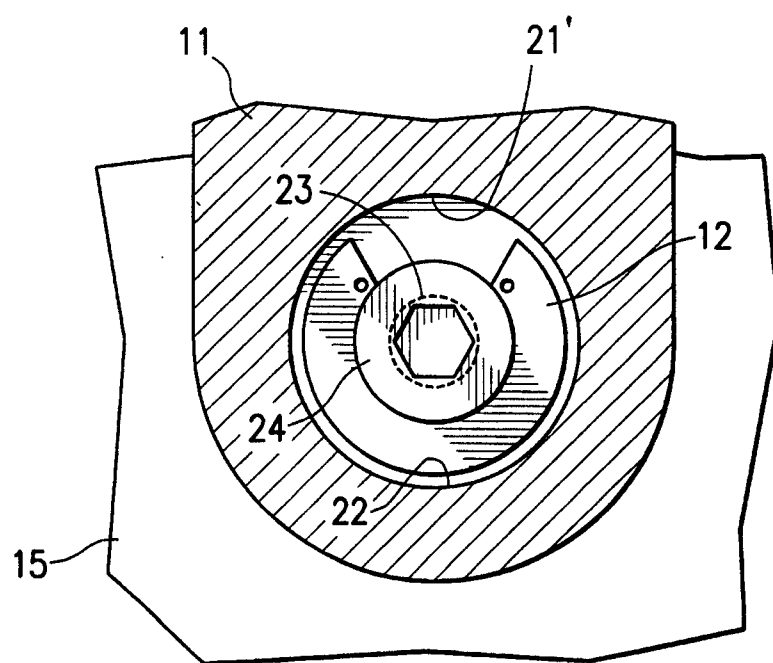


FIG. 4A

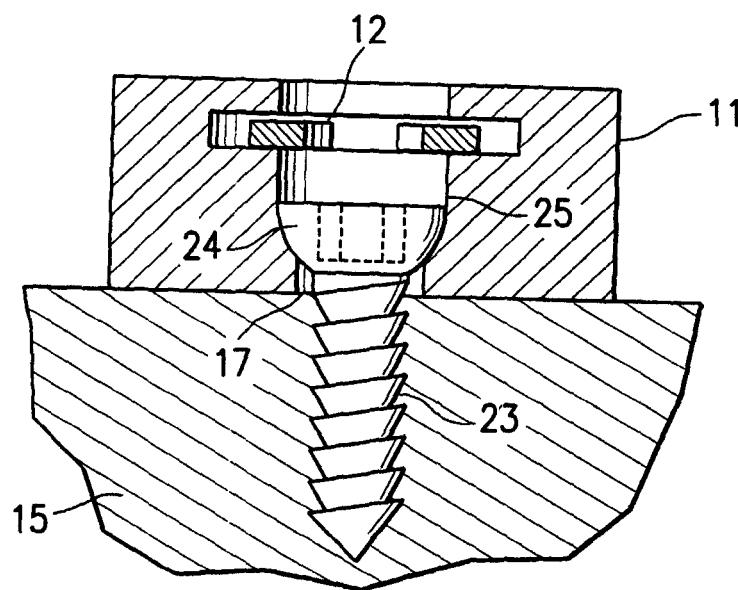


FIG. 5

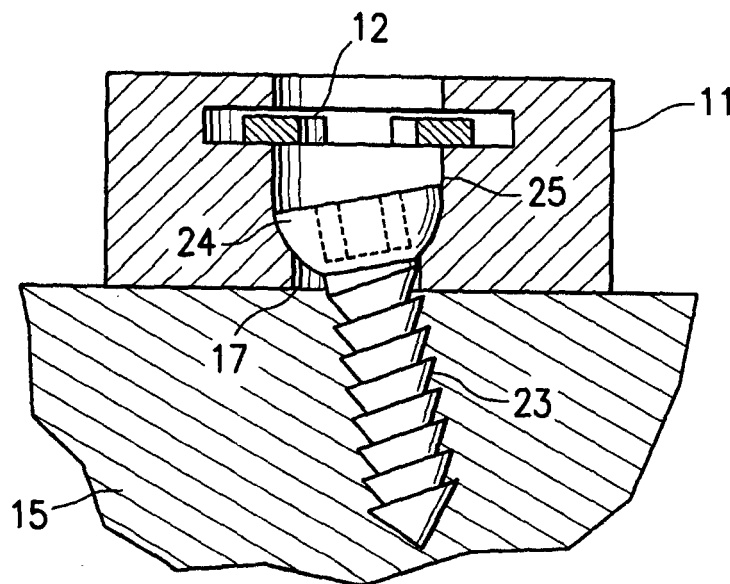


FIG. 6

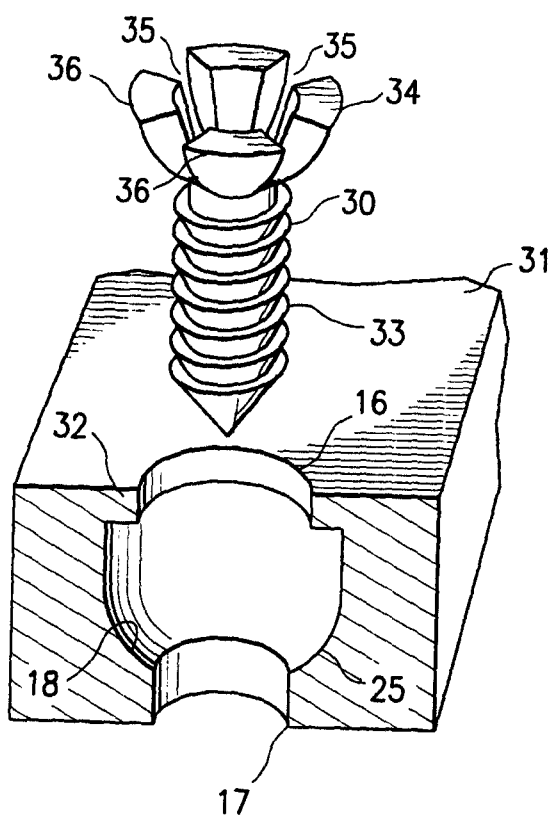


FIG. 7

FIG. 9

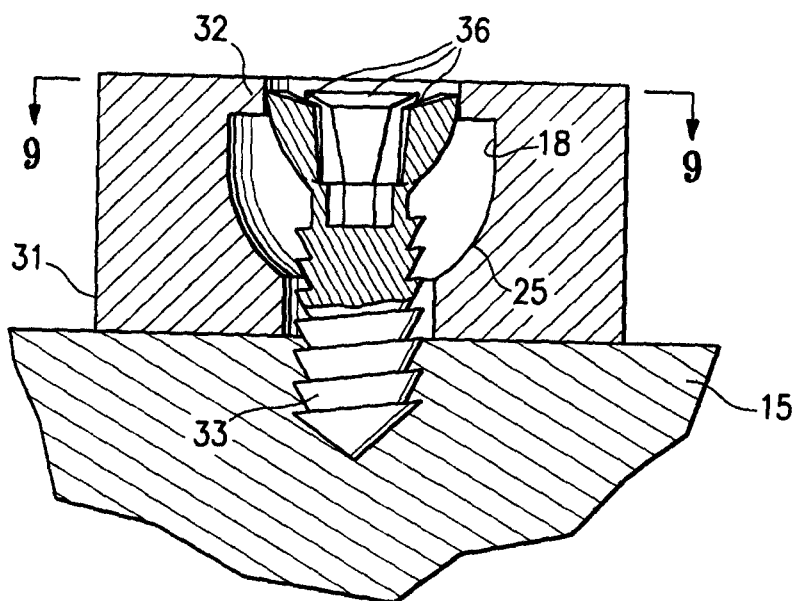
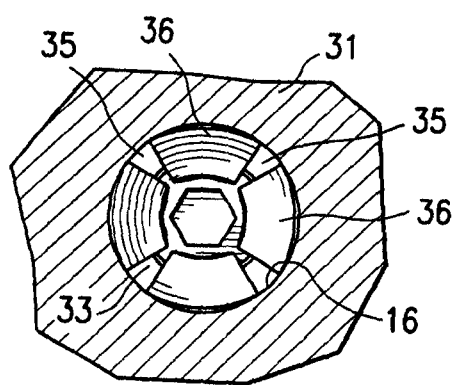


FIG. 8

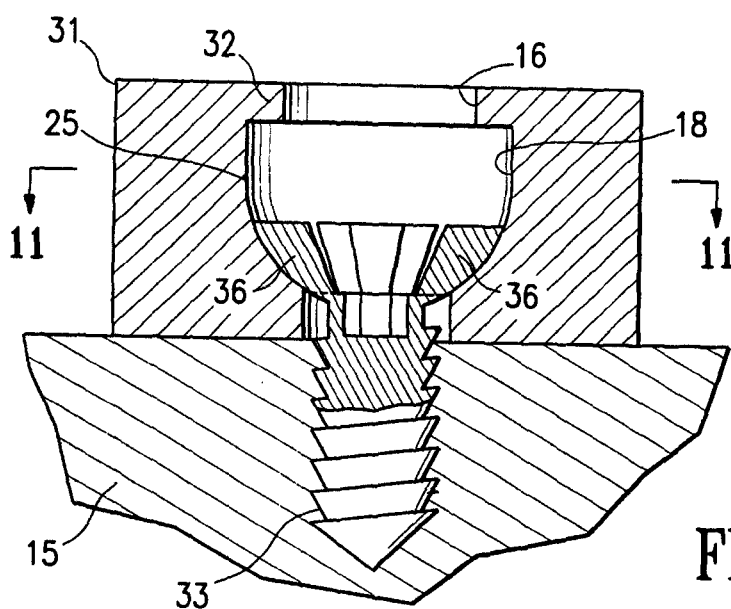


FIG. 10

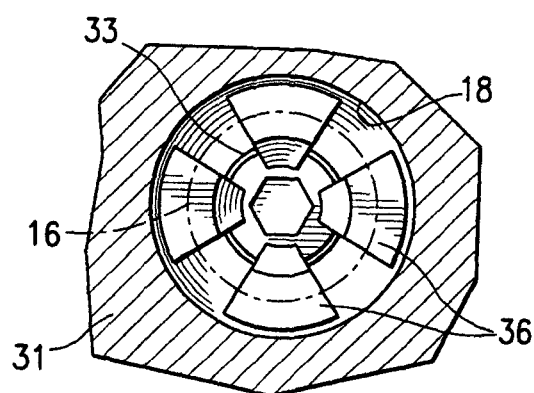


FIG. 11

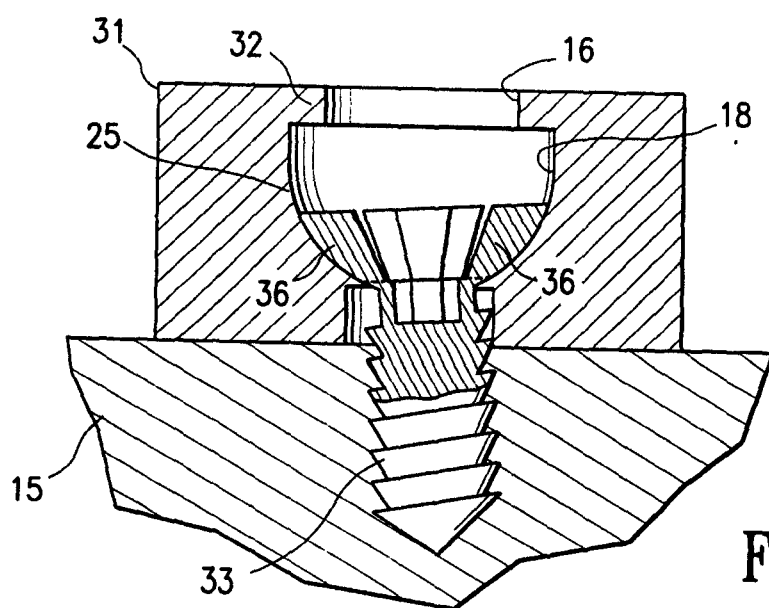


FIG. 12

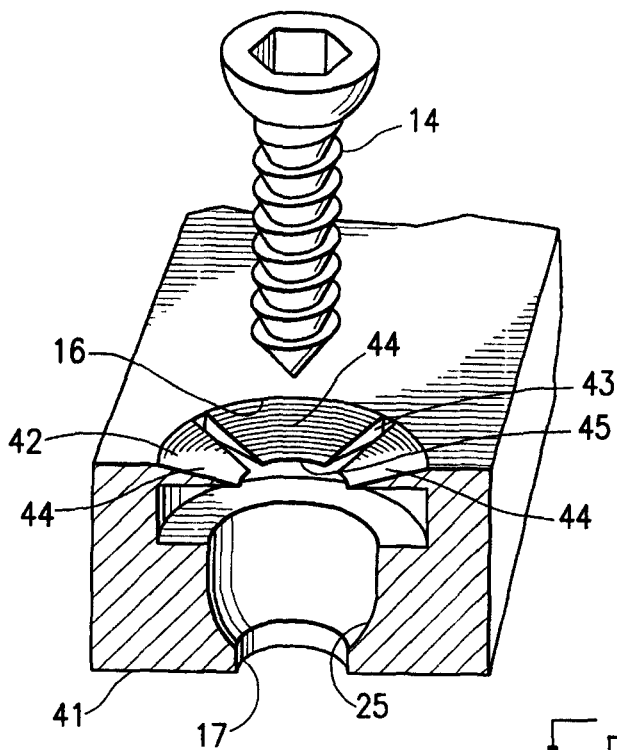


FIG. 13

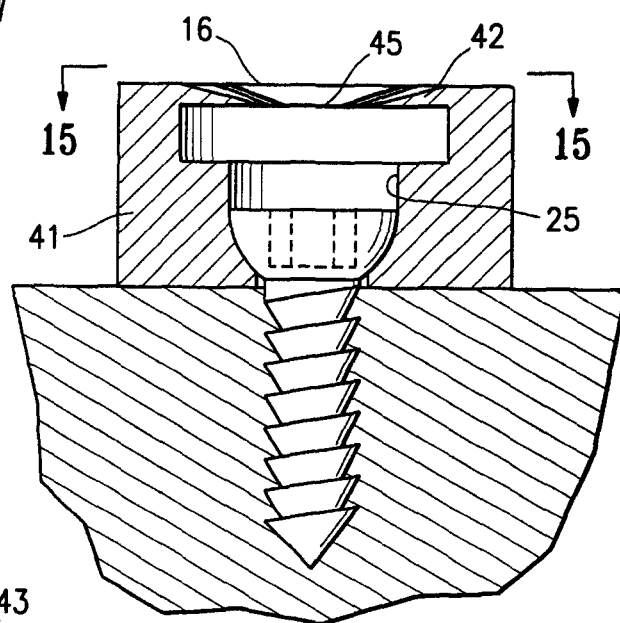


FIG. 14

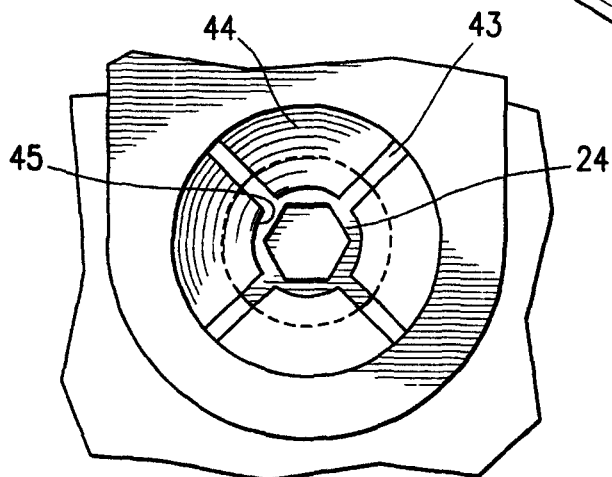


FIG. 15

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ORTHOPEDIC IMPLANT ASSEMBLY**BACKGROUND OF THE INVENTION**

This invention generally relates to the field of medical devices, and particularly to an orthopedic implant for joining bone segments and methods of use thereof.

A variety of medical conditions may necessitate the joining of bone segments together, as for example, in the treatment of broken bones, spinal disorders, or the fusion of vertebrae following the removal of a spinal disk. Orthopedic implants used to join bone segments include rods, plates, and screws. In the case of rods and plates, the implants have been attached to the bone using a variety of methods including cementing and screwing the implant to the bone. The bone is typically drilled out to receive the screw therein, or to receive an anchor having a hollow shank which fixedly receives the screw therein. However, one disadvantage has been the tendency of the implants to loosen or detach from the bone over time.

It would be a significant advance to provide an orthopedic implant for joining bone segments together which durably and securely attaches to the bone.

SUMMARY OF THE INVENTION

This invention is directed to an orthopedic implant assembly generally comprising a stabilizing element, a securing element which attaches the stabilizing element to the patient's bone, and a stopping member in the stabilizing element which defines at least in part a passageway and which inhibits or prevents the securing element from loosening or backing out of the bone.

The stabilizing element is generally a plate or rod, which has at least one bore therein having a first opening in the anterior surface of the stabilizing element, a second opening in the posterior surface of the stabilizing element, and a transverse passageway extending from the first opening to the second opening. The term posterior should be understood to mean an inner portion of the assembly closer to the bone to which the assembly is attached, and the term anterior should be understood to mean an outer portion of the assembly farther away from the bone.

In one embodiment, the stopping member defines a reversibly expandable passageway, and is biased to the unexpanded, or smaller diameter, passageway configuration. In one embodiment, the biased stopping member comprises an annular collar having a reversibly expandable inner diameter. The biased stopping member may be configured to be positioned in a groove in the transverse passageway after the securing element is in place in the transverse passageway of the stabilizing element. Alternatively, in a presently preferred embodiment, the biased stopping member is configured to allow the securing element to pass posteriorly through the stopping member passageway from the anterior surface of the stabilizing element into a posterior section of the transverse passageway. In another embodiment, the biased stopping member is secured to the stabilizing element within the transverse passageway, and is deflectable. The deflectable stopping member reversibly flexes as the head of the securing element is posteriorly displaced through the deflectable stopping member to expand the passageway defined by the stopping member. The deflectable stopping member is biased to the undeflected or smaller diameter passageway configuration. The stopping member prevents the securing element from anteriorly backing out of the posterior section of the transverse passageway. As a result, the securing element durably attaches the stabilizing element to the bone.

2

The securing element is configured to attach to bone, and generally comprises an elongated body and a head at one end of the body and integral therewith. The term integral should be understood to mean the securing element is a one-piece unit, with the head secured to the body so that there is no relative movement between the head and the body. In one embodiment, the securing element is selected from the group consisting of screws, pins, and nails. In a presently preferred embodiment where the collar is seated within the groove in the stabilizing element before the securing element is advanced therein, the head of the securing element has a shaped posterior surface which contacts the collar and gradually expands the collar as the head is displaced into the posterior section of the transverse passageway of the stabilizing element. In a presently preferred embodiment, the head of the securing element has a curved posterior surface. However, other suitable shapes may be used including tapered posterior surfaces.

The invention also includes methods of attaching an orthopedic implant assembly to a bone of a patient. The bone is typically prepared for receiving the body of the securing element, as for example by drilling a cavity into the bone, and/or tapping the cavity. A method generally comprises positioning the posterior surface of the stabilizing element against the surface of the bone, with the stopping member within the groove of the stabilizing element in the unexpanded configuration, introducing the body of the securing element into the transverse passageway, posteriorly displacing the head of the securing element through the stopping member and thereby expanding the stopping member, and attaching the stabilizing element to the bone by advancing the head of the securing element posteriorly of the stopping member so that the stopping member contracts and returns to a smaller transverse, i.e., unexpanded diameter, configuration. The head of the securing element is positioned within a posterior section of the transverse passageway between the stopping member and the second opening in the stabilizing element, and the body of the securing element is positioned within the patient's bone. In an alternative embodiment, the stopping member may be placed within the groove after the head of the securing element is positioned within the posterior section of the transverse passageway. The stabilizing element is attached to the bone by the securing element, which is attached to the bone and retained within the transverse passageway.

In another embodiment of the invention, the head of the securing element can be reversibly compressed, and the stopping member is secured to an anterior section of the transverse passageway. The stopping member defines a passageway with a fixed diameter, but the compressed configuration of the head of the securing element has a diameter less than the diameter of the stopping member so that the head can pass through the stopping member passageway. In the uncompressed configuration, the head of the securing element has a diameter larger than the diameter of the stopping member and the diameter of the second opening in the stabilizing element, so that the head can be advanced posteriorly of the stopping member and retained within the transverse passageway between the stopping member and the second opening.

To facilitate the correct placement of the orthopedic implant assembly on the bone, the transverse passageway between the collar and the second opening in the stabilizing element may be configured so that the securing element may be angularly displaceable therein and the body of the securing element may be positioned at an angle within the patient's bone.

3

In the assembly of the invention, the securing element is prevented from backing out of the bone by the interaction of the securing element head and the stopping member. As a result, a separate anchor means implanted in the bone to receive the screw is not required, and the resulting loss of bone and intraoperative time required to implant the anchor is avoided. Moreover, in a preferred embodiment, the stopping member is within the transverse passageway at the beginning of the procedure, so that the surgeon can attach the implant assembly to the bone with the single motion of advancing the securing element through the stopping member passageway and into the bone. The implant assembly of the invention thus reduces the time required to attach the assembly to the bone and provides improved implant performance.

The orthopedic implant assembly of the invention can be durably attached to bone, and the securing element prevented from significantly backing out of the bone due to the head of the securing element being retained within the stabilizing element. These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view of an orthopedic implant assembly which embodies features of the invention.

FIG. 2 is an exploded view, partially in section, of the orthopedic implant assembly shown in FIG. 1.

FIG. 3 is a cross section of the orthopedic implant assembly shown in FIG. 1 taken along lines 3—3.

FIG. 3A is a transverse cross section of the orthopedic implant assembly shown in FIG. 3 taken along lines 3A—3A.

FIG. 4 illustrates the orthopedic implant assembly shown in FIG. 3, as the securing element is being advanced into the patient's bone.

FIG. 4A is a transverse cross section of the assembly shown in FIG. 4, taken along lines 4A—4A.

FIG. 5 illustrates the orthopedic implant assembly shown in FIG. 3, with the securing element advanced into the posterior section of the transverse passageway of the stabilizing element.

FIG. 6 illustrates the orthopedic implant assembly shown in FIG. 3, with the securing element angularly disposed within the patient's bone.

FIG. 7 is an exploded view, partially in section, of an orthopedic implant assembly having a securing element with a compressible head, which embodies features of the invention.

FIG. 8 illustrates the orthopedic implant assembly shown in FIG. 7 as the securing element is being advanced into the patient's bone.

FIGS. 9 is a transverse cross section of the assembly shown in FIG. 8, taken along lines 9—9.

FIG. 10 illustrates the orthopedic implant assembly shown in FIG. 7 with the securing element advanced into the posterior section of the transverse passageway of the stabilizing element.

FIG. 11 is a transverse cross section of the assembly shown in FIG. 10, taken along lines 11—11.

FIG. 12 illustrates the orthopedic implant assembly shown in FIG. 7, with the securing element angularly disposed within the patient's bone.

4

FIG. 13 is an exploded view, partially in section, of an orthopedic implant assembly having a deflectable stopping member, which embodies features of the invention.

FIG. 14 illustrates the orthopedic implant assembly shown in FIG. 13 with the securing element advanced into the posterior section of the transverse passageway of the stabilizing element.

FIGS. 15 is a plan view of the assembly shown in FIG. 14, taken along lines 15—15.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 illustrates one embodiment of the orthopedic implant assembly 10 of the invention, generally including a stabilizing element 11, with a biased stopping member 12 in a bore 13 therein, and a securing element 14, configured for securing to a patient's bone 15. In the embodiment illustrated in FIG. 1, the biased stopping member comprises an annular collar, although a variety of suitable members may be used, as for example, one or more contractible fingers biased to extend into the transverse passageway (not shown).

As best illustrated in FIG. 2 showing an exploded, partially in section, view of the assembly shown in FIG. 1, the bore 13 of the stabilizing element has a first opening 16 in an anterior surface of the stabilizing element, a second opening 17 in a posterior surface of the stabilizing element, a transverse passageway 18 extending therein, and a groove 21 in an anterior portion of the transverse passageway. Annular collar 12 defines a passageway 22, and is configured to be seated within the groove 21, and has a reversibly expandable inner and outer diameter. As illustrated in FIG. 3, illustrating the assembly shown in FIG. 1 partially in section taken along lines 3—3, and FIG. 3A illustrating a transverse cross sectional view of the assembly shown in FIG. 3 taken along lines 3A—3A, the annular collar 12 is biased to an unexpanded outer diameter which is less than the diameter of the groove and greater than the diameter of the transverse passageway, so that the collar seats within the groove. The expanded outer diameter of the collar is less than the diameter of the groove, and the height of the collar is less than the height of the groove, so that the collar can be expanded therein.

The securing element 14 has an elongated body 23 and an integral head 24 secured to one end of the body 23. In a presently preferred embodiment of the invention illustrated in FIG. 1, the securing element comprises a screw. The head of the securing element is configured to be posteriorly displaceable through the passageway 22 of the collar seated within the groove, from an anterior to a posterior surface of the collar, and retained within a posterior section 25 of the transverse passageway 18 between the posterior surface of the collar 12 and the second, i.e., posterior, opening 17 in the stabilizing element. In the embodiment illustrated in FIG. 1, the head of the securing element has a curved posterior surface 26 with a convex shape and with a smaller diameter than an anterior surface of the head. The curved posterior surface 26 has a minimum outer diameter which is smaller than the unexpanded inner diameter of the collar, and which is positionable within the passageway of the collar, to contact and expand the collar as the head is displaced posteriorly therein.

FIGS. 3—5 illustrate the attachment of the assembly to the patient's bone. As illustrated in FIG. 3, the stabilizing element is positioned against a surface of a bone 15, and the posterior end of the body of the securing element 14 is

5

placed within the stabilizing element transverse passageway. The head 24 of the securing element is posteriorly advanced within the passageway 22 of the collar 12, thereby applying a radially expanding force against an inner surface of the collar to expand the inner diameter of the collar, as illustrated in FIG. 4 showing the expanded collar and the head of the securing element partially displaced through the collar passageway. Arrows in FIG. 4 illustrate the expansion of the collar as the head of the securing element is passed there-through. FIG. 4A illustrates a transverse cross section of the assembly shown in FIG. 4, taken along lines 4A—4A. The expanded inner diameter of the collar is therefore larger than the maximum diameter of the head of the securing element, to allow the head of the securing element to pass posteriorly through the collar. The head of the securing element is advanced posteriorly of the collar and into the posterior section 25 of the transverse passageway, so that the collar returns to the unexpanded configuration having an unexpanded inner diameter smaller than the maximum diameter of the head of the securing element, as illustrated in FIG. 5. In the embodiment illustrated in FIG. 5, the flat anterior surface of the head of the securing element has a diameter which is larger than the unexpanded inner diameter of the collar, and the posterior surface of the collar is perpendicular to the longitudinal axis of the transverse passageway. Thus, the anterior surface of the head will butt up against the posterior surface of the collar without expanding the collar, to prevent the securing element from being anteriorly displaced out of the posterior section of the transverse passageway. In the embodiment illustrated in the FIG. 5, a posterior portion of the transverse passageway is curved to conform to the curved posterior surface of the head, providing maximum contact between the securing element and the stabilizing element. The curved surfaces of the posterior portion of the transverse passageway and the posterior surface of the head have the same radius of curvature, and the diameter of the curved surface of the head is large enough so that the wall defining the transverse passageway contacts the head around the circumference of the curved posterior surface of the head, but is small enough so that the head can be displaced within the transverse passageway. With the head of the securing element positioned within the posterior section 25 of the transverse passageway, the body of the securing element is embedded in, and secured to, the bone of the patient.

In the embodiment illustrated in FIG. 5, the posterior section 25 of the transverse passageway is sufficiently longer than the head 24 of the securing element so that the head can be displaced anteriorly and posteriorly, and is thus longitudinally displaceable within the posterior section of the transverse passageway. Additionally, the body of the securing element 23 has a smaller diameter than the diameter of the second opening 17 in the stabilizing element, and can be displaced from side to side, i.e., medial-lateral displacement, within the second opening 17. As a result, the securing element is angularly displaceable within the transverse passageway posterior section 25 between the collar 12 and the second opening 17 in the stabilizing element, as illustrated in FIG. 6. The securing element can thus be tilted within the transverse passageway at an angle relative to the transverse passageway longitudinal axis, to facilitate positioning the securing element at a desired location in the bone by advancing the body of the securing element within the bone at an angle relative to the surface of the bone. The securing element can be angularly displaced up to an angle of about 45°, preferably up to about 20° relative the longitudinal axis of the transverse passageway.

6

The stopping member 12 is preferably elastically deformable, and formed of titanium, and superelastic or pseudoelastic materials such as NiTi alloys. The unexpanded inner diameter of the stopping member is about 0.1 to about 40 mm, preferably about 0.5 to about 20 mm, and is about 0.05 to about 20 mm, preferably about 0.1 to about 15 mm less than the maximum transverse dimension of the head of the securing element. The unexpanded outer diameter of the stopping member is about 0.2 to about 50 mm, preferably about 1.0 to about 30 mm. The expanded inner diameter of the stopping member is about 0.15 to about 50 mm, preferably about 0.75 to about 30 mm, and the expanded outer diameter of the stopping member is about 0.5 to about 60 mm, preferably about 1.5 to about 40 mm. The height of the stopping member is about 0.01 to about 5 mm, preferably about 0.05 to about 3 mm.

FIGS. 7–12 illustrate another embodiment of the invention, generally comprising a securing element 30, and a stabilizing element 31 similar to the stabilizing element in the embodiment illustrated in FIG. 1, except the stopping member is not seated within a groove in the transverse passageway 18. Instead, a stopping member 32 is provided at an anterior section of the transverse passageway, which may be formed integrally with the stabilizing element or as a separate member secured thereto. In the embodiment illustrated in FIG. 7, the stopping member is a collar at the anterior end of the transverse passageway and defining the first opening 16 in the stabilizing element 31. The securing element 30 has an elongated body 33, and head 34 secured to one end of the body having a compressed configuration and an uncompressed configuration. In the embodiment illustrated in FIG. 7, the head has a plurality of slots 35 defining circumferentially spaced members 36 having posterior ends secured to the body of the securing element. The circumferentially spaced members 36 have anterior ends radially moveable toward a longitudinal axis of the head to form the compressed configuration, having a diameter less than the inner diameter of the collar. FIG. 8 illustrates the head of the securing element in the compressed configuration within the passageway defined by the collar. FIG. 9 illustrates a transverse cross sectional view of the assembly shown in FIG. 8, taken along lines 9—9. FIG. 10 illustrates the head of the securing element advanced posteriorly of the collar and into the posterior section of the transverse passageway, thereby returning the circumferentially spaced members 36 to the uncompressed configuration by release of the radially compressive force of the collar. FIG. 11 illustrates a transverse cross section of the assembly shown in FIG. 10, taken along lines 11—11, with the first opening 16 shown in phantom. The securing element is angularly and longitudinally displaceable within the transverse passageway posterior section 25, as discussed above with regard to the embodiment illustrated in FIG. 1, and as illustrated in FIG. 12.

FIGS. 13–15 illustrate another embodiment of the invention, generally comprising a stabilizing element 41 similar to the stabilizing element in the embodiment illustrated in FIG. 1, except with a deflectable stopping member 42 provided in an anterior section of the transverse passageway, which may be formed integrally with the stabilizing element or as a separate member secured thereto. In the embodiment illustrated in FIG. 13, the stopping member comprises a collar 42 having a plurality of slots 43 defining circumferentially spaced members 44 and a tapered or sloping anterior surface providing axial flexibility in a posterior direction, so that the collar deflects posteriorly when the head of the securing element is posteriorly dis-

placed through the collar. As a result, the circumferentially spaced members 44 have a wedge shape and a height which tapers towards the central passageway 45 defined by the collar, which facilitates displacing the head of the securing element therethrough and reversibly enlarging the passageway 45. In the embodiment illustrated in FIG. 13, the collar is integrally formed with the stabilizing element 41 at the anterior end of the transverse passageway, and defines the first opening 16 in the stabilizing element 41. The securing element may be the same as, or similar to, the securing element 14 discussed above in connection with the embodiment illustrated in FIG. 1, and as illustrated in FIG. 13. However, securing element 30 having head 34 with a compressed configuration and an uncompressed configuration, as discussed above in connection with the embodiment illustrated in FIG. 7, may also be used. FIG. 15 illustrates a plan view of the assembly shown in FIG. 14, taken along lines 15—15, with the head of the securing element 14 partially in phantom. The angular and longitudinal displacement of the securing member in the posterior section 25 of the transverse passageway is as discussed above.

The stabilizing element is preferably formed of a metal such as titanium or stainless steel. The length of the stabilizing element is typically about 7 to about 300 mm, preferably about 13 to about 200 mm, and the width of the stabilizing element is typically about 5 to about 50 mm, preferably about 10 to about 30 mm. The height of the stabilizing element is typically about 0.5 to about 10 mm, preferably about 1.0 to about 6.0 mm although the dimensions of the stabilizing element will vary depending on the application for which the assembly is to be used.

The securing element is preferably formed of a metal, such as titanium or stainless steel. The head of the securing element is configured, as for example with a hexagonal opening, for releasable connection to a tool for advancing the securing element into the bone. The body of the securing element has a length of about 2 to about 50 mm, preferably about 5 to about 20 mm, and the head of the securing element has a length of about 0.05 to about 1.5 mm, preferably about 0.5 to about 1.0 mm. One skilled in the art will recognize that a variety of suitable securing elements may be used, which may be optimized for use in a particular orthopedic environment, as is well known in the art. For example, a high thread pitch may be used to limit screw back out from bone.

The assembly of the invention is suitable for use in a variety of medical procedures, including securing fractured bone segments or vertebrae following disk removal. In the illustrated embodiments, the stabilizing element comprises a plate, although other suitable elements such as rods may be used. Additionally, the stabilizing element may be shaped to conform to the surface of the bone or bones to which it will be attached. For example, a presently preferred embodiment of the stabilizing element comprises a plate with a concave posterior surface, and is configured for attaching to vertebrae.

While the present invention has been described herein in terms of certain preferred embodiments, those skilled in the art will recognize that modifications and improvements may be made without departing from the scope of the invention. For example, while the stopping member is discussed primarily in terms of a collar, other configurations may also be used. Additionally, while a particular feature may be discussed in connection with one embodiment, it should be understood that features of one embodiment may be used with the other embodiments herein.

What is claimed is:

1. An orthopedic implant assembly, comprising
 - a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening;
 - b) a biased stopping member defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration; and
 - c) a securing element having an elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element.

2. The assembly of claim 1 wherein the biased stopping member comprises a collar defining a passageway, enlargable from an unexpanded inner diameter to an expanded inner diameter, wherein the head of the securing element has a maximum diameter greater than the unexpanded inner diameter of the collar and less than the expanded inner diameter of the collar.

3. The assembly of claim 2 wherein the head of the securing element has a curved posterior surface which has a minimum outer diameter smaller than the unexpanded inner diameter of the collar, configured to be displaceable posteriorly of the collar through the passageway of the collar from an anterior to a posterior surface thereof.

4. The assembly of claim 2 wherein the bore has a groove in an anterior portion of the transverse passageway having a diameter and a height, and wherein the collar is a reversibly expandable annular collar seated in the groove, the collar having an expanded outer diameter, and an unexpanded outer diameter which is less than the diameter of the groove and greater than a diameter of the transverse passageway.

5. The assembly of claim 4 wherein the head of the securing element has a curved posterior surface which has a minimum outer diameter smaller than the unexpanded inner diameter of the collar, and which is configured to contact the collar anterior surface and expand the collar as the head is displaced posteriorly through the collar passageway.

6. The assembly of claim 2 wherein the collar is secured to an anterior section of the transverse passageway, and has a plurality of slots and circumferentially spaced members, the circumferentially spaced members having a deflected configuration defining the expanded inner diameter of the collar.

7. The assembly of claim 6 wherein the head of the securing element has a curved posterior surface which has a minimum outer diameter smaller than the unexpanded inner diameter of the collar, and which is configured to contact the collar anterior surface and deflect the circumferentially spaced members away from a longitudinal axis of the transverse passageway as the head is displaced posteriorly through the collar passageway.

8. The assembly of claim 6 wherein the collar has an anterior surface which tapers toward a center of the transverse passageway.

9. The assembly of claim 3 wherein a posterior portion of the transverse passageway is curved to conform to the curved posterior surface of the head.

11

having a reversibly compressed configuration with a compressed diameter less than a diameter of the first opening and an uncompressed configuration with a diameter greater than the diameter of the stopping member and the second opening, so that the head of the securing element is retained within the transverse passageway between the stopping member and the second opening in the stabilizing element;

- c) positioning the body of the securing element in the transverse passageway and posteriorly advancing the head of the securing element within a passageway defined by the stopping member and thereby compressing the diameter of the head of the securing element; and

12

- d) attaching the stabilizing element to the bone by advancing the head of the securing element posteriorly of the stopping member so that the diameter of the head of the securing element returns to the uncompressed configuration, to position the head within a posterior section of the transverse passageway between the stopping member and the second opening in the stabilizing element and the body of the securing element within the patient's bone, so that the securing element is attached to the bone and is retained within the posterior section of the transverse passageway of the stabilizing element.

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FOREIGN FILING LICENSE GRANTED 08/05/1999				
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Foreign priority claimed 35 USC 119 (a-d) conditions met Verified and acknowledged Examiner's Name Initials		STATE OR COUNTRY WI	SHEETS DRAWINGS 7	TOTAL CLAIMS 28
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TITLE ORTHOPEDIC IMPLANT ASSEMBLY				
FILING FEE RECEIVED \$**491	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:		O All Fees O 1.16 Fees (Filing) O 1.17 Fees (Processing Ext. of Time) O 1.18 Fees (Issue) O Other _____ O Credit _____	

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09/349,519	07/08/99	623	3738	2505-100

APPLICANT

DAVID J. TALABER, LIVERMORE, CA; JAMES R. BROWN, W. M. GROVE, WI.

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****FOREIGN APPLICATIONS*******

VERIFIED

NSWK

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 08/05/99 ** SMALL ENTITY **

Foreign Priority claimed 35 USC 119 (a-d) conditions met	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS
Verified and Acknowledged	<i>2/16</i>		CA	7	22
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TITLE

ORTHOPEDIC IMPLANT ASSEMBLY

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4493		

Application of

David J. Talaber

and

James R. Lloyd

for

UNITED STATES LETTERS PATENT

on

ORTHOPEDIC IMPLANT ASSEMBLY

Sheets of Drawings: Seven (7)
Attorney Docket No.: 25205-1000

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Provisional Application of
David J. Talaber et al.

For: **ORTHOPEDIC IMPLANT ASSEMBLY**

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BOX PATENT APPLICATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

1. Transmitted herewith for filing is the above-identified patent application, consisting of the following parts:

- X Papers required for a filing date under 37 CFR § 1.53(b);
 29 Pages in the specification including:
 18 pages of Description; 10 pages of Claims; 1 page of Abstract;
 7 Sheets of drawings X informal formal;
 X Declaration and Power of Attorney;
 Assignment with Transmittal (PTO-1595);
 X Verified Statement (Declaration) Claiming Small Entity Status;
 Information Disclosure Statement and PTO-1449 Form;
 X Return Receipt Postcard.

2. Filing Fee Calculation

Description	Claims	Extra	Rate	Fee Code	Fee
Basic Filing Fee				201	\$380
Independent Claims	4 - 3 =	1 x	\$39 =	202	39
Total Claims	28 - 20 =	8 x	\$9 =	203	72

Total Filing Fee..... \$491

3. Payment of Fees.

- X Enclosed herewith is a check in the amount of \$491.
 X The Commissioner is hereby authorized to charge any additional fees and to credit any overpayment which may be required under 37 C.F.R. §1.16 and §1.17, to Deposit Account 08-1641, referencing Atty. Docket No. 25205-1000.
A copy of this sheet is attached.

By: Priscilla Mark

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09/349,519

ABSTRACT

An orthopedic implant assembly comprising a stabilizing element, a securing element which attaches the stabilizing element to the bone, and a stopping member in the stabilizing element which inhibits the securing element from loosening or backing out of the bone. The stabilizing element has at least one bore with the stopping member therein. In one embodiment, the stopping member has a reversibly expandable inner and outer diameter to allow the securing element to pass posteriorly through the stopping member, but thereafter prevent or inhibit the securing element from anteriorly backing out of the posterior section of the transverse passageway. In another embodiment, the stopping member is secured to an anterior section of the transverse passageway, and the head of the securing element generally has a compressed configuration with a diameter less than the diameter of the stopping member, in which configuration the head can pass through the stopping member, and an uncompressed configuration with a diameter larger than the diameter of the stopping member.

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ORTHOPEDIC IMPLANT ASSEMBLY

BACKGROUND OF THE INVENTION

This invention generally relates to the field of medical devices, and particularly to an orthopedic implant for joining bone segments and
5 methods of use thereof.

A variety of medical conditions may necessitate the joining of bone segments together, as for example, in the treatment of broken bones, spinal disorders, or the fusion of vertebrae following the removal of a spinal disk. Orthopedic implants used to join bone segments include
10 rods, plates, and screws. In the case of rods and plates, the implants have been attached to the bone using a variety of methods including cementing and screwing the implant to the bone. The bone is typically drilled out to receive the screw therein, or to receive an anchor having a hollow shank which fixedly receives the screw therein. However, one
15 disadvantage has been the tendency of the implants to loosen or detach from the bone over time.

It would be a significant advance to provide an orthopedic implant for joining bone segments together which durably and securely attaches to the bone.

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Docket No. 25205-1000

SUMMARY OF THE INVENTION

This invention is directed to an orthopedic implant assembly generally comprising a stabilizing element, a securing element which attaches the stabilizing element to the patient's bone, and a stopping member in the stabilizing element which defines at least in part a passageway and which inhibits or prevents the securing element from loosening or backing out of the bone.

The stabilizing element is generally a plate or rod, which has at least one bore therein having a first opening in the anterior surface of the stabilizing element, a second opening in the posterior surface of the stabilizing element, and a transverse passageway extending from the first opening to the second opening. The term posterior should be understood to mean an inner portion of the assembly closer to the bone to which the assembly is attached, and the term anterior should be understood to mean an outer portion of the assembly farther away from the bone.

In one embodiment, the stopping member defines a reversibly expandable passageway, and is biased to the unexpanded, or smaller diameter, passageway configuration. In one embodiment, the biased stopping member comprises an annular collar having a reversibly expandable inner diameter. The biased stopping member may be configured to be positioned in a groove in the transverse passageway

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after the securing element is in place in the transverse passageway of the stabilizing element. Alternatively, in a presently preferred embodiment, the biased stopping member is configured to allow the securing element to pass posteriorly through the stopping member passageway from the anterior surface of the stabilizing element into a posterior section of the transverse passageway. In another embodiment, the biased stopping member is secured to the stabilizing element within the transverse passageway, and is deflectable. The deflectable stopping member reversibly flexes as the head of the securing element is posteriorly displaced through the deflectable stopping member to expand the passageway defined by the stopping member. The deflectable stopping member is biased to the undeflected or smaller diameter passageway configuration. The stopping member prevents the securing element from anteriorly backing out of the posterior section of the transverse passageway. As a result, the securing element durably attaches the stabilizing element to the bone.

The securing element is configured to attach to bone, and generally comprises an elongated body and a head at one end of the body and integral therewith. The term integral should be understood to mean the securing element is a one-piece unit, with the head secured to the body so that there is no relative movement between the head and the body. In one embodiment, the securing element is selected from the

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group consisting of screws, pins, and nails. In a presently preferred embodiment where the collar is seated within the groove in the stabilizing element before the securing element is advanced therein, the head of the securing element has a shaped posterior surface which
5 contacts the collar and gradually expands the collar as the head is displaced into the posterior section of the transverse passageway of the stabilizing element. In a presently preferred embodiment, the head of the securing element has a curved posterior surface. However, other suitable shapes may be used including tapered posterior surfaces.

10 The invention also includes methods of attaching an orthopedic implant assembly to a bone of a patient. The bone is typically prepared for receiving the body of the securing element, as for example by drilling a cavity into the bone, and/or tapping the cavity. A method generally comprises positioning the posterior surface of the stabilizing element
15 against the surface of the bone, with the stopping member within the groove of the stabilizing element in the unexpanded configuration, introducing the body of the securing element into the transverse passageway, posteriorly displacing the head of the securing element through the stopping member and thereby expanding the stopping
20 member, and attaching the stabilizing element to the bone by advancing the head of the securing element posteriorly of the stopping member so that the stopping member contracts and returns to a smaller transverse,

i.e., unexpanded diameter, configuration. The head of the securing element is positioned within a posterior section of the transverse passageway between the stopping member and the second opening in the stabilizing element, and the body of the securing element is positioned within the patient's bone. In an alternative embodiment, the stopping member may be placed within the groove after the head of the securing element is positioned within the posterior section of the transverse passageway. The stabilizing element is attached to the bone by the securing element, which is attached to the bone and retained within the transverse passageway.

In another embodiment of the invention, the head of the securing element can be reversibly compressed, and the stopping member is secured to an anterior section of the transverse passageway. The stopping member defines a passageway with a fixed diameter, but the compressed configuration of the head of the securing element has a diameter less than the diameter of the stopping member so that the head can pass through the stopping member passageway. In the uncompressed configuration, the head of the securing element has a diameter larger than the diameter of the stopping member and the diameter of the second opening in the stabilizing element, so that the head can be advanced posteriorly of the stopping member and retained

within the transverse passageway between the stopping member and the second opening.

To facilitate the correct placement of the orthopedic implant assembly on the bone, the transverse passageway between the collar
5 and the second opening in the stabilizing element may be configured so that the securing element may be angularly displaceable therein and the body of the securing element may be positioned at an angle within the patient's bone.

In the assembly of the invention, the securing element is prevented
10 from backing out of the bone by the interaction of the securing element head and the stopping member. As a result, a separate anchor means implanted in the bone to receive the screw is not required, and the resulting loss of bone and intraoperative time required to implant the anchor is avoided. Moreover, in a preferred embodiment, the stopping
15 member is within the transverse passageway at the beginning of the procedure, so that the surgeon can attach the implant assembly to the bone with the single motion of advancing the securing element through the stopping member passageway and into the bone. The implant assembly of the invention thus reduces the time required to attach the
20 assembly to the bone and provides improved implant performance.

The orthopedic implant assembly of the invention can be durably attached to bone, and the securing element prevented from significantly

backing out of the bone due to the head of the securing element being retained within the stabilizing element. These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view of an orthopedic implant assembly which embodies features of the invention.

Fig. 2 is an exploded view, partially in section, of the orthopedic implant assembly shown in Fig. 1.

10

Fig. 3 is a cross section of the orthopedic implant assembly shown in Fig. 1 taken along lines 3-3.

Fig. 3A is a transverse cross section of the orthopedic implant assembly shown in Fig. 3 taken along lines 3A-3A.

Fig. 4 illustrates the orthopedic implant assembly shown in Fig. 3, as the securing element is being advanced into the patient's bone.

Fig. 4A is a transverse cross section of the assembly shown in Fig. 4, taken along lines 4A-4A.

Fig. 5 illustrates the orthopedic implant assembly shown in Fig. 3, with the securing element advanced into the posterior section of the transverse passageway of the stabilizing element.

Fig. 6 illustrates the orthopedic implant assembly shown in Fig. 3, with the securing element angularly disposed within the patient's bone.

Fig. 7 is an exploded view, partially in section, of an orthopedic implant assembly having a securing element with a compressible head, which embodies features of the invention.

Fig. 8 illustrates the orthopedic implant assembly shown in Fig. 7
5 as the securing element is being advanced into the patient's bone.

Figs. 9 is a transverse cross section of the assembly shown in Fig. 8, taken along lines 9-9.

Fig. 10 illustrates the orthopedic implant assembly shown in Fig. 7
10 with the securing element advanced into the posterior section of the transverse passageway of the stabilizing element.

Figs. 11 is a transverse cross section of the assembly shown in Fig. 10, taken along lines 11-11.

Fig. 12 illustrates the orthopedic implant assembly shown in Fig. 7, with the securing element angularly disposed within the patient's bone.

15 Fig. 13 is an exploded view, partially in section, of an orthopedic implant assembly having a deflectable stopping member, which embodies features of the invention.

Fig. 14 illustrates the orthopedic implant assembly shown in Fig. 13 with the securing element advanced into the posterior section of the
20 transverse passageway of the stabilizing element.

Figs. 15 is a plan view of the assembly shown in Fig. 14, taken along lines 15-15.

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DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates one embodiment of the orthopedic implant assembly 10 of the invention, generally including a stabilizing element 11, with a biased stopping member 12 in a bore 13 therein, and a
5 securing element 14, configured for securing to a patient's bone 15. In the embodiment illustrated in Fig. 1, the biased stopping member comprises an annular collar, although a variety of suitable members may be used, as for example, one or more contractible fingers biased to extend into the transverse passageway (not shown).

10 As best illustrated in Fig. 2 showing an exploded, partially in section, view of the assembly shown in Fig. 1, the bore 13 of the stabilizing element has a first opening 16 in an anterior surface of the stabilizing element, a second opening 17 in a posterior surface of the stabilizing element, a transverse passageway 18 extending therein, and a
15 groove 21 in an anterior portion of the transverse passageway. Annular collar 12 defines a passageway 22, and is configured to be seated within the groove 21, and has a reversibly expandable inner and outer diameter. As illustrated in Fig. 3, illustrating the assembly shown in Fig. 1 partially in section taken along lines 3-3, and Fig. 3A illustrating a transverse
20 cross sectional view of the assembly shown in Fig. 3 taken along lines 3A-3A, the annular collar 12 is biased to an unexpanded outer diameter which is less than the diameter of the groove and greater than the

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diameter of the transverse passageway, so that the collar seats within the groove. The expanded outer diameter of the collar is less than the diameter of the groove, and the height of the collar is less than the height of the groove, so that the collar can be expanded therein.

5 The securing element 14 has an elongated body 23 and an integral head 24 secured to one end of the body 23. In a presently preferred embodiment of the invention illustrated in Fig. 1, the securing element comprises a screw. The head of the securing element is configured to be posteriorly displaceable through the passageway 22 of the collar
10 seated within the groove, from an anterior to a posterior surface of the collar, and retained within a posterior section 25 of the transverse passageway 18 between the posterior surface of the collar 12 and the second, i.e., posterior, opening 17 in the stabilizing element. In the embodiment illustrated in Fig. 1, the head of the securing element has a
15 curved posterior surface 26 with a convex shape and with a smaller diameter than an anterior surface of the head. The curved posterior surface 26 has a minimum outer diameter which is smaller than the unexpanded inner diameter of the collar, and which is positionable within the passageway of the collar, to contact and expand the collar as the
20 head is displaced posteriorly therein.

Figs. 3-5 illustrate the attachment of the assembly to the patient's bone. As illustrated in Fig. 3, the stabilizing element is positioned



against a surface of a bone 15, and the posterior end of the body of the
securing element 14 is placed within the stabilizing element transverse
passageway. The head 24 of the securing element is posteriorly
advanced within the passageway 22 of the collar 12, thereby applying a
5 radially expanding force against an inner surface of the collar to expand
the inner diameter of the collar, as illustrated in Fig. 4 showing the
expanded collar and the head of the securing element partially displaced
through the collar passageway. Arrows in Fig. 4 illustrate the expansion
of the collar as the head of the securing element is passed therethrough.
10 Fig. 4A illustrates a transverse cross section of the assembly shown in
Fig. 4, taken along lines 4A-4A. The expanded inner diameter of the
collar is therefore larger than the maximum diameter of the head of the
securing element, to allow the head of the securing element to pass
posteriorly through the collar. The head of the securing element is
15 advanced posteriorly of the collar and into the posterior section 25 of the
transverse passageway, so that the collar returns to the unexpanded
configuration having an unexpanded inner diameter smaller than the
maximum diameter of the head of the securing element, as illustrated in
Fig. 5. In the embodiment illustrated in Fig. 5, the flat anterior surface
20 of the head of the securing element has a diameter which is larger than
the unexpanded inner diameter of the collar, and the posterior surface of
the collar is perpendicular to the longitudinal axis of the transverse

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passageway. Thus, the anterior surface of the head will butt up against the posterior surface of the collar without expanding the collar, to prevent the securing element from being anteriorly displaced out of the posterior section of the transverse passageway. In the embodiment
5 illustrated in the Fig. 5, a posterior portion of the transverse passageway is curved to conform to the curved posterior surface of the head, providing maximum contact between the securing element and the stabilizing element. The curved surfaces of the posterior portion of the transverse passageway and the posterior surface of the head have the
10 same radius of curvature, and the diameter of the curved surface of the head is large enough so that the wall defining the transverse passageway contacts the head around the circumference of the curved posterior surface of the head, but is small enough so that the head can be displaced within the transverse passageway. With the head of the
15 securing element positioned within the posterior section 25 of the transverse passageway, the body of the securing element is embedded in, and secured to, the bone of the patient.

In the embodiment illustrated in Fig. 5, the posterior section 25 of the transverse passageway is sufficiently longer than the head 24 of the
20 securing element so that the head can be displaced anteriorly and posteriorly, and is thus longitudinally displaceable within the posterior section of the transverse passageway. Additionally, the body of the

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securing element 23 has a smaller diameter than the diameter of the second opening 17 in the stabilizing element, and can be displaced from side to side, i.e., medial-lateral displacement, within the second opening 17. As a result, the securing element is angularly displaceable within the transverse passageway posterior section 25 between the collar 12 and the second opening 17 in the stabilizing element, as illustrated in Fig. 6. The securing element can thus be tilted within the transverse passageway at an angle relative to the transverse passageway longitudinal axis, to facilitate positioning the securing element at a desired location in the bone by advancing the body of the securing element within the bone at an angle relative to the surface of the bone. The securing element can be angularly displaced up to an angle of about 45°, preferably up to about 20° relative the longitudinal axis of the transverse passageway.

The stopping member 12 is preferably elastically deformable, and formed of titanium, and superelastic or pseudoelastic materials such as NiTi alloys. The unexpanded inner diameter of the stopping member is about 0.1 to about 40 mm, preferably about 0.5 to about 20 mm, and is about 0.05 to about 20 mm, preferably about 0.1 to about 15 mm less than the maximum transverse dimension of the head of the securing element. The unexpanded outer diameter of the stopping member is about 0.2 to about 50 mm, preferably about 1.0 to about 30 mm. The

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Docket No. 25205-1000

expanded inner diameter of the stopping member is about 0.15 to about 50 mm, preferably about 0.75 to about 30 mm, and the expanded outer diameter of the stopping member is about 0.5 to about 60 mm, preferably about 1.5 to about 40 mm. The height of the stopping member is about 0.01 to about 5 mm, preferably about 0.05 to about 3 mm.

Figs. 7-12 illustrate another embodiment of the invention, generally comprising a securing element 30, and a stabilizing element 31 similar to the stabilizing element in the embodiment illustrated in Fig. 1, except the stopping member is not seated within a groove in the transverse passageway 18. Instead, a stopping member 32 is provided at an anterior section of the transverse passageway, which may be formed integrally with the stabilizing element or as a separate member secured thereto. In the embodiment illustrated in Fig. 7, the stopping member is a collar at the anterior end of the transverse passageway and defining the first opening 16 in the stabilizing element 31. The securing element 30 has an elongated body 33, and head 34 secured to one end of the body having a compressed configuration and an uncompressed configuration. In the embodiment illustrated in Fig. 7, the head has a plurality of slots 35 defining circumferentially spaced members 36 having posterior ends secured to the body of the securing element. The circumferentially spaced members 36 have anterior ends radially

moveable toward a longitudinal axis of the head to form the compressed configuration, having a diameter less than the inner diameter of the collar. Fig. 8 illustrates the head of the securing element in the compressed configuration within the passageway defined by the collar.

5 Fig. 9 illustrates a transverse cross sectional view of the assembly shown in Fig. 8, taken along lines 9-9. Fig. 10 illustrates the head of the securing element advanced posteriorly of the collar and into the posterior section of the transverse passageway, thereby returning the circumferentially spaced members 36 to the uncompressed configuration
10 by release of the radially compressive force of the collar. Fig. 11 illustrates a transverse cross section of the assembly shown in Fig. 10, taken along lines 11-11, with the first opening 16 shown in phantom. The securing element is angularly and longitudinally displaceable within the transverse passageway posterior section 25, as discussed above
15 with regard to the embodiment illustrated in Fig. 1, and as illustrated in Fig. 12.

Figs. 13-15 illustrate another embodiment of the invention, generally comprising a stabilizing element 41 similar to the stabilizing element in the embodiment illustrated in Fig. 1, except with a deflectable
20 stopping member 42 provided in an anterior section of the transverse passageway, which may be formed integrally with the stabilizing element or as a separate member secured thereto. In the embodiment illustrated

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in Fig. 13, the stopping member comprises a collar 42 having a plurality of slots 43 defining circumferentially spaced members 44 and a tapered or sloping anterior surface providing axial flexibility in a posterior direction, so that the collar deflects posteriorly when the head of the securing element is posteriorly displaced through the collar. As a result, the circumferentially spaced members 44 have a wedge shape and a height which tapers towards the central passageway 45 defined by the collar, which facilitates displacing the head of the securing element therethrough and reversibly enlarging the passageway 45. In the embodiment illustrated in Fig. 13, the collar is integrally formed with the stabilizing element 41 at the anterior end of the transverse passageway, and defines the first opening 16 in the stabilizing element 41. The securing element may be the same as, or similar to, the securing element 14 discussed above in connection with the embodiment illustrated in Fig. 1, and as illustrated in Fig. 13. However, securing element 30 having head 34 with a compressed configuration and an uncompressed configuration, as discussed above in connection with the embodiment illustrated in Fig. 7, may also be used. Fig. 15 illustrates a plan view of the assembly shown in Fig. 14, taken along lines 15-15, with the head of the securing element 14 partially in phantom. The angular and longitudinal displacement of the securing member in the posterior section of the transverse passageway is as discussed above.

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The stabilizing element is preferably formed of a metal such as titanium or stainless steel. The length of the stabilizing element is typically about 7 to about 300 mm, preferably about 13 to about 200 mm, and the width of the stabilizing element is typically about 5 to about 50 mm, preferably about 10 to about 30 mm. The height of the stabilizing element is typically about 0.5 to about 10 mm, preferably about 1.0 to about 6.0 mm although the dimensions of the stabilizing element will vary depending on the application for which the assembly is to be used.

10 The securing element is preferably formed of a metal, such as titanium or stainless steel. The head of the securing element is configured, as for example with a hexagonal opening, for releasable connection to a tool for advancing the securing element into the bone. The body of the securing element has a length of about 2 to about 50 mm, preferably about 5 to about 20 mm, and the head of the securing element has a length of about 0.05 to about 1.5 mm, preferably about 0.5 to about 1.0 mm. One skilled in the art will recognize that a variety of suitable securing elements may be used, which may be optimized for use in a particular orthopedic environment, as is well known in the art.

20 For example, a high thread pitch may be used to limit screw back out from bone.

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The assembly of the invention is suitable for use in a variety of medical procedures, including securing fractured bone segments or vertebrae following disk removal. In the illustrated embodiments, the stabilizing element comprises a plate, although other suitable elements
5 such as rods may be used. Additionally, the stabilizing element may be shaped to conform to the surface of the bone or bones to which it will be attached. For example, a presently preferred embodiment of the stabilizing element comprises a plate with a concave posterior surface, and is configured for attaching to vertebrae.

10 While the present invention has been described herein in terms of certain preferred embodiments, those skilled in the art will recognize that modifications and improvements may be made without departing from the scope of the invention. For example, while the stopping member is discussed primarily in terms of a collar, other configurations may also be
15 used. Additionally, while a particular feature may be discussed in connection with one embodiment, it should be understood that features of one embodiment may be used with the other embodiments herein.

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WHAT IS CLAIMED IS:

1. An orthopedic implant assembly, comprising

a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having

5 a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening;

b) a biased stopping member defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration; and

c) a securing element having an elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the stabilizing element, so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element.

2. The assembly of claim 1 wherein the biased stopping member comprises a collar defining a passageway, enlargeable from an unexpanded inner diameter to an expanded inner diameter, wherein the head of the securing element has a maximum diameter greater than the unexpanded inner diameter of the collar and less than the expanded inner diameter of the collar.

3. The assembly of claim 2 wherein the head of the securing element has a curved posterior surface which has a minimum outer diameter smaller than the unexpanded inner diameter of the collar, configured to be displaceable posteriorly of the collar through the passageway of the collar from an anterior to a posterior surface thereof.

4. The assembly of claim 2 wherein the bore has a groove in an anterior portion of the transverse passageway having a diameter and a height, and wherein the collar is a reversibly expandable annular collar seated in the groove, the collar having an expanded outer diameter, and an unexpanded outer diameter which is less than the diameter of the groove and greater than a diameter of the transverse passageway.



9. The assembly of claim 3 wherein a posterior portion of the transverse passageway is curved to conform to the curved posterior surface of the head.

10. The assembly of claim 1 wherein the head of the securing
5 element is longitudinally displaceable within the transverse passageway between a posterior surface of the biased stopping member and the second opening in the posterior surface of the stabilizing element.

11. The assembly of claim 10 wherein the body of the securing
10 element has a diameter smaller than the second opening in the stabilizing element, and the securing element may be angularly displaced within the transverse passageway and second opening in the stabilizing element.

12. The assembly of claim 1 wherein the stabilizing element includes at least two bores.

13. The assembly of claim 1 wherein the stabilizing element is
15 configured to conform to and extend between at least two bone segments.

14. The assembly of claim 13 wherein the stabilizing element has a curved surface.

15. The assembly of claim 1 wherein the stabilizing element is
20 selected from the group consisting of rods and plates.

16. The assembly of claim 1 wherein the securing element is selected from the group consisting of screws and nails.

17. The assembly of claim 2 wherein the collar is formed of an elastically deformable material.

5 18. The assembly of claim 2 wherein the collar is formed of a material selected from the group consisting of titanium and superelastic material.

10 19. The assembly of claim 2 wherein the collar has a posterior surface perpendicular to a longitudinal axis of the transverse passageway.

20. The assembly of claim 4 wherein the collar has a height less than the height of the groove.

~~21.~~ A method of attaching an orthopedic implant assembly to a bone of a patient, comprising

15 a) positioning a stabilizing element against a surface of the patient's bone, the stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse
20 passageway extending from the first opening to the second

opening, and a biased stopping member within the bore and defining at least in part a reversibly expandable passageway having a smaller diameter configuration and a larger diameter configuration;

5 b) providing a securing element having an elongated body, and a head at one end of the body and integral therewith, the head having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the
10 stabilizing element, so that the head is retained within the transverse passageway between the biased stopping member and the second opening in the stabilizing element;

15 c) positioning the body of the securing element in the transverse passageway and posteriorly advancing the head of the securing element within the passageway defined by the biased stopping member and thereby displacing the biased stopping member to form the larger diameter configuration passageway defined thereby; and

20 d) attaching the stabilizing element to the bone by advancing the head of the securing element posteriorly of the biased stopping member so that the passageway defined thereby returns to the smaller diameter configuration, to position the head

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Docket No. 25205-1000

within a posterior section of the transverse passageway between the biased stopping member and the second opening in the stabilizing element, and to position the body of the securing element within the patient's bone, so that the securing element is attached to the bone and is retained within the posterior section of the transverse passageway of the stabilizing element.

22. The method of claim 21 including, after the head of the securing element is positioned between the biased stopping member and the second opening in the stabilizing element, the step of longitudinally and angularly displacing the head of the securing element within the transverse passageway, so that the body of the securing element is positioned at an angle within the patient's bone relative to the surface of the bone.

23. An orthopedic implant assembly, comprising

a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening, and a stopping member at an anterior section of the transverse passageway; and

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b) a securing element having an elongated body and a head secured to one end of the body, the head having a reversibly compressed configuration with a compressed diameter less than the diameter of the first opening and an uncompressed configuration with a diameter greater than the diameter of the stopping member and the second opening, so that the head of the securing element is retained within the transverse passageway between the stopping member and the second opening in the stabilizing element.

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24. The assembly of claim 23 wherein the head of the securing element is configured to be displaceable posteriorly through the stopping member from an anterior to a posterior surface thereof.

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25. The assembly of claim 23 wherein the head of the securing element has a plurality of slots defining circumferentially disposed members having posterior ends secured to the body of the securing element, and anterior ends radially moveable toward a longitudinal axis of the head of the securing element to form the compressed configuration, and away from the longitudinal axis to form the uncompressed configuration.

26. The assembly of claim 23 wherein the stopping member is at the anterior end of the transverse passageway and defines the first opening in the stabilizing element.

27. The assembly of claim 23 wherein the stopping member has
5 a posterior surface perpendicular to a longitudinal axis of the transverse passageway.

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28. A method of attaching an orthopedic implant assembly to a bone of a patient, comprising

10 a) positioning a stabilizing element against a surface of the patient's bone, the stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening, and a stopping member at an anterior section of the
15 transverse passageway;

20 b) providing a securing element a securing element having an elongated body and a head secured to one end of the body, the head having a reversibly compressed configuration with a compressed diameter less than the diameter of the first opening and an uncompressed configuration with a diameter greater than

the diameter of the stopping member and the second opening, so that the head of the securing element is retained within the transverse passageway between the stopping member and the second opening in the stabilizing element;

5 c) positioning the body of the securing element in the transverse passageway and posteriorly advancing the head of the securing element within the passageway defined by the stopping member and thereby compressing the diameter of the head of the securing element; and

10 d) attaching the stabilizing element to the bone by advancing the head of the securing element posteriorly of the stopping member so that the diameter of the head of the securing element returns to the uncompressed configuration, to position the head within a posterior section of the transverse passageway
15 between the biased stopping member and the second opening in the stabilizing element and the body of the securing element within the patient's bone, so that the securing element is attached to the bone and is retained within the posterior section of the transverse passageway of the stabilizing element.

DECLARATION AND POWER OF ATTORNEY

As the below named inventors, we hereby declare that:

Our residence and post office addresses and our citizenships are as stated below next to our names.

We believe that we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled **ORTHOPEDIC IMPLANT ASSEMBLY**, the specification of which is being filed herewith.

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

We acknowledge the duty to disclose information which is material to the examination of this application and to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

We hereby claim foreign priority benefits under Title 35, United States Code §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: Prior Foreign Application(s) None.

We hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56, which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

We hereby declare under penalty of perjury under the laws of the United States of America that all statements made herein of our 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 §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.

We hereby appoint the following attorneys to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith:

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Citizenship: United States of America

Full name of Second and Joint Inventor: James R. Lloyd

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Residence: 1080 Circle Drive, Elm Grove, WI 53122

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Executed on the 26th day of May, 1999

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Citizenship: United States of America

In re the Application of David J. Talaber and James R. Lloyd
Serial No.: Not Assigned
Filed: Herewith
For: **ORTHOPEDIC IMPLANT ASSEMBLY**
Attorney Docket No.: 25205-1000

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTORS**

As the below named inventors, we hereby declare that we are qualified as independent inventors as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under §41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled **ORTHOPEDIC IMPLANT ASSEMBLY** as described in

☒ the specification filed herewith
☐ serial no. _____, filed _____
☐ patent no. _____, issued _____

We have not assigned, granted, conveyed or licensed and are under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which we have assigned, granted, conveyed, or licensed or are under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit ☐ Continued on Appendix A (attached hereto).

We acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 CFR 1.28(b)).

We hereby declare that all statements made herein of our own knowledge are true and that all statements made herein 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 §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of First and Joint Inventor David J. Talaber

Executed on the 24th day of June, 19 99

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In re the Application of David J. Talaber and James R. Lloyd
Serial No.: Not Assigned
Filed: Herewith
For: **ORTHOPEDIC IMPLANT ASSEMBLY**
Attorney Docket No.: 25205-1000

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTORS**

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☒ the specification filed herewith
☐ serial no. _____, filed _____
☐ patent no. _____, issued _____

We have not assigned, granted, conveyed or licensed and are under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which we have assigned, granted, conveyed, or licensed or are under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

NAME _____

ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit ☐ Continued on Appendix A (attached hereto).

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We hereby declare that all statements made herein of our own knowledge are true and that all statements made herein 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 §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of First and Joint Inventor David J. Talaber

Executed on the _____ day of _____, 19____

Inventor's Signature _____

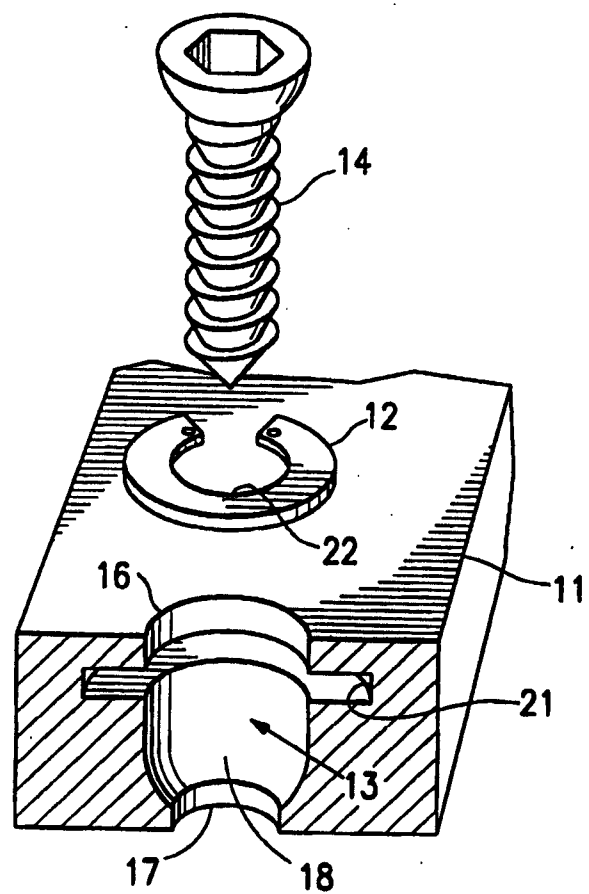
Address 5185 Charlotte Way, Livermore, CA 94550-3532

Name of Second and Joint Inventor James R. Lloyd

Executed on the 26th day of May, 1999

Inventor's Signature James R. Lloyd

Address 1080 Circle Drive, Elm Grove, WI 53122



2/7

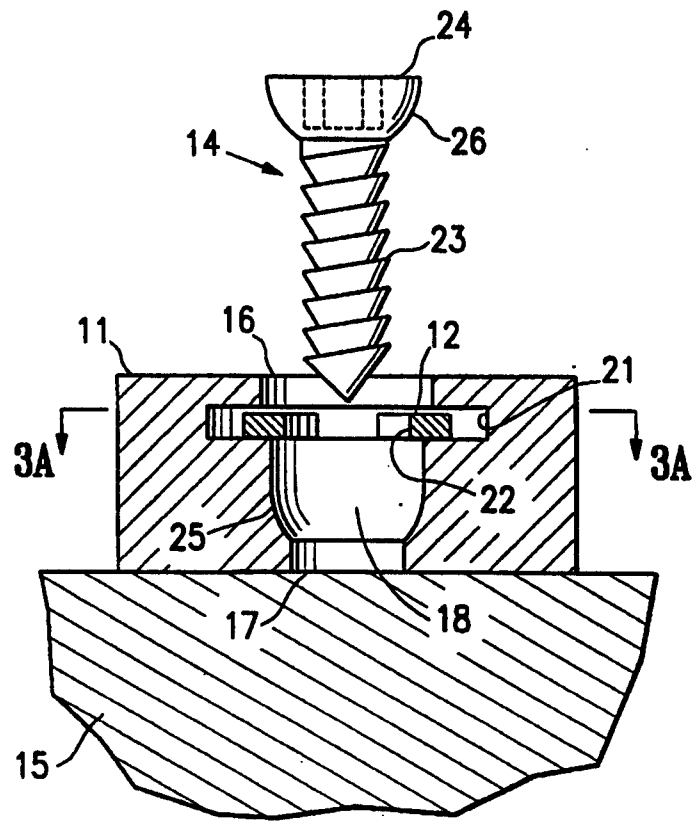


FIG. 3

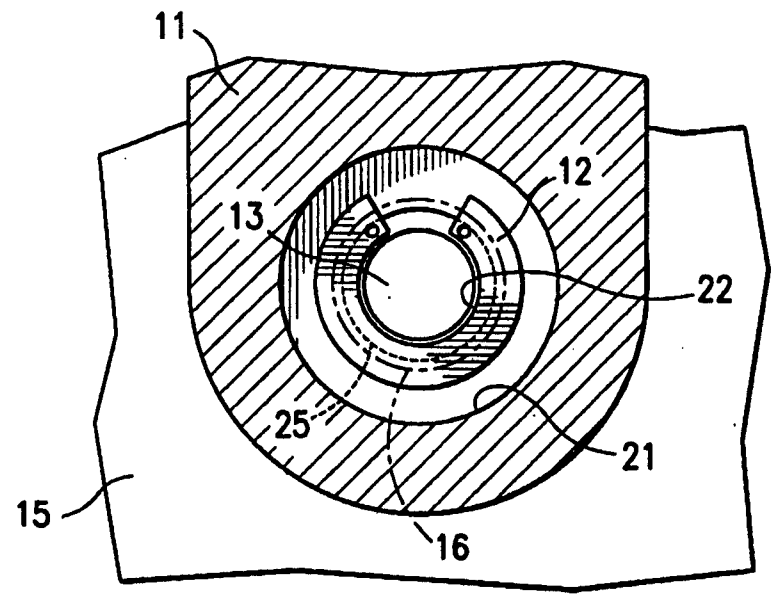


FIG. 3A

3/7

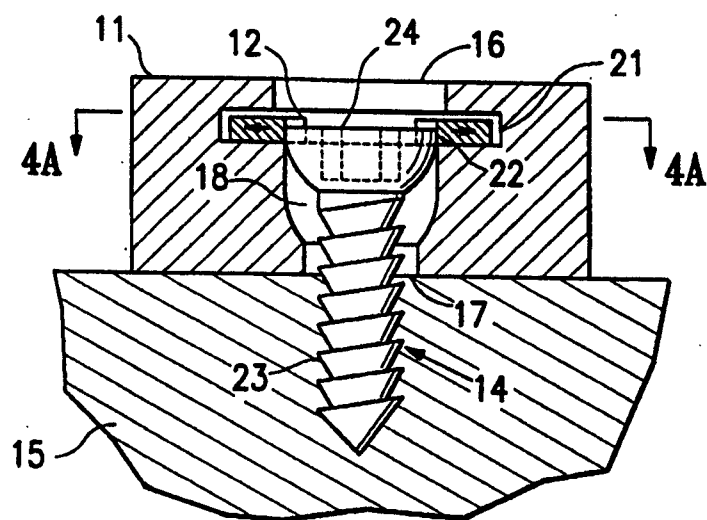


FIG. 4

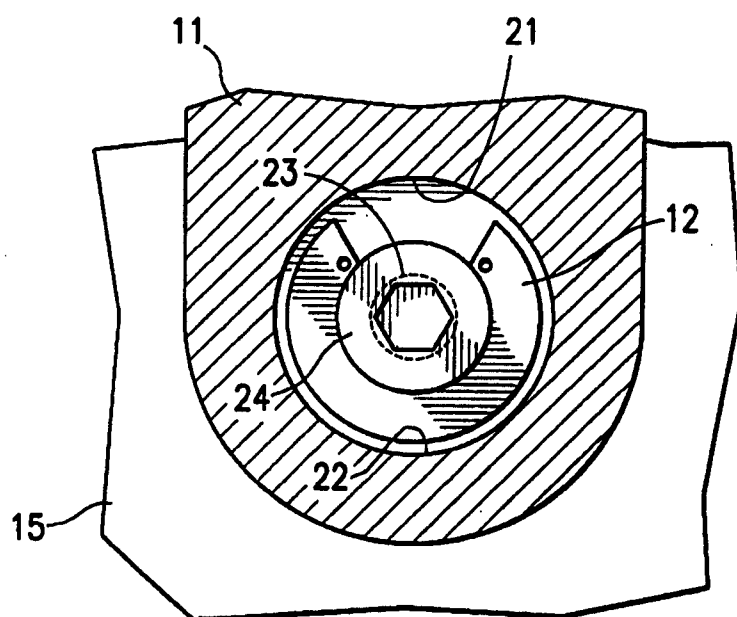


FIG. 4A

4/7

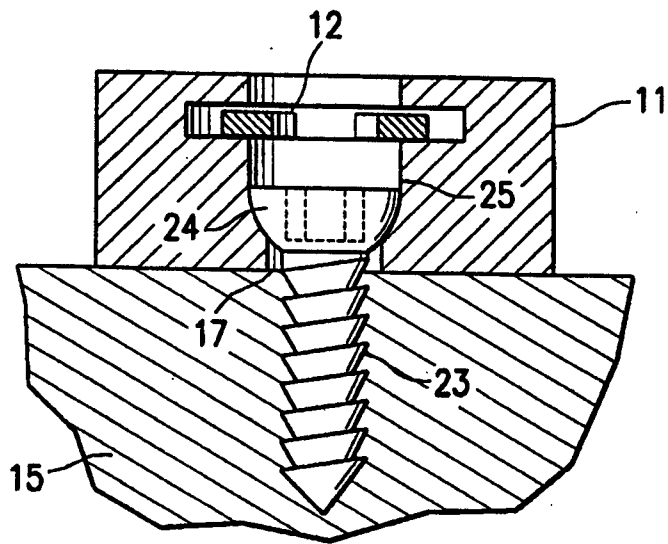


FIG. 5

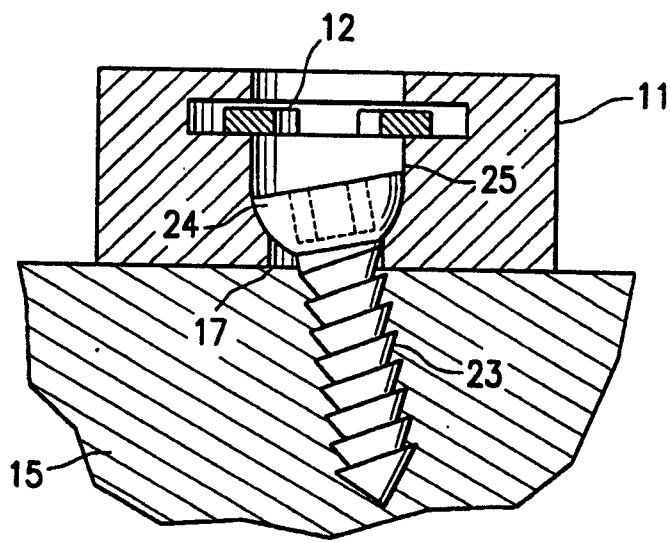


FIG. 6

5/7

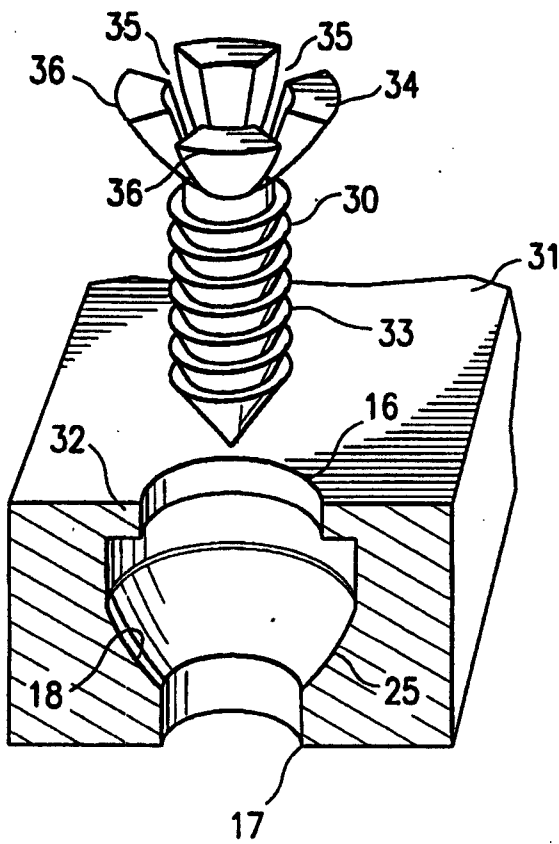


FIG. 7

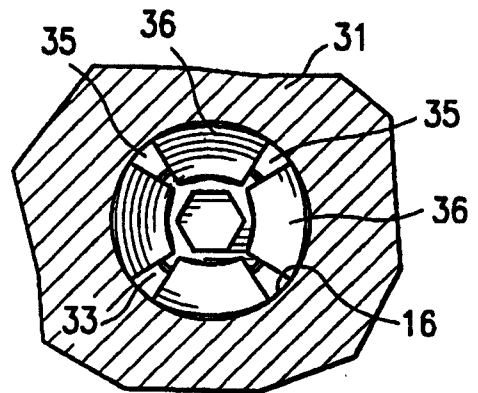


FIG. 9

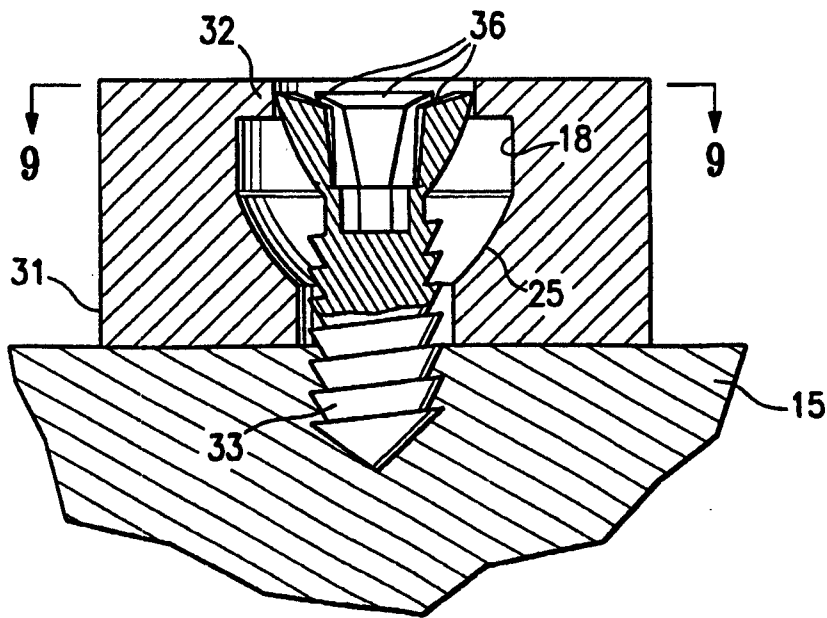


FIG. 8

6/7

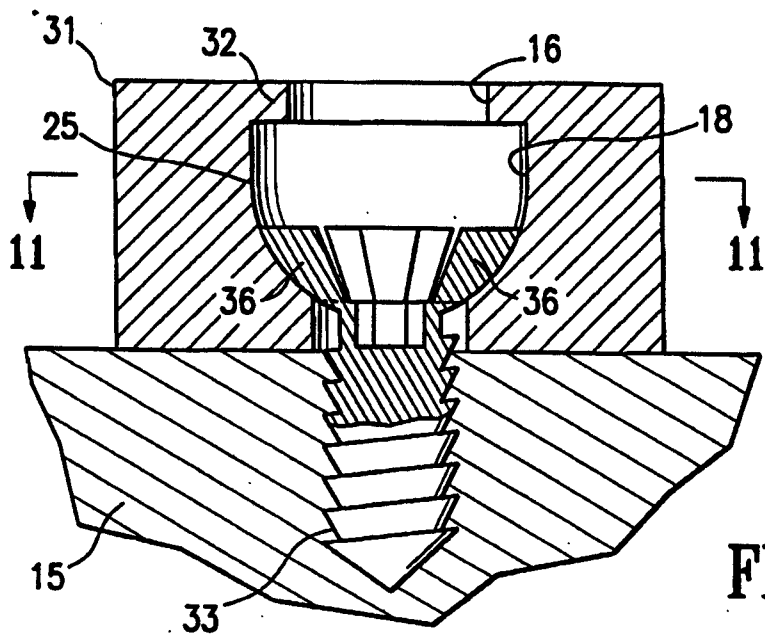


FIG. 10

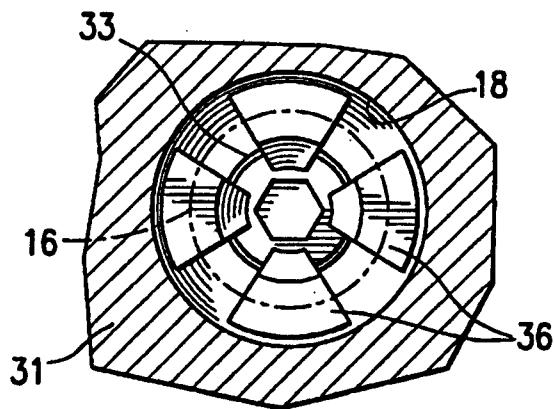


FIG. 11

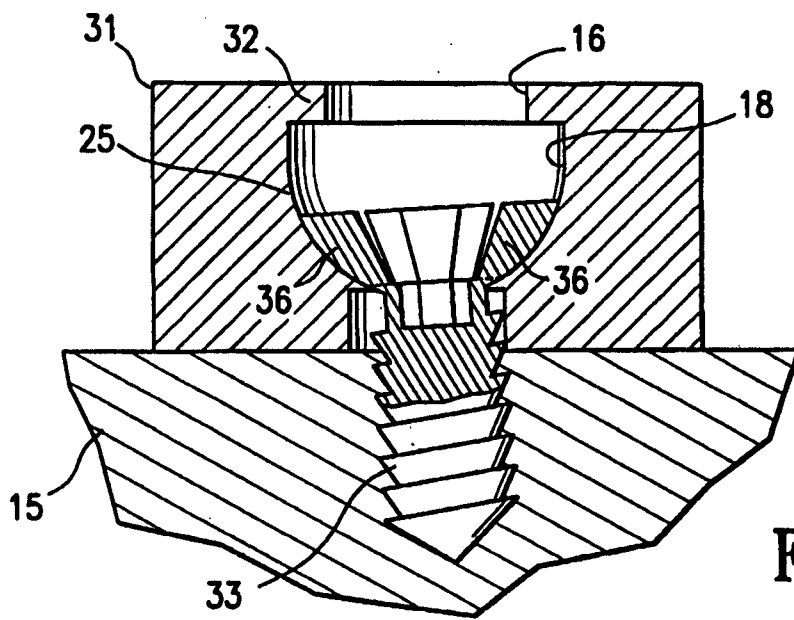
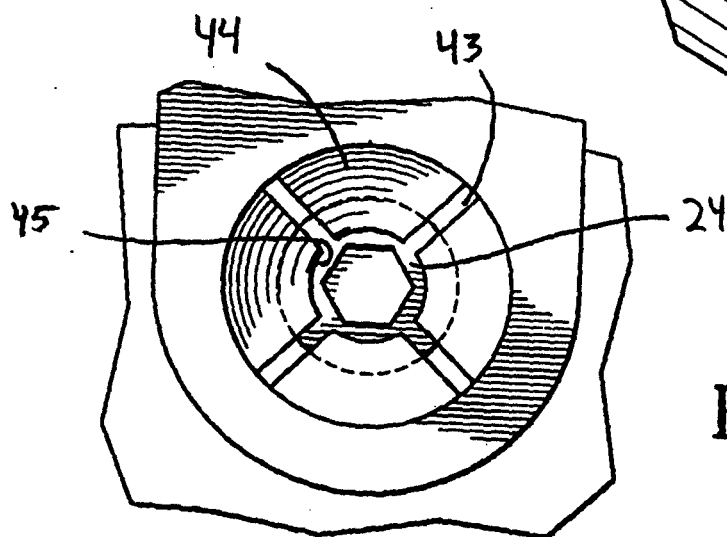
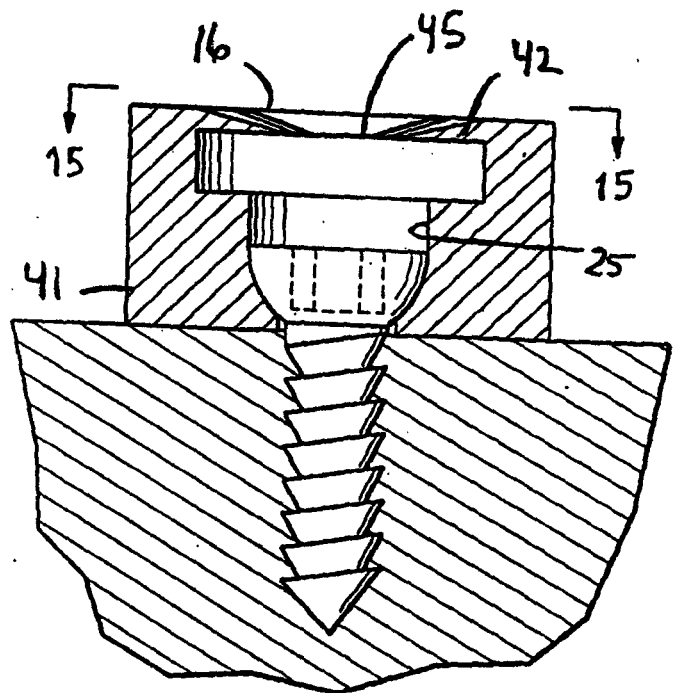
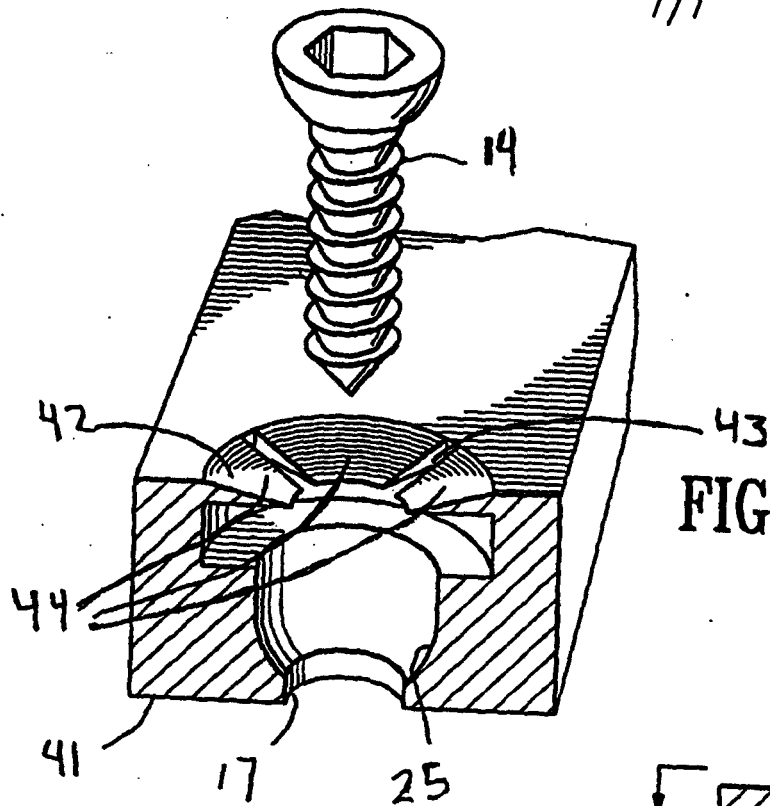


FIG. 12

7/7



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of
Talaber et al.

For: **ORTHOPEDIC IMPLANT ASSEMBLY**

Serial No.: 09/349,519

Filed: July 8, 1999

Docket No.: 25205-1000



) Examiner: Not Assigned

) Group Art Unit: 3738

) TRANSMITTAL

GP 3738
2

BOX NON-FEE AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

1. Transmitted herewith for filing in the above-identified patent application is a Preliminary Amendment and Information Disclosure Statement. Also enclosed is:

- X 1 Sheet of red-lined figures;
X PTO-1449 Form; Copies of 29 cited references;
X Return Receipt Postcard.

2. Claim Fee Calculation

- X No additional claim fee is required.
Amendment increases number of claims or multiple dependencies

ADDITIONAL CLAIM FEE CALCULATION

Description	Claims	Extra	Rate	Fee Code	Fee
Independent Claims	4- 4=	0 x	\$39=	102	0
Total Claims	28 - 28=	0 x	\$ 9=	103	0

3. Payment of Fees

- X No fee is due with this communication.
X The Commissioner is authorized to charge any additional fees and to credit any overpayment of fees which may be required with this communication under 37 CFR §1.16 or §1.17, to Deposit Account No. 08-1641, referencing Docket No. 25205-1000. A duplicate of this sheet is enclosed.

By:

Priscilla Mark

Priscilla Mark
Attorney for Applicants
Registration No. 41,970

CERTIFICATE OF MAILING PURSUANT TO 37 CFR §1.8

I hereby certify that this paper is being deposited in the USPS as first class mail with sufficient postage addressed to BOX NON-FEE AMENDMENT, Assistant Commissioner for Patents, Washington D.C. 20231, on January 31, 2000, in Palo Alto, CA.

Ng Miller

Feb. 9

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

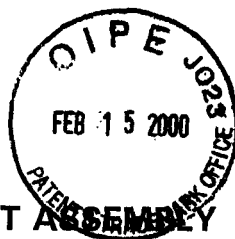
Talaber et al.

For: **ORTHOPEDIC IMPLANT ASSEMBLY**

Serial No.: 09/349,519

Filed: July 8, 1999

Docket No.: 25205-1000



) Examiner: Not Assigned

) Group Art Unit: 3738

PRELIMINARY AMENDMENT AND
INFORMATION DISCLOSURE STATEMENT

BOX NON-FEE AMENDMENT
Assistant Commissioner for Patents
Washington, D.C. 20231

RECEIVED
FEB 17 2000
TC 3700 MAIL ROOM

Dear Sir:

Please preliminarily amend the above application as indicated below.

IN THE FIGURES

In Fig. 13, add reference numerals --16--, and --45--, and associated lead lines as indicated in red on the attached copy of the drawing.

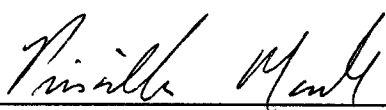
REMARKS

Applicants have amended Fig. 13 to make the figure consistent with the specification. Support for the amendment can be found on page 16, lines 5-12.

Applicants wish to bring to the attention of the Patent Office the references listed in the attached PTO-1449, and request that they be considered by the Examiner. This Information Disclosure Statement is being submitted pursuant to 37 CFR 1.97(b)(3), and therefore no fee is due.

Applicants submit the claims define patentable subject matter, and respectfully request consideration and early allowance.

Respectfully submitted,

By: 
Priscilla Mark
Attorney for Applicants
Registration No. 41,970

Heller Ehrman White & McAuliffe
525 University Avenue, Suite 1100
Palo Alto, CA 94301-1900
Direct Dial: (650) 324-7184
Telephone: (650) 324-7000
Facsimile: (650) 324-0638

180337 v01.PA (3V5D011.DOC)
1/31/00 12:58 PM (25205.1000)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56, §1.97, and §1.98 PTO-1449 FORM SHEET 1 OF 1	ATTORNEY DOCKET NO.: 25205-1000	SERIAL NO.: 09/349,519
	APPLICANTS: FEB 15 2000 Malaber et al.	
	FILING DATE: July 8, 1999	GROUP ART UNIT: 3738

U.S. PATENT DOCUMENTS

† EX'R INITIAL	*REF. #	PATENT NUMBER	DATE (MO/YR)	NAME	U.S. CLASS/ SUBCLASS	FILING DATE (If appropriate)
	A1	3,350,103	10/1967	AHLSTONE		8/1965
	A2	3,863,959	2/1975	BLASCHKE	285/24	3/1973
	A3	4,017,946	4/1977	SOJA	24/285	3/1976
	A4	4,280,742	7/1981	JUSTMAN	308/4 A	3/1980
	A5	4,662,461	5/1997	GARRETT	175/325	7/1981
	A6	4,696,290	9/1987	STEFFEE	128/69	3/1986
	A7	5,054,347	10/1991	JOHNSON ET AL.	83/140	9/1990
	A8	5,169,597	12/1992	DAVIDSON ET AL.	428/613	1/1991
	A9	5,275,601	1/1994	GOGOLEWSKI ET AL.	606/72	9/1991
	A10	5,364,399	11/1994	LOWERY ET AL.	606/69	2/1993
	A11	5,372,660	12/1994	DAVIDSON ET AL.	148/421	8/1993
	A12	5,509,933	4/1996	DAVIDSON ET AL.	623/16	3/1993
	A13	5,520,690	5/1996	ERRICO ET AL.	606/61	4/1995
	A14	5,534,032	7/1996	HODOREK	623/18	12/1994
	A15	5,569,251	10/1996	BAKER ET AL.	606/69	10/1996
	A16	5,578,034	11/1996	ESTES	606/61	6/1995
	A17	5,601,553	2/1997	TREBING ET AL.	606/61	10/1994
	A18	5,607,426	3/1997	RALPH ET AL.	606/61	2/1996
	A19	5,643,265	7/1997	ERRICO ET AL.	606/70	5/1995
	A20	5,725,588	3/1998	ERRICO ET AL.	623/22	4/1996
	A21	5,735,853	4/1998	OLERUD	606/71	6/1995
	A22	5,810,819	9/1998	ERRICO ET AL.	606/61	6/1997
	A23	5,807,396	9/1998	RAVCH	606/69	12/1996
	A24	5,843,082	12/1998	YUAN ET AL.	606/61	5/1996
	A25	5,876,402	3/1999	ERRICO ET AL.	606/61	3/1996
	A26	5,928,243	7/1999	GUYER	606/102	7/1997
	A27	5,935,133	8/1999	WAGNER ET AL.	606/103	12/1998
	A28	5,961,518	10/1999	ERRICO ET AL.	606/61	4/1998
	A29	5,964,769	10/1999	WAGNER ET AL.	606/74	8/1997

EXAMINER'S SIGNATURE 	DATE CONSIDERED 6-16-00
--------------------------	--------------------------------

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

* If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120. 37 C.F.R. 1.98(d).

Notice of Allowability

Application No.
09/349,519

Applicant(s)
Talaber et al.

Examiner
William Lewis

Group Art Unit
3731



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 and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to application filed 7-8-00.

☒ The allowed claim(s) is/are 1-28.

☐ The drawings filed on _____ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS FROM THE "DATE MAILED"** of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 3.

☒ including changes required by the proposed drawing correction filed on Jul 8, 1999, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☐ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

Application/Control Number: 09/349,519

Page 2

Art Unit: 3731

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: the primary reason for allowance is that the prior art fails to teach or adequately disclose a biased stopping member that prevents movement of a securing member.

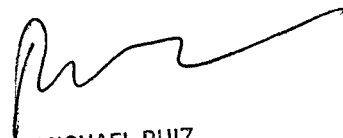
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to W. Lewis whose telephone number is (703) 308-0060.



WL

June 16, 2000



MICHAEL BUIZ
SUPERVISORY PATENT EXAMINER
GROUP 3300

6/18/00

09/349519

NOTICE OF DRAFTSPERSON'S
PATENT DRAWING REVIEWThe drawing(s) filed (insert date) 7/8/99 are:A. ☐ approved by the Draftsperson under 37 CFR 1.84 or 1.152.B. ☒ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be submitted according to the instructions on the back of this notice.1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings:
Black ink. Color.☐ Color drawings are not acceptable until petition is granted.

Fig(s) _____

☐ Pencil and non black ink not permitted. Fig(s) _____

2. PHOTOGRAPHS. 37 CFR 1.84 (b)

☐ 1 full-tone set is required. Fig(s) _____☐ Photographs not properly mounted (must use bristol board or photographic double-weight paper). Fig(s) _____☐ Poor quality (half-tone). Fig(s) _____

3. TYPE OF PAPER. 37 CFR 1.84(e)

☐ Paper not flexible, strong, white, and durable.

Fig(s) _____

☐ Erasures, alterations, overwritings, interlineations,☐ folds, copy machine marks not accepted. Fig(s) _____☐ Mylar, velum paper is not acceptable (too thin).

Fig(s) _____

4. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:

☐ 21.0 cm by 29.7 cm (DIN size A4)☐ 21.6 cm by 27.9 cm (8 1/2 x 11 inches)☐ All drawing sheets not the same size.

Sheet(s) _____

☐ Drawings sheets not an acceptable size. Fig(s) _____

5. MARGINS. 37 CFR 1.84(g): Acceptable margins:

Top 2.5 cm Left 2.5cm Right 1.5 cm Bottom 1.0 cm

SIZE: A4 Size

Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm

SIZE: 8 1/2 x 11

Margins not acceptable. Fig(s) _____

Top (T) _____

Left (L) _____

Right (R) _____

Bottom (B) _____

6. VIEWS. 37 CFR 1.84(h)

REMINDER: Specification may require revision to correspond to drawing changes.

Partial views. 37 CFR 1.84(h)(2)

☐ Brackets needed to show figure as one entity.

Fig(s) _____

☐ Views not labeled separately or properly.

Fig(s) _____

☐ Enlarged view not labeled separately or properly.

Fig(s) _____

7. SECTIONAL VIEWS. 37 CFR 1.84 (h)(3)

☐ Hatching not indicated for sectional portions of an object.

Fig(s) _____

☐ Sectional designation should be noted with Arabic or

Roman numbers. Fig(s) _____

8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)

☐ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____

9. SCALE. 37 CFR 1.84(k)

☐ Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction.

Fig(s) _____

10. CHARACTER OF LINES, NUMBERS, & LETTERS.

37 CFR 1.84(i)

☐ Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (poor line quality).

Fig(s) _____

11. SHADING. 37 CFR 1.84(m)

☐ Solid black areas pale. Fig(s) _____☐ Solid black shading not permitted. Fig(s) _____☐ Shade lines, pale, rough and blurred. Fig(s) _____

12. NUMBERS, LETTERS, & REFERENCE CHARACTERS.

37 CFR 1.84(p)

☒ Numbers and reference characters not plain and legible.Fig(s) 13-16☐ Figure legends are poor. Fig(s) _____☐ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(1)

Fig(s) _____

☐ English alphabet not used. 37 CFR 1.84(p)(2)

Figs _____

☐ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3)

Fig(s) _____

13. LEAD LINES. 37 CFR 1.84(q)

☐ Lead lines cross each other. Fig(s) _____☐ Lead lines missing. Fig(s) _____

14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)

☐ Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Sheet(s) _____

15. NUMBERING OF VIEWS. 37 CFR 1.84(u)

☐ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____

16. CORRECTIONS. 37 CFR 1.84(w)

☐ Corrections not made from prior PTO-948 dated _____

17. DESIGN DRAWINGS. 37 CFR 1.152

☐ Surface shading shown not appropriate. Fig(s) _____☐ Solid black shading not used for color contrast.

Fig(s) _____

COMMENTS

REVIEWER

T. Lequin

DATE

8/9/99

TELEPHONE NO.

703 3058335

ATTACHMENT TO PAPER NO.

3

Notice of References Cited		Application No. 09/349,519		Applicant(s) Talaber et al.		
		Examiner William Lewis		Group Art Unit 3731	Page 1 of 1	
U.S. PATENT DOCUMENTS						
*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
x	A	4,488,543	Dec. 1984	Tornier	606	66
x	B	5,904,683	May 1999	Pohndorf	606	69
	C				----	----
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					
FOREIGN PATENT DOCUMENTS						
*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS
	N					
	O					
	P					
	Q					
	R					
	S					
	T					
NON-PATENT DOCUMENTS						
*		DOCUMENT (Including Author, Title, Source, and Pertinent Pages)				DATE
	U					
	V					
	W					
	X					

* A copy of this reference is not being furnished with this Office action.
(See Manual of Patent Examining Procedure, Section 707.05(a).)



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

0032/0619

EDWARD J LYNCH
HELLER EHRMAN WHITE & McCAULIFFE
525 UNIVERSITY AVENUE
SUITE 1100
PALO ALTO CA 94301-1900

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/349,519	07/08/99	028	LEWIS, W	3731 06/19/00
First Named Applicant	TALABER, 35 USC 154(b) term ext. = 0 Days.			

TITLE OF INVENTION ORTHOPEDIC IMPLANT ASSEMBLY

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 25205-1000	606-069,000	026	UTILITY	YES	\$605.00	09/19/00

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE 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.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- Pay FEE DUE shown above, or
- File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

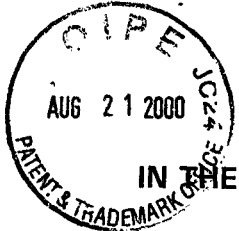
II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your **ISSUE FEE**. Even if the **ISSUE FEE** has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the **ISSUE FEE** to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box **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.

PATENT AND TRADEMARK OFFICE COPY

08-23-00



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of
Talaber et al.
For: **ORTHOPEDIC IMPLANT
ASSEMBLY**
Serial No.: 09/349,519
Filed: July 8, 1999
Atty. Docket No.: 25205-1000

) Examiner: W. Lewis
)
) Group Art Unit: 3731
)
)
) **CONTINUED PROSECUTION**
) **APPLICATION UNDER 37 CFR § 1.53(d)**

GAU 3731
10-19
PATENT
#4
RECEIVED
AUG 25 2000
TC 3700 MAIL ROOM

Express Mail Label No.: EL 294 130 563 US
Mailed in Palo Alto, CA on: August 21, 2000

BOX CPA
Assistant Commissioner for Patents
Washington, D.C. 20231

Match & Return

RECEIVED
AUG 25 2001
TC 3700 MAIL ROOM

Dear Sir:

This is a request for filing a continuation application under the Continued Prosecution Application Procedure, 37 C.F.R. §1.53(d), of the above-identified application.

It is understood that secrecy under 37 U.S.C. §122 is hereby waived to the extent that if information or access is available to any one of the applications in the file jacket of a 37 C.F.R §1.53(d) application, be it either the application or a prior application in the same file jacket, the PTO may provide similar information or access to all the other applications in the same file jacket.

1. This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above. With respect to the prior application from which the present application claims benefit under 35 U.S.C. §120, the inventor(s) in this application is/are:

/ X / the same.
/ / less than those in prior application. It is hereby requested that the following inventors be deleted: _____.

Match & Return

08/24/2000 EHAMMOND 00000013 09349519

01 FC:231 345.00 OP
02 FC:202 39.00 OP
03 FC:203 72.00 OP

✓

2. The names and current address(es) of the inventor(s) as originally filed is/are:

David J. Talaber
5185 Charlotte Way
Livermore, CA 94550-3532

James R Lloyd
1080 Circle Drive
Elm Grove, WI 53122

3. The inventorship for all the claims in this application is:

☒ / X / the same.

☐ / / not the same, and an explanation, including the ownership of the various claims at the time the last claimed invention was made, is submitted.

4. ☒ / X / Applicant(s) is a small entity:

☒ / X / small entity status established in prior application.

☐ / / small entity statement attached.

5. The filing fees are to be calculated on the claims pending in the application and the claims remaining as a result of:

☒ / X / the attached Preliminary Amendment.

☐ / / the unentered amendment filed pursuant to 37 C.F.R. §1.116 in the application, and which Applicants now request be entered.

☐ / / the claims allowed in the notice of allowance mailed .

FILING FEE CALCULATION

	Fee Code	Claims	Extra	Rate	Amount
Basic Fee	201				\$345
Total Claims	203	28 - 20	= 8 x	\$9	72
Independent Claims	202	4 - 3	= 1 x	\$39	39

Filing Fee **\$456.**

6. ☐ / / Applicant hereby petitions for an extension of time for 3 months from.

Fee Code

\$0.

TOTAL FEES DUE \$456.

7. ☐ / / Payment of filing fee is deferred.

8. ☒ / X / Enclosed is a check in the amount of \$456.00.

9. ☐ / ☐ / Please charge \$ _____ .00, to Deposit Account No. 08-1641
10. ☒ / ☒ / The Commissioner is hereby authorized to charge any additional fees and to credit any overpayment of fees which may be required under 37 CFR §1.16 and §1.17, to Deposit Account No. 08-1641, referencing Atty. Docket No. 25205-1000.
11. The application is assigned of record to: _____
12. The power of attorney in the application is to: Edward Lynch.
☒ / ☒ / The power appears in the original papers in the application.
☐ / ☐ / The power does not appear in the original papers, but was filed on: _____
☐ / ☐ / A new power has been executed and is attached.
13. Address all future communications to:

Edward J. Lynch
Heller Ehrman White & McAuliffe LLP
525 University Avenue, Suite 1100
Palo Alto, CA 94301-1900
14. Other documents enclosed herewith:
☒ / ☒ / Preliminary Amendment.
☒ / ☒ / Information Disclosure Statement, PTO-1449 Form, copy of 10 cited references.
☒ / ☒ / Return Receipt Postcard.
☐ / ☐ / Other (Specify: _____).

Respectfully submitted,

By: _____

Edward J. Lynch
Registration No. 24,422

Heller Ehrman White & McAuliffe LLP
525 University Avenue, Suite 1100
Palo Alto, CA 94301-1900
Telephone: (650) 324-7000
Facsimile: (650) 324-0638

245971 v01.PA (59SJ011.DOC)
08/21/00 9:26 AM



10-19

PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Talaber et al.

For: ORTHOPEDIC IMPLANT ASSEMBLY

Serial No.: 09/349,519

Filed: July 8, 1999

Docket No.: 25205-1000

Examiner: W. Lewis

Group Art Unit: 3731

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IDS
see
on

PRELIMINARY AMENDMENT AND
INFORMATION DISCLOSURE STATEMENT AND
COMMENTS ON STATEMENT FOR REASONS FOR ALLOWANCE

BOX CPA
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Please preliminarily amend the above application as indicated below.

IN THE CLAIMS

Please amend claims 6, 11, 23, 25 and 28, as follows:

a! 6. (Amended) The assembly of claim 2 wherein the collar is secured to an anterior section of the transverse passageway, and has a plurality of slots [defining] and circumferentially spaced members, the

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Serial No. 09/349,519
Docket No. 25205-1000

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a' circumferentially spaced members having a deflected configuration defining the expanded inner diameter of the collar.

Q2 11. (Amended) The assembly of claim 10 wherein the body of the securing element has a diameter smaller than the second opening in the stabilizing element, and the securing element may be angularly displaced within the transverse passageway and the second opening in the stabilizing element.

23. (Amended) An orthopedic implant assembly, comprising

Q3 a) a stabilizing element having an anterior surface, a posterior surface, and at least one bore, the bore having a first opening in the anterior surface, a second opening in the posterior surface smaller than the first opening, and a transverse passageway extending from the first opening to the second opening, and a stopping member at an anterior section of the transverse passageway; and

b) a securing element having an elongated body and a head secured to one end of the body, the head having a reversibly compressed configuration with a compressed diameter less than the diameter of the first opening and an uncompressed configuration with a diameter greater than [the] a diameter of the stopping member and the second opening, so that the

head of the securing element is retained within the transverse passageway
between the stopping member and the second opening in the stabilizing
element.

25. (Amended) The assembly of claim 23 wherein the head of the
securing element has a plurality of slots [defining] and circumferentially
disposed members, the circumferentially disposed members having posterior
ends secured to the body of the securing element, and anterior ends radially
moveable toward a longitudinal axis of the head of the securing element to
form the compressed configuration[,] and away from the longitudinal axis to
form the uncompressed configuration.

28. (Amended) A method of attaching an orthopedic implant
assembly to a bone of a patient, comprising

a) positioning a stabilizing element against a surface of the patient's
bone, the stabilizing element having an anterior surface, a posterior surface,
and at least one bore, the bore having a first opening in the anterior surface,
a second opening in the posterior surface smaller than the first opening, and
a transverse passageway extending from the first opening to the second
opening, and a stopping member at an anterior section of the transverse
passageway;

GS b) providing a securing element [a securing element] having an elongated body and a head secured to one end of the body, the head having a reversibly compressed configuration with a compressed diameter less than [the] a diameter of the first opening and an uncompressed configuration with a diameter greater than the diameter of the stopping member and the second opening, so that the head of the securing element is retained within the transverse passageway between the stopping member and the second opening in the stabilizing element;

c) positioning the body of the securing element in the transverse passageway and posteriorly advancing the head of the securing element within [the] a passageway defined by the stopping member and thereby compressing the diameter of the head of the securing element; and

d) attaching the stabilizing element to the bone by advancing the head of the securing element posteriorly of the stopping member so that the diameter of the head of the securing element returns to the uncompressed configuration, to position the head within a posterior section of the transverse passageway between the [biased] stopping member and the second opening in the stabilizing element and the body of the securing element within the patient's bone, so that the securing element is attached to the bone and is retained within the posterior section of the transverse passageway of the stabilizing element.

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Serial No. 09/349,519
Docket No. 25205-1000

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REMARKS

Applicants have amended claims 11, 23 and 28 to correct minor errors therein, and claims 6 and 25 to remove the requirement that the slots define the circumferentially spaced or disposed members.

Applicants wish to bring to the attention of the Patent Office the references listed in the attached PTO-1449, and request that they be considered by the Examiner. This Information Disclosure Statement is being submitted pursuant to 37 CFR 1.97(b)(3), and therefore no fee is due.

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

In the Notice of Allowance mailed June 19, 2000, the Examiner states in the Reasons for Allowance that primary reason for allowance is that the prior art fails to teach or adequately disclose a biased stopping member that prevents movement of a securing member. Applicants note that the reasons for allowance are incorrect as to claims 23 and 28 which do not require a biased stopping member. Specifically, claims 23 and 28 calls for a stopping member at an anterior section of the transverse passageway, but does not require a biased stopping member. Claims 23 and 28 require a stabilizing element having a stopping member, and a securing element having a head having a reversibly compressed configuration with a compressed diameter and an uncompressed configuration with a diameter greater than a diameter

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of the stopping member, which is not disclosed or suggested by the references. Regarding claims 1-22, claims 1 and 21 require a stabilizing element, a biased stopping member defining at least in part a reversibly expandable passageway having a larger diameter configuration and a smaller diameter configuration, and a securing element having a head at one end of the body and integral therewith, having a maximum diameter greater than the smaller diameter configuration of the passageway defined by the biased stopping member and greater than the second opening in the stabilizing element. None of the references disclose or suggest such a configuration.

Applicants submit the claims define patentable subject matter, and respectfully request consideration and early allowance.

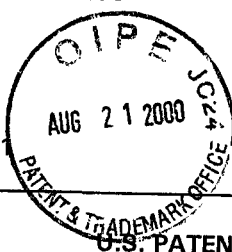
Respectfully submitted,

By: 
Edward J. Lynch
Attorney for Applicants
Registration No. 24,422

Heller Ehrman White & McAuliffe
525 University Avenue, Suite 1100
Palo Alto, CA 94301-1900
Contact: Priscilla Mark
Direct Dial: (650) 324-7184
Telephone: (650) 324-7000
Facsimile: (650) 324-0638

242093 v01.PA (56ST011.DOC)
8/18/00 10:46 AM (25205.1000)

IN THE UNITED STATES PATENT AND TRADE MARK OFFICE INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56, §1.97, and §1.98 PTO-1449 FORM SHEET 1 OF 1	ATTORNEY DOCKET NO.: 25205-1000	09/349,519
	APPLICANTS: Talaber et al.	
	FILING DATE: July 8, 1999	GROUP ART UNIT: 3731



U.S. PATENT DOCUMENTS

† EX'R INITIAL	*REF. #	PATENT NUMBER	DATE (MO/YR)	NAME	U.S. CLASS/ SUBCLASS	FILING DATE (If appropriate)
2P	A1	5,785,711	7/1998	Errico et al.	606/61	5/1997
	A2	5,989,250	11/1999	Wagner et al.	606/61	2/1998
	A3	5,997,539	12/1999	Errico et al.	606/61	4/1998
	A4	6,017,344	1/2000	Errico et al.	606/61	3/1999
	A5	6,030,389	2/2000	Wagner et al.	606/71	6/1998
	A6	6,045,579	4/2000	Hochshuler et al.	623/17	5/1997
↓	A7	6,053,921	4/2000	Wagner et al.	606/74	5/1998

FOREIGN PATENT DOCUMENTS

† EX'R INITIAL	*REF #	PATENT NUMBER	DATE (MO/YR)	COUNTRY	TRANSLATION (YES/NO)
2P	B1	WO 98/17188	4/1998	PCT	NO
3L	B2	WO 98/48739	11/1998	PCT	NO
2P	B3	WO 99/09904	3/1999	PCT	NO

OTHER DOCUMENTS

† EX'R INITIAL	*REF #	CITATION (Author, Article Title, Journal/Book Title, Date, Pertinent Page, et al.)

EXAMINER'S SIGNATURE 	DATE CONSIDERED 10/20/00
------------------------------	---------------------------------

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AUG 25 2001
10:37:00 MAIL ROOM

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

* If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120. 37 C.F.R. 1.98(d).

Notice of Allowability

Application No.
09/349,519

Applicant(s)
Talaber et al.

Examiner
William Lewis

Group Art Unit
3731



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 and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to CPA filed 8-21-2000.

☒ The allowed claim(s) is/are 1-28.

☐ The drawings filed on _____ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 3.

☒ including changes required by the proposed drawing correction filed on Jul 8, 1999, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☐ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☐ Examiner's Statement of Reasons for Allowance

MICHAEL BUIZ
SUPERVISORY PATENT EXAMINER
GROUP 3300

10/23/00



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

QM22/1023

EDWARD J LYNCH
HELLER EHRMAN WHITE & MCAULIFFE
525 UNIVERSITY AVENUE
SUITE 1100
PALO ALTO CA 94301-1900

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/349,519	07/08/99	028	LEWIS, W	3731 10/23/00
First Named Applicant	TALABER, 35 USC 154(b) term ext. = 0 Days.			

TITLE OF INVENTION ORTHOPEDIC IMPLANT ASSEMBLY

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3	25205-1000	606-069,000	U05 UTILITY	YES	\$620.00	01/23/01

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE 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.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- Pay FEE DUE shown above, or
- File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.
Please direct all communications prior to issuance to Box 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.

PATENT AND TRADEMARK OFFICE COPY



12-27-00

PATENT

CP 3731

*

GA

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Talaber et al.

For: **ORTHOPEDIC IMPLANT ASSEMBLY**

Serial No.: 09/349,519

Filed: July 8, 1999

Docket No.: 25205-1000

Examiner: W. Lewis

Group Art Unit: 3731

BATCH NO.: U05

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JAN 12 2001

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Mailed in Menlo Park, CA on December 22, 2000

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INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR 1.97(d)

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicants wish to bring to the attention of the Patent Office the references listed in the attached PTO-1449, and request that they be considered by the Examiner. Applicants hereby Petition for consideration of the information disclosure statement, under 37 CFR 1.97(d)(2), and hereby state that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, under 37 CFR 1.97(d)(1). Copies of the International Search Report and newly cited references are enclosed herewith.

U.S. Patent No. 6,117,173, included on the attached PTO-1449, is related to DE19545612. Although the 6,117,173 patent was not cited in the International Search Report, pursuant to a telephone conversation with Examiner Lewis, Applicants understand that the 6,117,173 patent will be considered by the Examiner pursuant to

MPEP 609.

This Information Disclosure Statement is being submitted pursuant to 37 CFR 1.97(d), and therefore the petition fee under 1.17(i) is due. The Commissioner is authorized to charge to Deposit Account 08-1641, referencing Docket No. 25205-1000, the amount of \$130, to cover Petition Fee Code 122. Any additional fees which may be required with this communication under 37 C.F.R. § 1.16 and § 1.17 should also be charged to Deposit Account 08-1641.

Respectfully submitted,

By: 

William Schmonsees
Registration No. 31,796

Heller Ehrman White & McAuliffe LLP
275 Middlefield Road
Menlo Park, CA 94025
Contact: Priscilla Mark
Direct Dial: (650) 324-7184
Telephone: (650) 324-7000
Facsimile: (650) 324-0638

269315 v01.PA (SRSZ011.DOC)
12/22/00 3:45 PM (25205.1000)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NO.:
25205-1000

SERIAL NO.:
09/349,519

APPLICANTS:
Talaber et al.

FILING DATE:
July 8, 1999

GROUP ART UNIT:
3731

INFORMATION DISCLOSURE STATEMENT

UNDER 37 CFR §1.56, §1.97, and §1.98

PTO-1449 FORM

Sheet 1 of 1

Stamp: OIPE, DEC 22 2000, PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

† EX'R INITIAL	* REF. #	PATENT NUMBER	DATE (MO/YR)	NAME	U.S. CLASS/ SUBCLASS	FILING DATE (If appropriate)
	A1	5,879,389	03/09/99	Koshino		
	A1	6,117,173	09/12/00	Taddia et al.		

FOREIGN PATENT DOCUMENTS

† EX'R INITIAL	* REF. #	PATENT NUMBER	DATE (MO/YR)	COUNTRY	TRANSLATION (YES/NO)
		DE 4409833 A1	10/05/95	Germany	
		DE 19545612 A1	06/12/97	Germany	

OTHER DOCUMENTS

† EX'R INITIAL	* REF. #	CITATION (Author, Article Title, Journal/Book Title, Date, Pertinent Pages, etc.)
		PCT International Search Report dated April 12, 2000: Application No. PCT/US00/18446

EXAMINER'S SIGNATURE

DATE CONSIDERED

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

* If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120. 37 C.F.R. 1.98(d).



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/349,519	07/08/99	TALABER	25205-1000

EDWARD J LYNCH
HELLER EHRMAN WHITE & MCAULIFFE
525 UNIVERSITY AVENUE
SUITE 1100
PALO ALTO CA 94301-1900

QM32/0208

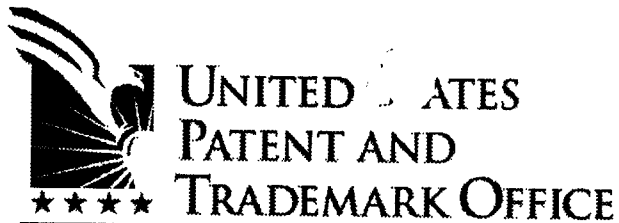
EXAMINER
LEWIS, W

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 02/08/01

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

Commissioner of Patents and Trademarks



UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
WWW.USPTO.GOV

Paper No. 8

Applicant: Talaber et al.
For: Orthopedic Implant Assembly
Serial No.: 09/349,519
Filed: July 8, 1999

Petition under 37 C.F.R. 1.97(d)(2)

An Information Disclosure Statement was filed on December 22, 2000.

A Notice of Allowance was mailed on October 23, 2000.

The Issue Fee was paid on January 23, 2000.

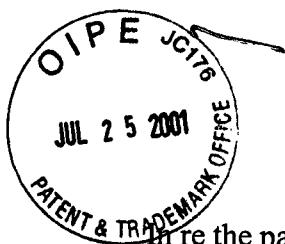
An Information Disclosure Statement (IDS), under 37 C.F.R. 1.97 (d), shall be considered by the Office: if filed after the mailing date of a Notice of Allowance under 37 C.F.R. 3.311, provided the IDS is accompanied by: 1) a certification as specified in 37 C.F.R. 1.97 (e), 2) a petition requesting consideration of the IDS and 3) the petition fee set forth in 37 C.F.R. 1.17 (i) (1).

The IDS filed on December 22, 2000 complies with the requirements of 37 C.F.R. 1.97 (d) and therefore, will be considered by the Examiner.

SUMMARY: Petition granted.

A handwritten signature in black ink, appearing to read "Henry J. Recla". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Henry J. Recla
Supervisory Patent Examiner
Technology Center 3700
703-308-1382



Match & Return *B*

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I am the patent of
Talaber et al.

For: **ORTHOPEDIC IMPLANT ASSEMBLY**

Serial No.: 09/349,519

Filed: July 8, 1999

Atty. Docket No.: 25205-1000

) Examiner: W. Lewis

) Group Art Unit: 3731

) Batch No.: U05

) Patent No.: 6,261,291

) Issued: July 17, 2001

) Customer No.: 25213

COMMUNICATION REGARDING INFORMATION DISCLOSURE STATEMENT

BOX ISSUE FEE

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicants filed a Supplemental Information Disclosure Statement (IDS) Under 37 C.F.R. § 1.97(d), on December 22, 2000, and resubmitted the same on January 23, 2001, with a request for a copy of the PTO-1449 initialled by the Examiner. Applicants received a communication mailed from the PTO on February 8, 2001, indicating that the IDS will be considered by the Examiner and an Issue Notification on July 10, 2001, however, to date Applicants have not received a copy of the PTO-1449 initialled by the Examiner. **Applicants hereby request a copy of the December 22, 2000 PTO-1449 initialled by the Examiner to indicate consideration thereof.**

No fees are due with this communication. The Commissioner is authorized to charge any fees which may be required to Deposit Account No. 08-1641, referencing Docket No. 25205-1000. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

By: _____

Derek P. Freyberg
Derek P. Freyberg
Registration No. 29,250

Heller Ehrman White & McAuliffe LLP
275 Middlefield Road
Menlo Park, CA 94025-3506
Contact: Priscilla Mark
Registration No.: 41,970
Direct Dial: (650) 324-7184
Facsimile: (650) 324-0638

CERTIFICATE OF MAILING PURSUANT TO 37 CFR §1.8

I hereby certify that this paper is being deposited in the United States Postal Service as first class mail with sufficient postage in an envelope addressed to BOX ISSUE FEE, Commissioner for Patents, Washington D.C. 20231, on July 23, 2001, in Menlo Park, CA.

1/7

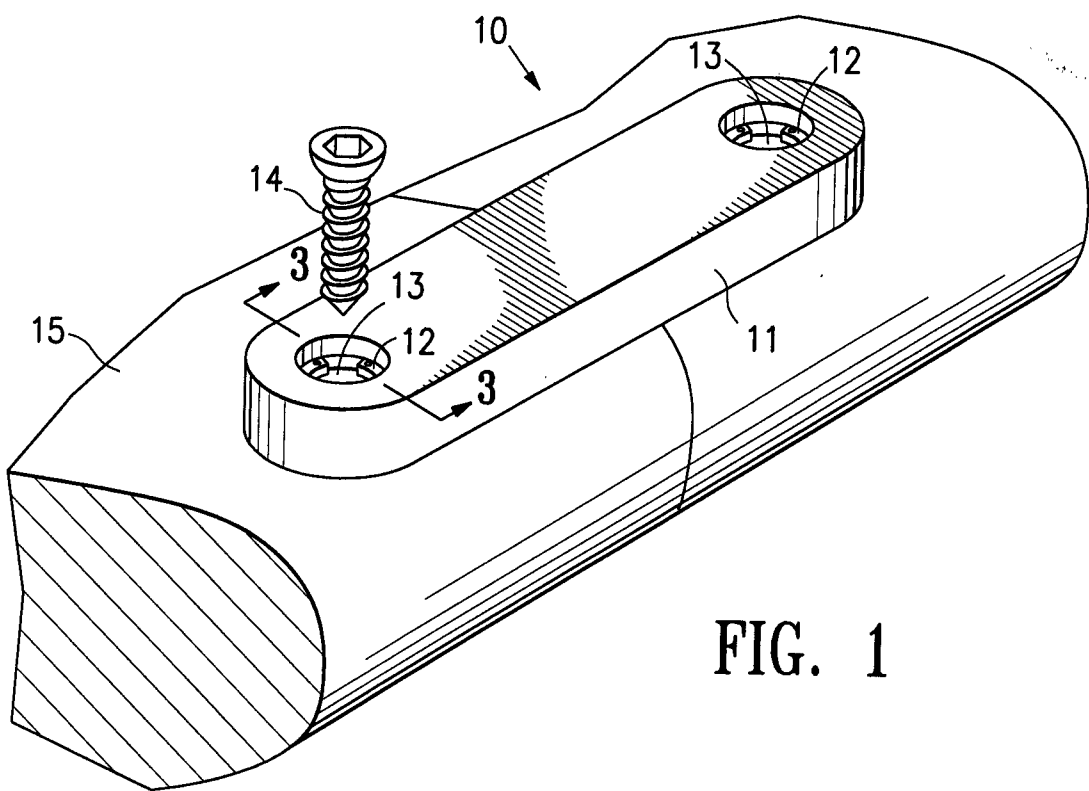
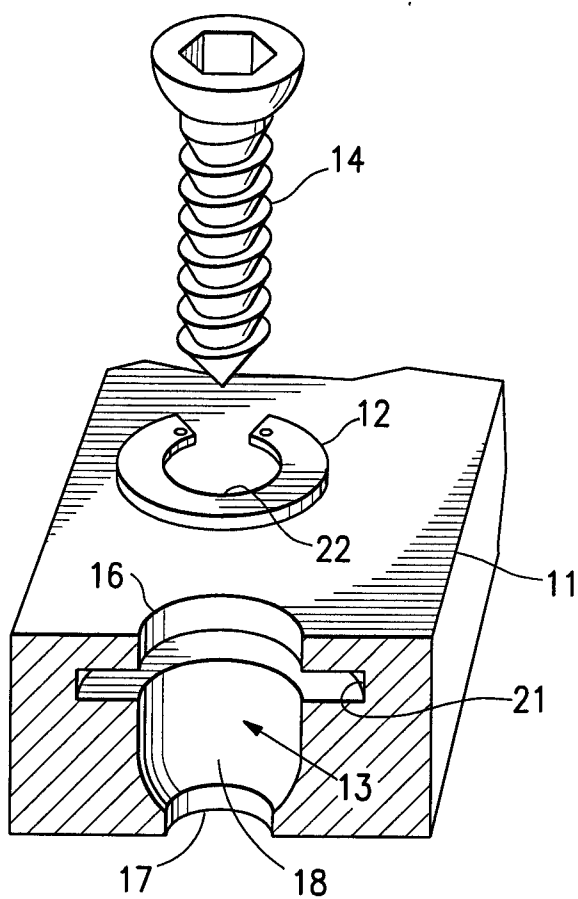


FIG. 1

FIG. 2



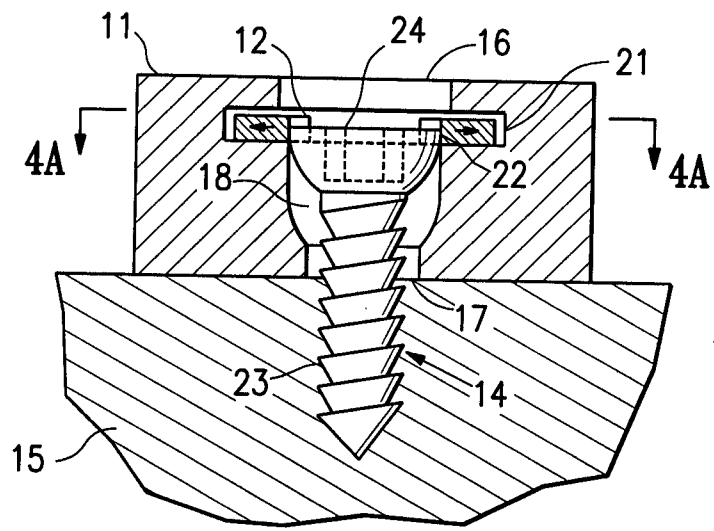


FIG. 4

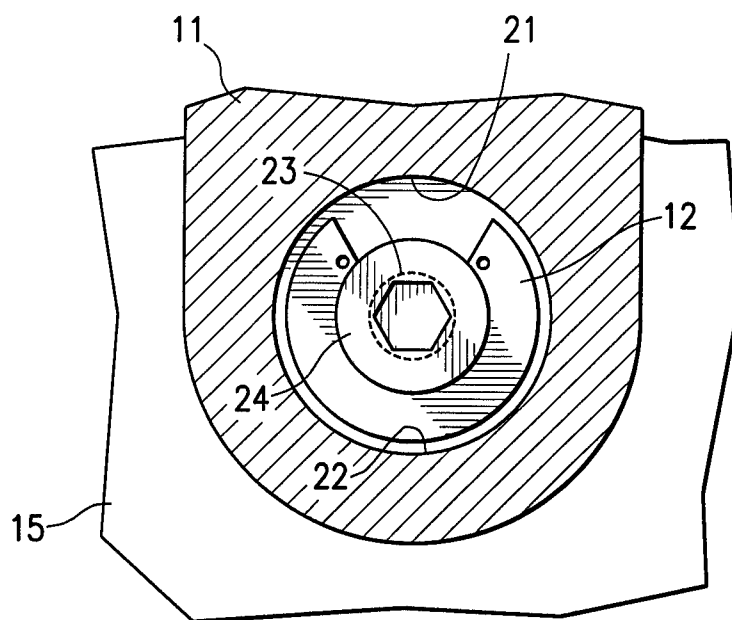


FIG. 4A

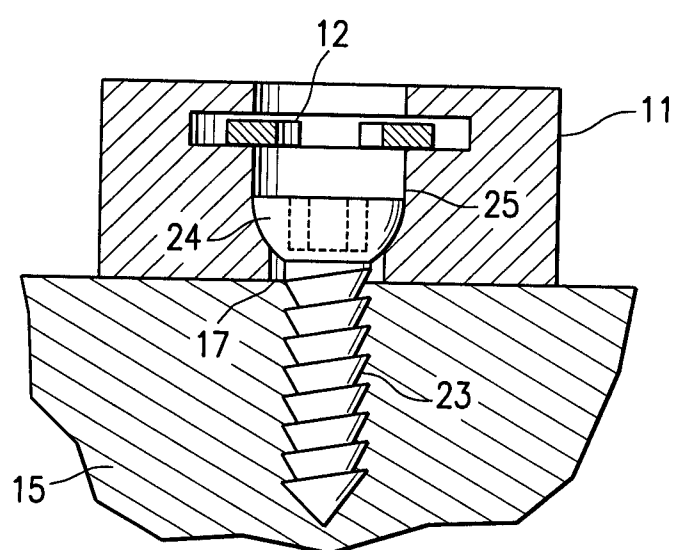


FIG. 5

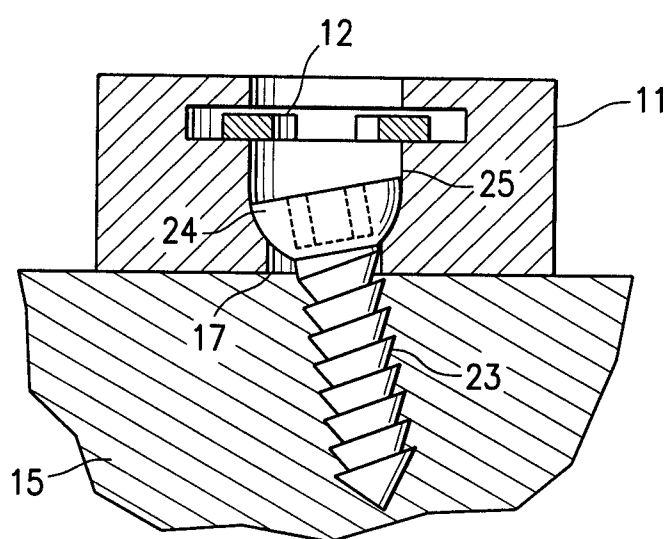


FIG. 6

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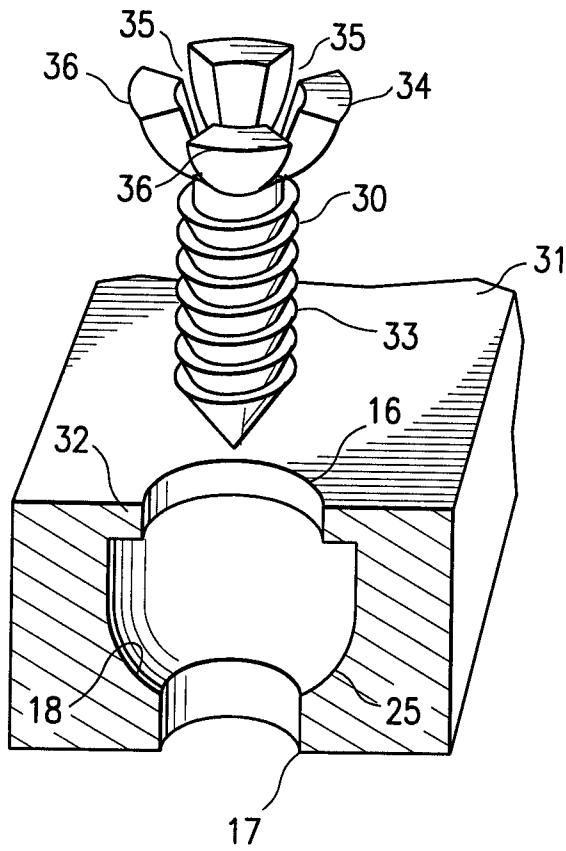


FIG. 7

FIG. 9

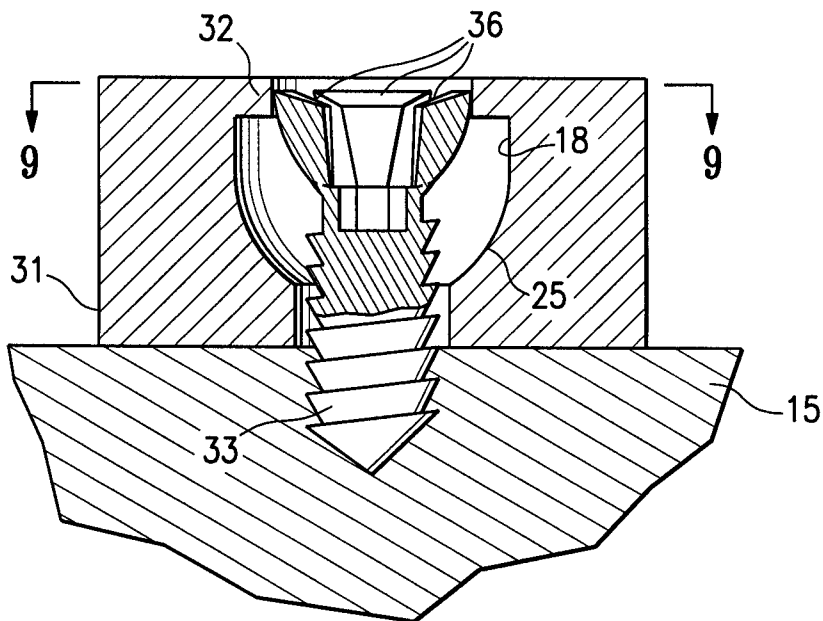
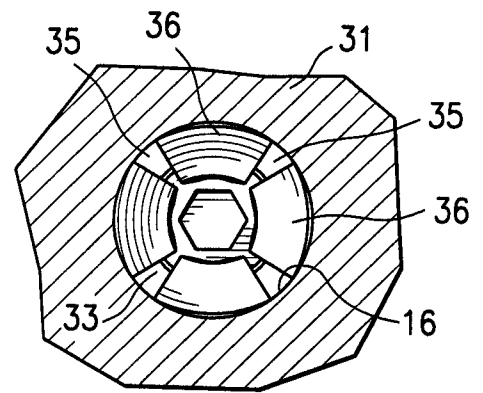


FIG. 8

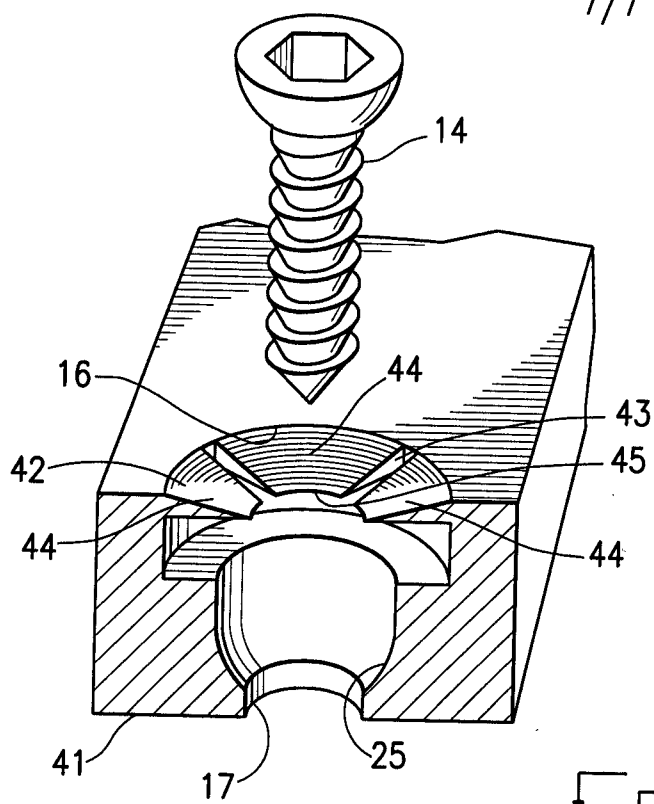


FIG. 13

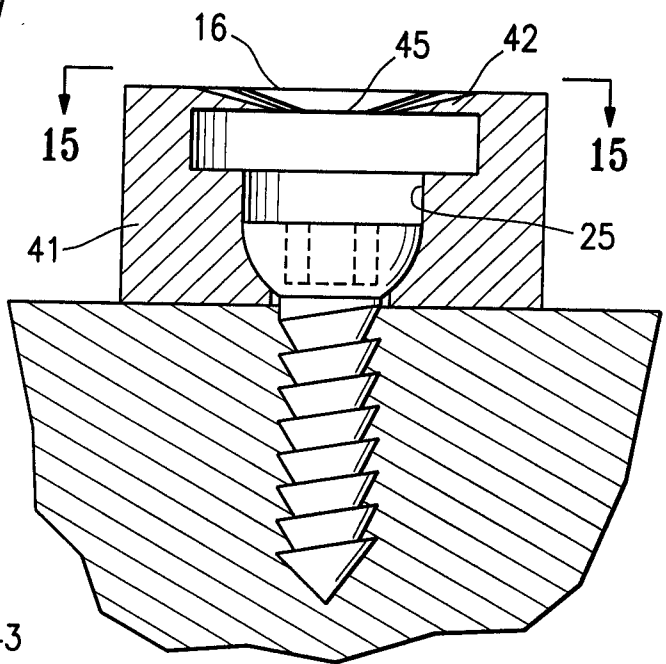


FIG. 14

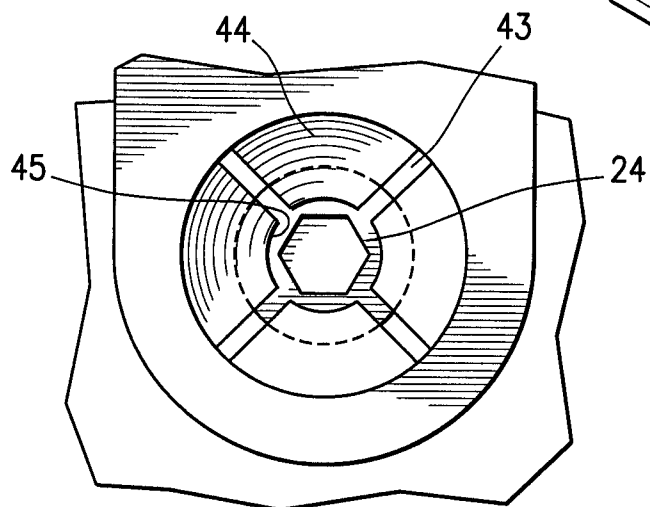


FIG. 15

PART B—ISSUE FEE TRANSMITTAL

Complete and mail this form, together with a

check, fees, to:

Box ISSUE FEE
Assistant Commissioner for Patents
Washington, D.C. 20231Express Mail Label No. EL731830951US
Mailed in Menlo Park, CA on 1/23/01

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 1 through 4 should be completed where appropriate. All correspondence including the Issue Fee Receipt, the Patent, advance order, and application correspondence address as indicated on the form below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

EDWARD J LYNCH
HELLER EHRMAN WHITE & MCAULIFFE
525 UNIVERSITY AVENUE 275 Middlefield Road
SUITE-1100 Menlo Park, CA 94025-3506
PALO ALTO CA 94301-1900

QM22/1023

Note: The certificate of mailing below can only be used for domestic mailings of the Issue Fee Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

Certificate of Mailing

I hereby certify that this Issue Fee Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/349,519	07/08/99	028	LEWIS, W	3731 10/23/00
First Named Applicant	TALABER,	35 USC 154(b) term ext. =	0 Days.	

TITLE OF INVENTION ORTHOPEDIC IMPLANT ASSEMBLY

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3	25205-1000	606-069.000	U05	UTILITY	YES \$620.00	01/23/01

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.

☐ 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) attached.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

Heller Ehrman White & McAuliffe LLP

2

3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)
PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY & STATE OR COUNTRY)

Please check the appropriate assignee category indicated below (will not be printed on the patent)

☐ Individual ☐ corporation or other private group entity ☐ government

4a. The following fees are enclosed (make check payable to Commissioner of Patents and Trademarks):

☒ Issue Fee
☒ Advance Order - # of Copies 10

4b. The following fees or deficiency in these fees should be charged to:

DEPOSIT ACCOUNT NUMBER 08-1641
(ENCLOSE AN EXTRA COPY OF THIS FORM)

☒ Issue Fee
☒ Advance Order - # of Copies 10

THE COMMISSIONER OF PATENTS AND TRADEMARKS IS requested to apply the Issue Fee to the application identified above.

(Authorized Signature)

Reg. No. 24,422

(Date)

1/23/01

NOTE: The Issue Fee 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 Patent and Trademark Office.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND FEES AND THIS FORM TO: Box Issue Fee, Assistant Commissioner for Patents, Washington D.C. 20231

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001

Heller Ehrman
ATTORNEYS

275 Middlefield Road
Menlo Park, CA 94025-3506
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Fax: (650) 324-0638

Facsimile Transmitted **RECEIVED**

JAN 19 2001

GROUP 3700

To: Examiner W. Lewis
Telephone: (703) 308-0060

Fax: (703) 305-3590 (3591)

From: Nita J. Miller
Telephone: (650) 324-7107

No. of Pages: 20 (including cover)

Date: January 19, 2001

5613/25205-1000

Re: U.S. Patent Application of
Talaber et al.
Serial No: 09/349,519
Filed July 8, 1999
For: ORTHOPEDIC IMPLANT ASSEMBLY
Atty. Docket No.: 25205-1000

Examiner: W. Lewis
Group Art Unit: 3731
Batch No.: U05
Customer No.: 25213

Message:

URGENT MESSAGE

PLEASE HAND DELIVER IMMEDIATELY TO:

EXAMINER W. LEWIS

GROUP ART UNIT 3731

Pursuant to your request, attached are copies of the following documents which were submitted to the PTO for filing on December 22, 2000:

- PTO stamped return postcard acknowledging receipt on December 22, 2000;
- Information Disclosure Statement;
- PTO-1449;
- International Search Report;
- German Application Nos. DE 44 09 833 A1 and DE 195 45 612 A1.

Should you have any questions, please contact us.

275342 v01.SV (5WG#011.DOC)
1/19/01 2:36 PM (25205.1000)

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Heller Ehrman White & McAuliffe LLP www.hewm.com

San Francisco Silicon Valley Los Angeles San Diego Seattle Portland Anchorage New York Washington D.C. Hong Kong Singapore
Affiliated Counsel Offices: Milan Rome Paris Padua Naples

0100

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002

R/

F/

A/ RECEIVED BY THE US PATENT AND TRADEMARK OFFICE:

D File No. / Attorney: 25205-1000 EJI/PM/
D Application No.: 09/349,519
Date Mailed: December 22, 2000

Documents:
Information Disclosure Statement (2 pages), PTO-1449 (1 page)
with 4 cited references.

Express Mail Label: EE 708 560 654 US



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Talaber et al.

For: ORTHOPEDIC IMPLANT ASSEMBLY

Serial No.: 09/349,519

Filed: July 8, 1999

Docket No.: 25205-1000

Examiner: W. Lewis

Group Art Unit: 3731

BATCH NO.: U05

FAX RECEIVED

JAN 19 2001

GROUP 3700

Express Mail Label No. EE 708 560 654 USMailed in Menlo Park, CA on December 22, 2000INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR 1.97(d)Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicants wish to bring to the attention of the Patent Office the references listed in the attached PTO-1449, and request that they be considered by the Examiner. Applicants hereby Petition for consideration of the information disclosure statement, under 37 CFR 1.97(d)(2), and hereby state that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, under 37 CFR 1.97(d)(1). Copies of the International Search Report and newly cited references are enclosed herewith.

U.S. Patent No. 6,117,173, included on the attached PTO-1449, is related to DE19545612. Although the 6,117,173 patent was not cited in the International Search Report, pursuant to a telephone conversation with Examiner Lewis, Applicants understand that the 6,117,173 patent will be considered by the Examiner pursuant to

MPEP 609.

This Information Disclosure Statement is being submitted pursuant to 37 CFR 1.97(d), and therefore the petition fee under 1.17(i) is due. The Commissioner is authorized to charge to Deposit Account 08-1641, referencing Docket No. 25205-1000, the amount of \$130, to cover Petition Fee Code 122. Any additional fees which may be required with this communication under 37 C.F.R. § 1.16 and § 1.17 should also be charged to Deposit Account 08-1641.

Respectfully submitted,

By: 

William Schmonsees
Registration No. 31,796

Heller Ehrman White & McAuliffe LLP
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Menlo Park, CA 94025
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269315 v01.PA (SRSZ011.DOC)
12/22/00 3:45 PM (25205.1000)

<p>IN THE UNITED STATES PATENT AND TRADEMARK OFFICE</p> <p>INFORMATION DISCLOSURE STATEMENT</p> <p>UNDER 37 CFR §1.56, §1.97, and §1.98</p> <p>PTO-1449 FORM</p> <p>Sheet 1 of 1</p>	<p>ATTORNEY DOCKET NO.</p> <p>25205-1000</p>	<p>SERIAL NO.:</p> <p>09/349,519</p>
	<p>APPLICANTS:</p> <p>Talaber et al.</p>	
	<p>FILING DATE:</p> <p>July 8, 1999</p>	<p>GROUP ART UNIT:</p> <p>3731</p>

U.S. PATENT DOCUMENTS


[illegible]

FOREIGN PATENT DOCUMENTS

† EXR INITIAL	* REF. #	PATENT NUMBER	DATE (MO/YR)	COUNTRY	TRANSLATION (YES/NO)
24		DE 4409833 A1	10/05/95	Germany	
24		DE 19545612 A1	06/12/97	Germany	

OTHER DOCUMENTS

† EX'R INITIAL	* REF. #	CITATION (Author, Article Title, Journal/Book Title, Date, Pertinent Pages, etc.)
		PCT International Search Report dated April 12, 2000: Application No. PCT/US00/18446

EXAMINER'S SIGNATURE	DATE CONSIDERED
	10/20/00

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

* If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120. 37 C.F.R. 1.98(d).

PATENT COOPERATION TREATY
PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 25205-5000PCT	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 00/18446	International filing date (day/month/year) 06/07/2000	(Earliest) Priority Date (day/month/year) 08/07/1999
Applicant TALABER, David, J. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (see Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1
☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/18446

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 195 45 612 A (AESCULAP) 12 June 1997 (1997-06-12)	17-20
Y	column 1, line 46 - line 68 column 2, line 36 - line 49; figure 2 ---	21
X	US 5 879 389 A (T.KOSHINO) 9 March 1999 (1999-03-09)	1,10-13
Y	column 12, line 41 - line 56	21
A	column 12, line 65 - column 13, line 23 column 13, line 58 - line 62; figure 6 ---	14-16
X	✓ US 5 876 402 A (J.P.ERRICO ET AL.) 2 March 1999 (1999-03-02)	1-5,9, 12-16
A	column 6, line 1 - line 12 column 7, line 41 - line 55; figures 3B,6 ---	11
	--- -/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

g document member of the same patent family

Date of the actual completion of the international search

27 November 2000

Date of mailing of the international search report

04/12/2000

Name and mailing address of the ISA
European Patent Office, P.B. 5618 Patentlaan 2

Authorized officer

01/19/2001 15:12 FAX

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008

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/18446

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 44 09 833 A (BIEDERMANN MOTECH) 5 October 1995 (1995-10-05) column 2, line 16 -column 3, line 3 column 3, line 25 - line 52; figures 3,4 -----	1,12,13

PATENT APPLICATION FEE DETERMINATION RECORD

Effective November 10, 1998

Application or Docket Number

09/349519

CLAIMS AS FILED - PART I

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA
BASIC FEE		
TOTAL CLAIMS	28 minus 20=	* 8
INDEPENDENT CLAIMS	4 minus 3 =	* 1
MULTIPLE DEPENDENT CLAIM PRESENT		

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

CLAIMS AS AMENDED - PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*		Minus	**	=
Independent	*		Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					

(Column 1)

(Column 2)

(Column 3)

AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*		Minus	**	=
Independent	*		Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					

(Column 1)

(Column 2)

(Column 3)

AMENDMENT C		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*		Minus	**	=
Independent	*		Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					

SMALL ENTITY TYPE ☒

OR OTHER THAN SMALL ENTITY

RATE	FEE		RATE	FEE
	380.00	OR		760.00
X\$ 9=	12	OR	X\$18=	
X39=	39	OR	X78=	78
+130=		OR	+260=	
TOTAL	491	OR	TOTAL	

SMALL ENTITY

OR OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 9=		OR	X\$18=	
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 9=		OR	X\$18=	
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 9=		OR	X\$18=	
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

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

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

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

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