Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Jeff Tyber	Nonprovisional Application Number (if known):	
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /David G. Lindenbaum/	Date 2021-05-18
Name (Print/Typed) David G. Lindenbaum	Practitioner Registration Number 51,951

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

Extremity Medical, LLC
EXHIBIT 2020 - Corrected
Fusion Orthopedics v. Extremity Medical
Case IPR2023-00894

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Filer:	David G. Lindenbaum
Attorney Docket Number:	024664

Filed as Small Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400
REQUEST FOR PRIORITIZED EXAMINATION	2817	1	2100	2100
Pages:				
Claims:				
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**3000**

Electronic Acknowledgement Receipt	
EFS ID:	42757513
Application Number:	17323923
International Application Number:	
Confirmation Number:	5684
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Customer Number:	27776
Filer:	David G. Lindenbaum
Filer Authorized By:	
Attorney Docket Number:	024664
Receipt Date:	18-MAY-2021
Filing Date:	
Time Stamp:	19:13:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$3000
RAM confirmation Number	E20215HJ13394550
Deposit Account	502968
Authorized User	David Lindenbaum
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	ADS.pdf	2127317 77e54f5c72eb0c62756fb1c306014a5b9d44a78f	no	8
Warnings:					
Information:					
2		Specification.pdf	187220 79b64e8ea5abddeedf936acf2d84eb4960335f1d	yes	31

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Abstract	31	31
Claims	27	30
Specification	1	26

Warnings:					
Information:					
3	Drawings-only black and white line drawings	Figures.pdf	2888511 6ffaa8757bcc89ef8ecaadacf0a86e57f0226223	no	20
Warnings:					
Information:					
4		Declarations.pdf	1956263 5674fcccee992f711383efe53690cde1f623c365	yes	2

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Oath or Declaration filed	2	2

	Oath or Declaration filed		1		1
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
5	Oath or Declaration filed	Substitute_Statement.pdf	526851 8c81925e42b37a880f17dfeb9a6cdaeb4ac676c5	no	2
Warnings:					
Information:					
6	TrackOne Request	TrackOneRequest.pdf	112284 8f5aaf39f730bb45adb9f383e2bb550f387e331f	no	2
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	39923 7e35ddbe184cddc6889980e00d26492492d7fd2e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	7838369		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/14 (12-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	024664
	Application Number	
Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jeff		Tyber	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	Bethlehem	State/Province	PA	Country of Residence	US

Mailing Address of Inventor:

Address 1	4201 Anthony Drive		
Address 2			
City	Bethlehem	State/Province	PA
Postal Code	18020	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jamy		Gannoe	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	West Milford	State/Province	NJ	Country of Residence	US

Mailing Address of Inventor:

Address 1	35 Green Terrace Way		
Address 2			
City	West Milford	State/Province	NJ
Postal Code	07480	Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Lawrence		Kiefer	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	024664
	Application Number	
Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE	

City	Lafayette	State/Province	NJ	Country of Residence	US

Mailing Address of Inventor:

Address 1	95 Beaver Run Road		
Address 2			
City	Lafayette	State/Province	NJ
Postal Code	07848	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	27776		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE		
Attorney Docket Number	024664	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	20	Suggested Figure for Publication (if any)	

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	024664
	Application Number	
Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	◯ Limited Recognition (37 CFR 11.9)
Customer Number	27776		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the application number blank.

Prior Application Status	Pending				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
	Continuation of	17002005	2020-08-25		
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17002005	Continuation of	15884048	2018-01-30	10751097	2020-08-25
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15884048	Continuation of	15181435	2016-06-14	9877752	2018-01-30
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15181435	Continuation of	14599671	2015-01-19	9364271	2016-06-14
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14599671	Division of	12658680	2010-02-11	9044282	2015-06-02
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12658680	Continuation in part of	12456808	2009-06-23	8303589	2012-11-06

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	024664
	Application Number	
Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
12456808	Claims benefit of provisional	61132932	2008-06-24

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☐ Authorization to Permit Access to the Instant Application by the Participating Offices

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	024664
	Application Number	
Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE	

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date o f filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☒

Organization Name	Extremity Medical LLC		
Mailing Address Information For Applicant:			
Address 1	300 Interpace Parkway		
Address 2	Building A, 4th Floor		
City	Parsippany	**State/Province**	NJ
Country	US	Postal Code	07054
Phone Number		Fax Number	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	024664
	Application Number	
Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE	

Email Address	

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

Organization Name	Extremity Medical LLC

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	300 Interpace Parkway		
Address 2	Building A, 4th Floor		
City	Parsippany	**State/Province**	NJ
Country i	US	Postal Code	07054
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Signature	/David G. Lindenbaum/			Date (YYYY-MM-DD)	2021-05-18
First Name	David	Last Name	Lindenbaum	Registration Number	51951

Additional Signature may be generated within this form by selecting the Add button. Add

PTO/AIA/14 (12-13)
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	024664
	Application Number	
Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ABSTRACT

An intramedullary assembly for intraosseous bone fusion includes a lag screw member and a tapered screw member. The lag screw member includes a first elongated body, where the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end. The tapered screw member is coupled to the lag screw member, and the tapered screw member includes a second elongated body, where the second elongated body includes a second threaded portion at a third end, and an opening at a fourth end.

IN THE CLAIMS:

1. An assembly for bone fusion, comprising:

a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;

a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;

a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis, wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, and a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member, wherein the first bore comprises an interior surface at the first aperture, wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,

wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the

third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle,

wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture,

wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture,

wherein the first angle is in the range of about 0 degrees to about 90 degrees,

wherein the second angle is in the range of about 0 degrees to about 90 degrees, and

wherein the second bore axis is substantially perpendicular to the third longitudinal axis.

2. The assembly of claim 1, wherein the head portion of the first member resides at least partially within the first bore.

3. The assembly of claim 2, wherein the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture.

4. The assembly of claim 3, wherein the head portion of the first member comprises a torque transmitting aperture.

5. The assembly of claim 1, wherein the first aperture of the third member is aligned on the first bore axis.

6. The assembly of claim 5, wherein the head portion of the first member resides at least partially within the first bore.

7. The assembly of claim 6, wherein the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture.

8. The assembly of claim 1, wherein the head portion of the first member is tapered.

9. The assembly of claim 1, wherein the first bore axis and the second bore axis intersect outside the third member.

10. The assembly of claim 1, wherein the first end of the first member includes a self-tapping edge for removing bone material.

11. The assembly of claim 10, wherein the first end of the second member includes a self-tapping edge for removing bone material.

12. An assembly for bone fusion, comprising:

a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;

a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;

a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis, wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, and a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member, wherein the first bore

comprises an interior surface at the first aperture, wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,

wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle,

wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture,

wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture,

wherein the second angle is in the range of about 0 degrees to about 90 degrees, and wherein the second bore axis is substantially perpendicular to the third longitudinal axis.

13. The assembly of claim 12, wherein the head portion of the first member resides at least partially within the first bore.

14. The assembly of claim 13, wherein the head portion of the first member is tapered.

15. The assembly of claim 12, wherein the head portion of the first member is tapered.

INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Patent Application No. 17/002,005, filed on August 25, 2020, which is a continuation of U.S. Patent Application No. 15/884,048, filed on January 30, 2018, which is a continuation of U.S. Patent Application No. 15/181,435, filed on June 14, 2016, which is a continuation of U.S. Patent Application No. 14/599,671, filed on January 19, 2015, which is a divisional of U.S. Patent Application No. 12/658,680, filed February 11, 2010, which is a continuation-in-part application of U.S. Patent Application No. 12/456,808, filed June 23, 2009, which claims the benefit of Provisional Patent Application No. 61/132,932, filed June 24, 2008. The entire contents of the entire chain of applications are herein incorporated by reference.

FIELD OF THE INVENTION

This invention relates to the field of orthopedic implant devices, and more particularly, to an intramedullary fixation assembly used for fusion of the angled joints, bones and deformity correction, such as the hand and foot bones.

BACKGROUND OF THE INVENTION

Orthopedic implant devices, such as intramedullary nails, plates, rods and screws are often used to repair or reconstruct bones and joints affected by trauma, degeneration, deformity and disease, such as Charcot arthropathy caused by diabetes in some patients, Hallux Valgus deformities, failed Keller Bunionectomies, Rheumatoid Arthritis, and severe deformities.

Moreover, infections and wound complications are a major concern in the aforementioned procedures. Wound closure is technically demanding for the surgeon, and devices that add surface prominence, such as plates or exposed screws, add to the difficulty by requiring greater tissue tension during incision reapproximation. This increases the risk of postoperative wound infections and dehiscence that may ultimately result in limb amputation.

Various implants have been utilized for surgical treatment of these bones and joints, including bone screws. Implants have also been utilized to treat severe deformities in the metatarsal and phalangeal bones, including multiple screws and plates. These multiple screws and plate implants have been commonly used in a first metatarsal-phalangeal fusion procedure to fuse the first metatarsal to the first phalangeal bone in hallux valgus deformities, failed keller bunionectomies, rheumatoid arthritis, and other types of severe deformities in the metatarsal and phalange bones. While these devices allow fixation and promote fusion, they do not deliver restoration of the arch in a Charcot foot, they are not effective in metatarsal-phalangeal (MTP) fusion procedures, nor do they deliver uniform compression for various predetermined angles of compression..

Particularly, screw implants in MTP procedures are ineffective in delivering sufficient compression to the bones in the foot, preventing screw head break out, or delivering effective bending resistance. Moreover, hard to control dorsiflexion and valgus angles as well skin irritation from proximity to the skin prevents these screw implants from being readily utilized for surgical treatment. Yet further, plate implants used with bone screws too have the same drawbacks as fixed varus and valgus angles, lack of direct compression across the MTP joint, and skin irritations from proximity to the skin reduce the effectiveness of these implants.

There is therefore a need for an intramedullary fixation assembly and method of use that overcomes some or all of the previously delineated drawbacks of prior fixation assemblies.

SUMMARY OF THE INVENTION

An object of the invention is to overcome the drawbacks of previous inventions.

Another object of the invention is to provide a novel and useful intramedullary fixation assembly that may be utilized to treat bones in a human body.

Another object of the invention is to provide a system for compressing bones using an intramedullary fixation assembly.

Another object of the invention is to fuse the bones in the human body through the use of an intraosseous intramedullary assembly.

Another object of the invention is to provide a fixed acute angle intramedullary fixation assembly for bone fixation.

Another object of the invention is to provide variable acute angles an intramedullary fixation assembly for bone fixation having variable acute angles of fixation.

Another object of the invention is to provide at least three point of compression on bone fragments through a variable angle intramedullary fixation assembly.

In a first non-limiting aspect of the invention, an intramedullary assembly for bone fusion is provided and includes a lag screw member and a tapered screw member. The lag screw member includes a first elongated body, where the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end. The tapered screw member is coupled to the lag screw member, and the tapered screw member includes a second elongated

body, where the second elongated body includes a second threaded portion at a third end, and an opening at a fourth end.

In a second non-limiting aspect of the invention, a method for bone fusion includes eight steps. In step one, an intramedullary assembly is provided, where the intramedullary assembly includes a lag screw member having a first elongated body. The first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end. The intramedullary assembly also includes a tapered screw member coupled to the lag screw member, where the tapered screw member includes a second elongated body having a second threaded portion at a third end, a tubular portion at a fourth end, and an opening at the fourth end. Step two includes making an incision in the foot. Step three includes drilling a first medullary canal in a first bone. Step four includes inserting the tapered screw member into the first medullary canal. Step five includes aligning the tapered screw member in the first medullary canal. Step six includes drilling a second medullary canal in the first bone. Step seven includes slideably coupling the lag screw member to the tapered screw member. Step seven includes inserting the lag screw member into the second medullary canal. Step eight includes applying compression to the lag screw member to lock the tapered screw member to the lag screw member, thereby fusing the first bone to the second bone.

BRIEF DESCRIPTION OF THE DRAWINGS

A further understanding of the invention can be obtained by reference to a preferred embodiment set forth in the illustrations of the accompanying drawings. Although the illustrated embodiment is merely exemplary of systems and methods for carrying out the invention, both the organization and method of operation of the invention, in general, together with further

objectives and advantages thereof, may be more easily understood by reference to the drawings and the following description. The drawings are not intended to limit the scope of this invention, which is set forth with particularity in the claims as appended or as subsequently amended, but merely to clarify and exemplify the invention.

For a more complete understanding of the invention, reference is now made to the following drawings in which:

Figure 1 is a perspective view of a fixation system according to a preferred embodiment of the invention.

Figure 2 is a perspective view of a proximal screw member used in the fixation system shown in Figure 1 according to the preferred embodiment of the invention.

Figure 3A is a perspective view of a distal member used in the fixation system shown in Figure 1 according to the preferred embodiment of the invention.

Figure 3B is a perspective cross-sectional view of the distal member shown in Figure 3A according to the preferred embodiment of the invention.

Figure 4 is a perspective view of the instrument member used in the fixation system shown in Figure 1 according to the preferred embodiment of the invention.

Figure 5 is a perspective view of the assembled intramedullary fixation assembly inserted into the bones of a patient's foot according to the preferred embodiment of the invention.

Figure 6 is a side view of the assembled intramedullary fixation assembly shown in Figure 5 according to the preferred embodiment of the invention.

Figure 7 is a flow chart illustrating the method of coupling the intramedullary fixation assembly shown in Figures 1-6 to tarsal and metatarsal bones in a patient's foot according to the preferred embodiment of the invention.

Figure 8 is a perspective view of an assembled intramedullary fixation assembly inserted into the bones of a patient's foot according to an alternate embodiment of the invention.

Figure 9 is a perspective view of the intramedullary fixation assembly shown in Figure 8 according to the alternate embodiment of the invention.

Figure 10 is a perspective view of the lag screw member used in the intramedullary fixation assembly shown in Figures 8-9 according to the alternate embodiment of the invention.

Figure 11 is a perspective view of the tapered screw member used in the intramedullary fixation assembly shown in Figures 8-9 according to the alternate embodiment of the invention.

Figure 12 is a flow chart illustrating the method of coupling the intramedullary fixation assembly shown in Figure 8-9 to bones in a patient's foot according to the alternate embodiment of the invention.

Figure 13 is a perspective view of an assembled intramedullary fixation assembly inserted into the bones of a patient's hand according to an alternate embodiment of the invention.

Figure 14 is a perspective view of the intramedullary fixation assembly shown in Figure 13 according to the alternate embodiment of the invention.

Figure 15 is a perspective view of the lag screw member used in the intramedullary fixation assembly shown in Figures 14 according to the alternate embodiment of the invention.

Figure 16 is a perspective view of the polyaxial screw member used in the intramedullary fixation assembly shown in Figure 14 according to the alternate embodiment of the invention.

Figure 17 is a perspective view of an assembled intramedullary fixation assembly according to an alternate embodiment of the invention.

Figure 18 is a perspective view of an assembled intramedullary fixation assembly having a plurality of lag screw members according to an alternate embodiment of the invention.

Figure 19 is an exploded perspective view of a cover member for a lag screw according to an alternate embodiment of the invention.

DETAILED DESCRIPTION

The invention may be understood more readily by reference to the following detailed description of preferred embodiment of the invention. However, techniques, systems, and operating structures in accordance with the invention may be embodied in a wide variety of forms and modes, some of which may be quite different from those in the disclosed embodiment. Consequently, the specific structural and functional details disclosed herein are merely representative, yet in that regard, they are deemed to afford the best embodiment for purposes of disclosure and to provide a basis for the claims herein, which define the scope of the invention. It must be noted that, as used in the specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly indicates otherwise.

Referring now to Figure 1, there is shown a fixation system 100 which is made in accordance with the teachings of the preferred embodiment of the invention. As shown, the fixation system 100 includes an intramedullary fixation assembly 110, comprising a proximal screw member 130 and a distal member 140. Proximal screw member 130 is provided on proximal end 135 of assembly 110 and is coupled to a distal member 140 that is provided on the distal end 145 of the fixation assembly 110. Also, proximal screw member 130 makes a fixed angle 150 with distal member 140 and this angle 150 determines the angle for arch restoration. Moreover, fixation system 100 includes instrument 120 that is utilized to couple intramedullary fixation assembly 110 to the bones in the mid-foot region (not shown). It should be appreciated that in one non-limiting embodiment, intramedullary fixation assembly 110 may be made from a

Titanium material, although, in other non-limiting embodiments, intramedullary fixation assembly 110 may be made from SST, PEEK, NiTi, Cobalt chrome or other similar types of materials.

As shown in Figure 2, proximal screw member 130 is generally cylindrical in shape and extends from first bulbous portion 202 to second tapered end 204. End 204 has a diameter that is slightly smaller than diameter 226 of bulbous portion 202. Additionally, bulbous portion 202 has a taper, such as a Morse taper, with a width that decreases from end 211 to end 212. The taper allows for a locked interference fit with tapered aperture 316 when tapered bulbous portion 202 is combined with tapered aperture 316, shown and described below. Moreover, bulbous portion 202 is generally circular and has a generally hexagonal torque transmitting aperture 208 that traverses length 210 of bulbous portion 202. However, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope of the invention. Torque transmitting aperture 208 is utilized to transmit a torque from bulbous portion 202 to tapered end 204 by rotating bulbous portion 202.

Further, proximal screw member 130 has a first smooth exterior portion 206 extending from end 212 of bulbous portion 202. Portion 206 comprises an internal aperture 214 that longitudinally traverses portion 206 in direction 201. Portion 206 terminates into a second generally tubular portion 216. Portion 216 may comprise internal circular aperture 220 that longitudinally traverses inside portion 216. Internal circular aperture 220 is aligned with apertures 214 and 208 along axis 203 to form a continuous opening (i.e., a cannula) from bulbous portion 202 to end 204. The continuous opening or cannula is provided to interact with a guide wire (not shown) by receiving the guide wire within the continuous opening thereby positioning and locating the proximal member 130. In other non-limiting embodiments, the

proximal member 130 may be provided without apertures 220 and 214 (i.e., the proximal member is solid).

Furthermore, tubular portion 216 has a plurality of circular threads, such as threads 218, which are circumferentially disposed on the external surface of portion 216 and, with threads 218 having an external diameter 224. Portion 216 may also be provided with a self-tapping leading edge 222 to provide portion 216 with the ability to remove bone material during insertion of proximal screw member 130 into bone. It should be appreciated that the length of the proximal member 130 may be selected of varying lengths to allow a surgeon to fuse different joints in a foot (not shown).

As shown in Figures 3A-3B, distal member 140 of the preferred embodiment is generally tubular in shape and tapers from a first end 302 to a second end 304 (i.e. end 302 has a diameter 306 that is slightly larger than diameter 308 of end 304). However, in another non-limiting embodiment, distal member 140 has a constant width from first end 302 to second end 304. Further, first end 302 is generally semi-spherical in shape and has an internal circular aperture 316, which traverses end 302 along direction 301 (i.e. end 302 is generally "donut" shaped). Additionally, circular aperture 316 emanates from surface 322, such that portion 310 has a generally tapered aperture 316 provided in portion 310. Circular aperture 316 comprises slope 320 from first end 302 to end 323 of portion 310. Further, aperture 316 is aligned along axis 303, which is offset from horizontal axis 305 of distal member 140. Axis 303 forms an angle 150 with horizontal axis 305 that determines the angle for arch restoration, as shown in figure 3A. Angle 150 may be any angle greater than 90 degrees and less than 180 degrees. Tapered aperture 316 when combined with tapered bulbous portion 202, shown in Figure 2, creates a locked interference fit between proximal member 130 and distal member 140. First end 302 has

a plurality of substantially similar grooves 326 and 328, which form an "L-shape" with surface 330 of end 302. Grooves 326 and 328 are provided to receive instrument 120 of fixation system 100, which is later described. In other non-limiting embodiments, other similar instruments may be provided to be received within grooves 326 and 328.

Distal member 140 further comprises a generally smooth portion 310 coupled to end 302. Portion 310 has a generally hexagonal shaped aperture 312, which opens into aperture 316 and which longitudinally traverses through portion 310 in direction 301. In other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized. Circular aperture 316 has a diameter 314 that is slightly larger than external diameter 224 of portion 216 and 206 of proximal screw member 130, with portions 216 and 206 being slidably received within aperture 316 of portion 310. Aperture 316 has a diameter that is smaller than diameter 226 of bulbous portion 202.

Portion 310 of distal member 140 terminates into a second generally cylindrical portion 318 which has a plurality of threads 324, which are circumferentially disposed on the external surface of portion 318. Portion 318 has an internal circular aperture 327 which is longitudinally coextensive with portion 318 in direction 301. Circular aperture 327 aligns with aperture 312 to form a continuous opening from end 302 to end 304.

As shown in Figure 4, instrument 120 is illustrated for coupling proximal screw member 130 to distal member 140. Particularly, instrument 120 includes a handle portion 402 coupled to a rod portion 404. Rod portion 404 emanates from handle portion 402 at end 406 and terminates into a rectangular planar portion 408 at end 410. Planar portion 408 is aligned along axis 401 and is fixably coupled to a generally cylindrical tubular portion 412 (i.e., an aiming device). Portion 412 traverses portion 408 from top surface 414 to bottom surface 416. Further, tubular

portion 412 is aligned along dissimilar axis 403, forming an angle 405 with axis 401. Also, tubular portion 412 has a through aperture 420 that longitudinally traverses portion 412 along axis 403.

Planar portion 408 is coupled to planar portion 422, with portion 422 having a width slightly smaller than width of portion 408. Portion 422 terminates into a generally "U-shaped" portion 424 with portion 424 being orthogonal to portion 422. Further, portion 424 has a plurality of substantially similar sides 426 and 428 which are provided to be slidably coupled to grooves 326 and 328 of distal member 140.

In operation, sides 426 and 428 of instrument 120 are received in respective grooves 326 and 328 of distal member 140, of Figures 3A-3B, thereby slidably coupling distal member 140 to instrument 120. In this position, axis 303 of aperture 316 is aligned along substantially the same axis as axis 403 of instrument 120. Proximal screw member 130 is coupled to distal member 140 by slidably coupling portions 206 and 216 through aperture 420 of tubular portion 412. Tubular portion 412 guides proximal screw member 130 through internal aperture 420 and into aperture 316 on surface 322 and may also guide a Kirschner wire (K wire) or a drill. Proximal screw member 130, of Figure 2, travels into bone as portions 216 and 206 travel further through aperture 316 at end 302 until bulbous portion 202 is restrained by surface 322 and end 302. Aperture 316, being tapered along axis 303, causes proximal screw member 130 to form an angle 150 with distal member 140, with proximal member 130 being aligned along an axis 303, which is substantially the same axis as axis 403 of tubular portion 412 of instrument 120.

In operation, and as best shown in Figures 5, 6 and 7, the fixation system 100 utilizes the intramedullary fixation assembly 110 for treating and fixating the deteriorated and damaged or fractured bones in the human foot 500. This restores the arch in a human foot 500 by coupling

the intramedullary fixation assembly 110 to the human foot 500 of a left leg. In one-non limiting example, and as shown in Figure 5, the intramedullary assembly 110 is coupled to the medullary canals of the first metatarsal 502, medial cuneiform 504, navicular 506 and talus bone 508. Talus bone 508 makes up part of the ankle joint where the threaded portion 216 of the proximal screw member 130 of the intramedullary assembly 110 is threadably coupled. The medial cuneiform 504 and navicular 506 bones are most affected by Diabetic Charcot foot disorder that causes deterioration and collapse of the arch of the foot 500. It should be appreciated that the intramedullary assembly 110 may be used within each of the five rays, with a ray representing a line drawn from each metatarsal bone to the talus. The angulation in the smaller rays will be smaller than the two rays (i.e., a line from the first and second metatarsal bones to the talus bone). Also, the diameter of distal member 140 will decrease from the large ray to the small ray. In one non-limiting example, the angulation may be any angle greater than 90 degrees and less than 180 degrees. For example, the angle for the first ray may be 150-170 degrees and the angles for the other rays may be 160-175 degrees.

As shown in Figures 6 and 7, the intramedullary fixation assembly 110 may be utilized to reconstruct an arch in a mid-foot region of a human foot 500. As shown, the method starts in step 700 and proceeds to step 702, whereby a Dorsal Lis Franc incision (i.e., mid-foot incision) (not shown) is made in foot 500 in order to gain access to the joint. In step 704, the joint capsule is separated by "Gunstocking" foot 500 in direction 601 (i.e., the foot 500 is bent mid-foot) to expose the articular surface 602 and the articulating cartilage is removed. Next, in step 706, the intramedullary canal is reamed and the distal member 140 is inserted into the intramedullary canal (not shown) of the metatarsal 502. In other non-limiting embodiments, the distal member

140 may be inserted by impaction, by press fit, by reaming a hole in the intramedullary canal (not shown) or substantially any other similar strategy or technique.

Next, in step 708, the instrument 120 is coupled to the distal member 140 by coupling sides 426 and 428 of instrument 120 to respective grooves 326 and 328. In step 710, initial positioning of the proximal member 130 is assessed with the use of a guide wire through portion 412 (i.e., aiming device). Next, in step 712, a countersink drill is inserted through portion 412 and the proximal cortex is penetrated. In this step, a cannulated drill or guide wire is used to pre-drill the hole through the joints selected for fusion. In step 714, the proximal screw member 130 is inserted over the guide wire and into the distal member 140. Particularly, the proximal member 130 is inserted through tubular portion 412 (i.e., aiming device), causing proximal member 130 to travel through internal longitudinal aperture 420, into distal member 140 and further into bones 504, 506 and 508 until rigid connection with the tapered aperture 316 is made, thereby compressing the joint. In one non-limiting embodiment, a locking element (not shown) such as a plate or a washer is coupled to end 302 of the intramedullary fixation assembly 110 to further secure proximal threaded member 130 to distal member 140. Next, in step 716 the instrument 120 is removed and the dorsal Lis Franc (i.e., mid-foot) incision is closed. The method ends in step 718.

It should be appreciated that a plurality of intramedullary fixation assemblies, such as intramedullary fixation assembly 110, may be inserted into any of the bones of a foot 500 such as, but not limited to the metatarsal, cuneiform, calcaneus, cuboid, talus and navicular bones, in order to restore the natural anatomical shape of the arch of the foot 500. Thus, the fixation system 100, in one non-limiting embodiment, is utilized to couple the intramedullary fixation assembly 110 to the foot 500, which causes the metatarsal 504, medial cuneiform 504, navicular

506 and talus 508 bones to be aligned to the proper anatomical shape of an arch when assembled within foot 500. It should be appreciated that the intramedullary fixation assembly 110 is delivered through a dorsal midfoot incision, thereby reducing the disruption to the plantar tissues and/or the metatarsal heads while at the same time minimizing the tension on the skin. This allows for improved wound closure, reduced operating room time, reduction in the number of incisions required and reduction in the total length of incisions. It should also be appreciated that in other non-limiting embodiments, the intramedullary assembly 110 may be utilized with graft material (i.e., autograft, allograft or other biologic agent).

In an alternate embodiment, as shown in Figure 8, an intramedullary fixation assembly 800 is provided in order to apply intraosseous compression to bones. Particularly, the intramedullary fixation assembly 800 comprises a tapered screw member 810 coupled to a lag screw member 815 at a fixed acute angle for the internal fusion of the bones of the human foot 805, such as, for example, the calcaneus bone 820, the talus bone 825, and the cuboid bone 830. In other non-limiting embodiments, the intramedullary fixation assembly 800 may be utilized for any other appropriate use for the internal fixation of the other bones. It should be appreciated that the intramedullary fixation assembly 800 may be provided at several lengths for the internal fixation of a variety of bone sizes in the human body.

Also as shown in Figure 9, the intramedullary fixation assembly 800 includes the tapered screw member 810 coupled to the lag screw member 815 at a fixed angle 905. The fixed angle 905 may be provided at various fixed angles depending on the bone segments that are being compressed. The fixed angle between the tapered screw member 810 and the lag screw member 815 causes the intramedullary fixation assembly 800 to "hook" into the bone segments and translates the compression applied to bone fragments across the members 810 and 815. It should

be appreciated that in one non-limiting embodiment, the intramedullary fixation assembly 800 may be made from a Titanium material, although, in other non-limiting embodiments, the intramedullary fixation assembly 800 may be made from SST, PEEK, NiTi, Cobalt chrome or other similar types of materials. It should also be appreciated that the intramedullary fixation assembly 800 is locked at the fixed angle after insertion of the same into bone. The intramedullary fixation assembly 800 translates compression applied to bone fragments by the tapered screw member 810 and the lag screw member 815 into uniform compression through multi-point fixation.

As shown in Figure 10, lag screw member 815 is generally cylindrical in shape and has a first smooth exterior portion 1005 that extends from first bulbous portion 1010 to a second threaded portion 1015. Additionally, bulbous portion 1010 has a taper, such as a Morse taper, with a width that decreases from end 1030 in direction 1000. The Morse taper allows for a locked interference fit with tapered aperture 1130 (shown in Figure 11) when tapered bulbous portion 1010 resides within tapered aperture 1130, which will be shown and described below. Moreover, tapered bulbous portion 1010 is generally cylindrical in shape and has a generally hexagonal-shaped aperture 1035 aligned along axis 1002 traversing the longitudinal length of bulbous portion 1010. However, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope of the invention. Aperture 1035 is provided to transmit torque from bulbous portion 1010 to threaded portion 1015 as bulbous portion 1010 is rotated in a direction that causes a corresponding rotation of threaded portion 1015.

Further, lag screw member 815 has a first smooth exterior portion 1005 that has a uniform diameter 1025 from first end 1040 to second end 1045. Portion 1005 includes an

internal aperture 1050 aligned along axis 1002 that traverses the longitudinal length of portion 1005 in direction 1000. Further, portion 1005 terminates into a threaded portion 1015. Threaded portion 1015 includes an internal aperture 1055 aligned along axis 1002 that longitudinally traverses threaded portion 1015. Internal aperture 1055 being aligned on the same axis 1002 as apertures 1035 and 1055 cooperatively form a continuous opening (i.e., a cannula) from end 1030 of bulbous portion 1010 to end 1060 of threaded portion 1015. The continuous opening or cannula is provided to interact with a guide wire (not shown) by receiving the guide wire within the continuous opening to help guide and position the lag screw member 815 during insertion of the lag screw member 815. In other non-limiting embodiments, the lag screw member 815 may be provided without apertures 1050 and 1055 (i.e., the lag screw member 815 is solid).

Furthermore, threaded portion 1015 has a plurality of circular threads, such as threads 1065, which are circumferentially disposed on the external surface of threaded portion 1015. Threaded portion 1015 has a diameter 1020 that is substantially the same as diameter 1025 of portion 1005. Threaded portion 1015 may also be provided with a self-tapping leading edge 1070 to provide portion 1015 with the ability to remove bone material during insertion of lag screw member 815 into bone. It should be appreciated that the length of the lag screw member 815 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should be appreciated that the lag screw member 815 may be positioned at one angle inside the tapered screw member 810. Also, lag screw member 815 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

As shown in Figure 11, tapered screw member 810 is generally cylindrical in shape and has a smooth exterior portion 1105 that extends from a tapered portion 1110 to a threaded

portion 1115. Tapered screw member 810 is aligned along longitudinal axis 1104, which is longitudinally coextensive with length of tapered screw member 810.

Further, tapered portion 1110 is generally tubular in shape and tapers from end 1120 to end 1125 (i.e. end 1120 has a diameter 1127 that decreases slightly in diameter from end 1120 in direction 1100). Further, first end 1120 has a tapered aperture 1130, which traverses tapered portion 1110 along axis 1102, which causes tapered aperture 1130 to emanate from surface 1135. Axis 1102 is offset from longitudinal axis 1104 at an angle 1140. Moreover, tapered portion 1110 has a generally hexagonal-shaped aperture contained within portion 1110, which is aligned along axis 1104 and is provided to receive an instrument (not shown) for applying torque to tapered screw member 810. In other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope of the invention. With tapered aperture 1130 being aligned along axis 1102, tapered aperture 1130 forms a fixed angle 1140 with longitudinal axis 1145. Fixed angle 1140 determines the angle for fixation of tapered screw member 810 with respect to lag screw member 815(shown in figure 10). It should be appreciated that fixed angle 1140 may be any angle less than 90 degrees to allow a surgeon the flexibility of determining the angle for internal fixation of bones in the human body. It should also be appreciated that tapered aperture 1130 when combined with tapered bulbous portion 1010, shown in Figure 10, creates a locked interference fit between tapered screw member 810 and lag screw member 815.

Further, tapered screw member 810 has a smooth exterior portion 1105 that has a uniform diameter 1145 from end 1125 to end 1150. Tapered screw member 810 is generally solid, however, in other non-limiting embodiments, screw member 810 may be cannulated. Further, portion 1105 terminates into a threaded portion 1115. Threaded portion 1115 is generally solid

and includes a plurality of circular threads, such as threads 1155, which are circumferentially disposed on the external surface of threaded portion 1115. Threaded portion 1115 has a diameter 1160 that is substantially the same as diameter 1145 of portion 1105. Threaded portion 1115 may also be provided with a self-tapping leading edge 1165 to provide portion 1115 with the ability to remove bone material during insertion of tapered screw member 810 into bone. It should be appreciated that the length of the tapered screw member 810 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should be appreciated that tapered screw member 810 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

As shown in Figures 8 and 12, the intramedullary fixation assembly 800 may be utilized to apply compression, for example to the bones in a human foot through an acute angle fixation of the tapered screw member 810 to the lag screw member 815. As shown, the method starts in step 1200 and proceeds to step 1205, whereby a central incision is made in the hind-foot region of foot 805. Next, in step 1210, a pilot hole is drilled into the calcaneus 820 and the cuboid 830 bones. In this step, a countersink drill is inserted a cannulated drill or guide wire is used to pre-drill the hole through the joints selected for fusion. Next, in step 1215, tapered screw member 810 is inserted into the intraosseous intramedullary canal (not shown) of the calcaneus 820. In other non-limiting embodiments, the tapered screw member 810 may be inserted by impaction, by press fit, by reaming a hole in the intramedullary canal (not shown) or substantially any other similar strategy or technique.

Next, in step 1220, the final position of the tapered screw member 810 is aligned so that the coupling of the lag screw member 815 forms a predetermined angle with the tapered screw

member 810. In step 1225, align a guide through tapered aperture 1130 at surface 1135 and pre-drill a hole through the joint substantially along axis 1102. Next, in step 1230, insert a K-wire (not shown) into the pre-drilled hole and into the tapered screw member 810 so that the K-wire makes an acute angle with the tapered screw member 810. Next, in step 1235, the lag screw member 815 is rotated and inserted over the K-wire and into the calcaneus bone 820 so that the K-wire guides the lag screw member 815. The K-wire, in assisting the lag screw member 815, penetrates end 1060 and emanates from end 1030. In some non-limiting embodiments, the lag member 815 may be inserted by impaction, by press fit, or substantially any other similar strategy or technique. Next, in step 1240, the K-wire is removed and the incision is closed. The method ends in step 1245.

In an alternate embodiment, as shown in Figure 13, an intramedullary fixation assembly 1300 is provided for the internal fixation of bones in a human hand 1305. Particularly, the intramedullary fixation assembly 1300 is substantially the same as the intramedullary fixation assembly 800 of the embodiment shown and described in Figure 8. The intramedullary fixation assembly 1300 includes a tapered screw member 1310 forming a fixed acute angle with the lag screw member 1315. The fixed acute angle is predetermined and the angle may be selected up to 90 degrees by, in one example, a surgeon to provide for the internal fixation of the bones in the human hand 1305, such as for example the radius 1320 and ulna 1325.

In another alternate embodiment, as shown in Figure 14, an intramedullary fixation assembly 1400 may be provided to vary the acute angle between 0 and 90 degrees after insertion of the intramedullary fixation assembly 1400. Particularly, the intramedullary fixation assembly 1400 comprises a polyaxial screw member 1410 coupled to a lag screw member 1415 and forming an angle 1405 between the two members 1410 and 1415. The angle 1405 between the

polyaxial screw member 1410 and the lag screw member 1415 causes the intramedullary fixation assembly 1400 to "hook" into the bone segments and translates the compression applied to bone fragments across the members 1410 and 1415. It should be appreciated that the intramedullary fixation assembly 1400 may be provided at several lengths for the internal fixation of a variety of bone sizes in the human body. It should also be appreciated that in one non-limiting embodiment, the intramedullary fixation assembly 1400 may be made from a Titanium material, although, in other non-limiting embodiments, the intramedullary fixation assembly 1400 may be made from SST, PEEK, NiTi, Cobalt chrome or other similar types of materials.

As shown in Figure 15, lag screw member 1415 is generally cylindrical in shape and has a first smooth exterior portion 1505 that extends from first bulbous portion 1510 to a second threaded portion 1515. Bulbous portion 1510 is generally semispherical in shape and has a diameter 1500 that is slightly larger than the internal diameter of aperture 1630 (shown in figure 16), which is provided to receive bulbous portion 1510. The bulbous portion 1510 resides within the internal aperture 1630 (shown in Figure 16) and provides for rotational movement of both the polyaxial screw member 1410 and the lag screw member 1415 at various angles between 0 and 90 degrees after insertion of the intramedullary fixation assembly 1400. Also, bulbous portion 1510 has a generally hexagonal-shaped aperture 1535 aligned along axis 1502 traversing the longitudinal length of bulbous portion 1510. In other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope of the invention. Aperture 1535 is provided to transmit torque from bulbous portion 1510 to threaded portion 1515 as bulbous portion 1510 is rotated in a direction that causes a corresponding rotation of threaded portion 1515. It should also be appreciated that axis 1502 is longitudinally coextensive with the length of lag screw member 1415.

Further, lag screw member 1415 has a first smooth exterior portion 1505 of a uniform diameter 1525 from first end 1540 to second end 1545. Portion 1505 includes an internal aperture 1550 aligned along axis 1502 that traverses the longitudinal length of portion 1505 along direction 1504. Further, portion 1505 terminates into the threaded portion 1515. Threaded portion 1515 also includes an internal aperture 1555 aligned along axis 1502 that longitudinally traverses threaded portion 1515. Internal aperture 1555 being aligned along the same axis 1502 as apertures 1535 and 1550 cooperatively form a continuous opening (i.e., a cannula) from bulbous portion 1510 to end 1560 of threaded portion 1515. The continuous opening or cannula is provided to interact with a guide wire (not shown) by receiving the guide wire within the continuous opening to help guide and position the lag screw member 1415 during insertion into bone. In other non-limiting embodiments, the lag screw member 1415 may be provided without apertures 1550 and 1555 (i.e., the lag screw member 1415 is non-cannulated or solid).

Furthermore, threaded portion 1515 has a plurality of circular threads, such as threads 1565, which are circumferentially disposed on the external surface of threaded portion 1515. Threaded portion 1515 has a diameter 1520 that is substantially the same as diameter 1525 of portion 1505. Threaded portion 1515 may also be provided with a self-tapping leading edge (not shown) to provide portion 1515 with the ability to remove bone material during insertion of lag screw member 1415 into bone. It should be appreciated that the length of the lag screw member 1415 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. Also, lag screw member 1415 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

As shown in Figure 16, polyaxial screw member 1410 is generally cylindrical in shape and has a smooth exterior portion 1605 that extends from portion 1610 to a threaded portion 1615. Polyaxial screw member 1410 is aligned along longitudinal axis 1604, which is longitudinally coextensive with length of polyaxial screw member 1410.

Further, portion 1610 is generally tubular in shape having a uniform diameter, which is slightly larger than diameter of aperture 1630 causing portion 1610 to abut the interior surface of portion 1610 at aperture 1630. However, in other non-limiting embodiments, portion 1610 may be tapered going from a larger diameter to a smaller diameter as we traverse portion 1610 along direction of axis 1600. Further, portion 1610 has a plurality of apertures 1620 and 1630 of dissimilar diameters. Aperture 1630 is a through aperture and is tapered along axis 1602, causing aperture 1630 to emanate from surface 1635. On the other hand, aperture 1620 is longitudinally disposed along axis 1604 and has a generally hexagonal shaped aperture, although in other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shapes aperture may be utilized. Aperture 1630 is offset from axis 1604 at an angle 1640. Angle 1640 determines the angle for rotation of lag screw member 1415 when bulbous portion 1510 (shown in Figure 15) resides in aperture 1630 with lag screw member 1415 rotating angularly around axis 1602. It should be appreciated that angle 1640 may be any angle less than 90 degrees to allow a surgeon the flexibility of fixing the rotation of polyaxial screw member 1410 and lag screw member 1415.

Further, polyaxial screw member 1410 has a smooth exterior portion 1605 having a uniform diameter from end 1625 to end 1650. The diameter of exterior portion 1605 is smaller than the diameter of aperture 1630. Polyaxial screw member 1410 is generally solid, however, in other non-limiting embodiments, polyaxial screw member 1410 may be cannulated. Further,

portion 1605 terminates into a threaded portion 1615. Threaded portion 1615 is generally solid and includes a plurality of circular threads, such as threads 1655, circumferentially disposed on the external surface of threaded portion 1615. Threaded portion 1615 has a uniform diameter that is slightly larger than the diameter of portion 1605. However, in other non-limiting embodiments, the respective diameters of portions 1605 and 1615 may be substantially the same. Threaded portion 1615 may also be provided with a self-tapping leading edge (not shown) to provide portion 1615 with the ability to remove bone material during insertion of polyaxial screw member 1410 into bone. It should be appreciated that the length of the polyaxial screw member 1410 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should be appreciated that polyaxial screw member 1410 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

In another alternate embodiment, as shown in Figure 17, length of the polyaxial screw member 1710 may be varied in order to accommodate the intramedullary fixation assembly 1700 in bones of various sizes. Particularly, the polyaxial screw member 1710 includes a smooth end portion 1720 coupled directly to a threaded portion 1725, thereby varying the angle 1705 that is formed between the polyaxial screw member 1710 and the lag screw member 1715. In all other respects, the intramedullary fixation assembly 1700 is substantially similar to the intramedullary fixation assembly 1400 as was shown and described in Figure 14.

In another alternate embodiment, as shown in Figure 18, an intramedullary fixation assembly 1800 having a plurality of lag screw members 1805 and 1810 coupled to a tapered screw member 1815 is provided in order to apply compression at multiple points on the bone fragment surface. Particularly, the lag screw members 1805 and 1810, and the tapered screw

member 1815 are substantially similar to the lag screw member 815 and tapered screw member 810 respectively shown and described in the embodiment of Figures 8-11. Each of the lag screw members 1805 and 1810 forms an fixed acute angle with the tapered screw member 1815, with these angles being predetermined by, for example, a surgeon to fix the bones in a human body.

As shown, tapered screw member 1815 is generally cylindrical in shape and has a smooth exterior portion 1820 that extends longitudinally along axis 1806 from end 1825 to a threaded portion 1830. Further, end 1825 has a tapered aperture 1835, which is aligned on axis 1802 and forms a fixed angle 1808 with axis 1806. Fixed angle 1808 determines the angle for fixation of tapered screw member 1810 with respect to lag screw member 1805. Also, tapered screw member 1815 has a second tapered aperture 1840, aligned along axis 1804 and forms a fixed angle 1812 with axis 1804. The fixed angle 1812 determines the angle for fixation of lag screw member 1810 with tapered screw member 1815. It should be appreciated that fixed angles 1808 and 1812 may be any angle less than 90 degrees to allow a surgeon the flexibility of determining the angle for internal fixation of bones in the human body. It should also be appreciated that tapered screw member 1815 creates a locked interference fit with each of the lag screw members 1805 and 1810.

Further, tapered screw member 1815 has a smooth exterior portion 1820 having a uniform diameter from end 1825 to threaded portion 1830. Tapered screw member 1815 is generally solid, however, in other non-limiting embodiments, screw member 1815 may be cannulated. Further, threaded portion 1830 is generally solid and includes a plurality of circular threads circumferentially disposed on the external surface of threaded portion 1830. Threaded portion 1830 may also be provided with a self-tapping leading edge to provide portion 1830 with the ability to remove bone material during insertion of tapered screw member 1815 into bone. It

should be appreciated that the length of the tapered screw member 1815 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should be appreciated that tapered screw member 1815 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

Also as shown in Figure 18, each of the respective lag screw members 1805 and 1810 are substantially similar to the lag screw member of the embodiment shown and described in Figure 10. Particularly, lag screw member 1805 is generally cylindrical in shape and has a first smooth exterior portion 1845 that extends from bulbous portion 1850 to a threaded portion 1855, while lag screw member 1810 has a smooth exterior portion 1860 that extends from bulbous portion 1865 to threaded portion 1870. Additionally, each of the bulbous portions 1850 and 1865 have a taper, such as a Morse taper, that provides for a locked interference fit with tapered apertures 1835 and 1840 respectively.

In an alternate embodiment, as shown in Figure 19, a lag screw member 1900 may include a cover or plug member 1905. The cover member 1905 includes a first end portion 1910 having substantially the same diameter as end portion 1915. The cover member 1905 also includes a second end portion 1920, which is smaller than the internal diameter of end portion 1915 and which is provided to be received inside aperture 1925 of lag screw member 1900.

It should be appreciated that any number of intramedullary fixation assemblies, such as intramedullary fixation assembly 800, may be inserted into the joints, for example, of the human foot in order to provide for compression of the bones of the foot. It should also be appreciated that the intramedullary fixation assembly 800 is delivered through an incision, thereby reducing the disruption to the plantar tissues while at the same time minimizing the tension on the skin.

This allows for improved wound closure, reduced operating room time, reduction in the number of incisions required and reduction in the total length of incisions. It should also be appreciated that the intramedullary fixation assembly 800 may also be utilized to restore any of the other bones in the human body. It should also be appreciated that in other non-limiting embodiments, the intramedullary assembly 800 may be utilized with graft material (i.e., autograft, allograft or other biologic agent).

It should also be understood that this invention is not limited to the disclosed features and other similar method and system may be utilized without departing from the spirit and the scope of the invention.

While the invention has been described with reference to the preferred embodiment and alternative embodiments, which embodiments have been set forth in considerable detail for the purposes of making a complete disclosure of the invention, such embodiments are merely exemplary and are not intended to be limiting or represent an exhaustive enumeration of all aspects of the invention. The scope of the invention, therefore, shall be defined solely by the following claims. Further, it will be apparent to those of skill in the art that numerous changes may be made in such details without departing from the spirit and the principles of the invention. It should be appreciated that the invention is capable of being embodied in other forms without departing from its essential characteristics.

FIG. 1

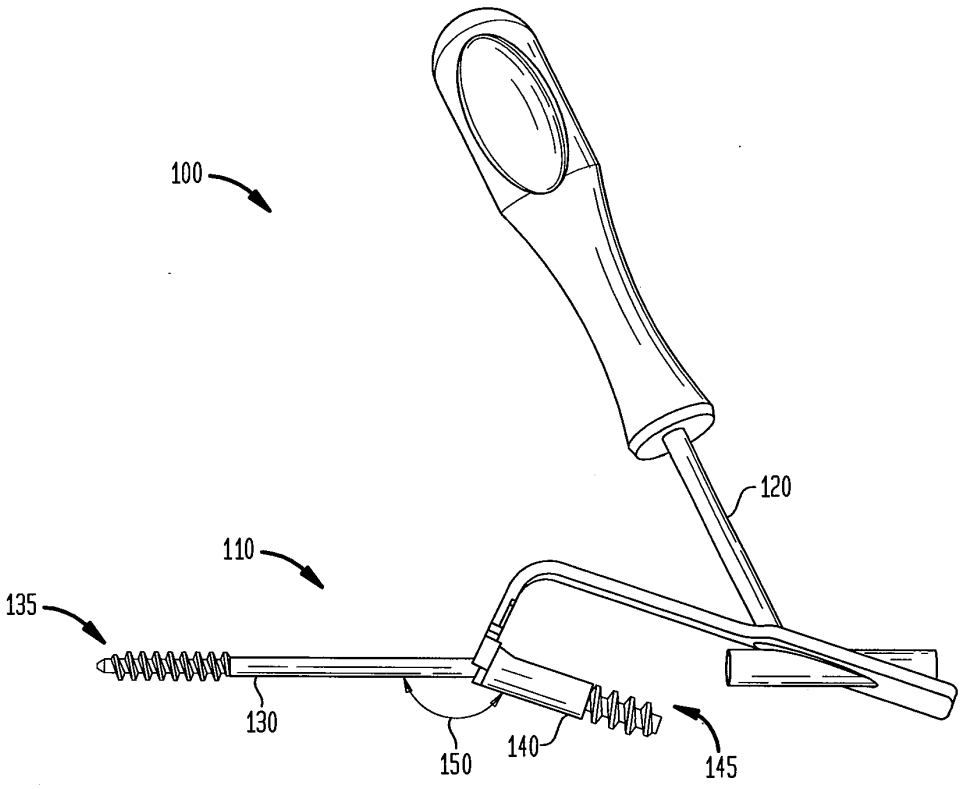


FIG. 2

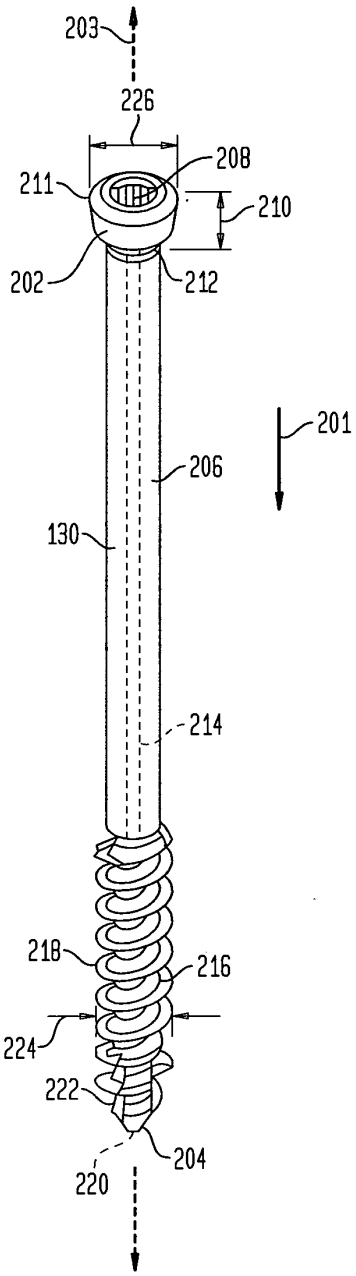

203
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211
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212
201
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130
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218
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222
204
220

FIG. 3A

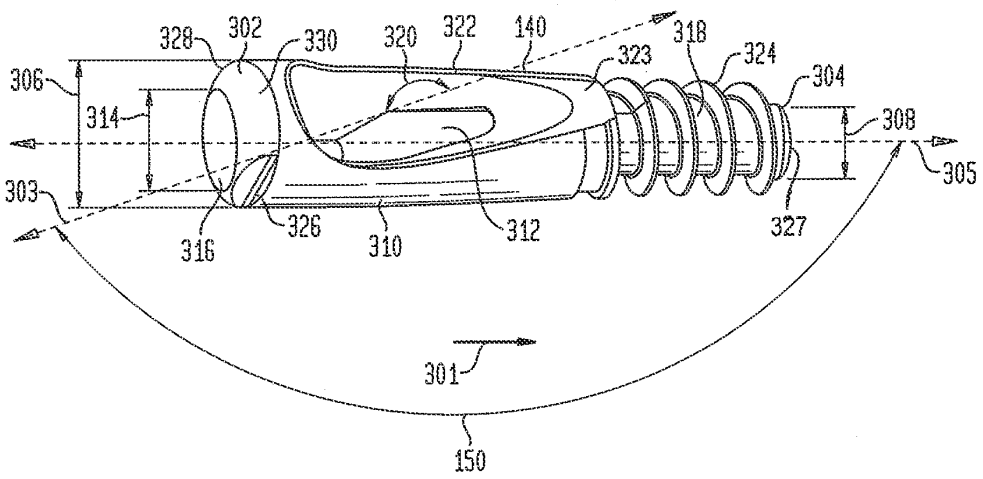

328
302
330
320
322
140
318
323
324
304
306
314
308
305
303
316
326
310
312
327
301
150

FIG. 3B

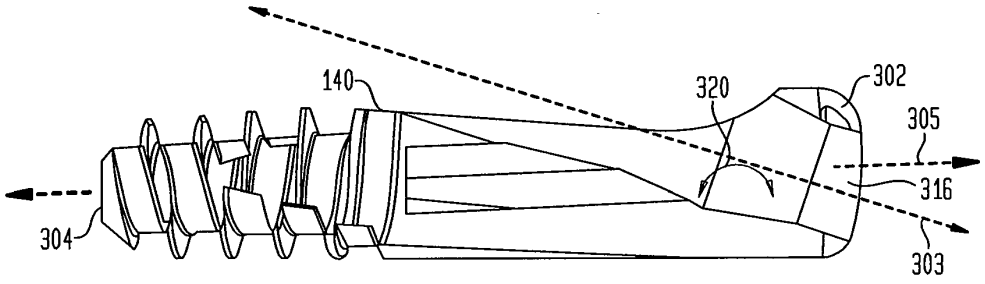
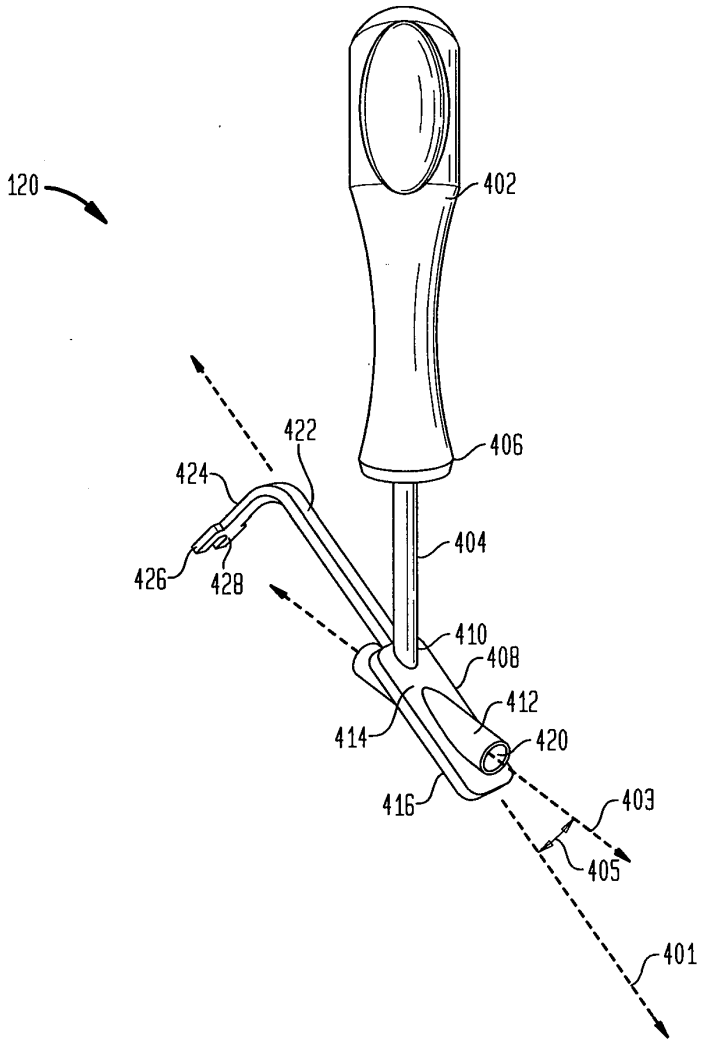


FIG. 4


120
402
406
422
424
426
428
404
410
408
412
414
420
416
403
405
401

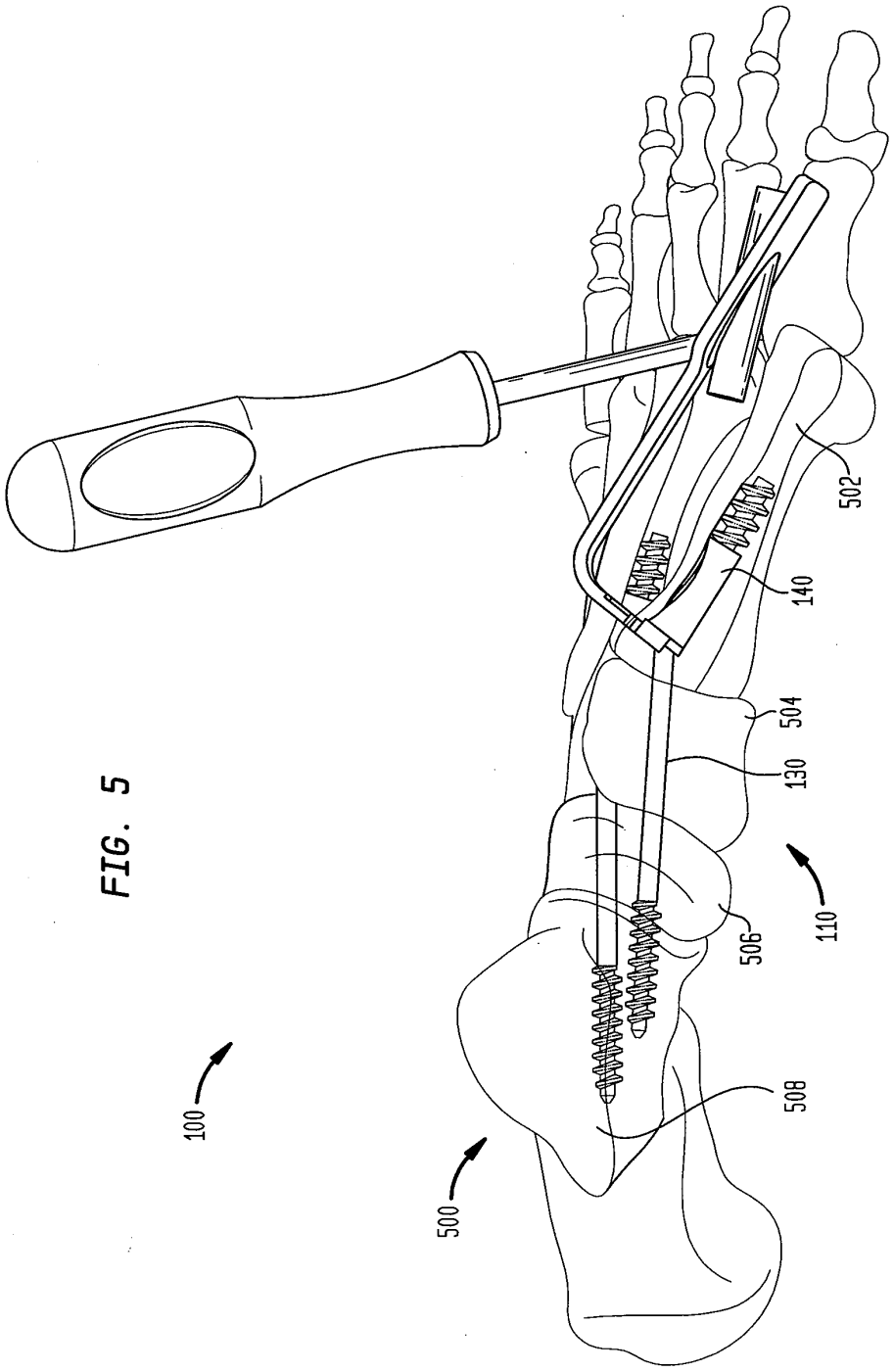


FIG. 5

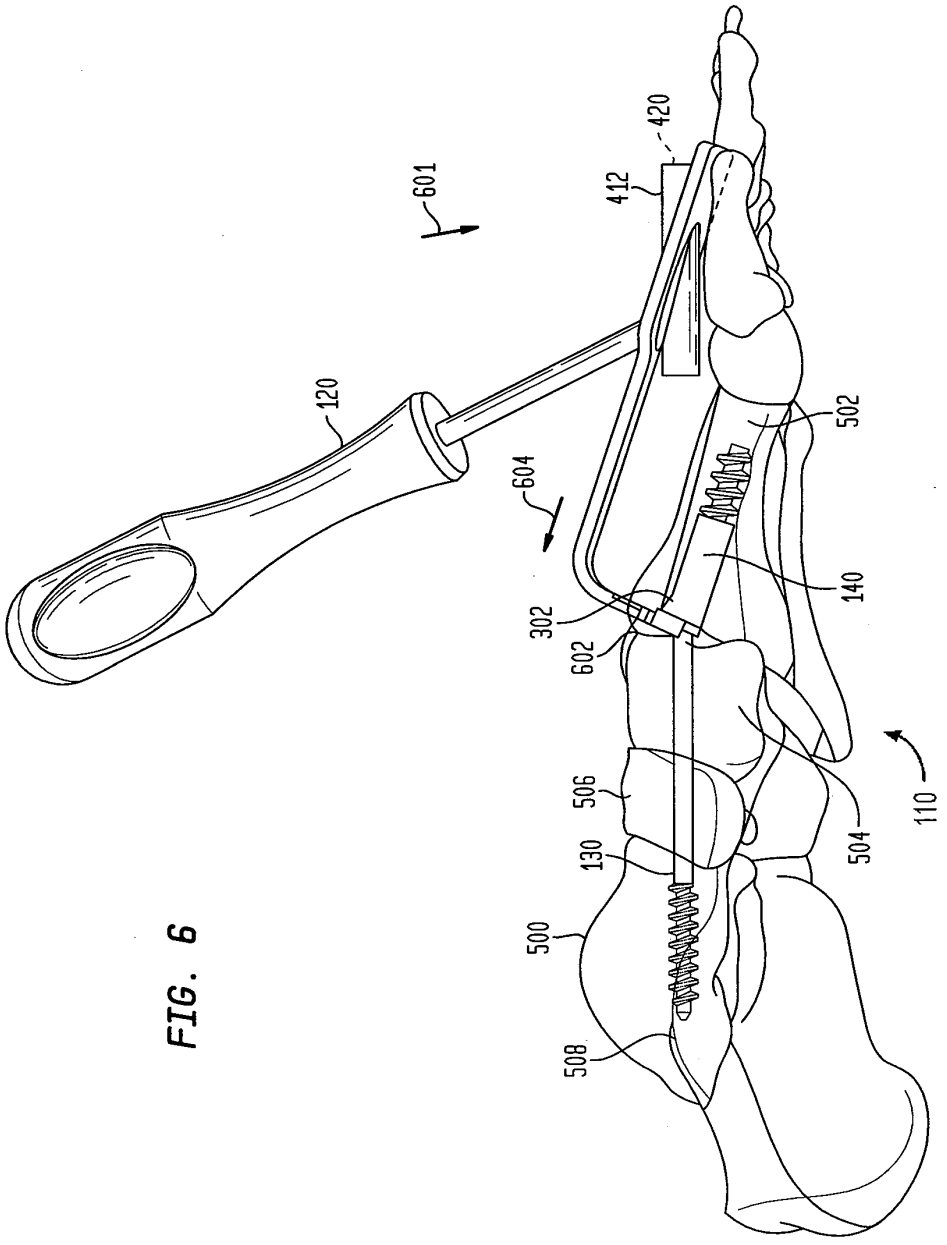


FIG. 6

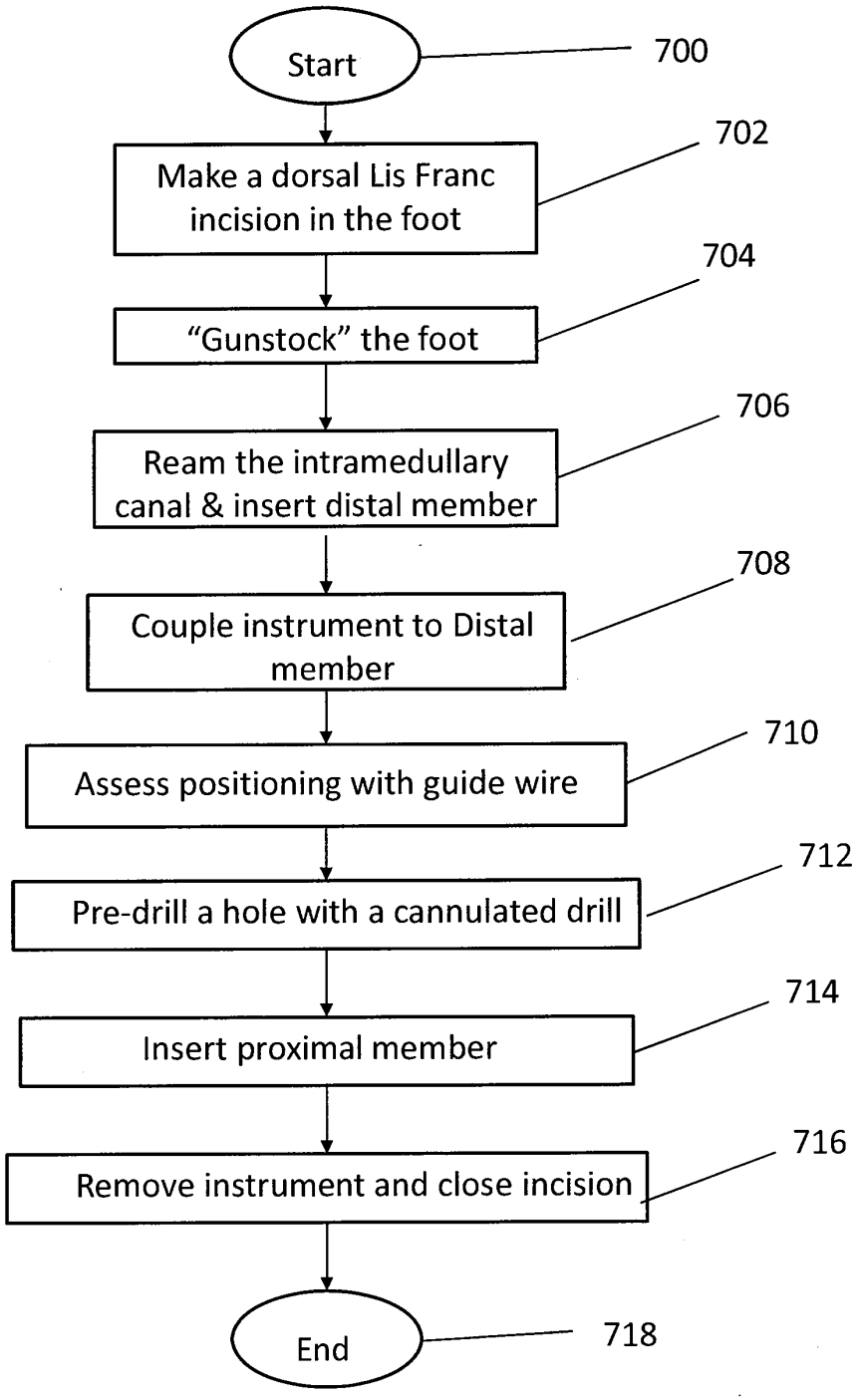

Start
700
Make a dorsal Lis Franc incision in the foot
702
"Gunstock" the foot
704
Ream the intramedullary canal & insert distal member
706
Couple instrument to Distal member
708
Assess positioning with guide wire
710
Pre-drill a hole with a cannulated drill
712
Insert proximal member
714
Remove instrument and close incision
716
End
718

FIG. 7

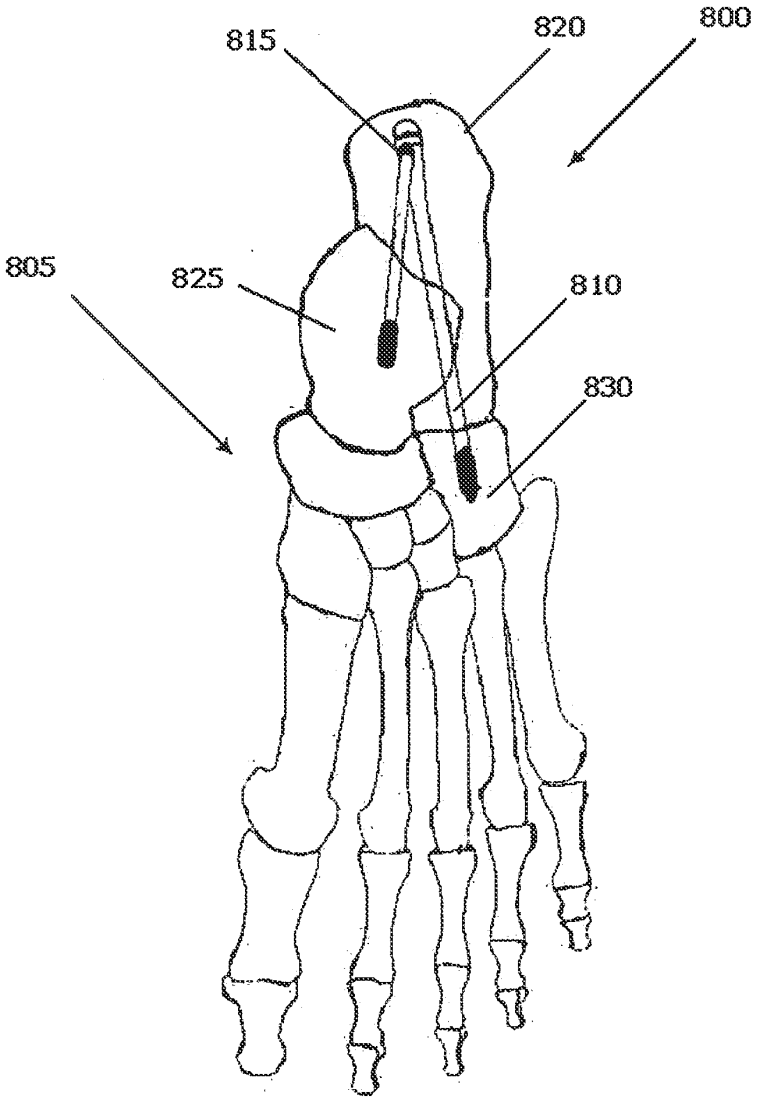


FIG. 8

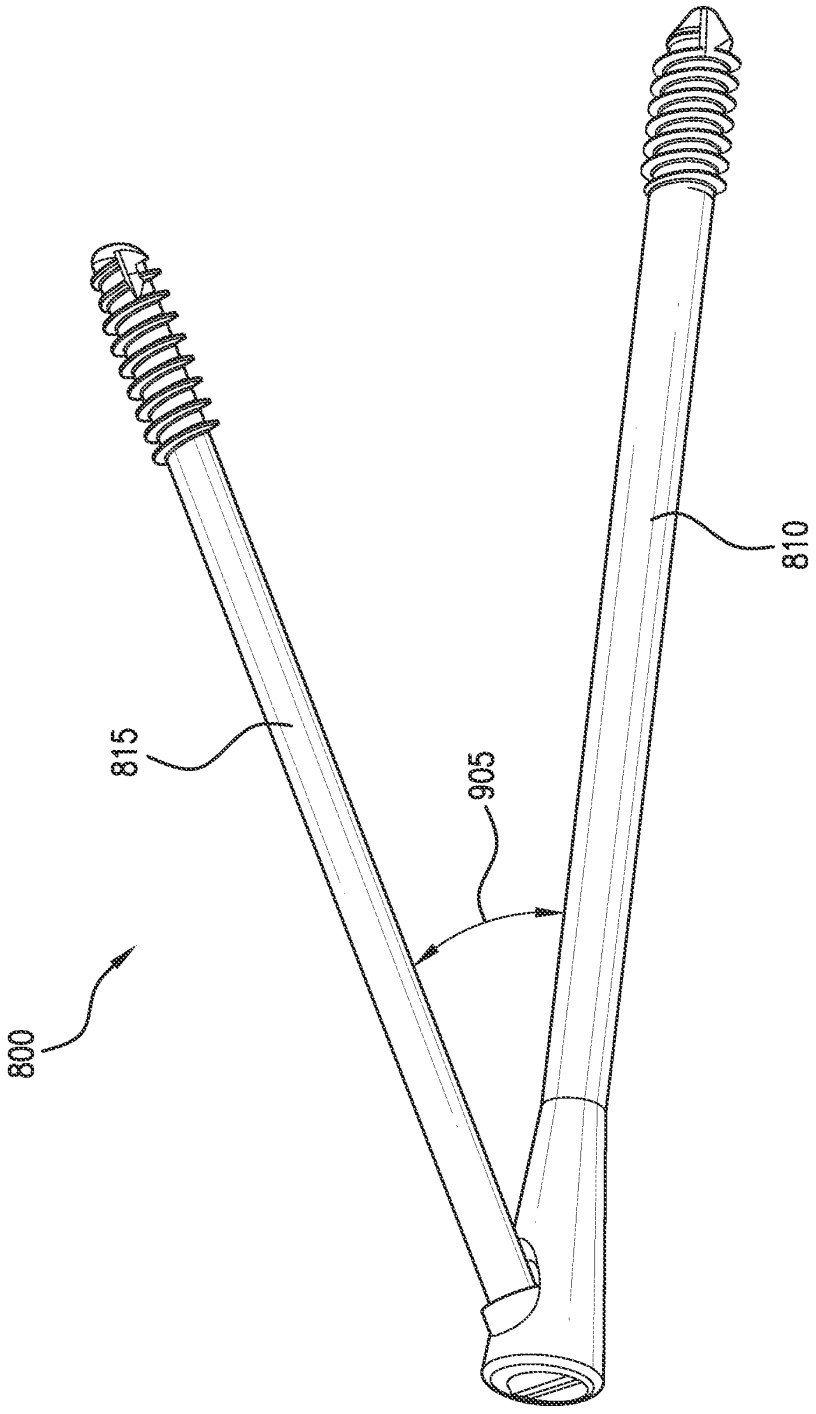


FIG. 9

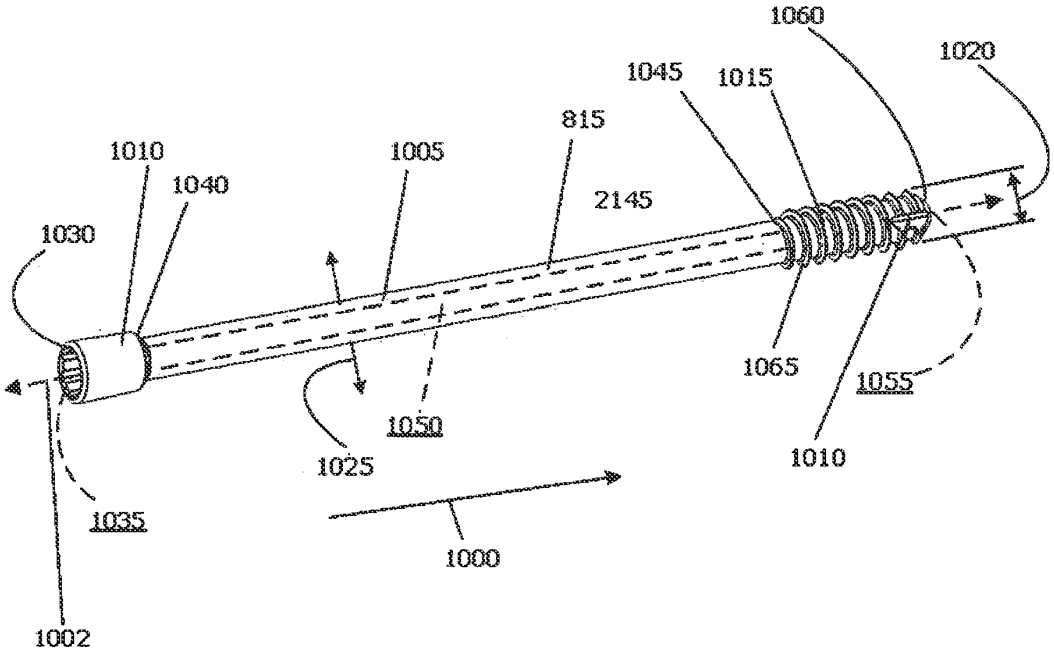

1060
1020
1045
1015
815
1010
1040
1005
2145
1030
1065
1055
1050
1025
1010
1035
1000
1002

FIG. 10

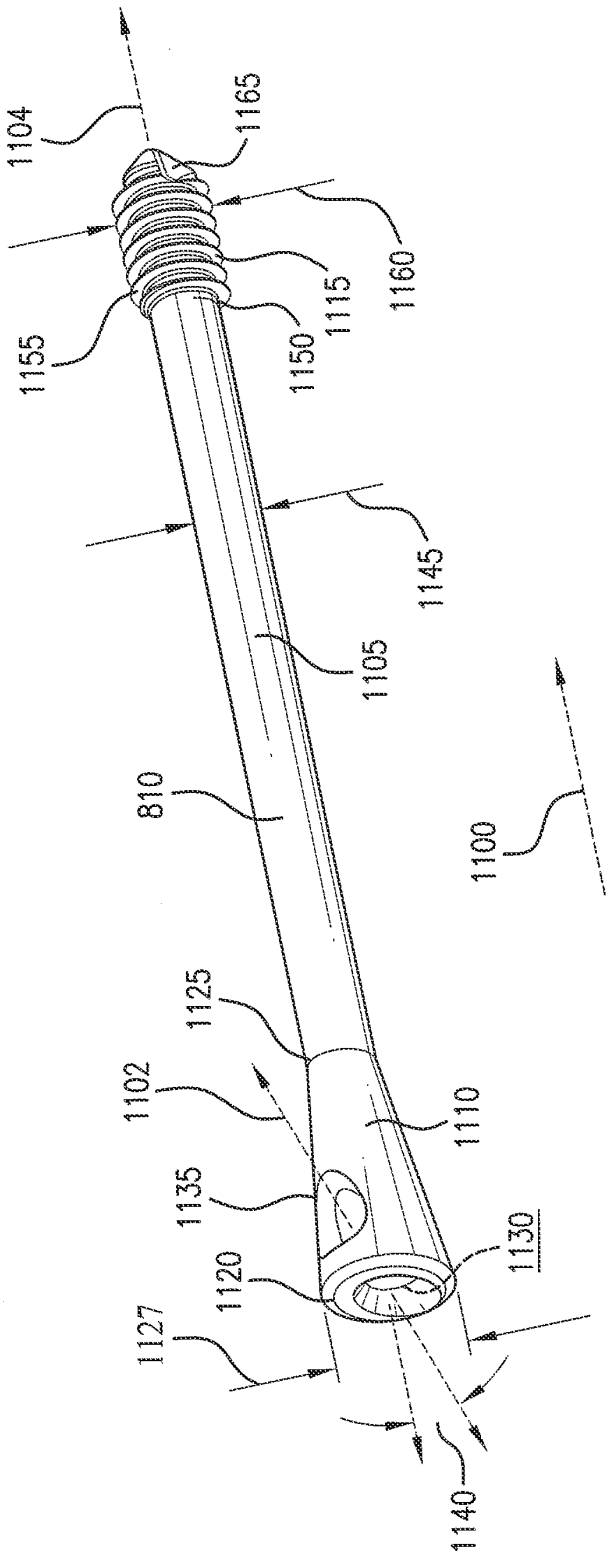

1104
1165
1160
1115
1155
1150
1145
1105
810
1100
1125
1102
1110
1135
1130
1120
1127
1140

FIG. 11

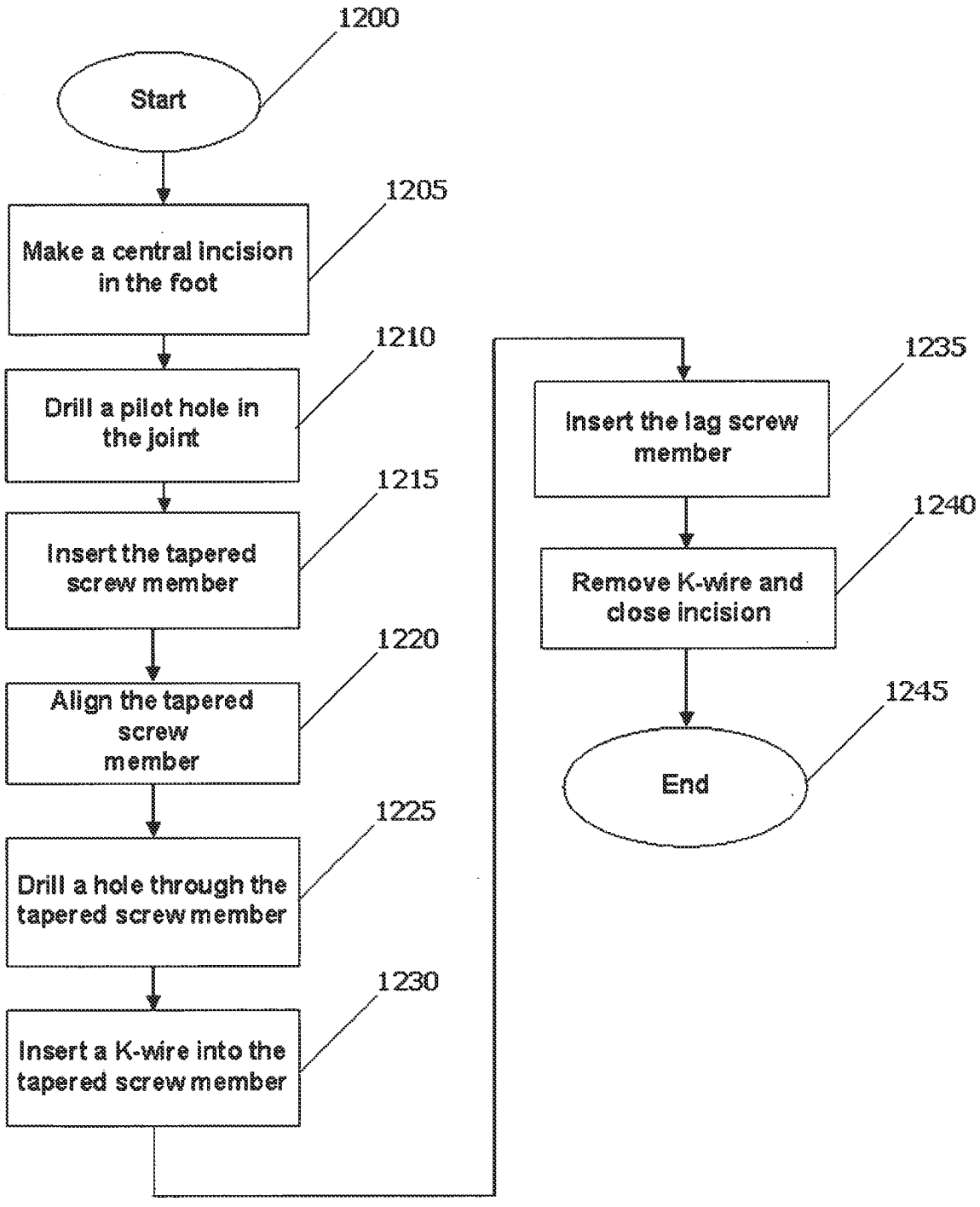

1200
Start
1205
Make a central incision in the foot
1210
Drill a pilot hole in the joint
1215
Insert the tapered screw member
1220
Align the tapered screw member
1225
Drill a hole through the tapered screw member
1230
Insert a K-wire into the tapered screw member
1235
Insert the lag screw member
1240
Remove K-wire and close incision
1245
End

FIG. 12

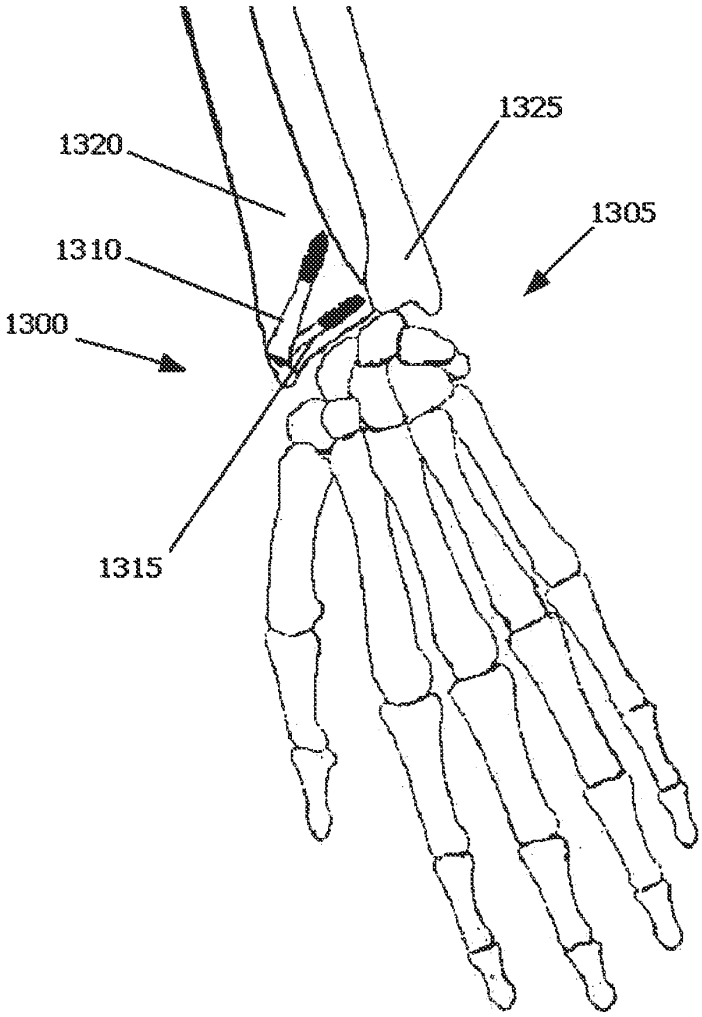


FIG. 13

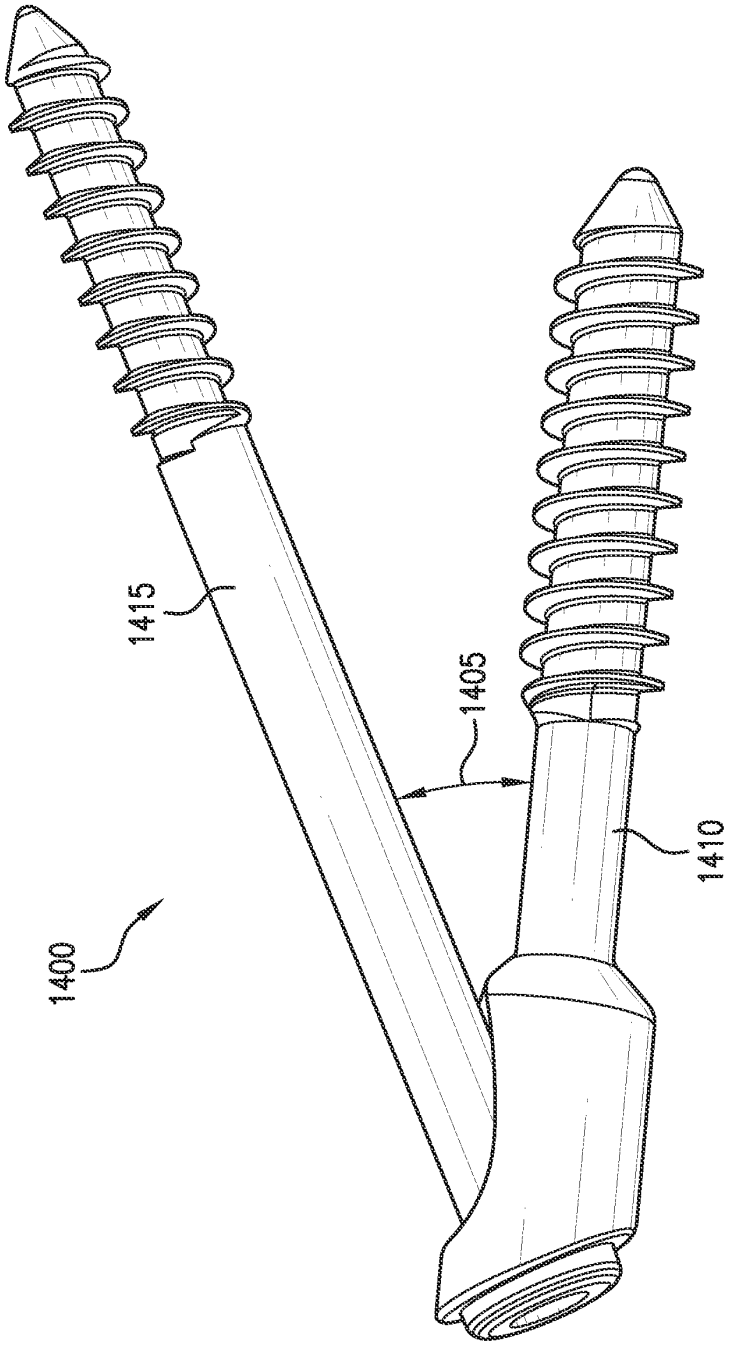


FIG. 14

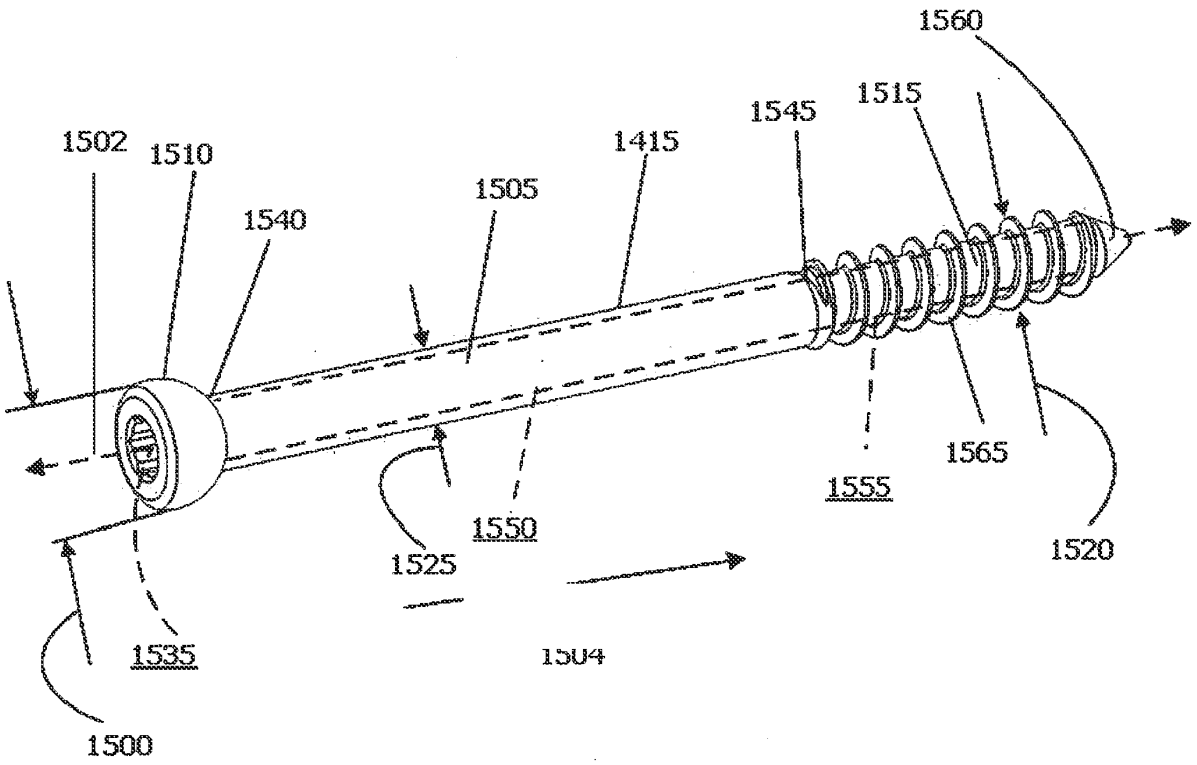

1560
1515
1545
1502
1510
1415
1505
1540
1565
1555
1550
1525
1520
1535
1504
1500

FIG. 15

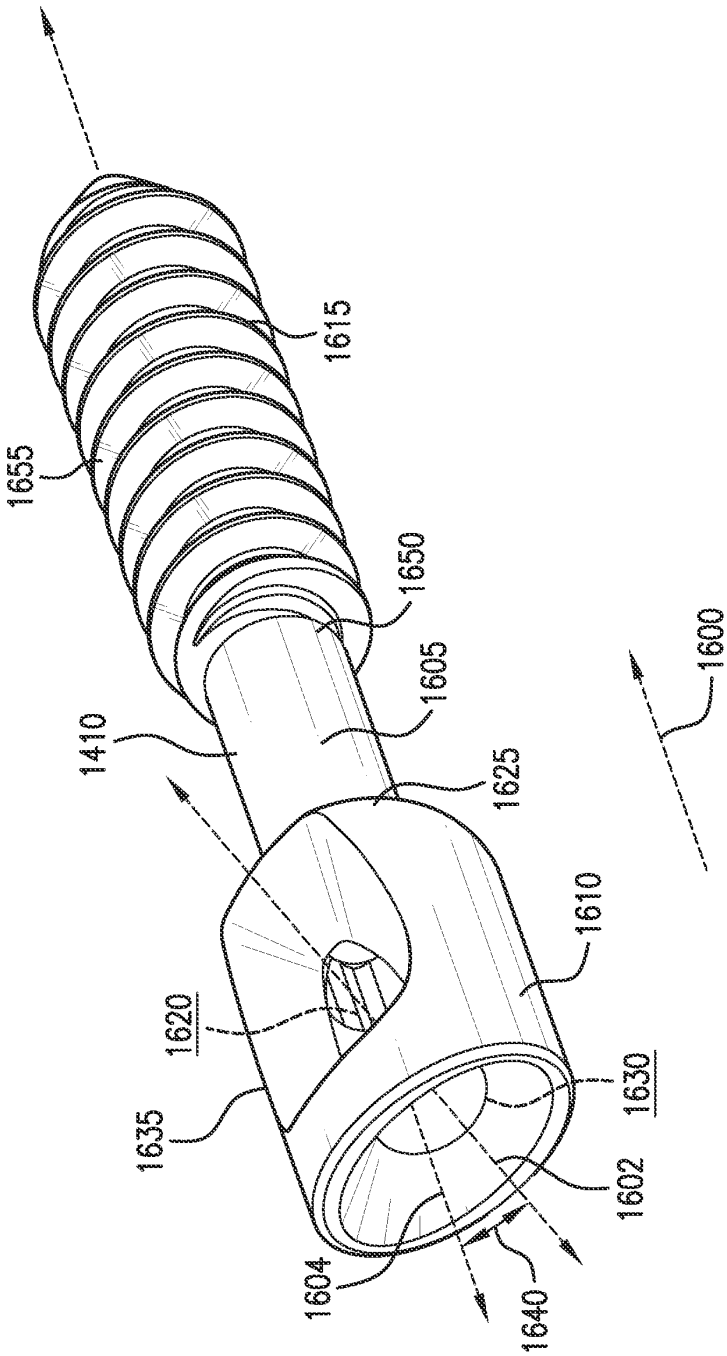

1655
1615
1650
1605
1410
1625
1610
1620
1630
1635
1602
1604
1640
1600

FIG. 16

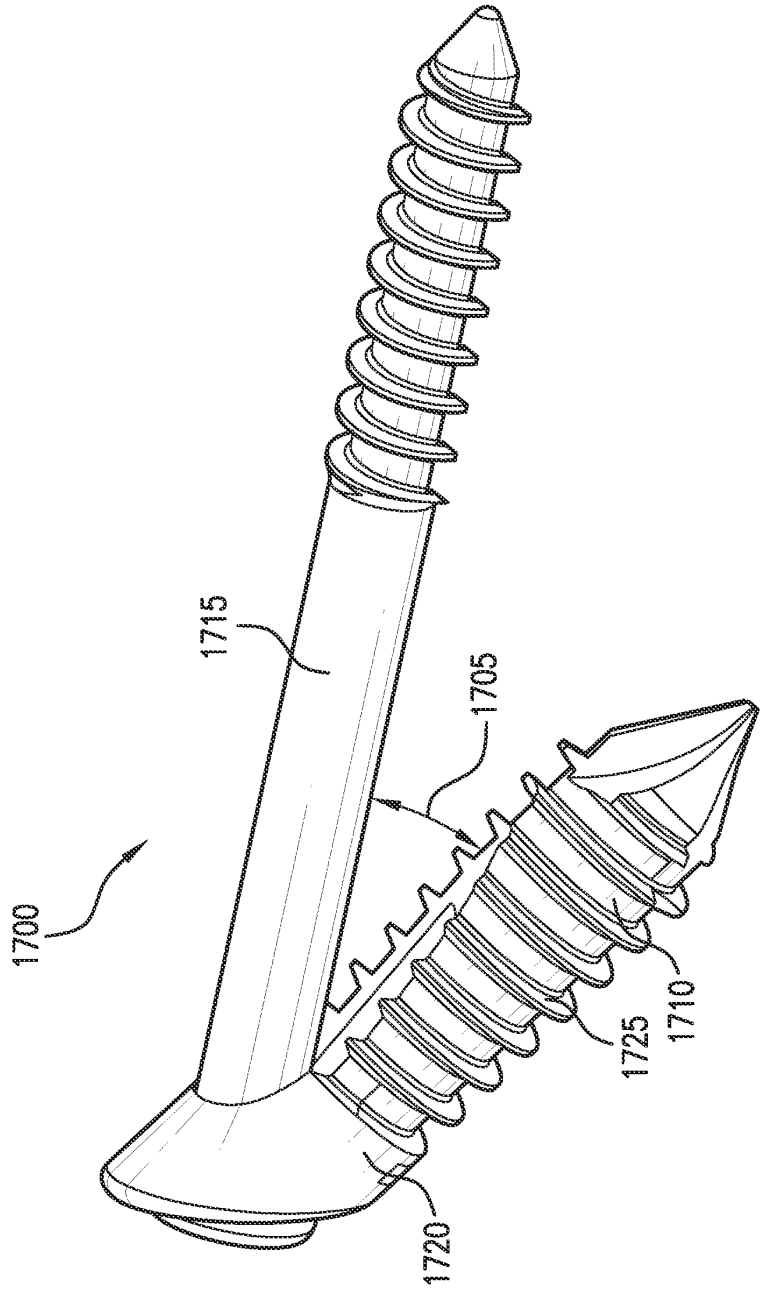


FIG. 17

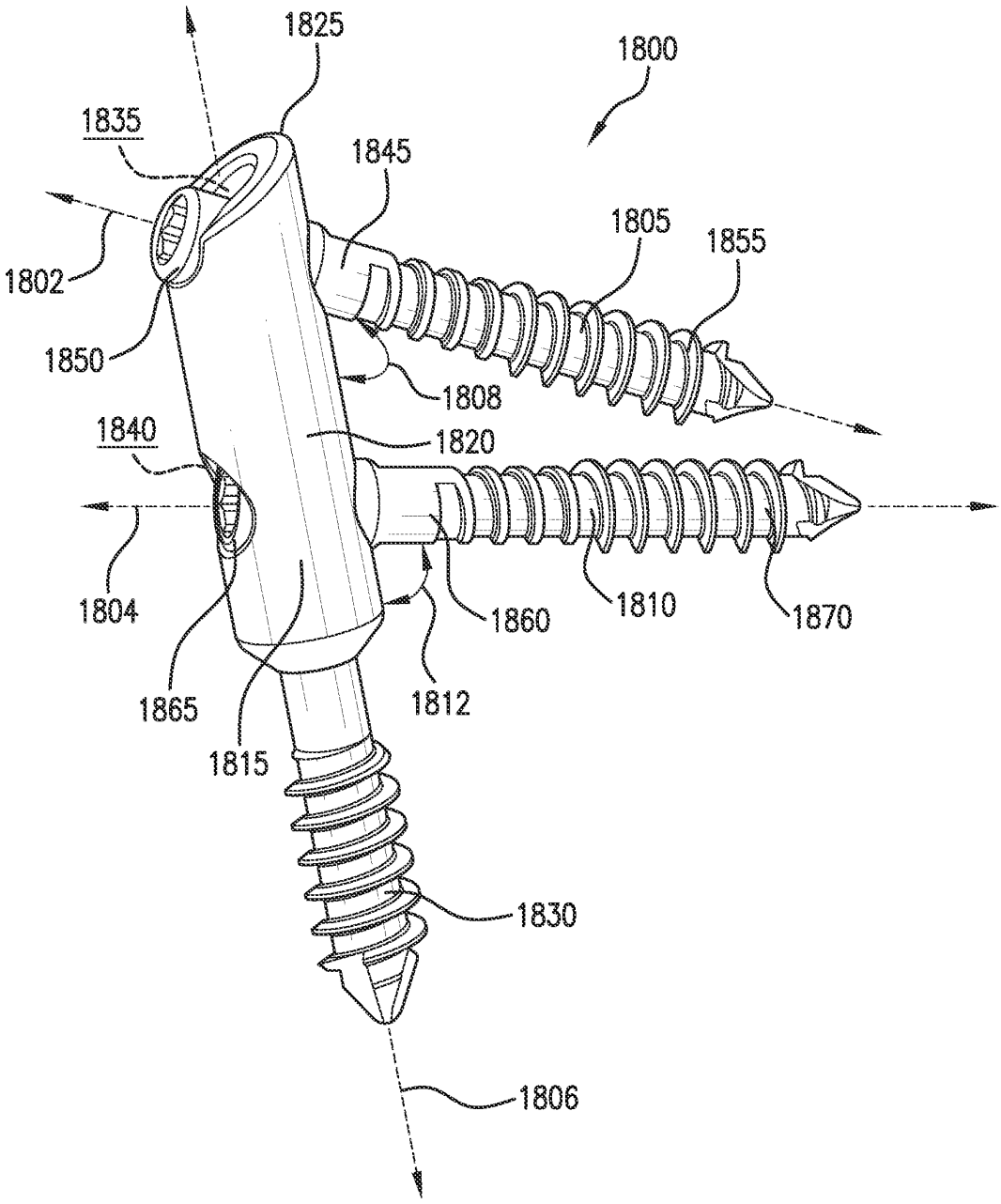

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FIG. 18

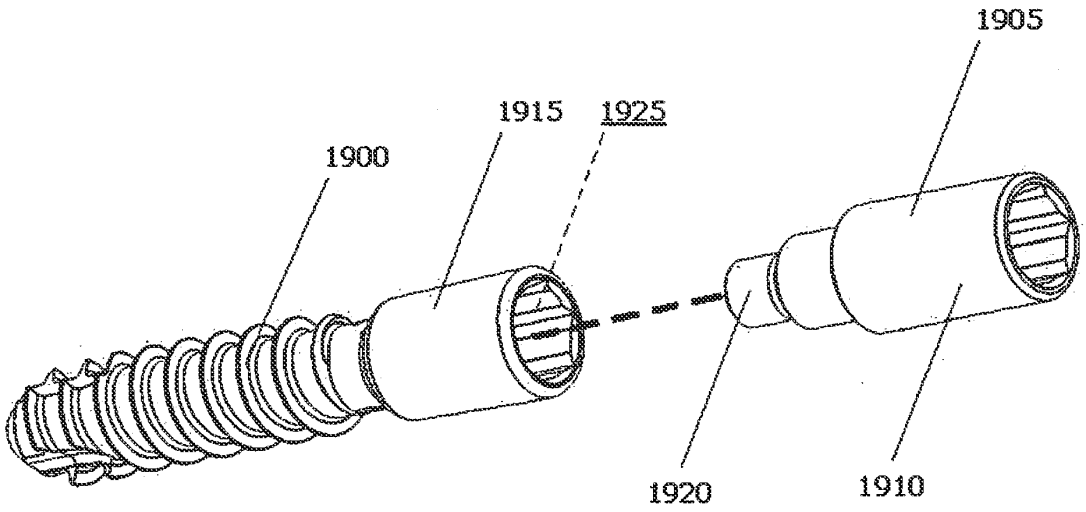


FIG. 19

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 14599671

filed on 19-JAN-2015.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor Jamy Gannoe Date (Optional) :

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 14599671

filed on 19-JAN-2015.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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LEGAL NAME OF INVENTOR

Inventor: Jeff Tyber Date (Optional): 02/20/15

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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Doc code: Oath
Document Description: Oath or declaration filed

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SUBSTITUTE STATEMENT IN LIEU OF AN OATH OR DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (35 U.S.C. 115(d) AND 37 CFR 1.64)

Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

This statement is directed to:

☒ The attached application,

OR

☐ United States application or PCT international application number _____ filed on _____.

LEGAL NAME of inventor to whom this substitute statement applies:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Lawrence Kiefer

Residence (except for a deceased or legally incapacitated inventor):

City	State	Country
Lafayette	NJ	US

Mailing Address (except for a deceased or legally incapacitated inventor):

95 Beaver Run Road

City	State	Zip	Country
Lafayette	NJ	07848	US

I believe the above-named inventor or joint inventor to be the original inventor or an original joint inventor of a claimed invention in the application.

The above-identified application was made or authorized to be made by me.

I hereby acknowledge that any willful false statement made in this statement is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

Relationship to the inventor to whom this substitute statement applies:

- ☐ Legal Representative (for deceased or legally incapacitated inventor only),
- ☒ Assignee,
- ☐ Person to whom the inventor is under an obligation to assign,
- ☐ Person who otherwise shows a sufficient proprietary interest in the matter (petition under 37 CFR 1.46 is required), or
- ☐ Joint Inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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SUBSTITUTE STATEMENT

Circumstances permitting execution of this substitute statement:

- ☐ Inventor is deceased.
- ☐ Inventor is under legal incapacity.
- ☒ Inventor cannot be found or reached after diligent effort, or
- ☐ Inventor has refused to execute the oath or declaration under 37 CFR 1.63.

If there are joint inventors, please check the appropriate box below:

- ☒ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) naming the entire inventive entity has been or is currently submitted.

OR

- ☐ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) has not been submitted. Thus, a Substitute Statement Supplemental Sheet (PTO/AIA/11 or equivalent) naming the entire inventive entity and providing inventor information is attached. See 37 CFR 1.64(b).

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

PERSON EXECUTING THIS SUBSTITUTE STATEMENT:

Name: Matthew Lyons | Date (Optional):

Signature:

APPLICANT NAME AND TITLE OF PERSON EXECUTING THIS SUBSTITUTE STATEMENT:

If the applicant is a juristic entity, list the applicant name and the title of the signer:

Applicant Name: Extremity Medical, LLC

Title of Person Executing This Substitute Statement: CEO

The signer, whose title is supplied above, is authorized to act on behalf of the applicant.

Residence of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent):

City Parsippany | State NJ | Country US

Mailing Address of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent)

300 Interpace Parkway, Suite 410

City Parsippany | State NJ | Zip 07054 | Country US

Note: Use an additional PTO/AIA/02 form for each inventor who is deceased, legally incapacitated, cannot be found or reached after diligent effort, or has refused to execute the oath or declaration under 37 CFR 1.63.

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17323923
Filing Date	2021-05-18
First Named Inventor	Jeff Tyber
Art Unit	2833
Examiner Name	TBD
Attorney Docket Number	024664

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5984681		1999-11-16	Huang Barney	
	2	9289970		1909-07-27	Mueller, Emanuel	
	3	5112333		1992-05-12	Fixel	
	4	6168595		2001-01-02	Durham, et al	
	5	7229448		2007-06-12	Goble, et al	
	6	5531748		1996-07-02	de la Carfiniere	
	7	6019761		2000-02-01	Gustillo	
	8	6106528		2000-08-22	Durham, et al	

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	Filing Date	2021-05-18
	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

	9	6221074		2001-04-24	Cole, et al	
	10	6235031		2001-05-22	Hodgeman, et al	
	11	6261290		2001-07-17	Friedl	
	12	6270499		2001-08-07	Leu, et al	
	13	6402753		2002-06-11	Cole, et al	
	14	6569165		2003-05-27	Wahl, et al	
	15	6629976		2003-10-07	Gnos, et al	
	16	6648889		2003-11-18	Bramlet, et al	
	17	6692496		2004-02-17	Wardlaw	
	18	6709436		2004-03-23	Hover, et al	
	19	6793659		2004-09-21	Putnam	

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	Filing Date	2021-05-18
	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

	20	6808527		2004-10-26	Lower, et al	
	21	7018380		2006-03-28	Cole	
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	26	7341588		2008-03-11	Swanson	
	27	7527627		2009-05-05	Ferrante, et al	
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	Filing Date	2021-05-18
	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

	31	7763022		2010-07-27	Speitling, et al	
	32	7763023		2010-07-27	Gotfried	
	33	4940467		1990-07-10	Tronzo	
	34	7785326		2010-08-31	Green, et al	
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	Examiner Name	TBD
	Attorney Docket Number	024664

	42	8057476		2011-11-15	Ekholm, et al	
	43	6527775		2003-03-04	Warburton	
	44	7160302		2007-01-09	Warburton	
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	53	5888203		1999-03-30	Goldberg	
	54	5505731		1996-04-09	Tornier	
	55	4622959		1986-11-01	Marcus	
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	Attorney Docket Number	024664

	64	4947502		1990-08-14	Engelhardt	
	65	3018986		1962-02-06	Behrle	
	66	5718705		1998-02-17	Sammarco	
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	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

	75	3411398		1968-11-19	Blakeley et al	
	76	7601153		2009-10-13	Shinjo, et al	
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	82	5779704		1998-07-14	Kim	
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	84	3474537		1969-10-28	Christensen	
	85	4795294		1989-01-03	Takada et al	

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	Examiner Name	TBD
	Attorney Docket Number	024664

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	87	4930963		1990-06-05	Rockenfeller et al	
	88	4987714		1991-01-29	Lemke	
	89	5501557		1996-03-26	Wakai	
	90	5857816		1999-01-12	Assmundson	
	91	5779705		1998-07-01	Matthews	
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	93	8353910		2013-01-01	Dell-Oca	
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	95	6247883		2001-06-19	Monserratt	
	96	5865559		1999-02-02	Yang	

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	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

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	99	7794483		2010-09-14	Capanni	
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	104	7582107		2009-09-01	Trail et al	
	105	7331962		2008-02-19	Branemark	
	106	8100910		2012-01-24	Warburton	
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	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

	108	4381770		1983-05-03	Neufield	
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	114	5540694		1996-07-30	DeCarlo, Jr., et al	
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	117	5613971		1997-03-25	Lower, et al	
	118	5620449		1997-04-15	Faccioli, et al	

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	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

	119	7731721		2010-06-08	Rathbun, et al	
	120	5766221		1998-06-16	Benderev, et al	
	121	5891150		1999-04-06	Chan	
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	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

	130	6679888		2004-01-20	Green, et al	
	131	6692503		2004-02-17	Foley, et al	
	132	6712849		2004-03-30	Re, et al	
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	134	7063724		2006-06-20	Re, et al	
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	137	5209753		1993-05-11	Biedermann	
	138	5718706		1998-02-17	Roger	
	139	5997541		1999-12-07	Schenk	
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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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A61B 17/72
A61B 17/86

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[72] 设计人 林 晋 龙震宇 陆正光

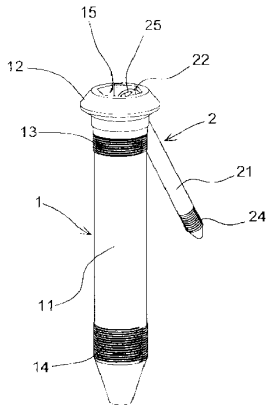
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[54] 实用新型名称 骨髓内钉的锁合螺丝构造

[57] 摘要

一种骨髓内钉的锁合螺丝构造，其包括有两个分别由组接部及端部所构成的第一、二锁固件，组接部的二端外缘是分别环设有一螺纹部，端部是具有一凹陷部，第一锁固件的凹陷部上是具有一邻近组接部的贯穿孔，使第二锁固件是固设于第一锁固件的贯穿孔中。具有增加锁合螺丝的强度，于锁合螺丝锁固后具有不易松脱的功效。



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1、一种骨髓内钉的锁合螺丝构造，其特征是：它包括有两个分别由组接部及端部所构成的第一、二锁固件；该第一锁固件是由一组接部及一设置于组接部一端的端部所构成，该组接部的二端外缘是分别环设有一螺纹部，该端部是具有一凹陷部，该凹陷部上是具有一邻近该组接部的贯穿孔；该第二锁固件是固设于所述第一锁固件的贯穿孔中，该第二锁固件是由一组接部及一设置于组接部一端的端部所构成，该组接部的二端外缘是分别环设有一螺纹部，该端部是具有一凹陷部。

2、根据权利要求1所述的骨髓内钉的锁合螺丝构造，其特征是：该第一、二锁固件的端部的外径是大于该组接部的外径。

3、根据权利要求1所述的骨髓内钉的锁合螺丝构造，其特征是：该第一、二锁固件的端部的凹陷部是具有配合不同螺合工具的不同形状。

4、根据权利要求1所述的骨髓内钉的锁合螺丝构造，其特征是：该贯穿孔是呈一倾斜状。

5、根据权利要求1所述的骨髓内钉的锁合螺丝构造，其特征是：该贯穿孔内是设有一内螺纹部。

骨髓内钉的锁合螺丝构造

技术领域

本实用新型是有关于一种用于骨髓内钉的锁合螺丝构造，特指一种可增加锁合螺丝的强度，且于锁合螺丝锁固后达到不易松脱的现象。

背景技术

如图6所示，传统用于骨髓内钉的锁合螺丝5，是由一环设有螺纹51的锁合部52及设置于锁合部52一端的接合部53所构成，螺纹51是从头到尾布满于锁合部52的外缘。

当使用时，是以一工具（如螺丝起子）配合接合部53，将锁合部52利用其螺纹51螺固于骨头及骨髓内钉之间，达到使骨髓内钉固设于骨头的适当处，虽然所述传统的锁合螺丝5可将骨髓内钉固设于骨头的适当处，但是其主要缺陷在于：

1、由于锁合螺丝5的锁合部52上是从头到尾布满螺纹51，因此锁合部52上螺纹51与螺纹51间的外径则变的较小，以锁合部52作为支撑骨髓内钉时，在其构造上是较为脆弱；

2、况且，骨髓内钉仅是以一锁合螺丝5作为锁固，因此极易造成松脱的现象，故，一般传统的骨髓内钉的锁合螺丝5于实际使用上，并不能符合使用者的所需。

发明内容

本实用新型的主要目的是提供一种骨髓内钉的锁合螺丝构造，克服现有

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技术的弊端，达到增加锁合螺丝的强度，且于锁合螺丝的第一、二锁固件锁固后达到不易松脱的目的。

本实用新型的目的是这样实现的：一种骨髓内钉的锁合螺丝构造，其特征是：它包括有两个分别由组接部及端部所构成的第一、二锁固件；该第一锁固件是由一组接部及一设置于组接部一端的端部所构成，该组接部的二端外缘是分别环设有一螺纹部，该端部是具有一凹陷部，该凹陷部上是具有一邻近该组接部的贯穿孔；该第二锁固件是固设于所述第一锁固件的贯穿孔中，该第二锁固件是由一组接部及一设置于组接部一端的端部所构成，该组接部的二端外缘是分别环设有一螺纹部，该端部是具有一凹陷部。

该第一、二锁固件的端部的外径是大于该组接部的外径。该第一、二锁固件的端部的凹陷部是具有配合不同螺合工具的不同形状。该贯穿孔是呈一倾斜状。该贯穿孔内是设有一内螺纹部。

下面结合较佳实施例和附图进一步说明。

附图说明

图1是本实用新型的立体示意图。

图2是本实用新型的立体分解示意图。

图3是本实用新型的剖面示意图。

图4是本实用新型的使用状态侧视图一。

图5是本实用新型的使用状态侧视图二。

图6是传统结构的立体示意图。

具体实施方式

参阅图1-图3所示，分别是本实用新型的立体示意图、立体分解示意图及剖面状态示意图。

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本实用新型是一种用于骨髓内钉的锁合螺丝构造，其是由第一锁固件1及第二锁固件2所构成。通过第一、二锁固件1、2的构造增加锁合螺丝的强度，且可通过第一、二锁固件1、2的配合，于锁合螺丝锁固后，达到不易松脱的目的。

第一锁固件1是由一组接部11及一设置于组接部11一端的端部12所构成，而该端部12的外径是大于组接部11的外径，且组接部11的二端外缘是分别环设有一螺纹部13、14，而二端的螺纹部13、14间并无设置螺纹，而端部12是具有一凹陷部15，凹陷部15是可配合不同的螺合工具而为不同的形状，如一字形、十字形或内六角形等，且端部的凹陷部15上是具有一邻近组接部11的贯穿孔16，贯穿孔16内是设有一内螺纹部17，且贯穿孔16是呈一倾斜状；

第二锁固件2是固设于第一锁固件1的贯穿孔16中，且第二锁固件2是由一组接部21及一设置于组接部21一端的端部22所构成，而端部22的外径是大于组接部21的外径，组接部21的二端外缘是分别环设有一螺纹部23、24，而二端的螺纹部23、24间并无设置螺纹，并于端部22是具有一凹陷部25，端部22的凹陷部25是配合不同的螺合工具而为不同的形状，如一字形、十字形或内六角形等。通过所述的构造构成一全新的用于骨髓内钉的锁合螺丝构造。

参阅图4-图5所示，是本实用新型的使用状态侧视图，当本实用新型于使用时，是先以一工具（图中未示）配合第一锁固件1的凹陷部15，将第一锁固件1的组接部11锁固于骨髓内钉3上，使组接部11二端的螺纹部13、14可结合骨髓内钉3及骨头4部分，并使二端的螺纹部13、14间无设置螺纹的部分固设于骨髓内钉3的内部，而由于二螺纹部间无设置螺纹，而是一实心柱体，且外径较二螺纹部13、14大，因此，可使骨髓内钉3通过组接部11无设置螺纹处作为较具有强度的支撑；

待第一锁固件1固设之后，再以一工具配合第二锁固件2的凹陷部25，将第二锁固件2的组接部21固设于所述第一锁固件1的贯穿孔16中，而使第二锁

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固件2的组接部21通过二端的螺纹部23、24，并以倾斜的方式配合贯穿孔16中的内螺纹部17，而锁固于骨髓内钉3上，除同样可达到如第一锁固件1的功效只外，并可作为辅助第一锁固件1的功效，使第一锁固件1通过第二锁固件2的配合，于第一锁固件1锁固于骨髓内钉3之后，达到不易松脱的目的。

以上所述，仅为本实用新型的较佳实施例，凡依本实用新型的内容所作的简单的等效变化与修饰，皆应属于本实用新型的保护范围之内。

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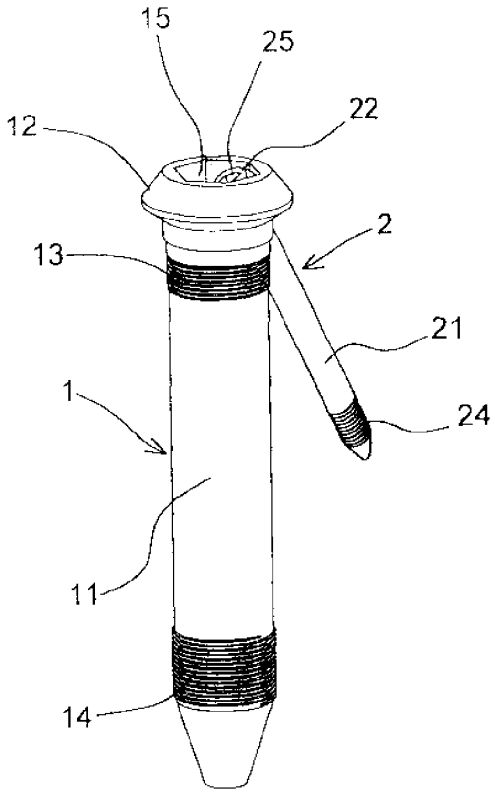


图 1

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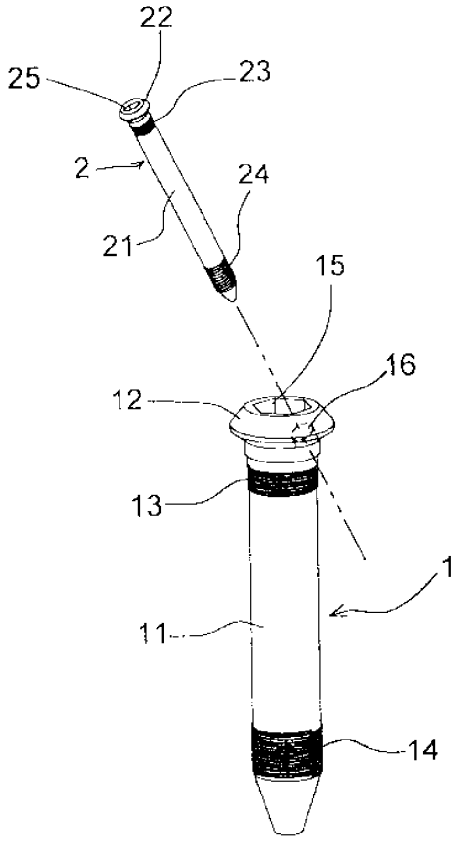


图 2

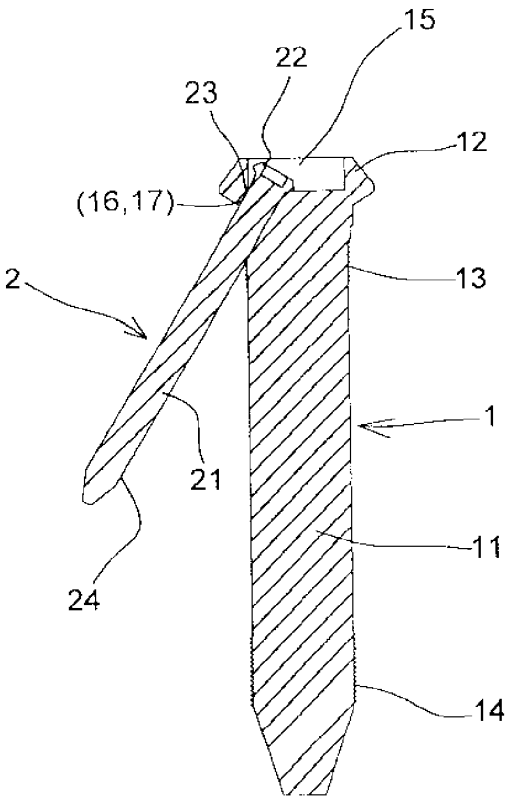


图 3

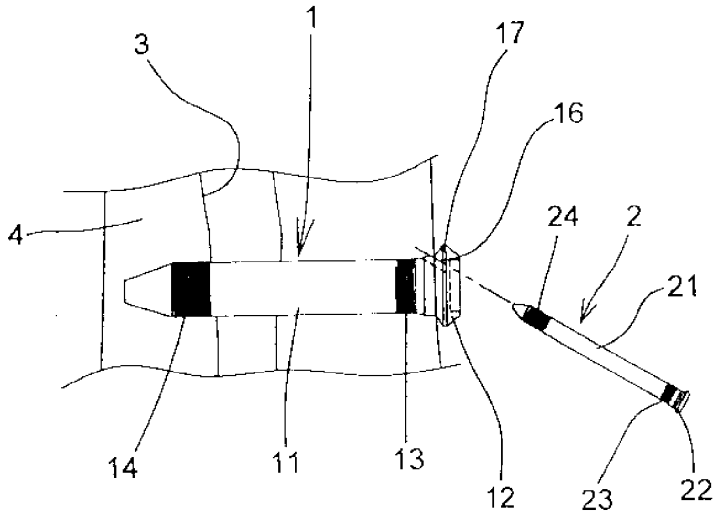


图 4

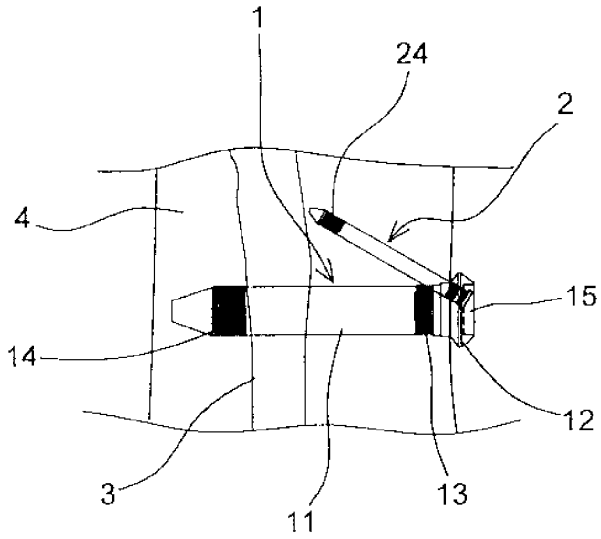


图 5

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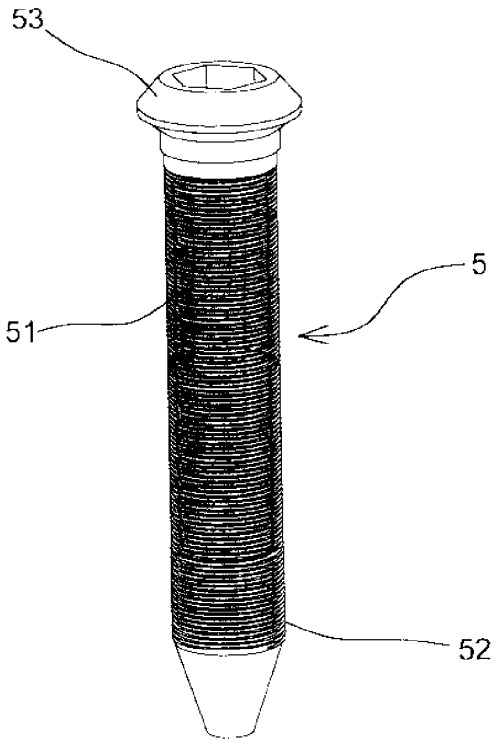


图 6

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Espacenet

Bibliographic data: CN2738745 (Y) — 2005-11-09

Locking screw structure of intramedullary nail

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- cooperative:

Application number: CN20042096282U 20040928

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Abstract of CN2738745 (Y)

The utility model provides a locking screw structure of intramedullary nail, comprising a first and a second lock firmwares which are respectively composed of the jointing parts and the end parts. The outer margin of the jointing parts both ends are respectively circularly provided with a screw thread part, and the end part is provided with a dishing part. The first lock firmware dishing part is provided with a through hole which is near to the jointing part, and the second lock firmware is fixed in the through hole of the first lock firmware, which is provided with the effect of increasing the intensity of the locking screw and the unease of getting loose after the locking screw being firmly locked.

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DESCRIPTION CN2738745

The invention relates to a locking screw structure of an intramedullary nail, which comprises two first and second locking members respectively formed by a connecting portion and an end portion, and the outer edges of the two ends of the connecting portion are respectively provided with a threaded portion. The end portion has a recessed portion, and the recessed portion of the first locking member has a through hole adjacent to the connecting portion, so that the second locking member is fixed in the through hole of the first locking member. The utility model has the advantages of increasing the strength of the locking screw, and has the effect of being loosened after the locking screw is locked.

Locking screw structure of intramedullary nail

Technical field

The utility model relates to a lock screw structure for an intramedullary nail, in particular to an increase in the strength of the locking screw, and the phenomenon that the locking screw is not easy to loosen after being locked.

Background technique

As shown in FIG. 6, the lock screw 5 conventionally used for the intramedullary nail is composed of a lock portion 52 provided with a thread 51 and a joint portion 53 provided at one end of the lock portion 52. The thread 51 is a slave head. The tail is covered with the outer edge of the locking portion 52.

When in use, a tool (such as a screwdriver) is used to engage the joint portion 53, and the lock portion 52 is screwed between the bone and the intramedullary nail with the thread 51 to achieve the fixation of the intramedullary nail to the bone. Although the conventional locking screw 5 can fix the intramedullary nail to the proper place of the bone, the main drawbacks are:

1、
Since the locking portion 52 of the locking screw 5 is covered with the thread 51 from the beginning to the end, the outer diameter between the thread 51 and the thread 51 of the locking portion 52 becomes smaller, and the locking portion 52 serves as a supporting bone marrow. When nailed, it is more fragile in its construction;

2、
Moreover, the intramedullary nail is only locked by a locking screw 5, so it is easy to cause looseness. Therefore, the conventional locking screw 5 of the intramedullary nail is not practically used. Required.

Summary of the invention

The main purpose of the utility model is to provide a locking screw structure of an intramedullary nail, which overcomes the disadvantages of the prior art and achieves an increase in the strength of the locking screw, and is achieved after the first and second locking fasteners of the locking screw are locked. Not easy to loose.

The purpose of the utility model is as follows: a locking screw structure of an intramedullary nail, characterized in that it comprises two first and second locking members respectively composed of a connecting portion and an end portion; A locking piece is formed by a set of connecting portions and an end portion disposed at one end of the connecting portion, wherein the outer edges of the two ends of the connecting portion are respectively provided with a threaded portion, and the end portion has a recessed portion. The recessed portion has a through hole adjacent to the set of joints; the second lock is fixed in the through hole of the first fastener, and the second lock is disposed by a set of joints and a The end of one end of the connecting portion is formed, and the outer edges of the two ends of the connecting portion are respectively provided with a threaded portion, and the end portion has a concave portion.

The outer diameters of the ends of the first and second fasteners are larger than the outer diameter of the set of joints.

The recesses at the ends of the first and second fasteners have different shapes for mating different screwing tools.

The through hole is inclined. An internal threaded portion is provided in the through hole.

The following is further described in conjunction with the preferred embodiment and the accompanying drawings.

DRAWINGS

Figure 1 is a perspective view of the utility model.

2 is a perspective exploded view of the present invention.

Figure 3 is a schematic cross-sectional view of the present invention.

Figure 4 is a side view of the state of use of the present invention.

Fig. 5 is a side view 2 of the state of use of the present invention.

Figure 6 is a perspective view of a conventional structure.

detailed description

1 to 3 are respectively a perspective view, a perspective exploded view, and a schematic cross-sectional view of the present invention.

The utility model relates to a lock screw structure for an intramedullary nail, which is composed of a first lock body 1 and a second lock body 2. The strength of the locking screw is increased by the configuration of the first and second locking members 1, 2, and the locking of the first and second locking members 1, 2 can be achieved

after the locking screw is locked.

The first lock body 1 is composed of a set of joints 11 and an end portion 12 disposed at one end of the joint portion 11, and the outer diameter of the end portion 12 is larger than the outer diameter of the joint portion 11, and the joint portion The outer edges of the two ends of the 11 are respectively provided with a threaded portion 13 and 14, and the threaded portions 13 and 14 of the two ends are not provided with a thread, and the end portion 12 has a recessed portion 15, and the recessed portion 15 can be matched with different The screwing tool has different shapes, such as a shape of a cross, a cross or an inner hexagon, and the recessed portion 15 at the end has a through hole 16 adjacent to the connecting portion 11, and the through hole 16 is provided with an internal thread. a portion 17, and the through hole 16 is in an inclined shape;

The second locking member 2 is fixed in the through hole 16 of the first locking member 1, and the second locking member 2 is composed of a plurality of connecting portions 21 and an end portion 22 disposed at one end of the connecting portion 21, and The outer diameter of the end portion 22 is larger than the outer diameter of the assembly portion 21, and the outer edges of the two end portions of the assembly portion 21 are respectively provided with a threaded portion 23, 24, and the threaded portions 23, 24 of the two ends are not provided with a thread. And the end portion 22 has a recessed portion 25, and the recessed portion 25 of the end portion 22 is different in shape with different screwing tools, such as a figure, a cross or an inner hexagon. With the described construction, a completely new lock screw configuration for the intramedullary nail is constructed.

Referring to FIG. 4 to FIG. 5, it is a side view of the state of use of the utility model. When the utility model is used, the tool portion (not shown) is first matched with the recess portion 15 of the first fastener 1 and The assembly portion 11 of the first fastener 1 is locked to the intramedullary nail 3, so that the threaded portions 13, 14 at the two ends of the assembly portion 11 can combine the intramedullary nail 3 and the bone 4 portion, and the threaded portion 13 at both ends, 14 unthreaded portions are fixed inside the intramedullary nail 3, and because there is no thread between the two thread portions, but a solid cylinder, and the outer diameter is larger than the two thread portions 13, 14 The intramedullary nail 3 is not provided with a thread at the joint portion 11 as a relatively strong support;

After the first fastener 1 is fixed, the tooling portion 21 of the second fastener 2 is fixed to the through hole 16 of the first fastener 1 by a tool. The assembly portion 21 of the second fastener 2 is passed through the threaded portions 23, 24 of the two ends, and the internal thread portion 17 of the through hole 16 is fitted in an inclined manner to be locked to the intramedullary nail 3, except The function of the first lock 1 can be achieved as well as the function of the first lock 1 , so that the first lock 1 is locked to the first lock 1 by the cooperation of the second lock 2 . After the intramedullary nail 3, it is not easy to loosen.

The above is only a preferred embodiment of the present invention, and all simple equivalent changes and modifications made in accordance with the contents of the present invention are within the scope of protection of the present invention.

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(54) BIONIC DENTAL IMPLANT

(57) A bionic dental implant. The bionic dental implant includes a main root (1), a basal platform (2) and a platform bolt (3). The said main root (1) includes a fixing root part (11), a neck part (12) located on the upper end of the fixing root part (11), and a mounting channel (13) located inside the main root (1). An aperture (21) is provided inside the basal platform (2). The platform bolt (3) communicates with the aperture (21) to make the basal platform (2) to be fixed on the main root (1). The said main root (1) also includes a t least one subsidiary root (4). The main root (1) has the same number of inclined holes (14) as the subsidiary root, the said inclined holes (14) form a sharp angle with respect to the mounting channel (13) and communicates with it. The upper ends of the said subsidiary roots (4) are fixed inside the inclined holes (14) of the main root.

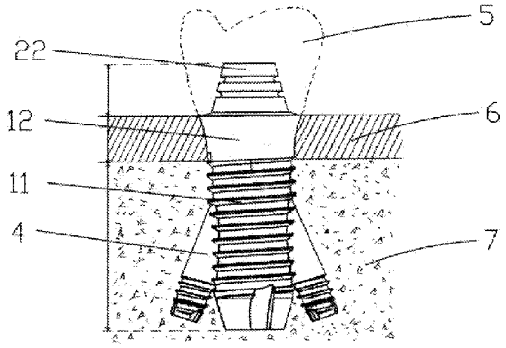


Fig.25

EP 2 151 213 A1

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Description

Field of the Invention

[0001] The invention relates to an artificial dental system, particularly to a bionic dental implant which is implanted into a jaw bone and serves as an artificial tooth root. Meanwhile, the invention also relates to a main root, a subsidiary root and an implanting method which are applied to the bionic dental implant.

Background of the Invention

[0002] For the convenience and long-term stability of clinical application, currently, the implant body which is successfully used for so many times by dentists is a cylinder-cone-shaped rotation in-position type implant body which is similar to a natural-tooth-root shape. The shape is an axial-symmetrical-cylinder shaped implant body or a cone-shaped implant body. The surface of the implant body generally has screw threads which can be rotatably positioned at a bone hole of the prepared jaw bone. Therefore, certain initial-stage stability can be obtained. Furthermore, as various methods (such as surface coarsening and plasma spray coating) in which the same jaw bone biological contact area is increased on the surface of the implant body is implemented, the implant body is popularly used in the world currently.

[0003] The invention, which has publication No. CN1826089A and name of "dental implant", discloses a dental implant consisting of a fixing root part, a neck part and a basal platform part. The patent is a classic cylinder-cone-shaped rotation in-position type implant. As being a single-cylinder body or a cone-shaped body, the implant body can not form the mutual tensile action similar to that between a plurality of root teeth of a natural tooth so as to fulfill the anti-rotation and anti-twist function. Only the limited initial fixing action of the threads of the surface of an implant body can not resist various torque force interference produced on the implant body by the teeth on the base of the implant body when food is chewed. Therefore, currently, most of the implant bodies should wait several months after having been implanted into the jaw bone, and the teeth can not be mounted and stressed and can not implement chewing function; otherwise, the organic bone combination on the contact interface between the implant body and the jaw bone will be destroyed, and the implant body will eventually become loosened and the implanting will failed.

Summary of the invention

[0004] The invention relates to an artificial dental system, particularly to a bionic dental implant which is implanted into a jaw bone and serves as an artificial tooth root. Meanwhile, the invention also relates to a main root, a subsidiary root and an implanting method which are applied to the bionic dental implant.

[0005] One of the purposes of the invention is to provide a bionic dental implant similar to the natural tooth root so as to cover the shortages of the prior art. The bionic dental implant not only has good initial stable performance and initial anti-rotation and anti-twist function but also can increase the contact area between the implant body and the jaw bone and increase the success ratio of immediate stress and long-term stability and effectiveness after being implanted.

[0006] In order to obtain the above purposes, the technique scheme of the bionic dental implant of the invention is as follows:

[0007] A bionic dental implant comprises a main root, a basal platform and a platform bolt. The main root includes a fixing root part, a neck part located on the upper end of the fixing root part and a mounting channel located inside the main root. An aperture is provided inside the basal platform, the platform bolt communicates with the aperture to make the basal platform to be fixed on the main root. The invention is **characterized in that** the main root also includes at least one subsidiary root, the main root has the same number of inclined holes as the subsidiary root, the inclined holes form a sharp angle with respect to the mounting channel and communicate with it, and the upper end of the subsidiary root are fixed inside the inclined holes of the main root.

[0008] As one main embodiment of the invention, a mounting channel of a main root comprises a cone hole, a multi-square hole and a screw hole in the order from the top down. A basal platform comprises a basal platform part, a cone body located at the lower end of the basal platform part and matched with a cone hole and a multi-square body located at the lower end of the cone body and matched with the multi-square hole of the main root. The sides of the multi-square body of the basal platform are provided with a dovetail groove corresponding to the number of a subsidiary root. A dovetail joint matched with the dovetail groove on the multi-square body is provided on the end surface of the subsidiary root of the upper end of the subsidiary root. After the basal platform is inserted into the mounting channel, the dovetail groove on the basal platform and a dovetail joint on the subsidiary root are clamped together. The subsidiary root is fixedly mounted in an inclined hole of the main root. A mounting positioning hole is provided in the end surface of the subsidiary root.

[0009] As another embodiment of the invention, a mounting channel of a main root comprises a cone hole, a multi-square hole and a screw hole in the order from the top down. The basal platform comprises a basal platform part, a cone body located at the lower end of the basal platform part and matched with the cone hole of the main root and a multi-square body located at the lower end of the cone body and matched with the multi-square hole of the main root. The sides of the multi-square body of the basal platform are provided with a dovetail joint corresponding to the number of a subsidiary root. A dovetail groove matched with the dovetail joint on the multi-

square body is provided on the end surface of the subsidiary root of the upper end part of the subsidiary root. A groove passed through the dovetail joint is provided inside of the multi-square hole of the main root. After the basal platform is inserted into the mounting channel, the dovetail joint on the basal platform and a dovetail groove of the subsidiary root are clamped with each other; therefore, the subsidiary root is fixed and mounted in an inclined hole of the main root. A mounting positioning hole is provided in the end surface of the subsidiary root.

[0010] As another main embodiment of the invention, a mounting channel of a main root comprises a cone hole, a multi-square hole and a screw hole. A basal platform comprises a basal platform part, a cone body located at the lower end of the basal platform part and matched with the cone hole of the main root and a multi-square body located at the lower end of the cone body and matched with the multi-square hole of the main root. The upper end part of a subsidiary root is a cone body. The cone body of the subsidiary root gradually becomes bigger along an axis toward the end surface of the subsidiary root. The end surface of the subsidiary root is a concave surface matched with the periphery surface of the cone body of the basal platform. A mounting positioning hole is provided at the end surface of the subsidiary root. The shape of an inclined hole of the main root is a cone hole matched with the cone body of the subsidiary root. After the basal platform is inserted into the mounting channel, the outer surface of the cone body of the basal platform contacts and is matched with the concave surface on the end surface of the subsidiary root. Therefore, the subsidiary root is fixed and mounted in the inclined hole of the main root.

[0011] Another purpose of the invention aims at covering the shortages of the prior art and provides a main root applied to a bionic dental implant. The concrete technique scheme is as follows:

[0012] The main root is provided with at least an inclined hole. The inclined holes form a sharp angle with respect to a mounting channel and communicate with it. Therefore, the upper end of a subsidiary root is fixed and mounted in the inclined hole of the main root.

[0013] Another purpose of the invention aims at covering the shortages of the prior art and provides a subsidiary root of a bionic dental implant. The concrete technique scheme is as follows:

[0014] The outer diameter of the upper end of a subsidiary root is matched with the inner diameter of the inclined hole. Therefore, the upper end of the subsidiary root is fixed and mounted in the inclined hole of the main root.

[0015] Another purpose of the invention aims at covering the shortages of the prior art and provides an implanting method applied to a bionic dental implant. The concrete technique scheme is as follows:

[0016] (1)A hole is drilled by a drilling tool in a jaw bone which is needed to be implanted in advance;

[0017] (2)The inner wall of a bone hole is threaded by a threading tool, and a thread hole matched with the outer thread of the main root is formed;

[0018] (3)Multi-square holes are connected with each other by a tool. The main root is screwed into the bone hole;

[0019] (4)A small drilling tool of which the diameter is mated with the subsidiary root is passed through a mounting channel and a inclined hole and reaches a j aw bone. The hole is drilled obliquely. The drilling depth is the same as the depth by which the subsidiary root is implanted into a jaw bone;

[0020] (5)After mounting positioning holes are connected with each other by a mounting positioning tool, a subsidiary root is passed through a mounting channel and a inclined hole and reaches a bone hole, which guarantees the end surface of the subsidiary root and the sides of a multi-square hole of a main root are positioned at the same plane;

[0021] (6)A basal platform is placed downwards from a mounting channel. A dovetail groove or a dovetail joint of the sides of a multi-square body is smoothly inserted, is combined with the dovetail joint or the dovetail groove of a subsidiary root and forms a tight tabling. The subsidiary root is fixed and mounted in a inclined hole of a main root;

[0022] (7)A bolt of a basal platform is winded up and the above parts form a tight integration one.

[0023] The advantages of the invention are that a bionic dental implant of the invention forms at least a multi-dental implant body fixing system which has more than two fixing roots; therefore, it not only forms multi-root plane type resistance distribution which fulfills the tensile action between the roots and resists the chewing and rotation interference but also forms a multi-root steric type resistance distribution. It embodies the physiological feature of the natural tooth of "the bigger the area between the tooth roots is, the more stable the teeth are". It obviously enhances the initial stability of the implant body. The mutual tensile action between the multi-roots stimulates the bone fibers of a jaw bone, which better accords with the physiological feature of the jaw bone. Therefore, the invention has the advantages of more bone tissue hyperplasia, less absorption and effective enhancement of the combination of the implant body and the bone tissue.

[0024] Furthermore, through the change of the angle between a main root and a subsidiary root, the scope of shape of a bionic dental implant almost comprises the shapes of the tooth root structures of various natural teeth. Therefore, the stressed method and the resistance method of the dental implant are more similar to that of the natural physiological status of the natural teeth. As the intersecting implanting method of a subsidiary root and a main root, the lengths, sizes, direction and intersecting parts, intersecting angle of the subsidiary root and the main root, and the inclined angle of the whole implant body can be selected flexibly according to the status, texture, anatomical structure conditions of the

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bone in the implanted area of a jaw bone before the operation when the bionic dental implant is implanted. Therefore, multiple roots of a steric combinative structure in multiple planes are formed. The potential implanting space in the jaw bone is further widened. Meanwhile, non-damage anatomical structures on the jaw bone such as tubes, cavities and sinuses can be avoided, and the implanting adaptation scope can be widened.

[0025] Furthermore, the invention has good initial stability performance and initial anti-rotation and anti-twist performance. It can increase the contacting area between an implant body and a jaw bone. It also increases the success ratio of immediate stress after the implanting and the success ratio of stably fulfilling the chewing action for long term. Particularly, compared with the single implant body of the prior art, the implanting position of a subsidiary root is more biased toward the inner side and/or the outer side of a jaw bone. Therefore, the fixing root part of the implant body is easier to be implanted in the cortical bone in higher bone density and is obliquely and rotatably fixed in the cortical bone, which can obtain bigger fixing force of the high-density bone. Therefore, compared with the single implant body of the prior art and the implant body one part of surface of or most of the surface of which is positioned in the spongy bone with less bone density, the invention has remarkable and good initial stability. Meanwhile, the intersecting implanting technique of multiple roots of the invention effectively embodies the biomechanical features of mutual tension, mutual support and commonly resisting the resolution of the lateral torque force when the chewing force is held between a plurality of the dental roots of natural teeth. Therefore, it not only increases the initial stressing level of the implant body but also has the material base for decreasing the absorption which is formed by the torque force interference conducted in the sclerotin on the implant body interface of the jaw bone. The implanting method of a bionic dental implant is the same as the existing implanting operation, which is operated through an implanting port; furthermore, the implanting method of axially rotation entering positioning is both adopted by a main root and a subsidiary root. Therefore, the invention maintains the advantages of the simple operation and better practicability of the operation method when the dental implant is implanted into the jaw bone, and obtains the obvious advantages of the implanting of multiple roots.

Brief Description of the Drawings

[0026] Fig. 1 shows a spatial view of an overall structure according to the embodiment 1 of the invention.

[0027] Fig. 2 shows a spatial view of a main root according to the embodiment 1 of the invention.

[0028] Fig. 3 shows a sectional view of Fig. 2.

[0029] Fig. 4 shows a vertical view of Fig. 2.

[0030] Fig. 5 shows a spatial view of the inner structure after the cut of Fig. 2.

[0031] Fig. 6 shows a spatial view of a subsidiary root according to the embodiment 1 of the invention.

[0032] Fig. 7 shows a spatial view of the inner structure after the assembly of a main root and a subsidiary root according to the embodiment 1 of the invention.

[0033] Fig. 8 shows a spatial view of a basal platform according to the embodiment 1 of the invention.

[0034] Fig. 9 shows a spatial view of the mutual tabling of a subsidiary root and a main root according to the embodiment 1 of the invention.

[0035] Fig. 10 shows a spatial view of the inner structure after the assembly of a main root, a subsidiary root and a basal platform according to the embodiment 1 of the invention.

[0036] Fig. 11 shows a spatial view of the inner structure after the assembly of a main root, a subsidiary root, a basal platform and a basal platform bolt according to the embodiment 1 of the invention.

[0037] Fig. 12 shows a spatial view of an overall structure according to the embodiment 2 of the invention.

[0038] Fig. 13 shows a spatial view of a main root according to the embodiment 2 of the invention.

[0039] Fig. 14 shows a sectional view of Fig. 13.

[0040] Fig. 15 shows a vertical view of Fig. 13.

[0041] Fig. 16 shows a vertical view of Fig. 12.

[0042] Fig. 17 shows a spatial view of a basal platform according to the embodiment 2 of the invention.

[0043] Fig. 18 shows a spatial view of the inner structure after the assembly of a main root, a subsidiary root and a basal platform according to the embodiment 2 of the invention.

[0044] Fig. 19 shows a spatial view of an overall structure according to the embodiment 3 of the invention.

[0045] Fig. 20 shows a spatial view of an overall structure according to the embodiment 4 of the invention.

[0046] Fig. 21 shows a spatial view of an overall structure according to the embodiment 5 of the invention.

[0047] Fig. 22 shows a spatial view of an overall structure according to the embodiment 6 of the invention.

[0048] Fig. 23 shows a spatial view of an overall structure according to the embodiment 7 of the invention.

[0049] Fig. 24 shows a spatial view of an overall structure according to the embodiment 8 of the invention.

[0050] Fig. 25 shows a schematic diagram of the use state according to the invention.

[0051] Fig. 26 shows a spatial view of the inner structure after the assembly of a main root and a subsidiary root according to the embodiment 9 of the invention.

[0052] Fig. 27 shows a sectional view of a main root according to the embodiment 9 of the invention.

[0053] Fig. 28 shows a spatial view of a subsidiary root according to the embodiment 9 of the invention.

[0054] Fig. 29 shows a spatial view of a basal platform according to the embodiment 9 of the invention.

[0055] Fig. 30 shows a spatial view of the inner structure after the assembly of a main root and a subsidiary root according to the embodiment 10 of the invention.

[0056] Fig. 31 shows a spatial view of a basal platform

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according to the embodiment 10 of the invention.

[0057] Fig. 32 is a sectional view of a main root according to the embodiment 10 of the invention.

[0058] Label Declaration Section: main root 1, fixing root part 11, neck part 12, mounting channel 13, cone hole 131, square hole 132, screw hole 133, trigonal hole 134, groove 135, inclined hole 14, leaf-shaped cut groove 15, screw thread 16, basal platform 2, aperture 21, basal platform part 22, basal platform groove 221, cone body 23, square body 24, dovetail groove 25, dovetail joint 26, trigonal body 27, basal platform bolt 3, subsidiary root 4, dovetail joint 41, dovetail groove 42, cone body 43, subsidiary root end surface 44, mounting positioning hole 45, screw thread 46, leaf-shaped cut groove 47, artificial tooth 5, tooth sinew 6 and jaw bone 7.

Embodiments:

[0059] With the figures, the preferred embodiments of the invention are further described as the following:

[0060] Embodiment 1:

[0061] Referring to Figs 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 25, a bionic dental implant comprises a main root 1, a basal platform 2 and a basal platform bolt 3. The diameter of the main root 1 is 4.8 mm. The main root 1 comprises a fixing root part 11, a neck part 12 located at the upper end of the fixing root part 11 and a mounting channel 13 located inside the main root 1. An aperture 21 communicated with the two ends of the basal platform 2 is provided inside the basal platform 2. The basal platform bolt 3 is passed through the aperture 21 and fixes and mounts the basal platform 2 at the main root 1. The dental implant also comprises two subsidiary roots 4. The diameter of the subsidiary root 4 is 2 mm. The main root is provided with two inclined holes 14. The inclined holes 14 form a sharp angle with respect to the mounting channel 13 and communicate with it. The outer diameter of the upper end of the subsidiary hole 4 is matched with the inner diameter of the inclined hole 14 and is fixed and mounted in the inclined hole 14 of the main root. The included angle of the subsidiary root 4 and the main root 1 is 21 degrees.

[0062] The mounting channel 13 of the main root 1 comprises a cone hole 131, a square hole 132 and a screw hole 133 in the order from the top down. A basal platform 2 comprises a basal platform part 22, a cone body 23 located at the lower end of the basal platform part 22 and matched with the cone hole 131 of the main root 1 and a square body 24 located at the lower end and matched with a square hole 132 of the main root 1. The cone hole 131 becomes thinner from the top down. The sides of the square body 24 of the basal platform 2 are provided with two symmetrical dovetail grooves 25. The end surface 44 of the subsidiary root of the upper end part of the subsidiary root 4 is provided with a dovetail joint 41 matched with the dovetail groove 25 on the square body 24. The subsidiary root 4 and the basal platform 2 can be automatically locked after the dovetail groove 25 and the dovetail joint 41 are clamped together. Therefore, the subsidiary root is fixed and mounted in an inclined hole 14 of the main root 1. A mounting positioning hole 45 is provided in the end surface 44 of the subsidiary root. The shape of the mounting positioning hole 45 is a square hole. After a mounting tool and the mounting positioning hole 45 are connected together, the subsidiary root 4 can be positioned in a bone hole and be winded up.

[0063] Referring to Fig. 1, the lower end parts of the outer peripheries of a main root 1 and a subsidiary root 4 are provided with threads 16, 46. The section shapes of ridges of the threads are unsymmetrical trapezoids. The angle (α) between the upper end surfaces of the ridges and the axes of the main root 1 and the subsidiary root 4 are 102 degrees. The angle (β) between the lower end surfaces of the ridges and the axes of the main root and the subsidiary root is 123 degrees. Three leaf-shaped cut grooves 15, 47 are evenly distributed at the position close to the end surfaces of the threads 16, 46.

[0064] The basal platform part 22 of the basal platform 2 is also provided with a plurality of ring-shaped basal platform grooves 221, which offers convenience for an artificial tooth 5 to be stably mounted on the basal platform part 22.

[0065] An implanting method of a dental implant according to the embodiment 1 is as follows:

[0066] (1)A jaw bone 7 which is determined to be implanted in advance is drilled by a drilling tool;

[0067] (2)The inner wall of a bone hole is tapped by a tapping tool, and a tread hole matched with an outer thread 16 of a main root 1 is formed;

[0068] (3)Square holes 132 are connected by a tool. The main root 1 is screwed in the bone hole;

[0069] (4)A small drilling tool of which the diameter is matched with a subsidiary root is passed through a mounting channel 13 and an inclined hole 14 and drilled obliquely in a jaw bone. The depth of the drilling is the same as the implanting depth of the subsidiary root in the jaw bone;

[0070] (5)After a mounting positioning hole 45 of a subsidiary root 4 is connected by a mounting positioning tool, the subsidiary root 4 is passed through the mounting channel 13 and the inclined hole 14 and screwed into a bone hole. The end surface 44 of the subsidiary root and the sides of the square hole 132 of the main root 1 are guaranteed to be in the same plane;

[0071] (6)The basal platform 2 is placed downwards from a mounting channel 13. The dovetail groove 25 of the sides of the square body 24 is smoothly inserted downwards, is clamped with the dovetail joint 41 and forms the tight tabling. The subsidiary root 4 is fixed and mounted in the inclined hole 14 of the main root 1.

[0072] (7)The basal platform bolt 4 is winded up so that the above parts can be a tight integration one.

[0073] Embodiment 2:

[0074] Referring to Fig. 12, 13, 14, 15, 16, 17 and 18, the embodiment 1 is taken as reference. The same parts are not described repeatedly. The different part is that

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the number of a subsidiary root 4 becomes three, and the number of the inclined hole 14 on the corresponding main root 1 is changed from two to three. A square hole 132 of the main root 1 becomes a trigonal hole 134. A square body 24 of the basal platform 2 becomes a trigonal body 27. The number of the dovetail grooves 25 becomes three, which is respectively positioned on the three sides of the trigonal body 27.

[0075] Embodiment 3:

[0076] Referring to Fig. 19, the embodiment 1 is taken as reference. The same parts are not described repeatedly. The different part is that the number of the subsidiary root 4 becomes one. The number of inclined holes 14 of the corresponding main root 1 is changed from two to one. The number of a dovetail groove 25 on a square body 24 becomes one. The angle between the main root 1 and the subsidiary root 4 becomes 13 degrees.

[0077] Embodiment 4:

[0078] Referring to Fig. 20, the embodiment 3 is taken as reference. The same parts are not described repeatedly. The different part is that a main root 1 is oblique. The corresponding mounted basal platform 2 in the main root 1 is also oblique. The oblique angle is the same as that of the main root. The crossing angle between the main root 1 and the subsidiary root 4 is 43 degrees.

[0079] Embodiment 5:

[0080] Referring to Fig. 21, the embodiment 4 is taken as reference. The same parts are not described repeatedly. The different part is that the lower end of a main root is in a cone shape and becomes smaller along the direction from a neck part 12 to a fixing root part 11.

[0081] Embodiment 6:

[0082] Referring to Fig. 22, the embodiment 1 is taken as reference. The same parts are not described repeatedly. The different part is that a main root is relatively short; i.e. the lower end of the main root 1 is obviously higher than the lower end surface of the subsidiary root 4. The included angle between the main root 1 and the subsidiary root 4 is 26 degrees.

[0083] Embodiment 7:

[0084] Referring to Fig. 23, the embodiment 2 is taken as reference. The same parts are not described repeatedly. The different part is that a main root 1 is relatively short; i.e. the lower end of the main root 1 is obviously higher than the lower end surface of a subsidiary root 4. The angle between the main root 1 and the subsidiary root 4 is 26 degrees.

[0085] Embodiment 8:

[0086] Referring to Fig. 24, the embodiment 6 is taken as reference. The same parts are not described repeatedly. The different part is that the number of subsidiary roots becomes four. The number of the inclined holes 14 on the corresponding main root 1 is changed from two to four. The number of the dovetail grooves 25 on a square body becomes four.

[0087] Embodiment 9:

[0088] Referring to Fig. 26, 27, 28 and 29, the embodiment 1 is taken as reference. The same parts are not described repeatedly. The different part is that the position of a dovetail groove 25 located on a square body 24 of a basal platform 2 is replaced with the position of a dovetail joint 41 on a subsidiary root 4. The dovetail joint 26 is arranged on the square body 24 of the basal platform. The dovetail groove 42 is arranged on the subsidiary root 4. Correspondingly, in order that the basal platform 2 can be inserted into a main root 1, the inside of a square hole 132 of the main root 1 is provided with a groove 135 which is passed through the dovetail joint 26.

[0089] After the dovetail groove 42 and the dovetail joint 26 of the embodiment are clamped together, the subsidiary root 4 and the basal platform 2 are automatically locked. Therefore, the subsidiary root 4 is fixed and mounted in the inclined hole 14 of the main root 1. The implanting method of the embodiment is the same as the embodiment 1. Therefore, it will not be described repeatedly.

[0090] Embodiment 10:

[0091] Referring to Fig. 30, 31 and 32, a mounting channel 13 of a main root 1 of a bionic dental implant comprises a cone hole 131, a multi-square hole 132 and a screw hole 133 in the order from the top down. A basal platform 2 comprises a basal platform part 22, a cone body 23 located at the lower end of the basal platform part 22 and matched with the cone hole 131 of the main root 1 and a square body 24 located at the lower end of the cone body 23 and matched with the square body 132 of the main root 1. The upper end part of the subsidiary root 4 is a cone body 43. The cone body gradually becomes bigger along the axial direction toward the end surface of the subsidiary root. The end surface 44 of the subsidiary root is a concave surface matched with the cone body 23 of the basal platform 2. The end surface 44 of the subsidiary root is provided with a mounting positioning hole 45.An inclined hole 14 of the main root 1 is a cone hole matched with the cone body 42 of the upper end part of the subsidiary root 4.

[0092] Embodiment 11:

[0093] Based on any one of the embodiment 1 to embodiment 9, the widths of a dovetail groove 25, 42 and a dovetail joint 26, 41 gradually become bigger along the axial direction of a main root downwards so that a basal platform 2 can be easily placed in a mounting channel 13.

[0094] Embodiment 12:

[0095] Based on any one of the embodiment 1 to embodiment 11, a multi-square hole of a main root 1 and the multi-square hole of a basal platform 2 gradually becomes thinner along the direction from a cone hole 131 to the multi-square hole.

[0096] Fig. 25 is a mounting schematic diagram of a dental implant. From the figure, a fixing root part 11 of a main root 1 and a subsidiary root is mounted in a jaw bone 7. A neck part 12 of a main root 1 is mounted in a tooth sinew. A basal platform part 22 of a basal platform 2 protrudes from the tooth sinew. An artificial tooth 5 is mounted on the basal platform part 22. The main root 1 and the subsidiary root 4 can not be mounted in the jaw

bone at the same time. After the main root must be mounted firstly, the subsidiary root is then mounted in an inclined hole 14 of the main root 1 through a mounting channel 13 in the main root 1. According to the medical requirement, the mounted main root 1 and the subsidiary root 4 must be stably connected with each other as an integration one. The subsidiary root 4 can not have displacement with respect to the inclined hole 14 of the main root 1. In order to obtain the above requirement of the function, the embodiment of the invention discloses that a dovetail groove 42 or a dovetail joint 41 matched with the dovetail joint 26 or the dovetail groove 25 on the basal platform is arranged at the end part of the subsidiary root. The structures of the dovetail groove 42 and the dovetail joint 41 meet the requirements of the above function. The invention also discloses that a cone body matched with the inclined hole of the main root 1 is arranged at the end part of the subsidiary root. Furthermore, the end surface of the cone body of the subsidiary root 4 forms the concave surface matched with the cone body 23 of the basal platform so as to meet the above requirements. However, the embodiments can not be understood that they are the limit of the invention. Every structure which can stably connect the main root 1 and the subsidiary root 4 as an integration one after the main root 1, the subsidiary root 4 and the basal platform 2 are assembled together belongs to the protection scope of the invention.

[0097] In the invention, the number of a subsidiary root can be flexibly selected according to the requirements, such as one, two, three, four and a plurality of the subsidiary roots. The mounting direction and the angle of the subsidiary root 4 also can be flexibly selected according to the requirements. As the limited space, specifications are not described one by one.

[0098] In the invention, the angle between a subsidiary root and a main root can be a sharp angle in the biggest scope theoretically. But in the practical application, the best scope of the angle is from 13 degrees to 26 degrees when a main root is upright; the best scope of the angle between the main root and the subsidiary root is from 26 degrees and 43 degrees when the main root is oblique.

[0099] In the invention, a square hole and a trigonal hole in a mounting channel of the main root 1 mainly offer convenience for the mounting of the main root. A multi-square-hole structure such as a pentagon hole and a hexagon hole can be adopted.

[0100] In the invention, the thread type of a main root and a subsidiary root and the included angle (α), (β) can be flexibly selected according to the requirements.

[0101] In conclusion, the technicians of the field will know that the embodiments help the readers to understand the principles of the invention; therefore, it should be understood that the protection scope of the invention does not limit the specifications and the embodiments.

Claims

1. A bionic dental implant comprises a main root (1), a basal platform (2) and a basal bolt (3), the main root (1) comprises a fixing root part (11), a neck part (12) located at the upper end of the fixing root part (11) and a mounting channel (13) located inside the main root (1), the inner part of the basal platform (2) is provided with an aperture communicated with the two ends, the basal platform bolt (3) is passed through the aperture (21) and fixes and mounts the basal platform (2) on the main root (1), wherein the bionic dental implant also comprises at least one subsidiary root (4), the main root (1) has inclined holes (4) of which the number is the same as that of the subsidiary root (4), the inclined holes (14) form a sharp angle with respect to the mounting channel (13) and are communicated with the mounting channel (13), the upper end of the subsidiary root (4) is fixed and mounted in the inclined hole (14) of the main root (1).

2. The bionic dental implant according to claim 1, wherein the mounting channel (13) of the main root (1) comprises a cone hole (131), a multi-square hole and a screw hole (133) in the order from the top down, the basal platform (2) comprises a basal platform part (22), a cone body (23) located at the lower end of the basal platform part (22) and matched with the cone hole (131) of the main root (1) and a multi-square body located at the lower end of the cone body (23) and matched with the multi-square hole of the main root (1), the sides of the multi-square body of the basal platform (2) are provided with a dovetail groove (25) of which the number corresponds to that of the subsidiary root (4), the end surface (44) of the subsidiary root (4) of the upper end of the subsidiary root (4) is provided with a dovetail joint (41) matched with the dovetail groove (25) on the multi-square body, after the basal platform (2) is inserted into the mounting channel (13), the dovetail groove (25) on the basal platform (2) and the dovetail joint (41) on the subsidiary root (4) are clamped together, the subsidiary root (4) is fixed and mounted in the inclined hole (14) of the main root (1), the end surface (44) of the subsidiary root is provided with a mounting positioning hole (45).

3. The bionic dental implant according to claim 1, wherein the mounting channel (13) of the main root (1) comprises the cone hole (131), the multi-square hole and the screw hole (133) in the order from the top down the basal platform (2) comprises the basal platform part (22), the cone body (131) located at the lower end of the basal platform part (22) and matched with the cone hole (131) of the main root (1) and the multi-square body located at the lower end of the cone body (23) and matched with the multi-

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square hole of the main root (1), the sides of the multi-square body of the basal platform (2) are provided with a dovetail groove (26) of which the number corresponds to that of the subsidiary root (4), the end surface (44) of the subsidiary root (4) of the upper end surface of the subsidiary root (4) is provided with a dovetail joint (26) matched with the dovetail groove (42) on the multi-square body, the inner sides of the multi-square body of the main root (1) is provided with a groove (135) passed through the dovetail joint (26), after the basal platform (2) is inserted into the mounting channel (13), the dovetail joint (26) on the basal platform (2) and the dovetail groove (41) on the subsidiary root (4) are clamped together, therefore, the subsidiary root (4) is fixed and mounted in the inclined hole (14) of the main root (1), the end surface (44) of the subsidiary root is provided with the mounting positioning hole (45).

4. The bionic dental implant according to claim 2 or 3, wherein the widths of the dovetail groove (25) and the dovetail joint (26, 41) gradually becomes bigger along the axial direction of a main root downwards.

5. The bionic dental implant according to claim 1, wherein the mounting channel (13) of the main root (1) comprises the cone hole (131), the multi-square hole and the screw hole (133) in the order from the top down, the basal platform (2) comprises the basal platform part (22), the cone body (23) located at the lower end of the basal platform part (22) and matched with the cone hole (131) of the main root (1) and the multi-square body located at the lower end of the cone body (23) and matched with the multi-square hole of the main root (1), the upper end part of the subsidiary root (4) is the cone body (43), the cone body (43) of the subsidiary root (4) gradually becomes bigger along the axis toward the end surface (44) of the subsidiary root, the end surface (44) of the subsidiary root is the concave surface matched with the outer periphery surface of the cone body (23), a mounting positioning hole (45) is provided in the end surface (44) of the subsidiary root, the shape of the inclined hole (14) of the main root (1) is the cone hole matched with the cone body (43) of the subsidiary root (4), after the basal platform (2) is inserted into the mounting channel (13), the outer surface of the cone body (23) of the basal platform (2) contacts and is matched with the concave surface on the end surface (44) of the subsidiary root (4); therefore, the subsidiary root (4) is fixed and mounted in the inclined hole (14) of the main root (1).

6. The bionic dental implant according to any one of claim 1-3 or 5, wherein the multi-square hole of the main root (1) and the multi-square body of the basal platform (2) gradually become thinner along the direction from the cone hole (131) to the multi-square hole.

7. The bionic dental implant according to any one of claim 1-3 or 5, wherein the included angle between the main root (1) and the subsidiary root (4) is 13 degrees -26 degrees.

8. The main root of the bionic dental implant according to claim 1-3 or 5, wherein the main root (1) is provided with at least one inclined hole (14), the inclined hole (14) forms a sharp angle with respect to a mounting channel (13) and is communicated with it, therefore, the upper end of the subsidiary root (4) is fixed and mounted in the inclined hole (14) of the main root (1).

9. The subsidiary root of the bionic dental implant according to any one of claim 1-3 or 5, wherein the outer diameter of the upper end of the subsidiary root (4) is matched with the inner diameter of a inclined hole (14); therefore, the upper end of the subsidiary root (4) is fixed and mounted in the inclined hole (14) of the main root (1).

10. The implanting method of the bionic dental implant applied to claim 2 or 3 comprises the following steps:

(1) A jaw bone which is determined to be implanted in advance is drilled by a drilling tool;
(2) The inner wall of the bone hole is tapped by a tapping tool, which forms a thread hole matched with the outer thread (16) of the main root (1);
(3) The multi-square holes of the main root are connected together by a tool. The main root (1) is screwed into the bone hole;
(4) A small drilling tool of which the diameter is matched with the subsidiary root is passed through the mounting channel (13) and the inclined hole (14) and obliquely drilled the jaw bone. The drilling depth is the same as the depth of the subsidiary root (4) implanted in the jaw bone;
(5) After the mounting positioning hole (45) of the subsidiary root (4) is connected by the mounting positioning tool, the subsidiary root (4) is passed through the mounting channel (13) and the inclined hole (14) and screwed into the bone hole, and the end surface (44) of the subsidiary root (44) is guaranteed to be in the same plane of the sides of the multi-square hole of the main root (1);
(6) The basal platform (2) is placed downward the mounting channel (13).The dovetail groove (25) or the dovetail joint of the sides of the multi-square body are smoothly inserted, is clamped with the dovetail joint (41) or the dovetail groove of the subsidiary root (4) and forms a tight tabling; therefore, the subsidiary root (4) is fixed

Exhibit 2020 - Page 127

and mounted in the inclined hole (14) of the main root (1);
(7) The basal bolt (3) is screwed, which facilitates the above parts to form a tight integration one.

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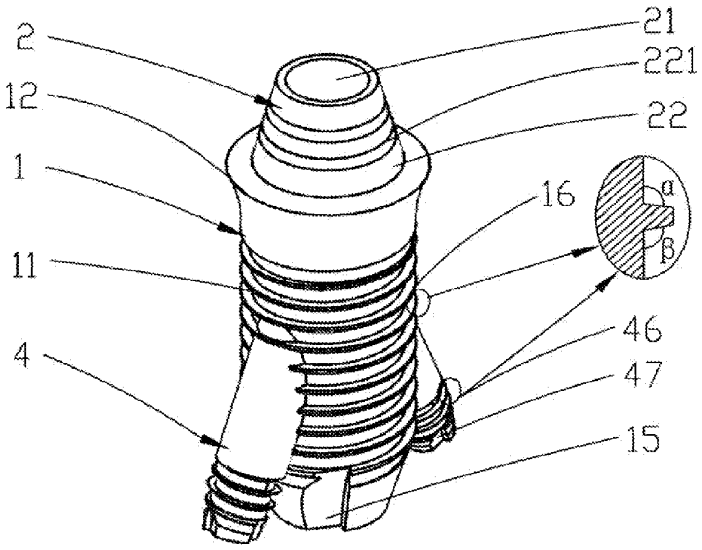


FIG. 1

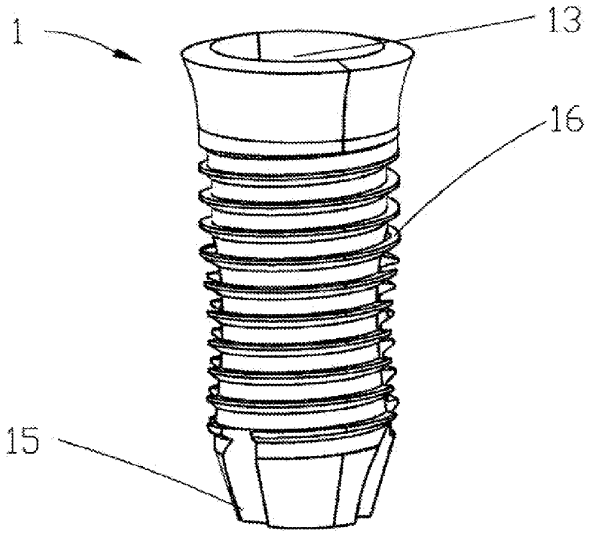


FIG. 2

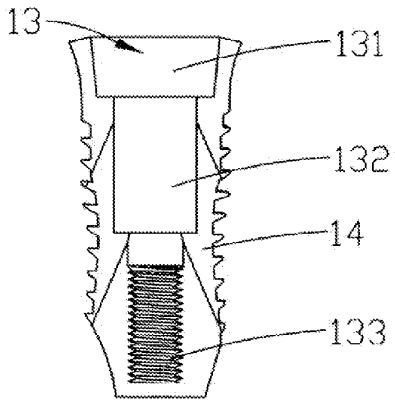


FIG. 3

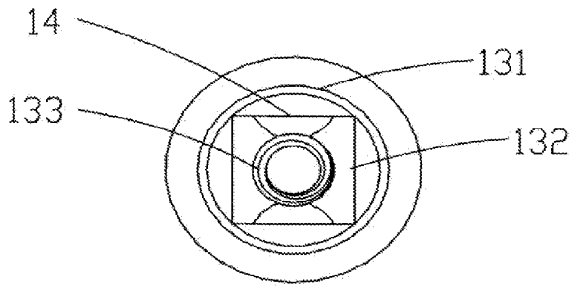


FIG. 4

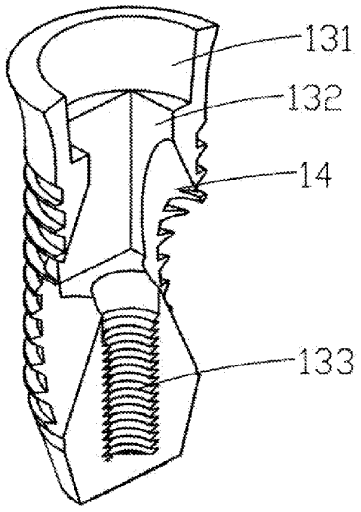


FIG. 5

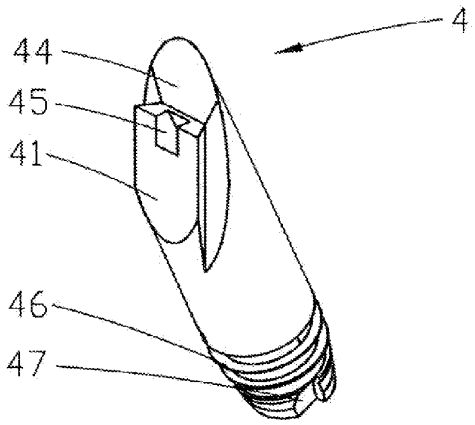


FIG. 6

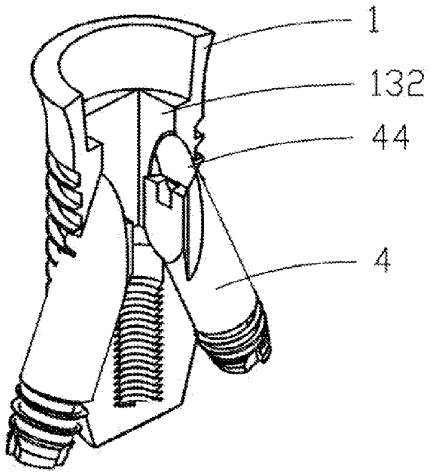


FIG. 7

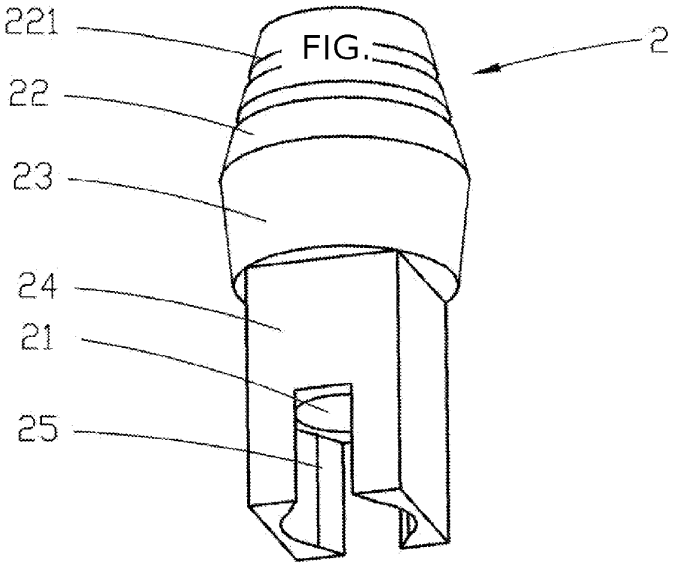


FIG. 8

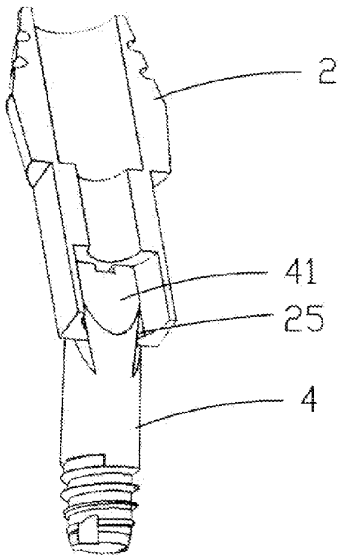


FIG. 9

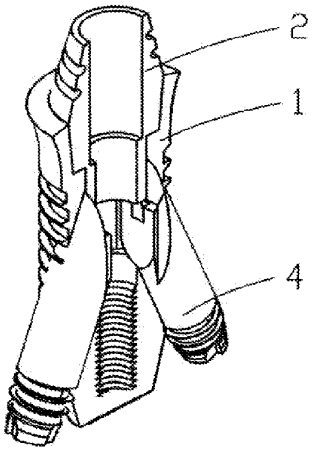


FIG. 10

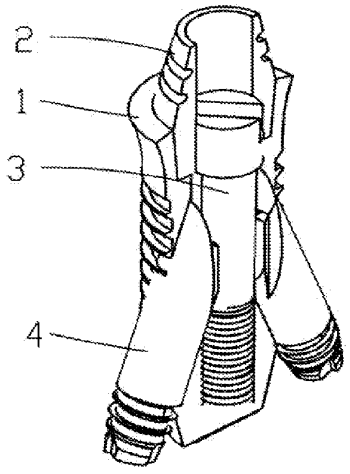


FIG. 11

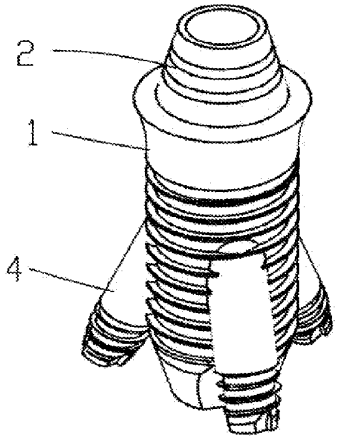


FIG. 12

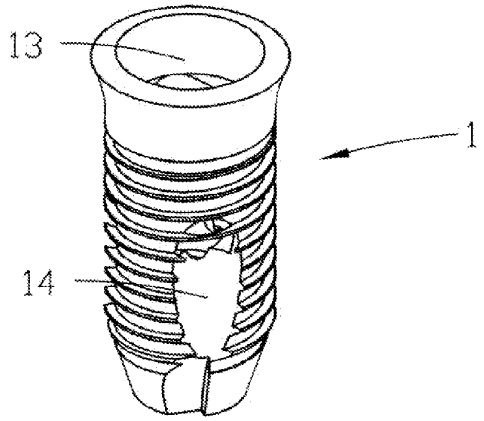


FIG. 13

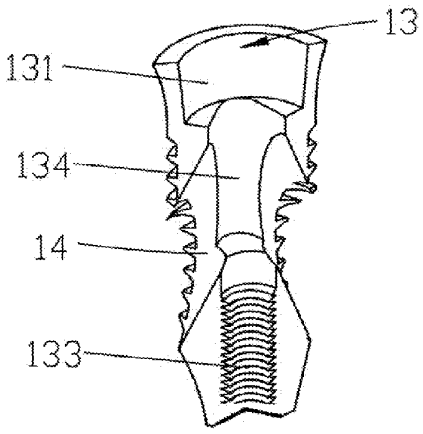


FIG. 14

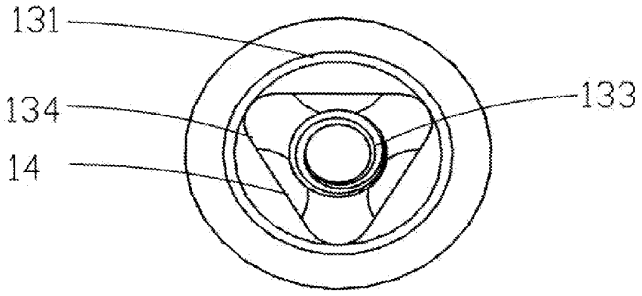


FIG. 15

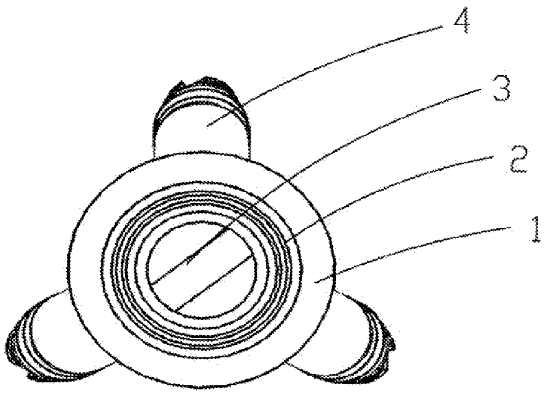


FIG. 16

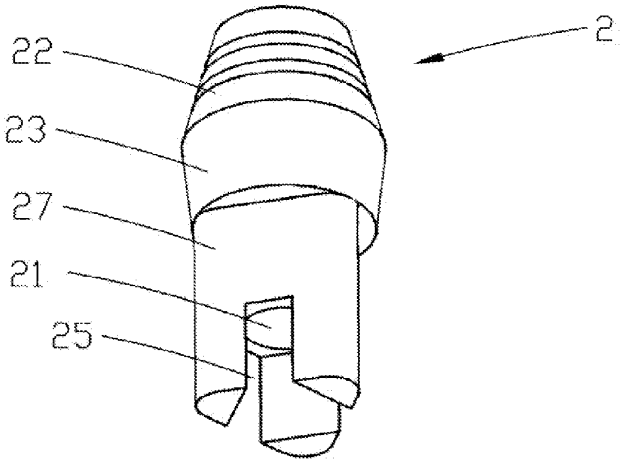


FIG. 17

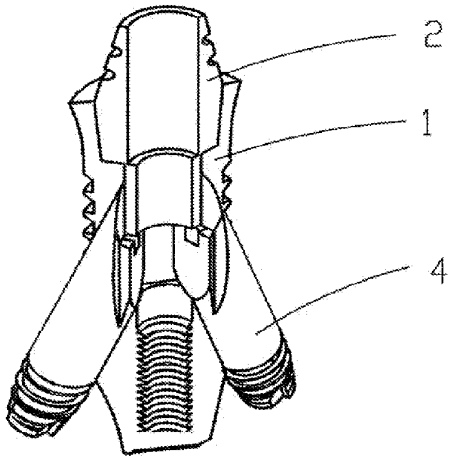


FIG. 18

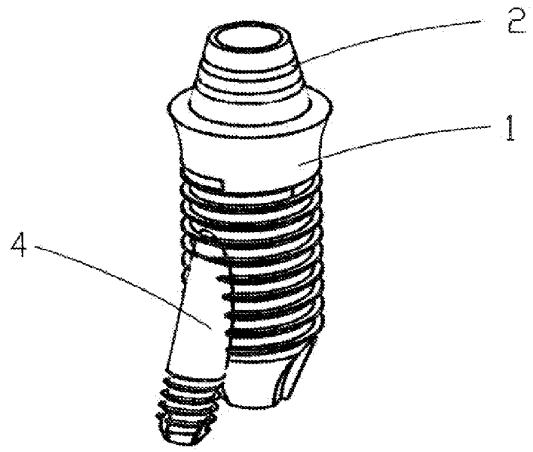


FIG. 19

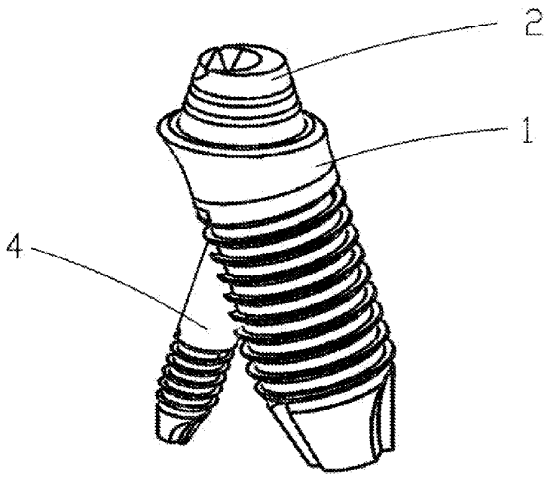


FIG. 20

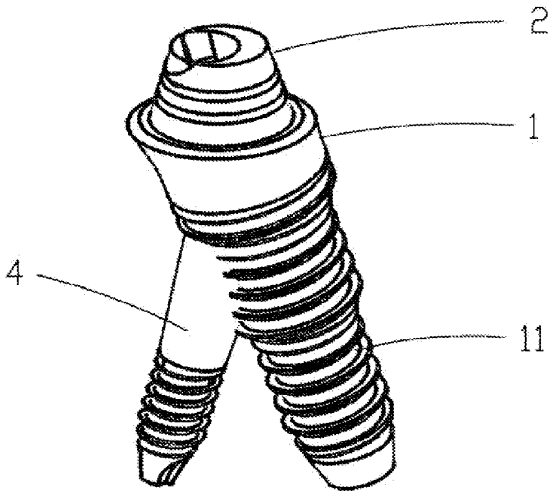


FIG. 21

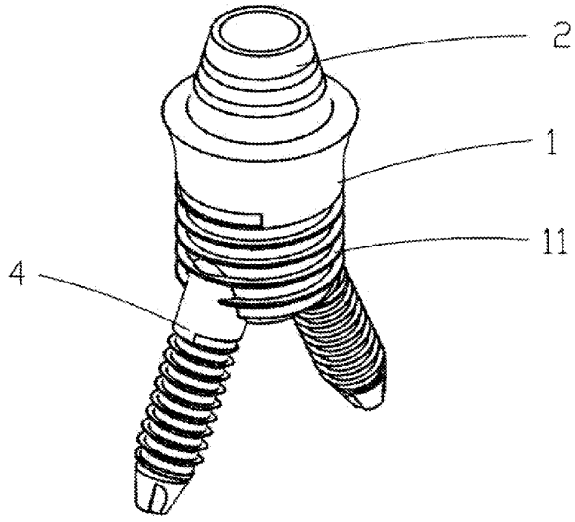


FIG. 22

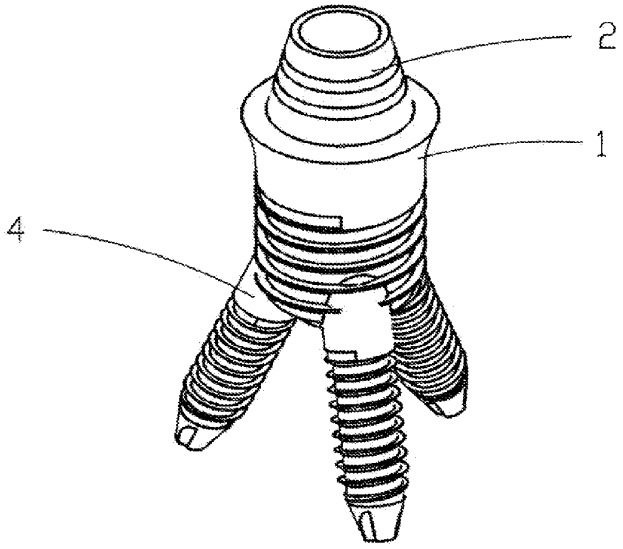


FIG. 23

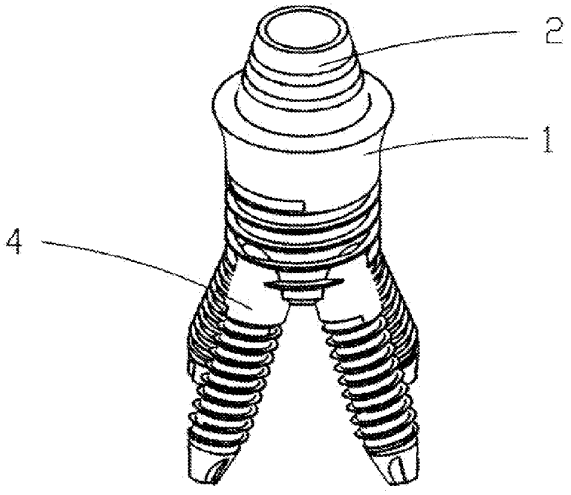


FIG. 24

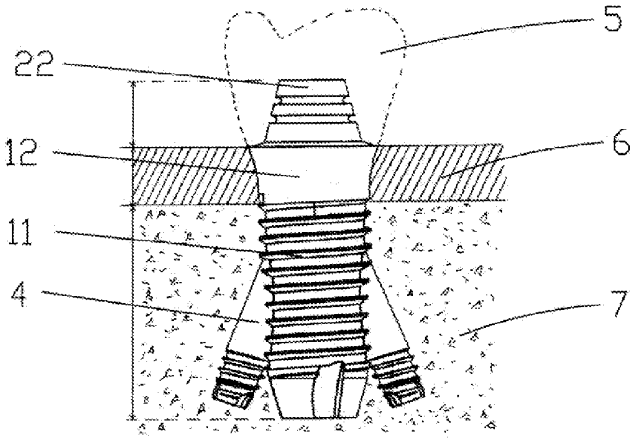


FIG. 25

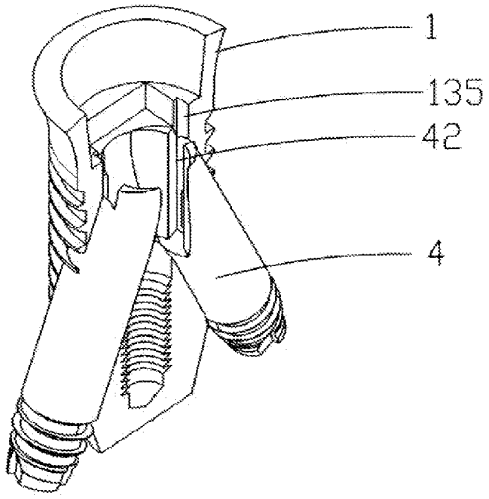


FIG. 26

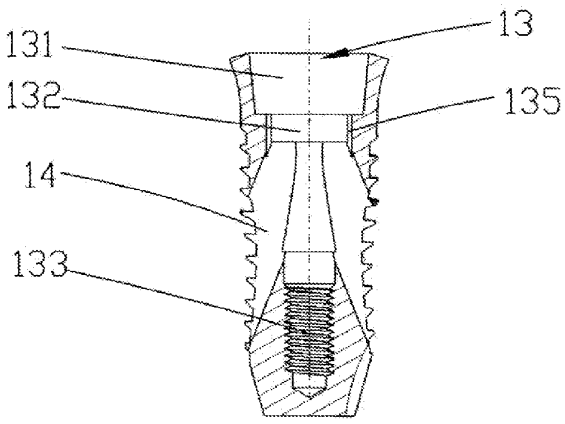


FIG. 27

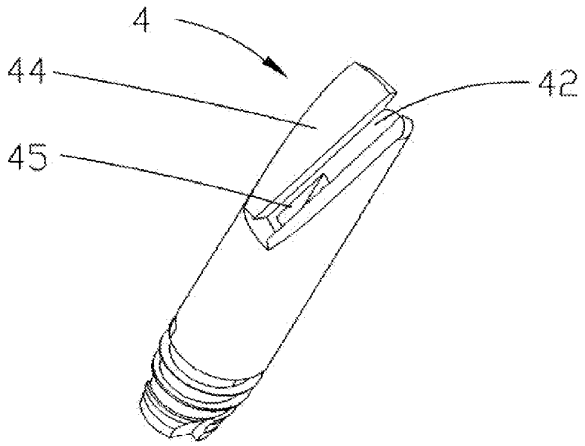


FIG. 28

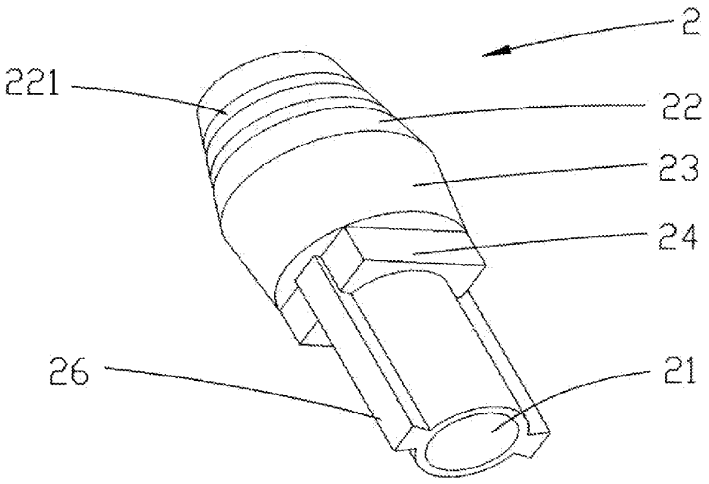


FIG. 29

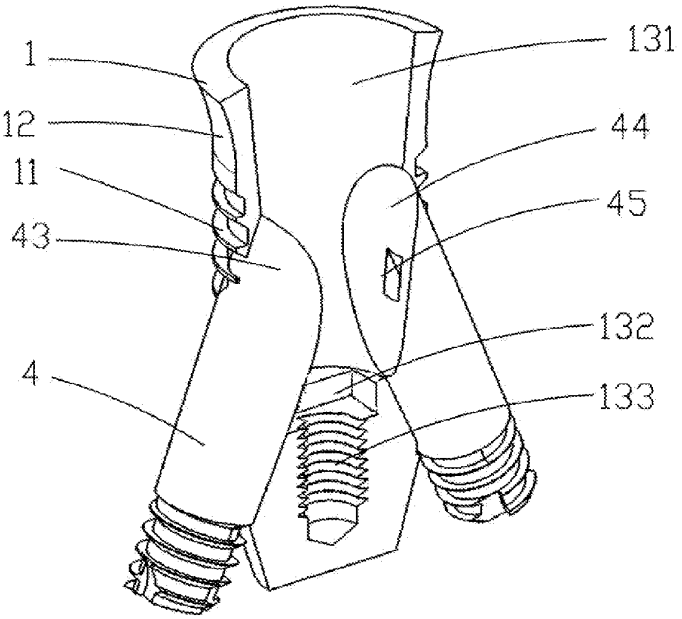


FIG. 30

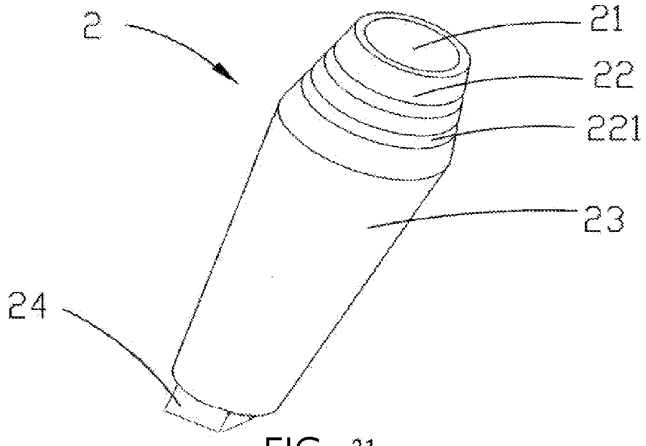


FIG. 31

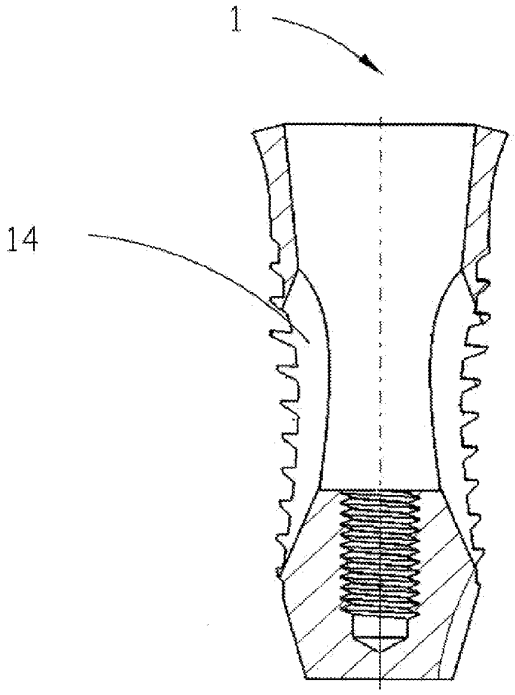


FIG. 32

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2008/070674

A. CLASSIFICATION OF SUBJECT MATTER

See extra sheet

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 A61C

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

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

WPI, EPODOC, PAJ, CNPAT, CNKI
IMPLANT? , MULTIPLE, BIONIC, MULTI, ROOT? , EXPAND???

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US5890902A (SAPIAN S L) 06 Apr. 1999 (06.04.1999), columns 3-5 in the specification, Figs. 1-6.	1,8,9
Y	US5564925A (SHAMPANIER A) 15 Oct.1996(15.10.1996), columns 2-3 in the specification, Figs. 1-5.	1,8,9
A	JP11318942A (YOSHIDA SEISAKUSHO KK) 24 Nov.1999(24.11.1999), the whole document.	1-9
A	JP2000060872 A (KANEKO AGRICULT MACHINERY et al) 29 Feb. 2000 (29.02.2000), the whole document.	1-9
A	CN1163743 A (LI,Dawei et al) 05 Nov. 1997(05.11.1997), the whole document.	1-9

☐ Further documents are listed in the continuation of Box C. ☒ See patent family 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 application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim (S) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 Jun. 2008(23.06.2008)	**17 Jul. 2008 (17.07.2008)**
Name and mailing address of the ISA/CN The State Intellectual Property Office, the P.R.China 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088 Facsimile No. 86-10-62019451	Authorized officer TIAN, Yunqing Telephone No. (86-10)62085631

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2008/070674

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 10
because they relate to subject matter not required to be searched by this Authority, namely:

Claim 10 concerns a method for treatment of human by surgery or therapy excluded by Rule 39.1(iv) PCT.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on protest
☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2007)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2008/070674

Patent Documents referred in the Report	Publication Date	Patent Family	Publication Date
US5890902A	06.04.1999	None	
US5564925A	15.10.1996	IL112989	15.06.1998
JP11318942A	24.11.1999	None	
JP2000060872 A	29.02.2000	None	
CN1163743 A	05.11.1997	None	

Form PCT/ISA/210 (patent family annex) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2008/070674

CLASSIFICATION OF SUBJECT MATTER

A61C 8/00 (2006.01) i
A61C 13/01 (2006.01) i

Form PCT/ISA/210 (extra sheet) (April 2007)

Exhibit 2020 - Page 149

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- CN 1826089 A **[0003]**

(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) **N° de publication :** **2 861 576**
(à n'utiliser que pour les commandes de reproduction)

(21) **N° d'enregistrement national :** **03 12825**

(51) Int Cl[7] : **A 61 B 17/72**

(12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt :** 31.10.03.

(30) **Priorité :**

(43) **Date de mise à la disposition du public de la demande :** 06.05.05 Bulletin 05/18.

(56) **Liste des documents cités dans le rapport de recherche préliminaire :** *Se reporter à la fin du présent fascicule*

(60) **Références à d'autres documents nationaux apparentés :**

(71) **Demandeur(s) :** *COGNET JEAN MICHEL* — FR.

(72) **Inventeur(s) :** COGNET JEAN MICHEL.

(73) **Titulaire(s) :**

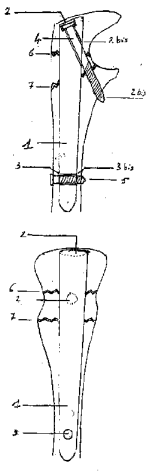
(74) **Mandataire(s) :**

(54) DISPOSITIF D'OSTEOSYNTHESE DES FRACTURES DE L'EXTREMITE PROXIMALE DU CUBITUS.

(57) L'invention concerne un dispositif permettant de réaliser une ostéosynthèse des fractures de l'olécrane telle que l'on puisse entreprendre une rééducation post-opératoire immédiate, et sans qu'il soit nécessaire de ré-intervenir secondairement pour réaliser l'ablation du dispositif du fait du caractère non gênant de celui-ci.

Il est constitué d'un clou (1) présentant un orifice ou tunnel proximal (2) et au moins deux orifice vis à vis l'un de l'autre ou un tunnel distal (3) dans lesquels seront introduites des vis, l'une en situation proximale (4), et l'autre (5) ou les autres en situation distale.

Le dispositif selon l'invention est particulièrement destiné à l'ostéosynthèse des fractures de l'olécrane.



FR 2 861 576 - A1

La présente invention concerne un dispositif d'ostéosynthèse des fractures de l'extrémité proximale du cubitus (olécrane).

Les dispositifs existant actuellement nécessitent pour la plupart leur ablation à moyen terme en raison de la gène occasionnée par le matériel (saillie sous la peau). Cette ablation se fait au bloc opératoire sous anesthésie, ce qui implique une seconde intervention (avec une augmentation de la morbidité inhérente à toute intervention) et une nouvelle hospitalisation.

Il s'agit soit de dispositifs constitués de 2 broches qui, introduites de part et d'autre du foyer de fracture en assurent la tenue grâce à un fil d'acier passé en 8 autour des broches (hauban), soit de plaques vissées qui constituent une gène de part leur épaisseur en situation sous cutanée, soit de clous intra médullaire ne permettant pas d'assurer une stabilité du foyer de fracture telle qu'on puisse entreprendre une rééducation rapide.

Le dispositif selon l'invention permet de remédier à ces inconvénients. Il comporte en effet selon une première caractéristique un clou traversé par au moins deux vis permettant l'ancrage de ce clou dans l'os. Le clou peut être plein ou creux. Si le clou est plein, il comporte des tunnels permettant aux vis de le traverser. Si le clou est creux il comporte des orifices permettant aux vis de le traverser.L'extrémité supérieure de ce clou est biseautée et suit la courbure naturelle de l'os à cet endroit de l'anatomie évitant ainsi son extériorisation. Le diamètre proximal du clou est supérieur à son diamètre le plus distal. Un orifice ou un tunnel est présent au sommet du clou et suit un trajet descendant oblique, en direction de l'apophyse coronoïde. Ce trajet descendant oblique est destiné à recevoir une vis selon un passage de la partie proximale vers la partie distale qui permet l'ancrage osseux du clou et la compression du foyer de fracture. Ce clou présente également au moins un orifice ou un tunnel situé à la partie distale du clou, perpendiculaire à l'axe de celui-ci, et destiné à recevoir une vis qui permet l'ancrage osseux du clou, évite sa mobilisation vers la partie proximale de l'olécrane et empêche la rotation du foyer de fracture. L'ensemble du dispositif permet ainsi d'entreprendre une rééducation précoce en post-opératoire immédiat grâce à une synthèse stable et un matériel enfoui dans l'os.

Selon les variations anatomiques des patients à opérer et les modes particuliers de réalisation :

Le diamètre et la longueur du clou peuvent varier

Le clou peut être plein ou creux

Le diamètre et la longueur des vis peuvent varier

Le matériau utilisé pour la fabrication du clou ou des vis peut varier

L'angulation du tunnel proximal avec l'axe du clou peut varier

Le nombre et la position des tunnels distaux peuvent varier

Les dessins annexés illustrent l'invention :

La figure 1 représente en coupe sagittale le dispositif de l'invention

La figure 2 représente en coupe frontale le dispositif de l'invention

En référence à ces dessins, le dispositif comporte un clou (1) qui peut être plein ou creux. Si le clou est creux, il comporte au moins 4 orifices ; un orifice au sommet (2), un autre à sa partie moyenne (2 bis) et au moins deux autres à sa partie distale (3 et 3 bis). Si le clou est plein, il comporte au moins deux tunnels ; un tunnel partant du sommet du clou selon une direction oblique par rapport à l'axe du clou (2), et au moins un tunnel situé à la partie distale du clou et perpendiculaire à l'axe de celui-ci (3). Ces tunnels sont destinés à recevoir chacun une vis permettant leur ancrage dans l'os. La vis passant dans le tunnel proximal (4) permet d'assurer la compression du foyer de fracture (6 et 7). La ou les vis en situation distale (5) permettent de bloquer les rotations et d'empêcher l'ascension du clou.

La partie proximale du clou comportant à son sommet un orifice (2) est d'un diamètre supérieur au diamètre de sa partie distale. Cette différence de diamètre permet une meilleure stabilité du clou dans la partie proximale du cubitus, plus large au niveau de l'olécrane. Cette partie proximale du clou prend une forme biseautée de telle sorte qu'elle s'adapte à l'anatomie de l'olécrane.

La vis proximale (4) comporte un filetage sur sa partie distale uniquement. Ce filetage est destiné à assurer sa prise dans l'os. La partie proximale et distale de cette vis est lisse et ne comporte pas de filetage ; il s'agit de la partie en contact avec le clou. Le sommet de la vis comporte une tête, d'un diamètre plus large que le diamètre du corps de la vis et que le tunnel (2) par lequel passe la vis ce qui permet d'arrêter la progression de la vis dans son tunnel et d'obtenir un effet de compression au niveau du foyer de fracture.

La ou les vis distale(s) (5) comporte(ent) un filetage continue de telle sorte que la prise puisse se faire sur les deux corticales de l'os. Elle dispose(ent) également d'une tête d'un diamètre supérieur au diamètre du corps de la (des) vis et du tunnel (3) qu'emprunte(ent) cette (ces) vis.

Le dispositif d'ostéosynthèse précédemment décrit est associé à un ancillaire destiné à faciliter la pose du dit matériel et notamment à réaliser le vissage par visée automatique.

Le dispositif selon l'invention est particulièrement destiné au traitement des fractures de l'olécrane.

Revendications

1°) Dispositif d'ostéosynthèse des fractures de l'extrémité supérieure de l'ulna (olécrane) caractérisé en ce qu'il est constitué d'un clou (1) pourvu à sa partie supérieure d'un moyen permettant de positionner une vis (4) de fixation supérieure en position oblique par rapport à l'axe du clou (1) et à sa partie inférieure d'au moins un moyen (3) permettant de positionner une ou plusieurs vis (5) de fixation en position perpendiculaire par rapport à l'axe du clou (1).

2°) Dispositif selon la revendication 1 caractérisé en ce que le clou (1) est plein

3°) Dispositif selon la revendication 1 caractérisé en ce que le clou (2) est creux

4°) Dispositif selon les revendications 1 et 2 caractérisé en ce que le moyen permettant de positionner la vis (4) de fixation supérieure en position oblique est constitué d'un tunnel permettant le passage de la vis (4) dans le clou (1).

5°) Dispositif selon les revendications 1 et 3 caractérisé en ce que le moyen permettant de positionner la vis (4) de fixation supérieure en position oblique est constitué de deux orifices (2, 2 bis) permettant le passage de la vis (4) dans le clou (1), l'un (2)au sommet du clou, le second (2 bis)situé dans la partie moyenne du clou (1).

6°) Dispositif selon les revendications 1, 2 et 4 caractérisé en ce que le moyen permettant de positionner la ou les vis (5) de fixation inférieure en position perpendiculaire à l'axe du clou (1) comporte au moins un tunnel (3) permettant le passage de la vis (5) dans le clou (1).

7°) Dispositif selon les revendications 1, 3 et 5 caractérisé en ce que le moyen permettant de positionner la ou les vis (5) de fixation inférieure en position perpendiculaire à l'axe du clou (1) comporte au moins deux orifices (3 bis) vis à vis l'un de l'autre permettant le passage d'au moins une vis (5) dans le clou (1).

8°) Dispositif selon la revendication 1 caractérisée en ce qu'il comporte une partie proximale d'un diamètre supérieur à son extrémité distale.

9°) Dispositif selon la revendication 1 caractérisé en ce que son extrémité proximale est biseautée de telle sorte qu'elle s'adapte à l'anatomie de l'olécrane.

Planche clinique

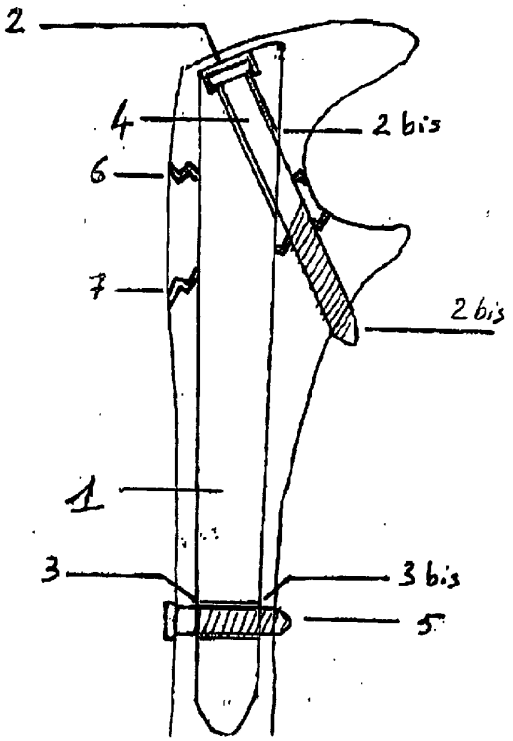


figure 1

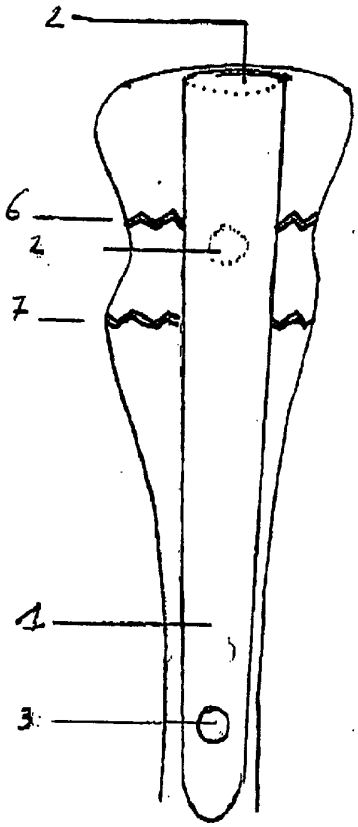


figure 2

RÉPUBLIQUE FRANÇAISE

2861576

INPI
INSTITUT NATIONAL DE LA PROPRIETE INDUSTRIELLE

RAPPORT DE RECHERCHE PRÉLIMINAIRE

établi sur la base des dernières revendications déposées avant le commencement de la recherche

N° d'enregistrement national

FA 644598
FR 0312825

DOCUMENTS CONSIDÉRÉS COMME PERTINENTS		Revendication(s) concernée(s)	Classement attribué à l'invention par l'INPI
Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes		
X	EP 1 095 626 A (SULZER ORTHOPEDICS LTD) 2 mai 2001 (2001-05-02) * colonne 3, ligne 4 - ligne 35; figures 1,2 *	1,2,4-9	A61B17/72
X	WO 99/35989 A (HABERNEK HANS ; HERZA CLAUS (AT)) 22 juillet 1999 (1999-07-22) * abrégé *	1-9	
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			DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7)
			A61B

1

Date d'achèvement de la recherche	Examinateur
22 juin 2004	Ducreau, F

CATÉGORIE DES DOCUMENTS CITÉS

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ANNEXE AU RAPPORT DE RECHERCHE PRÉLIMINAIRE
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La présente annexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de recherche préliminaire visé ci-dessus.
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Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
EP 1095626 A	02-05-2001	EP 1095626 A1	02-05-2001
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Pour tout renseignement concernant cette annexe : voir Journal Officiel de l'Office européen des brevets, No.12/82

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DESCRIPTION FR2861576

The present invention relates to a fracture osteosynthesis device

from the proximal end of the ulna (olecranon).

Currently existing devices require for the most part their ablation in the medium term because of the gene caused by the material (protruding under the skin). This ablation is done in the operating room under anesthesia, which involves a second intervention (with an increase in the morbidity inherent in any intervention) and a new hospitalization.

They are either devices consisting of 2 pins which, introduced on both sides of the fracture focus, hold them thanks to a steel wire passed at 8 around the pins (guy wire), or screwed plates which constitute a gene because of their subcutaneous thickness, ie intra-medullary nails not making it possible to ensure stability of the fracture site such that rapid reeducation can be undertaken.

The device according to the invention overcomes these disadvantages. It comprises in fact according to a first feature a nail traversed by at least two screws for anchoring this nail in the bone. The nail can be full or hollow. If the nail is full, it has tunnels allowing the screws to cross it. If the nail is hollow it has orifices allowing the screws to cross it. The upper end of this nail is beveled and follows the natural curvature of the bone at this point in the anatomy thus avoiding its externalization. The proximal diameter of the nail is greater than its most distal diameter. An orifice or tunnel is present at the top of the nail and follows an oblique descending path towards the coronoid process. This oblique descending path is intended to receive a screw in a passage from the proximal portion to the distal portion which allows the bone anchoring of the nail and the

compression of the fracture focus.

This nail also has at least one orifice or tunnel located at the distal portion of the nail, perpendicular to the axis thereof, and intended to receive a screw which allows the bone anchoring of the nail, avoids its mobilization towards the part. proximal to the olecranon and prevents rotation of the fracture site. The entire device thus makes it possible to undertake early rehabilitation in immediate postoperative thanks to a stable synthesis and material buried in the bone.

According to the anatomical variations of the patients to operate and the particular modes of realization: The diameter and the length of the nail can vary The nail can be full or hollow The diameter and the length of the screws can vary The material used for the manufacture of the nail or the The angulation of the proximal tunnel with the axis of the nail may vary. The number and position of the distal tunnels may vary. The accompanying drawings illustrate the invention: FIG. 1 represents in sagittal section the device of the invention FIG. 2 shows a front section of the device of the invention. Referring to these drawings, the device comprises a nail (1) which can be solid or hollow. If the nail is hollow, it has at least 4 holes; an orifice at the top (2), another at its middle part (2a) and at least two others at its distal part (3 and 3a). If the nail is full, it has at least two tunnels; a tunnel starting from the top of the nail in a direction oblique to the axis of the nail (2), and at least one tunnel located at the distal portion of the nail and perpendicular to the axis thereof (3).

These tunnels are intended to each receive a screw for anchoring in the bone. The screw passing through the proximal tunnel (4) makes it possible to compress the fracture site (6 and 7). The screw (s) distal (5) can block rotations and prevent the rise of the nail.

The proximal portion of the nail having at its apex an orifice (2) is of a diameter greater than the diameter of its distal portion. This difference in diameter allows a better stability of the nail in the proximal portion of the ulna, wider at the olecranon. This proximal part of the nail takes a beveled shape so that it adapts to the anatomy of the olecranon.

The proximal screw (4) has a thread on its distal portion only. This thread is intended to ensure its grip in the bone. The proximal and distal portion of this screw is smooth and has no threading; it is the part in contact with the nail. The top of the screw comprises a head, of a diameter greater than the diameter of the body of the screw and the tunnel (2) through which the screw passes which stops the progression of the screw in its tunnel and to obtain a compression effect at the fracture

site.

The distal screw (s) (5) has (ent) a continuous thread so that the catch can be done on the two cortices of the bone. It also has a head with a diameter greater than the diameter of the body of the screw (s) and the tunnel (3) that borrows (ent) this (these) screws.

The osteosynthesis device described above is associated with an ancillary device to facilitate the installation of said material and in particular to achieve the screwing by automatic aiming.

The device according to the invention is particularly intended for the treatment of fractures of the olecranon.

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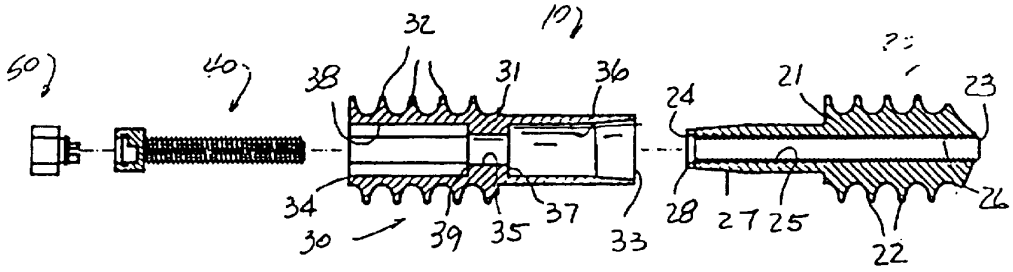
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(54) Title: MULTIPIECE INTERFRAGMENTARY FIXATION ASSEMBLY



(57) Abstract

This invention is a multipiece, interfragmentary, fixation assembly (10) for interconnecting bone fragments across a fracture therebetween. The fixation assembly (10) comprises a first axially elongated fastener (20) having external threading (22) for anchoring the first fastener (20) into the bone substance of the first bone fragment. The first fastener (20) defining a coaxial through bore (25) with internal threading (26) extending along the length thereof. The fixation assembly (10) also includes a second fastener (30) attachable in non-movable relation relative to the second bone fragment. An elongated connector (40) operably interconnects the fasteners (20, 30) such that rotation of the connector (40) draws the fasteners (20, 30) and the bone fragments attached to each into a predetermined compressive relationship relative to each other. A retaining apparatus (50) prevents the connector (40) from inadverteently turning and thereby maintains the predetermined compressive relationship between the fasteners (20, 30) and the bone fragments to promote healing of the fracture.

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MULTIPIECE INTERFRAGMENTARY FIXATION ASSEMBLY

Related Applications

This patent application is a continuation-in-part of my copending patent application serial No. 08/576,813 filed December 21, 1996.

Field of the Invention

The present invention generally relates biological medical instruments and, more particularly, to a multipiece fixation assembly for interconnecting two pieces of a fractured bone under a predetermined and substantially constant compressive force to promote optimum healing of the fracture.

Background of the Invention

The scaphoid represents one of the most frequently injured bones of the wrist. Unfortunately, it also represents one of the most frequently missed wrist injuries. Scaphoid fractures commonly result from an acute dorsiflexion stress such as occurs following a fall on an outstretched hand. If the fracture is initially recognized and properly immobilized, healing rates approaching 95% have been documented for acute fractures.

Fractures have historically been divided into three types based on the level of the fracture. The fractures through the middle one-third of the scaphoid are most common and occur approximately 70% of the time. Fractures through the proximal one-third of the scaphoid occur approximately 20% of the time, and are at greater risk for developing avascular necrosis.

Fractures of the distal scaphoid are very uncommon, occurring approximately 10% of the time, and have a very high union rate with proper immobilization.

Fractures of the scaphoid have also been classified based on the orientation of the fracture line in relation to the longitudinal axis of the scaphoid. The majority of fractures occur transverse to the longitudinal axis of the scaphoid and will sometimes heal with as little as six weeks of immobilization. Horizontal oblique fractures are the second most common, occurring approximately 35% of the time, with vertical oblique fractures being quite rare. Both horizontal and oblique fractures can require a longer period of immobilization to obtain union between the fractured bone fragments. The vast majority of scaphoid fractures will heal with twelve weeks of immobilization, and anything past four months may be regarded as a delayed union. Fractures that have not healed within six months of immobilization from the time of injury, and that have definite sclerotic margins at the fracture lines, can be considered to be an established non-union of the fractured bone fragments.

Several factors contribute to the ability of the fractured bone fragments to be united with each other. The unique anatomy of the blood supply to the carpal navicular is one factor. The degree of injury to the supporting soft tissues and the degree of displacement of the bone fragments relative to each other are other factors. Associated carpal instability is still another factor that must be considered when evaluating the likelihood of the bone fractures to unite relative to each other. Early detection and proper immobilization of the fractured scaphoid are still further factors that contribute to the development of the non-union of the fractured scaphoid segments.

Scaphoid fractures have been classified as stable based upon a minimal degree of displacement at the fracture site. Fractures that are displaced greater than one millimeter are considered to be unstable and are frequently accompanied by rupture of the supporting ligaments of the scaphoid. Increased displacement is typically associated with a higher incidence of non-union of the fractured bone fragments.

Failure to disclose, to reduce, or to adequately immobilize scaphoid fractures is directly responsible for development of delayed union or non-union. Technetium bone scans have been used both for early detection of scaphoid fractures and for detection of scaphoid pseudarthrosis. Trispiral tomography is helpful both in the initial detection of scaphoid fractures, in evaluating the degree of displacement of the fractured bone fragments relative to each other, and in determining union following bone grafting of a non-union or a prolonged period of cast immobilization.

Significant limitations of wrist motion can occur secondary to a scaphoid non-union. Without intervention, patient's with an established scaphoid non-union have an extremely high likelihood of developing an arthritic wrist. This most commonly follows the pattern of Scapho-Lunate Advanced Collapse (SLAC) with sparing of the radio-lunate joint and radius-proximal scaphoid fragment joint. Patient's with an asymptomatic scaphoid non-union should be advised the development of an arthritic wrist is highly probable.

Surgical fastener assemblies for rejoining and holding fractured or broken bone fragments in place are known in the art. Where cross-fixation of the bone fragments is required, maintaining and holding both bone fragments in compression relative to each other enhances the likelihood of success of the surgical procedure. As will be readily appreciated, a gap or

displacement between the adjacent bone fragments is highly undesirable because fibrous tissue will grow therebetween before the fracture can heal with boney unions. Thus delaying the healing process. Space between the bone fragments also tends to allow the bone fragments to shift or displace relative to each other thus adding to the retardation of the healing process. On the other hand, if the surgeon is able to bring the bone fragments into contact relative to each other and maintain the bone fragments in contact with each other, the space between the bone fragments is minimized and the bone fragments are inhibited from shifting, thus promoting the healing process. Moreover, when the bone fragments heal in proper alignment relative to each other, there is a reduction in the risk of the secondary development of arthritis.

In many instances, the entire fastener assembly is wholly arranged or completely buried within the bone substance. Screws commonly used in securing fractured bone fragments to each other typically include an elongated threaded portion that terminates, toward one end, in an enlarged head portion. Certain surgical repair procedures, however, do not lend themselves to use of a headed bone screw. For example, a headed bone screw does not lend itself to those situations wherein there is inadequate bone substance or stock to allow countersinking of the enlarged head portion of the bone screw. Providing a countersunk configuration in the bone substance, however, also often destroys cartilage needed in a joint for its proper functioning.

Moreover, severe problems can result from use of these types of bone screws. That is, after the biological operation has been completed, the bone tissue about the bone screw tends to recede by boney resorption thereby allowing the bone screw to loosen, thus destroying the compressive force that maintains the bone fragments in close proximity relative to each other. Besides those problems mentioned above that can result when the bone fragments are not

maintained in close proximity, and as will be appreciated, as the bone screw loosens, it is not uncommon for the head portion to protrude through the skin of the patient having such fracture. This, of course, results in significant additional problems including the possibility of additional surgery requirements to correct the problem. Additional surgery means additional expenses for the patient and loss of employment during the surgical recuperation period.

Responding to the above noted problems, attempts have been made to improve upon bone screws. U.S. Patent No. 4,175,555 issued November 27, 1979 to T. J. Herbert discloses a bone screw device for interconnecting two bone fragments under compression and which lacks the drawbacks associated with a headed bone screw and allows the bone screw device to be totally or wholly embedded within the bone substance of the patient. The Herbert device has screw threads which are like handed but of different pitch on its leading and trailing ends. More specifically, the pitch of the threads at the leading end exceeds the thread pitch at the trailing end. Thus, the leading end of the screw advances at a slightly faster rate than the trailing end thereby causing the bone fragments to be brought together under some degree of compression.

While offering certain advantages over heretofore known bone screw devices, the Herbert device also has certain drawbacks. Because of the relatively small difference in the thread pitch between the leading and trailing threads, the Herbert device has a limited ability to draw the fractured bone fragments that are not already proximate to each other into compressive relationship relative to each other. Moreover, and because the thread pitch of the leading and trailing threads differs, the diameter of the leading threads must be smaller than the core of the root diameter of the trailing threads to prevent binding of the screw. Accordingly, the leading end of the Herbert screw has a lesser or weaker bone material purchase than does the trailing

end. This lesser degree of bone purchase can have an adverse effect on the ability of the bone screw to remain fixed in the bone when subjected to pulling forces applied thereagainst.

The surgeon generally judges the proper compressive force to be applied between the fractured bone components by "feeling" for tightness. The Herbert device, however, does not afford the surgeon this luxury. When the Herbert device is used to secure two bone fragments across the fracture thereof, the trailing threads are not and cannot be tapped into the bone fragment because of thread synchronization problems. Accordingly, during use of the Herbert device, the surgeon feels only the resistance necessary to allow penetration of the trailing threads into the bone thus resulting in the possibility of sub-optimal repairs.

U.S. Patent No. 4,858,601 to R. R. Glisson discloses a compression screw assembly including a pair of externally threaded members that are interconnected in an axially fixed and abutting relationship relative to each other by a spindle. After insertion of the spindle through both members of the screw assembly, the spindle is fixedly connected to one of the threaded members. By turning the screw assembly in a first direction, the surgeon can thread both screw members and the spindle into the bone substance of the fragments that are to be repaired or joined to each other. Thereafter, one screw member is rotated or turned in an opposite direction and relative to the other screw member to draw the bone fragments toward each other.

Surgical repair of fractured bones involves complicated procedures. The Glisson device only serves to furthermore complicate an already complex surgical procedure. That is, with the Glisson device the surgeon must initially rotate or turn the screw assembly in a first direction and then turn only one screw member of the assembly in a second direction, opposite to the first direction. As will be appreciated by those skilled in the art, initially turning both screws in a

first direction and then turning one of the screw members in a second and opposite direction detracts from the ability of the screw assembly to establish and maintain a strong purchase with the bone substance or tissue of fragmented bones that are to be joined to each other. Nothing is provided on the Glisson device, however, for preventing the screw members from rotating relative to each other for a prolonged time period after the screw assembly is initially inserted into the patient. Thus, the setting between the screw members initially selected by the surgeon can readily be lost or destroyed simply by the screw members turning relative to each other. Furthermore, nothing associated with the Glisson device suggests to a person skilled in the art how it could be used to facilitate reattachment of ligamentous tissues to bone fragments.

Frequently, with an acute hyperextension injury to the wrist the scaphoid will not fracture but instead a series of ligamentous damage can occur about the wrist of the patient. The volar wrist ligaments certainly contribute to instability about the wrist. Many are of the opinion, however, that the dorsal scapholunate interosseous ligament is a primary constraining force that, when ruptured, leads to disassociation between the scaphoid and lunate bones. Failure to reconstruct this ligament can lead to the development of progressive arthritis about the wrist.

Various techniques and devices have been proposed to reconstruct the ligaments between the scaphoid and lunate bone. One common technique involves arthroscopy of the wrist and the percutaneous pinning between the scaphoid and lunate that have been manipulated back into the proper positions. With a failure of this technique, which frequently occurs in clinical situations, there is scapholunate instability. A number of soft tissue ligamentous techniques for reconstructing these ligaments have been described, but these known techniques frequently lead to failure, due to the reconstructed ligaments stretching out and losing their degree of stability

between the two bones. This can result in progressive loss of the integrity of the reconstructed ligament, resulting in the development of a scapholunate advanced collapse pattern of the wrist. Alternative techniques such as fusing the scaphoid bone to the lunate have been fraught with a high rate of non-union.

Although the Herbert device is not particularly suited for ligament reattachment, alternative anchoring devices have been proposed to attach ligaments to bone. There are a paucity of devices, however, wherein a ligament, with an attached fragment of bone can be readily reattached to a bone using a compression screw. A toggle bolt type mechanism does not allow for adequate reattachment of a bony fragment with sufficient tolerances to enable adequate strength of compression of the bone ligament construct to effect a rigid enough period of compression to heal within the channel created in the scaphoid when a bone ligament bone construct is utilized to reconstruct the scaphoid lunate interosseous ligament.

Thus, there remains a need and a desire for a bone screw assembly that permits first and second bone fragments to be interconnected to each other under compression and wherein the proper compression between the bone fragments is measured by the surgeon's feel of the bone screw. Moreover, there is a clear need for a more universal system for facilitating the reattachment of ligaments to bone fragments.

SUMMARY OF THE INVENTION

In view of the above, and in accordance with the present invention, there is provided a multipiece interfragmentary fixation assembly that is wholly contained within the bone substance such that it can serve a number of useful purposes for dealing with fractures and reconstructive

procedures in the field of orthopedic surgery. The interfragmentary fixation assembly of the present invention includes a first axially elongated fastener that defines an elongated axis and has external threading for anchoring the first fastener into a first bone fragment and a second fastener that is attachable in non-movable relation relative to a second bone fragment. The first fastener defines a coaxial opening with internal threading extending along at least a portion of the length thereof. The coaxial opening permits endwise passage of a guide therethrough thus facilitating proper placement and anchoring of the first fastener within the first bone fragment.

To allow the first and second fasteners and thereby the first and second bone fragments to be drawn toward and ultimately into compressive relationship relative to each other, the fixation assembly further includes an elongated connector that interconnects the first and second fasteners and allows the surgeon to adjust the proper compressive force between the bone fragments as a function of "feel." The connector includes a head portion and a shank portion. The head portion of the connector is configured to accommodate a driving tool. The shank portion of the connector includes external threading corresponding to the internal threading on the first fastener. The shank portion of the connector is configured to extend endwise through the second fastener and into threaded engagement with the first fastener while the head portion of the connector operably engages with the second fastener such that rotation of the connector draws the first and second fasteners toward and into compressive relationship relative to each other. The connector is prevented from inadvertently rotating relative to the fastener with which a threaded connection is established thereby maintaining the predetermined compressive relationship between the bone fragments and thereby promoting healing and union therebetween.

In a preferred form of the invention, the first fastener is formed from a bone compatible material form the class of: stainless steel, titanium, or a cobalt chromium molybdenum alloy. The external threading on the first fastener has a substantially uniform pitch. To promote engagement with bone substance, a leading end of the first fastener preferably has a pointed end configuration. A trailing end of the first fastener is configured to accommodate a driving tool capable of turning the first fastener such that the external threading thereon threadably engages and anchors the first fastener within the bone fragment. In a most preferred form of the invention, the first fastener has a reduced diameter portion axially extending from the terminal end of the threading. The reduced portion of the first fastener has an axially tapering configuration along an outer surface thereof.

According to one aspect of the present invention, the second fastener has an axially elongated configuration with external threading for anchoring the second fastener within the bone substance of the second bone fragment. The external threading on this preferred form of the invention has a substantially uniform pitch along the length thereof that corresponds to the pitch on the external threading of the first fastener. The second fastener is formed from a bone compatible material from the class including: stainless steel, titanium, or a cobalt chromium molybdenum alloy. In this embodiment of the invention, the second fastener has a coaxial opening extending endwise therethrough for allowing the second fastener to be initially guided into generally axial alignment and operable relationship with said first fastener. The trailing end of this embodiment of the second fastener is configured to accommodate a driving tool capable of turning the second fastener such that the external threading threadably engages and anchors the second fastener into the bone substance of the second bone fragment.

In a most proffered form of the present invention, the axial bore defined by the second fastener has a first lengthwise portion that opens to a trailing end of the second fastener and a second lengthwise portion that opens to a leading end of the second fastener. The second lengthwise portion of the second fastener has a configuration that is specifically sized such that only the threaded shank portion of the connector can endwise extend therethrough. Moreover, the second portion of the axial bore in the second fastener is specifically configured to coact with the axially tapering extension on the first fastener. Preferably, the configuration of the axial bore defined by the second fastener has an axially tapering configuration that complements the tapered configuration on the first fastener whereby effecting axially alignment of the fasteners and thereby the fractured bone fragments relative to each other thus promoting the healing process.

According to another aspect of the present invention, the second fastener comprises a member configured with a generally concave shaped section that is generally centralized between multiple prongs extending radially away from the central section. An apertured hemi-spherically shaped element is adapted to be seated for rocking movement within the central section of the member. The shank portion of the connector is configured to endwise extend through the member and the element into threaded engagement with the first fastener. The head portion of the connector being operably engagable with the element such that rotation of the connector draws the member and the first fastener and the respective bone fragments engaged by each toward and into compressive relationship relative to each other such that minimal tissue growth is effected between the fractured bone fragments whereby enhancing union of the bone fragments to each other. In this preferred form of the invention, the central section of the member defines

an enlarged opening that permits the member to rock relative to the connector and the element thereby enhancing the attachment of the prongs to the second bone fragment.

To promote the attachment of ligament pieces to bone fragments, another aspect of the present invention configures the second fastener as an apertured disk. The apertured disk fits about the shank portion of the connector and operably engages an underside of the head portion of the connector to permit relative rotation therebetween. The disk has a series of apertures that permit the second bone fragment to be secured thereto as with stitches, sutures, or the like.

Still another aspect of the present invention concerns configuring the second fastener to maintain the second bone fragment in a hole or bore provided by the surgeon in the first bone fragment. To accomplish such ends, the second fastener is configured as an elongated member having first and second ends and an axial bore for allowing the shank portion of the connector to extend endwise through the second fastener and into threaded engagement with the first fastener. In this embodiment of the invention, the member of the second fastener further includes a rigid bone fragment retainer extending radially away from the elongated member. In a most preferred form of the invention, the elongated member has a generally cylindrical configuration between opposite ends thereof. Alternatively, the elongated member of the second fastener has a frusto-conical configuration between opposite ends thereof.

The interfragmentary fixation assembly of the present invention can also be utilized for arthrodesis of small joints. An alternative variation for use in a joint where flexion is desired, such as a proximal interphalangeal or metacarpal joint, involves alternatively configuring the second fastener as a plate-like member that fixedly attaches to the second bone fragment. The plate-like member has upper and lower generally parallel surfaces with an indentation or

depression having a closed margin defined by the periphery of the plate-like member and including a wall depending at an acute angle relative to the upper surface of the plate-like member. The indentation or depression fits into a recess formed in the bone fragment to which the plate-like member is attached to allow smooth gliding of tendons overlying the second fastener. The wall defined by the indentation is apertured to allow the shank portion of the connector to endwise extend into threaded engagement with the internal threading on said first fastener. The wall of the indentation maintains the head portion of the connector on an opposite side of the plate from the first fastener. Moreover, in a preferred form of the invention, the upper and lower surfaces of the plate-like member have a generally convex configuration that generally parallels the outer surface configuration of the bone fragment to which this second fastener is attached.

In the preferred form of the invention, the enlarged head portion of the connector operably engages with the second fastener thus causing the second fastener to move toward and, ultimately, into a compressive relationship with the first fastener in response to its threaded engagement with and rotation of the connector relative to the first fastener. The free end of the connector's head portion is preferably configured with a socket for releasably accommodating a driving tool.

According to the present invention, the connector is inhibited from inadvertently rotating relative to the fastener with which a threaded connection is established. In one form of the invention, a retaining apparatus or element having a cross-sectional configuration that complements the cross-sectional configuration of the first portion of the axial bore defined by the second fastener and opening to the trailing end of the second fastener serves to engage with

the connector in a manner preventing rotation of the connector relative to the fastener with which the connector has a threaded engagement. Moreover, in this form of the invention, the element or retainer apparatus is releasably coupled to the head portion of the connector thereby preventing rotation of the connector and, thus, maintaining substantially constant predetermined compressive force initially established by the surgeon between the first and second fasteners so as to promote the healing process.

Alternatively, the retaining apparatus of the present invention comprises a non-metal insert preferably arranged lengthwise along the internal threading of the first fastener. In this embodiment of the invention, as the connector threadably engages and moves along the length of the internal threading on the first fastener it likewise engages with the non-metal insert thereby inhibiting inadvertent rotation of the connector after the surgeon establishes that degree of compression desired between the first and second fasteners. Because the insert prevents inadvertent rotation of the connector, the first and second fasteners are maintained under the predetermined compressive force established by the surgeon thus maintaining the fractured bone pieces not only in compression but also in close proximity thereby enhancing the healing process.

In still another form of the invention, an internal locking thread form is defined within the fastener with which the connector is threadably fastened so as to prevent the connector from inadvertently rotating relative to the fastener. That is, the internal locking thread form coacts with the conventional external threading on the connector to prevent inadvertent rotation of the connector thereby maintaining the predetermined compression between the fasteners and, thus,

the bone fragments, as a function of the surgeon's "feel". Moreover, the use of an internal locking thread form simplifies the design of the fixation assembly.

According to another aspect of the present invention, there is provided an interfragmentary compression kit. The kit includes a collection of first axially elongated fasteners. Each fastener in the collection has a different length from other like fasteners in the collection. Each fastener in the collection can be further distinguished by the diameter of the threaded portion. The different shapes and sizes of the fasteners in the collection allows the surgeon to chose which particular fastener has the desired maximum purchase with the particular bone fragment being repaired. The kit further includes a series of second fasteners. To provide the surgeon with the appropriate fastener, each fastener in the series of second fasteners is different from other fasteners in the series of fasteners to provide the surgeon with the maximum ability to interchange fasteners and select the best for the particular bone fragment being repaired. Moreover, a set of elongated connectors are likewise arranged in the kit. The connectors in the kit have different configurations from other connectors in the set. Suffice it to say, the kit of the present invention allows the surgeon to chose the appropriate fasteners and connectors for the particular surgical procedure and patient.

The present invention advantageously provides a biological fixation assembly that is wholly embedded within the bone substance of the patient and permits the bone fragments to be interconnected to each other with abutting surfaces of the bone fragments arranged in close proximity and under a predetermined level of compression relative to each other. The interfixation assembly further includes a retaining apparatus that maintains that predetermined level of compression between the bone components thus promoting healing. Moreover, the

fixation assembly of the present invention prevents the connector from inadvertently becoming unthreaded thus eliminating the problem of the connector backing out of the bone and potentially protruding through the skin of the patient. In that embodiment of the invention wherein both fasteners are threaded, the fixation assembly has equal pull out strength on opposite sides of the fracture. Another important feature of the present invention is that the level of compression is adjustable to provide the surgeon with the proper "feel" of tightness.

These and other objects, aims and advantages of the present invention will become readily apparent from the following detailed description, appended claims, and the following drawings.

Detailed Description of the Drawings

FIGURE 1 is a schematic representation of the various bones contained in the hand of a patient;

FIGURE 2 is an enlarged cross section view similar to FIGURE 1 showing an embodiment of a multipiece interfragmentary fixation assembly according to the present invention wholly embedded within a fractured scaphoid;

FIGURE 3 is an enlarged elevational view of that embodiment of the multipiece interfragmentary fixation assembly shown in FIGURE 2;

FIGURE 4 is a right end view of the multipiece interfragmentary fixation assembly illustrated in FIGURE 3;

FIGURE 5 is a left end view of the multipiece interfragmentary fixation assembly illustrated in FIGURE 4;

FIGURE 6 is a perspective view of components of the fixation assembly illustrated in longitudinally spaced relation relative to each other;

FIGURE 7 is a longitudinal sectional view of component parts of the present invention shown in separated relation relative to each other;

FIGURE 8 is a sectional view taken along line 8-8 of FIGURE 3;

FIGURE 9 is a perspective view of one component fastener forming part of the present invention;

FIGURE 10 is a left end view of the component fastener illustrated in FIGURE 9;

FIGURE 11 is a right end view of the component fastener illustrated in FIGURE 9;

FIGURE 12 is a sectional view taken along line 12-12 of FIGURE 10;

FIGURE 13 is a perspective view of another component fastener forming part of the present invention;

FIGURE 14 is a left end view of the component fastener illustrated in FIGURE 13;

FIGURE 15 is a right end view of the component fastener illustrated in FIGURE 13;

FIGURE 16 is a longitudinal sectional view taken along line 16-16 of FIGURE 14;

FIGURE 17 is a perspective view, with sections being broken away, of a connector forming part of the present invention;

FIGURE 18 is another perspective view, with sections being broken away, of the connector illustrated in FIGURE 17;

FIGURE 19 is a left end view of the connector illustrated in FIGURES 17 and 18;

FIGURE 20 is an elevational view of the connector with a head portion thereof being shown in section as seen along line 20-20 of FIGURE 19;

FIGURE 21 is a perspective view of one embodiment of a retainer apparatus forming part of the present invention;

FIGURE 22 is an elevational view of the retainer apparatus illustrated in FIGURE 21;

FIGURE 23 is a left end view of the retainer apparatus illustrated in FIGURE 22;

FIGURE 24 is a right end view of the retainer apparatus illustrated in FIGURE 22;

FIGURE 25 is an enlarged schematic view of a fractured scaphoid bone;

FIGURE 26 is a cross section of a fractured scaphoid having a guide passing through both scaphoid fragments;

FIGURE 27 is a cross section of a fractured scaphoid showing a cannulated drill arranged along and about the guide;

FIGURE 28 is a cross section of a fractured scaphoid showing the cannulated drill passing downwardly through the fractured scaphoid bone;

FIGURE 29 is a cross section of the fractured scaphoid bone fragments after the cannulated drill is removed therefrom;

FIGURE 30 is a cross section of the fractured scaphoid showing a cannulated tap arranged along and about the guide for insertion into a drilled bore formed by the cannulated drill;

FIGURE 31 is a cross section of the fractured scaphoid showing the tap fully inserted therein;

FIGURE 32 is a cross section of the fractured scaphoid with the tap being removed therefrom;

FIGURE 33 is a cross section of the fractured scaphoid showing a fastener similar to that illustrated in FIGURES 9 through 11 being arranged for sliding movement over and along the guide;

FIGURE 34 is a cross section of the fractured scaphoid showing the first fastener fully inserted in one of the bone fragments and wherein the trailing end of the first fastener is rotated by a driving tool;

FIGURE 35 is a cross section of the fractured scaphoid showing a second fastener similar to that illustrated in FIGURES 13 through 16 being arranged for guided sliding movement over and along the guide;

FIGURE 36 is a cross section of the fractured scaphoid showing the second fastener fully inserted in the second scaphoid bone fragment and wherein the second fastener is rotated by a driving tool;

FIGURE 37 is a cross sectional view similar to FIGURE 36 but showing the driving tool for the second fastener being removed therefrom;

FIGURE 38 is a cross section of the fractured scaphoid showing the guide removed from the scaphoid;

FIGURE 39 is a perspective view, partly in section, showing the first and second fasteners of one embodiment of the present invention in axially spaced relation relative to each other;

FIGURE 40 is a perspective view similar to FIGURE 39, and partly shown in section, showing the first and second fasteners in partially overlapping relation relative to each other;

FIGURE 41 is a perspective view, partly broken away, showing a connector similar to that illustrated in FIGURES 17 through 20 passing partially endwise through the second fastener and into threaded engagement with a trailing end of the first fastener;

FIGURE 42 is a perspective view, partly in section, showing the connector as it serves to draw the second fastener into compressed axial relationship relative to the first fastener;

FIGURE 43 is a cross section of the fractured scaphoid showing a tool for rotating the connector into threaded engagement with the first fastener;

FIGURE 44 is a cross section of the fractured scaphoid showing a retainer apparatus similar to that illustrated in FIGURES 21 through 24 being inserted into operable engagement with other components of the fixation assembly of the present invention;

FIGURE 45 is a perspective view, partly in section, and similar to FIGURE 44 but enlarged to show the retainer apparatus being inserted into operable association with other components of the fixation assembly of the present invention;

FIGURE 46 is a view similar to FIGURE 45, and partly in section, showing the fastener apparatus inserted further into operable engagement with components of the fastener assembly of the present invention;

FIGURE 47 is a cross section of the fractured scaphoid showing a tool for inserting the retainer apparatus into operable engagement with the other components of the fixation assembly of the present invention;

FIGURE 48 is an enlarged perspective view showing the retainer apparatus and the headed end of the connector in axially spaced relation relative to each other with parts broken away to show detail;

FIGURE 49 is an elevational view, partially in section, of the retainer apparatus and connector shown in FIGURE 48;

FIGURE 50 is an enlarged perspective view showing the retainer apparatus and the headed end of the connector, partially in section, arranged in partial combination relative to each other;

FIGURE 51 is an elevational view, partly in section, showing one form of retainer apparatus and connector in partial operable combination relative to each other;

FIGURE 52 is an enlarged perspective view, partly in section, showing the retainer apparatus arranged in full engagement with the headed end of the connector;

FIGURE 53 is an elevational view, partly in section, showing the retainer apparatus schematically illustrated in FIGURE 52 in full engagement with the headed end of the connector;

FIGURE 54 is a perspective view, with parts broken away, showing one form of retainer apparatus in operable combination with the connector;

FIGURE 55 is a perspective view, similar to FIGURE 54, showing one form of retainer apparatus arranged in operable combination with the connector;

FIGURE 56 is a sectional view similar to FIGURE 12 but showing an alternative embodiment of retainer apparatus;

FIGURE 57 is a longitudinal sectional view of the fixation assembly of the present invention with component parts, including the fastener shown in FIGURE 56, illustrated in axially spaced relation relative to each other and with;

FIGURE 58 is a perspective view of the fixation assembly schematically illustrated in FIGURE 57;

FIGURE 59 is a longitudinal sectional view of the fixation assembly of the present invention with component parts, including the fastener shown in FIGURE 56, illustrated in assembled relation relative to each other;

FIGURE 60 is a view similar to FIGURES 12 and 56 but showing another alternative embodiment of retainer apparatus;

FIGURE 61 is a perspective view of a fixation assembly according to the present invention having an alternative embodiment of a retainer apparatus;

FIGURE 62 is an elevational view showing a second fastener, a connector, and the alternative embodiment of a retainer apparatus as schematically illustrated in FIGURE 61;

FIGURE 63 is a longitudinal sectional view of the fixation assembly illustrated in FIGURE 61;

FIGURE 63A is a fragmentary and enlarged longitudinal sectional view of an alternative form of fixation assembly according to the present invention;

FIGURE 63B is an enlarged sectional view of the area encircled in FIGURE 63A;

FIGURE 64 is a perspective view of another embodiment of the interfragmentary fixation assembly of the present invention;

FIGURE 65 is a perspective view of an alternative embodiment of a second fastener and connector for the fixation assembly of the present invention;

FIGURE 66 is a partial sectional view of the alternative embodiment of the second fastener illustrated in FIGURE 65, with components of the second fastener being shown in spaced relation relative to each other and showing the connector adapted to pass endwise therethrough;

FIGURE 67 is a view similar to FIGURE 66 showing the component parts of the second fastener arranged in operable combination with each other and with the connector passing therethrough; with the phantom lines showing the range of motion of the second fastener;

FIGURE 68 is a cross sectional view of a fractured bone showing the alternative embodiment of the interfragmentary fixation assembly illustrated in FIGURES 65 through 67 arranged in operable combination therewith;

FIGURE 69 is a schematic representation of the bones in a patient's hand with a particular area shown for harvesting a section of bone-ligament-bone for grafting;

FIGURE 70 is a schematic view similar to FIGURE 69 but showing a lunate bone channeled to accept a bone-ligament-bone graft;

FIGURE 71 is a schematic view similar to FIGURE 70 but showing a lunate and scaphoid bone channeled to accept a bone-ligament-bone graft;

FIGURE 72 is a schematic view similar to FIGURE 71 but showing K-wires inserted into lunate and scaphoid bones for movement control;

FIGURE 73 is a perspective view of another alternative embodiment of the interfragmentary fixation assembly with component parts thereof shown in axially spaced relation relative to each other;

FIGURE 74 is a perspective view of the alternative embodiment of a second fastener used in combination with the fixation assembly schematically illustrated in FIGURE 73;

FIGURE 75 is a left end view of the alternative embodiment of fixation assembly shown in FIGURE 73;

FIGURE 76 is a right end view of the fixation assembly illustrated in FIGURE 73;

FIGURE 77 is a partial sectional view taken along line 77-77 of FIGURE 75;

FIGURE 78 is a schematic view of a bone-ligament-bone graft shown secured to components parts of alternative embodiments of the second fastener;

FIGURE 79 is a schematic view similar to FIGURE 72 (with K-wires omitted for clarity), but showing a first fastener of the interfragmentary fixation assembly inserted into a lunate;

FIGURE 80 is a view similar to FIGURE 79 with a first fastener of the fixation assembly secured into a scaphoid;

FIGURE 81 is a schematic view similar to FIGURE 79 showing the fixation assembly of the present invention used to partially attach the bone-ligament-bone graft to a lunate;

FIGURE 82 is a view similar to FIGURE 81 but showing another fixation assembly according to the present invention being used to attach an opposite portion of the bone-ligament-bone graft to the scaphoid;

FIGURE 83 is a schematic view similar to FIGURE 82 but showing a bone-ligament-bone graft procedure completed;

FIGURE 84 is a cross section of a scaphoid with another embodiment of the fixation assembly of the present invention having a bone graft attached thereto;

FIGURE 85 is an end view of the scaphoid shown in FIGURE 84;

FIGURE 86 is a perspective view of an alternative embodiment of the second fastener used in combination with a fixation assembly of the type illustrated in FIGURE 84 and having a connector passing endwise therethrough;

FIGURE 87 is a perspective view of the alternative embodiment of the second fastener illustrated in FIGURE 86;

FIGURE 88 is a bottom plan view of the second fastener illustrated in FIGURE 87;

FIGURE 89 is an elevational view of the second fastener illustrated in FIGURE 87;

FIGURE 90 is a top plan view of the second fastener illustrated in FIGURE 87;

FIGURES 91 through 99 are perspective views of alternative embodiments of the second fastener similar to that illustrated in FIGURE 87;

FIGURE 100 is a schematic view showing an alternative embodiment of the fixation assembly as used in combination with a small joint arthrodesis;

FIGURE 101 is an enlarged view of that area encircled in FIGURE 100;

FIGURE 102 is a top plan view of an alternative embodiment of the second fastener;

FIGURE 103 is an elevational view of the alternative embodiment of second fastener illustrated in FIGURE 102;

FIGURE 104 is a right end view of the second fastener illustrated in FIGURE 102;

FIGURE 105 is a sectional view taken along line 105-105 of FIGURE 103;

FIGURE 106 is a sectional view taken along line 106-106 of FIGURE 102; and

FIGURE 107 is an illustration of an interfragmentary fixation kit according to one aspect of the present invention.

Detailed Description of the Present Invention

While the present invention is susceptible of embodiment in various forms, there are shown in the drawings and will hereinafter be described preferred embodiments of the invention with the understanding that the present disclosure is to be considered as setting forth

exemplifications of the invention which are not intended to limit the invention to the specific embodiments illustrated.

Referring now to the drawings, wherein like reference numerals refer to like parts throughout several views, in FIGURE 1, there is schematically represented a scaphoid which is fractured into two fragments. The scaphoid fracture is used as a model wherein the interfragmentary fixation assembly of the present invention can be utilized to compress the bone fragments under a predetermined force selected by the surgeon to enhance healing thereof. As would be appreciated, the present invention is equally applicable to other situations beyond repair of the scaphoid as will be described below.

One embodiment of the multipiece interfragmentary fixation assembly is shown in FIGURE 2 as being wholly embedded within the scaphoid and is represented in its entirety by reference numeral 10. As illustrated in FIGURE 2, a leading portion of the fixation assembly 10 is secured or attached to the bone substance of the proximal fragment 12 of the scaphoid while a trailing portion of the fixation assembly 10 is secured or attached to the bone substance of a distal fragment 14 of the scaphoid.

As shown in FIGURE 3, the multipiece interfragmentary fixation assembly 10 includes first and second fasteners 20 and 30, respectively. Returning to FIGURE 2, the first fastener 20 is attachable in nonmovable relation to the first bone fragment 12 and the second fastener 30 is attachable in nonremovable relation to the second bone fragment 14.

As shown in FIGURES 3 and 4, the first fastener 20 comprises an elongated member 21 having external threading 22 extending axially rearwardly from a generally pointed end 23 thereof. In this preferred form of the invention, the first fastener 20 has a trailing end 24 that

cooperates and combines with the second fastener 30 to affect alignment of the fractured bone fragments 12 and 14 (FIGURE 2).

Turning to FIGURES 3 and 5, in this illustrated embodiment of the invention, the second fastener 30 comprises an elongated member 31 having external threading 32 extending axially forwardly from a trailing end 34 thereof. In this preferred form of the invention, the second fastener 30 has a leading end 33 that combines with the first fastener 20 to affect alignment of the fractured bone fragments 12 and 14 (FIGURE 2).

As shown in FIGURES 6, 7 and 8, the multipiece interfragmentary fixation assembly 10 further includes any elongated threaded connector 40 and an apparatus 50 for inhibiting inadvertent or free turning rotation of the connector 40. The connector 40 serves to operably interconnect the first and second fasteners 20 and 30, respectively, under a predetermined compressive force selected by the surgeon. Notably, the compressive force selected by the surgeon is developed as a result of the surgeon's "feel" as the first and second fasteners 20 and 30, respectively and the bone fragments 12 and 14 connected to each fastener are drawn into confronting relation relative to each other. The fixation assembly 10 is further configured to maintain the compressive force between the first and second fasteners 20 and 30, respectively, and the bone fragments attached to each thereby preventing inadvertent turning movement of the connector so as to promote union between the bone fragments and healing of the fracture.

Turning to FIGURE 9, the elongated member 21 of the first fastener 20 is preferably fabricated from a biocompatible material selected from a class comprised of: titanium, stainless steel, or a cobalt chromium molybdenum alloy. The external threading 22 extends axially lengthwise of member 21 and has a uniform pitch between leading and trailing ends thereof.

In the illustrated embodiment of the fastener 20, the external threading 22 axially extends for a distance equal to about one-half the distance between the proximal and distal ends 23 and 24, respectively, of member 21.

As shown in FIGURES 9 through 12, member 21 defines an axial bore 25 that extends through member 21 and opens to the leading and trailing ends 23 and 24, respectively, thereof. For at least a portion and preferably for the entire length thereof, bore 25 defines conventional internal threading 26 which is preferably of uniform pitch. The internal threading 26 axially extends from the trailing end 24 toward the leading end 23 for at least a portion of the length of the axial bore 25. In a most preferred form of the invention, the internal threading 26 extends along the entire axial length of bore 25. As shown in FIGURES 9, 10 and 12, in this preferred form of fastener 20, member 21 further defines an axial lengthwise section or portion 27 having a diameter which is less than or reduced from the diameter of the threaded portion 22 and extending axially and forwardly from the trailing end 24 of the fastener 20. Moreover, this reduced diameter portion 27 of fastener 20 has an axially tapered configuration. In the illustrated embodiment, the diameter of the reduced portion 27 of member 21 increases as a function of the distance measured from the trailing end 24 of the fastener 20.

Fastener 20 is further configured to allow a suitable driving tool (FIGURE 34) to be releasably connected to the fastener 20 to affect the rotation thereof. In the illustrated embodiment shown in FIGURES 9, 10 and 12, the trailing end 24 of member 21 is configured with a transverse slot 28 that releasably accommodates a flat tip of a screwdriver or other suitable tool. As will be appreciated, other tool receiving configurations would likewise suffice as long as such configurations are capable of releasably accommodating a driving tool capable

of turning the first fastener 20 such that the external threading 22 threadably engages with the respective bone fragment thereby anchoring the fastener to the respective bone fragment.

Turning to FIGURE 13, the elongated member 31 of the second fastener 30 is preferably fabricated from a biocompatible material preferably selected from the class comprised of: titanium, stainless steel, or a cobalt chromium molybdenum alloy. As shown in FIGURES 13 through 16, member 31 of the second fastener defines an axial bore 35 that extends through member 31 and opens to the leading and trailing ends 33 and 34 thereof. Notably, the external threading 32 extending along the axial length of member 31 has a uniform pitch between leading and trailing ends thereof. It is also important to note, the external threading 32 extending axially along the length of the second fastener 30 is like-handed and generally corresponds to the pitch of the threading of the external threading 22 extending axially along the first fastener 20. In the illustrated embodiment of the second fastener 30, the external threading 32 axially extends for a distance equal to about one-half the length between distal and proximal ends 33 and 34, respectively, of the second fastener 30. Suffice it to say, that the external threading 22, 32 on the fasteners 20, 30, respectively, has a relatively course pitch such that a substantive holding force or purchase will be developed when the fasteners are threadably secured within the respective bone fragments.

As shown in FIGURES 15 and 16, the axial bore 35 defined by member 31 includes a counterbore portion 36 extending axially away from the proximal or leading end 33 of fastener 30. As shown in FIGURE 16, in this embodiment of the second fastener 30, the counterbore portion 36 has a larger inside diameter than is the inside diameter of bore 35 thus defining an annular shoulder 37 axially spaced a predetermined distance inwardly from the

leading end 33 of fastener 30. Moreover, the counterbore portion 36 of bore 35 has an inside diameter generally equal to the outside diameter of the reduced diameter portion 27 of the first fastener 20. In a most preferred form of the second fastener, the counterbore portion 36 has an axially tapering configuration that compliments the axially tapering configuration on the reduced diameter portion 27 of the first fastener 20.

As shown in FIGURES 14 and 16, the axial bore 35 defined by member 31 also includes a counterbore portion 38 extending axially inwardly from the distal or trailing end 34 of fastener 30. In this preferred form of the second fastener 30, the counterbore portion 38 has a specific cross-sectional shape extending the axial length thereof. In this particular embodiment of the second fastener, the counterbore portion 38 has a generally hexagonal cross-sectional shape extending inwardly from the distal or trailing end 34 of the second fastener 30. The cross-sectional shape of the counterbore 38, of course, could be other than hexagonal, such as triangular, square, octagonal or pentagonal without detracting from the spirit and scope of the present invention. Amongst other features described below, the counterbore portion 38 is configured to allow a suitable driving tool (FIGURE 36) to be releasably connected to the fastener 30 such that the driving tool is capable of turning the second fastener 30 such that the external threading 32 threadably engages with the second bone fragment 14 of the scaphoid. Because of the different cross-sectional configurations of bore 35 and counterbore 38, however, a shoulder 39 (FIGURE 16) is defined therebetween.

One form of connector 40 is illustrated in FIGURES 17 through 20. As shown, the connector includes an enlarged head portion 42 and an axially elongated externally and conventionally threaded shank portion 44. The external threading on the shank portion 44 of

connector 40 has a pitch that corresponds to the pitch of the internal threading 26 extending along at least a portion of the bore 25 defined by the first fastener 20. In the embodiment of the connector 40 shown, the diameter of the shank portion 44 is specifically sized to fit endwise through the smallest diameter portion of the axial bore 35 defined by the second fastener 30 so as to allow the proximal end of the shank portion 44 of connector 40 to threadably engage with the internal threading 26 of the axial bore 25 of the first fastener 20. Moreover, the head portion 42 is sized to endwise move through the counterbore portion 38 of the second fastener and engage the shoulder 39 that acts as a stop for the connector 40.

As shown in FIGURE 19, the head portion 42 of connector 40 defines a blind socket 46 that opens to a distal end of the head portion 42 of connector 40 and is configured to releasably accommodate a driving tool (FIGURE 43) capable of imparting turning movement to the connector 40. In a most preferred form, the blind socket 46 of connector 40 has a hexagonal cross-sectional configuration although other like configurations would equally suffice.

In the illustrated form, the head portion 42 of the connector 40 includes at least one finger 47 that axially projects through the blind socket 46 and toward the open end thereof. In a most preferred form of the connector 40, and as shown in FIGURE 19, three equally spaced and axially extending fingers 47 are provided in the blind socket 46 and project toward the open end thereof.

The head portion 42 of the connector 40 preferably further includes an annular channel 48 having a diameter that is greater than the blind socket opening 46. Notably, the annular channel 48 defines an outer surface 49 that is spaced a predetermined distance from the blind or closed end of cavity 46.

The means for retaining the connector 40 against rotation and thereby maintaining the predetermined compressive relationship between the fasteners 20, 30 and, thus, the bone fragments secured to each, can take a myriad of different forms. The retainer apparatus 50 is arranged in operable combination with and holds the connector 40 against rotation thereby maintaining the predetermined compressive relationship between the fasteners 20, 30. One form of retainer apparatus 50 is illustrated in FIGURES 21 through 24. As shown, the retainer apparatus 50 includes an element 52 formed from a biocompatible material selected from the class comprised of: nylon or an ultra high molecular weight polyethylene. In its illustrated form, element 52 of retainer apparatus 50 includes a body portion 54 with a cross-sectional configuration that generally corresponds to the cross-sectional configuration of the counterbore 38 in the second fastener 30. Suffice it to say, the body portion 54 of element 52 has a cross-sectional configuration that operates in combination with the cross-sectional configuration of the counterbore 38 to prevent rotation of the element 52 relative to the second fastener 30.

In the illustrated embodiment of the retainer apparatus 50 shown in FIGURES 21, 22 and 24, element 52 further includes an axial extension 56 that projects from a proximal end thereof. At its free end, the axial extension 56 defines at least one finger 57 that is adapted to cooperate and combine with finger 47 defined in the blind socket 46 of the connector 40. In a most preferred form of the invention, and as shown in FIGURE 24, the axial extension 56 of element 52 includes three equally spaced fingers 57 that project from the free end of the axial extension 56.

In this particular illustrated form of the retainer apparatus 50, the axial extension 56 furthermore includes an annular ring 58 having an outside diameter that is generally equal to the inside diameter of the channel 48 of connector 40. Preferably, the annular ring 58 on the axial extension 56 is formed from a pliable material that is biocompatible with the bone and tissue substance wherein the fixation assembly of the present invention is adapted for use. Suffice it to say, the annular ring 58 is formed of a material that allows the ring to compress and subsequently snap into the channel 48 and combine with surface 49 of channel 48 to prevent inadvertent axial displacement of the element 52 toward the trailing end 34 of the second fastener 30. As shown in FIGURES 22 and 23, element 52 further defines a threaded bore 59 for purposes to be described hereinafter.

Turning to FIGURE 25, the proximal and distal bone fragments 12 and 14, respectively, of scaphoid 10 are schematically shown with a fracture extending generally transverse to the longitudinal axis of the scaphoid 10. Next, and as schematically shown in FIGURE 26, the bone fragments 12 and 14 are drilled to define a bore 62 extending through both fragments and a guide 64 is tightly inserted into the bore 62.

As shown in FIGURE 27, a conventional cannulated drill 66 is axially fitted over and slides along the guide 64. As shown in FIGURE 28, the drill 66 is operated to provide a bore 68 that passes through the bone substance of fragment 14 and for a substantial distance into the bone substance of fragment 12. Because the drill 66 moves endwise along guide 64, that portion of bore 68 defined by fragment 14 is axially aligned with that portion of bore 68 defined by fragment 12. After the bore 68 is provided, drill 66 is removed from the guide 64 as shown in FIGURE 29.

Next, a conventional cannulated tap 70 is arranged along the guide 64 as shown in FIGURE 30. As is typical, tap 70 is passed along the guide 64, as shown in FIGURE 31, to provide internal threading 72 to the bore 68. Notably, the internal threading 72 extends through the bone substance of fragment 14 and for a substantial axial distance of bone fragment 12. Also, it is to be noted, that the internal threading 72 provided by tap 70 is of like hand and corresponds to the external threading 22 and 32 provided on fasteners 20 and 30, respectively. After the tapping operation is complete, the tap 70 is removed from the bore 68 as shown in FIGURE 32.

The first fastener 20 is next inserted into the fractured scaphoid. As shown in FIGURE 33, the bore 25 in the elongated member 21 allows fastener 20 to be guided and vertically positioned proximate to the end of fragment 14. Thereafter, a suitable tool is used to engage the transverse slot 28 at the distal end of member 21. The surgeon rotates the fastener 20 with the tool whereby the external threading 22 of member 21 engages and follows the interior threading 72 in the bone fragments 12 and 14. As shown in FIGURE 34, the surgeon rotates the first fastener 20 until the entire fastener 20 is thready buried within the bone substance of the first fragment 12. Then, the surgeon removes the tool used to drive the first fastener 20.

Next, the second fastener 30 is inserted into the fractured scaphoid and into operable combination with the first fastener 20. As shown in FIGURE 35, the bore 35 in the elongated member 31 allows the fastener 30 to be vertically guided and positioned proximate the end of fragment 14. Thereafter, and as shown in FIGURE 36, a suitable tool is inserted into the cross-sectioned counterbore 38 of fastener 30 at the distal end thereof. The surgeon rotates the fastener 30 with the tool whereby the external threading 31 engages and follows the internal

threading 72 in bone fragment 14 until the entire fastener 30 is thready buried within the bore substance of the second fragment 14. Thereafter, the surgeon removes the tool used to drive the second fastener 30 as shown in FIGURE 37.

With the first and second fasteners 20 and 30, respectively, secured or buried in the bone fragments 12 and 14, the surgeon removes the guide 64 as shown in FIGURE 38.

FIGURE 39 schematically represents the axial alignment of the first and second fasteners 20 and 30, respectively. As shown in FIGURES 33, 34 and 39, when the first fastener 20 is threadably inserted into the bone substance of the scaphoid, the pointed end 23 is arranged to initially engage the internal threading 72 in the bone substance thereby facilitating threaded engagement of the fastener 20 within the bone substance and with the reduced diameter portion 27 preferably projecting axially toward the open end of bore 68. As shown in FIGURE 39, the open ended counterbore portion 36 of the second fastener 30 is then inserted first into the bore 68 in the bone fragment.

Turning to FIGURES 36 and 40, and as mentioned above, as the second fastener 30 is threaded into the bore 68, the counterbore portion 36 of fastener 30 fits over and into operable combination with the reduced diameter portion 27 of fastener 20 to effect axial alignment of the fasteners 20 and 30 and the bone fragments 12 and 14. As will be appreciated, the axially tapering configuration on the reduced diameter portion 27 of fastener 20 cooperates with the complimentary tapered configuration at the leading end of the counterbore portion 36 to facilitate and act as a cam to effect axial alinement of the first and second fasteners 20 and 30 and the bone fragments 12 and 14 fastened thereto, respectively. Moreover, it is within the spirit and scope of the present invention that the configurations at the trailing and leading ends of the first

and second fasteners 20 and 30, respectively, could be reversed without detracting or departing from the spirit and scope of the present invention.

Turning now to FIGURES 41 and 42, after the first and second fasteners 20 and 30, respectively, are threaded into the bone substance of the scaphoid, the connector 40, as shown in FIGURES 17 through 20, is inserted into combination with the fasteners 20, 30. As shown, the shank portion 42 of connector 40 endwise passes first through the counterbore portion 38, then through bore 35, and finally through the counterbore portion 36 of fastener 30 and, ultimately, into threaded engagement with the internal threading 26 axially extending along a least portion of the length of the bore 25 of fastener 20. As shown in FIGURE 43, a suitable tool releasably fits into the open end of the blind socket 46 to turn the connector 40 relative to the first and second fasteners 20 and 30.

It will be appreciated at this point in the procedure some degree of gap or separation may exist between the bone fragments 12 and 14. Notably, and as schematically illustrated in FIGURE 42, the head end or portion 42 of connector 40 is larger than bore 35 defined by fastener 30 thus preventing passage of the head portion 42 past the shoulder 39 defined by the second fastener 30. Any gap or separation existing between the bone fragments 12, 14 is narrowed by the surgeon rotating the connector 40. That is, with the head portion 42 of connector 40 in operable engagement with the shoulder 39 of the second fastener 30, continued rotation of the connector 40 will cause and result in the first and second fasteners 20 and 30, respectively, and the bone fragments attached to each being drawn toward each other. Ultimately, the bone fragments 12, 14 are preferably drawn into abutting relationship under a predetermined compression relative to each. Since the fasteners 20 and 30 are already fixed in

the bone substance, the ability to rotate the connector 40 allows the surgeon an appropriate "feel" when the bone fragments 12, 14 are drawn into a predetermined and proper compressive relationship relative to each other.

Next, and as shown in FIGURE 44, a preferred form of retainer apparatus 50 is placed in operable combination with the fastener 30 to maintain the predetermined and proper level of compression between the fasteners 20, 30 and the bone fragments 12, 14 to promote the healing process. As shown in FIGURE 45, the element 52 of the retainer apparatus 50 is initially and slidably positioned into the counterbore portion 38 of the fastener 30 with the axial extension 56 and fingers 57 directed toward the connector 40. As shown in FIGURE 47, a suitable tool is releasably connected to the element 52 to facilitate axial placement of the retainer apparatus 50 into combination with the fastener 30 and connector 40. As shown in FIGURES 48 and 49, the fingers 57 of this preferred form of retainer apparatus 50 are initially spaced from the fingers 47 in the blind socket 46 defined by the head portion 42 of connector 40.

Turning now to FIGURE 46, the element 52 of the retainer apparatus 50 is slidably moved toward the connector 40 such that the fingers 57 on the axial projection 56 of element 52 operably engage with the fingers 47 in the blind cavity 46 of the head portion 42 of connector 40. The relationship of the fingers 47 on the connector to the fingers 57 on the retaining apparatus is further illustrated in FIGURES 50 and 51.

As illustrated in FIGURES 52 and 53, the element 52 of retainer apparatus 50 is further axially moved toward the connector until the annular ring 58 resiliently snaps into the channel 48 defined by the head portion 42 of the connector 40. When the retainer ring 58 snaps into the channel 48, the retainer apparatus 50 is prevented from inadvertently moving away from the

connector 40 while concomitantly preventing the connector 40 from turning thereby maintaining the predetermined level of compression between the fasteners 20 and 30 and the fragments 12 and 14, respectively, carried thereby to promote the healing process.

The retainer apparatus 50 is maintained in operable combination with the connector 40, as shown in FIGURES 54 and 55, until a suitable tool is used to purposefully remove the retainer apparatus 50. To affect removal of the retainer apparatus 50 from operable combination with the connector 40, in the illustrated form of the invention, the releasable tool used to position the retainer apparatus 50 is threadably engaged with the threaded bore 59 (FIGURES 22 and 23) defined by the element 52. Forcible retraction of the tool will likewise cause the retainer ring 58 to disengage from the channel 48 and thereby allow the retainer apparatus 50 to be removed from operable association with the connector 40.

FIGURE 56 schematically illustrates an alternative form of retainer apparatus 150. As shown, this alternative retainer apparatus 150 comprises an insert 152 arranged axially along and in combination with the internal threading 26 of the first fastener 20. The insert 152 is formed from a biocompatible material preferably chosen from the class consisting of: nylon, or an ultra high molecular weight polyethylene.

Turning to FIGURE 57, the alternative form of retainer apparatus is preferably positioned proximate to the trailing end 24 of the first fastener 20 and in combination with a trailing end of the internal threading 26. As shown in FIGURES 57 and in 58, the second fastener 30 of the multi-piece interfragmentary fixation assembly of the present invention remains substantially the same as discussed above.

As schematically in shown in FIGURES 57 and 59, the alternative retainer apparatus 150 allows a conventional socket headed screw or connector 140 to be used in combination with the fasteners 20 and 30. That is, the connector 140 includes an enlarged head 142 and a shank portion 144 with external conventional threading that corresponds to the internal threading 26 extending along the axial bore 25 of the first fastener 20. The connector 140 functions in an analogous manner to that described above with respect to connector 40. As the connector 140 passes inwardly along the internal threading 26 of the first fastener 20, the external threading on the shank portion 144 of fastener 140 engages with the retainer apparatus 150 in a manner preventing inadvertent turning of the connector 140 and thereby maintaining the compressive force preselected by the surgeon between the fasteners 20 and 30 to promote the healing process.

FIGURE 60 schematically illustrates another alternative form of retainer apparatus 250. As shown, this alternative retainer apparatus 250 comprises an annular insert 252 arranged axially along and in combination with the internal threading 26 of the first fastener 20. The annular insert 252 is preferably formed from a biocompatible material preferably chosen from the class consisting of: nylon, or an ultra high molecular weight polyethylene. The retainer apparatus 250 functions in an analogous manner to that described above regarding the alternative form of retainer apparatus 150. Thus, no further detailed description need be provided therefor for a complete understanding of its function and operation.

Still another form of retainer apparatus 350 is schematically illustrated in FIGURES 61 through 63. In this embodiment, the retainer apparatus 350 comprises an element 352 including a body portion 354 with a cross-sectional configuration generally corresponding to the cross-sectional configuration of the counter bore 38 in the second fastener 30. Suffice it to say, the

body portion 354 of element 352 has a cross-sectional configuration that operates in combination with the cross-sectional configuration of the counterbore 38 to prevent rotation of the element 352 relative to the second fastener 30. In this embodiment, element 352 of the retainer apparatus 350 includes a retaining ring 358 that is carried by the body 354 of element 352.

This alternative form of retainer apparatus 350 is adapted to operate in combination with a conventional socket headed screw or connector 340. The connector 340 functions in an analogous manner to that discussed above with respect to connector 40 except that connector 340 does not require the specifically shaped blind socket portion as does connector 40.

As schematically illustrated in FIGURES 62 and 63, the second fastener 30 defines an annular channel 348 that is spaced a predetermined distance from the shoulder 39 defined by the second fastener. The predetermined distance separating channel 348 and shoulder 39 is equal to the axial length of the headed portion 342 of connector 340 and the axial length the ring 358 is disposed from a leading edge of the body portion 354 of element 352. Preferably, the annular ring 358 on the element 352 is formed from a pliable material that is biocompatible with the bone and tissue substance wherein the fixation assembly of the present invention is adapted for use. Suffice it to say, the annular ring 358 is formed from a material that allows the ring 358 to compress and subsequently snap into and combine with the channel 348 in a manner preventing inadvertent axial displacement of the element 352 toward the trailing end of the fastener 30. Accordingly, once the surgeon selects the predetermined level of compression between the fasteners, the retainer apparatus 350 is inserted until the annular ring 358 snaps into the annular channel 348 thereby preventing the fastener 30 from turning with the second fastener

30 and thereby maintaining the predetermined level of compression between the fasteners 20 and 30.

As shown in FIGURES 62 and 63, element 352 of retainer apparatus 350 further defines a threaded bore 359. As will be appreciated, the retainer apparatus 350 is maintained in operable combination with the second fastener 30 and prevents inadvertent rotation of the fastener 340 until a suitable tool removes the retainer apparatus 350 from association with the connector 340. To effect the removal of retainer apparatus 350, in this illustrated form of the invention, a releasable tool is threadably engaged with the threaded bore 359 defined by the element 352. Forcible retraction of the tool will likewise cause the retainer ring 358 to disengage from the channel 348 and thereby allow the retainer apparatus 352 to be removed from the interfragmentary fixation assembly 10.

FIGURE 63A illustrates still another alternative configuration for retaining the fasteners 20 and 30 of the fixation assembly 10 in a preset or predetermined compressive relationship relative to each other. This alternative configuration includes the conventional socket headed screw or connector 340 mentioned above. As mentioned above regarding connector 140, the connector 340 includes an enlarged head portion 342 and a shank portion 344 with conventional external threading 346 extending axially therealong. The connector 340 functions in an analogous manner to that described above with respect to connectors 40 and 140.

In this embodiment of the invention, an internal locking thread form 326 (FIGURE 63B) is defined along at least a portion of the axial length of the bore 25 defined by the first fastener 20. In a preferred form of the invention, the internal locking thread form 326 extends an axial lengthwise distance from the trailing end 24 of member 21 and along the bore 25 of fastener 20.

It should be appreciated, the internal locking thread form 326 can extend the entire or a distance somewhat less than the entire length of bore 25. In a most preferred form of the invention, the internal locking device 326 is sold under the trademark SPIRALOCK by Detroit Tool Industries and offers preload locking between the connector and threadably interconnected fastener through a unique internal thread configuration.

As shown in FIGURE 63B, and in the illustrated form of the invention, the unidirectional internal thread form 326 has an added 30° wedge ramp 327 at the root of each internal thread defined by fastener 20. The internal thread from 326 still mates with the standard or conventional 60° threading on the external threading 346 of the shank portion 344 of connector 340.

When a clamp load is applied to the connector 340 thereby drawing the fasteners 20 and 30 into predetermined compressive relationship relative to each other, the internal thread form or configuration 326 defined by fastener 20 locks the standard or conventional male threading 346 extending along the length of shank 344 of fastener 340 tightly against the wedge ramp 327 thereby preventing movement of the connector 340 relative to fastener 20 and thereby maintaining the predetermined compressive relationship between the fasteners 20, 30. At this point, the crests of the conventional external threading 346 are drawn tightly against the ramp surfaces 327 of the thread form 326 thus eliminating radial clearances and creating a continuous spiral, line contact along the entire length of thread engagement. This continuous line contact spreads the clamp force more evenly over all the engaged threads thus reducing fatigue failure and increasing the integrity of the threaded connection between connector 340 and fastener 20. Moreover, the internal thread form 326 for preventing the connector 340 from rotating following

establishment of the predetermined compressive relationship between fastener 20, 30 furthermore yields the surgeon with the ability to "feel" the proper relationship n the identical fashion the surgeon is accustomed to working with using other arrangements. As will be appreciated, other internal thread forms could likewise be used along the length of axial bore 25 and the external threading 346 of connector 340 without detracting or departing from the spirit and scope of the present invention.

The use of an internal thread form or configuration 326 for preventing inadvertent rotation of the connector used to join the fasteners of the present invention offers several benefits. First, the internal thread form 326 is a tested and proven technique which works well under severe conditions. Second, the internal thread form 326 simplifies the fixation assembly design. Notably, when the internal thread form 326 is utilized, a conventional connector 340 is used to draw the fasteners 20, 30 into a predetermined compressive relationship relative to each other. Moreover, when a thread form 326 is used in connection with the present invention, the design of fastener 30 is simplified. That is, the counterbore 38 defined by fastener 30 is a simplified counterbore having no specific cross-sectional configuration thereto. For these and other reasons, an internal thread form is preferably used to inhibit rotation of the connector 340 relative to the fasteners thereby maintaining the preselected compressive force between the fasteners 20, 30 and, thus, the bone fragments secured to each fastener.

Not all types of bone fractures will necessarily lend themselves to the embodiment of the invention schematically illustrated in FIGURES 3 through 8 wherein two axially elongated fasteners are maintained in a compressive and end-to-end relationship relative to each other.

Accordingly, the present invention contemplates alternative forms of the multipiece interfragmentary fixation assembly.

An alternative form of the multipiece interfragmentary fixation assembly is illustrated in FIGURES 64 through 68 and is generally designated by reference numeral 400. As with the first embodiment of the invention, the multipiece interfragmentary fixation assembly 400 functions to maintain bone fragments 412 and 414 in compressive relationship relative to each other. The elements of this alternative embodiment of the fixation assembly 400 that are identical or functionally analogous to those in earlier embodiments discussed above are designated by reference numerals identical to those used above with the exception that this alternative embodiment reference numerals are in the 400 series.

As shown in FIGURE 68, this alternative embodiment of the fixation assembly 400 includes a first axially elongated fastener 420 secured to bone fragment 412, a second fastener 430 that is secured to bone fragment 414, a connector 440 that serves to maintain the first and second fasteners 420 and 430 and the bone fragments 412 and 414 attached to each, respectively, in compressive relationship relative to each other, and an apparatus 450 for maintaining the compressive relationship between the first and second fasteners 420 and 430, respectively, and the bone fragments attached to each. Suffice it to say, the first fastener 420 and the connector 440 are substantially similar to that embodiment of the invention illustrated in FIGURES 56 through 59. Moreover, this alternative embodiment of the fixation assembly further includes a retainer apparatus similar to that illustrated in FIGURES 56 or 60. It should be appreciated, however, the apparatus 450 for holding the connector 440 against rotation could involve an internal thread form similar to that disclosed in FIGURES 63A and 63B and discussed above in

detail. Accordingly, no further detailed description need be provided therefor for a complete understanding of those features of the invention.

The alternative embodiment of the second fastener 430 is best illustrated in FIGURES 65 through 67. The second fastener 430 comprises a member 431 and element 432 arranged in operable combination relative to each other. Member 431 of a fastener 430 is configured with a generally concave shaped and apertured section 433 that is generally centralized between a plurality of prongs 434 that project radially outward and away from the central section 433. Although the second fastener 430 is illustrated as having four prongs 434 extending therefrom, it will be readily appreciated by those skilled in the art that less than four prongs could radially extend away from the central section 433 of the fastener without departing or detracting from the spirit and scope of the present invention. As shown, the central section 433 defines a hemispherical shaped recess with an aperture 435 opening thereto. Element 432 likewise has a hemispherical shape that complements the concave shaped section 433. Moreover, element 432 defines an aperture 436 and element 432 is sized to permit the externally threaded shank portion 444 of fastener 440 to pass endwise therethrough while preventing the enlarged headed portion 442 of fastener 440 to pass endwise therethrough.

In an assembled relationship as shown in FIGURES 67, element 432 sits within the apertured central section 433 of member 431 and is permitted to rockingly move within the socket defined by element 431. Returning now to FIGURE 68, the first fastener 420 is initially threaded into the bone substance of bone fragment 412 and the external threading 422 fixedly maintains the fastener 420 in place. The connector 440 is then passed endwise through the element 432 and member 431 of the second fastener and into threaded engagement with the

internal threading 426 axially extending along at least a portion of the length of the bore 425 of fastener 420.

At this point in the procedure, some degree of gap or separation may exist between the bone fragments 412 and 414. Notably, and as illustrated in FIGURES 66 and 67, the head end 442 of connector 440 is larger than the bore 436 defined in element 432 of fastener 430. Any gap or separation existing between the bone fragments 412 and 414 is narrowed by the surgeon rotating the connector 440. That is, with the head portion 442 of connector 440 in operable engagement with the element 432 of the second fastener 430, continued rotation of the connector 440 will cause and result in the first and second fasteners 420 and 430, respectively, and the bone fragments attached to each being drawn toward each other. Ultimately, the bone fragments 412 and 414 are preferably drawn into abutting relationship under predetermined compression relative to each other. The ability to rotate the connector 440 allows the surgeon an appropriate "feel" when the bone fragments 412, 414 are drawn into a predetermined proper compressive relationship relative to each other. The predetermined and proper compressive relationship between the fasteners 420 and 430 and, thereby, the fragments 412 and 414 relative to each other is maintained by preventing the connector 440 from inadvertently turning as through a retainer apparatus similar to that described in detail above.

Notably, the aperture 435 in member 431 is sized and configured such that the member 431 of the second fastener 430 is permitted to rock about the elongated axis of connector 440. As such, the prongs 434 extending radially outwardly from the central section 431 of member 430 are better able to graspingly secure to the bone fragment 414. Moreover, and as shown in

FIGURE 64, the prong configuration of member 431 readily lends itself to having a ligament L attached thereto.

Frequently, with an acute hyperextension injury to the wrist, the scaphoid will not fracture but instead a series of ligamentous damage can occur about the wrist. The volar wrist ligaments certainly contribute to instability about the wrist. The dorsal scapholunate interosseous ligament is a primary constraining force that when ruptured leads to disassociation between the scaphoid and lunate bones. Failure to reconstruct this ligament can lead to the development of progressive arthritis about the wrist. Another alternative embodiment of the fixation assembly of the present invention readily lends itself to replacement and/or repair of ligaments between adjacent bones. Although a bone-ligament-bone graft is hereinafter illustrated in combination with lunate and scaphoid bones, it should be appreciated that other bones in a patient's body are equally susceptible to the present invention and the present invention should not be limited to that shown for exemplary purposes.

FIGURE 69 shows the bones of a patient's hand with a particular area shown for harvesting a bone-ligament-bone for grafting. After the bone-ligament-bone section is harvested, the surgeon configures the lunate bone LB to accept the graft as shown in FIGURE 70. The surgeon then conditions or configures the scaphoid bone SB to accept the graft as shown in FIGURE 71. As shown in FIGURE 72, conventional K-wires are then inserted into the lunate bone and scaphoid bone for movement control.

Another embodiment of the fixation assembly according to the present invention is illustrated in FIGURES 73 through 77 and is designated generally by reference numeral 500. The fixation assembly 500 functions to secure the bone-ligament-bone graft to the lunate bone

LB and the scaphoid bone SB. The elements of this alternative embodiment of the fixation assembly 500 that are identical or functionally analogous to other components mentioned above are designated by reference numerals identical to those used above with the exception that this embodiment reference numerals are in the 500 series.

As shown in FIGURE 73, this alternative embodiment of the fixation assembly 500 includes a first axially elongated fastener 520, a second fastener 530, a connector 540 and a retaining apparatus 550 (FIGURE 77). The first fastener 520, the connector 540 and the retaining apparatus 550 may each be similar to those similar components illustrated in FIGURES 56 through 59 and discussed in detail above. Alteratively, an internal thread form similar to that disclosed in FIGURES 63A and 63B and discussed in detail above could likewise be used to prevent rotation of the connector 540 without detracting or departing from the spirit and scope of the present invention. Thus, no further detailed description need be provided therefor at this time.

This alternative embodiment of the second fastener 530 is best illustrated in FIGURES 73, 74 and 77. The second fastener 530 is formed from a biocompatible material to the bone tissue wherein the fastener is used and preferably from the class consisting of: titanium, stainless steel, or a cobalt chromium molybdenum alloy. As shown, the second fastener 530 comprises a generally planar member 531 having upper and lower generally parallel surfaces 532 and 533. The planar member 531 also defines a preferably centralized through bore 534 that permits a shank portion 544 of connector 540 to pass endwise therethrough and is specifically sized to prohibit the head portion 542 of the connector 540 from passing therethrough. The

second fastener 530 is further provided with a plurality of holes or apertures 535 arranged in a generally circumferential relation relative to the centralized through bore 534.

Turning now to FIGURE 78, the bone-ligament-bone graft is fixedly attached to the second fastener 530. As shown, a bore is provided in each bone fragment of the bone-ligament-bone graft such that access is provided to the head portion 542 of each connector 540. Notably, sutures or other suitable fastening apparatus passes through the apertures 535 in the second fastener and about the bone of the bone-ligament-bone graft thereby securing a bone fragment to the second fastener.

Turning to FIGURE 79, after configuring or channelling the lunate bone LB, the first fastener 520 of the fixation assembly is threadably secured within the bone substance of the lunate bone. As shown in FIGURE 80, a first fastener 520 of this embodiment of the fixation assembly is threadably secured within the bone substance of the scaphoid bone. Notably, the pitch of the threads on the first fastener 520 prohibit the fastener from becoming dislodged from the bone substance of the respective bone fragment.

Turning to FIGURE 81, the bone-ligament-bone graft is then secured within the channel or configuration of the lunate/scaphoid bone. As shown in FIGURE 81, a suitable tool is used to threadably secure the bone graft to the first fastener in the lunate bone. Preferably, such tool includes a flexible shank portion. Because the second fastener is fixedly attached to the bone fragment, the rotating action of the connector 540 forcibly draws the bone fragment into the channelled configuration of the lunate bone LB. Turning to FIGURE 82, the other bone fragment is secured in the channelled configuration of the scaphoid bone in a similar manner.

FIGURE 83 schematically illustrates the bone-ligament-bone graft secured in place between the lunate bone LB and scaphoid bone SB.

Still another embodiment of the multipiece fixation assembly according to the present invention is schematically illustrated in FIGURES 84 and 85. In this embodiment of the invention, the fixation assembly is utilized to affix a bone plug 614 to a scaphoid bone 612. This alternative embodiment of fixation assembly is schematically illustrated in FIGURES 84 and 85 and is designated generally therein by reference numeral 600. As with the other embodiments of the invention, the fastener assembly 600 functions to maintain the bone plug 614 in a proper compressive relationship relative to the scaphoid bone fragment 612. The elements of this alternative embodiment of the fixation assembly that are identical or functionally analogous to those in earlier embodiments discussed above are designated by reference numerals identical to those used above with the exception that the reference numerals in this alternative embodiment are in the 600 series.

As shown in FIGURE 84, this alternative embodiment of the fixation assembly 600 includes a first axially elongated fastener 620, a second fastener 630, a connector 640 and a retainer apparatus (not shown). The first fastener 620, connector 640, and retainer apparatus (not shown) can be like those elements schematically illustrated in FIGURES 56 through 59. Alteratively, an internal thread form similar to that disclosed in FIGURES 63A and 63B and discussed in detail above could likewise be used to prevent rotation of the connector 640 without detracting or departing from the spirit and scope of the present invention.

The alternative embodiment of the second fastener 630 is illustrated in FIGURES 86 through 90. The second fastener 630 comprises a member 631 defining a coaxial bore extending

therethrough and having a plurality of prongs extending radially outwardly away from member 631.

In the embodiment illustrated in FIGURES 86 through 90, member 631 of fastener 630 has an axially elongated frusto-conically shaped configuration. Preferably, the prongs 634 extend from that end of member having a larger diameter. Member 631 of fastener 630 is formed from a biocompatible material preferably from a class of materials comprised of: titanium, stainless steel, or a cobalt chromium molybdenum alloy. Alternatively, an outer surface of the member comprising fasteners 620 and 630 can be treated in a well known manner to promote bone growth.

As shown in FIGURE 86, the throughbore or aperture 632 defined by member 631 of the second fastener 630 is specifically sized relative to the connector 640. More specifically, the throughbore 632 is sized to allow an externally threaded shank portion 644 of connector 640 to extend axially through the second fastener 630 and into threaded engagement with the internal threading (not shown) of the first fastener 620. The head portion 642 of the connector 640 is prohibited, however, from passing endwise through the second fastener 630.

With this embodiment of the invention, the bone plug 614 is placed into the configured channel of the scaphoid bone 612. Thereafter, the first fastener 620 is secured within the bone substance of the bone fragment 612 in a manner discussed in detail above. Thereafter, the threaded connector 640 is passed through the second fastener and threadably engaged with the first fastener. As will be appreciated, rotation of the connector 640 will draw the second fastener 630 toward the first fastener 620 thereby allowing the prong 634 on the second fastener to forcibly move the bone plug 614 into compressive relationship relative to the bone fragment

612. Continued rotation of the connector 640 will continue until the surgeon develops the appropriate "feel" of the fasteners 620, 630 relative to each other thereby establishing a predetermined level of compression between the fasteners and, thus, the bone plug 614 and bone fragment 612. As discussed in detail above, the retaining apparatus (not shown) associated with this embodiment of the invention will maintain the first and second fastener 620 and 630, respectively, in the predetermined compressive relationship by prohibiting the connector 640 from turning thereby maintaining the bone plug 614 and bone fragment 612 in a predetermined compressive relationship during the healing process and in a manner promoting tissue growth therebetween.

FIGURES 91 through 99 schematically illustrate other forms of fasteners that would be equally applicable for use with this embodiment of the invention.

Another alternative embodiment of the present invention is likewise useful regarding repair of a small joint such as in the finger of a patient. As shown in FIGURE 100, this alternative embodiment of the fixation assembly of the present invention is used to secure bone 712 to bone 714 under a predetermined compressive force.

For use in combination with such an environment, an alternative embodiment of the multi-piece fixation assembly according to the present invention is illustrated in FIGURES 100 and 101 and is designated generally by reference numeral 700. The fixation assembly 700 is similar, and functions in a similar manner, to the other embodiments of the fixation assembly described above. The elements of this alternative embodiment of the fixation assembly 700 that are identical or functionally analogous to those of other embodiments of the fixation assembly are designated by reference numerals identical to those used for the alternative embodiments with

the exception that this embodiment reference numerals are in the 700 series. As shown in FIGURE 101, this alternative embodiment of the fixation assembly 700 includes the first axially elongated fastener 720 secured to bone 712, a second fastener 730 fixedly attached to bone 714, a connector 740 for interconnecting the first and second fasteners 720 and 730, respectively, and a retaining apparatus (not shown).

The first fastener 720, the connector 740 and the retainer apparatus (not shown) used in combination with this embodiment of the invention are substantially similar to those components schematically illustrated in FIGURES 56 through 59 and discussed in detail above. Alternatively, a thread form similar to that disclosed in FIGURES 63A and 63B and discussed in detail above could be used to prevent inadvertent rotation of the connector 740 without detracting or departing from the spirit and scope of the present invention. Therefore, no further detail description need be provided therefor for complete understanding of the present invention.

The alternative embodiment of the second fastener 730 is illustrated in FIGURES 102 through 106. The second fastener 730 is formed from a bone compatible material preferably chosen from the class consisting of: titanium, stainless steel, or a cobalt chromium molybdenum alloy and is attachable to an exterior of the second bone 714 (FIGURE 101). As shown in FIGURES 102 through 104, the second fastener 730 comprises an elongated and narrowed plate-like member 731. Member 731 has upper and lower generally parallel surfaces 732 and 733, respectively. The plate-like member 731 further includes an indentation 734 preferably extending longitudinally of member 731 and has a closed margin defined within the periphery 735 of member 731 and including a wall 736 depending in an acute angle relative to the upper surface 732 of the plate-like member 731. The depending wall 736 defines an aperture 737.

Notably, the aperture 737 defined by the plate-like member 731 is sized such that the shank portion 744 (FIGURE 101) of the connector 740 is permitted to endwise pass therethrough. Moreover, the aperture 737 in plate-like member 731 is sized such that the head portion 742 (FIGURE 101) of the connector 740 is prevented from passing endwise therethrough. Instead, the head portion 742 of connector 740 abuts with the depending wall 736 of the plate-like member 731.

Returning to FIGURE 101, the first fastener 720 is secured in the bone substance of bone 712. Notably, the external threading 722 on the first fastener 720 is sufficient to prevent the fastener 720 from becoming dislodged from the bone substance when subjected to axial forces applied thereagainst. Next, the surgeon configures the bone fragment 714 to accept the indentation 734 defined by the plate-like member 731. More specifically, the bone 714 is configured with a step against which wall 736 is permitted to abut. Thereafter, the shank portion 744 of connector 740 passes through bore 737 and into threaded engagement with the first fastener 720.

It will be appreciated at this point in the procedure that some degree of gap or separation may exist between bones 712 and 714. Notably as mentioned above, the head end or portion 742 of connector 740 is larger than bore 737 defined by depending wall 736 of indentation 734 thus preventing passage of the head portion 742 of connector 740 past the wall 736 of plate-like member 731. Any gap or separation existing between the bone 712 and 714 is narrowed by the surgeon rotating the connector 740. That is, with the head portion 742 of connector 740 in operable engagement with wall 736 of plate-like member 731 and with wall 736 abutting against the configured bone 714, continued rotation of the connector 740 will cause and result in the

first and second fasteners 720 and 730, respectively, and the bones attached to each being drawn toward each other. Ultimately, the bone 712 and 714 are preferably drawn into abutting relationship under a predetermined compression relative to each. Since the fasteners 720 and 730 are already fixed to the bone substance of each bone 712 and 714, the ability to rotate the connector 740 allows the surgeon an appropriate "feel" when the bones 712, 714 are drawn into a predetermined and proper compressive relationship relative to each other. Moreover, the retaining apparatus (not shown) associated with this embodiment of the invention prevents the connector 740 from inadvertently turning thus maintaining the predetermined compressive relationship between the fasteners 720 and 730 and the bones 712 and 714, respectively, connected to each.

Another aspect of the present invention relates to providing an interfragmentary fixation kit as schematically illustrated in FIGURE 107. The interfragmentary fixation kit comprises a collection of first axially elongated fasteners. Each fastener in the collection has an elongated length that is different from the elongated length of other fasteners in the collection. Notably, each fastener in the collection has external threading for anchoring the first fastener into a bone fragment. The configuration of the external threading of each fastener in the collection may differ from other fasteners in the collection. Accordingly, the surgeon is permitted to choose from the interfragmentary fixation kit the appropriate sized fastener. The interfragmentary fixation kit further includes a series of second fasteners. Each of said second fasteners in the series is adapted for attachment in nonmovable relation to the second bone in the patient and has a different configuration than the other fasteners in the series of second fasteners, thus yielding a selection from which the surgeon can chose the most appropriate fastener from the particular

fracture being repaired. Moreover, a set of elongated connectors are provided in combination with the interfragmentary fixation kit. Each connector in the set of connectors has a head portion that accommodates a driving tool and an elongated lengthwise shank portion having external uniformly pitched threading that corresponds to the internal threading of each fastener in the collection of first fasteners. Understandably, the length of the shank portion of each connector in the set of connectors varies from one another to allow various fasteners to be used in combination relative to each other. Accordingly, the surgeon is permitted to mix and match sets of components to the appropriate circumstances which require repair.

Regardless of the particular fixation assembly embodiment used, the multipiece interfragmentary fixation assembly permits first and second bone fragments to be connected under compression. Another important feature of the present invention is that the interfragmentary fixation assembly allows the bone fragments to be interconnected under adjustable compression that is preselected by the surgeon during the connection process. Thus, with the present invention, the surgeon is provided with a "feel" for the level or degree of compression to be established between the fasteners and, thus, bone fragments to promote healing of bone fragments. Although some of the components of the fixation assembly of the present invention are completely buried within the bone substance of the bone fragments requiring repair, a salient feature of the present invention is the provision of a retainer mechanism that maintains the predetermined level of compression between the fasteners by preventing the connector between the fasteners from inadvertently turning.

From the foregoing, it will be observed that numerous modifications and variations can be effected without departing from the true spirit and scope of the novel concept of the present

invention. It will be appreciated that the present disclosure is intended as an exemplification of the invention, and is not intended to limit the invention to the specific embodiment illustrated. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.

WHAT IS CLAIMED IS:

1. A multipiece interfragmentary fixation assembly for connecting portions of bone across a fracture therebetween, said interfragmentary fixation assembly comprising:

a first axially elongated fastener defining an elongated axis and having external threading for anchoring said first fastener into a first bone fragment, said first fastener defining an coaxial opening with internal uniformly pitched threading extending along at least a portion of the length thereof;

a second fastener attachable in non-movable relation with a second bone fragment;

an elongated connector including a head portion that accommodates a tool and a shank portion having external uniformly pitched threading corresponding to the internal threading of said first fastener, and wherein the shank portion of said connector extends endwise through the second fastener and into threaded engagement with said first fastener while the head portion of said connector operably engages with said second fastener such that rotation of said connector draws the first and second fasteners and thereby the first and second bone fragments into compressive and proper relation relative to each other; and

a retaining apparatus for preventing said connector from inadvertently rotating relative to said second fastener thereby maintaining the proper compressive relationship between the fasteners and the bone fragments.

2. The multipiece interfragmentary fixation assembly according to Claim 1 wherein a leading end of said first fastener has a pointed configuration while a trailing end of said first

fastener is configured to accommodate a driving tool capable of turning said first fastener such that the external threading threadably engages with said first bone fragment.

3. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said second fastener has an elongated configuration with external threading for anchoring said second fastener in said second bone fragment.

4. The multipiece interfragmentary fixation assembly according to Claim 3 wherein said second fastener has a coaxial opening extending between leading and trailing ends thereof.

5. The multipiece interfragmentary fixation assembly according to Claim 4 wherein the trailing end of said second fastener is configured to accommodate a driving tool capable of turning said second fastener such that the external threading threadably engages with said second bone fragment.

6. The multipiece interfragmentary fixation assembly according to Claim 4 wherein said retaining apparatus comprises an insert fitted within said coaxial opening and operably associated with said second fastener for preventing inadvertent rotation of said connector thereby maintaining the proper compressive relationship between the fasteners and the bone fragments.

7. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said second fastener comprises a member formed from a bone compatible material and

configured with a generally concave shaped section that is generally centralized between multiple prongs extending radially away from said central section, and an apertured hemi-spherically shaped element that is seated for rocking movement within said central section of said member, and wherein the shank portion of said elongated connector extends endwise through the said member and said element into threaded engagement with said first fastener, with the head portion of said connector being operably engagable with said element such that rotation of said connector draws the member and said first fastener and the respective bone fragments engaged by each toward and into compressive relationship relative to each other.

8. The multipiece interfragmentary fixation assembly according to Claim 7 wherein the concave centralized section of said member defines an enlarged opening that permits said member to rock relative to said connector and said element thereby enhancing attachment of said prongs to said second bone fragment.

9. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said retaining apparatus comprises a non-metallic insert disposed along the length of the coaxial opening of said first fastener for engaging the external threading on said connector and thereby preventing inadvertent rotation of said connector.

10. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said second fastener comprises apertured disk that fits about the shank portion of said connector and operably engages an underside of the head portion of said connector to permit relative

rotation therebetween, the apertures in said disk permitting said second bone fragment to be attached thereto.

11. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said second fastener comprises an elongated member having first and second ends and an axial bore for allowing the shank portion of said connector to extend endwise therethrough and into threaded engagement with said first fastener, the elongated member of said second fastener further including a bone fragment retainer extending radially away from said elongated member.

12. The multipiece interfragmentary fixation assembly according to Claim 11 wherein the elongated member of said second fastener has a generally cylindrical configuration between opposite ends thereof.

13. The multipiece interfragmentary fixation assembly according to Claim 11 wherein the elongated member of said second fastener has a frusto-conical configuration between opposite ends thereof.

14. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said second fastener comprises a plate having upper and lower generally parallel surfaces with an indentation having a closed margin defined by said plate and including a wall depending at an acute angle relative to the upper surface of said plate, said wall defining an aperture through which the shank portion of said connector extends into threaded engagement with the internal

threading of said first fastener while the wall of said indentation maintains the head portion on an opposite side of said plate from said first fastener.

15. A multipiece interfragmentary fixation assembly for interconnecting first and second bone fragments to each other across a fracture defined therebetween, said interfragmentary fixation assembly comprising:

a first axially elongated fastener formed from a bone compatible material and having external threading for anchoring said first fastener within an interior of the first bone fragment, said first fastener defining an opening with internal uniformly pitched threading;

a second fastener formed from a bone compatible material and attachable to an exterior of the second bone fragment, said second fastener comprising a member configured with a generally concave shaped and apertured section that is generally centralized between prongs extending radially outward and away from the central section of said member, said second fastener further including an apertured hemi-spherically shaped element configured to rockingly seat within the central section of said member;

an elongated screw connector including an enlarged head portion that accommodates a driving tool and an elongated threaded shank portion having external uniform pitched threading extending over the length thereof corresponding to the internal threading of said first fastener, and wherein the shank portion of said connector extends endwise through the apertured element and the apertured center section of the member of said second fastener and into threaded engagement with said internal threading of said first fastener while the enlarged head portion of said connector operably engages with the element of said second fastener such that rotation of

said connector draws the first and second fasteners and thereby the first and second bone fragments toward and into preselected compressive relationship relative to each other, and wherein the apertured center section of the member of said second fastener is configured to allow said member to rock relative to said element with the connector passing therethrough to enhance the ability of the prongs of said member to positively engage the exterior of said second bone fragment to the fullest extend possible; and

wherein said first fastener further includes a retaining apparatus arranged along the internal threading thereof for operably engaging the external threading of said connector and thereby preventing inadvertent rotation of said connector thus maintaining the preselected compressive relationship between said first and second fasteners and the first and second bone fragments attached thereto.

16. The multipiece interfragmentary fixation assembly according to Claim 15 wherein said retaining apparatus comprises a non-metallic ring arranged along the length of the internal threading of said first fastener for operably engaging the external threading of said connector and thereby preventing inadvertent rotation of said connector thus maintaining the preselected compressive relationship between the first and second fasteners.

17. A multipiece interfragmentary fixation assembly for connecting portions of bone across a fracture therebetween, said interfragmentary fixation assembly comprising:

an axially elongated fastener having external threading for anchoring said first fastener into a first bone fragment, said first fastener defining a coaxial opening with internal uniformly pitched threading extending the length thereof;

a generally planar member having upper and lower generally parallel surfaces, said planar member defining a generally centralized throughbore with a plurality of apertures arranged in generally circumferential relation relative to said throughbore;

an elongated connector including an enlarged head portion that accommodates a driving tool and is configured to prevent its movement through said throughbore of said planar member but is smaller than the spacings between opposed apertures defined by said planar member, said connector further including a shank portion defining an elongated axis and that is sized to extend endwise through said throughbore defined by said planar member whereby said planar member is free to turn beneath said enlarged head of said member about said axis defined by said shank portion, and wherein said shank portion has external uniformly pitched threading corresponding to the internal threading of said first fastener; and

a retaining apparatus arranged along the internal threading thereof for operably engaging the external threading of said connector and thereby preventing inadvertent rotation of said connector relative to said fastener.

18. A multipiece interfragmentary fixation assembly for interconnecting first and second bone fragments, comprising:

a first bone screw having external threading for anchoring said first bone screw in said first bone fragment, said first bone screw defining an axial bore having uniformly pitched internal threading along the majority length thereof;

a second bone screw having external threading for anchoring said second bone screw in said second bone fragment, said second bone screw defining an axial bore extending therethrough;

an elongated connector including a head portion that is configured to accommodate a tool and an elongated shank portion with external uniformly pitched threading that corresponds to the internal threading of said first screw, and wherein the shank portion of said connector extends endwise through the axial bore defined by said second fastener and into threaded engagement with said the axial bore defined in said first fastener while the head of the connector operable engages with the second fasteners such that rotation of said connector draws said first and second fasteners and thereby the first and second bone fragments toward and into compressive relationship relative to each other; and

a retainer apparatus for preventing said connector from turning relative to said second fastener thereby maintaining the proper compressive relationship between the fasteners and the bone fragments.

19. The multipiece interfragmentary fixation assembly according to Claim 18 wherein a first end of said first bone screw has a pointed configuration while a second end of said first bone screw is configured to accommodate a driving tool capable of turning said first bone screw such that the external threading engages with said first bone fragment.

20. The multipiece interfragmentary fixation assembly according to Claim 18 wherein the external threading on said first and second bone screws generally correspond relative to each other.

21. The multipiece interfragmentary fixation assembly according to Claim 18 wherein a trailing end of the axial bore defined by said second bone screw is configured to accommodate a driving tool capable of turning said second bone screw such that the external threading threadably engages with said second bone fragment.

22. The multipiece interfragmentary fixation assembly according to Claim 18 wherein the axial bore defined by said second bone screw has a first lengthwise portion that opens to a trailing end of said second bone screw and has a non-circular cross-sectional configuration that is sized to allow the head portion and shank portion of said connector to pass endwise therethrough and a second lengthwise portion that opens to a leading end of said second bone screw and is sized to allow only said shank portion of said connector to pass endwise therethrough.

23. The multipiece interfragmentary fixation assembly according to Claim 22 wherein said retainer apparatus comprises a element having a cross-sectional configuration generally corresponding to the cross-section of the first portion of the axial bore defined by said second bone screw whereby said element is prevented from turning relative to said second bone screw, said element having a pliant annular ring that operably engages with said second bone screw for

preventing the connector from inadvertently turning in a direction whereby loosening the compressive relationship between the fasteners beyond a preset amount.

24. The multipiece interfragmentary fixation assembly according to Claim 22 wherein the head portion of said connector defines a socket and an annular recess radially extending outwardly from the socket, and wherein said retainer apparatus comprises an element having a cross-sectional configuration generally corresponding to the cross-section of the first portion of the axial bore defined by said second bone screw whereby said element is prevented from turning relative to said second bone screw, said element having a pliant annular ring that operably engages with the annular recess in the socket defined by said connector, and wherein said element further includes a finger that axially extends from said element into said socket and operably engages with said connector for preventing said connector from turning relative to said second member.

25. The multipiece interfragmentary fixation assembly according to Claim 24 wherein said element includes a plurality of fingers that axially extend from one end of said element and into the socket and operable engagement with said connector for preventing inadvertent turning movement of said connector relative to said second bone screw.

26. The multipiece interfragmentary fixation assembly according to Claim 18 wherein said retaining apparatus comprises a non-metallic insert disposed along the length of the internal

threading of said axial bore for engaging the external threading on said connector and thereby preventing inadvertent rotation of said connector.

27. A multipiece interfragmentary fixation assembly for interconnecting first and second bone fragments, comprising:

a first bone screw having external threading axially extending away from a proximal end of said first screw along a lengthwise portion of said screw for anchoring said first bone screw in said first bone fragment and a reduced diameter portion extending from said external threading to a distal end of said first screw, with said reduced diameter portion of said screw having an axially tapering configuration along an outer surface thereof, said first bone screw defining an axial bore having uniformly pitched internal threading along the majority length thereof;

a second bone screw having external threading axially extending away from a distal end of said second screw and along a lengthwise portion of said second screw for anchoring said second bone screw in said second bone fragment and a reduced diameter portion extending from said external threading to a proximal end of said second screw, said second bone screw defining an axial bore extending therethrough, and wherein the axial bore defined by said second screw includes a counterbore portion extending axially away from the distal end of said screw, said counterbore having an axially tapered configuration that complements the tapered configuration on the reduced diameter portion of said first screw;

an elongated connector including a head portion that is configured to accommodate a tool and an elongated shank portion with external uniformly pitched threading that corresponds to the

internal threading of said first screw, and wherein the shank portion of said connector extends endwise through the axial bore defined by said second fastener and into threaded engagement with said the axial bore defined in said first fastener while the head of the connector operable engages with the second fasteners such that rotation of said connector draws said first and second fasteners and thereby the first and second bone fragments toward and into a predetermined compressive relationship relative to each other and with the reduced diameter portion of said first screw fitting axially into the counterbore portion defined by said second screw whereby effecting alignment of the bone fragments relative to each other.

28. The multipiece interfragmentary fixation assembly according to Claim 27 further including a retaining apparatus for preventing said connector from inadvertently rotating relative to said bone screws thereby maintaining the predetermined compressive relationship between the screws and the bone fragments attached thereto.

29. The multipiece interfragmentary fixation assembly according to Claim 27 wherein a trailing end of the axial bore defined by said second bone screw is configured to accommodate a driving tool capable of turning said second bone screw such that the external threading threadably engages with said second bone fragment.

30. The multipiece interfragmentary fixation assembly according to Claim 27 wherein the axial bore defined by said second bone screw has a first lengthwise portion that opens to a trailing end of said second bone screw and has a non-circular cross-sectional configuration that

is sized to allow the head portion and shank portion of said connector to pass endwise therethrough and a second lengthwise portion that opens to a leading end of said second bone screw and is sized to allow only said shank portion of said connector to pass endwise therethrough.

31. The multipiece interfragmentary fixation assembly according to Claim 30 wherein said retainer apparatus comprises a element having a cross-sectional configuration generally corresponding to the cross-section of the first portion of the axial bore defined by said second bone screw whereby said element is prevented from turning relative to said second bone screw, said element having a pliant annular ring that operably engages with an annular grove disposed along the length of said first portion of said axial bore defined by said second bone screw for preventing the connector from inadvertently turning in a direction whereby loosening the compressive relationship between the fasteners beyond a preset amount.

32. The multipiece interfragmentary fixation assembly according to Claim 30 wherein the head portion of said connector defines a socket and an annular recess radially extending outwardly from the socket, and wherein said retainer apparatus comprises an element having a cross-sectional configuration generally corresponding to the cross-section of the first portion of the axial bore defined by said second bone screw whereby said element is prevented from turning relative to said second bone screw, said element having a pliant annular ring that operably engages with the annular recess in the socket defined by said connector, and wherein said element further includes a finger that axially extends from said element into said socket and

operably engages with said connector for preventing said connector from turning relative to said second member.

33. The multipiece interfragmentary fixation assembly according to Claim 32 wherein said element includes a plurality of fingers that axially extend from one end of said element and into the socket and operable engagement with said connector for preventing inadvertent turning movement of said connector relative to said second bone screw.

34. The multipiece interfragmentary fixation assembly according to Claim 28 wherein said retaining apparatus comprises a non-metallic insert disposed along the length of said coaxial opening for engaging the external threading on said connector and thereby preventing inadvertent rotation of said connector.

35. A multipiece interfragmentary fixation assembly for connecting fragments of bone across a fracture therebetween, said interfragmentary fixation assembly comprising:

a first axially elongated fastener with external threading for anchoring said first fastener into a first bone fragment;

a second fastener configured for non-movable attachment to a second bone fragment; and

a rotatable and elongated connector for drawing the first and second fasteners and thereby the bone fragments attached to each into compressive and proper relationship relative to each other, with the connector and said first fastener being threadably interconnected to each other along at least a portion of their length, and wherein at least a portion of the threadable

connection being configured to prevent the connector from inadvertently rotating relative to said first fastener thereby maintaining the proper compressive relationship between the fasteners and the bone fragments.

36. The multipiece interfragmentary fixation assembly according to Claim 35 wherein a leading end of said first fastener has a pointed configuration while a trailing end of said first fastener is configured to accommodate a driving tool capable of turning said first fastener such that the external threading threadably engages with said first bone fragment.

37. The multipiece interfragmentary fixation assembly according to Claim 35 wherein said second fastener has an elongated configuration with external threading for anchoring said second fastener in said second bone fragment.

38. The multipiece interfragmentary fixation assembly according to Claim 37 wherein said second fastener has a coaxial opening extending between leading and trailing ends thereof.

39. The multipiece interfragmentary fixation assembly according to Claim 38 wherein the trailing end of said second fastener is configured to accommodate a driving tool capable of turning said second fastener such that the external threading threadably engages with said second bone fragment.

40. The multipiece interfragmentary fixation assembly according to Claim 35 wherein said second fastener comprises a member formed from a bone compatible material and configured with a generally concave shaped section that is generally centralized between multiple prongs extending radially away from said central section, and an apertured hemi-spherically shaped element that is seated for rocking movement within said central section of said member, and wherein a shank portion of said elongated connector extends endwise through the said member and said element into threaded engagement with said first fastener, with a head portion of said connector being operably engagable with said element such that rotation of said connector draws the member and said first fastener and the respective bone fragments engaged by each toward and into compressive relationship relative to each other.

41. The multipiece interfragmentary fixation assembly according to Claim 40 wherein the concave centralized section of said member defines an enlarged opening that permits said member to rock relative to said connector and said element thereby enhancing attachment of said prongs to said second bone fragment.

42. The multipiece interfragmentary fixation assembly according to Claim 35 wherein said second fastener comprises an apertured disk that fits about a shank portion of said connector and operably engages an underside of a head portion of said connector to permit relative rotation therebetween, the apertures in said disk permitting said second bone fragment to be attached thereto.

43. The multipiece interfragmentary fixation assembly according to Claim 35 wherein said second fastener comprises an elongated member having first and second ends and an axial bore for allowing a shank portion of said connector to extend endwise therethrough and into threaded engagement with said first fastener, the elongated member of said second fastener further including a bone fragment retainer extending radially away from said elongated member.

44. The multipiece interfragmentary fixation assembly according to Claim 35 wherein the elongated member of said second fastener has a generally cylindrical configuration between opposite ends thereof.

45. The multipiece interfragmentary fixation assembly according to Claim 35 wherein said second fastener comprises a plate having upper and lower generally parallel surfaces with an indentation having a closed margin defined by said plate and including a wall depending at an acute angle relative to the upper surface of said plate, said wall defining an aperture through which a shank portion of said connector extends into threaded engagement with the internal threading of said first fastener while the wall of said indentation maintains a head portion of said connector on an opposite side of said plate from said first fastener.

46. A multipiece interfragmentary fixation assembly for interconnecting first and second bone fragments to each other across a fracture defined therebetween, said interfragmentary fixation assembly comprising:

a first axially elongated fastener formed from a bone compatible material and having external threading for anchoring said first fastener within an interior of the first bone fragment;

a second fastener formed from a bone compatible material and attachable to an exterior of the second bone fragment, said second fastener comprising a member configured with a generally concave shaped and apertured section that is generally centralized between prongs extending radially outward and away from the central section of said member, said second fastener further including an apertured hemi-spherically shaped element configured to rockingly seat within the central section of said member;

an elongated screw connector including an enlarged head portion that accommodates a driving tool and an elongated and externally threaded shank portion extending endwise through the apertured element and the apertured center section of the member of said second fastener and into threaded engagement with internal threading of said first fastener while the enlarged head portion of said connector operably engages with the element of said second fastener such that rotation of said connector draws the first and second fasteners and thereby the first and second bone fragments toward and into preselected compressive relationship relative to each other, and wherein the apertured center section of the member of said second fastener is configured to allow said member to rock relative to said element with the connector passing therethrough to enhance the ability of the prongs of said member to positively engage the exterior of said second bone fragment to the fullest extend possible, and wherein at least a lengthwise portion of the internal threading of said fastener is configured such that when the preselected compressive relationship is established between the fasteners the external threading on the connector is wedged against the internal threading of the first fastener to prevent inadvertent rotation of the

connector thereby maintaining the preselected compressive relationship between the fasteners and the bone fragments connected thereto.

47. A multipiece interfragmentary fixation assembly for interconnecting first and second bone fragments, comprising:

a first bone screw having external threading axially extending away from a proximal end of and along a lengthwise portion of said first bone screw for anchoring said first bone screw to said first bone fragment;

a second bone screw having external threading along a lengthwise portion thereof for anchoring said second bone screw in said second bone fragment, said second bone screw defining an axial bore extending therethrough; and

an elongated screw connector including an enlarged head portion that accommodates a driving tool and an elongated and externally threaded shank portion extending endwise through the axial bore of said second bone screw and into threaded engagement with internal threading of said first bone screw while the enlarged head portion of said connector operably engages with the second bone screw such that rotation of said connector draws the first and second bone screws and thereby the first and second bone fragments toward and into preselected compressive relationship relative to each other, and wherein at least a lengthwise portion of the internal threading of said first bone screw is configured such that when the preselected compressive relationship is established between the bone screws the external threading on the connector is wedged against the internal threading of the first bone screw to prevent inadvertent rotation of

the connector thereby maintaining the preselected compressive relationship between the bone screws and the bone fragments connected thereto.

48. The interfragmentary fixation assembly according to Claim 47 wherein the internal threading defined by said first bone screw further includes a wedge ramp at a root of each thread defined by said first bone screw.

49. The interfragmentary fixation assembly according to Claim 1 wherein said retaining apparatus comprises a unidirectional thread form extending axially along the internal threading defined by said first elongated fastener such that crest areas of the external threading on said connector coact therewith in a manner preventing the connector form inadvertently rotating relative to said second fastener.

50. An interfragmentary fixation kit, comprising:

a collection of first axially elongated fasteners, each fastener in said collection having an elongated length that is different from the elongated length of another fastener in said collection, and with each fastener in said collection having external threading for anchoring said first fastener into a first bone fragment, and wherein each fastener in said collection of fasteners having a coaxial bore extending therethrough with internal uniformally pitched threading extending the length of said bore;

a series of second fasteners, with each fastener in said series of fasteners being adapted for attachment in non-movable relation relative to a second bone fragment and having a different configuration than the other fasteners in said series of second fasteners;

a set of elongated connectors, each connector in said set of connectors having a head portion that accommodates a driving tool and an elongated lengthwise shank portion having external uniformly pitched threading corresponding to the internal threading of each fastener in said collection of first fasteners, and wherein the length of the shank portion of each connector in said set of connectors varies from one another, and wherein the shank portion of each connector in said set of connectors is configured to extend endwise through each fastener in said series of second fasteners and into threaded engagement with the internal threading of a fastener chosen from said collection of first fasteners while the head portion of said connector is adapted to operably engage with a second fastener chosen from said series of second fasteners such that rotation of the connector draws the first and second fasteners chosen from said collection of first fasteners and the series of second fasteners into a predetermined compressive relationship relative to each other and thereby drawing the bone fragments attached to the respective fasteners into a predetermined compressive relationship relative to each other.

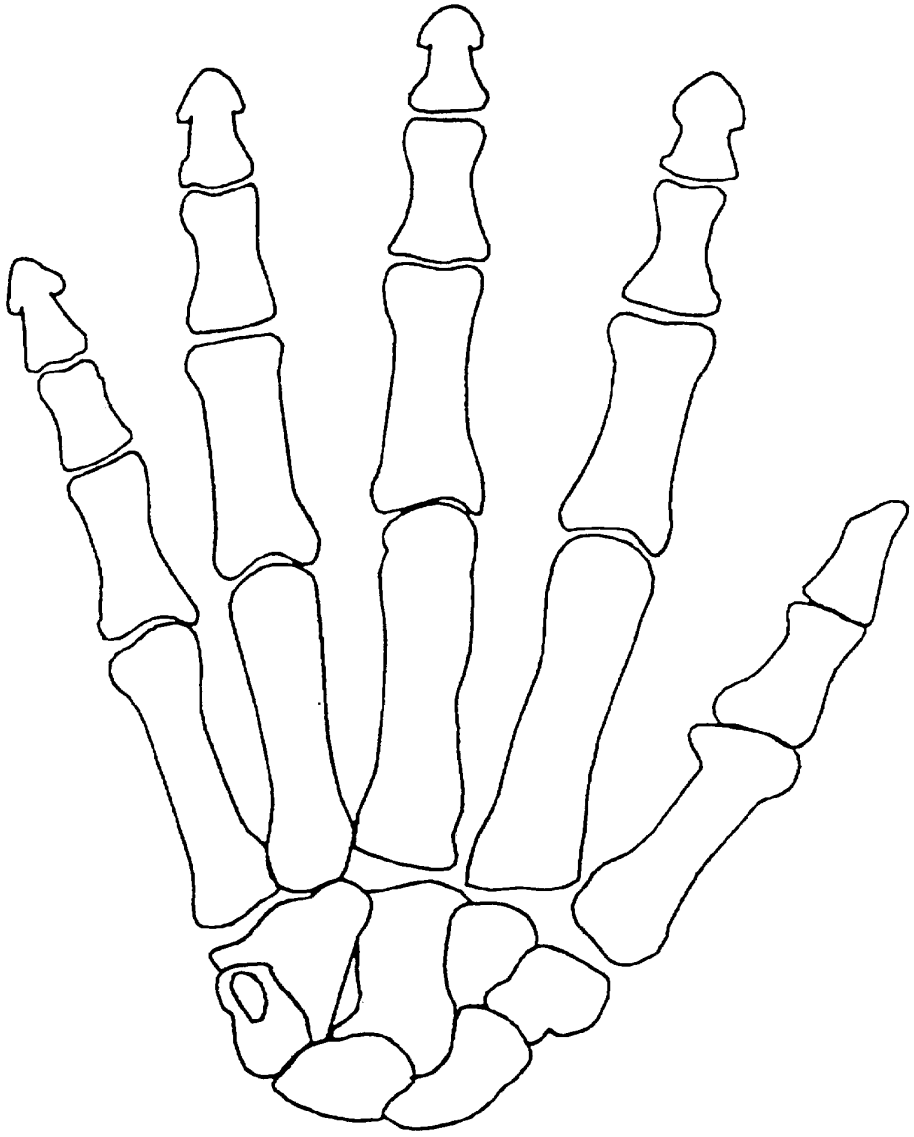
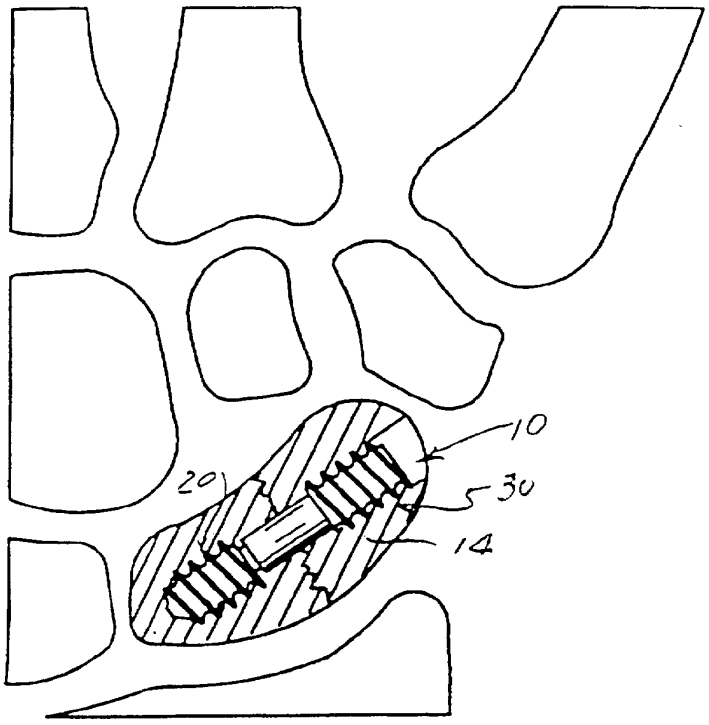


FIG. 1



2 FIG. 2

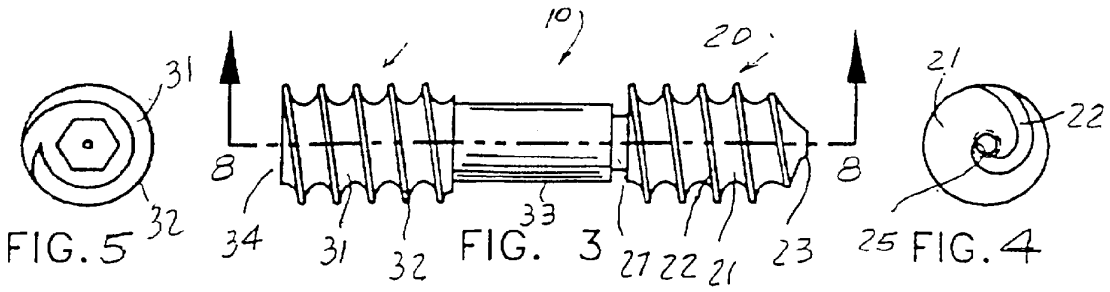


FIG. 5 FIG. 3 FIG. 4

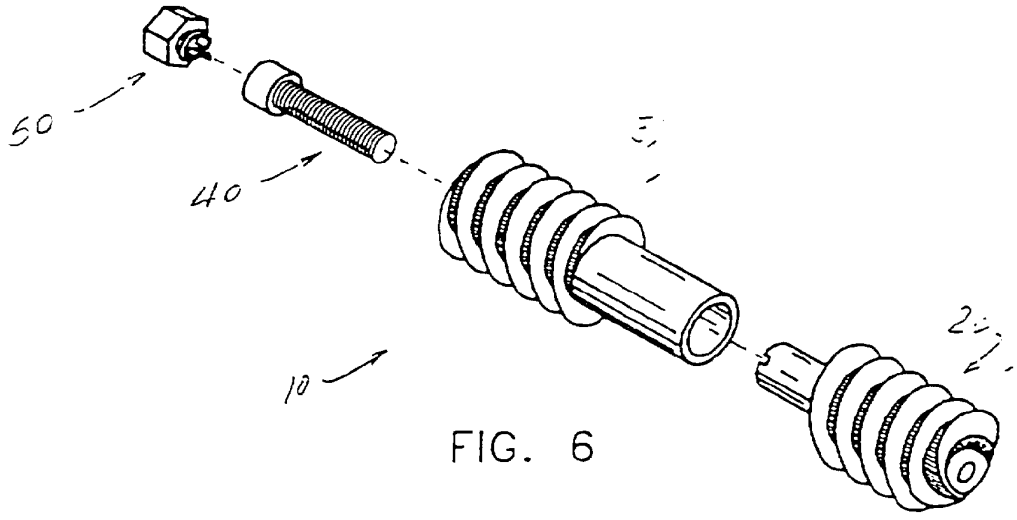


FIG. 6

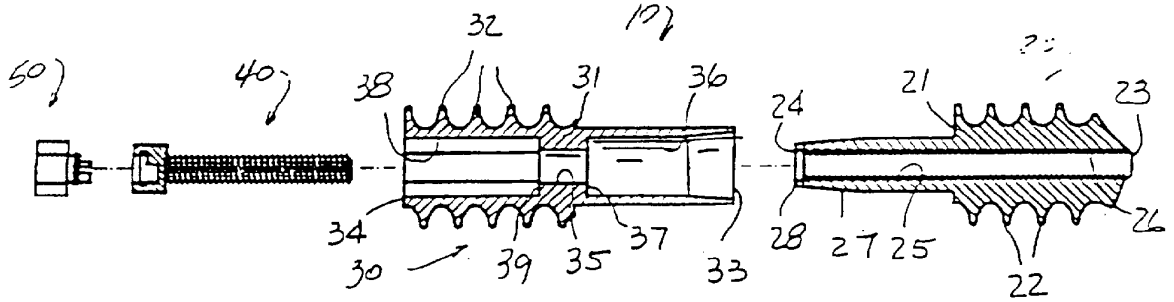


FIG. 7

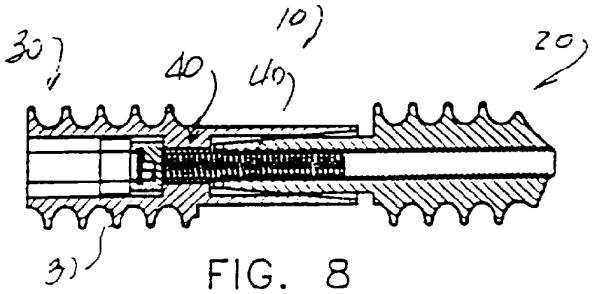


FIG. 8

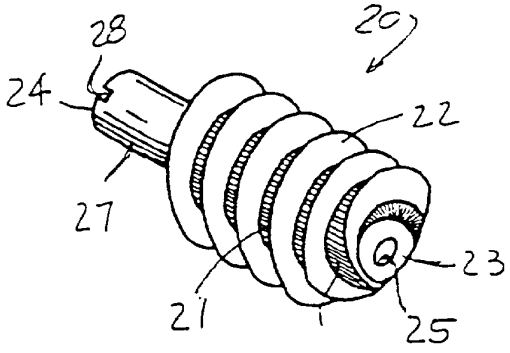


FIG. 9

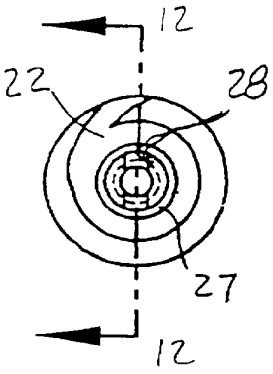


FIG. 10

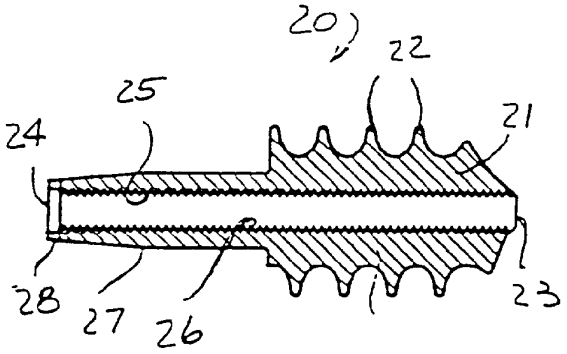


FIG. 12

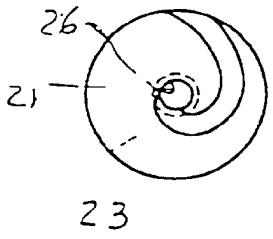


FIG. 11

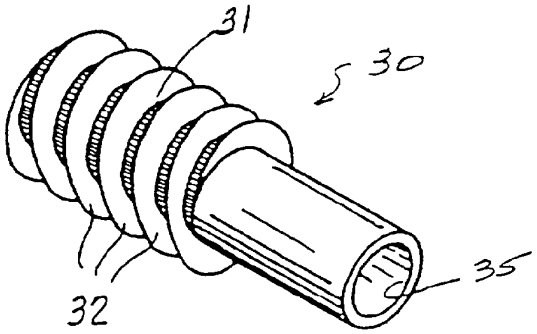


FIG. 13

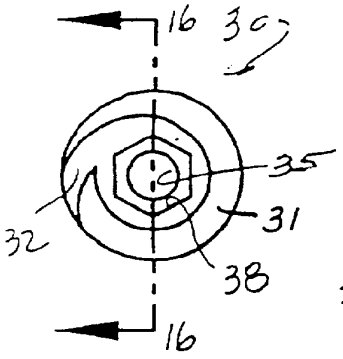


FIG. 14

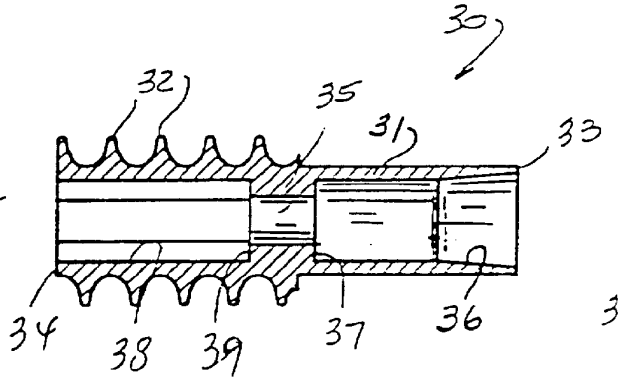


FIG. 16

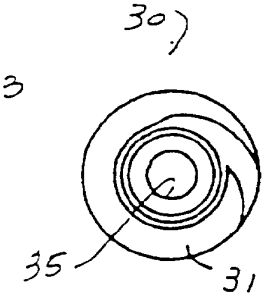


FIG. 15

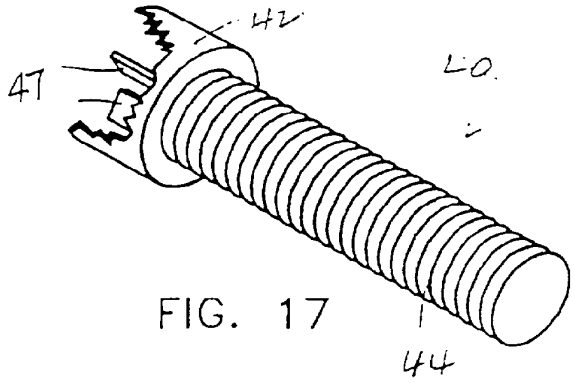


FIG. 17

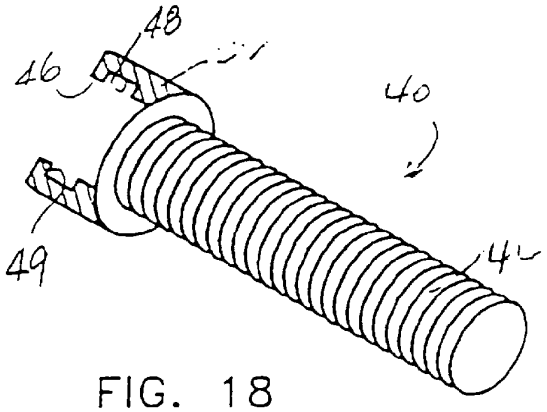


FIG. 18

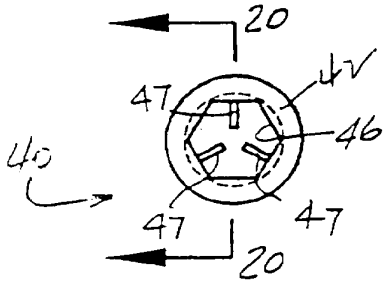


FIG. 19

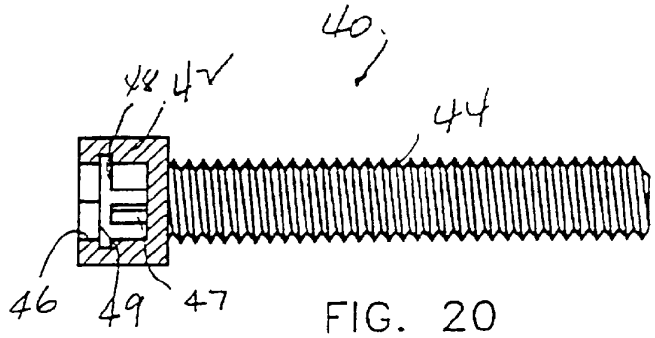


FIG. 20

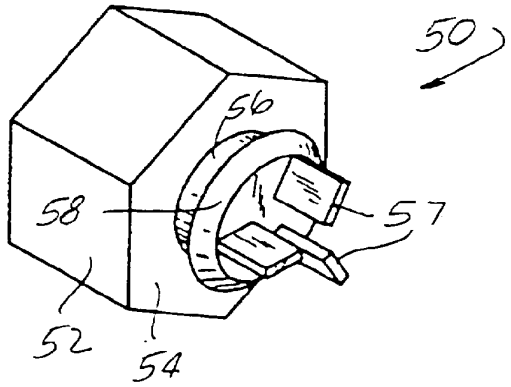


FIG. 21

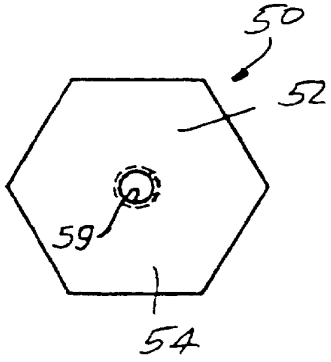


FIG. 23

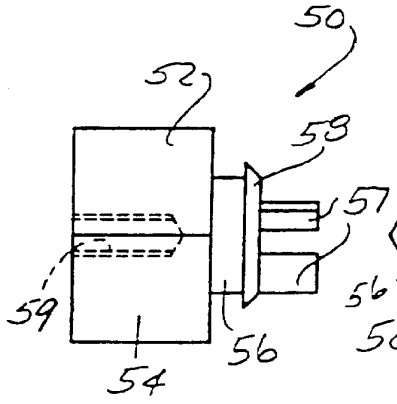


FIG. 22

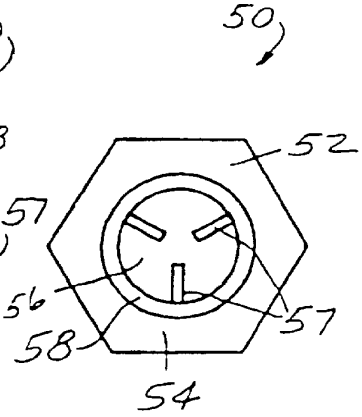


FIG. 24

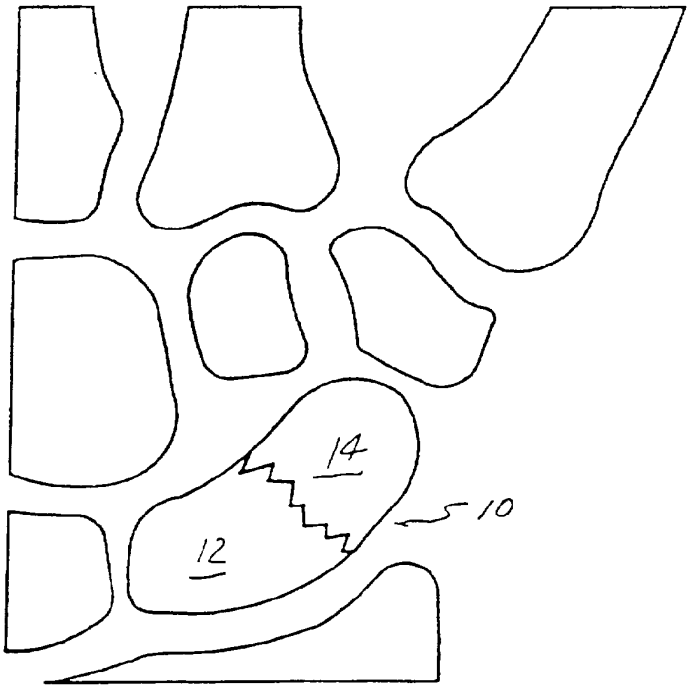


FIG. 25

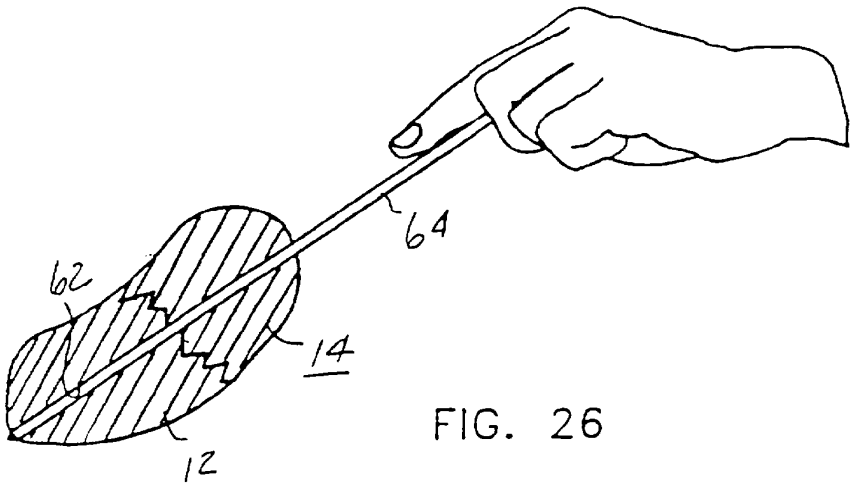


FIG. 26

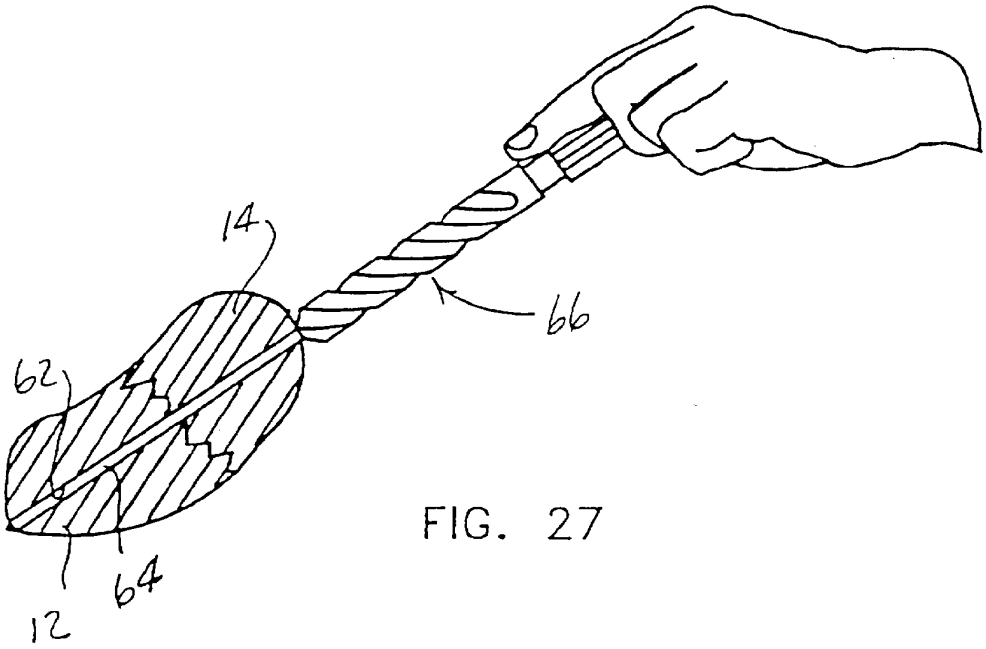


FIG. 27

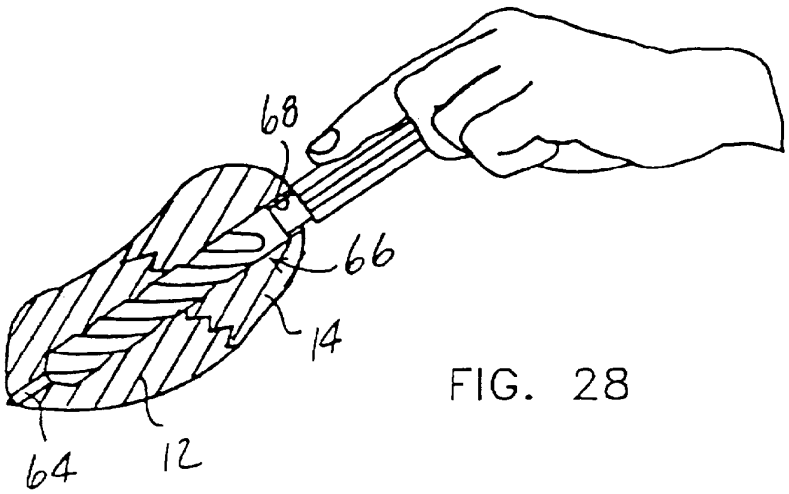


FIG. 28

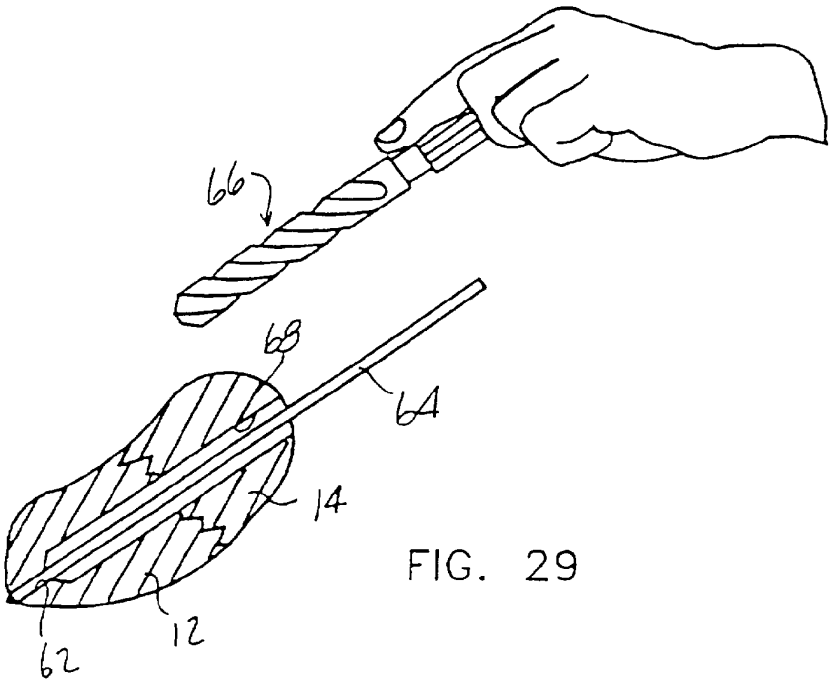


FIG. 29

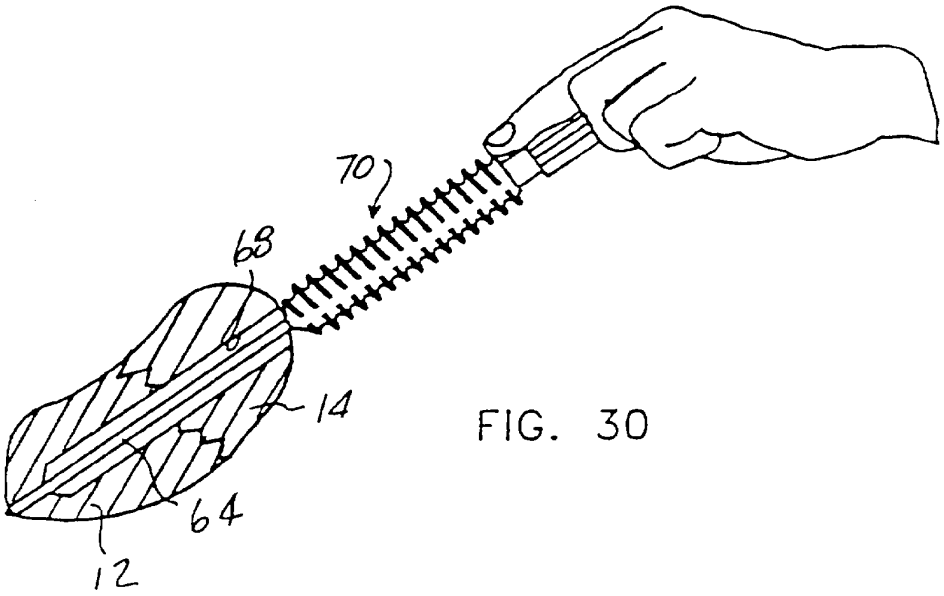


FIG. 30

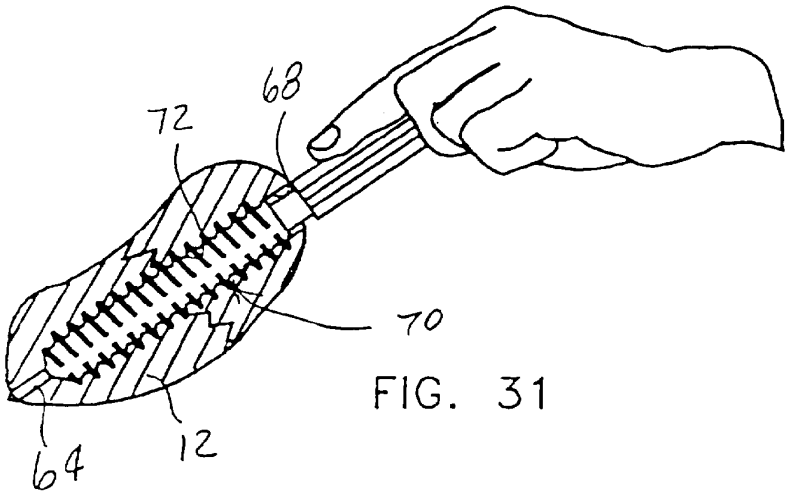


FIG. 31

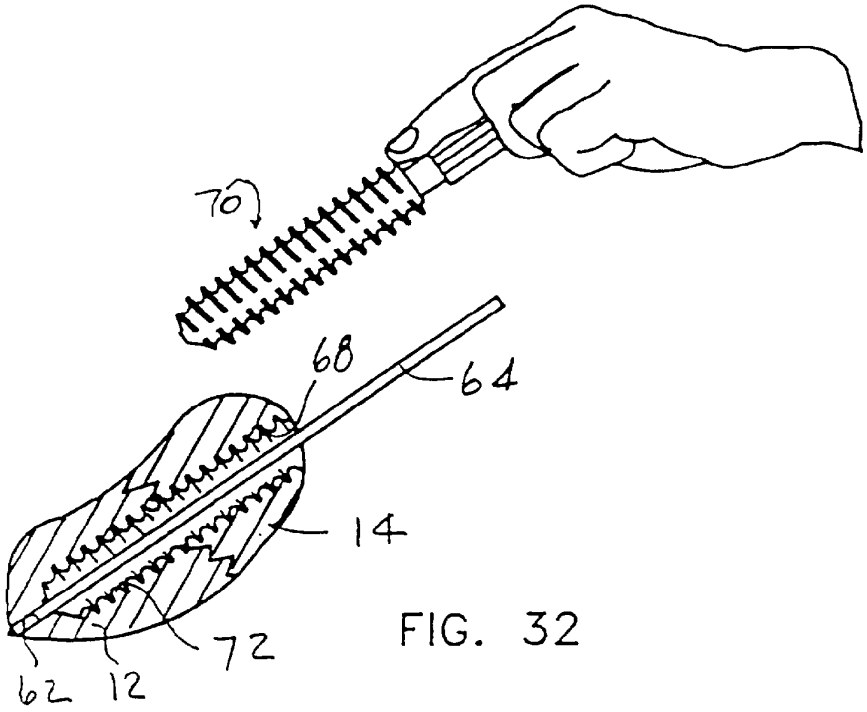


FIG. 32

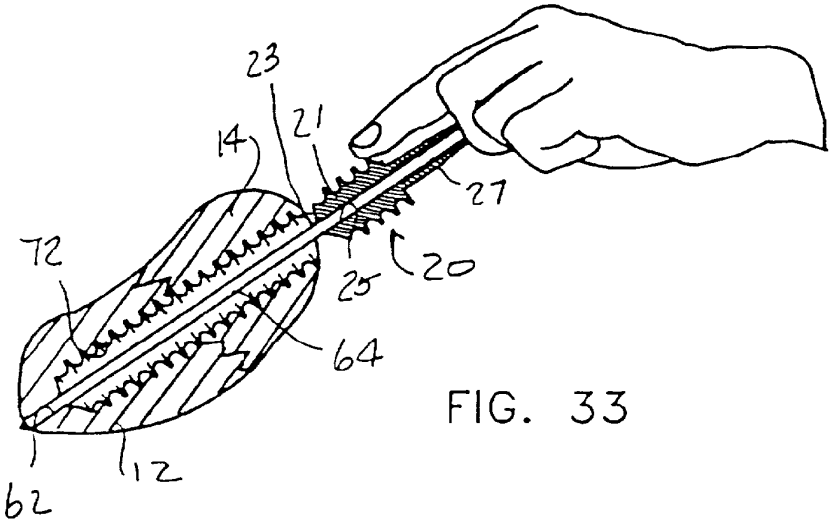


FIG. 33

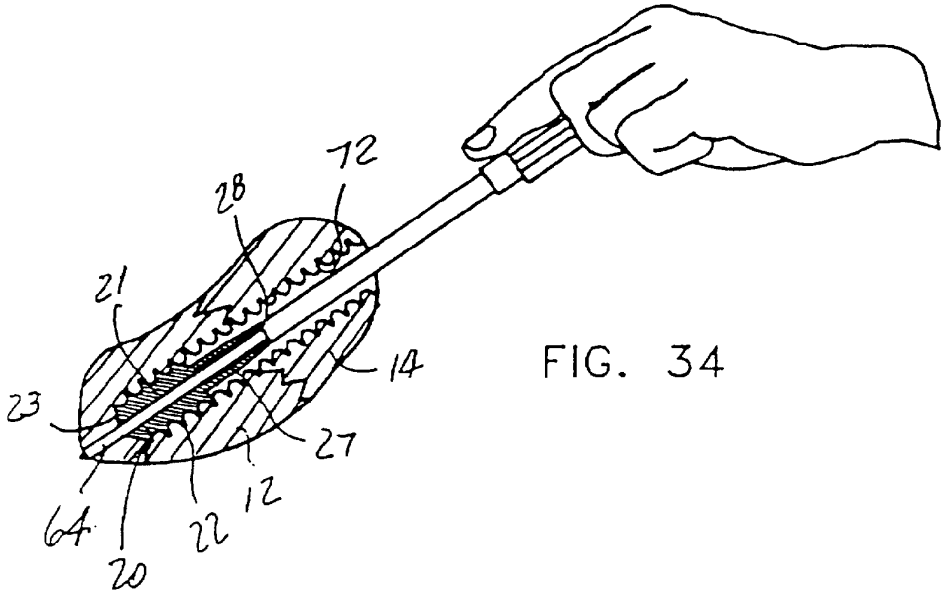


FIG. 34

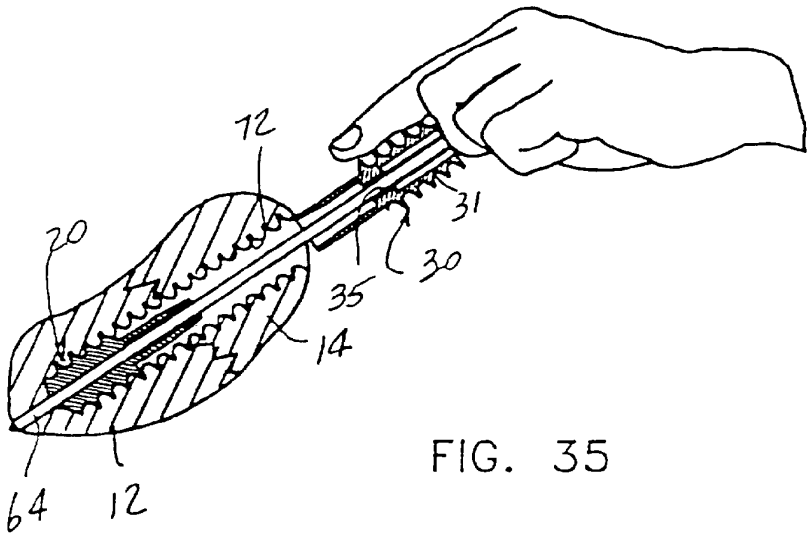


FIG. 35

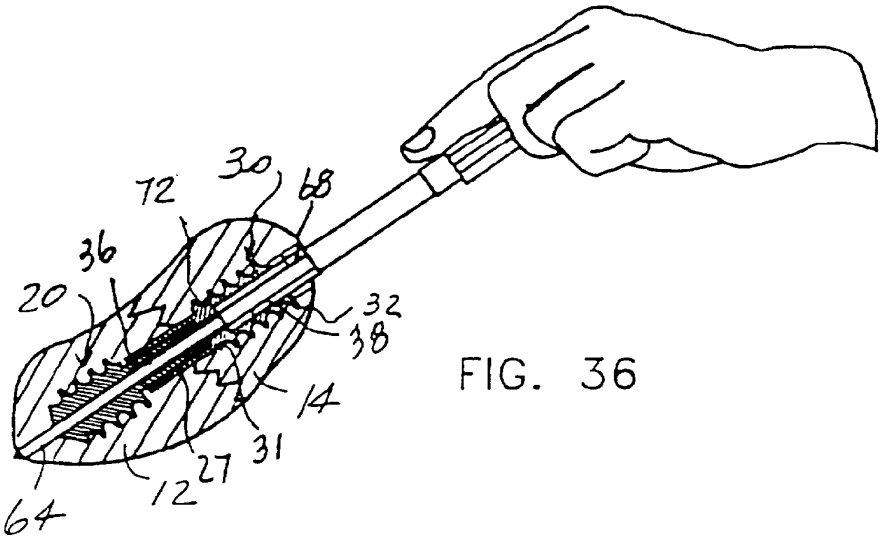


FIG. 36

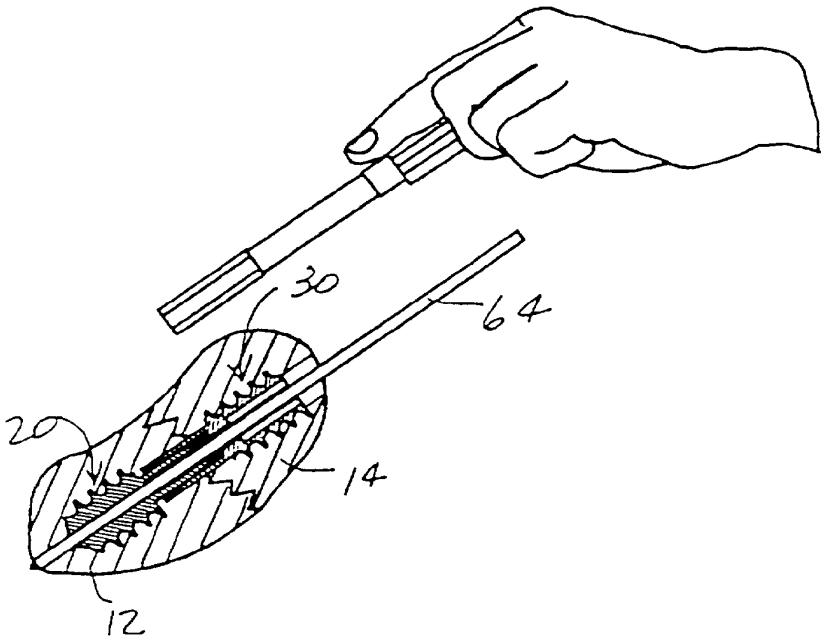


FIG. 37

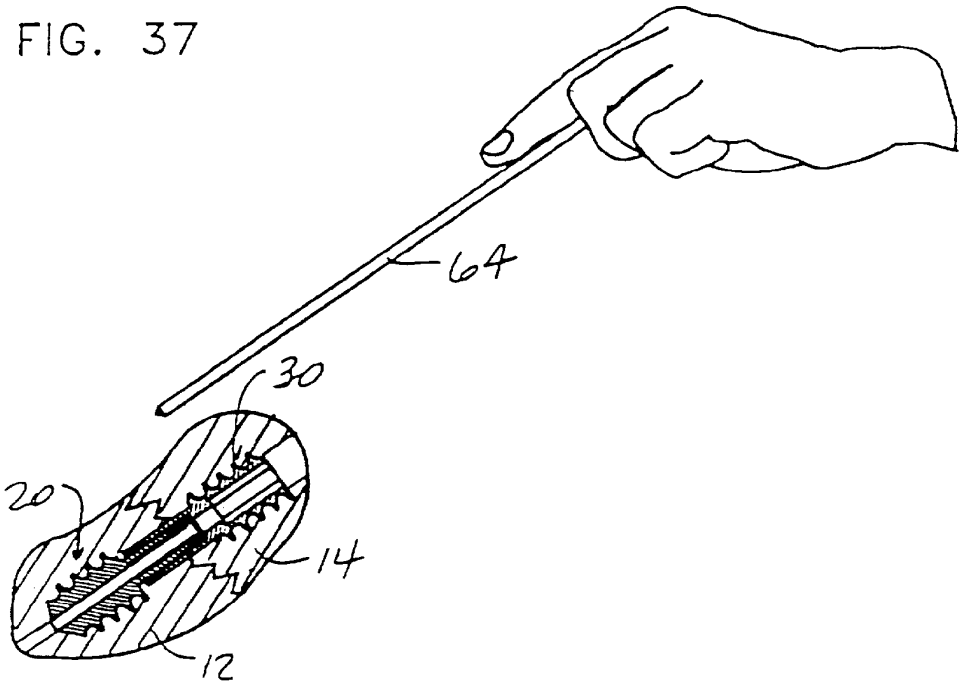


FIG. 38

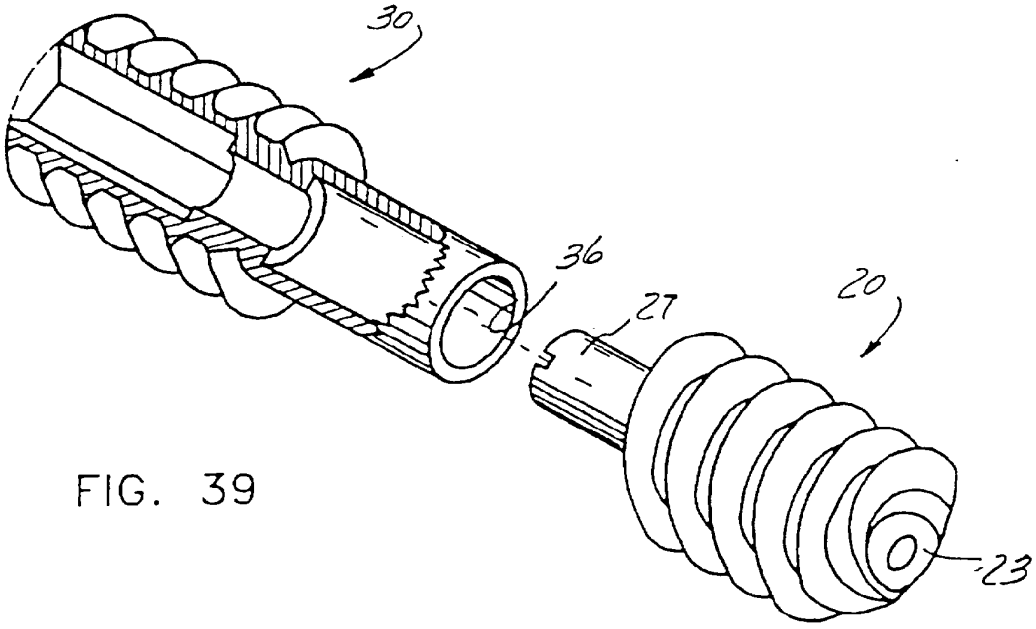


FIG. 39

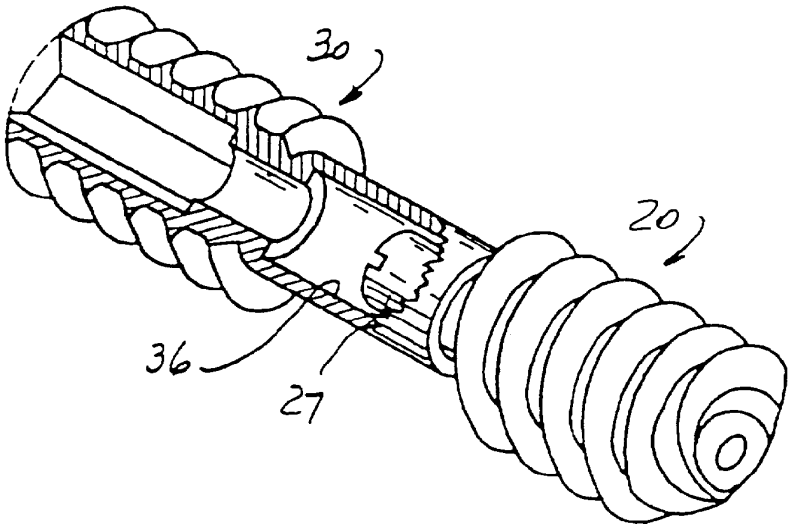


FIG. 40

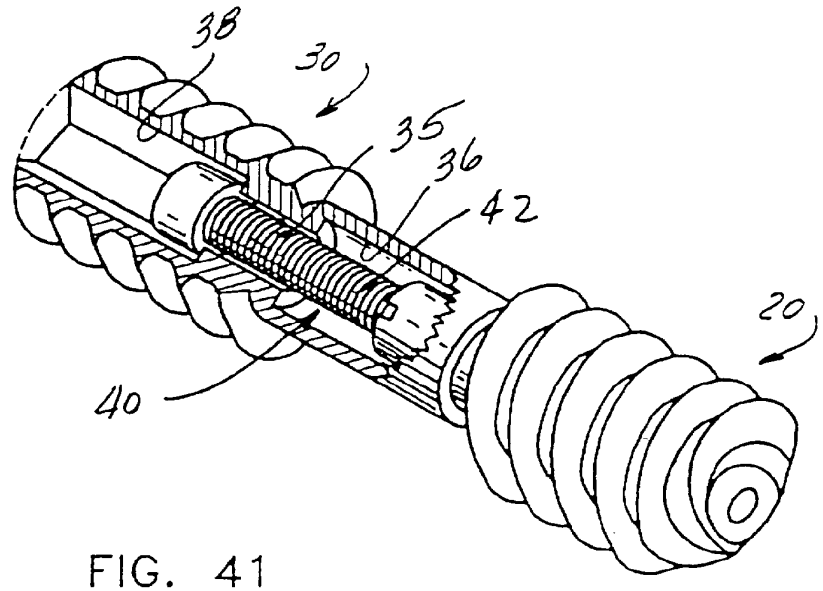


FIG. 41

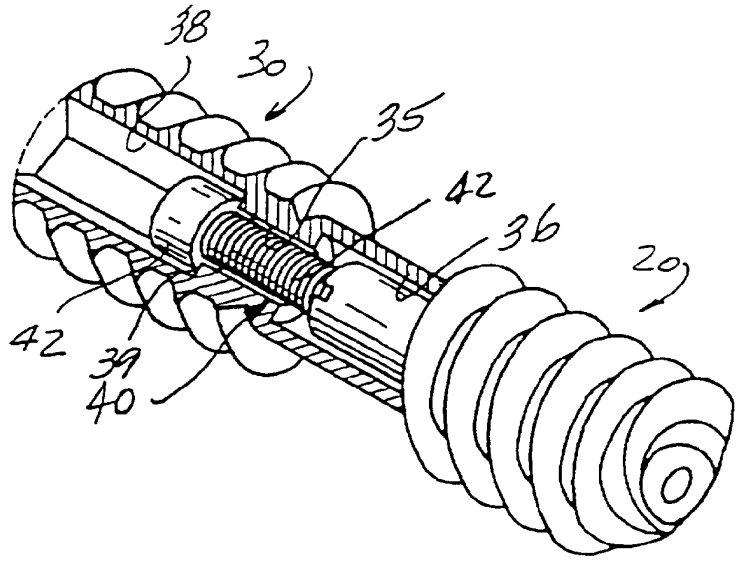


FIG. 42

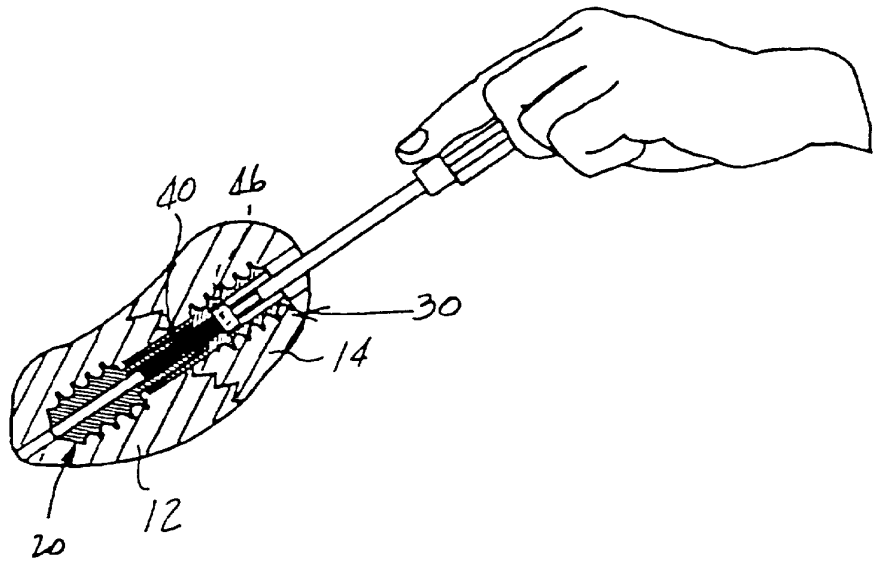


FIG. 43

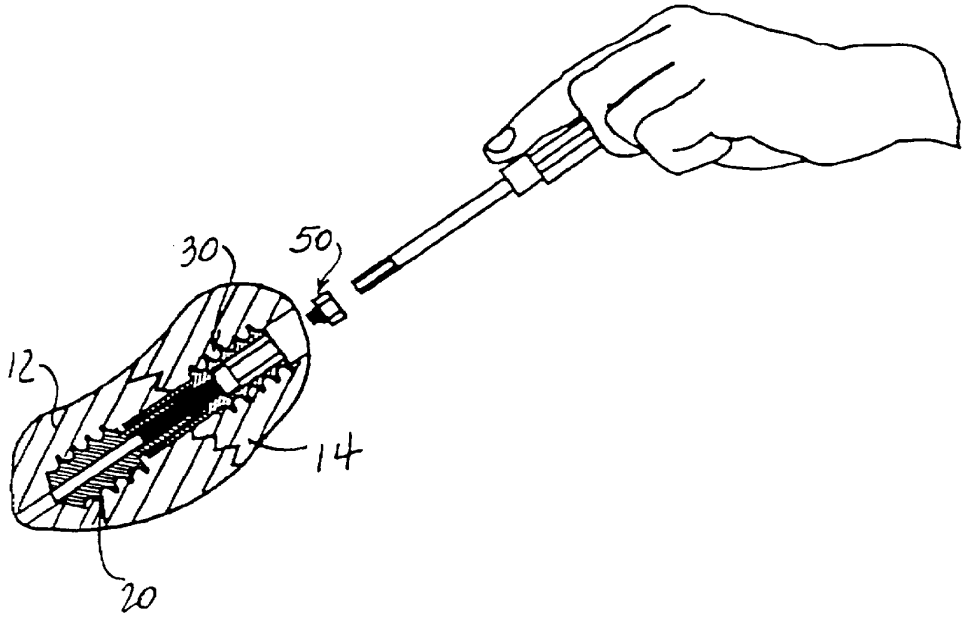


FIG. 44

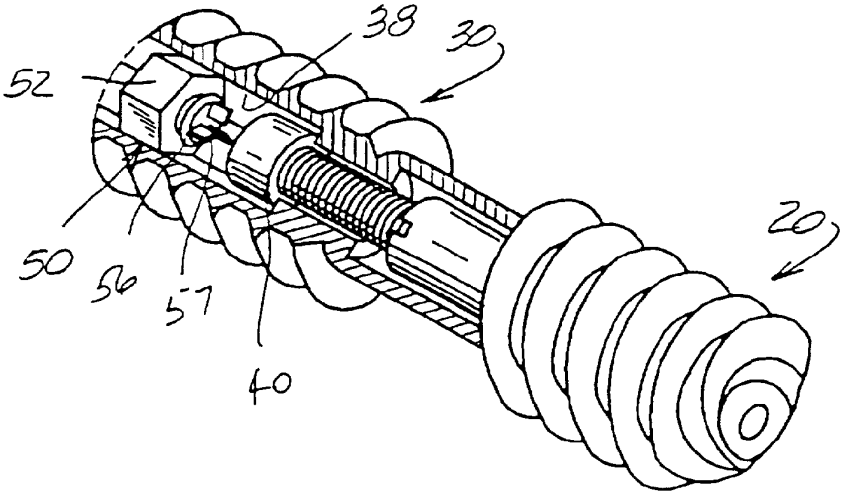


FIG. 45

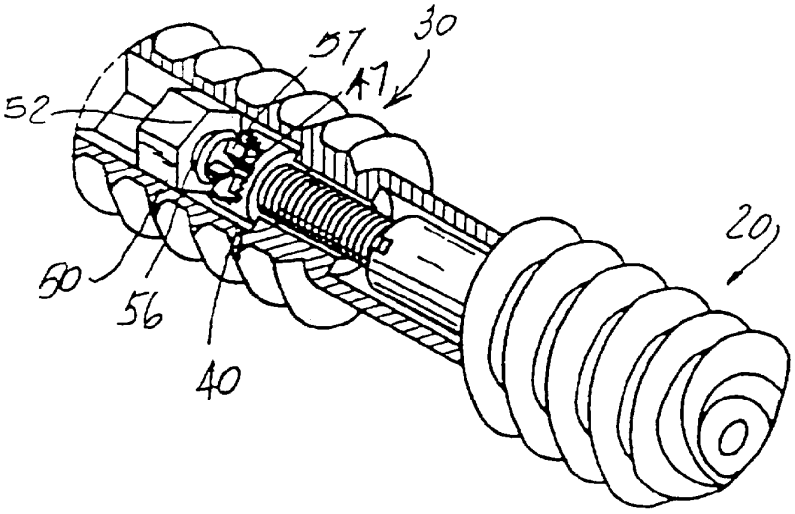


FIG. 46

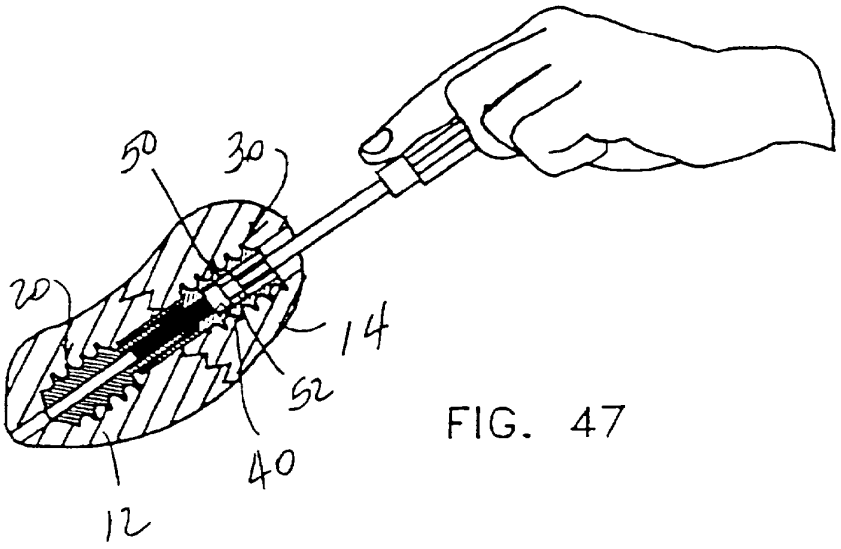


FIG. 47

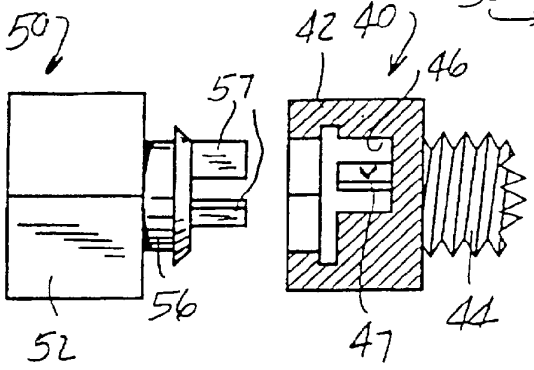


FIG. 49

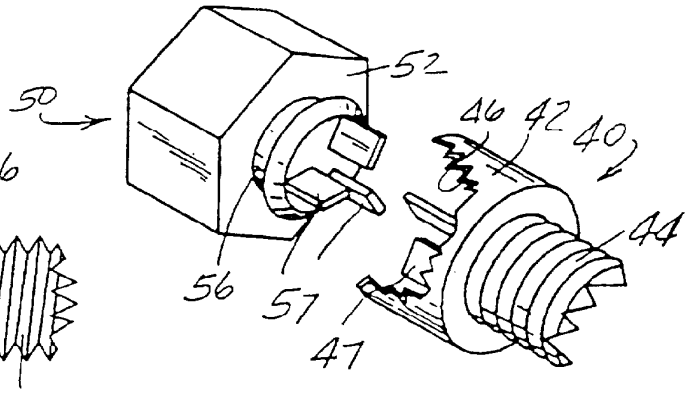


FIG. 48

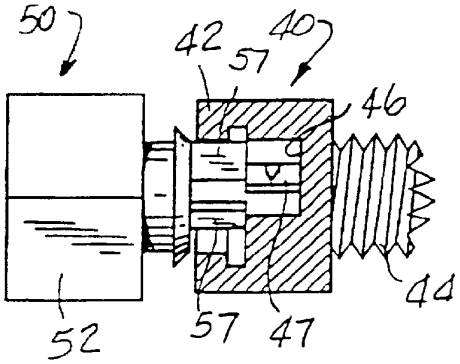


FIG. 51

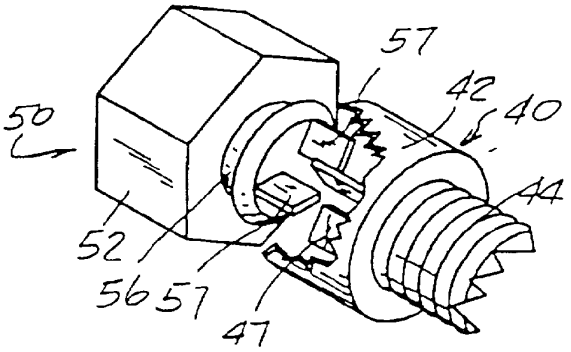


FIG. 50

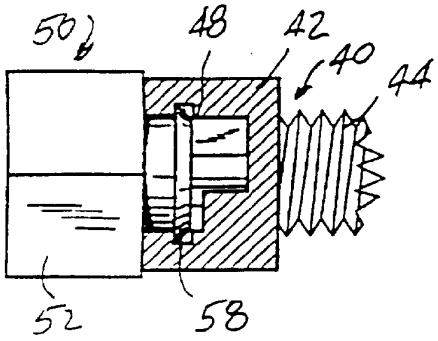


FIG. 53

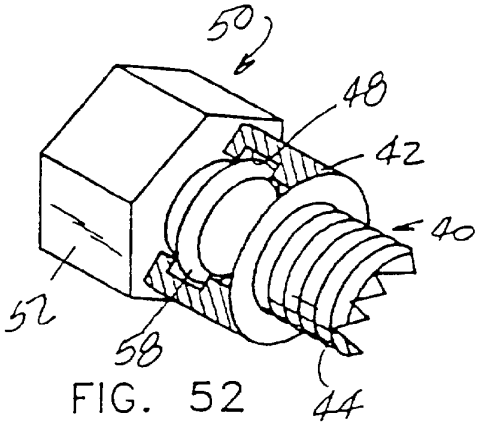


FIG. 52

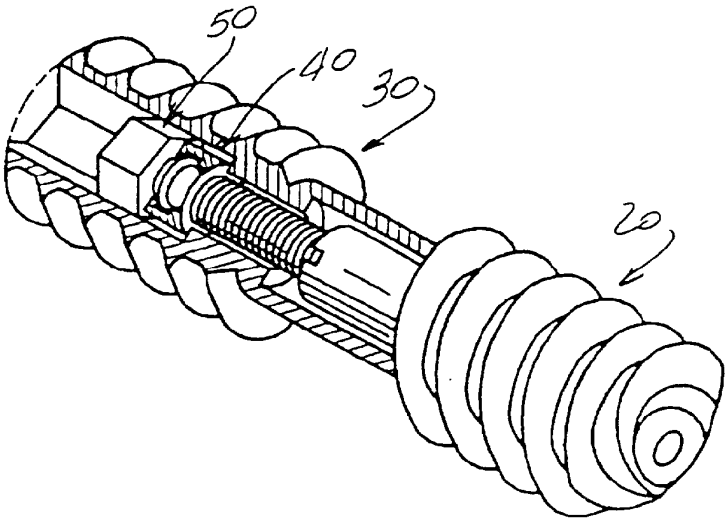


FIG. 54

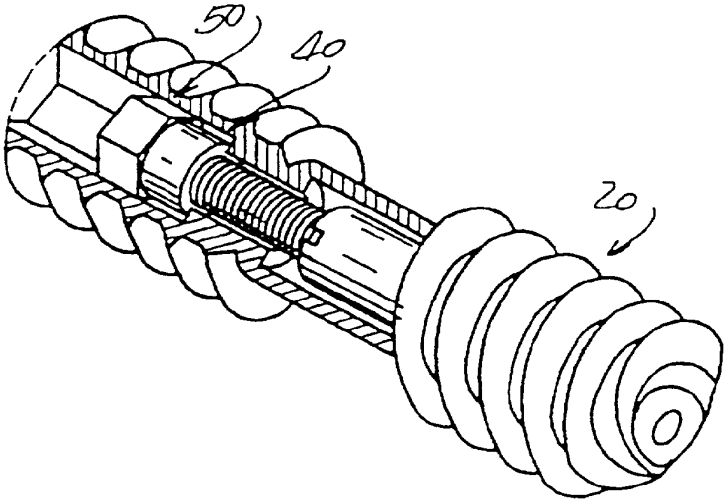


FIG. 55

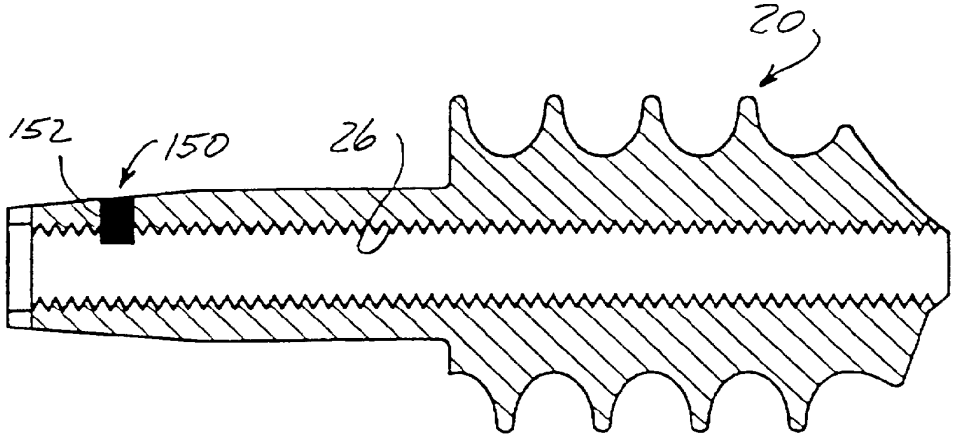


FIG. 56

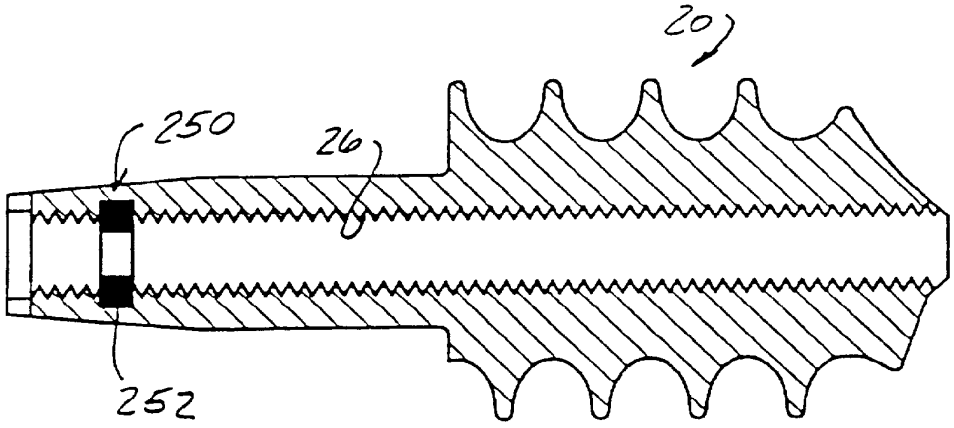


FIG. 60

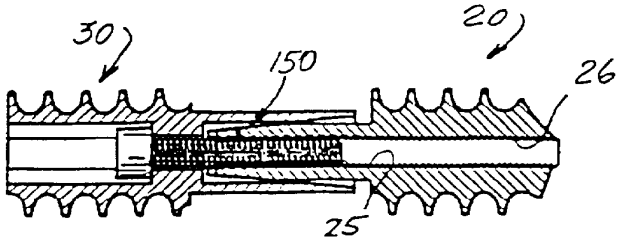


FIG. 59

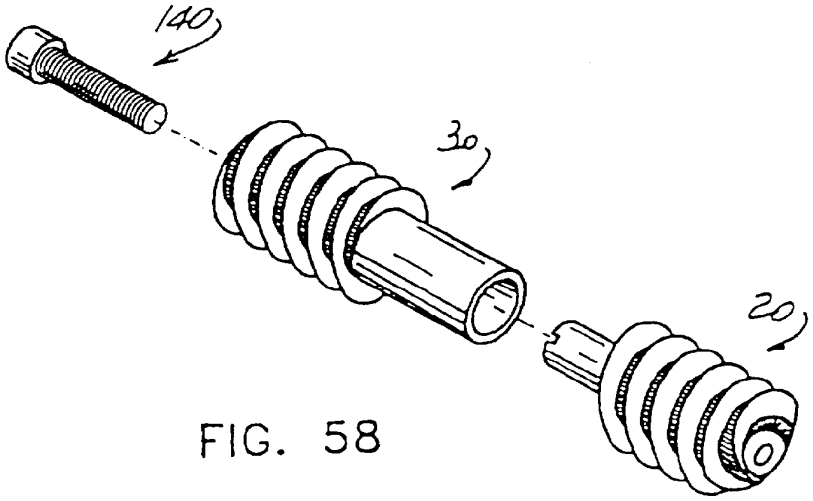


FIG. 58

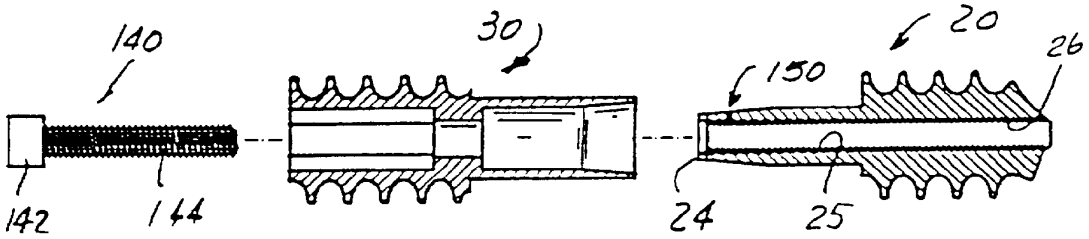


FIG. 57

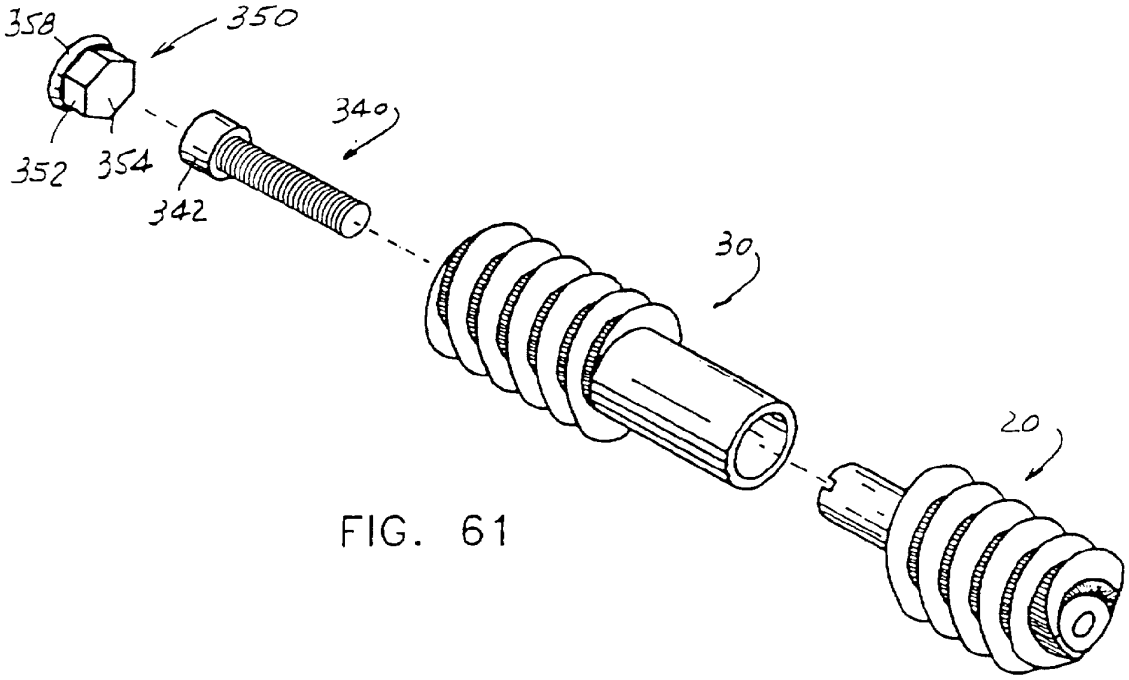


FIG. 61

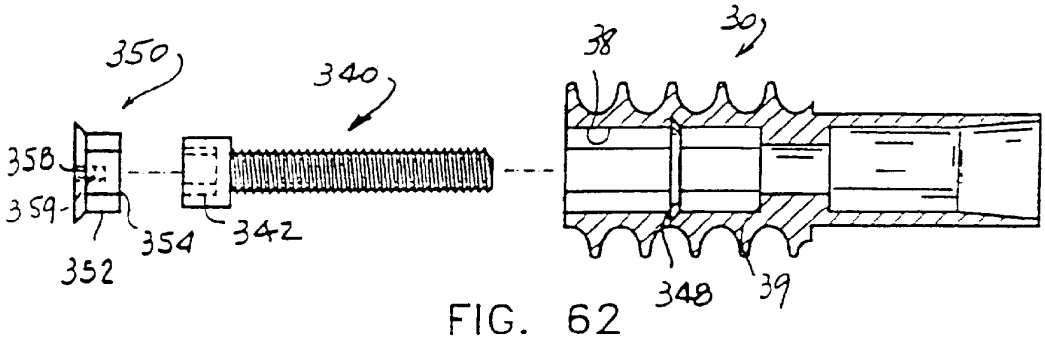


FIG. 62

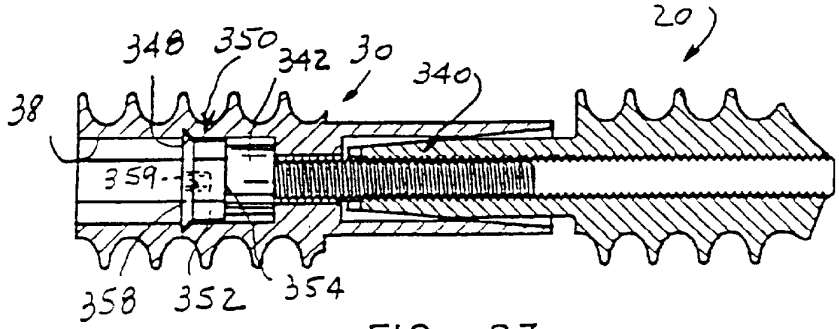


FIG. 63

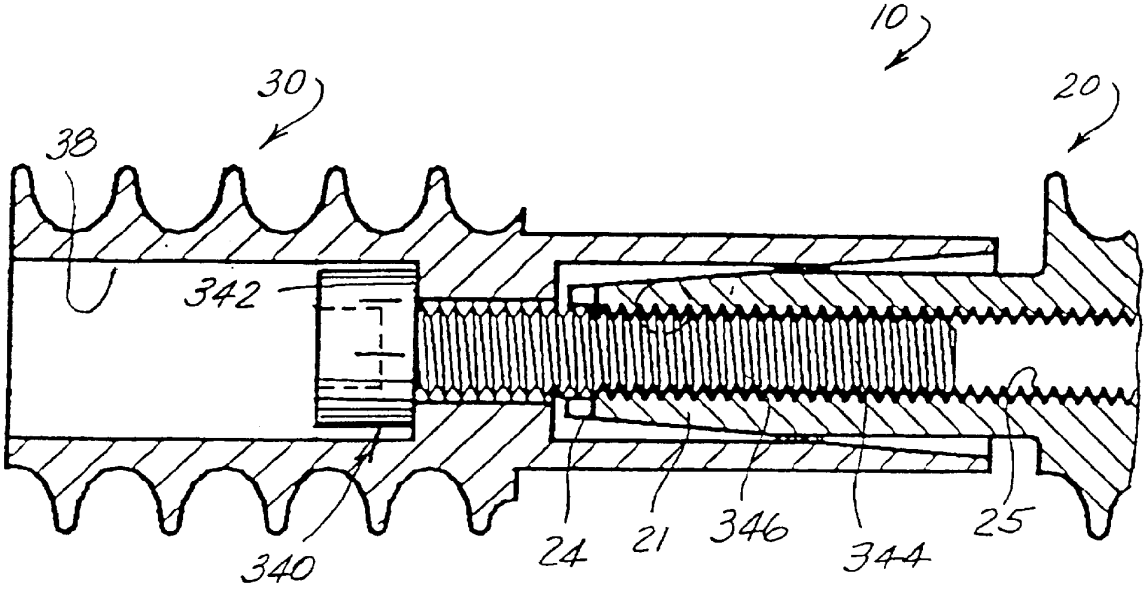


FIG. 63A

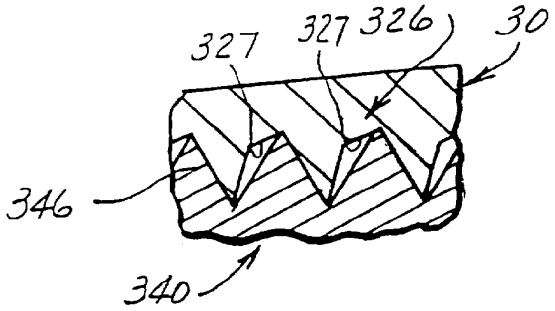


FIG. 63B

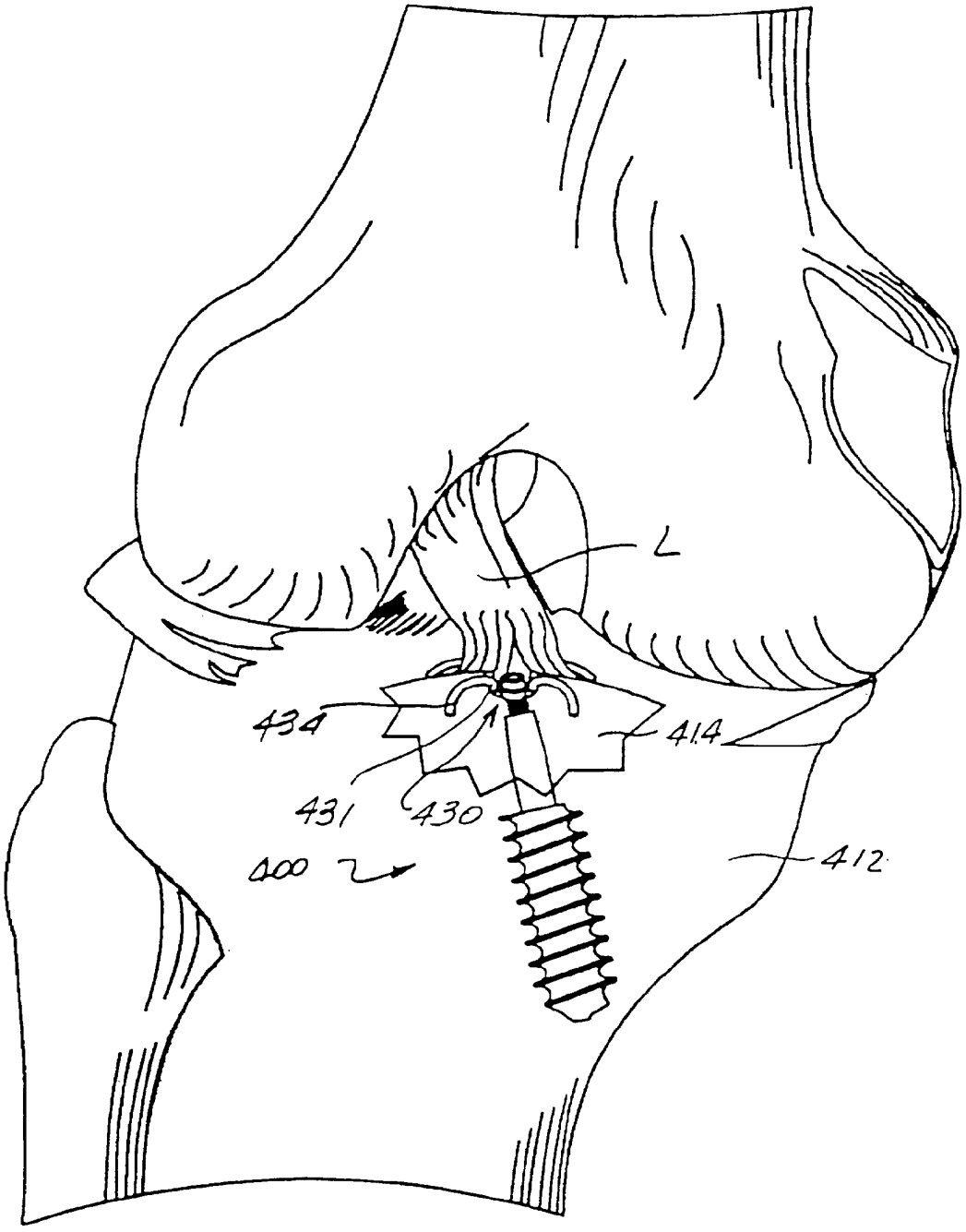


FIG. 64

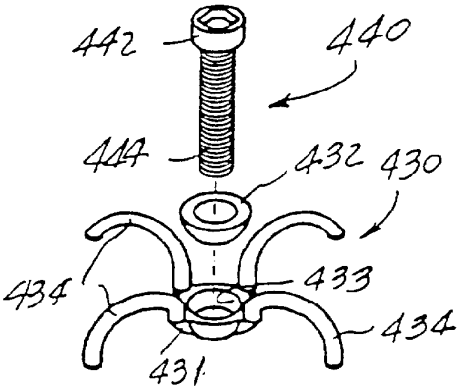


FIG. 65

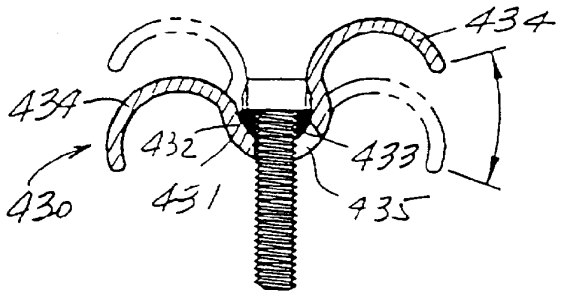


FIG. 67

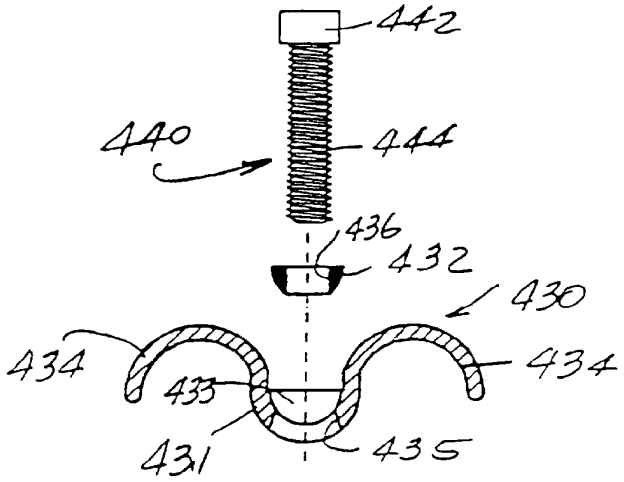


FIG. 66

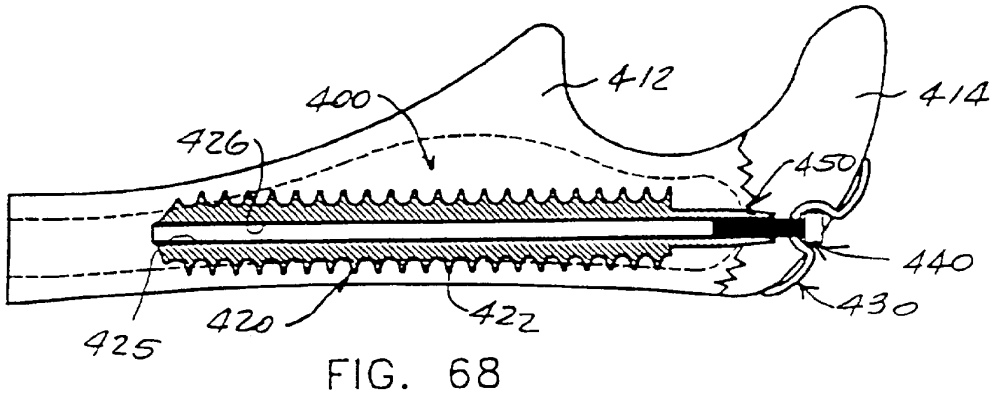


FIG. 68

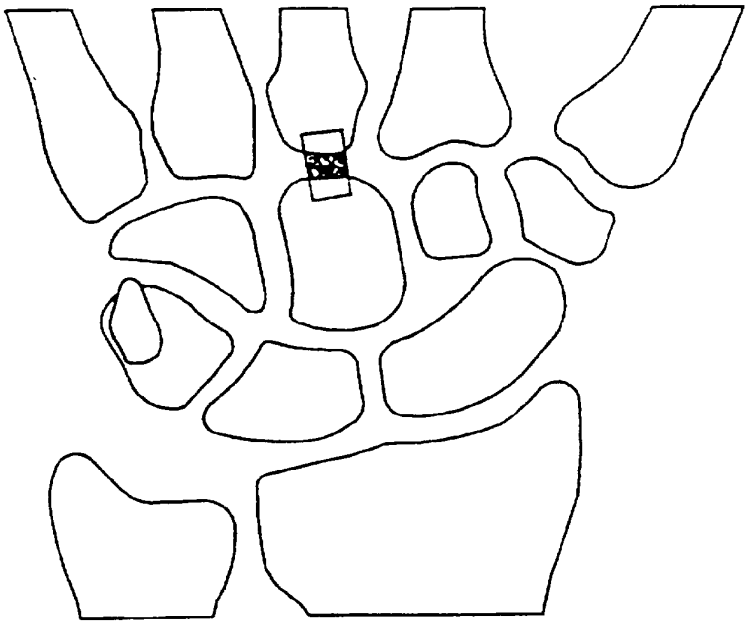


FIG. 69

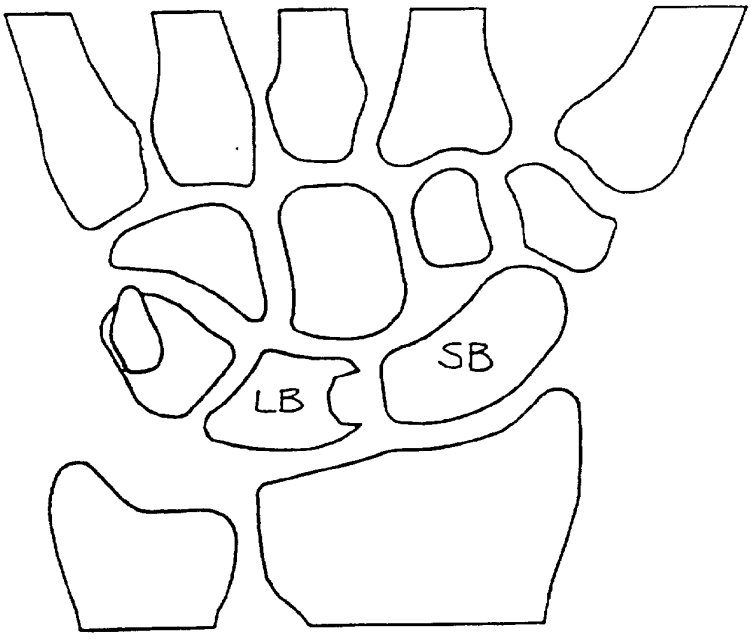


FIG. 70

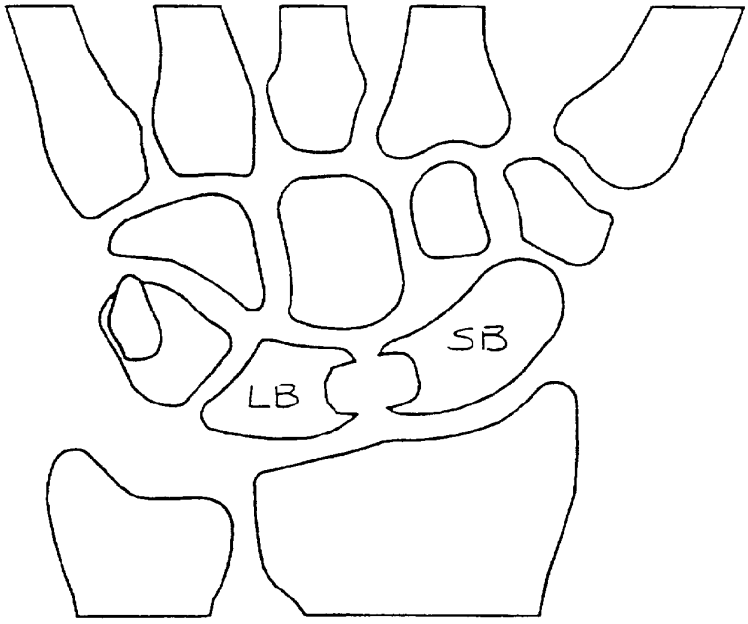


FIG. 71

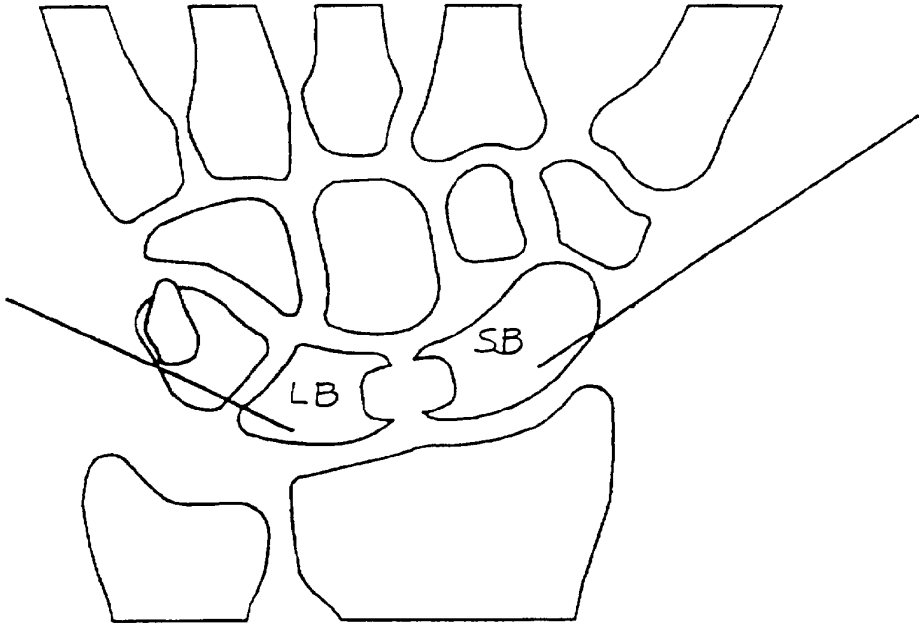


FIG. 72

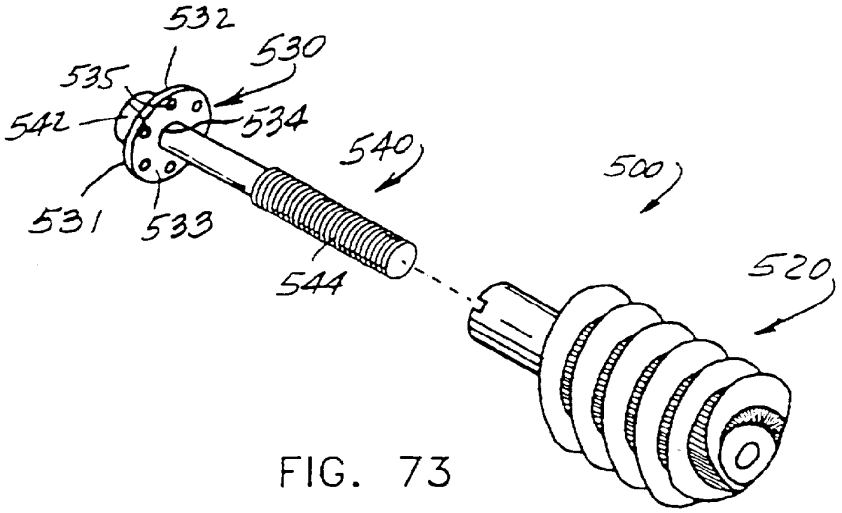


FIG. 73

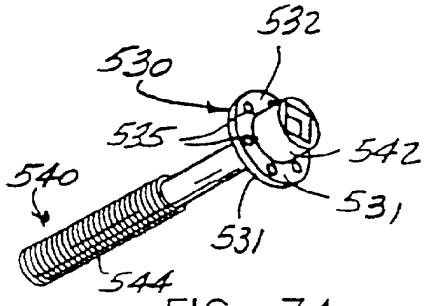


FIG. 74

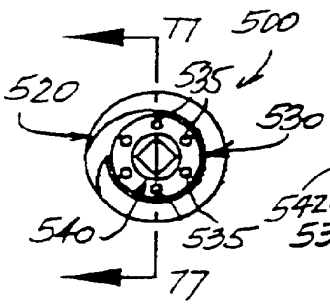


FIG. 75

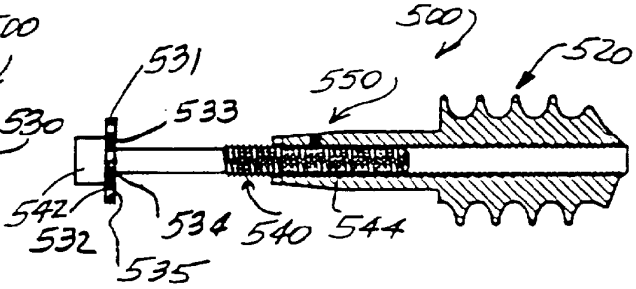


FIG. 77

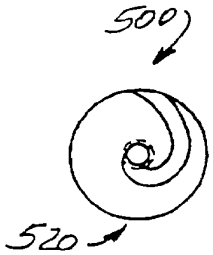


FIG. 76

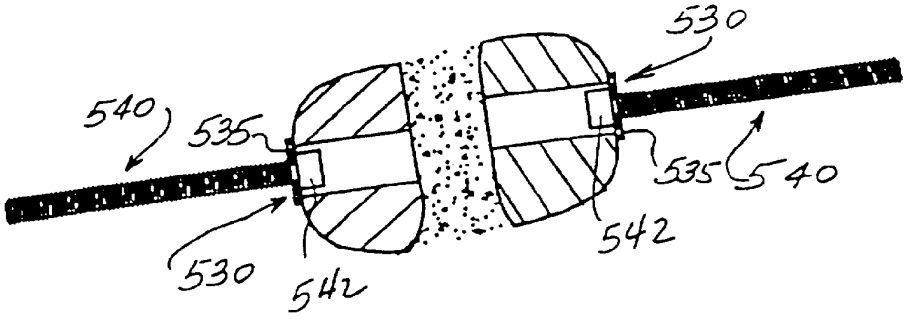


FIG. 78

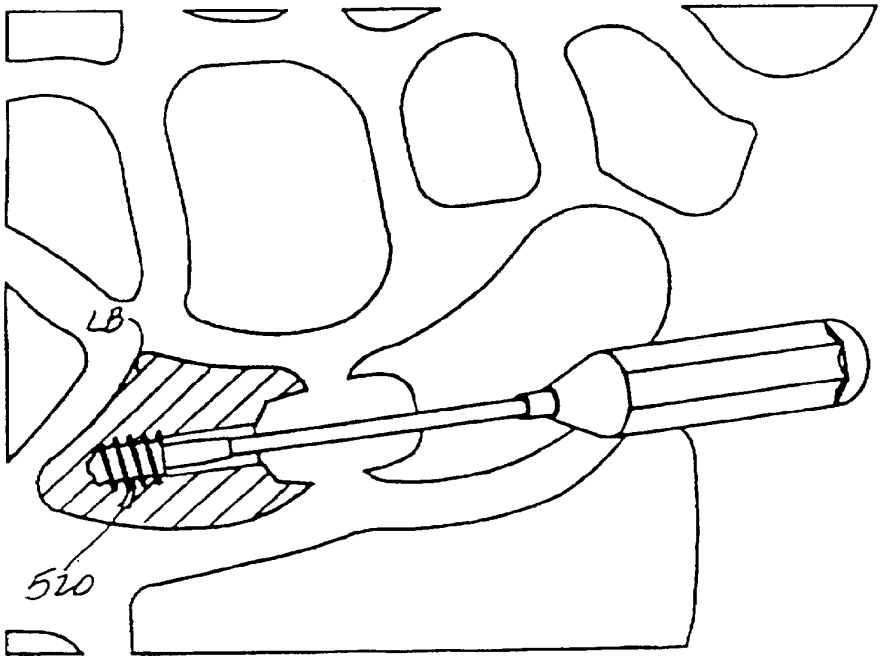


FIG. 79

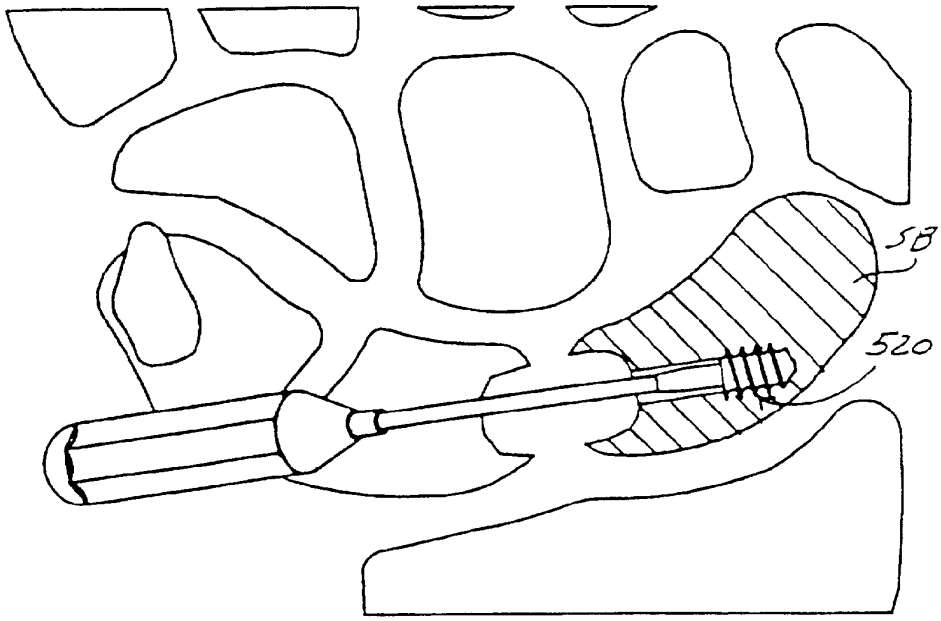


FIG. 80

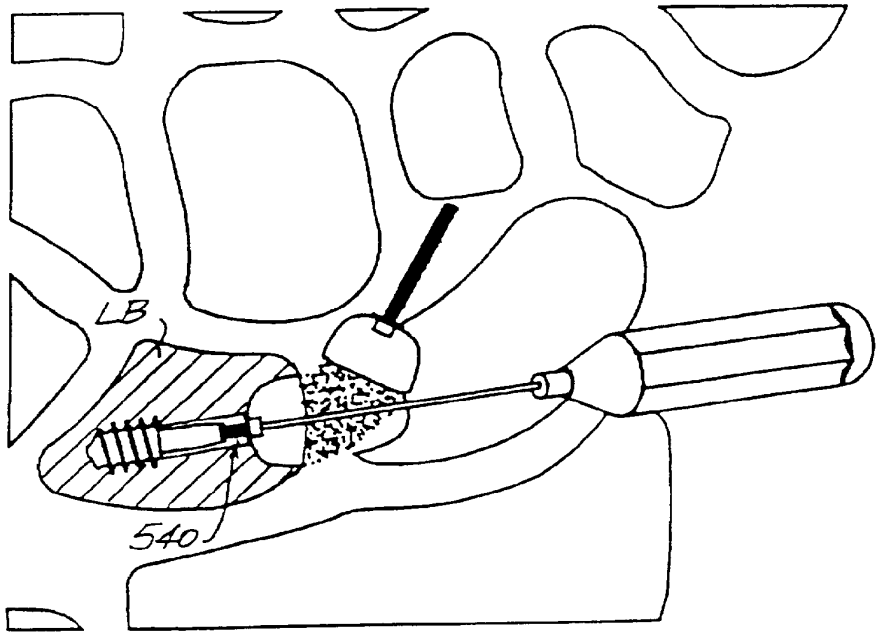


FIG. 81

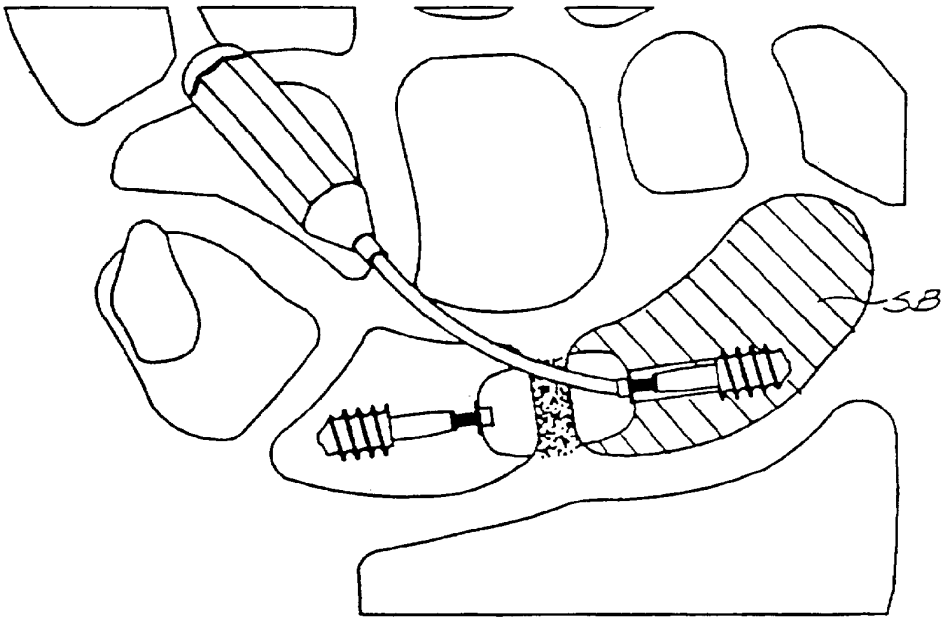


FIG. 82

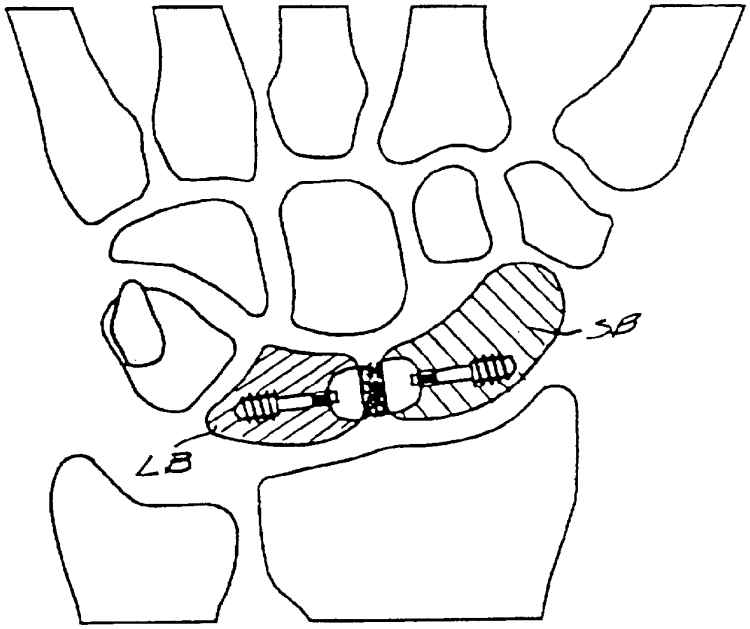


FIG. 83

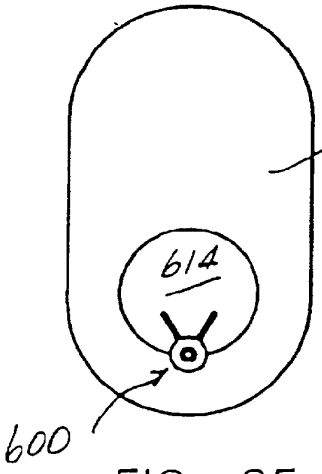


FIG. 85

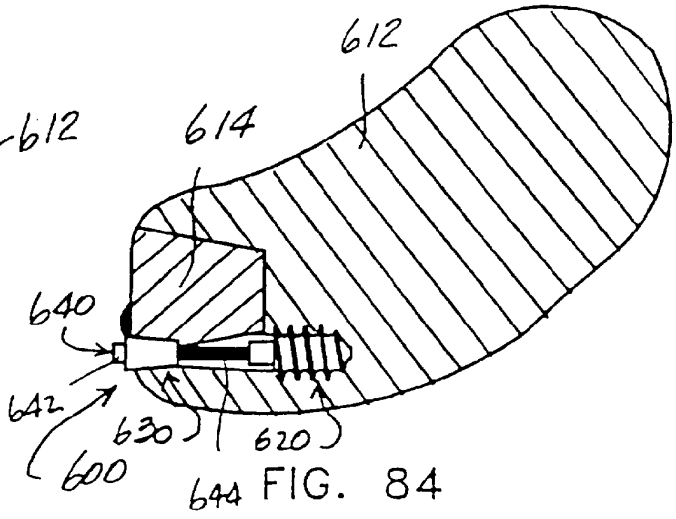


FIG. 84

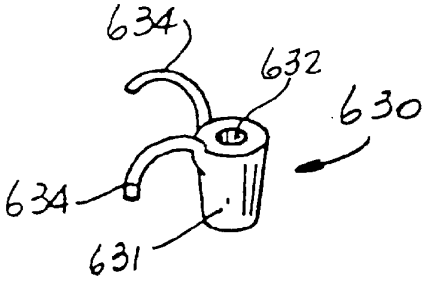


FIG. 87

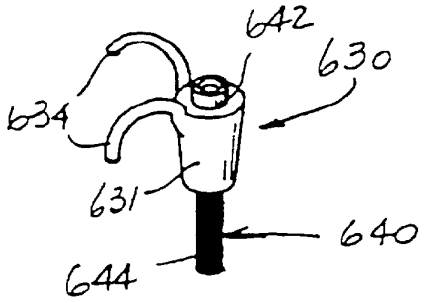


FIG. 86

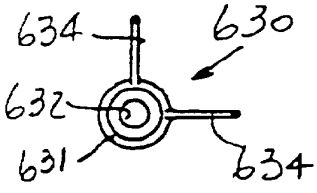


FIG. 88

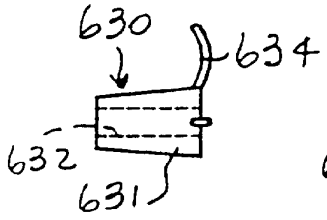


FIG. 89

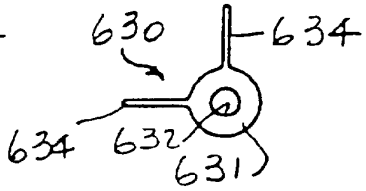


FIG. 90

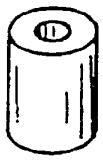


FIG. 91

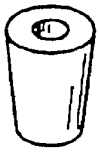


FIG. 92

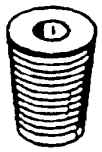


FIG. 93

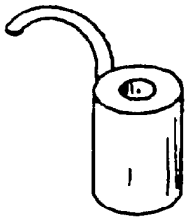


FIG. 94

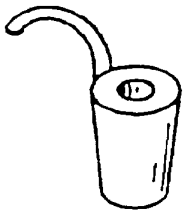


FIG. 95

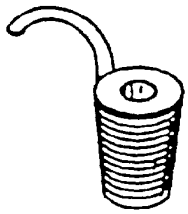


FIG. 96

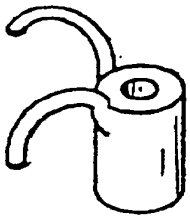


FIG. 97

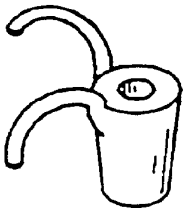


FIG. 98

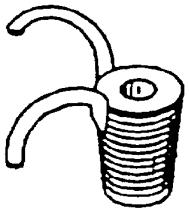


FIG. 99

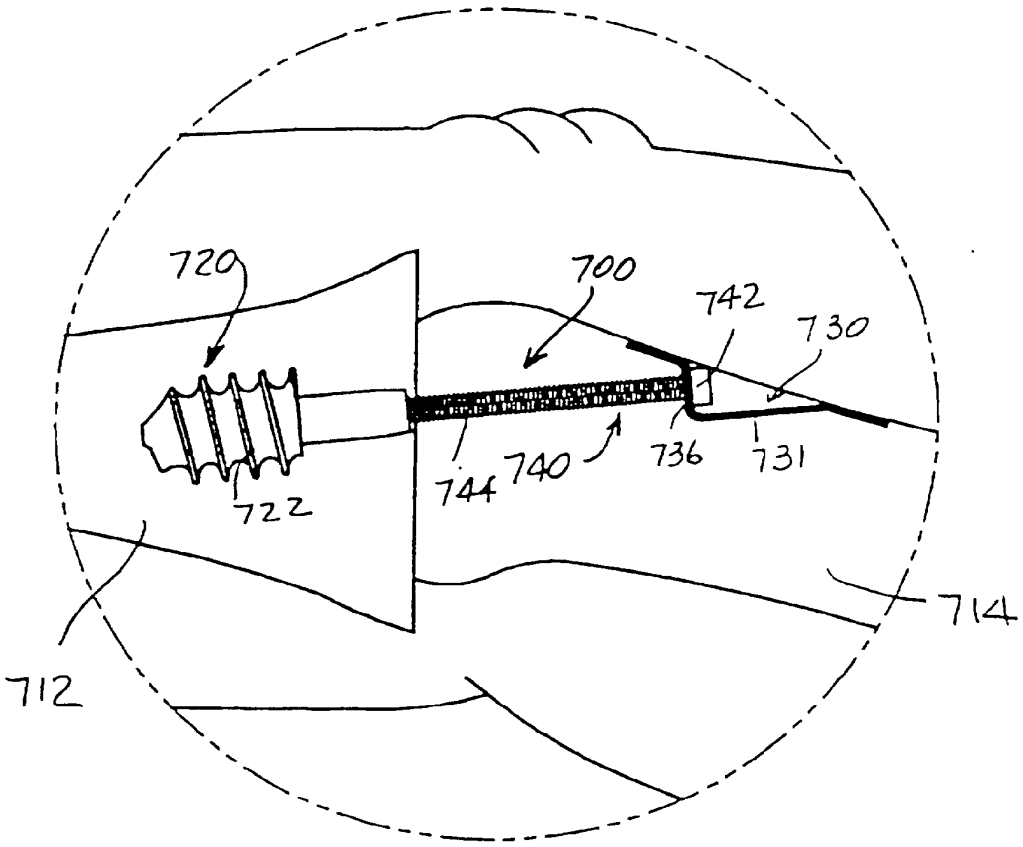


FIG. 101

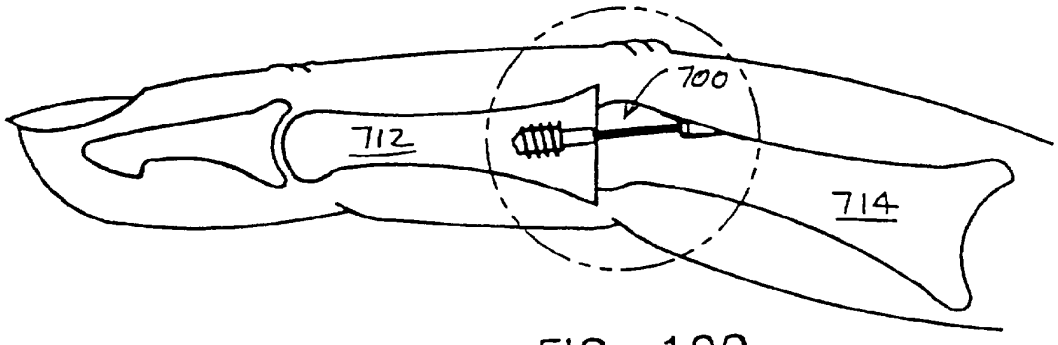


FIG. 100

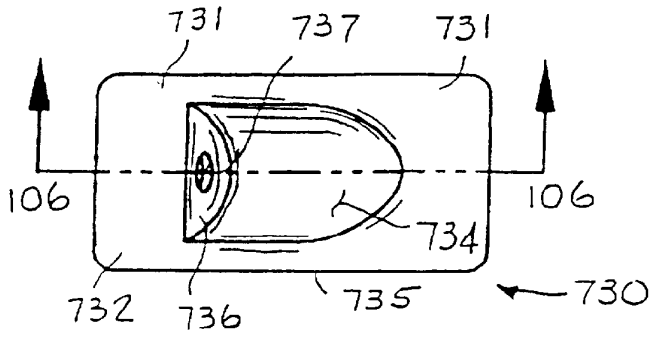


FIG. 102

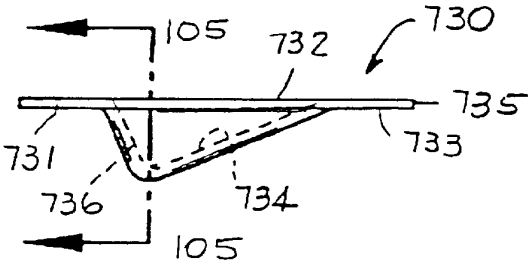


FIG. 103

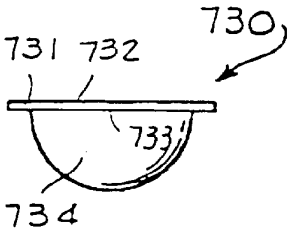


FIG. 104

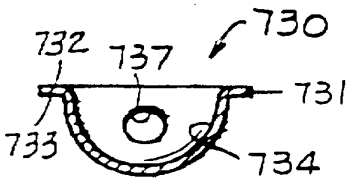


FIG. 105

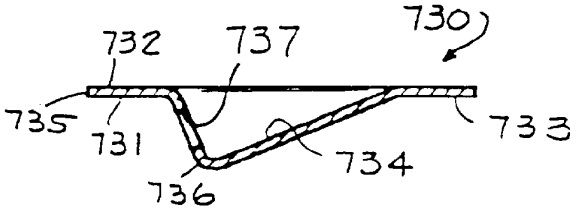


FIG. 106

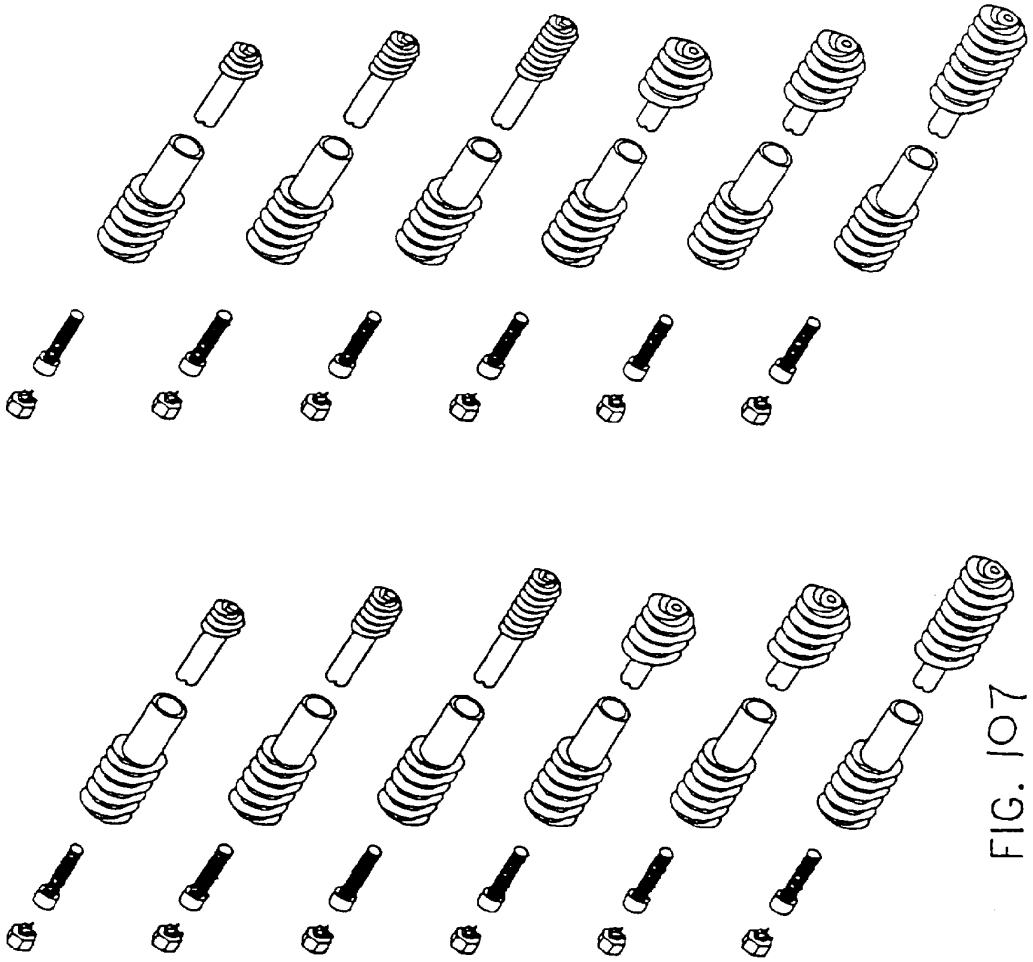


FIG. 107

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/20588

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/00; A61F 5/04
US CL :411/81, 166; 606/72, 73, 104, 105
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : Please See Extra Sheet.

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3,990,438 A (PRITCHARD) 09 November 1976, Figs. 6-8.	1-50
A	US 5,100,405 A (McLAREN) 31 March 1992, Figs. 5-8.	1-50

☐ Further documents are listed in the continuation of Box C. ☐ See patent family 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 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

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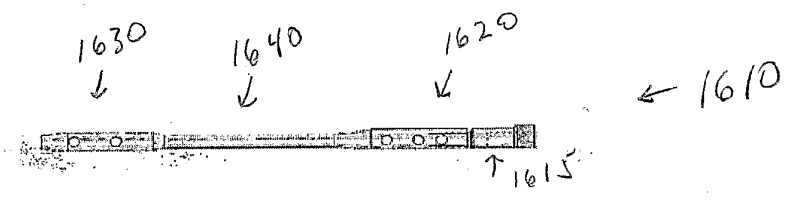
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(54) Title: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE



(57) Abstract: Bone fracture fixation devices, systems and methods of use and manufacture are provided. One such bone fixation device includes an elongate element having a responsive zone. The element is adapted to be coupled to the bone so that the responsive zone is positioned adjacent a fracture or fusion site in the bone. The responsive zone is adapted to apply a desired pressure to the bone when coupled thereto. In some embodiments, the responsive zone comprises a shape memory material, which may be nickel titanium or Nitinol, to apply compressive pressure across the fracture or fusion site for longer periods of time than standard bone screws.

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OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of U.S. Patent Application No. 11/112,865 filed April 21, 2005, and is related to U.S. Provisional Patent Application No. 60/563,952, filed April 21, 2004, the complete disclosures of which are incorporated herein by reference for all purposes.

BACKGROUND OF THE INVENTION

[0002] The present application relates generally to bone fracture repair, and more specifically, to osteosynthetic implants for fracture repair and methods of their use and manufacture.

[0003] In 1959, a group of Swiss Orthopedic and General Surgeons formed the Arbeitsgemeinschaft fur Osteosynthesefragen (AO), also known as the Association for the Study of Internal Fixation (ASIF). The AO/ASIF is now a multi-national group of doctors and scientists with the expressed purpose of studying bone healing and continuous development of fracture fixation techniques for patient care. In the United States, as well as most other countries, AO/ASIF guidance regarding skeletal fixation has become the standard of care for traumatic fracture as well as therapeutic osteotomy fixation techniques. It is under these AO/ASIF guidelines that the surgeon plans and carries out procedures to achieve the desired end result of bone healing and skeletal function.

[0004] Problems can arise when the bone fracture or fusion site is not sufficiently stabilized during the healing timeframe. Depending on the nature of the fracture, screws and plates may be used alone, or in combination. One objective of osteosynthetic implants is the anatomic reduction of the fracture. Another objective would be to minimize or eliminate interfragmentary motion. Still another objective involves increasing or maximizing blood supply to the fracture site by reducing or minimizing additional vascular damage. Sustained compressive therapy can also be osteoinductive, due to its piezoelectric effects on osteoblasts themselves. Excessive interfragmentary motion results in the formation of fibrous, unmineralized scar tissue (resulting in a non-union or pseudo-arthrosis) versus the

regeneration of bone. The unmineralized scar tissue is not load supporting and skeletal function is lost. A sufficient blood supply must be maintained to support skeletal metabolism, bone regeneration, and remodeling of the fracture site. The current standard of care includes osteosynthetic devices that are made of either stainless steel or titanium.

[0005] The use of stainless steel or titanium in osteosynthetic devices has a long history and reasonable record of success. Over time, however, the stainless steel and titanium fixation constructs (both screws and plates) do not maintain compression across the fracture fragments. The reduction of compression of certain standard material constructs has been observed to be thirty-two percent (32%) over a two week period. As the necrotic surfaces of the fracture are resorbed, a non-load bearing gap develops between the fragments, thereby decreasing compression and increasing the risk of interfragmentary motion and scar tissue formation. Loss of compression is contrary to the objectives of fracture fixation in general, and osteosynthetic implants in particular. Improvements are desired to help maintain compressive load across the fracture site over a longer period of healing.

BRIEF SUMMARY OF THE INVENTION

[0006] The present application relates generally to bone fracture repair and bone fusion, and more specifically, to osteosynthetic implants for fracture/fusion repair and methods of their use and manufacture. Fracture repair devices, systems and methods include those for repairing intentional fracture sites, such as but not limited to osteotomies, for reconstructive purposes. Bony fusions of surgically resected joints throughout the body are included as well within the scope of the present invention. Fracture fixation devices, systems and methods of the present invention help maintain compressive loads across the fracture site for longer periods of time compared to prior devices. In some embodiments, the use of shape memory materials, including nickel titanium, delivers improved fracture repair characteristics. The present invention further includes methods of use and methods of manufacture of such bone fixation devices and systems.

[0007] In one embodiment, a bone fixation device according to the present invention includes an elongate element having a responsive zone. The elongate element is a plate, a nail, or a bone screw in alternative embodiments. The elongate element is adapted to be coupled to the bone so that the responsive zone is positioned adjacent a fracture or fusion site in the bone. The responsive zone is adapted to apply a desired pressure to the bone when

coupled thereto. In a preferred embodiment, the responsive zone comprises a shape memory material, which may be nickel titanium or Nitinol.

[0008] In some embodiments, the elongate element comprises nitinol, while in other aspects, the responsive zone is pseudoelastic at a body temperature. In this manner, the elongate element may be used to apply desired forces at the fracture site. In some embodiments, the responsive zone is generally centrally located in the elongate element. In one aspect, the responsive zone has a smaller overall cross section than a cross section of an end of the elongate element. Such a configuration helps locate the stresses or pressures at a desired location within the elongate element, and more specifically, at the responsive zone.

[0009] In some aspects, the bone fixation device further includes a coupler adapted to couple the elongate element to the bone. The coupler may include one or more bone screws, which in some embodiments comprise a shape memory material. In a particular embodiment, the elongate element has first and second end sections each with at least one hole adapted to receive a coupler therethrough to couple the element to the bone. Other embodiments may use two, three, four, or more holes in one or both end sections to fixedly couple the device to the fractured bone.

[0010] The present invention further provides bone fixation systems. In one embodiment, the system includes an elongate element having a responsive zone of shape memory material, for example in its pseudoelastic state, and a coupler adapted to couple the elongate element to the bone so that the responsive zone is positioned adjacent a fracture site in the bone. In some embodiments, the system includes a removable clamp, with the clamp adapted to maintain the elongate element responsive zone in a desired position prior to coupling of the element to the bone, and may further be adapted to be removed from the elongate element after coupling of the element to the bone. In one aspect, the responsive zone is adapted to apply a desired pressure to the bone when the elongate element is coupled to the bone.

[0011] The present invention further provides methods of stabilizing a fractured bone. In one such embodiment, the method includes providing an elongate element, which may be a plate, an intermedullary or intramedullary nail, a bone screw, a pin, or related devices. The elongate element has a responsive zone of a shape memory material, with the responsive zone adapted to apply a desired pressure to the bone when coupled thereto. The method includes coupling the elongate element to the bone so that the responsive zone is positioned adjacent a fracture site in the bone.

[0012] In one aspect, the method includes applying a force to the elongate element to lengthen the responsive zone a desired amount, maintaining the element in the lengthened position, coupling the element to the bone so that the lengthened responsive zone is positioned adjacent the fracture site, and releasing the elongate element. In some aspects, a clamp is used to maintain the element in the lengthened position. In this manner, the elongate element may be released by removing the clamp. As a result, the stress formed in the responsive zone can be applied to the bone to facilitate fracture and fusion site compression, stability, healing, and the like.

[0013] In a particular aspect, coupling the elongate element to the bone includes attaching a first coupler to the element and to the bone on a first side of the fracture site, and attaching a second coupler to the element and to the bone on a second side of the fracture site. In this manner, the responsive zone is positioned adjacent the fracture site. In one aspect, the force applied to the elongate element to lengthen the responsive zone the desired amount corresponds to a desired compressive force to be applied to the fractured bone when the element is coupled thereto. Again, the shape memory material may be nitinol, or other shape memory materials compatible with the human body.

[0014] In one aspect, embodiments of the present invention provide a bone fixation system. The sytem can include a bone fixation device having a responsive zone, and a clamp configured to be received at least partially within an internal lumen of the bone fixation device, where the internal lumen disposed along an axial length of the bone fixation device. The clamp can be adjustable between a first mode that induces or maintains a first amount of strain in the responsive zone along the axial length of the bone fixation device, and a second mode that induces or maintains a second amount of strain in the responsive zone along the axial length of the bone fixation device. The clamp may be removably coupled with the bone fixation device. In some instances, the clamp includes an end cap and an internal brace. The end cap can be adjustably engaged with the bone fixation device at an end cap first section, and adjustably engaged with the internal brace at an end cap second section. Relatedly, the end cap can be threadably engaged with the bone fixation device at an end cap first section, and i threadably engaged with the internal brace at an end cap second section. In some aspects, a central longitudinal axis defined by the internal lumen of the bone fixation device is collinear with a central longitudinal axis defined by the internal brace. In related aspects, the central longitudinal axis defined by the lumen of the bone fixation device is collinear with a central longitudinal axis defined by the end cap.

[0015] The bone fixation device can be, for example, an intramedullary or intermedullary nail, a screw, a plate, a pin, a compression rod, a vertebral fixation device, and the like. The responsive zone can have a physical characteristic similar to human tissue. In some cases, the physical characteristic is a modulus such as an elastic modulus. For example, the modulus can have a value in a range from between about 10 GPa to about 70 GPa. In some cases, the human tissue is bone. Often, the responsive zone includes a shape memory material, which may be a shape memory alloy. A shape memory alloy can include a nickel alloy, a copper alloy, and the like. In some cases, the shape memory alloy includes a nickel titanium alloy, a copper zinc aluminum alloy, a copper aluminum nickel alloy, or the like. The responsive zone is configured to provide a predetermined or preset compressive force across a bone fracture or fusion site when the clamp is removed or inactivated. Similarly, the responsive zone can be configured to recover to a predetermined or preset length when the clamp is removed or inactivated.

[0016] In another aspect, embodiments provide a bone fixation device that includes a machined responsive zone having a hardness value within a range from about 5 HRB to about 60 HRC on the Rockwell B and C Hardness Scales. The responsive zone may include a nickel titanium alloy. In still another aspect, embodiments provide a method of preparing a bone fixation system. The method can include providing a bone fixation device having a responsive zone, inserting a clamp at least partially within an internal lumen of the bone fixation device, where the internal lumen disposed along an axial length of the bone fixation device, and inducing, maintaining, controlling, or modulating a strain in the responsive zone along the axial length of the bone fixation device with the clamp. Such methods can also include threadably engaging an end cap of the clamp with the bone fixation device at an end cap first section, and threadably engaging the end cap with an internal brace of the clamp at an end cap second section.

[0017] In yet another aspect, embodiments include methods of deploying a bone fixation device in a patient. Such methods can include, for example, providing a bone fixation device having a first portion, a second portion, and a responsive zone disposed therebetween, and inserting a clamp at least partially within an internal lumen of the bone fixation device. The internal lumen can be disposed along an axial length of the bone fixation device. The method may also include inducing, maintaining, controlling, or modulating a strain in the responsive zone along the axial length of the bone fixation device with the clamp, coupling the bone fixation device with a bone of the patient by attaching the first portion of device to a first

bone location, and attaching the second portion of the device to a second bone location. The bone typically includes a fracture or fusion site disposed between the first and second bone locations. The method can further include securing the bone fixation device to an external brace assembly, removing the clamp from the bone fixation device, and removing the external brace assembly from the bone fixation device. The bone fixation device can remain coupled with the patient's bone, and the responsive zone can be allowed to relax so as to transmit a compressive force to the fracture or fusion site of the patient's bone via the bone fixation device.

[0018] In one aspect, embodiments include methods of processing a shape memory material for use in a bone fixation device. Methods may include, for example, treating the shape memory material with a first treatment to transform the shape memory material from a first state to a second state, machining the shape memory material while it is in the second state, and treating the machined shape memory material with a second treatment to transform the shape memory material from the second state to the third state. The first treatment may include a first heat cycle of at least 5 minutes at a temperature of about 600° C. The first treatment may also include a second heat cycle of at least 5 minutes at a temperature within a range from between about 200° C to about 550° C. In some embodiments, the first state has a first hardness value, the second state has a second hardness value, and the first hardness value is between about 100% and about 500% of the second hardness value. The first state can have a first shape recovery value, the third state can have a third shape recovery value, and the third shape recovery value may be at least 95% of the first shape recovery value. In some cases, the shape memory material includes a shape memory alloy such as a nickel titanium alloy, a copper zinc aluminium alloy, or a copper aluminium nickel alloy. The third state may have an optimal pseudoelastic property profile for the shape memory material. In some aspects, the first state can have a first hardness value, the third state can have a third hardness value, and a difference between the first hardness value and the third hardness value may be less than about 3 HRC on the Rockwell C Hardness Scale. In some cases, the difference may be less than about 10 HRC.

[0019] In another aspect, embodiments encompass methods of preparing a bone fixation device. Methods may include providing a bone fixation device comprising a shape memory material, and machining the shape memory material while the temperature of the shape memory material is maintained at or above an austenitic transition temperature. In some

aspects, the shape memory material remains in a stiff austenite phase and does not transition to a malleable austenite phase during the machining.

[0020] Additional embodiments and features are set forth in part in the description that follows, and in part will become apparent to those skilled in the art upon examination of the specification or may be learned by the practice of the invention. The features and advantages of the invention may be realized and attained by means of the instrumentalities, combinations, and methods described in the specification.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] Fig. 1A is an overall view of a dynamic compression bone screw according to an embodiment of the present invention;

[0022] Figs. 1B and 1C are simplified views of steps for forming the dynamic compression bone screw depicted in Fig. 1A;

[0023] Figs. 2A-2C schematically depict the use of the dynamic compression bone screw of Fig. 1A for repairing a bone fracture;

[0024] Fig. 3A is a side view of the dynamic compression bone screw of Fig. 1A;

[0025] Figs. 3B and 3C are close-up views of the screw head and threaded portion, respectively, for the bone screw depicted in Fig. 3A;

[0026] Fig. 3D is a longitudinal cross-sectional view of the bone screw depicted in Fig. 3A;

[0027] Fig. 3E is a top view of the bone screw depicted in Fig. 3A;

[0028] Fig. 3F is an overall view of the bone screw depicted in Fig. 3A;

[0029] Fig. 3G is an overall view of a dynamic compression bone screw according to an alternative embodiment of the present invention;

[0030] Fig. 4 is an overall view of two bone fixation devices according to an embodiment of the present invention;

[0031] Fig. 5A is an overall view of the bone fixation device shown in Fig. 4;

[0032] Figs. 5B-5I are additional views of the fixation device shown in Fig. 5A, including a bottom view (Fig. 5A), a top view (Fig. 5B), a longitudinal cross-sectional view (Fig. 5C), a

close-up bottom view of an expansive zone (Fig. 5D), an end view (Fig. 5E) and a side view (Fig. 5F);

[0033] Figs. 6A and 6B are overall views of a fixation device coupled to a bone having a fracture site;

[0034] Figs. 7A and 7B are exploded and assembled overall views, respectively, of a bone fixation system according to an embodiment of the present invention using the fixation device shown in Fig. 4;

[0035] Fig. 8 is an overall view of a bone fixation device according to an alternative embodiment of the present invention;

[0036] Figs. 9A and 9B are graphical views of material properties of bone fixation screws and devices according to an embodiment of the present invention; and

[0037] Figs. 10A and 10B are graphical depictions of characteristics of bone screws and fixation devices according to embodiments of the present invention.

[0038] Figs. 11 and 11B illustrate an end cap according to embodiments of the present invention.

[0039] Fig. 12 shows an internal brace according to embodiments of the present invention.

[0040] Fig. 13A and 13B show a bone fixation system according to embodiments of the present invention.

[0041] Fig 14 shows a jig or external fixation device according to embodiments of the present invention.

[0042] Fig. 15 shows a restrainer bar according to embodiments of the present invention.

[0043] Fig. 16 illustrates a bone fixation device according to embodiments of the present invention.

[0044] Fig. 17 depicts a patient's leg and a jig and restrainer bar according to embodiments of the present invention.

[0045] Fig. 18 depicts a patient's leg, a jig and restrainer bar, and a bone fixation device according to embodiments of the present invention.

[0046] Fig. 19 depicts a patient's leg, a jig and restrainer bar, a bone fixation device, and cross pins according to embodiments of the present invention.

[0047] Fig. 20 depicts a patient's leg and a bone fixation device according to embodiments of the present invention.

[0048] Fig. 21 depicts a patient's leg, a jig and restrainer bar, cross pins, a bone fixation device, and bone screws according to embodiments of the present invention.

[0049] Figs 22A and 22B show a patient's leg, a jig and restrainer bar, cross pins, a bone fixation device, and bone screws according to embodiments of the present invention.

[0050] Fig. 23 depicts a patient's leg, a bone fixation device, and bone screws according to embodiments of the present invention.

[0051] Figs 24A to 24H show a prototypical intramedullary nail having exemplary dimensions.

[0052] Fig. 25 shows a hardness versus heat treatment graph according to embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0053] It has been determined that when a bone is set and a compressive force is applied to the fracture or fusion fixation device, the force between the fragments ends decreases rapidly as a function of time. Ideally, the fixation device is able to maintain a compressive force, which will allow for the continuation of healing through reduction of the fracture gap, and stability of the fracture gap. If this does not occur, a loss of compression may be followed by the lack of union and stability of the fracture site, which in turn reduces the healing. A fracture fixation device is put in place to stabilize the fracture site, however, if the compressive force is not present then micro-motion between the fracture ends may occur. This, in turn, may cause unnecessary resorption, which will lead to non-union of the bone or the presence of large voids. These reasons show the importance of a device to actively match the changes in the body, as well as have a similar response as bone.

[0054] Embodiments of the present invention include bone fixation devices, including plates, bone nails such as intramedullary nails, bone screws, and the like, that can provide sustained compression (spontaneous dynamic compression) across a bone fracture over time.

The dynamic compressive forces are stable or generally stable as a function of bone surface resorption at the fracture site, facilitating improved bone healing and reducing non-union rates. Some bone fixation devices of the present invention will allow for approximately six percent (6%) relaxation before compressive force loss. In contrast, typical stainless steel or titanium bone screws lose their compressive forces after about one percent (1%) resorption at the fracture surface.

[0055] Figs. 1A-2C depict a dynamic compression bone screw 100 according to an embodiment of the present invention. Bone screw 100 shown in Fig. 1A is further described in conjunction with Figs. 3A-3F. In a particular embodiment, bone screw 100 is formed from nickel titanium, a shape memory alloy referred to as Nitinol. As shown in Fig. 1B and 1C, screw 100 is formed from a Nitinol stock or block, and may be heat treated to produce desired characteristics. Shape memory alloys, such as Nitinol, exhibit the capacity to recover relatively large strains (e.g., about 6%) by the application of heat (shape memory) or by gradual unloading (pseudo-elasticity). The present invention exploits the large strain capacity and recovery behavior of shape memory alloys such as Nitinol for bone repair with novel devices, systems, and methods. In one embodiment, the fixation devices, such as screw 100, are machined from a shape memory material such as Nitinol that is thermally treated to exhibit pseudo-elasticity at body temperature. The overall screw geometry, responsive element geometry, and material heat treatment will be specified to sustain the necessary compressive forces as a function of fracture or fusion site conditions.

[0056] The shape memory effect of Nitinol is the temperature-induced transformation between the malleable martensite (lower temperature) phase and the more rigid austenite phase (higher temperature) that exhibits the desired pre-set shape. Exploitation of the thermally driven phase change helps some embodiments of the present invention deliver desired bone fixation results. The pseudoelastic effect of Nitinol refers to the return to its pre-set austenite configuration upon unloading after elastic deformation. The initiation of superelastic behavior of Nitinol requires the formation of stress induced martensite (SIM) from the austenite phase, such as by the application of an external load or stress. Reduction of the external load or stress induces formation of the austenite phase and hence its pre-set configuration. Nitinol is able to accumulate large deflection (strain) at a nearly constant load (stress). The relatively flat region of the Nitinol load-to-deflection relationship can be used for some devices of the present invention.

[0057] Some embodiments of the present invention take advantage of the stress/strain (modulus) of NiTi, depicted in Fig. 9A. Such characteristics of NiTi are beneficial in the development and use of improved total joint implants, for example. This property of NiTi decreases overall bone to implant interface stresses, resulting in a longer implant lifetime. Embodiments of the present invention, particularly those using NiTi, help the bone maintain load, which increases healing and helps smaller implants to maintain the same or similar stability as larger ones in similar areas of fixation by reducing stress/strain and sheering forces.

[0058] Formation of SIM phase within a responsive zone of screw 100, or other osteosynthetic implants and devices, may be achieved prior to surgical placement or as a result of surgical placement. For the bone screws 100 depicted in Fig. 1A, the responsive zone of screw will be designed to initiate SIM formation as a result of the installation process. This occurs, at least in part, due to the elongating forces applied to the screw when the screw is used. Additional details on the responsive zone are discussed in conjunction with Figs. 3A-3F.

[0059] One technique for fracture fixation is the placement of a lag screw across the appositional ends of a break in the bony cortex. Inserting the screw across the fracture site helps generate the dynamic force capacity in the screw. As shown in Fig. 2A, bone screw 100 is inserted at an angle relative to a fracture site 210. Screw 100 is rotated to draw the two bone fragments 220 towards one another, creating a compressive force therebetween. The rotational torque used to turn screw 100 is translated into axial compression between bone fragments 220. The result is the proper alignment of bone fragments 220 as shown in Fig. 2B. Screw 100 maintains a compressive force on bone fragments 220 for a much longer period of time than traditional bone screws formed of steel, titanium, or the like. As a result, a more fully healed fracture site 210 results (Fig. 2C). During healing and bone absorption, the force generated by prior-art screws can decrease leaving a less compressive force acting across the fracture site 210 over time. In contrast, bone screws 100 of the present invention are a dynamic screw that can maintain higher compression values over a longer course of healing. Advantages of screw 100 includes better promotion of direct bone healing, reduction in non-union rates in high risk fracture sites, and a reduction in bone implant site resorption. In some embodiments, at least some of these advantages are achieved by the use of a shape memory material, such as Nitinol, and its inherently similar stress/strain properties to those of bone.

[0060] Fig. 3A-3F depict further details on bone screw 100 according to an embodiment of the present invention. It will be appreciated by those skilled in the art that Figs. 3A-3F depict a particular example, and the present invention is not limited to the dimensions and configurations shown therein. As can best be seen in Figs. 3A, 3D, and 3F, bone screw 100 has a shank portion 110 with a diminished thickness or radius compared to the radius or thickness of a threaded portion 120 or of a head 130. In this manner, the reduced area of shank portion 110 allows for a stress concentration to be localized over shank portion 110, which allows shank portion 110 to elongate to form a responsive element or zone. In one embodiment, the elongation of shank portion 110 occurs during the insertion process into the fractured bone, as depicted in Fig. 2B. By using the responsive element or shank portion 110, bone screw 100 is able to localize the force caused by the SIM over the fracture site. The non-responsive screw portions, such as head 130, stays generally strain-free and contributes little force to the bone due to SIM.

[0061] In an alternative embodiment, a bone screw 300 depicted in Fig. 3G has a generally uniform diameter through a shank portion 310. In this embodiment, only shank portion 310 is formed of a shape memory material, with threaded end portion 320 comprising a stiffer region less susceptible to elongation.

[0062] Turning now to Fig. 4, a bone fixation device 400 according to an embodiment of the present invention will be described. Bone fixation device 400 allows for a longer and greater sustained compressive force. For example, current bone plates applied to a fractured surface tend to lose compressive force within two days to two weeks after surgery, thus slowing the healing process. Additional problems with prior-art plates, such as deflections and rigidness, also result in a greater chance of refracture and slow healing. In one embodiment of the present invention, bone fixation device 400 comprises a shape memory alloy, that may be Nitinol or the like. Fixation device 400 is a dynamic device that can change over time with the human body into which it is inserted. In a preferred embodiment, device 400 comprises Nitinol, due in part to its capacity to recover large strains over time. In one embodiment, this is accomplished through the creation of device 400 having a responsive zone section 410. In some embodiments, responsive zone 410 has a smaller overall cross-sectional area than the non-responsive zone(s) of device 400. Responsive zone 410 is used to localize the elongation of device 400 to that area. In one embodiment, device 400 is elongated based on the application of a force similar to or the same as the force required to stabilize the fracture to which device 400 is applied. Device 400 will be elongated based on

the force required to stabilize the fracture and apply the necessary healing force. After device 400 has been elongated, in one embodiment it is held in an elongated state by an external clamp or similar structure to prevent recovery motion of device 400. After device 400 is affixed to the fracture site, the clamp, or other retaining mechanism can be removed. Further details on the use of device 400 are discussed in conjunction with Figs. 7A and 7B.

[0063] Figs. 5A-5I depict various views of device 400 or portions of device 400, according to particular embodiments of the present invention. Again, the dimensions, including the lengths, widths, thicknesses and radii of curvature, may vary within the scope of the present invention from those shown in the figures. More specifically, the figures include a longitudinal cross-sectional view (Fig. 5C), a top view (Fig. 5B), a bottom view (Fig. 5A), a side view (Fig. 5F), an end view (Fig. 5E), and a close-up bottom view of expansive zone 410 (Fig. 5D), of device 400. In a preferred embodiment, device 400 is coupled to a bone having a fracture site so that responsive zone 410 is disposed adjacent the fracture site. This arrangement can be seen in Figs. 6A and 6B.

[0064] As shown, device 400 has one or more holes 430 disposed on each side of responsive zone 410 so that device 400 may be coupled to a fractured bone 600. While Figs. 6A and 6B depict four holes 430 on each side of the fracture site, a greater or lesser number of holes 430 may be used within the scope of the present invention. In some embodiments, holes 430 are adapted to receive a screw or other fixation element to affix device 400 to bone 600. The coupling of device 400 to bone 600 preferably positions responsive zone 410 across or adjacent a bone fracture site 610. This may involve attaching one end of device 400 to one bone segment 620 and the second end of device 400 to the opposing bone segment 620. In some embodiments, the screw or fixation element used to couple device 400 to bone segment 620 comprises a bone screw, which may be made of stainless steel, titanium or the like. In a particular embodiment, screws or fixation elements used to coupled device 400 to bone 600 comprise a shape memory alloy, such as Nitinol.

[0065] Figs. 7A and 7B depict a bone fixation system 700 according to an embodiment of the present invention. System 700 includes fixation device 400 as previously described, and a clamp 710. While Fig. 7A depicts a single example of clamp 710, other clamp types fall within the scope of the present invention. Further, alternative devices may be used in lieu of clamp 710, provided the alternative devices are capable of attaching to device 400, and preferably are capable of holding device 400 in a desired position or elongated state. In

operation, an elongating force is applied to device 400 to stretch or elongate device 400 to a prescribed length. As described further below, the application of the prescribed force is determined at least in part by the necessary force to provide healing effect to the bone to which device 400 will be applied. Once device 400 is elongated to the desired length, clamp 710 is used to maintain device 400 in the elongated position. Clamp 710 maintains the elongated position of device 400 until device 400 is attached to the fractured bone. Once device 400 is attached to the fractured bone, clamp 710 may be removed from device 400. In this manner, device 400 is attached to the fractured site and, upon the release of clamp 710, device 400 provides the desired compressive force through the fractured location. Again, in some embodiments device 400 comprises a shape memory material, and in a particular embodiment comprises Nitinol. Preferably, the application of the compressive force is of sufficient duration to facilitate healing as well as to avoid some or all of the other problems associated with prior-art devices constructed of stainless steel, titanium, or similar materials.

[0066] In the depicted embodiment, clamp 710 comprises a main component 712, first and second device-engaging components 714, and a wedge element 716. In one embodiment, device-engaging components 714 are disposed so that screws, lugs, posts or the like 718 extending from components 714 pass at least partially through corresponding holes 430 in device 400. Main component 712 is then coupled to device-engaging components 714 with wedge element 716 positioned therebetween. By rotating or depressing a pressure applicator 720, which in one embodiment is a screw, a force is applied to wedge 716. The application of a force to wedge 716 in the direction shown by arrow 722 causes an outward force to be applied to components 714, as shown by arrows 724. As can be seen in Fig. 7A, the force depicted by arrows 724 results in an elongating force being applied to device 400 through the use of screws, lugs, or posts 718. By controlling the physical relationship between pressure applicator 720 and components 714, the elongating force to device 400 may be controlled. The coupled configuration of clamp 700 with device 400 is generally depicted in Fig. 7B.

[0067] In another embodiment, a separate device or system is used to apply the elongating force to device 400. This may occur, for example, by pulling on opposing ends of device 400 to create an elongating force similar to that represented by arrows 724. Once device 400 has been elongated the desired amount, clamp 710 may be coupled to device 400 in the manner substantially as described above to hold device 400 in the elongated position. In this embodiment, pressure applicator 720 is operated so that the screws, lugs, or posts 718 engage holes 430 to hold device 400 in its desired elongated state. Again, device 400 is then coupled

to bone 600, which preferably positions responsive zone 410 across or adjacent bone fracture site 610. This may involve attaching one end of device 400 to one bone segment 620 and the second end of device 400 to the opposing bone segment 620. Once device 400 is coupled to bone 600, clamp 700 is removed.

[0068] The present invention further provides bone fixation rods, nails and the like. In one embodiment, a bone fixation rod or nail 800 has a first end 810 and a second end 812, with a middle section 814 disposed therebetween. In one embodiment, some or all of rod 800 comprises a shape memory alloy, that in a preferred embodiment comprises Nitinol. For example, in one embodiment, middle section 814 comprises Nitinol. In this manner, middle section 814 is a responsive zone having the characteristics as generally described herein. In another embodiment, one or both of first end 810 and second end 812 comprise Nitinol. In still another embodiment, the entire rod 800 is Nitinol.

[0069] In one embodiment, rod 800 is a dynamic intramedullary nail. Such a device may be used, for example, in retrograde tibio-talo-calcaneal fusions. Nail 800 addresses fusion or fracture site compression problems, as described generally herein in conjunction with prior embodiments, as well as vascular preservation issues. For example, rod 800 may provide dynamic compression across a fusion site in a manner that allows for the use of smaller rods 800, or nails. By having a smaller diameter rod or nail 800 compared to prior art nails of titanium or the like, this would aid in preserving the endosteal/medullary blood supply.

[0070] As shown in Fig. 8, rod or nail 800 is inserted into a bone 850. Rod 800 insertion occurs, in one embodiment, by reaming the bone's medullary canal, and hammering or otherwise driving nail 800 into place. Nail 800 then may be locked relative to the bone with one or more interference or locking screws 820. While the embodiment shown in Fig. 8 depicts a single screw 820 near end 810 and two screws 820 near end 812, it will be appreciated by those skilled in the art that the number of screws 820 may vary within the scope of the present invention. Further, the interference or locking screws 820 may comprise nails, pins or the like. The dimensions of rod 800 and screws 820, including the lengths, widths, diameters, and thicknesses, may vary within the scope of the present invention and may determined, at least in part, by the particular bone(s) and/or joint(s) into which the device is being inserted or otherwise coupled.

[0071] In some embodiments, nail or rod 800 is designed to allow for the release of the responsive element or zone portion thereof, allowing the rod or nail 800 to shorten. This is

accomplished, at least in part, by having the responsive zone of rod 800 comprise a shape memory alloy such as Nitinol as described above in conjunction with screw 300. In this manner, the release of the responsive element-portion of nail 800 draws locking screws 820 on opposing sides of the responsive zone closer together. Dynamic compression on bone 850 results. In one embodiment, the responsive zone, which may include ends 810, 812 and/or middle section 814, is positioned at a desired location(s) within bone 850 or joint 860 to facilitate bone healing. For example, the responsive zone may be positioned adjacent or spanning a fracture site within bone 850, may be positioned within a joint 860, or at other locations at which increased and/or sustained dynamic pressure is desired.

[0072] Bone fixation devices of the present invention, including nails 800, screws 300 and plates 400, may be inserted with one or more sets of instrumentation that also are included within the scope of the present invention. For example, the instrumentation for implantation may be comprised of screws and plates, hammers or other compression devices, clamps or other holding devices, torsion devices such as screwdrivers, torque wrenches or the like for inserting screws, rods and plates. In one embodiment, a torque wrench is provided having a preloaded setting that allows the surgeon to determine whether the screw 300 pseudo elasticity has been activated upon insertion at the fracture site.

[0073] Figs. 9A depicts the stress-strain diagram for living tissues and a nickel titanium alloy. Nickel titanium, and in particular Nitinol, exhibits desirable strain recovery characteristics. The temperature at which Nitinol recovers is known as the transformation temperature (T_t). The transformation temperature may be determined using various heat treatments on the material. The material then may demonstrate pseudo elastic (PE) and shape memory (SM) properties, depending at least in part on the relationship between T_t and the surrounding temperature T_a (e.g., atmospheric temperature, internal body temperature, or the like). The PE state is observed when T_a is greater than T_t. When the material is stretched from an applied force, a permanent strain is observed. When the force is removed, the material recovers the strain. The SM state occurs when T_t is greater than T_a. The material is deformed at above T_a, and remains deformed until a temperature is applied which is above T_t. These characteristics are useful for fashioning fixation devices according to some embodiments of the present invention. Fig. 9B depicts the inventors experimental results showing the affect of total strain on the unloading profile of SIM Nitinol.

[0074] The force that the physician wants to place over fracture site 210 or 610 with screw 100, nail 800, plate 400 or other fixation devices within the scope of the present invention can be defined as F_R. The physician also can determine the anticipated change in length (ΔL) of relaxation/resorption needed to maintain the stability in the fracture. This may involve determining the distant or amount the bone and/or surrounding tissues will relax during the healing period. From this information the cross sectional area and length of a bone fixation device, such as screw 100, nail 800 and/or device 400 can be calculated, respectively.

[0075] Using equation (1) below, the cross sectional area can be calculated. Using equation (2) below, the total length of the responsive element can be calculated. In these equations, A is the cross-sectional area, F_R is the physician-specified recovery force, σ_R is the tensile recovery stress (a material property), L is the length of the responsive zone or element, ΔL is the physician-specified change in length of the responsive zone or element, and ϵ is the tensile strain (a material property). The total length and cross sectional area are used for the manufacturing of the plate or screw in order to meet the physician's needs. Figs. 10A and 10B show an example of possible areas and length, that can be determined by the physician.

$$A=F_R/\sigma_R \qquad (1) \qquad\qquad L=\Delta L/\epsilon \qquad (2)$$

[0076] The responsive element or responsive zone, in a preferred embodiment, has a smaller cross sectional area than the non-responsive part. This reduction of the area allows for the stress to be localized over the element or zone, which in turn elongates only the responsive element or zone. By using the responsive element or zone, the application is able to localize the force caused by the Stress Induced Martensite (SIM) over the fracture, while the non-responsive element stays generally strain free and contributes minimal forces to the bone due to SIM.

[0077] Several devices and systems of the present invention are developed from a Shape Memory Alloy (SMA) to actively respond to the changes of the human body, especially in the bone response. In some embodiments, the inventors studied and used the SMA nickel titanium, or Nitinol. NiTiNOL is biologically compatible with the endoskeleton structure, as well as being strong and durable. Several embodiments of the present invention harness the material characteristics of NiTiNOL.

[0078] The below discussion covers the steps to manufacture a dynamic compression bone screw, nail, bone fixation device or plate, and other active devices from NiTiNOL, and the

machining of NiTiNOL devices. A brief description of the heat treating, composition and deformation techniques used will be addressed. It will be appreciated by those skilled in the art that the manufacturing techniques described represent just some of the embodiments of the present invention.

Material Preprocesses

[0079] It is desirable to develop an accurate stress strain response for various states of the NiTiNOL. Below are the steps used to characterize a particular composition of an SMA of NiTiNOL according to an embodiment of the present invention:

1. Bars of Hot Rolled Ti-50.9% at %Ni, and Cold Drawn Ti-50.9% at.%Ni. were obtained from Special Metals.
2. The materials are cut into desired bone plate, nail and screw shapes from the bars using Electro Discharge Machining (EDM). This process allowed for the presence of mechanical work to be minimal in the samples. The specimens were cut into dog bone samples for tension and rectangular blocks for compression. All tests are run in monotonic strain control.
3. Various heat treatments were applied to the Hot Rolled Material, based on the use of Ti_3Ni_4 precipitants to move the Martensite start (M_s) and finish (M_f) temperatures, as well as the Austenite start (A_s) and finish temperatures (A_f). The results were determined through the transformation peaks being observed using a Differential Scanning Calorimeter.
4. The various stress-strain responses were examined with regard to heat treatment. This allows for certain characteristics to be harnessed in the design. The uses of various heat treatments allow for the stress recovery and strain recovery to be changed.
5. Using the material response in its loaded condition, a cross sectional area is designed as briefly discussed in conjunction with Figs. 10A-10B.

Bone Screw/Nail

[0080] Some embodiments of bone fixation devices of the present invention are developed to actively adapt to the resorption across the fracture site. One such bone screw manufacturing process according to the present invention is provided below. The

manufacture of other fixation devices within the scope of the present invention follow a similar or same process.

1. Using the manufacturing results 1-5 above, the actual design of the responsive element or responsive zone can be determined. The specific calculations of the responsive element for the bone screw are discussed briefly in conjunction with Figs. 10A-10B, and in more detail in Provisional Application No. 60/563,952, previously incorporated herein by reference.

2. The bars of NiTiNOL are sent to be EDM into smaller cylindrical sections. At this time, no heat treatment has been applied and the material is said to be in its as-received state.

3. The smaller cylinders are heat treated for about 600°C for about 30 minutes, which in turn reduces the hardness and places the material in a state more susceptible to machining.

4. The screw is machined, such as on a lathe, at a cutting speed similar to stainless steel (e.g., about 300 RPMs). Concurrently, the NiTiNOL is flooded with cutting fluid to reduce the work hardening effects of the cutting surface.

5. After machining, the final part is heat treated to the appropriate temperature based on the material characterization and design phase, listed above. In a particular embodiment, the heat treatment related to the material composition of 50.9 is about 350°C for about 1.5 hours.

6. The screw is autoclaved and deployed. The reactive element is stretched using the principle of the screws head and threads.

Bone Fixation Device or Plate

[0081] Use of a bone fixation device or a bone plate may be necessary to add a large area of stabilization over the fracture site. The device or plate may be used in unison with a bone screw. The bone fixation device or plate actively adapts to the resorption of a fracture site and compensates for the resorption located at the head and threads of the screws. Below are the instructions used to develop a NiTiNOL bone plate according to an embodiment of the present invention.

1. Using the manufacturing results 1-5, the actual design of the responsive element can be determined. The specifics of the responsive element are discussed briefly in conjunction with Figs. 10A-10B, and in more detail in Provisional Application No. 60/563,952, previously incorporated herein by reference.

2. Based on the type of fracture and amount of resorption expected, the final compressive force required for the plate to respond to the bone is designed using the stress / strain diagram.

3. The bars of the NiTiNOL are sent to be EDM into the final design of the plates. At this time, no heat treatment has been applied and the material is said to be in its as-received state.

It is possible to use the above "softening" heat treatment to machine the plates on a mill. The smaller rectangles will be cut from the bar, and then heat treated at about 600°C for about 30 minutes, which in turn reduces the hardness and places the material in a more "machining friendly" state.

4. The plate has its oxide layer left from the EDM mechanically removed.

5. Based on the results of the material characterization stage, the as-received bone plates are heat treated to get the desired properties. Similar to the screw, the heat treatment related to the material composition of 50.9 is about 350°C for about 1.5 hours.

6. Once the application of the plate is known, it is stretched using an external device to a predetermined strain and held fixed in place with a brace.

7. The entire setup is then sterilized by autoclave and finally deployed over the fracture site.

Other NiTiNOL Devices Including a Responsive Element

[0082] Other devices can benefit from the use of NiTiNOL or other SMA in an active responsive element. For example an interlocking bone marrow nail can be formed. The design of the nail is similar to the screw, and encompasses a similar responsive element. The design comes from the characterization of the NiTiNOL as discussed herein. Still other devices that could incorporate the responsive element include an artificial disk replacement used in a patient's vertebra. The responsive element could be designed to allow different forces between particular vertebrae. For example, a person with a large upper torso has

different stress contribution between the upper vertebrae and lower vertebrae, than a person with a smaller torso. Other uses of SMAs such as Nitinol also exist for creating actively responsive elements.

Bone Fixation Systems and Methods of Use and Manufacture

[0083] In some embodiments, a bone fixation system can include a bone fixation device having a responsive zone, and a clamp having an end cap and an internal brace. Figs. 11A and 11B illustrate an end cap 1110 according to one embodiment of the present invention. End cap 1110 includes a first section 1112 and a second section 1114. In some embodiments, an end cap can be designed to couple with or sit at a distal end of an intramedullary nail and provide additional support to a jig. An end cap can also provide a connection for an internal brace. In some cases, an end cap can be manufactured from Ti6Al-4V and can have an internal threaded cavity or other threaded surface. Fig. 12 shows an internal brace 1210 according to one embodiment of the present invention. Internal brace 1210 includes a first section 1212 and a second section 1214. Typically, end cap 1110 and internal brace 1210 are configured for adjustable cooperation. For example, end cap first section 1112 and internal brace first section 1212 can be threadably engaged. In some embodiments, an internal brace can be designed to sit inside an intramedullary nail and provide a barrier or impediment to premature recovery of the nail. An internal brace can be threaded into an end cap, and can be designed to allow for a guide rod to be inserted inside both the brace and the nail construct. In some cases, the internal brace is manufactured from Ti6Al-4V and has an internal threaded cavity or other threaded surface.

[0084] Figs. 13A and 13B show a bone fixation system 1310 according to one embodiment of the present invention. Bone fixation system 1310 includes a bone fixation device 1320 having a responsive zone 1322, and a clamp 1330 having an end cap 1340 and an internal brace 1350. Clamp 1330 is disposed partially within an internal lumen of bone fixation device 1320, where the internal lumen is disposed along an axial length of bone fixation device 1320. Clamp 1330 can be adjusted to a first mode, as shown in Fig. 13A, that induces or maintains a first amount of strain in responsive zone 1322 along the axial length of bone fixation device 1320. Similarly, clamp 1330 can be adjusted to a second mode, as shown in Fig. 13B, that induces or maintains a second amount of strain in responsive zone 1322 along the axial length of bone fixation device 1320. Often, adjustment to or between the first or second mode involves adjusting the length of clamp 1330. In some cases, the amount of

strain in the first or second mode can be zero. Clamp 1330 can operate to prevent, inhibit, or otherwise control or modulate recovery in responsive zone 1322. Clamp 1330 may be removably coupled with bone fixation device 1320. It is appreciated that the device may be provided in a packaged state, where the device is held stretched by an end cap and internal brace.

[0085] As seen in Figs. 13A and 13B, end cap first section 1342 is adjustably engaged or coupled with bone fixation device 1320, and end cap second section 1344 is adjustably engaged or coupled with internal brace first section 1352. Relatedly, end cap first section 1342 can be threadably engaged with bone fixation device 1320, and end cap second section 1344 can be threadably engaged with internal brace first section 1352. In some embodiments, a central longitudinal axis 1326 defined by an internal lumen of bone fixation device 1320 can be collinear with a central longitudinal axis 1356 defined by internal brace 1350. In some embodiments, central longitudinal axis 1326 can be collinear with a central longitudinal axis 1346 defined by end cap 1340. Relatedly, central longitudinal axis 1356 can be collinear with central longitudinal axis 1346. It is appreciated that bone fixation device can include any of a variety of osteopathic devices, such as nails, screws, plates, rods, compression rods, vertebral and other fixation devices, and the like.

[0086] Responsive zone 1322 can be manufactured or otherwise adapted to have a physical characteristic similar to human tissue, such as bone. For example, the physical characteristic can be a modulus value, for example an elastic modulus value. In some cases, the modulus of the responsive zone can be within a range from about 10 GPa to about 70 GPa. Responsive zone 1322 can include a shape memory material, which may be a shape memory nickel or copper alloy. The shape memory material may include a nickel titanium alloy, a copper zinc aluminum alloy, a copper aluminum nickel alloy, and the like. In some embodiments, responsive zone 1322 is configured to provide a predetermined or preset compressive force across a bone fracture site when the clamp is removed or inactivated. For example, a predetermined or preset compressive force may be within a range from about 2kN to about 4 kN for AO. It is appreciated that therapeutic loads may lie within, below, or beyond this range. Relatedly, responsive zone 1322 can be configured to recover to a predetermined or preset length, for example when clamp 1330 is removed or inactivated so that it no longer imparts a tension to bone fixation device 1320. In some embodiments, the present invention provides a bone fixation device that includes a machined responsive zone having a hardness

value within a range from about 5 HRB to about 60 HRC on the Rockwell B and C Hardness Scales.

[0087] The present invention also contemplates method embodiments for preparing bone fixation systems. For example, bone fixation system 1310 can be prepared by providing bone fixation device 1320 having responsive zone 1322, and inserting clamp 1330 at least partially within an internal lumen of bone fixation device 1320. A strain in responsive zone 1322 along the axial length of bone fixation device 1320 can be induced, maintained, or adjusted by setting clamp 1330 to the appropriate configuration. In some embodiments, bone fixation device 1320 is an intramedullary nail manufactured from NiTiNOL using a series of heat treatments to reduce the hardness from the bulk material. After the nail is manufactured an aging treatment can be supplied to the nail to induce a pseudoelastic response at body temperature (e.g. about 37° C) from the bulk material. The nail can be designed so that during an elongation method only the responsive element will stretch. This can allow for the main recovery of resorption to occur over a bone fracture site. The nail can be designed to recover immediately or quickly upon unloading, thus a clamp or other internal restrain system can be designed to package and maintain the stretched section of the nail.

[0088] Fig. 14 illustrates an external fixation device or jig device 1410 that is designed to maintain the stretched form of a bone fixation device when a clamp is removed therefrom. In some embodiments, a jig can be designed to maintain a stretched form of an intramedullary nail when an internal brace is removed therefrom. An external fixation device or jig can also provide functionality for implantation and locking screw placement. A jig can be preset so that screw holes of the nail, inside the bone, are aligned with screw holes in the jig, outside the leg, thus aiding placement of the locking screws through the soft tissues and bones. Fig. 15 shows a restrainer bar 1510 that can be used to fix an end cap relative to a jig and prevent or inhibit the nail from prematurely traveling up or within the intramedullary cavity. An intramedullary nail, an internal brace, and an end cap can be designed to slip through a restrainer bar until a flange of the end cap comes into contact with the bar. This can lock the intramedullary nail into place and can help align the jig into place. The jig may be configured in any of a variety of suitable shapes. For example, the jig may have a "U" shape.

[0089] In some embodiments, the present invention provides a method of deploying a bone fixation device in a patient. The bone fixation device 1610 shown in Fig. 16 is coupled with a clamp 1615 and includes a first portion 1620, a second portion 1630, and a responsive zone

1640 disposed therebetween. In some embodiments, this can represent the stretching and holding of a nail, whereby the nail is held fixed with an internal brace and an end cap. Clamp 1615 is partially disposed within an internal lumen of device 1610, where the internal lumen is disposed along an axial length of device 1610. Claim 1615 can be configured to induce or maintain a strain in responsive zone 1640 along the axial length of device 1610.

[0090] In an exemplary procedure, a surgeon performs standard techniques to prepare a patient's ankles and subtalar joints for ankle fusion. Fig. 17 depicts an external brace assembly 1710 that includes a jig 1720 and a restrainer bar 1730. Also shown here, relative to external brace assembly 1710, is a patient's lower leg 1740. The external brace assembly can assist the surgeon in properly aligning the ankle for surgery. Using a suitably placed guide wire, a surgeon can ream a hole in the intramedullary cavity to an appropriate size for an outer diameter of an intramedullary nail. In some embodiments, a jig can be placed over a patient's foot or other body part and attach to an intramedullary nail via an end cap at a distal end of the body part, for example at a distal end of the ankle.

[0091] As shown in Fig. 18, a bone fixation device 1810 can be placed adjacent or inside of a patient's bone 1820, and the first portion 1830 of device 1810 can be coupled with the restrainer bar 1830. In some embodiments, a stretched intramedullary nail construct is inserted into an intermediary cavity until the construct comes into contact with the restrainer bar. When contact is made between the construct and the bar, the restrainer bar can be used to align the nail into the proper position. Fig. 19 shows cross pins 1910 effectively coupling bone fixation device 1920 with a first location 1922 of patient's bone 1930 and stabilizing bone 1930 relative to the jig 1940. Cross pins can also be used to similarly fix a second location of the patient's bone to the bone fixation device and may contain a drill tip. Typically, the bone includes a fracture site disposed between the first and second bone locations. Bone fixation device 1920 can therefore be secured relative to jig 1940. In some embodiments, once an intramedullary nail is embedded and aligned inside of an intermediary canal, the surgeon can drill 2-3 holes to place cross pins across a proximal side of the tibia. The cross pins can be designed to provide a fixation point to transfer a load from an internal brace or nail to a jig. As seen in Fig. 20, once the cross pins are installed, the surgeon can preload the jig by removing the internal brace 2010 using an appropriate device such as a hex Allen key drill or hand tool. As the brace is removed the load is transferred through the intramedullary nail and end cap into the jig. The surgeon can monitor external brace and nail placement.

[0092] As illustrated in Fig. 21, after the internal brace has been removed and the load transferred across to the jig, the surgeon can install calcaneal screws 2110 first on the distal side of the ankle and then the proximal/tibial side locking screws can be placed. Bone screws can allow the nail to apply compression through the ankle. As seen in Fig. 22A and 22B, once the screws have been installed on both ends of the intramedullary nail, the end cap 2210 can be slowly loosened or removed using an appropriate tool, such as an Allan key wrench. The gradual unscrewing of end cap 2210 can transfer the load from the external brace 2220 to the intramedullary nail and ankle. In some embodiments, multiple screws may be installed prior to full end cap removal. As depicted in Fig. 23, after the end cap is fully removed, the cross bars or pins can be removed and replaced with bone screws 2310 to secure the remaining portion of the nail. Once the end cap is removed, the nail is in a dynamic state and applies a constant compressive force across the fusion site. A solid end cap can then be placed in the nail to secure the distal end. The surgeon can then suture the remaining incisions and prepare for post-op. The jig can then be dismantled and removed from the patient's foot. The nail is fully loaded and installed.

[0093] The techniques described herein can be used at any part of the body where dynamic axial compressive load is desired. For example, these approaches can be used for treating fractures in long bones fractures, including humeral, radial, tibial, and femoral fractures. Advantageously, these techniques provide for reproducible, true dynamic load, applied from an internal fixation device. Relatedly, these techniques can be used in opposite applications to apply a dynamic distraction force across a site. For example, such opposite applications can be used in limb lengthening procedures or for large "long bone defect implants" for example humeral replacement status post osteosarcoma resection in a non-skeletally mature patient. These systems and methods can also be used to apply controlled distraction/compression in increments activated by radio-frequency or magnetic manipulation. Moreover, the systems and methods can be used to couple a responsive zone with an existing or current implant such as a total hip or a total knee, to allow for greater surgeon margin or error with regard to limb length discrepancies status post joint replacement. In some embodiments, these techniques allow for adjustments months or years after an implant has been placed and the patients individual resorptive bone response has occurred. It is appreciated that these approaches can be implemented in a variety of controllable compression/distention practices involving an internal implant.

[0094] Figs. 24A-24H show a prototypical intramedullary nail with exemplary dimensions. Fig. 25 shows multiple hardness responses achievable from aging of NiTi. Hardness can be related to machinability of a material. In some embodiments, the softer a material is, the easier it is to machine. When a shape memory material such as NiTi behaves pseudoelastically (superelastic) the hardness is at a peak. Thus, the material can be difficult to machine. It may be helpful to age the material into a low hardness state, machine it, then erase the low hardness state and reprogram it to the high hardness state.

[0095] In one embodiment, a method of processing a shape material for use in a bone fixation device can include treating the shape memory material with a first treatment to transform the shape memory material from a first state to a second state, machining the shape memory material while it is in the second state, and treating the machined shape memory material with a second treatment to transform the shape memory material from the second state to the third state. Often, the treatments are designed to establish or optimize pseudoelastic or shape memory characteristics in the material. The first treatment may include a first heat cycle of at least 5 minutes, or in some cases of about 5 minutes to about 1.5 hours, at a temperature of about 600° C or above. It is appreciated that depending on the type of material being processed, the duration and temperature may vary. The first treatment may further include a second heat cycle of at least 5 minutes, or in some embodiments of about 5 minutes to about 1.5 hours, at a temperature of 300° C, 350° C, 400° C, 450° C, 500° C, or 550° C, or at a temperature within a range between about 200° C to about 550° C. In some embodiments, the first state has a first hardness value, the second state has a second hardness value, and the first hardness value is between about 100% and about 500% of the second hardness value. Relatedly, in some cases the first state has a first shape recovery value, the third state has a third shape recovery value, and the third shape recovery value is at least 95% of the first shape recovery value. The shape memory material can include a shape memory alloy such as a nickel titanium alloy, a copper zinc aluminum alloy, or a copper aluminum nickel alloy, or any precipitated shape memory alloy.

[0096] The third state can exhibit an optimal pseudoelastic or superelastic property profile for the shape memory material. Similarly, the third state may also exhibit an optimal shape memory state. In some embodiments, the first state can have a first hardness value, the third state can have a third hardness value, and a difference between the first hardness value and the third hardness value can be less than about 3 HRC on the Rockwell C Hardness Scale. In some cases, this difference may be less than about 10 HRC.

[0097] In another embodiment, the present invention provides a method of preparing a bone fixation device. The method includes providing a bone fixation device that includes a shape memory material, and machining the shape memory material while the temperature of the shape memory material is maintained at or above an austenite or r-phase transition temperature. In some embodiments, during the machining the shape memory material remains in a stiff austenite phase and does not transition to a malleable austenite.

[0098] Embodiments of the invention have now been described in detail. However, it will be appreciated that the invention may be carried out in ways other than those illustrated in the aforesaid discussion, and that certain changes and modifications may be practiced within the scope of the appended claims. Accordingly, the scope of this invention is not intended to be limited by those specific examples, but rather is to be accorded the scope represented in the following claims.

WHAT IS CLAIMED IS:

1. A bone fixation device, comprising:

an elongate element comprising a responsive zone, the element adapted to be coupled to the bone so that the responsive zone is positioned adjacent a fracture or fusion site in the bone; and

wherein the responsive zone is adapted to apply a desired pressure to the bone when coupled thereto.

2. The bone fixation device as in claim 1 wherein the responsive zone comprises a shape memory material.

3. The bone fixation device as in claim 2 wherein the responsive zone comprises Nitinol.

4. The bone fixation device as in claim 1 wherein the elongate element comprises Nitinol.

5. The bone fixation device as in claim 1 wherein the responsive zone is pseudoelastic at a body temperature.

6. The bone fixation device as in claim 1 wherein the responsive zone is generally centrally located in the elongate element, the responsive zone having a smaller overall cross section than a cross section of an end of the elongate element.

7. The bone fixation device as in claim 1 further comprising a coupler adapted to couple the elongate element to the bone.

8. The bone fixation device as in claim 7 wherein the coupler comprises at least one bone screw.

9. The bone fixation device as in claim 8 wherein the bone screw comprises a shape memory material.

10. The bone fixation device as in claim 1 wherein the elongate element comprises a plate, the plate having first and second end sections each comprising at least one hole adapted to receive a coupler therethrough to couple the plate to the bone.

11. The bone fixation device as in claim 1 wherein the elongate element comprises a bone screw.

12. The bone fixation device as in claim 1 wherein the elongate element comprises a nail.

13. A bone fixation system, comprising:

an elongate element comprising a responsive zone of shape memory material; and

a coupler adapted to couple the elongate element to the bone so that the responsive zone is positioned adjacent a fracture or fusion site in the bone.

14. The bone fixation system as in claim 13 further comprising a removable clamp, the removable clamp adapted to maintain the elongate element responsive zone in a desired position prior to coupling of the elongate element to the bone.

15. The bone fixation system as in claim 14 wherein the removable clamp is adapted to be removed from the elongate element after coupling of the elongate element to the bone.

16. The bone fixation system as in claim 13 wherein the responsive zone is adapted to apply a desired pressure to the bone when the elongate element is coupled to the bone.

17. The bone fixation system as in claim 13 wherein the responsive zone has a smaller cross-sectional area than a cross-sectional area of an end of the elongate element.

18. The bone fixation system as in claim 13 wherein the responsive zone comprises Nitinol.

19. The bone fixation system as in claim 13 wherein the elongate element comprises an intramedullary nail.

20. A method of stabilizing a fractured bone, the method comprising:

providing an elongate element comprising a responsive zone of a shape memory material; and

coupling the elongate element to the bone so that the responsive zone is positioned adjacent a fracture site in the bone;

wherein the responsive zone is adapted to apply a desired pressure to the bone when coupled thereto.

21. The method as in claim 20 further comprising:

applying a force to the elongate element to lengthen the responsive zone a desired amount;

maintaining the elongate element in the lengthened position;

coupling the elongate element to the bone so that the lengthened responsive zone is positioned adjacent the fracture site in the bone; and

releasing the elongate element.

22. The method as in claim 21 wherein applying the force to the elongate element to lengthen the responsive zone the desired amount corresponds to a desired compressive force to be applied to the fractured bone when the elongate element is coupled thereto.

23. The method as in clam 20 wherein coupling the elongate element to the bone comprises attaching a first coupler to the elongate element and to the bone on a first side of the fracture site, and attaching a second coupler to the elongate element and to the bone on a second side of the fracture site.

24. The method as in claim 20 wherein the shape memory material comprises Nitinol.

25. The method as in claim 20 wherein the elongate element comprises a bone screw.

26. The method as in claim 20 wherein the elongate element comprises an intramedullary nail.

27. A bone fixation system, comprising:

a bone fixation device having a responsive zone; and

a clamp configured to be received at least partially within an internal lumen of the bone fixation device, the internal lumen disposed along an axial length of the bone fixation device;

wherein the clamp is adjustable between a first mode that induces or maintains a first amount of strain in the responsive zone along the axial length of the bone fixation device, and a second mode that induces or maintains a second amount of strain in the responsive zone along the axial length of the bone fixation device.

28. The bone fixation system as in claim 27, wherein the clamp is removably coupled with the bone fixation device.

29. The bone fixation system as in claim 27, wherein the clamp comprises an end cap and an internal brace.

30. The bone fixation system as in claim 29, wherein the end cap is adjustably engaged with the bone fixation device at an end cap first section, and is adjustably engaged with the internal brace at an end cap second section.

31. The bone fixation system as in claim 29, wherein the end cap is threadably engaged with the bone fixation device at an end cap first section, and is threadably engaged with the internal brace at an end cap second section.

32. The bone fixation system as in claim 29, wherein a central longitudinal axis defined by the internal lumen of the bone fixation device is collinear with a central longitudinal axis defined by the internal brace.

33. The bone fixation system as in claim 32, wherein the central longitudinal axis defined by the lumen of the bone fixation device is collinear with a central longitudinal axis defined by the end cap.

34. The bone fixation system as in claim 27, wherein the bone fixation device comprises a member selected from the group consisting of a nail, a screw, a plate, a pin, a compression rod, and a vertebral fixation device.

35. The bone fixation system as in claim 27, wherein the responsive zone comprises a physical characteristic similar to human tissue.

36. The bone fixation system as in claim 35, wherein the physical characteristic comprises an elastic modulus.

37. The bone fixation system as in claim 36, wherein the modulus comprises a value between a range from about 10 GPa to about 70 GPa.

38. The bone fixation system as in claim 35, wherein the human tissue comprises bone.

39. The bone fixation system as in claim 27, wherein the responsive zone comprises a shape memory material.

40. The bone fixation system as in claim 39, wherein the shape memory material comprises a shape memory alloy.

41. The bone fixation system as in claim 40, wherein the shape memory alloy comprises a member selected from the group consisting of a nickel alloy and a copper alloy.

42. The bone fixation system as in claim 40, wherein the shape memory alloy comprises a member selected from the group consisting of a nickel titanium alloy, a copper zinc aluminum alloy, and a copper aluminum nickel alloy.

43. The bone fixation system as in claim 27, wherein the responsive zone is configured to provide a predetermined compressive force across a bone fracture site when the clamp is removed or inactivated.

44. The bone fixation system as in claim 27, wherein the responsive zone is configured to recover to a preset length when the clamp is removed or inactivated.

45. A bone fixation device comprising a machined responsive zone having a hardness value within a range from about 5 HRB to about 60 HRC on the Rockwell B and C Hardness Scales.

46. The bone fixation device as in claim 45, wherein the responsive zone comprises a nickel titanium alloy.

47. A method of preparing a bone fixation system, comprising:

providing a bone fixation device having a responsive zone;

inserting a clamp at least partially within an internal lumen of the bone fixation device, the internal lumen disposed along an axial length of the bone fixation device; and

inducing or maintaining a strain in the responsive zone along the axial length of the bone fixation device with the clamp.

48. The method of preparing a bone fixation system as in claim 47, comprising threadably engaging an end cap of the clamp with the bone fixation device at an end cap first section, and threadably engaging the end cap with an internal brace of the clamp at an end cap second section.

49. A method of deploying a bone fixation device in a patient, comprising:

providing a bone fixation device having a first portion, a second portion, and a responsive zone disposed therebetween;

inserting a clamp at least partially within an internal lumen of the bone fixation device, the internal lumen disposed along an axial length of the bone fixation device;

inducing or maintaining a strain in the responsive zone along the axial length of the bone fixation device with the clamp;

coupling the bone fixation device with a bone of the patient by attaching the first portion of device to a first bone location, and attaching the second portion of the device to a second bone location, wherein the bone includes a fracture site disposed between the first and second bone locations;

securing the bone fixation device to an external brace assembly;

removing the clamp from the bone fixation device; and

removing the external brace assembly from the bone fixation device;

wherein the bone fixation device remains coupled with the patient's bone, and the responsive zone is allowed to relax so as to transmit a compressive force to the fracture or fusion site of the patient's bone via the bone fixation device.

50. A method of processing a shape memory material for use in a bone fixation device, comprising:

treating the shape memory material with a first treatment to transform the shape memory material from a first state to a second state;

machining the shape memory material while it is in the second state; and

treating the machined shape memory material with a second treatment to transform the shape memory material from the second state to the third state.

51. The method as in claim 50, wherein the first treatment comprises a first heat cycle of at least 5 minutes at a temperature of about 600° C.

52. The method as in claim 50, wherein the first treatment further comprises a second heat cycle of at least 5 minutes at a temperature within a range from about 200° C to about 550° C.

53. The method as in claim 50, wherein the first state has a first hardness value, the second state has a second hardness value, and the first hardness value is between about 100% and about 500% of the second hardness value.

54. The method as in claim 50, wherein the first state has a first shape recovery value, the third state has a third shape recovery value, and the third shape recovery value is at least 95% of the first shape recovery value.

55. The method as in claim 50, wherein the shape memory material comprises a shape memory alloy selected from the group consisting of a nickel titanium alloy, a copper zinc aluminium alloy, and a copper aluminium nickel alloy.

56. The method as in claim 50, wherein the third state comprises an optimal pseudoelastic property profile for the shape memory material.

57. The method as in claim 50, wherein the first state has a first hardness value, the third state has a third hardness value, and a difference between the first hardness value and the third hardness value is less than about 3 HRC on the Rockwell C Hardness Scale.

58. A method of preparing a bone fixation device, comprising:

providing a bone fixation device comprising a shape memory material; and

machining the shape memory material while the temperature of the shape memory material is maintained at or above an austenitic transition temperature.

59. The method as in claim 58, wherein during the machining the shape memory material remains in a stiff austenite phase and does not transition to a malleable austenite phase.

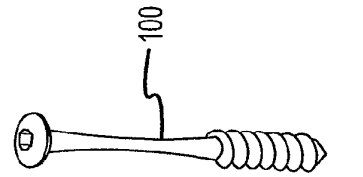


FIG.1A

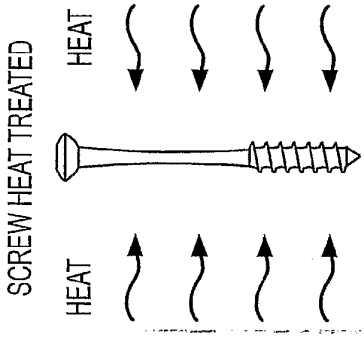


FIG.1C

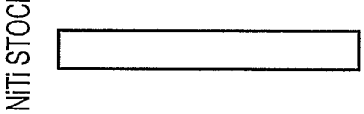


FIG.1B

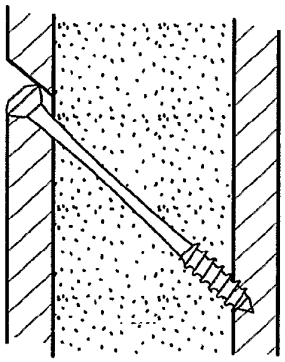


FIG.2C

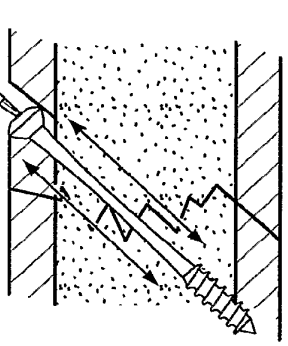


FIG.2B

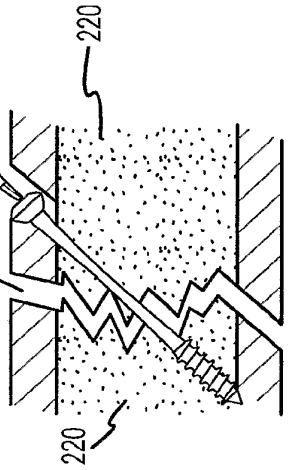


FIG.2A

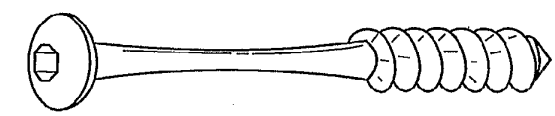


FIG.3F

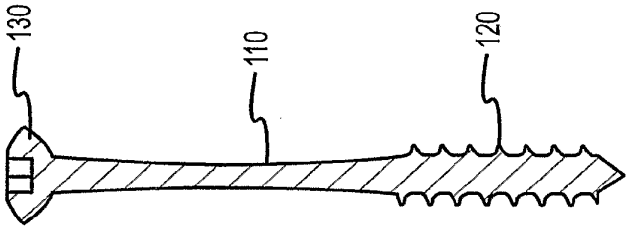


FIG.3D

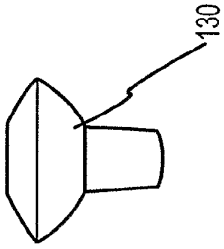


FIG.3B

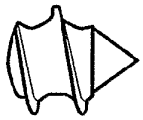


FIG.3C

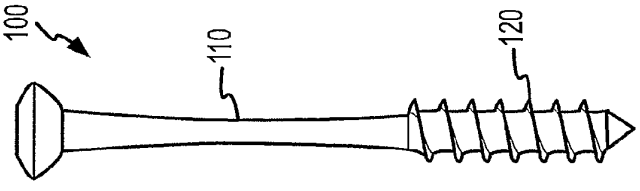


FIG.3A

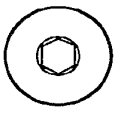


FIG.3E

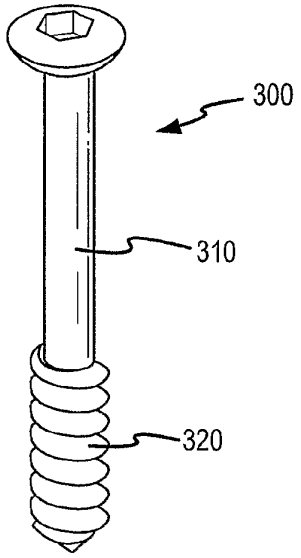


FIG.3G

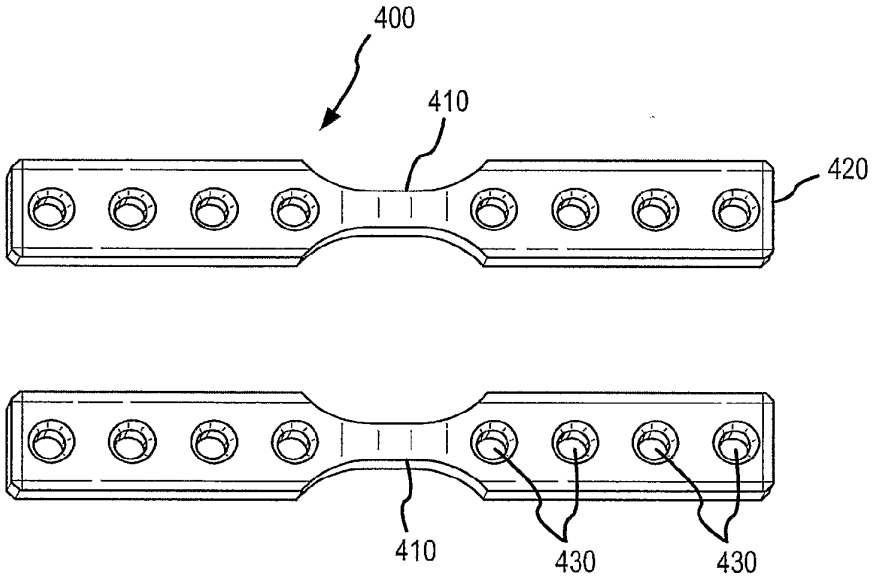
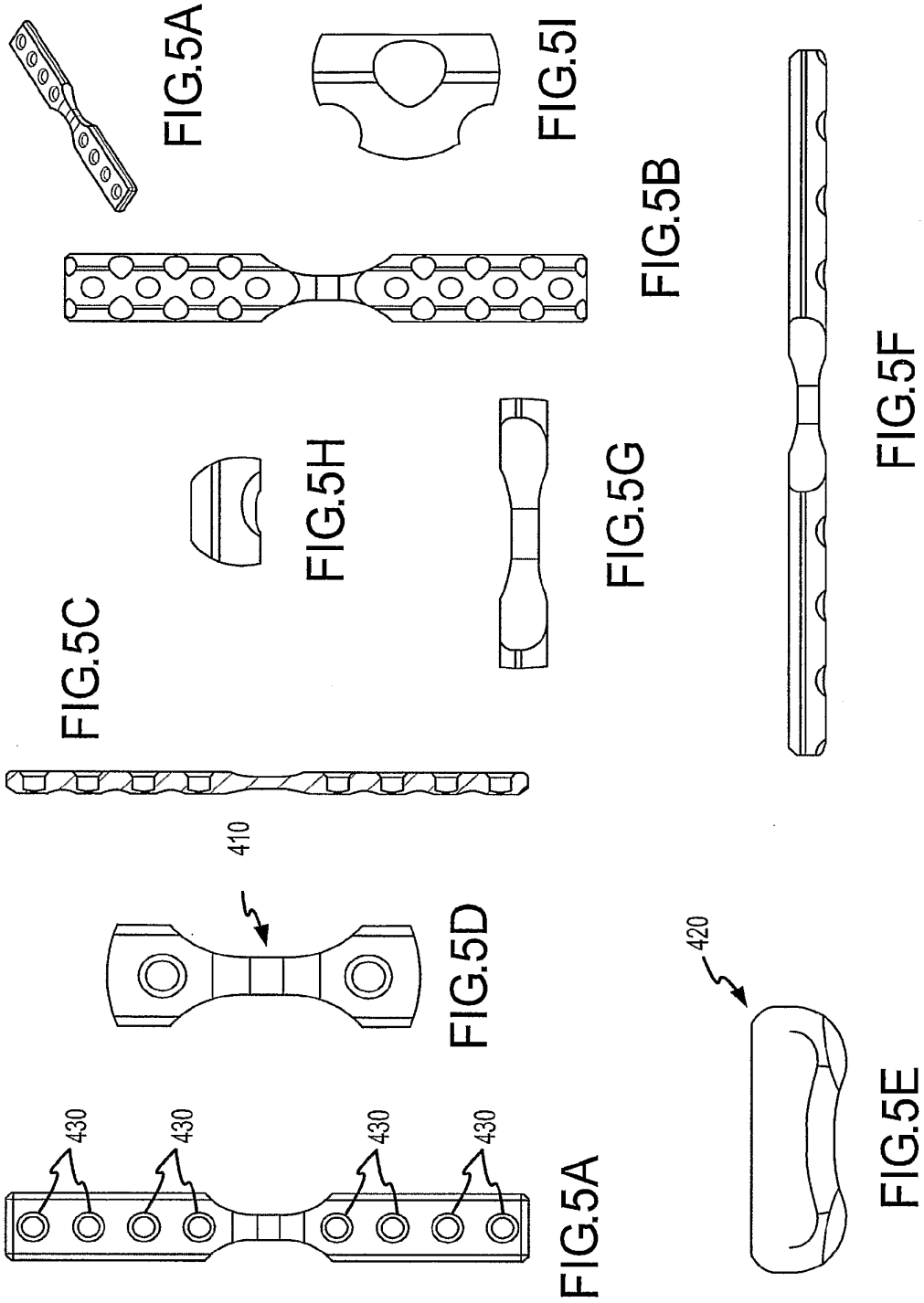


FIG.4


FIG.5A
FIG.5I
FIG.5B
FIG.5H
FIG.5G
FIG.5F
FIG.5C
410
FIG.5D
420
FIG.5E
430
430
430
430
FIG.5A

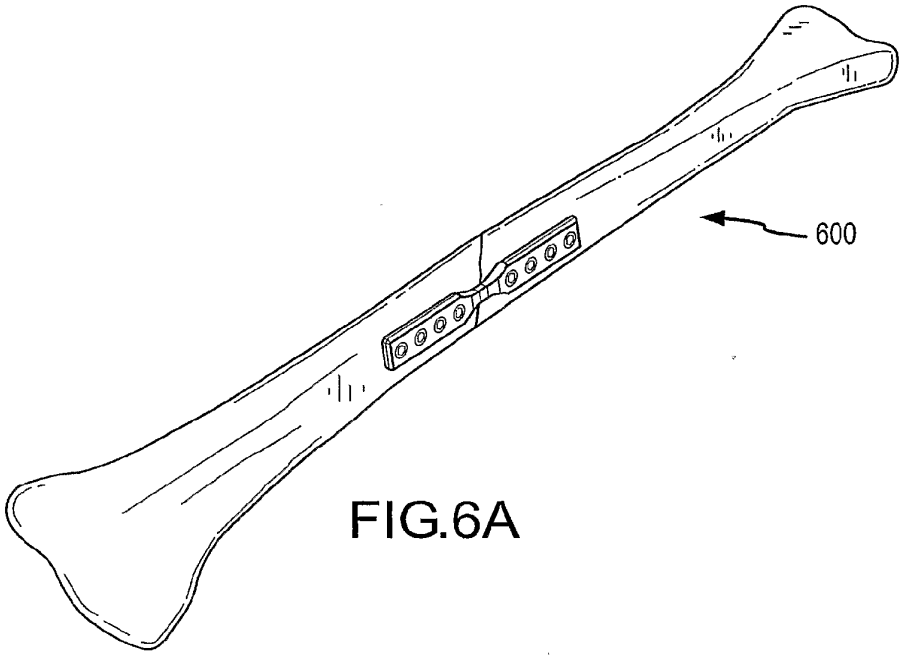


FIG.6A

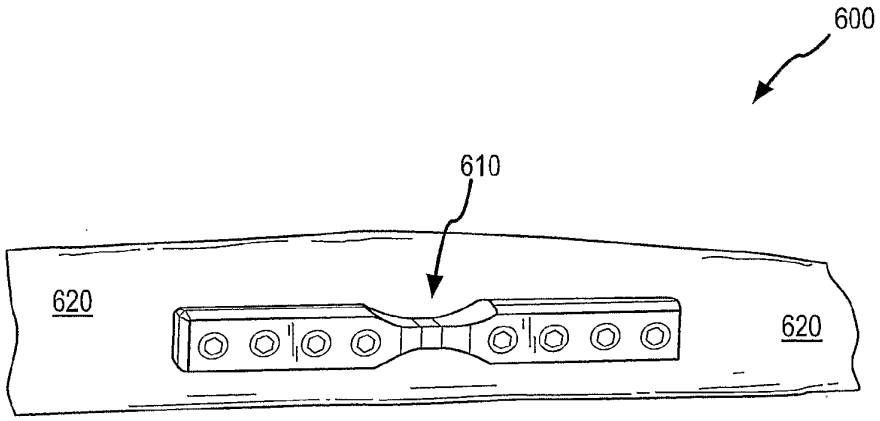


FIG.6B

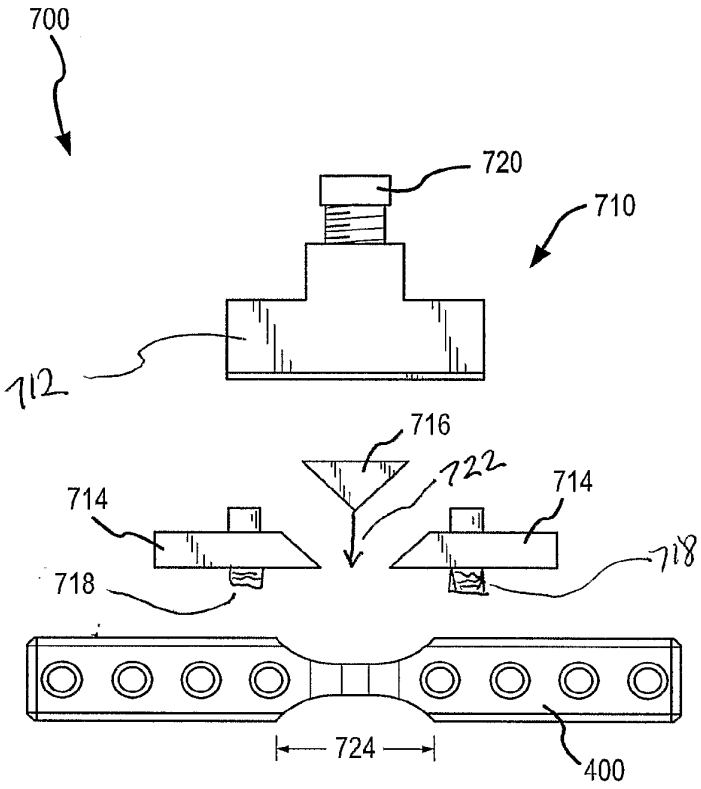


FIG.7A

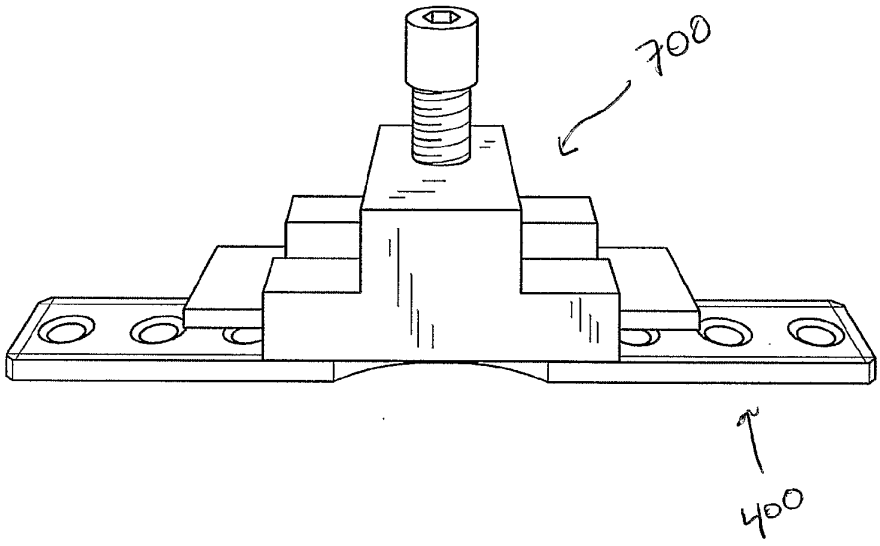


FIG.7B

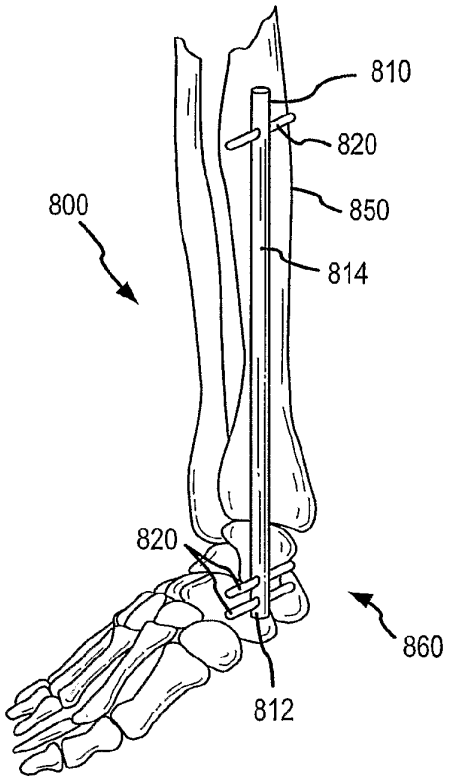
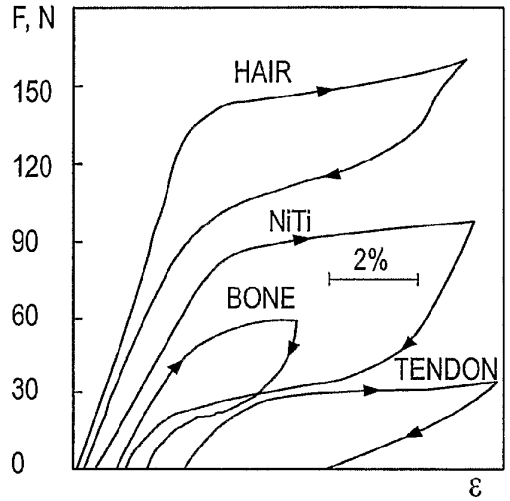


FIG.8



THE STRESS-STRAIN DIAGRAM FOR LIVING TISSUES AND A NiTi ALLOY [I].

FIG.9A

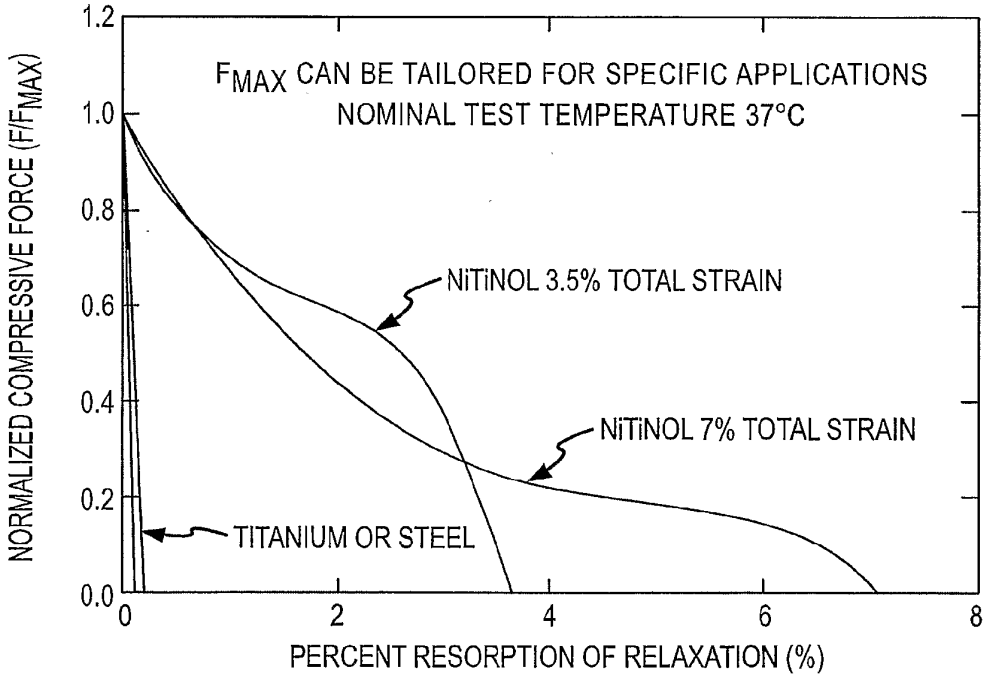


FIG.9B

$A=F_R/\sigma_R$ (1) $L=\Delta L/\varepsilon$ (2)

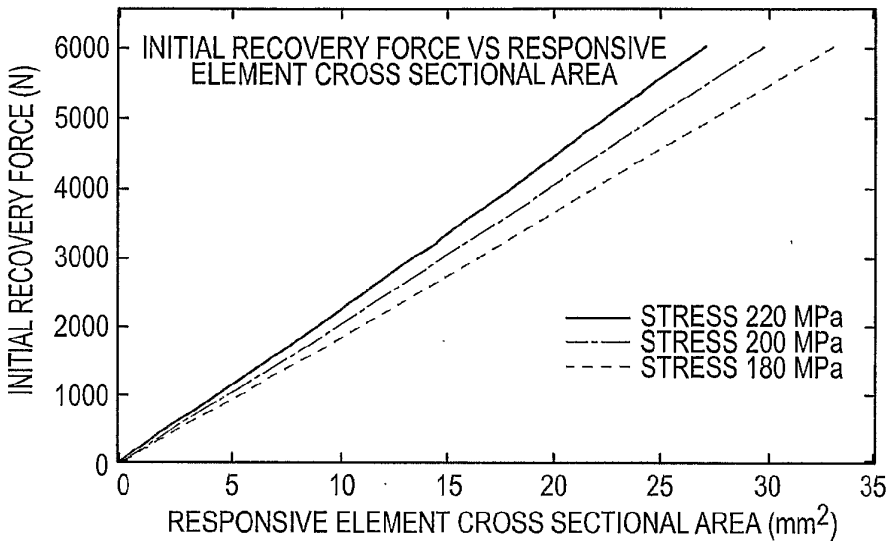


FIG.10A

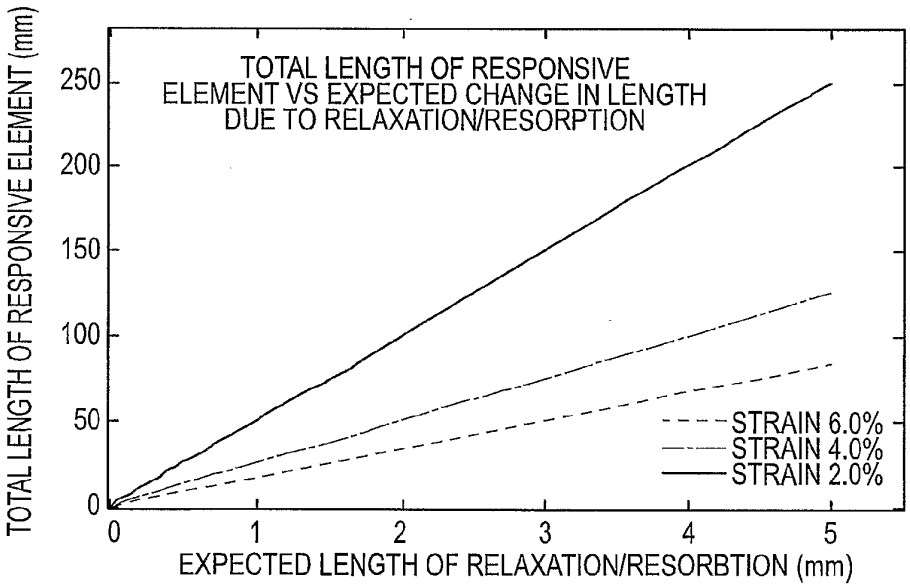


FIG.10B

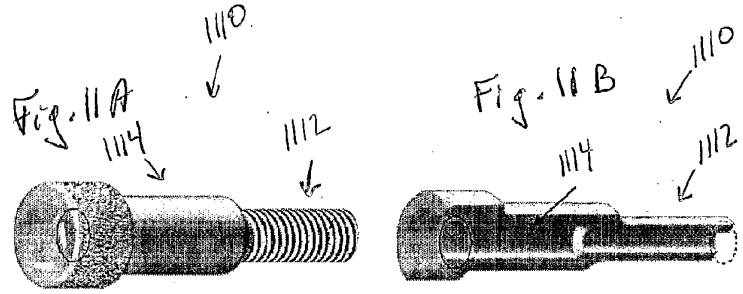


Fig. 11A

Fig. 11B

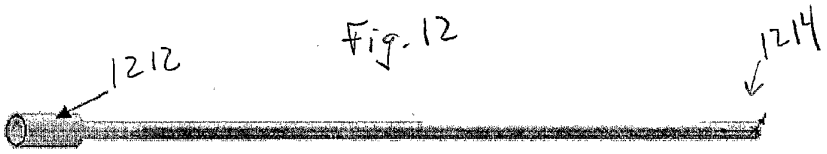


Fig. 12

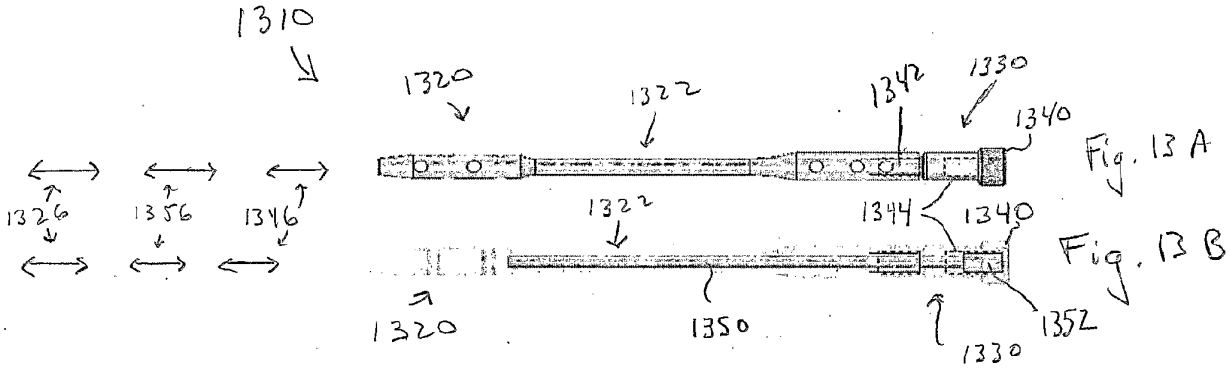


Fig. 13A

Fig. 13B

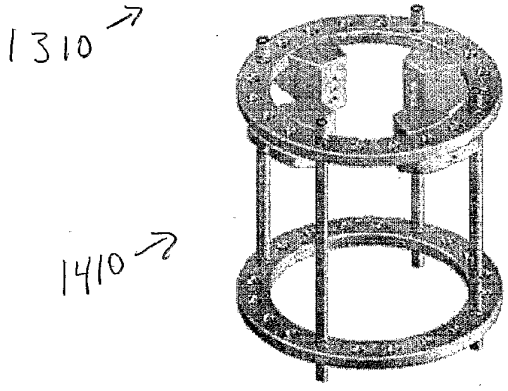


Fig. 14

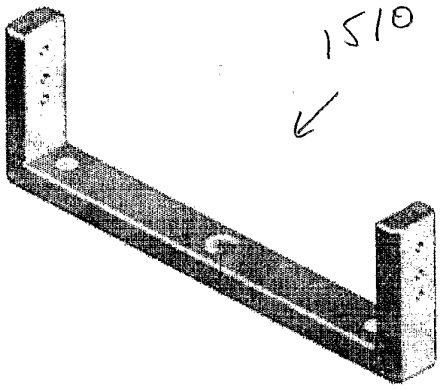
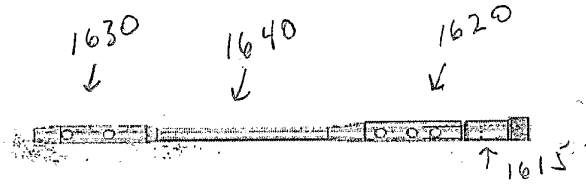


Fig. 15

Fig. 16



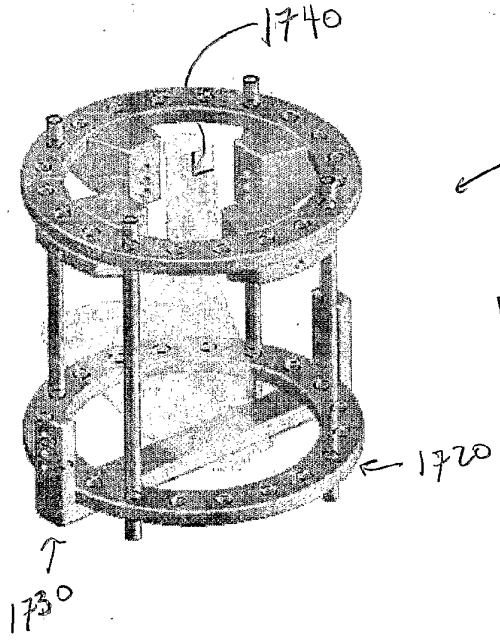


Fig. 17

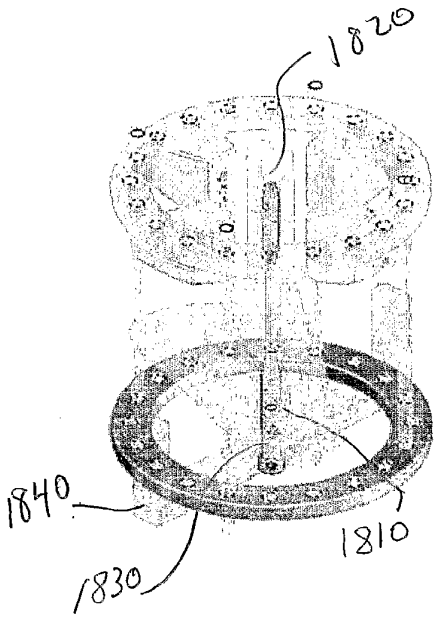


Fig. 18

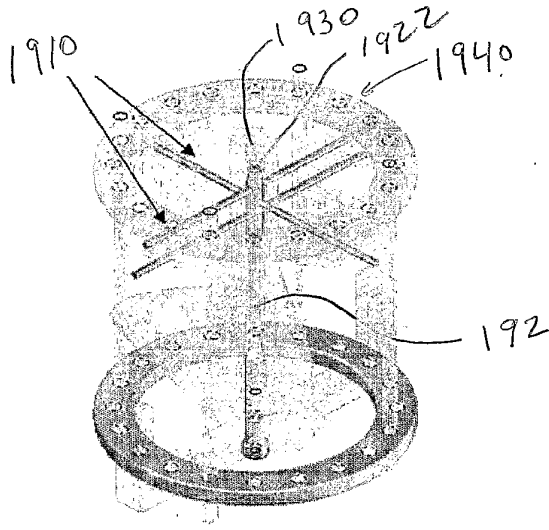


Fig. 19

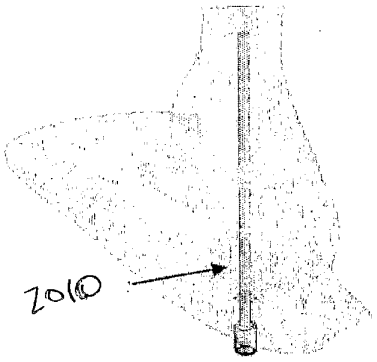


Fig. 20

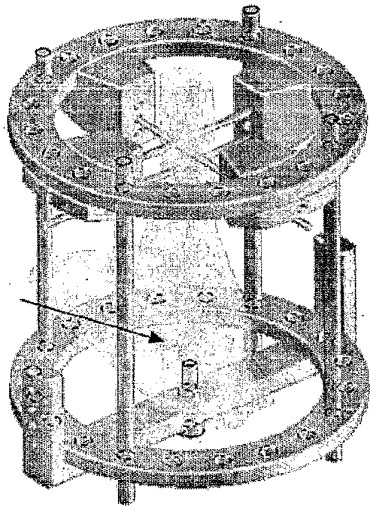


Fig. 21

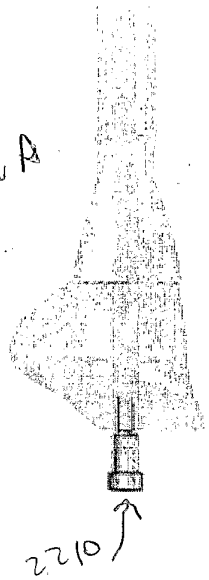


Fig. 22A

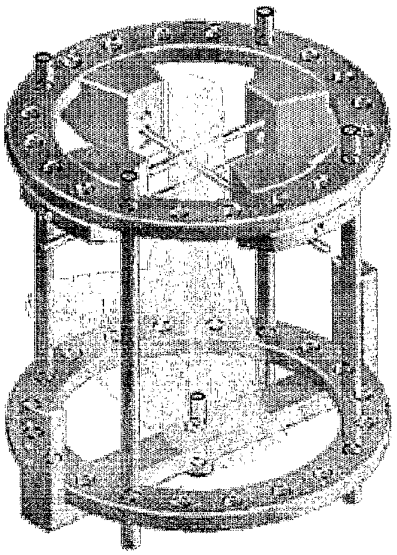


Fig. 22B

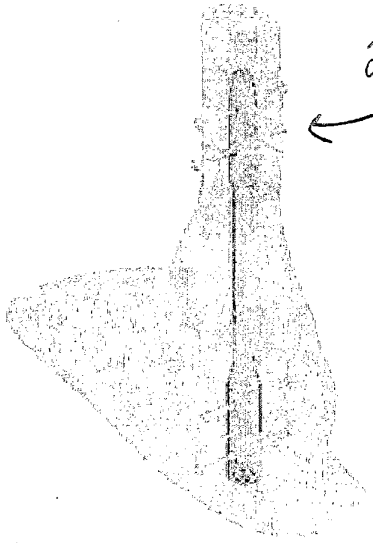


Fig. 23

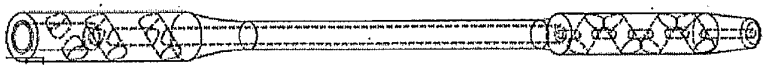


Fig. 24H



Fig. 24E



Fig. 24F

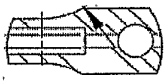


Fig. 24G

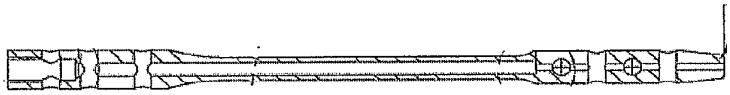


Fig. 24D

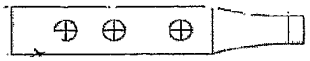




Fig. 24B

Fig. 24C

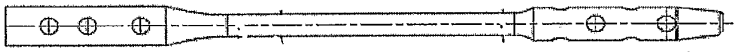
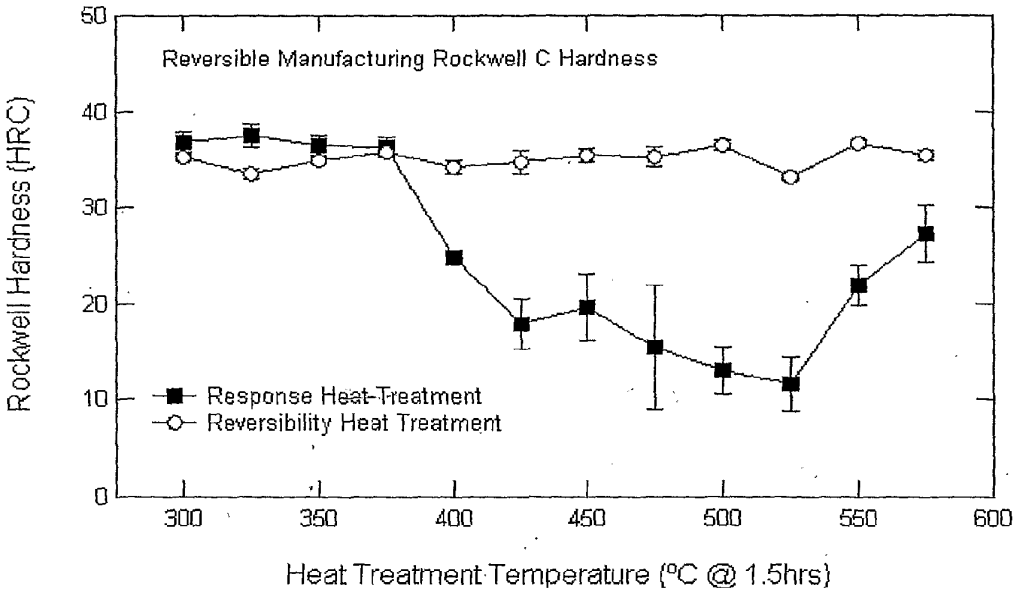


Fig. 24A

Fig. 25


Reversible Manufacturing Rockwell C Hardness
Rockwell Hardness (HRC)
Response Heat-Treatment
Reversibility Heat Treatment
Heat Treatment Temperature (°C @ 1.5hrs)
0
10
20
30
40
50
300
350
400
450
500
550
600

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US06/15207

A. CLASSIFICATION OF SUBJECT MATTER

IPC: **A61B 17/56**(2006.01)

USPC: 606/72

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/72, 61, 73

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,120,175 A (ARBEGAST et al) 09 June 1992 (09.06.1992), see whole document.	1-59
X	US 6,688,828 B1 (POST) 10 February 2004 (10.02.2004), see whole document.	1-59
A	US 6,637,995 B1 (WHITE) 28 October 2003 (28.10.2003), see whole document.	1-59
A	US 5,265,456 A (KENNEDY et al) 30 November 1993 (30.11.1993), see whole document.	1-59

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

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"E" earlier application or patent 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

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Date of the actual completion of the international search

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Date of mailing of the international search report

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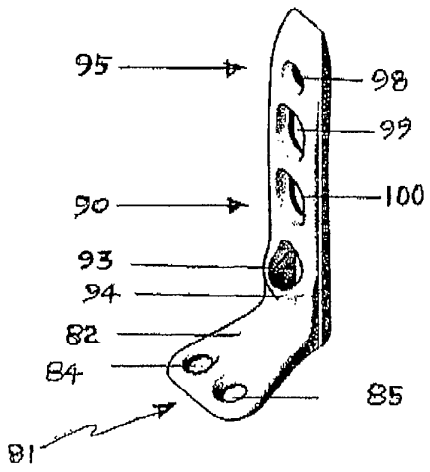
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(54) **Title:** ANKLE FUSION PLATE



(57) **Abstract:** A fusion plate for arthrodesis, the plate comprising: a plate body including a first portion disposed in a first plane and having a first bone engaging surface and a second opposing surface, a second portion disposed in a second plane and having a first bone engaging surface and a second opposing surface, a third portion disposed in a third plane and having a first bone engaging surface and a second opposing surface. The first portion includes at least one opening which receives at least one fixation means. The second portion includes at least one opening which receives at least one fixation means and the third portion includes at least one opening which receives at least one fixation screw.

WO 2007/131287 A1

ANKLE FUSION PLATE

BACKGROUND

The present invention relates to prosthetic devices and raore particularly relates to an ankle fusion plate for fusion of the anterior ankle. More particularly the invention relates to an ankle plate in which openings in the plate receive Fixation screws allowing compression of bones being fused. Thc invention further, relates o a method of inscrtion of an antcrior anklc plate so that optimal compression is achieved in anterior ankle joint fusion. This invention further relates to a kit including a selection of ankle fusion plates and a selection of fasteners for fixation of the ankle plate in a prescribed manner such that orientation of the screws provide optimal compression and therefore mechanical advantage. More particularly, this invention relates to an improved apparatus for fusion of ankle joints.

PRIOR ART

The prior art is replete with orthopaedic devices for repairing bones and particularly diseased bones and bone fractures. The prior art teaches a variety of bone fixation systems using plates and screws.

For example, United States Patent 6,235,034 discloses a bone plate comprising a base plate having at least two screw holes and at least two bone screws capable of securing the bone plate to a bone by insertion through the screw holes into the bone, The bone screws have heads shaped to toggle within the screw holes. A retaining plate is provided that is fixedly attachable to the base plate. The retaining plate covers at least a portion of each of the bone screws. The retaining plate and base plate each contain set screw apertures, A set screw is provided to retain the retaining plate in place ovcr thc basc platc by screwing thc sct screw through thc sct screw apertures in the retaining plate and base plate. This design prevents the bone screw from backing out from the bone once screwed in through the base plate.

Another example of plate fixation by screw is disclosed in United States Patent 5,951.558 which discloses a fixation device for keeping two or more bone pieces together, either pieces of a broken bone or two distinct bones, for undergoing junction of the pieces by natural welding. The device described is capable of immobilizing flat or round bones, long or short bones, for example, parts of a broken femur or two contiguous vertebrae. The device comprises a fixation plate and fixation screws, the plate having orifices for passing the screws through the plate and fastening the screws into the bone tissue. A screw blocking or locking mechanism is provided in the plate to block the screws in the fastening position once the screws have been passed through the plate and screwed into the bone pieces, for preventing the screws from unscrewing from the bone pieces and moving out of the fixation plate once and after the fixation plate and the screws have been firmly installed in the bones.

Another prior art bone fusion device is taught in United States Patent 6,830,589 which describes expandable bone fusion devices and methods of use. The fusion device according to the invention described in that patent includes a first member and a second member which can be deployed and locked into an expanded configuration to stabilize the adjacent bone during fusion of the bone.

More generally United States Patent 6,663.669 discloses a total ankle replacement system and novel surgical method for total ankle replacement. Novel surgical tools for performing the surgical method are also described. The total ankle replacement system includes the calcaneus in fixation of a lower prosthesis body, thereby significantly increasing the amount of bone available for fixation of the lower prosthesis body and allowing the lower prosthesis body to be anchored with screws. The total ankle replacement system further includes a long tibial stem which can also be anchored into the tibia with, for example, screws, nails, anchors, or some other means of attachment.

Bones which have been fractured, either by accident or severed by surgical procedure, must be kept together for .lengthy periods of time in order to permit the recalcification and bonding of the severed parts. Accordingly, adjoining parts of a severed or fractured bone are typically clamped together or attached to one another by means of plates, pins or screws driven through the rejoinud parts. Movement of the pertinent part of the body may then be kept at a minimum, such as by application of a cast, brace, splint, or other conventional technique, in order to promote healing and avoid mechanical stresses that may cause the bone parts to separate during bodily activity. The surgical procedure of attaching two or more parts of a bone with a pin-likc dcvicc normally rcquircs an incision into thc tissuc surrounding the bone and the drilling of a hole through the bone parts to be joined. Due to the significant variation in bone size, configuration, and load requirements, a wide variety of bone fixation devices have been developed in the prior art. In general, the current methods rely upon a. variety of metal wires, screws, plales and damps to stabilize the bone fragments during the healing process. Following a sufficient bone healing period of time, the site may require re-opening to permit removal of the bone fixation device.

The internal fixation techniques commonly followed today frequently rely upon the use of wires, intramedullary pins, plates and screws, and combinations thereof. The particular device or combination of devices is selected to achieve the best anatomic and functional condition of the traumatized bone with the simplest operative procedure and with a minimal usc of forcign-implantcd stabilizing matcrial. It is important in bonc rcpair that the fracture be stable axially, torsionally and rotationally.

ANKLE FUSION

The goal of ankle replacement is to resurface the ankle joint with mechanical parts ibat allow continued ankle motion and function without pain. The models currently used include the Agility Ankle and the Scandinavian Total Ankle Replacement (STAR). Not all known systems are approved for use. Like hip and knee replacements, these devices are constructed of meials and plastics, and, as such, are mechanical parts that can wear out. Currently, patients who are best served by an ankle

replacement are those who will put low mechanical demands on their artificial joints. These include average or lightweight patients who would like to stand and walk with limited or no pain. Certain patient groups are less likely to have good and long-lasting results from ankle replacements, including patients with; previous deep ankle infection, lower limb neuropathy, osteoporosis, high physical demands, obesity, poor skin or vascular problems. Ankle arthroplasty for post-traumatic tibiotalar arthritis remains controversial. The current literature strongly recommends arthrodesis, especially in those patients who will overload the joint: the young, the active and overweight patients. Total ankle arthroplasty has become a viable alternative to ankle arthrodesis. Selected patients can be offered a total ankle replacement as an alternative option to arthrodesis in the treatment of end-stage ankle arthritis. The optimal total ankle replacement patient is an older person who applies low loads and has multiple joint problems.

The ankle joint is a comparatively small joint relative to the weight bearing and torque it must withstand. Total ankle replacement systems attempting to address pain control and improved function have in the past experienced significant failure rates due to the technical difficulty of simulating ankle geometry and loadings. The main alternative to total ankle replacement is arthrodesis. Both procedures are intended to reduce pajji but the total ankle replacement is additionally intended to improve function. If an arthrodesis or ankJe rcplaccmcnt is not propcrly alignccl, significant gait abnormalitics may result. The principal limitations of past total ankle replacement have been loosening of the prosthesis, requiring revision. If the prosthesis requires removal, a subsequent arthrodesis can be considered. Different prostheses require different amounts of removal of bone, potentially compromising the success of a subsequent arthrodesis, Some ankles with implant components often require revision or arthrodesis. Ankle arthrodesis is currently a widely accepted surgical procedure but good, uniform results are not always achievable. Patients treated by compression ankle arthrodesis do not always have an effective fusion rate. The commonly used external fixation devices afford stability in only one plane and do not give rigid

immobilization. A device known as a Triangular Compression Device has been used successfully. A successful Arthrodesis of the ankle can result in a painless, normal walking gait. However., complications in ankle arthrodesis can be major, and can occur when anatomy, deformity, or bony deficiency is not properly addressed. Arthrodesis is usually considered after conservative treatment (such as arthroscopy) fails. Infections, deformity, sensory deficiencies, and botiy defects are complications which require special consideration. External compression enhances the likelihood of a successful arthrodesis.

Presently ankle fusion has had a rate of failure in the literature between 15% and 70%. It is believed that this is largely a result of Initial fixation that is not rigid enough. As in other areas of the skeletal body, superior fusion rates have been achieved by plating rather than fixation by other means Pantalar fusion has been achieved with a revision foot rod. This has been a very technically difficult device to use with poor fusion rates.

Attempts have in the past been made in the prior art to bend and shape an already existing plate on the market but this does not fulfil the requirements, as screws cannot be placed in the desired places or angles to achieve optimal fixation.

A known plate marketed under the trade mark name Tomofix ™ has been crudely adapted for anterior arthrodesis of the aoJde but this is unsatisfactory because the plate is designed for stable fixation of osteotomies close to the knee.

Proper plate fixation relies on the integrity of the screw bone interface, screw insertion angle, screw tightness and effective co operation between screw head and the screw insertion hole. These requirements dictate plate design for a particular anatomical location and repair objective. To date there is no arthrodesis plate and particularly ankle arthrodesis plate which

satisfies the requisite fixation criteria and which is purpose designed to overcome the prior art disadvantages of the known plates.

Since the ankle is the only joint which to date does not have a specific plate for arthrodesis, there is a long felt want in the field to provide a fusion plate that is effective and useful in primary ankle fusion and which will reduce or eliminate fusion failure rates and which provides appropriate geometry to facilitate integrity of the screw bone interface, screw insertion angle, screw tightness and effective co operation between screw head and the screw insertion hole.

INVENTION

The present invention seeks to ameliorate or eliminate the aforesaid problems inherent in the prior art devices and apparatuses and particularly those used in ankle arthrodesis.

The present invention provides an improved arthrodesis fusion plate for fusion of the anterior ankle. More particularly the invention provides an ankle plate in which openings in the plate receive fixation screws allowing compression of bones being fused and orientation of the fixation screws to optimise accommodation of bone loading for efficient and effective fusion. The invention further provides a method of insertion of an anterior ankle plate so that optimal compression is achieved and fixation screws are inserted at appropriate angles in anterior ankle joint fusion. This invention further relates to a kit including an anterior ankle fusion plate and which includes a selection of fasteners for fixation of the ankle plate in a prescribed manner so that the orientation of the screws provide optimal compression and bone fusion.

This ankle fusion plate according to the invention can be inserted into the anterior ankle joint and is used in primary ankle fusion, covetin severe hind foot deformity, pantalar fusion and also in the salvage of ankle replacement.

Although the invention will be described with reference to its application to ankle fusion it will be appreciated by persons skilled in *the art* that the

invention may be applied to the repair/ fusion of other bones requiring axial alignment.

In one broad form the present invention comprises:

a fusion plate for arthrodesis, the plate comprising:

a plate body including a first portion disposed in a first plane and having a first bone engaging surface and a second opposing surface,

a second portion disposed in a second plane and having a first bone engaging surface and a second opposing surface,

a third portion disposed in a third plane and having a first bone engaging surface and a second opposing surface,

the first portion including at least one opening which receives at least one fixation means;

the second portion including at least one opening which receives at least one fixation means ;

the third portion including at least one opening which receives at least one fixation screw.

Tn another broad form the present invention comprises:

an implant kit for arthrodesis fusion the kit comprising:

a fusion plate; and

a set of plate fixation screws;

the plate comprising, a first portion disposed in a First plane and having inner and outer surfaces, the inner surface opposing a bone surface, the first portion including at least one opening including a formation which receives at least one bone fixation screw in a first orientation, a second portion disposed in a second plane and having inner and outer surfaces, the inner surface opposing Ji bone surface, the second portion including at least one opening including a formation which receives a bone fixation screw in at least one orientation, a third portion disposed in a third plane and having inner and outer surfaces, the inner surface opposing a bone surface, the third portion including at least one opening which receives at least one bone fixation screw in a first orientation.

In its broadest form the present invention comprises:

a fusion plate for arthrodesis, the plate comprising:
a plate body including a first portion disposed in a first plane and having a first bone engaging surface and a second opposite surface,
a second portion disposed in a second plane and having a first bone engaging surface and a second opposing surface,
the first portion including at least one opening which receives at least one fixation means;
the second portion including at least one opening which receives at least one fixation means.

Preferably the inner surface of the first portion of the plate opposes the anterior tibia. Preferably the inner surface of the second portion of the plate also opposes the anterior tibia. Preferably, the inner surface of the third portion of the plate disposed in the first plane opposes the talus. The first portion includes at least one opening including a formation which receives a plurality of bone screws of said first type and which on insertion of the plate are disposed normal to the plane of the plate at that region. The second portion of the plate includes a slotted opening which receives a screw of a second type which is of sufficient length to penetrate the tibia, talus and Calcaneus bones. The third portion preferably has two spaced apart openings which receive at least one of a first screw type which are implanted into the Talus,

According to one embodiment, the first portion has a region at is extremity which is thinner.

The screws in each portion of the plate are directed at required angles according to the joint's required for arthrodesis, This is also necessary to achieve maximal compression of the fusion site/s. The fixation screw design is adapted to ensure the above plate fitting objectives are achieved. According to a preferred embodiment, the plate depth changes at different locations. Preferably, the depth at the beginning arid end points of the L shaped contour over the ankle joint in the second region will be at it's maximum thickness. This location adjacent the ankle joint will preferably be

the thickest part ol the plate and will preferably fall within the range 4-8mm. Thickness throughout this specification will refer to the dimension measured from the bone engaging face to an opposite outer face The plate will taper at at least one but preferably two different points of the plate. A first taper will occur at a proximal point of the plate over the tibia. The desired effect is foτ the plate to taper in and decrease in thickness proximally. The taper decreases down to around lmm in thickness and at its proximal extent it is 4mm in width. The second point of plate depth and width change is over the phalanges at the distal point of the plate. At this point the plate according to one embodiment, lapers out and again the thickness at this point would be in the order of about lmm. These points wil) preferably resemble and conform to the typical geometry of the anatomical region. In locations where this does not occur, further manipulation or moulding of the plate geometry can be achieved as required. Preferably, the plates arc configured to generally conform to the anatomic contours of the ankle joint. A range of different plate sizes (at least five) is contemplated with differences in the range of contour and degree of angle over the ankle joint and lengths both proxirnally and distally. In practice 2- 3 three plate sizes are likely to provided a complete inventory.

BRIEF DESCRIPTION OF THE DRAWINGS

Thc prcscnt invcntion will now bc dcscribcd in morc detail according to a preferred, but non limiting embodiment and with reference to the accompanying illustrations wherein:

FIGURE. 1 shows a side elevation view of a plate according to one embodiment and attached via fixation screws to an abbreviated ankle joint (dotted lines)

FIGURE. 2 shows a front clcvation vicw of thc platc of figurc 1 showing alignmcni and spacing of predrilled holes for fixation screws.

FIGURE. 3 shows an elevation view of a first screw type according to one embodiment adapted for insertion in openings for the tibia.

FIGURE 4 shows an elevation view of a second screw type according to one embodiment adapted for insertion in the plate of figures 1 and 2 and allowing adjustable orientation.

FIGURE 5 shows a side cross sectional elevation view of a plate according to a preferred embodiment isolated from an ankle joint.

FIGURE 6 shows a front elevation view of the plate of figure 5 with corresponding numbering .

FIGURE 7 shows a perspective view of the plate of figure 5 with corresponding numbering .

FIGURE 8 shows a cross sectional view of the plate of figure 5 taken at A-A in figure 6.

FIGURE 9 shows the cross sectional side elevation view of the plate of figure 5 (taken along line A of figure 10) showing a non limiting geometry of the plate according to one embodiment.

FIGURE 10 shows a front elevation view of the plate of figure 9 showing a non limiting geometry of the plate according to one embodiment

FIGURE 11 shows a cross sectional view of the plate of figure 10 taken at D-D in figure 10 showing a non limiting geometry of the plate according to one embodiment.

FIGURE 12 shows an enlarged view of detail B in figure 9 showing a non Limiting geometry of the opening.

FIGURE 13 shows an enlarged view of detail C in figure 9 showing a non limiting geometry of the opening.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to figure 1 there is shown a side elevation generally schematic view of a. fusion plate 1 for arthrodesis according to one embodiment. Plate 1 is attached to an ankle joint 2 opposing the Talus bone 3 and Tibial bone 4.

Plate 1 according to the embodiment shown comprises a portion 5 disposed in a first plane which generally aligns with an anterior surface 6 of the talus 3. Portion 5 has an outer surface 7 and inner surface 8 which opposes talus surface 6 for fixation thereto. Disposed in portion 5 are fixation screws 9 and 10 wb.ic.b pass through openings 11 and 12 of portion 5 and engage talus 3 at different orientations. Screws 9 and 10 are disposed at different angles to a vertical resulting in each having different respective horizontal and vertical components of force along orthogonal X and Y axes. Each of openings 11 and 12 have formations which direct respective screws 9 and 10 in the oricntations shown. For cxamplc thc anglc of oricntation of countcrsink in formation 13 of opening 12 directs screw 10 at a predetermined angle which optimises fixation.

Portion 20 of plate 1 has an outer surface 21 and inner surface 22 which opposes anterior surface 23 of tibia 4 for fixation thereto. Disposed in portion 20 is fixation screw 25 which passes through opening 26 in formation 27. Formation 27 is configured so that screw 25 is implanted at an angje within a predetermined allowable angular range. The allowable range will preferably be within a 40 degree arc. Screw 25 engages tibia 4, talus 3, and calcmeus 28 effectively providing three points of fixation according to this embodiment Portion 20 is angled relative to portion 5 at about 100 degrees. This angel is non limiting and may be greater or less than 100 degrees according to the dictates of design-

Portion 30 of plate 1 has an inner surface 31 and an outer surface 32 and preferably disposed normal or near normal to the plane of portion 5. Portion 30 includes openings 33, 34 and 35 which receive fastening screws 36, 37 and 38 each preferably in the same orientation and which engage tibia 4. Screws 36, 37 and 38 are according to one embodiment 4.5mm in diameter and may be of the same screw type as those used for screws 9 and 10 fixing

portion 5. This diameters is non limiting. Also a different type of fixation screw to the configuration of that shows may be employed.

As may be seen from figure 1 the screws axe placed in a particular orientation and required angle to the joint/s required for arthrodesis. This is also necessary to achieve maximal compression of the fusion site/s.

Preferably, portion 30 is disposed in a first plaüe which generally aligns with an opposing face of tibia 4. Portion 20 lies in a second plane at a first angle relative to the fixst plane and aligns with an opposing face of the distal tibia. Portion. 5 lias in a third plane at a second angle relative to the first plane and engages the talus.

Figure 2 shows a front elevation view of the plate of figure 1 showing alignment and spacing of predrilled holes for fixation screws. Figure 2 has corresponding numbering for corresponding parts. From this view it may be seen that according to this embodiment, plate 1 undergoes changes along its length depending upon the bone each part of the plate opposes. Region 30 is narrower than region 20 tapering as the tibia narrows heading proximal Iy. Jn addition, the loads at region 30 can be absorbed by the thinner profile as internal moments are less. As the plate moves distally, the -thickness preferably increases to accommodate the increased compression and rotational loads. The waisted region 50 generally confirms to the contour of the tibia. Openings 33, 34 and 35 are preformed and receive a first preferably countersunk screw type such as that shown in figure 3. Opening 27 which is also preformed, receives a countersink screw which is allowed adjustable orientation. The enlarged slotted holes allow a fine adjustment of the attitude of the screws within a range of around 30 degrees, although it will be appreciated that this range can be narrowed or extended!.

Figure 3 shows an elevation view of a first screw type 60 according to one embodiment adapted for insertion in openings 33, 35 and 36 for the tibial region fixation.

Figure 4 shows an elevation view of a second screw type 70 according to one embodiment adapted for insertion in the plate of figures 1 and 2 and allowing adjustable orientation. Screw type 70 has a longer shank to increase

depth of penetratio α and has an abbreviated threaded portion to allow the majority of the sbank to slide through aligned tibial and talus screw holes finally anchoring in the calcaneus bone.

Figure 5 shows a side elevation view of a plate 80 according to a preferred embodiment isolated from an ankle joint. Plate 80 which is attachable to an ankle joint opposing the Talus bone and Tibial bone, comprises a portion 81 disposed in a first plane which generally aligns with an anterior surface of the talus. Portion 81 has an outer surface 82 and inner surface 83 which opposes a talus for fixation thereto, Disposed in portion 81 are fixation screws (not shown) which pass through openings 84 and 85 of portion 81 engaging the talus at selected orientations. Screws inserted in openings 84 and 85 are preferably disposed at different angles to a vertical resulting in each having different respective horizontal and vertical components of force along orthogonal X and Y axes. Each of openings 84 and 85 have formations 86 and 87 which direct screws in a particular orientation. The angle of orientation of countersink formations 86 and 87 directs screws at a predetermined angle which optimises fixation.

Portion 90 of plate 80 has an outer surface 91 and inner surface 92 which opposes an anterior surface of tibia for fixation thereto. Disposed in portion 90 is a fixation screw which passes through opening 93 in formation 94. Formation 94 is configured so that a fixation screw is directed at an angle within a predetermined allowable angular range. Portion 90 is angled relative to portion 81 at a non Jimitmg angle of about 100 degrees.

Portion 95 of plate] has an inner surface 96 and an outer surface 97 and preferably disposed normal or near normal to the plane of portion. Portion 95 includes openings 98 and 99 which receive fastening screws each preferably in the same orientation and which engage the tibia. Screws which fix plate 80 via openings 98 and 99 may be of the same screw type as those used for fixation through openings 84 and 85.

As may be seen from figure 1 the screws are placed in a particular orientation and required angle to the joint/s required for arthrodesis. This is also necessary to achieve maximal compression of the fusion site/s.

Preferably, portion 95 is disposed in a first plane which generally aligns with an opposing face of a tibia. Portion 90 lies in a second plane at a first angle relative to the first plane and also aligns with an opposing face of the distal tibia. Portion 5 lies in a third plane at a second angle relative to the first plane and engages the talus. Openings 99 and 100 are elongated to allow alignment adjustments.

Figure 6 shows a front elevation view of the plate of figure 5 with corresponding numbering .

Figure 7 shows a perspective view of the plate of figure 5 with corresponding numbering .

Figure 8 shows a cross sectional and plan views of the plate of figure 5 taken at A-A in figure 6.

According to a preferred embodiment the depth/ thickness of the plate 80 will change at different locations on the plate. The depth at the beginning and end points of the generally L shaped contour over the ankle joint formed by portions 81 and 90 will be at it's maximum thickness as it is at this region that the highest loading will occur in normal use. This depth (the thickest part of the plate) will be within the range 5-6mm. The plate will taper at two different points on the plate. Firstly, the proximal end. region of the plate over the tibia. The desired effect is for the plate to taper in and decrease depth at its extremities where loading is least. This would decrease down to around 1mm in thickness and 4mm in width. The second point of plate depth and width change would be over the phalanges at the distal point of the plate. At this point the plate would taper out and again the depth would be that of around the 1mm mark. These points will resemble the average geometry of this anatomical region in the cases where this is not occurring it is at these points that further manipulation or moulding can be achieved if required.

In view of the anatomic contour of ankle joint, there are at least five different sized plates with differences in the range of contour and degree of angle over the ;mkle joint and lengths both proximally and distal Iy. Typically a kit selection or inventory would provide choice of two or three plate sizes. ,

Preferably, the custom shaped L- plate would need to be moulded to an angle in the region of 110 degrees at the point of the contact with the patient bone surface. The range in sizes for this would preferably be 95,, 100, 105 110 and 115 degrees, with corresponding lengths to suit.

An ideal tibial length of the plate would be approximately 80mm. The contour of geometry over the distal aspect of the tibia will be incorporated into the design of the plate. The length from the L point out to the phalanges would be about 25mm in length and at this point the plate would taper out to around 35mm. The plate width before tapering in or out would be in the region of I1 mm. One preferred material for the plate is chrome Cobalt. .

Figure 9 s-hows the cross sectional side elevation view of the plate of figure 5 with corresponding numbering (taken along line A of figure 10) showing a non limiting geometry of the plate according to one embodiment. The dimensions indicated are in millimetres and indicate proportionality of the geometry of the preferred embodiment plate. Shown are distances between openings, size of openings relative angles of separate portions 81, 90 and 95 of the plate. **Figure** 1.0 shows a front elevation view of the plate of figure 9 showing a non limiting geometry of the plate according to one embodiment. **Figure 11** shows a cross sectional view of the plate of figure 10 taken at D-D in figure 10 showing a non limiting geometry of the plate according to one embodiment. **Figure 12** shows an enlarged view of detail B of opening 100. in figure 9 showing a non limiting geometry of the opening. **Figure 13** shows an enlarged view of detail C of opening 98 in figure 9 showing a non limiting geometry of the opening.

This plate significantly increases the ease of pantalar fusion and also allows the ability to start-with ankle fusion and add the pantalar arthrodesis component as required, It is believed that in the pantatar fusion setting, one of the reasons for failure is necrosis of the talus, which occurs due to the multiple incisions tbat are needed. Avoiding amedial incision in this procedure will reduce the rate of talus necrosis after pantalar fusion. This plate also significantly increases the ease of pantalar fusion and also allows the ability to start with ankle fusion and add the pantalar arthrodesis component as required.

The specific dimensions of any of the bone fixation plate of the present invention can be readily varied depending upon the intended application, as will be apparent to those of skill in the art in view of the disclosure herein. Moreover, although the present invention has been described in terms of certain preferred embodiments, other embodiments of the invention including variations in dimensions, configuration and- materials will be apparent to those of skill in the art in view of the disclosure herein. In addition, all features discussed In connection with any one embodiment herein can be readily adapted for use in other embodiments herein. The use of different terms or reference numerals for similar features in different embodiments does not imply differences other than those which may be expressly set forth. Accordingly, the present invention is not limited to the preferred embodiments disclosed herein.

The invention may also be provided as a kit including a plurality of plates and associated fixation screws. Typically a kit may comprise three to five plates for a surgeon to select from depending upon the particular anatomy of the patient. One significant advantage of the plate described herein is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required. Screw sizes may be adjusted to allow for particular insertion points and specific characteristics (e.g. bone density) of bone at points of fixation. The plate may also be manufactured with varied thickness at regions requiring additional strength and contoured to a geometry to best suit ankle anatomy. Screw openings

may be offset to allow three point talar fixation and plate compression. Another advantage of the plate is its pliability at regions when bending may be required for conformity with bone anatomy. The plate allows the talus to be fused with the tibia thereby providing a supporting bridge which is helpful for patients with large ankle defects. The plate also reduces the number of incisions in the patient and may be inserted through an anterior section of joint using the same incision required for a total ankle replacement. For example if a surgeon is revising a total ankle replacement, the same incision can be used as that used when removing a joint replacement and treating with arthrodesis. This techniques provides unproved results in a case where large amounts of bone dissection following a total ankle replacement.

ANALYSIS OF STIMULATED IN - VIVO PERFORMANCE

Studies and testing of a preferred embodiment of the fusion plate have been conducted which determine capacity of the plate to withstand anticipated loadings. The testing considers ankle fusion plate's response to in-vivo loads. The objective of the study was to determine finite element stresses in the plate which result from applied loads and was intended to simulate as closely as possible the in vivo static and dynamic loading conditions. Mechanical properties were taken as that specified as minima in the relevant ISO standards or a? specified by the material supplier.

Equipment used i nthe testing

DELL INSPI RON 5150
ANSYS/ WORJCBENCH V 11 .0
SOLIDEDOE V 19.0

The loading regimes selected for the plate system and parameters was used for load simulation are listed below:

Load Case	Normal Load *(N)*	Loaded surface
1	.1,200	Distal face

2	3600	Distal face

The plate was screw fixed along its the proximal length onto an idealised tibia. Each screw was initially rigidly fixed into the simulated bone side and had a simulated friction effect of sliding against the plate counter faces.

A second simulation was performed to determine the effects of variable bone density on the distal tibia,

Properties for the 316L stainless steel (BioDur 108) alloy were selected as Young's Modulus.. E 200 GPa, Poisson's ratio = 0.3 and a tensile yield strength of 938MPa and ultimate tensile strength of 1269 MPa. The bone stiffness was varied from 0.5GPa to 3 GPa and Poisons ratio of 0.3.

The following load conditions were simulated :

1. Screws rigidly fixed,	1 .20ON (120kg) Distally fixed.
2. Bone with low stiffness,	1 ,20ON (120kg) Distally loaded.
3. Bone with high stiffness,	1,20ON (120kg) Distally loaded.
4. Bone with low stiffness,	3,60ON (360kg) Distally loaded.

The resulting stress distributions in the neck and stem were compared.

The simulations were solved as non-linear elastic stress analysis, mesh refinement was applied to the regions of high stress concentration. An initial mesh size was selected as 1mm, the resulting stresses were recorded. A subsequent run was performed with a refined mesh around high stress locations. A mesh density of half was used and the subsequent change in stress was compared to the original run, the results of these simulations was within 10%, thus a mesh density of lmm was selected for all simulations.

Observations from Results.

The initial simulation (1,2OQN - 120kg load) simulated the fixation screws rigidly fixed into the bone, i.e. the bone did not allow the screws to be pulled with the bone. This simulation would be analogous to hard cortical bone fixation of the screws. As would be anticipated the results showed that the highest stresses occur on the inner surface of the plate approximately were a change in section thickness occurs just above the angled screw formation. This is due to the reduction in effective (cross sectional) area of the plate at that location. The magnitude of peak tensile stress at that location was 495 MPa, which is approximately 47% less than the yield strength of the material, thus providing a factor of safety of 1.9 which well satisfies engineering design standards.

When the bone quality is reduced (stiffness of supporting bone reduces) the stress increases. The stress increases over a range from 495 to 713 to 910 MPa moving from optimally stiff bone to low bone quality respectively. The location in the plate of the high stress concentration region was unchanged with the magnitude increasing with decreased bone quality. The testing found that for poor distal tibia bone quality the factor of safety is reduced to approximately 1. as the maximum tensile stress is approximately at the yield strength of the malerial. The maximum deformation in the plate occurs at the tip of the distal surface (toe) of the plate and varies from 0.37 to 0 53 and 0.97mm for the highest to lowest bone quality respectively.

A simulation was performed to determine the integrity of the plate with a 3,60ON load (360kg) on the rigidly supported "home run" lag screw. The maximum stress in the plate is in the same location as before with the exception that it has increased from 495MPa to 1 .484MPa for the 1,200N (120kg) and 3,60ON (360kg) loads respectively. The ultimate tensile strength of the BioDurlO8 alloy is approximately 1269MPa. Thus, for the applied load of 3,60ON (360 kg) the material failed at the region of the screw opening (distal tibia engagement region) where the effective cross sectional area of the plate is reduced to accommodate the fixation screw at that point.

It can be estimated that the maximum load the tested plate can take prior to failure is 3,075N (308kg).

For perfect (rigid) tibial bone quality the plate can carry 1,200N (120kg) with a factor of safety of 1.9. Decreasing the bone quality decreases the load carry capacity of the plate. With the lowest bone quality (stiffness of 1.0 GPa) for an applied load of 1,200N (120kg) the stress in the plate increased to 910MPa just below the yield strength of the material. The plate tested will only carry approximately 3,000N (300kg) when rigidly fixed to the tibia, at a load of 3,600N (360kg) the stress in the plate exceeds the ultimate strength of the alley.

The above tests provide performance indications for a plate of the particular type and geometry tested. Arthrodesis plates with different geometry and dimension such as alternative thickness distributions and angulations may result in different measured loadings and plate response. Alternative plates made from different materials and different geometry will be likely to have different load capacity results for equivalent in vivo simulations but without compromise to fusion result provided the right plate is selected from the particular patient. Accordingly, the above observations and findings should be taken as a non limiting example of tested simulated in vivo performance for one plate of a particular size, geometry and material and should not be construed as limiting of load capacities and performance of alternative ankle fusion plates made in accordance with the present invention. Proportionate plate sizes may vary from patient to patient but consistency of plate performance in vivo will be geometry of the plate

It will be recognised by persons skilled in the art that numerous variations and modifications maybe made to the invention as broadly described herein without departing from the overall spirit and scope of the invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1 A fusion plate for arthrodesis, the plate comprising:
a plate body including a first portion disposed in a first plane aud having a first bone engaging surface and a second opposing surface,
a second portion disposed in a second plane and having a first bone engaging surface and a second opposing surface,
a third portion disposed in a third plane and having a first bone engaging surface and a second opposing surface,
the first portion including at least one opening which receives at least one fixation means;
the second portion including at least one opening which receives at least one fixation means ;
the third portion including at least one opening which receives at least one fixation screw.

2 A fusion plate according to claim 1 wherein, the second portion of the plate, body is disposed at a first angle relative to the first plane and the third portion is disposed at a second angle relative to the first plane.

3 A fusion plate according to claim 2 wherein the second angle is greater than the first angle ,

4 A fusion plate according to claim 3 wherein, the first portion includes an opening of a first size and a second opening of a second size.

5 A fusion plate according to claim 4 wherein the second portion includes a first opening of a first size and a second opening of a second size.

6 A fusion plate according to claim 5 wherein the third portion includes at least two openings of the same size.

7 A fusion plate according to claim 6 wherein a second opening in the first portion is larger than the first opening.

8 A fusion plate according to claim 7 wherein the second opening in the first portion is elongated.

9 A fusion plate according to claim 8 wherein the first opening in the second portion is the same size as the second opening in the first portion.

10 A fusion plate according to claim 9 wherein the second opening in the second portion is circular.

11 A fusion plate according to claim 10 wherein, the opposing face of the second portion includes a formation which includes said second opening .

12 A fusion plate according to claim U wherein the formation is a shoulder including a countersunk recess for receiving a fastener head.

13 A fusion plate according to claim 12 wherein the first and second portion of the plate body are approximately the same width.

14 A fusion plate according to claim 13 wherein the third portion of the plate body has a first proximal narrow end and a second distal flared end.

15 A fusion plate according to claim 14 wherein the flared end has two openings to receive fixation screws.

16 A fusion plate according to claim 15 wherein the plate is symmetrical about a longitudinal axis but asymmetric about a transverse axis normal the longitudinal axis .

17 An impI-LUt kit for arthrodesis fusion, the kit comprising:
at least o.ne fusion plate; and

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at least one set of plate fixation screws;

each platc comprising, a first portion disposcd in a first planc and having inner and outer surfaces, the inner surface opposing a bone surface, the first portion including at least one opening including a formation which receives at least one bone fixation screw in a first orientation, a second portion disposed in a second plane and having inner and outer surfaces, the inner surface opposing a bone surface, the second portion including at least one opening including a formation which receives a bone fixation screw in at least one orientation, a third portion disposed in a third plane and having inner and outer surfaces, the inner surface opposing a bone surface, the third portion including at least one opening which receives at least one bone fixation screw in a first orientation.

18 A kit according to claim 17 wherein the plate geometry i$ arrangcd to at least partially conform to thc shapc of lhc anatomy of bones to which the plate is f xed.

19 A kit according to claim 18 further comprising a selection of said fixation screws of at least two types.

20 A kit according to claim 19 further comprising a selection of said fixation screws of at least two sizes.

21 A kit according to claim 20 wherein the plate is fixed to ankle bones.

22 A kit according to claim 21 wherein the inner surface gf the first portion of thc platc disposcd in thc first planc, whcn fitted to a patient opposes the anterior tibia,.

23 A kit according to claim 22 wherein the inner surface of the second portion of the plate, when fitted to a patient, opposes the anterior tibia,

24 A kit according to claim 23 wherein the inner surface of the third portion of the plate, when fitted to a patient, opposes the anterior talus.

25 A kit according to claim 24 whcrcin thc first portion prcfcrably has two spaced apart openings which receive at least one of a first screw type which are implanted into the tibia

26 A kit according to claim 25 wherein the second portion of the plate includes a slotted opening which .receives a screw of a sccond typc which is of sufficicnt lcngth to pcnctratc thc tibia, talus and Calcaneus bones.

27 A kit according to claim 26 wherein the first portion includes at least one opening which receives a plurality of bone screws of said first type and which on insertion of the plate are disposed normal to the plane of the plate at that region.

28 A kit according to claim 27 wherein the openings in the plate are arranged so that fixation screws may each be directed at a predetermined angle,

29 A kit according to claim 28 wherein the plate thickness varies at different locations and wherein the portion of the plate which lays over the ankle joint has maximum thickness.

30 A kit according to claim 29 wherein the thickest part of the plate will be within the range 4-8mm.

31 A kit according to claim 30 wherein the plate has a first taper at a proximal point of the plate over the tibia.

32 A kit according to claim 31 wherein there are at least five plates in the kit.

33 A fusion plate according to claim 3 wherein the first plane is a longitudinal tibial plane, the second is a tibïa-talar joint plane including an oblique formation and the third plane is a talar plane lying *along* the talus.

34 A fusion plate according to claim 33 wherein the first plane extends from the tibia-talar plane proximally along the tibia for approximately 60-65mm.

35 A fusion plate according to claim 33 wherein as the plate extends along tlie tibia its thickness decreases from 2.5mm to 2mm.

36 A fusion plate according to claim 33 wherein as the plate extends along the tibia width decreases from 12.5mm to 8mm.

37 A fusion plate according to claim 36 wherein the first portion has two screw openings the first being of smaller size than the second.

38 A fusion plate according to claim 37 wherein the first screw is 4 millimeters in diameter and the second screw opening is elongated.

39 A fusion plate according to claim 38 wherein the elongated opening is 10mm in length and 4.5mm in width.

40 A fusion plate according to claim 39 wherein the elongated opening receives 4.5mm cortical screws.

41 A fusion plate according to claim 40 wherein, the tibia-talar joint plane tejminate$ distally in a generally L shaped convex bend.

42 A fusion plate according to claim 41 wherein the L shaped bend is the thickest part of the plate.

43 A fusion plate according to claim 42 wherein, the plate is 3.5mm thick at the bend.

44 A fusion plate according to claim 43 wherein the plate is 12.5mm thick at Hie bend.

45 A fusion plate according to claim 44 wherein the second portion includes a shoulder which includes an oblique screw opening.

46 A fusion plate according to claim 45 wherein, the oblique opening receives a. 6.5mm cannulated fastening screw.

47 A fusion plate according to claim 46 wherein the oblique opening allow the screw to be inserted at one of a plurality of available angles.

48 A fusion plate according to claim 47 wherein, the third portion lies over the (alar bone.

49 A fusion plate according to claim 48 wherein the third portion splays outward distally from a width of about 12.5πrrn to 2OmJTL.

50 A fusion plate according to claim 49 wherein the thickness of the third portion decreases distally from about 3.5mm to 2mm.

51 A fusion plate according to claim 50 wherein the plate the angle between the first portion and the third portion is within the range of 95 - 115 degrees.

52 A fusion plate according to claim 51 wherein, the length of the plate along the tibia is between 60 - 65mm.

53 A fusion plate according to claim 52 wherein the length of the plate over the talus is within the range of 20—23mm.

54 A fusion plate according to claim 53 wherein the plate is manufactured from materials selected from stainless steel, titanium, polyethylene, plastics or other biomedical material.

55 A fusion plate for arthrodesis, the plate comprising:
a plate body including a first portion disposed in a first plane and having a first bone engaging surface and a second opposite surface,
a second portion disposed in a second plane and having a first bone engaging surface and a second opposing surface,
the first portion including at least one opening which receives at least one fixation means;
the second portion including at least one opening which receives at least one fixation means.

56 A fusion plate according to claim 55 wherein, the second portion of the plate body is disposed at a first angle relative to the first plane.

57 A fusion plate according to claim 56 wherein, the first portion includes an opening of a first size and a second opening of a second size.

58 A fusion plate according to claim 57 wherein the second portion includes a first opening of a first size and a second opening of a second size.

59 A fusion plate according to claim 58 wherein a second opening in the first portion is larger than the first opening.

60 A fusion plate according to claim 59 wherein the second opening in the first portion is elongated.

61 A fusion plate according to claim 60 wherein the first opening in the second portion is the same size as the second opening in the first portion.

62 A fusion plate according to claim 61 wherein the second opening in the second portion is circular. the third portion includes at least two openings of the same size.

63 A fusion plate according to claim 62 wherein, the opposing face of the second portion includes a formation which includes said second opening .

64 A fusion plate according to claim 63 wherein the formation is a shoulder including a countersunk recess for receiving a fastener head.

65 A fusion plate according to claim 64 wherein a third portion of the plate body has a first proximal narrow end and a second distal flared end.

66 A fusion plate according to claim 65 wherein the first and second portions of the plate body are approximately the same width.

67 A fusion plate according to claim 66 wherein the flared end has two openings to receive fixation screws.

68 A fusion plate according to claim 67 wherein the plate is symmetrical about a longitudinal, axis but asymmetric about a transverse axis normal the longitudinal axis ,

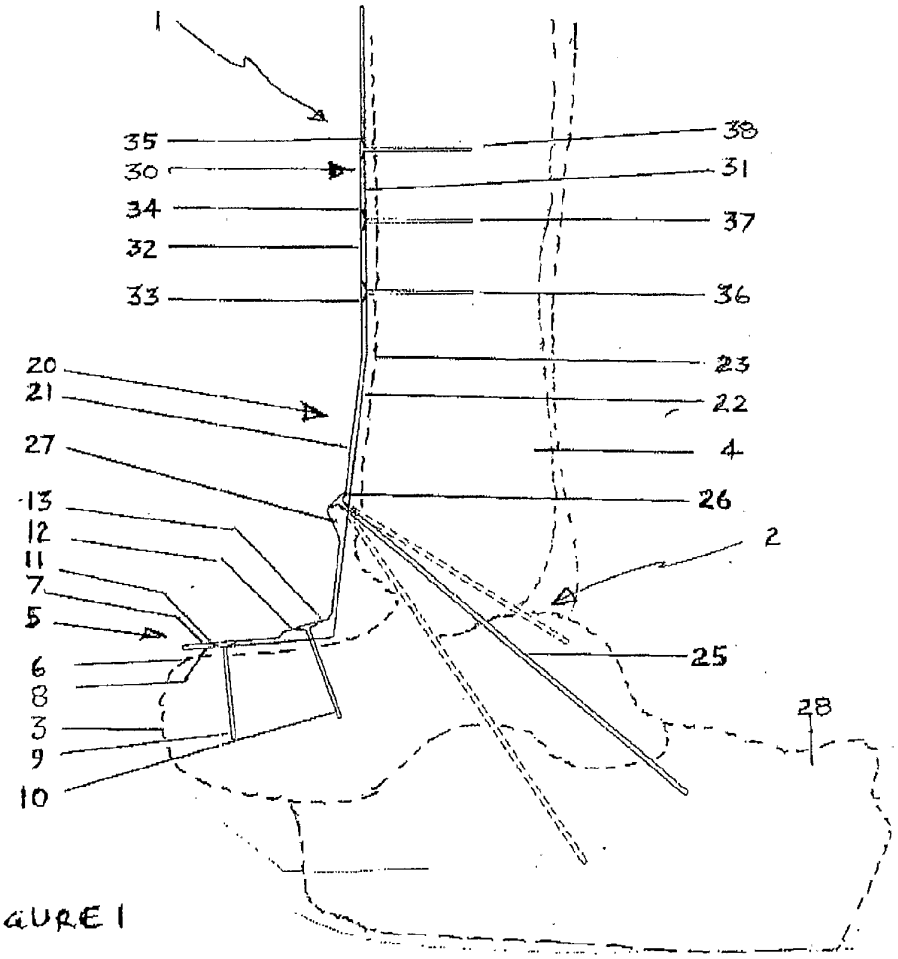

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FIGURE 1

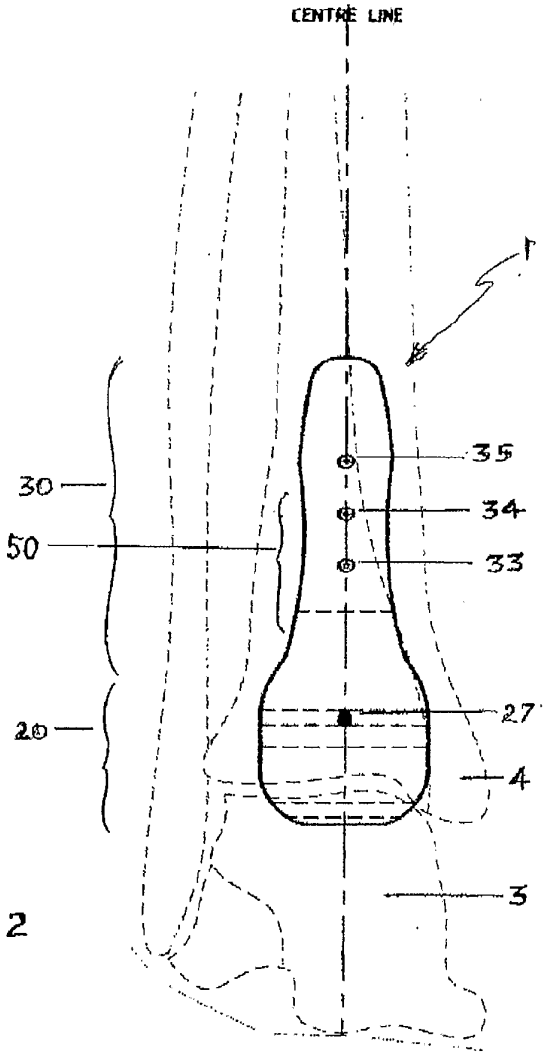


FIGURE 2

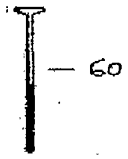


FIGURE 3

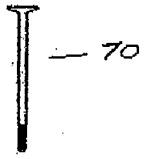


FIGURE 4

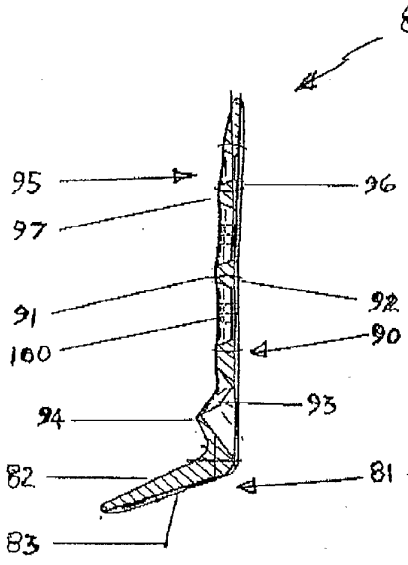


FIGURE 5

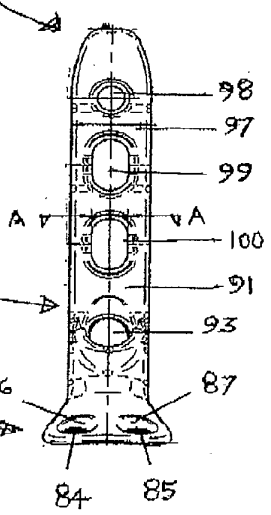


FIGURE 6

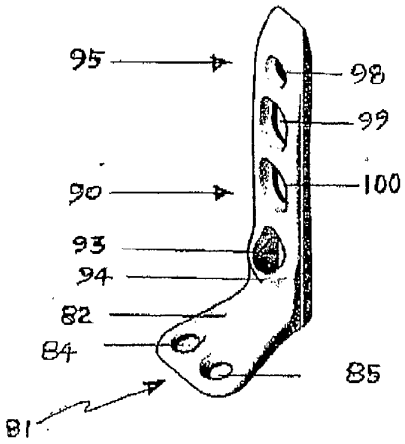


FIGURE 7

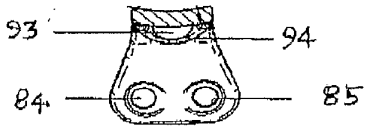


FIGURE 8

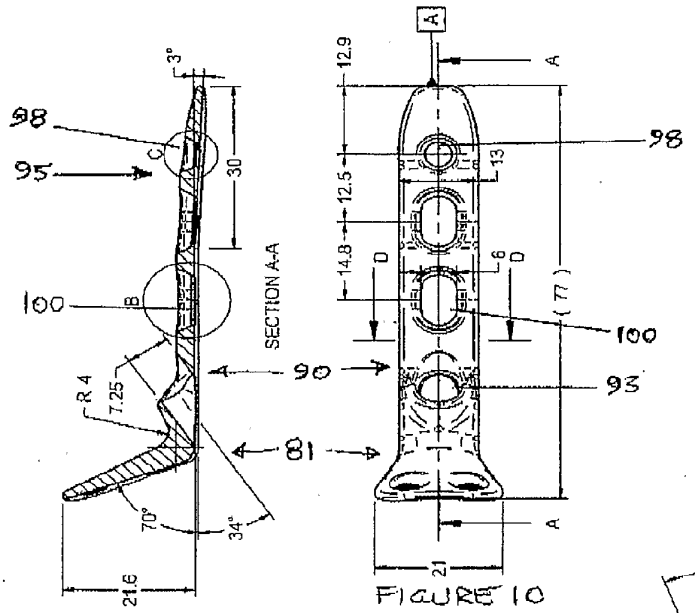


FIGURE 9

FIGURE 10

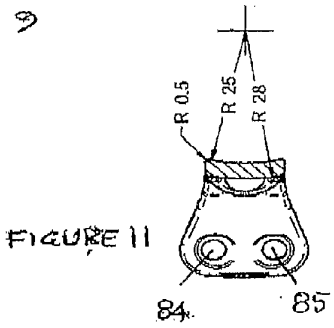


FIGURE 11

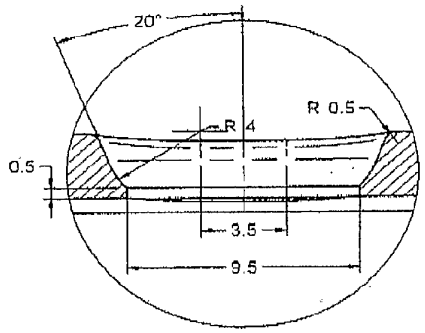
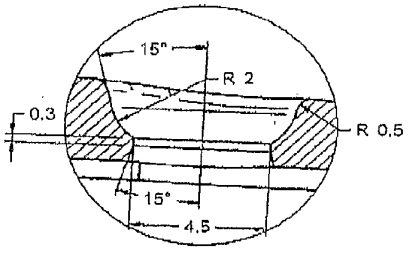


FIGURE 12

2 * DETAIL B
4:1



DETAIL C
5:1

FIGURE 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/AU2007/000656

A CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61B 17/58 (2006.01) ***A61B 17/62*** (2006.0 1)

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

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

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

DWPI - IPC A61B 17/- & keywords, (bone, osteo+, oss+, fuse, plate, arthrodesis, or joint, ankle or foot, feet, angle, angular, bend, non-linear) and similar terms.
USPTO: arthrodesis, ankle, plate, fuse
Espace (arthrodesis) and (ankle) and (plate) and (fuse) and similar words.

C DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X A	DE 3332765 A1 (STRELI) 15 March 1984 Whole document	55-64 1-54, 65-68
X A	US 6355041 B1 (MARTIN) 12 March 2002 Whole document	55-64 1-54, 65-68

[X] Further documents are listed in the continuation of Box C [X] See patent family 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 application or patent but published on or after the international filing date

'L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P' document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 July 2007	17 JUL 2007
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INTERNATIONAL SEARCH REPORT

International application No.
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Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 6440131 B1 (HAIDUKEWYCH) 27 August 2002 Whole document	55-64 1-54, 65-68
X A	JP 8-126650 A (MEDICAL YG) 21 May 1996 Whole document	55-64 1-54, 65-68
X A	US 2003/0060827 A1 (COUGHLN) 27 March 2003 Whole document	55-64 1-54, 65-68
X A	US 2004/0102778 A1 (HUEBNER ET AL) 27 May 2004 Whole document	55-64 1-54, 65-68
A	US 2004/0039394 A1 (CONTI ET AL) 26 February 2004 Whole document	1-68

INTERNATIONAL SEARCH REPORT

Information on patent family members

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This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
DE	3332765	AT	341382	AT	378324	GB	2126903
		US	4565193				
US	6355041		NONE				
US	6440131	US	2002128653				
JP	8126650		NONE				
us	2003060827	EP	1297793	FR	2829920	HK	1054494
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us	2004102778	AU	2003291114	AU	2003294342	AU	2003294414
		AU	2003295749	EP	1567071	EP	1572045
		GB	2412590	GB	2412875	KR	2005007544
		KR	2005008391	US	7090676	US	7153309
		US	7189237	US	2004102775	us	2004102776
		US	2004102777	us	2004102788	us	2005085818
		WO	2004045384	WO	2004045389	WO	2004045455
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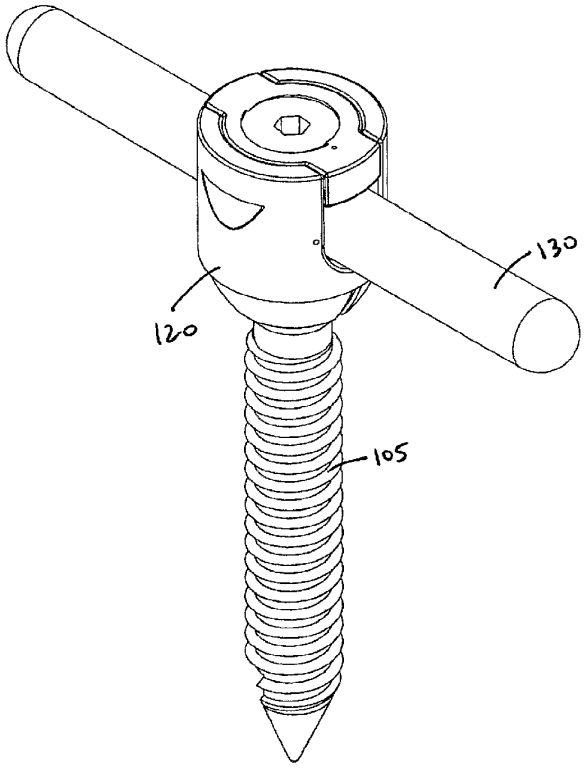
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(57) **Abstract:** The distal bone screw segment of a bone screw system is driven into bone. In a first state, the assembly permits relative motion between its component parts in order to facilitate the placement and correct alignment of an interconnecting rod that is used to couple multiple bone screw systems and/or other orthopedic devices. In a second state, the assembly provides relative immobilization between the assembly components and the inter-connecting rod.

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BONE SCREW SYSTEMS AND METHODS OF USE

REFERENCE TO PRIORITY DOCUMENT

This application claims priority of co-pending U.S. Provisional Patent Application Serial No. 60/839,014, filed August 21, 2006 and co-pending U.S. Provisional Patent Application Serial No. 60/921,570, filed April 3, 2007. Priority of the aforementioned filing dates is hereby claimed and the disclosures of the Provisional Patent Applications are hereby incorporated by reference in their entirety.

BACKGROUND

The present disclosure is related to orthopedic devices that are affixed onto skeletal segments. The implanted devices are used to adjust and maintain the spatial relationship(s) of adjacent bones. Depending on the implant design, the motion between the skeletal segments may be returned to normal, increased, modified, limited or completely immobilized.

Whether from degenerative disease, traumatic disruption, infection or neoplastic invasion, alterations in the anatomical relationships between the spinal vertebras can cause significant pain, deformity and disability. Spinal disease is a major health problem in the industrialized world and the surgical treatment of spinal pathology is an evolving discipline. The traditional surgical treatment of abnormal vertebral alignment and aberrant motion is the complete immobilization and bony fusion of the involved spinal segment. More recently, preservation of vertebral motion during the treatment of the spinal pathology has been the preferred strategy and many surgical techniques have been formulated to accomplish this treatment objective.

Regardless of whether the vertebral motion is abolished or preserved, many surgeons employ implantable orthopedic devices that adjust, align, support and/or maintain the spatial relationship(s) of the adjacent vertebral bones. The effectiveness of theses devices is vitally dependant on the adequacy of their fixation onto the underlying bone. Inadequate device fixation will effectively uncouple the device from the vertebral column and marginalize the beneficiary effects of the implant. Further, poorly anchored devices may damage the

attached bone by fracturing and/or avulsing bone fragments at the attachment sites.

Screw fixation into the pedicle portion of the vertebral body has emerged as the most common method of device fixation onto the vertebral column. However, it is known that repeated loading and unloading of these screws will lead to screw loosening and eventual pull-out. Implantable devices that promote spinal fusion must bear load for the few months needed to produce bone graft maturation and solid vertebral fusion. In contrast, devices that preserve vertebral motion must bear the cyclical load of movement for the remainder of the patient's life. With the change in treatment strategy towards motion preservation, the integrity of the bone/device interface and the durability of the device fixation sites are emerging as major determinants of implant's functional life span.

There remains a significant need in the art for bone screw assemblies and methods of implantation that provide superior fixation onto the vertebral column. This need will increase further as surgeons widen the application of the motion preservation procedures.

SUMMARY

This application discloses bone screw systems that are adapted to provide superior anchor fixation onto the vertebral bones and to increase the resistance to anchor pull-out from the underlying bone.

In an embodiment, the distal bone screw segment of a bone screw system is driven into bone. In a first state, the assembly permits relative motion between its component parts in order to facilitate the placement and correct alignment of an interconnecting rod that is used to couple multiple bone screw systems and/or other orthopedic devices. In a second state, the assembly provides relative immobilization between the assembly components and the inter-connecting rod. In an embodiment, the bone screw system is transitioned from a first state to a second state by the advancement of a locking member. Engagement of the locking member produces a downward force onto the interconnecting rod and a rotational movement of an inner housing member relative to an outer housing member about an abutment surface between the two housing members. With

rotation, the inner housing member functions as a grasping claw that applies a compressive force onto a portion of the bone screw. In this way, the bone screw and the bone to which it is attached are retained by the assembly and affixed onto the rod.

In another embodiment, the force needed to transition the system from a first state to a second state is provided by the action of a locking instrument that is transiently used during system implantation but is not a component of the screw assembly. As before, engagement of the locking instrument produces a downward force onto the interconnecting rod and a rotational movement of an inner housing member relative to an outer housing member about an abutment surface between the two housing members. With rotation, the inner housing member functions as a grasping claw that applies a compressive force onto a portion of the bone screw and onto the rod. The force placed on the rod propels it into a fixed position relative to the inner housing and maintains it in that locked position even after removal of the locking instrument.

In another embodiment, the bone screw segment of the system contains a sub-segment that is partially composed of bone, bone substitute and/or a feature adapted to promote bone in-growth or establish a mineralized connection between the bone and the bone screw. In an embodiment, the sub-segment is intimately retained within a recess of the bone screw and provides a mineralized shoulder within the bone screw that will tenaciously resist screw migration. In other embodiments, the sub-segment forms a feature that may be actuated to protrude into the surrounding bone. These bone screw features may be used with any of the disclosed screw system designs.

In one aspect, there is disclosed an orthopedic anchoring system that is adapted to fixate implants onto the skeletal bone of a human or animal subject, comprising: a bone anchor that attaches onto bone and a receptacle that is adapted to mate with a second implant; an assembly including housing members coupled to the bone anchor, wherein the assembly transitions between a first state and a second state, wherein the first state permits relative motion between the anchor and the receptacle and the second state immobilizes the anchor relative to the receptacle and wherein transition from the first state to the second

state requires non-linear movement between the housing members of the assembly; and a lock member that is contained within the assembly, wherein actuation of the lock member provides a force that causes the assembly to transition from the first state to the second state.

In another aspect, there is disclosed an orthopedic anchoring system that is adapted to fixate an implant onto the skeletal bone of a human or animal subject, comprising: a bone anchor that attaches onto bone and a receptacle that is adapted to mate with a second implant; an assembly including housing members coupled to the bone anchor, wherein the assembly transitions between a first state and a second state, wherein the first state permits relative motion between the anchor and the receptacle and the second state immobilizes the anchor relative to the receptacle and wherein transition from the first state to the second state requires non-linear movement between the housing members of the assembly; and a locking member coupled to the assembly wherein a force required to transition the assembly from the first state to the second state must be provided by an external instrument that is not contained within the assembly and wherein the assembly is capable of passively maintaining a locking force to maintain the assembly in the second state after removal of the external instrument that produced the force.

Other features and advantages will be apparent from the following description of various embodiments, which illustrate, by way of example, the principles of the disclosed devices and methods.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows perspective views of a first embodiment of a bone screw system.

Figures 2A-2C show top and side views of the system.

Figure 3 shows the system in an exploded state.

Figure 4 shows perspective and side cross-sectional views of the system.

Figure 5 shows a lock nut assembly of the system in an exploded state.

Figures 6 and 7 show perspective and cross-sectional views of the exploded lock nut assembly.

Figure 8 shows a top, cross-sectional view of the immobilized screw system that is taken through the lock nut assembly.

Figure 9 shows another embodiment of a lock nut assembly.

Figure 10 shows another embodiment of a bone screw system assembly in an exploded state.

Figure 11A shows the bone screw system of Figure 10 inserted into a pedicle segment of a vertebral body.

Figure 11B illustrates an alternative method of screw fixation onto the vertebral pedicle.

Figure 12 shows the bone screw system at the time of screw assembly removal. The screw head and the remainder of the locking assembly have been removed.

Figure 13 shows another embodiment of a bone screw system assembly in an exploded state.

Figures 14A and 14B show an exemplary embodiment of an outer shank member in a relaxed state and an engaged state, respectively.

Figures 15A and 15B show the bone screw system of Figure 13 mounted into bone with the shank assembly in the relaxed state and the engaged state, respectively.

Figures 16A and 16B show another embodiment of an inner shank member and outer shank member.

Figure 17 shows a cross-sectional view of the outer shank member.

Figure 18A and 18B show a cross-sectional view of the outer shank member before and after insertion of the inner screw shank member, respectively.

Figure 19 shows a perspective view of another embodiment of a bone screw system.

Figure 20 shows an exploded view of the system of Figure 19.

Figure 21 shows perspective and cross-sectional views of the system of Figure 19.

Figure 22 shows another embodiment of a bone screw system.

Figure 23 shows the system in an exploded state.

Figure 24 and 25 show cross-sectional views of the assembled system prior to rod placement.

Figures 26 and 27 show cross-sectional views of the assembly after the rod is placed. The assembly is in the locked configuration.

Figure 28 shows another embodiment of a bone screw system.

Figure 29 shows the system in an exploded state.

Figure 30 shows perspective and side cross-sectional views of an upper region of the system.

Figure 31 shows another embodiment of a bone screw system.

Figure 32 shows the system in an exploded state.

Figure 33 shows perspective and side cross-sectional views of an upper region of the system.

Figure 34 shows a perspective view of another embodiment of a bone screw system.

Figure 35 shows an exploded view of the bone screw system.

Figure 36A shows vertical sectional views of the device of Figure 35 taken through a hinge member.

Figure 36B shows a horizontal sectional view of the device of Figure 35 taken through the hinge members.

Figure 37 shows an alternative hinged system embodiment.

Figures 38A and 38B show an additional embodiment in perspective and exploded views, respectively.

Figure 39 shows cross-sectional views of the system.

Figures 4OA and 4OB show top views of the device of Figure 38 in the unlocked and locked configurations, respectively.

Figures 41A to 41C show views of another system embodiment.

Figures 42A and 42B show exploded views of the embodiment of Figure 41.

Figures 43A and 43B show cross-sectional views of the device of Figure 41.

Figures 44A and 44B illustrate the outer and inner saddle members, respectively.

Figures 45A and 45B show the assembly in the locked and unlocked configurations, respectively.

Figures 46A and 46B illustrate an additional embodiment.

Figure 47 shows an exploded view of the device in Figure 46.

Figures 48A and 48B show cross-sectional views of the device in Figure 46.

Figure 49 shows side views of an alternative inner saddle member.

Figure 50 shows the cross-sectional features using phantom lines.

Figures 51A-51C show perspective, exploded and cross-sectional views of an illustrative embodiment.

Figures 52A and 52B show an alternative embodiment adapted to allow a range of movement for the bone screw which is biased towards a preferred direction.

Figure 53 shows an alternative embodiment that biases the bone screw towards a preferred direction.

DETAILED DESCRIPTION

Figure 1 shows perspective views of a first embodiment of a bone screw system. Figures 2A-2C show top and side views of the system. Figure 3 shows the system in an exploded state and Figure 4 shows perspective and side cross-sectional views of the system. The system includes a bone screw having a

shank 105 that extends from a head 110. The shank 105 can be screwed into bone. In the assembled system, the head is seated within a saddle assembly that includes an outer saddle member 120 that removably couples to a pair of inner saddle members 125. The inner saddle members 125 fit partially inside the outer saddle member 125 with a portion of the inner saddle members 125 protruding downwardly therefrom. The inner saddle members 125 collectively form a seat that receives the screw head 110, as shown in Figure 4. The inner saddle members 125 also form a receptacle or seat that receives a second implant such as a rod 130, which also sits in a slot in the outer saddle members 120. As shown in Figure 4, the outer saddle member 120 mates with the inner saddle members 125 via a complementary-shaped interface therebetween. The interface holds the inner saddle and outer saddle in a connected relationship that can be tightened and locked via a lock nut assembly, which is described below with reference to Figures 3 and 5. When the lock nut assembly is fully tightened, the rod 130 and screw head 110 are immobilized relative to the saddle assembly.

With reference to Figure 3, the system further includes a lock nut assembly 135 that can be used to immobilize the screw head 110 and rod 130 relative to the saddle assembly, as described in detail below. The lock nut assembly 135 fits within and mates with an interior portion of the outer saddle member 120, as shown in Figure 1.

Figure 5 shows the lock nut assembly 135 in an exploded state. The lock nut assembly 135 includes an outer component 505, an inner component 510, and an annular or partially annular ring 518. The outer component 505 has a pair of laterally-extending wings 515 that are adapted to fit within the slots in the outer saddle member 120, as shown in Figure 1. The outer component 505 also has a threaded bore 520 that is sized to receive the complementary-shaped inner component 510 which can be a locking nut, as described below. An annular groove or slot 525 is located on the wall of the bore 520 wherein the slot 525 is sized and shaped to receive the ring 518, as described more fully below.

Figures 6 and 7 show perspective and cross-sectional views of the lock nut assembly in an exploded state. A plurality of radial-extending bore holes 610 are interspersed around the circumference of the threaded bore 520 of the outer

component 505. The bore holes 610 form openings in the slot 525 of the bore 520 and in the exterior of the outer component 505. A spherical ball 615 is movably positioned within each of the bore holes 610. The balls 615 are sized and shaped relative to the bore holes 610 such that the balls 615 can move along the length of the bore holes 610 but cannot be moved out of the bore holes 610.

The ring 518 is biased toward an enlarged state. The ring 518 can be compressed to a size that permits the ring 518 to be inserted into the bore 520 of the outer component 505 and into the annular slot 525. When the lock nut assembly 135 is in an assembled state, the ring is positioned within the slot 525. The ring 518 expands radially outward within the slot 525 to force the balls 615 toward an extended position wherein at least a portion of each of the balls 615 protrudes outside of the outer component 505, as shown in Figure 7. The compressible nature of the ring 518 permits the balls 610 to move radially inward in response to inward forces on the balls, unless the ring 518 is prohibited from being compressed, as described below. The assembled lock nut assembly 135 also includes the inner component 510, which is at least partially threaded into the bore 520 of the outer component 505. In this manner, the lock nut assembly 135 is essentially a unitary assembly that can be easily handled and manipulated.

In assembly, the inner saddles 125 are coupled to the outer saddle 120 with the head 110 of the bone screw seated in the inner saddle 120. The device is maintained in the assembled configuration by the action of assembly pins 126 and given to the surgeon as a unitary device. In use, screw 105 is driven into the underlying bone. Inter-connecting rod 130 is then lowered into the slot in the outer saddle 120 such that the rod 130 is seated within inner saddle members 125. After rod 130 is properly positioned, lock nut assembly 135 is then lowered into the outer saddle 120. Although the balls 615 are biased outward by the ring 518, the inner aspect of the outer saddle 120 pushes the balls 615 and the compressible ring 518 inward as the lock nut assembly 135 is advanced into the outer saddle 120. The lock nut assembly 135 is lowered until the balls 615 reach an annular groove 405 (Figure 4) in the inner aspect of the outer saddle 120. At this point, the ring 518 forces the balls to snap into the groove 405. The balls interface with the groove to retain the lock nut assembly 135 in the outer saddle

120. At this stage, the rod 130 and the screw head 110 are movably positioned relative to the saddle assembly and the rod position can be adjusted further. This feature permits the surgeon to apply a compressive or distractive force between individual screw systems before the systems are locked.

After the rod 130 is appropriately positioned, the screw system is immobilized by advancing the inner component 510 of the lock nut assembly 135 deeper into the outer components 505. As component 510 is advanced, it covers the inner aspect of the ring 518 so that the ring is no longer compressible. When the ring 518 becomes incompressible, the balls 615 are locked in the extended position within the grove of the outer saddle member. As the inner component 505 is advanced further, it exerts a downward force onto rod 130 and advances the rod relative to inner saddle member 125. The side walls of the rod-receiving potion of inner saddle member 125 are inclined, as shown in Figure 4, so that the upper portions of the side walls are separated by a greater distance than the lower portions of the side walls. Because of this wall configuration, advancement of rod 130 creates a distractive force between the side walls of the rod-receiving potion of inner saddle member 125 and produces rotation (i.e., non-linear movement) of each inner saddle member 125 relative to outer saddle member 120 about the abutment protrusions 129 of the outer saddle member. With rotation, the inferior segments of the inner saddle members are driven towards one another and they collectively function as a grasping claw that applies a compressive force onto head 110 of the bone screw. In this way, the assembly is rigidly immobilized relative to rod 130. A longitudinal cross-sectional view of the immobilized device is shown in Figure 4. A horizontal cross-sectional view of the locking nut assembly 135 is shown in Figure 8. As illustrated, ring 518 retains balls 615 in the extended state and, in the locked state, nut 510 prevents the compression of ring 518.

Figure 9 shows another embodiment of the lock nut assembly 135. In this embodiment, the ring and balls of the previous embodiment are replaced by a snap ring 905 that is biased toward a radially-expanded state. The snap ring 905 includes at least one protrusions 910 that fits into holes 915 in the outer member 505. The protrusions have sloped bottom surfaces such that the protrusions 910

are automatically forced inward as the lock nut assembly is lowered into the outer saddle 120. The protrusions 910 snap into the groove in the inner aspect of the outer saddle 120 in the same manner that the balls of the previous embodiment snap into the groove. Holes 911 are adapted to accept a removal instrument, wherein the instrument can exert a compressive force onto the ring 905 and remove the lock nut assembly 135. The illustrated lock nut assemblies provide retractable members that transiently retract on insertion to pass a screw assembly protrusion and then expand to occupy a position within a screw assembly indentation. In this way, the lock nut assembly forms an interference feature that retains the rod within the screw system assembly and, with advancement of the central nut of the lock nut assembly, rigidly locks the screw system components. It should be appreciated that this functional mechanism can be provided by lock nut assemblies that vary in structure from the illustrated embodiments.

Figure 10 shows another embodiment of a bone screw system in an exploded state. In this embodiment, the saddle and lock nut assembly features are similar or the same as in the previous embodiment but the bone screw has been modified in order to provide superior bone fixation. The bone screw is formed of multiple components, including a multi-piece shank assembly that removably couples to the head 110. The shank assembly includes an inner shank member 1005 that at least partially inserts into an internal bore in the outer shank member 1010. The inner shank member 1005 has an upper region 1015 that slidably mates into the bore within the outer shank member 1010, and a lower region 1020 that is threaded for locking onto bone. Upper region 1015 of inner shank 1005 has protrusion 1016 that cooperativejy fits within a complimentary indentation or slit within outer shank member 1010. Protrusion 1016 functions to prevent rotation of outer member 1010 relative to inner shank member 1005. Outer member 1010 is preferably at least partially made of bone, bone graft substitute and/or a feature adapted to promote bone in-growth or establish a mineralized connection between outer member 1010 and the surrounding vertebral bone. A coupler 1025, such as a threaded coupler, removably mates with the head 110 in the assembled device, as illustrated in Figure 11A, which shows the bone screw system inserted into a pedicle segment

of a vertebral body. The outer shank member 1010 is intimately applied to the upper region 1015 of inner shank 1005 so that, with bone in-growth into member 1010, a mineralized shoulder is formed within the substance of the bone screw. The mineralized segment will tenaciously resist screw migration and significantly increase the pull-out resistance of the screw.

Figure 11A illustrates screw placement within the pedicle portion P of the vertebra. Biomechanical research has shown that the pedicle P forms an optimal bone-attachment site for bone screws and other orthopedic devices. As with other segments of bone, the pedicle has a tough outer wall and a more spongy interior that is marrow-like in consistency. The pedicle is substantially cylindrical and roughly forms a circular or elliptical outline in coronal cross-section. Engagement of at least a portion of the tough outer wall increases the strength of fixation. Fixation can be additionally enhanced by the "capture" of the outer wall of the pedicle (along the long axis) within a segment of the bone screw. This fixation method may be accomplished in several ways. In Figure 11B, a pedicle is captured between a distal and a proximal protrusion segment of a bone screw. Alternatively, as shown in Figure 11A, a bone screw may have an intermediate member that is captured between two segments of the bone screw, wherein the intermediate member forms a mineralized connection with the surrounding bone. In the latter embodiment (Figure 11A), the tough outer pedicle surface is essentially extended into the substance of the bone screw by the action of the mineralized connection with the intermediate member.

After the mineralized connection has been established between a screw segment and the bone, the screw assembly can still be removed, when desired, by removal of the proximal segment - as illustrated in Figure 12. The distal screw is then attached to a bone drill and a ring of bone is cut around the screw segment that remains embedded in the vertebral bone. After cutting the mineralized connection, the retained screw segment can be backed-out without difficulty.

In additional embodiments, the outer shank member 1010 of the bone screw can be actuated to change configuration. The inner shank member 1005 may be configured in one of various ways such that, upon actuation, it can alter

the structural configuration of the outer shank member. For example, in an embodiment illustrated in Figures 13 to ,15, actuation of the screw system causes the outer shank member 1010 to expand outward and into the surrounding bone.

Figure 13 shows an exemplary embodiment, wherein the outer shank member is composed of a central member that is preferably at least partially made of bone, a bone graft substitute and/or a feature adapted to promote bone in-growth or establish a mineralized connection between outer member 1010 and the surrounding vertebral bone. At least one defect is found in member 1010 wherein a deformable member is housed. Figure 14A shows member 1010 with the deformable member in a first, un-deployed state while Figure 14B shows the deformable member in a second, deployed state. Note that the residual connecting bridge at the inferior aspect of member 1010 is broken by the deployment of the deformable member from the first to second state. The deformable member is actuated between the first and second states by the rotation of head 110 relative to shank 1005. This action shortens the height of the deformable member and increases its width, thereby producing the configuration change of member 1010 that is shown in Figure 14B. Figures 15A and 15B show cross-sectional views of the screw system of Figure 13 implanted within a vertebra, wherein Figure 15A shows the deformable member in a first, un-deployed state and Figure 15B shows the deformable member in a second, deployed state.

Figures 16A and 16B show another embodiment of an inner shank member and outer shank member. In this embodiment, the outer shank member 1010 has a head 110 with an opening 1105 that receives the inner shank member 1005. The inner shank member 1005 fits within an internal bore in the outer shank member. Figure 17 shows a cross-sectional view of the outer shank member 1010. The internal bore 1705 has an upper threaded region that mates with outer threads on the inner shank member 1005. The lower region of the bore 1705 is non-threaded. With insertion of the inner shank member 1005 into the bore 1705, the configuration of the inner bore 1705 is forced to conform to that of the inner shank member 1005. This alters the outer configuration of the outer shank member 1010 such that it undergoes a shape change. Figures 18A

and 18B show the structural configuration of the outer shank member before and after insertion of the inner shank member, respectively. Figure 18A shows the outer shank member alone in the "relaxed" configuration while Figure 18B shows the outer shank with the inner screw member in the "engaged" state. In the "engaged" configuration of the outer shank member, sections of the screw are propelled in pre-determined directions without an overall expansion of the screw or an increase in its size. This configuration change will increase the bone holding capability of the entire assembly and increase its resistance to pull-out.

While the bone screw is mainly embedded in bone, the portion of the screw system that provides the locking feature rests above the bone and below the skin. As previously described, the force required to lock the assembly is provided by lock nut assembly 135. In order to reduce the overall height of this segment and lower the profile of the system, several embodiments are disclosed in which the force required to lock the assembly is provided by the action of a locking instrument that is transiently used during screw system implantation but is not a component of the screw assembly itself. Figure 19 illustrates a perspective assembled and locked view of the current embodiment while Figure 20 shows an exploded view of the system. Figure 21 shows perspective and cross-sectional views of the system.

The system includes a bone screw having a shank 105 and a head 110. The head 110 sits in a saddle assembly that includes an outer saddle member 1905 which mates with a pair of inner saddle members 1910. The inner saddle members 1910 fit partially inside the outer saddle member 1905 with a portion of the inner saddle members 1910 protruding downwardly therefrom. The inner saddle members collectively form a seat that receives the screw head 110, as shown in Figure 21. In use, the device is maintained in the assembled configuration by the action of assembly pins and given to the surgeon as a unitary device.

The inner saddle members also form a seat that supports the rod 130, wherein the side walls of the rod-receiving seat of the inner saddle members are inclined, as shown in Figure 21, so that the upper portions of the side walls are separated by a greater distance than the lower portions of the side walls.

Because of this wall configuration, advancement of rod 130 creates a distractive force between the side walls of the rod-receiving seat of inner saddle member and produces rotation of each inner saddle member relative to outer saddle member 1905 about the abutment protrusions 1915 of the outer saddle member. With rotation, the inferior segments of the inner saddle members are driven towards one another and they collectively function as a grasping claw that applies a compressive force onto head 110 of the bone screw. The locking force is provided by a separate implantation instrument (not shown) and the locking force is maintained even after the instrument is removed by ridged protrusions, indentations or other retaining features on the inner aspects of the rod-receiving seat of the inner saddle members.

Figure 22 shows another embodiment of a bone screw system. Figure 23 shows the system in an exploded state and Figure 24 shows the system prior to rod placement. As in the embodiment of Figures 19-21 , a locking nut is not employed in this embodiment. The system includes a bone screw with a head 110 that sits in a saddle assembly. The saddle assembly includes an inner saddle member 2310 having a seat that receives the rod 130. The saddle assembly further includes intermediate saddle members 2315 that collectively receive the inner saddle member 2310. The saddle assembly further includes an outer saddle member 2320 in which the intermediate saddle members 2315 can be positioned. In Figure 24, the inner saddle member 2310 extends above the top surface of the screw. In this position, the upper aspect of the inner saddle member 2310 expands sufficiently to permit placement of the rod 130 into the inner saddle member 2310.

Figure 25 shows an enlarged cross-sectional view of the device prior to rod placement. As mentioned, the head 110 is positioned in a seat collectively formed by the intermediate saddle members 2315. Each of the intermediate saddle members 2315 has a protrusion 2325 that mates with an opening in the outer saddle member 2320. The saddle assembly components are freely movable relative to the bone screw.

The saddle assembly can be moved into a locked configuration by pushing the rod 130 downward into the inner saddle member 2310. Figures 26 and 27

show cross-sectional views of the assembly in the locked configuration. As a downward force is exerted onto the rod 130, the inner saddle member 2310 is pushed into a cavity within the confines of the intermediate saddle members 2315. As shown in Figure 27, the protrusions 2325 are positioned within indentations 2705 of the outer saddle member 2320. The inner saddle member 2310 exerts an outward force onto the upper aspect of the intermediate members 2315. This causes the members 2315 to rotate relative to the center of the protrusion 2325 and push the bottom potion of each of the intermediate saddle members 2315 towards one another. In this way, the intermediate saddle members 2315 lock onto the spherical head 110 of the bone screw. A Morse taper exists between the outer surface of the inner saddle member 2310 and the inner surface of the members 2315 and provides a locking mechanism for the assembly. Alternatively, or additionally, one or more interference locks could be used to maintain the locking force after the locking instrument has been removed.

Figure 28 shows another embodiment of a bone screw system. Figure 29 shows the system with a saddle assembly in an exploded state. As in some of the previous embodiments, a locking nut is not employed in this embodiment. The saddle assembly includes an outer saddle member 2805 and a pair of inner saddle members 2810 that are positionable within the outer saddle member 2805. An upper region of the inner saddle members 2810 collectively define a seat in which the rod 130 can be positioned. A lower region of the inner saddle members 2810 collectively form a spherical or partially spherical member 3005, as shown in the cross-sectional views of Figure 30.

With reference to the cross-sectional views of Figure 30, the spherical member 3005 is rotationally positioned within the head 3010 of the bone screw. The head 3010 is sized and shaped so at the form a spherical cup or seat in which the spherical member 3005 of the inner saddle members 2810 is positioned. A pair of protrusions 3015 are located on the inner aspect of the outer saddle member 2805. The protrusions abut an outer aspect of the inner saddle members 2810, which are coupled to one another via a protrusion 3020.

The saddle assembly is locked by pushing the rod 130 downward into the inner saddle members 2810 and pulling the outer saddle member 2805 upward

relative to the inner saddle members 2810. As the outer saddle member 2805 is pulled upward relative to the inner saddle members 2810, protrusions 3015 produce an inward directed force onto trie outer walls of the inner saddle members 2810. The force causes the upper aspects of the inner saddle members 281 0 to rotate about the center of protrusion 3020 so that the lower aspects of members 2810 move away from each other. The lower aspects of the inner saddle members 2810 forcefully constrain the bone screw head 3010 and immobilize the assembly.

Figure 31 shows another embodiment of a bone screw system. Figure 32 shows the system in an exploded state. Figure 33 shows perspective and side cross-sectional views of the system. The system includes a bone screw with a head 3010 that is configured in the same manner as the head in the embodiment of Figure 30. The saddle assembly includes an outer saddle member 3105 that houses a pair of intermediate saddle members 3110. In the assembled device, an inner saddle member 3115 is positioned between the intermediate saddle members such that the inner saddle member and intermediate saddle members collectively form a seat for the rod 130, as shown in Figure 33.

A pair of protrusions 3310 extend inward from an inner aspect of the outer saddle member 3105. As shown in Figure 33, the protrusions sit within a slot in the intermediate saddle members 3110. The rod 130 is pushed down to lock the saddle assembly. As the rod 130 is pushed down, it places a downward force onto inner saddle member 3115. The force causes each of the intermediate saddle members 3110 to rotate about the center of the protrusion 3310 so that the lower aspects of the intermediate members 31.10 move away from each other. The lower aspects of the intermediate saddle members 3110 forcefully constrain the bone screw head 3010. As a result, the assembly and rod are immobilized.

Figure 34 illustrates perspective views of another device embodiment. Figure 35 shows an exploded view while Figure 36A illustrates longitudinal sectional views through a hinge member of the device. In Figure 36B, a horizontal sectional view through the hinge members is shown. With reference to Figure 35, the device is comprised of two saddle members 7215, bone screw 105

with head 110 and a rod receptacle that is formed by opposing angled walls 7230 (Figure 36A) of members 7215. Each saddle member 7215 contains at least one side cut-out 7234 that is adapted to at least partially contain a segment of a hinge member 7238.

In assembly, two hinge members 7238 are used to interconnect the two saddle members 7215, wherein, one end of each hinge member 7238 is affixed to a saddle member 7215 by pin 7241 as shown in Figures 35 and 36. The device is maintained in the assembled configuration by the action of assembly pins 7241 and given to the surgeon as a unitary device. Note that hinge members 7238 and cut-outs 7234 are collectively configured to insure that the two bottom aspect of each saddle member 7215 can rotate towards but not away from one another. This feature insures that head 110 of screw 105 is securely retained within the assembly even when the device is in the unlocked state. Figure 36A illustrates longitudinal sectional views through a hinge member of the device. In Figure 36B, a horizontal sectional view through the hinge members is shown, wherein the line "D" illustrates the section of Figure 36A.

In application, the bone screw is driven into the underlying bone. A rod 130 is positioned within the rod receptacle formed by opposing angled walls 7230 of members 7215. Because of the angled wall configuration, advancement of rod 130 creates a distractive force between the walls 7230 of the rod-receiving seat of saddle members 7215 and produces rotation of the saddle member relative to the hinge members 7238. With rotation, the inferior segments of the saddle members are driven towards one another and they collectively function as a grasping claw that applies a compressive force onto head 110 of the bone screw. The locking force is provided by a separate implantation instrument (not shown) that pulls upwards onto ledge 7248 as it pushes down onto rod 130. The locking force is maintained even after the instrument is removed by ridged protrusions 7245 or, alternatively, by indentations, ratchets or other retaining features that may be placed on the inner aspects of the rod-receiving seat of the members 7215.

The saddle members of an additional hinged device embodiment are shown in Figure 37. The hinge features are shown as integral members of each

member 7215. Unlike the prior embodiment in which there was two rational axis that were off center relative to the long axis of the rod receptacle, the current embodiment has a single central axis of saddle member rotation. The remaining device features are similar to the preceding embodiment.

Figure 38A shows a perspective view of an additional embodiment. Figure 38B illustrates an exploded view and Figure 39 shows cross-sectional views of the embodiment. In this device, a rotational locking member 8233 is positioned between an inner and an outer saddle member. In assembly, the device is maintained in the assembled configuration by the actjon of assembly pins that movably couple the two saddle members and given to the surgeon as a unitary device. In application, the bone screw is driven into bone. A rod 130 is appropriately positioned within the rod receptacle portion of the saddle members and protrusions 8236 of rotational locking member 8233 are grasped by a locking instrument (not shown). The instrument straddles rod 130 and rotates the protrusions 8236 relative to the stationary rod 130 in order to transition the assembly into the locked configuration. Figures 4OA and 4OB shows a top view of the device in the unlocked and locked configurations, respectively. Note the cooperation between the features of the inner aspect of rotational locking member 8233 and the complimentary features on the outer wall of the inner saddle members. These features produce the inward movement of both inner saddle members and immobilize the device member, bone screw and rod relative to one another. Additional features on the inner aspect of the outer saddle member and the outer aspect of locking member 8233 insure that the locking member rotates smoothly.

Figures 4 1A-41 C show top and side views of another embodiment of a bone screw system. Figures 42A and 42B show the system in an exploded state. The system includes a bone screw and a saddle assembly that includes an outer saddle member 3705 that removably receives an inner saddle member 3710. As shown in the cross-sectional views of Figures 43A and 43B, the inner saddle member 371 0 forms a pair of seats that support the head 110 of the bone screw and the rod 130.

Figures 44A show perspective views of the outer saddle member 3705. The outer saddle member 3705 has a pair of slots 3905 for receipt of the rod 130. An outwardly extending shoulder or lip 3910 is positioned along an upper aspect of the outer saddle member 3705. A srriall slot 3915 is located in the upper aspect between the slots 3905. The outer saddle member 3705 defines a seat that is sized and shaped to receive the inner saddle member 3710.

Figures 44B show perspective views of the inner saddle member 3710. A seat 4010 is located on the upper aspect of the inner saddle member 3710 for the rod 130. A slot 401 5 extends through the inner saddle member 371 0 such that opposed sides of the inner saddle member 371 0 are separated by the slot 401 5. The slot 401 5 permits the opposed sides to flex toward and away from one another. A protrusion 4020 on one side of the inner saddle member 3710 has an opening 4023 that is sized and shaped to receive a pin 4030 (Figure 42). The opening 4023 is sized such that the pin 4030 can move within the opening 4023 when the pin is positioned therein. A borehole 4025 extends into the inner saddle member 3710 on one side.

Figures 45A and 45B show cross-sectional views of the saddle assembly in different states of movement. In Figure 45A, the inner saddie member 3710 is fully seated in the outer saddle member 3705. The outer saddle member 3705 has an inwardly extending lip 4 1 10 that abuts an outer surface of the inner saddle member 3710. The pin 4030 is positioned in the opening 4023 in the inner saddle member 3710. The pin 4030 also communicates with an opening 3715 (shown in Figures 42) in the outer saddle member 3705. The pin 4030 links the inner and outer saddle members and serves to limit or govern movement of the inner saddle member within the outer saddle member by virtue of the pin's interaction with the opening 4023. The opening 4023 is larger than the diameter of the pin 4030 to permit the pin to move up and down within the limits of the opening's size.

Figure 45B shows the saddle assembly with the inner saddle member 3710 moved relative to the outer saddle member 3705. Note that the pin 4030 has moved within the opening 4023 relative to the position shown in Figure 45A. Moreover, a side region of the inner saddle member 3710 has moved upward

relative to the outer saddle member 3705. The lip 4110 provides a bearing surface against the outer surface of the inner saddle member 3710 to guide movement between the inner and outer saddle members. In the assembled device, the head of the bone screw is positioned within the space 4120 such that the bone screw head can move along with the inner saddle relative to the outer saddle.

While all of the previous embodiments provide relative movement between the screw system assembly and the bone screw in the unlocked state, some surgical applications may require a greater angle of allowable movement during screw system implantation. Figure 46A shows a perspective view of an assembled screw system embodiment that permits greater movement between the locking assembly and the bone screw. Figure 46B shows side views of the device. Figure 47 illustrates an exploded view while Figures 48A and 48B show cross-sectional views. The bone screw has a threaded shank 105 and a toroid head 110 with central aperture 112. A second, complimentary toroid member 118 is positioned within aperture 112 and forms an articulation with the bone screw. Toroid member 118 can move freely relative to the bone screw in each of two substantially perpendicular planes but can not rotate independent of the bone screw. An outer housing 122 houses the bone screw and member 118. The proximal end of housing 122 has threads 124 that are adapted to engage the threads of a complimentary locking nut 126. The distal end of housing 122 has an aperture 127 that is of lesser diameter that the diameter of toroid member 118. In assembly, member 118 is positioned within the central aperture 112 of the bone screw and both members are retained within housing 122 by distal aperture 127. This screw system design allows more than one hundred degrees of movement between the bone screw and the housing member 122 in each of the two perpendicular planes of allowable movement.

In application, the bone screw is anchored into an underlying bone. The bone screw is rotated and driven into bone by a screw driver (not shown) that is adapted to engage and rotate "eye screw" bolts. These screw drivers are well known in the art and are commonly available. Housing 122 is appropriately positioned relative to the bone screw and rod 130 is placed within the rod-

receiving seat of housing 122. Locking nut 126 engages threads 124. With rotation and advancement, nut 126 will propel rod 130 into contact with a segment of toroid head 110 of the bone screw. With continued nut advancement, rod 130 will exert a downward force onto the bone screw and an upward force upon housing 122. In this way, the bone screw, toroid member 118, rod 130 and housing member 122 will be collectively immobilized relative to one another. In Figure 48A$_1$ the locked assembly is shown in sectional views that are perpendicular to the log axis of rod 130 while Figure 48B illustrates sectional views in the direction of the rod.

Devices embodiments without a locking nut can be also designed to permit a greater angle of movement between the locking assembly and the bone screw prior to assembly immobilization. With reference to the embodiment of Figures 41 to 45, for example, the inner saddle member may be modified to provide a larger angle of movement between the bone screw and the assembly in a desired direction. Figure 49 illustrates an inner saddle member that has a sloped bottom surface 4215 and allows greater movement relative to the bone screw, as described below. The inner saddle member 4210 is sized and shaped relative to the outer saddle member 3705 to provide greater relative movement therebetween in a desired direction than the previous embodiment of the inner saddle member 3710. Figure 50 shows side views of the inner saddle member with cross-sectional features shown in phantom lines.

These modifications of the inner saddle member can be similarly employed in other device embodiments. A representative embodiment of those devices without a locking nut, for example, is shown in Figures 51. The assembled device is illustrated in Figure 51A, the exploded device is shown in Figure 51B and a sectional view is shown in Figure 51C. Cross-sectional views of the modified device containing an inner saddle member with a slopped bottom surface is shown in Figures 52 and the screw's range of movement is illustrated. The head of the bone screw can rotate within the seat formed by the inner saddle member. The sloped bottom surface of the modified inner saddle member permits the bone screw to rotate to a greater left-most position than if the bottom surface were not sloped. Figure 53 shows a cross-sectional view of another

embodiment of the assembled system in which the upper surfaces of both the inner and outer saddle members are sloped in order to permit a sloped orientation of the rod 130.

The disclosed devices or any of their components can be made of any biologically adaptable or compatible materials. Materials considered acceptable for biological implantation are well known and include, but are not limited to, stainless steel, titanium, tantalum, combination metallic alloys, various plastics, resins, ceramics, biologically absorbable materials and the like. Any components may be also coated/made with osteo-conductive (such as deminerized bone matrix, hydroxyapatite, and the like) and/or osteo-inductive (such as Transforming Growth Factor "TGF-B," Platelet-Derived Growth Factor "PDGF," Bone-Morphogenic Protein "BMP," and the like) bio-active materials that promote bone formation. Further, any surface may be at least partially made with bone, bone substitute and/or a porous ingrowth surface (such as titanium wire mesh, plasma-sprayed titanium, tantalum, porous CoCr, and the like), provided with a bioactive coating, made using tantalum, and/or helical rosette carbon nanotubes (or other carbon nanotube-based coating) in order to promote bone in-growth or establish a mineralized connection between the bone and the implant, and reduce the likelihood of implant loosening. Lastly, the system or any of its components can also be entirely or partially made of a shape memory material or other deformable material.

Although embodiments of various methods and devices are described herein in detail with reference to certain versions, it should be appreciated that other versions, embodiments, methods of use, and combinations thereof are also possible. Therefore the spirit and scope of the appended claims should not be limited to the description of the embodiments contained herein.

CLAIMS

WHAT IS CLAIMED IS:

1. An orthopedic anchoring system that is adapted to fixate implants onto the skeletal bone of a human or animal subject, comprising:

a bone anchor that attaches onto bone and a receptacle that is adapted to mate with a second implant;

an assembly including housing members coupled to the bone anchor, wherein the assembly transitions between a first state and a second state, wherein the first state permits relative motion between the anchor and the receptacle and the second state immobilizes the anchor relative to the receptacle and wherein transition from the first state to the second state requires non-linear movement between the housing members of the assembly; and

a lock member that is contained within the assembly, wherein actuation of the lock member provides a force that causes the assembly to transition from the first state to the second state.

2. An orthopedic anchoring system that is adapted to fixate an implant onto the skeletal bone of a human or animal subject, comprising:

a bone anchor that attaches onto bone and a receptacle that is adapted to mate with a second implant;

an assembly including housing members coupled to the bone anchor, wherein the assembly transitions between a first state and a second state, wherein the first state permits relative motion between the anchor and the receptacle and the second state immobilizes the anchor relative to the receptacle

and wherein transition from the first state to the second state requires non-linear movement between the housing members of the assembly; and

a locking member coupled to the assembly wherein a force required to transition the assembly from the first state to the second state must be provided by an external instrument that is not contained within the assembly and wherein the assembly is capable of passively maintaining a locking force to maintain the assembly in the second state after removal of the external instrument that produced the force.

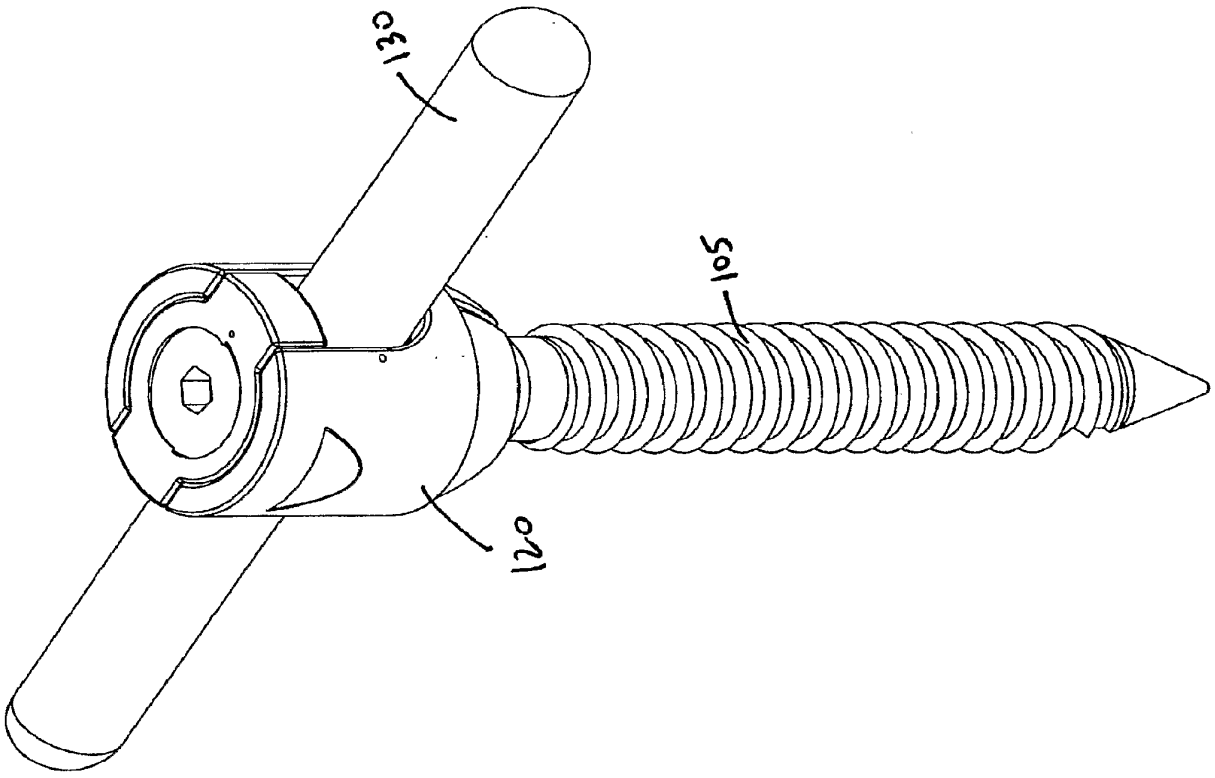


Fig. 1

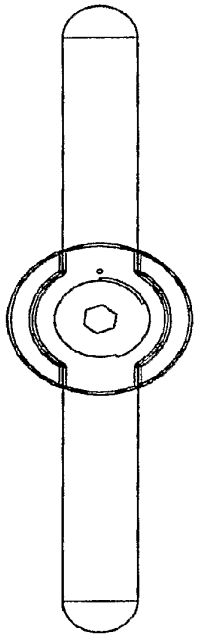


Fig. 2A

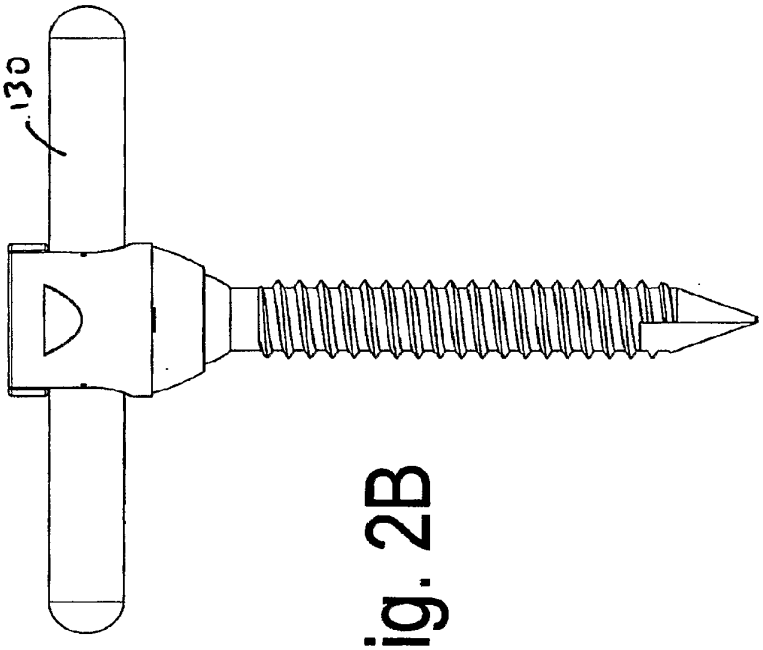


Fig. 2B

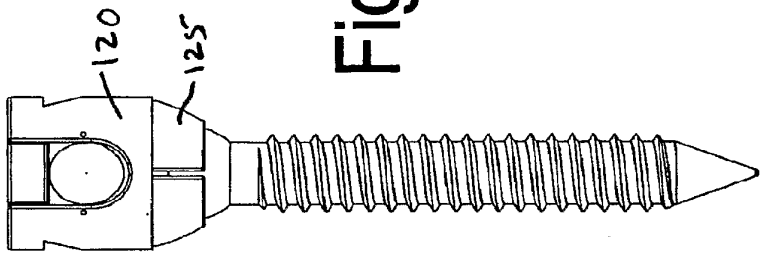


Fig. 2C

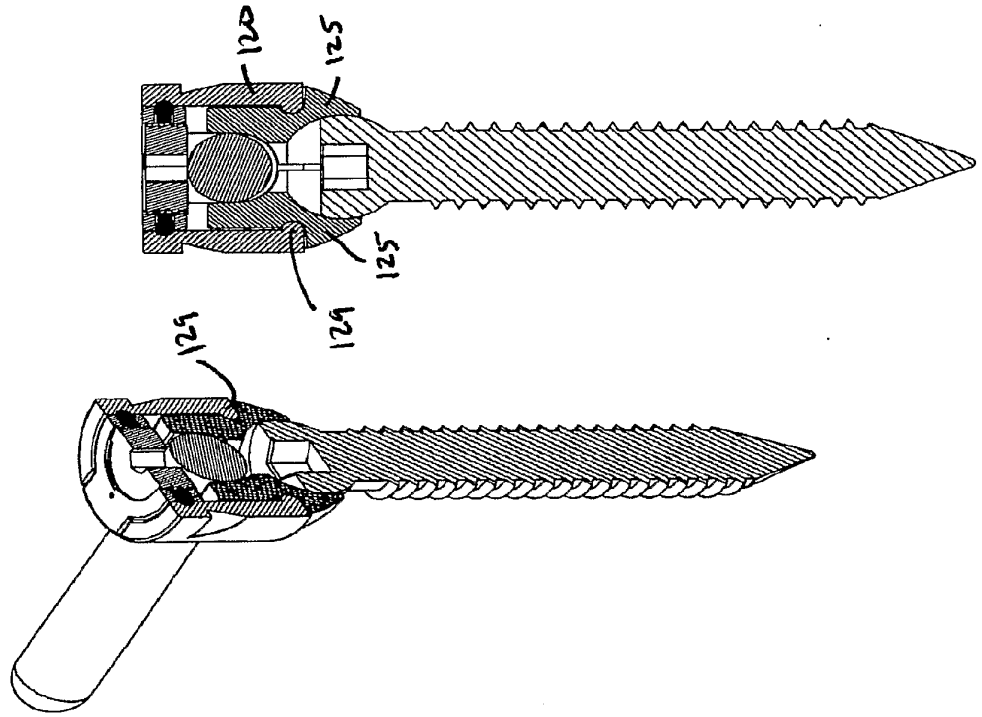


Fig. 4

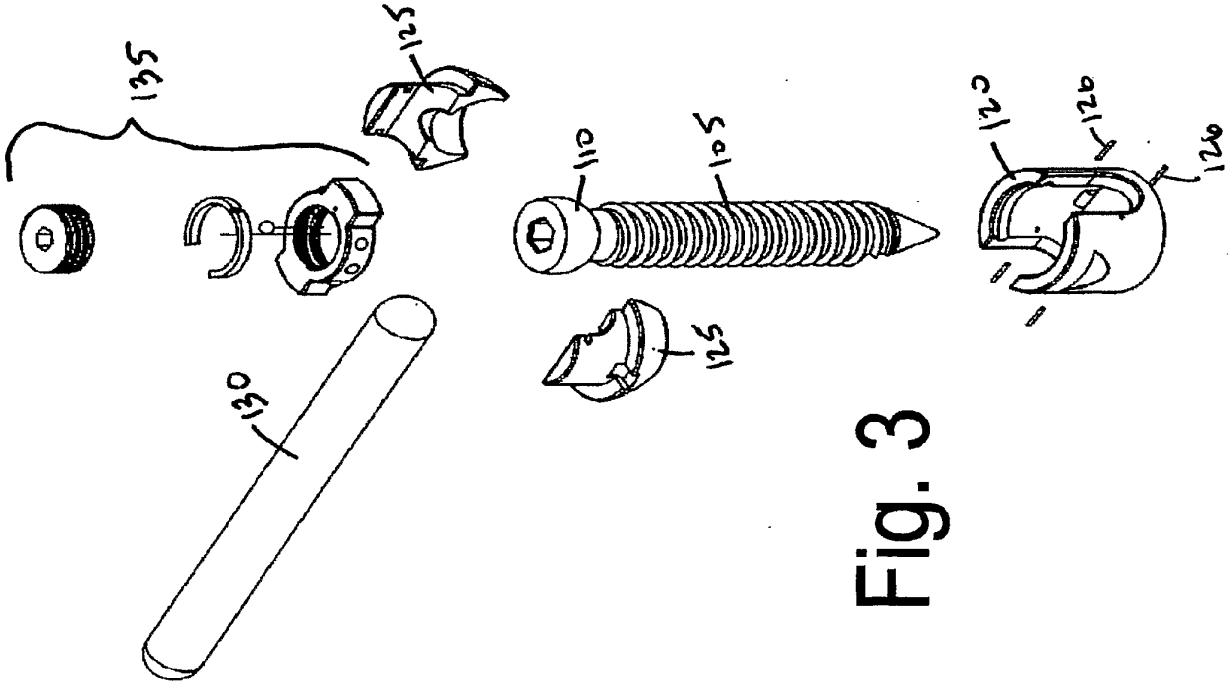
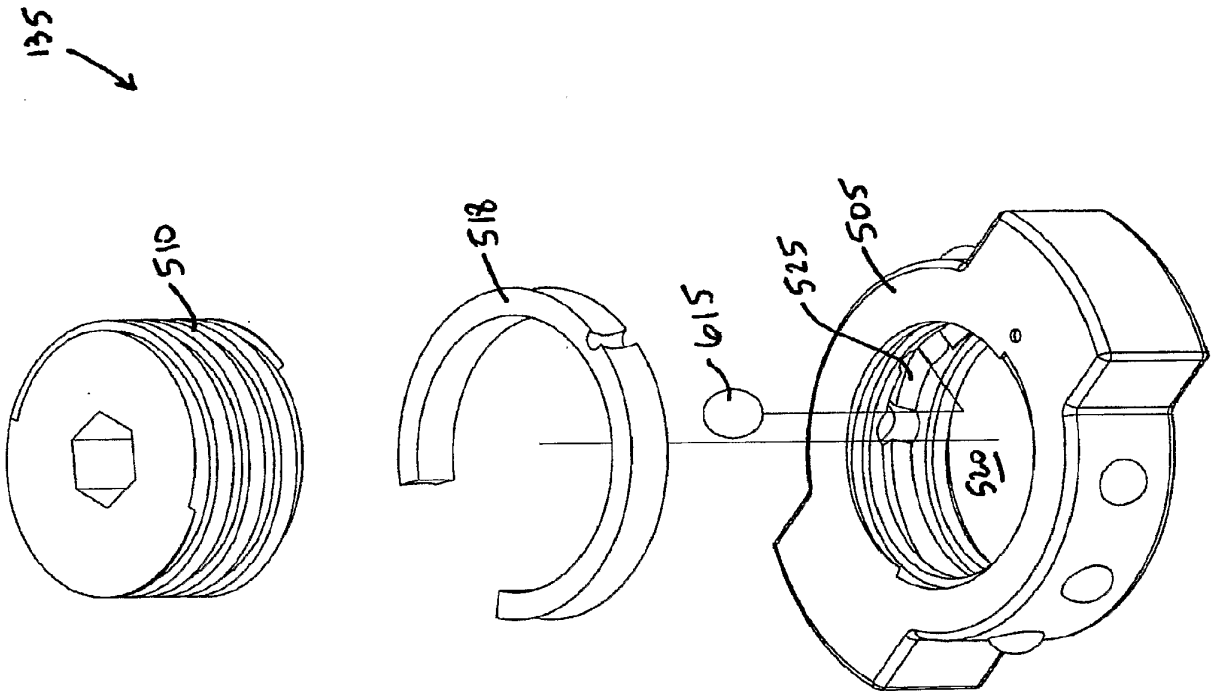
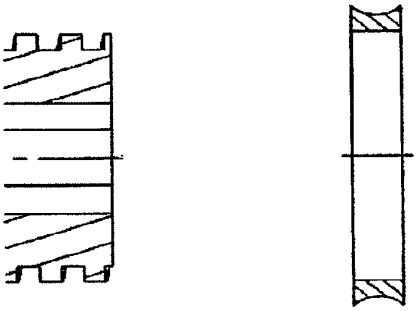


Fig. 3

Fig. 5





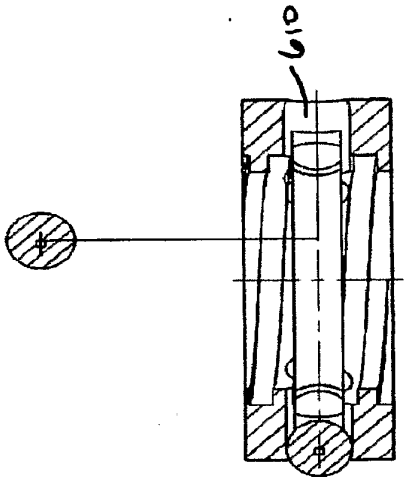
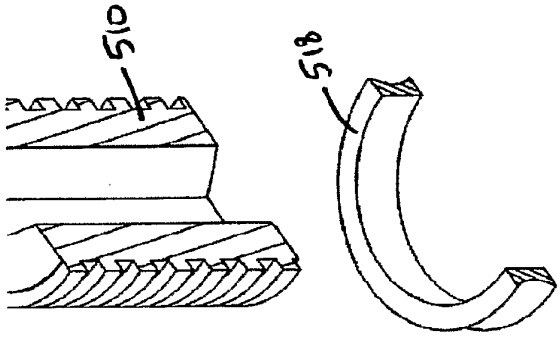


Fig. 7



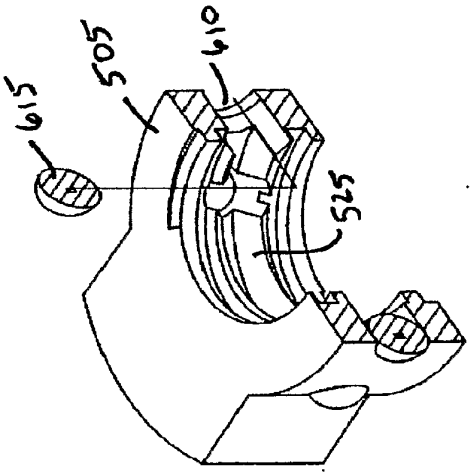


Fig. 6

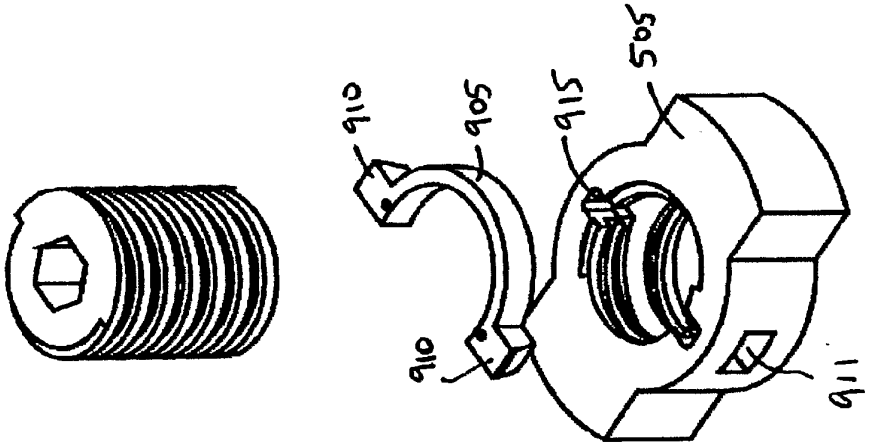


Fig. 9

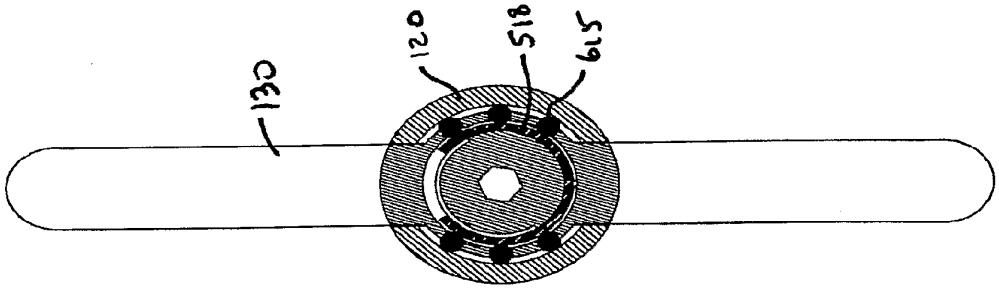


Fig. 8

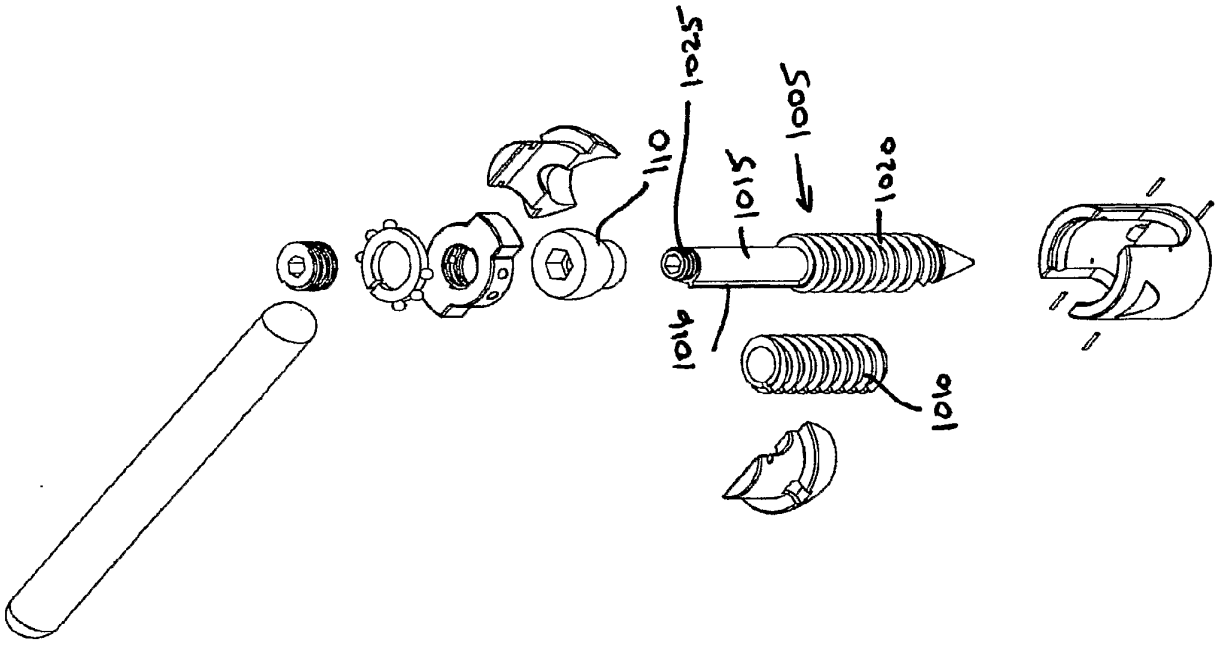


Fig. 10

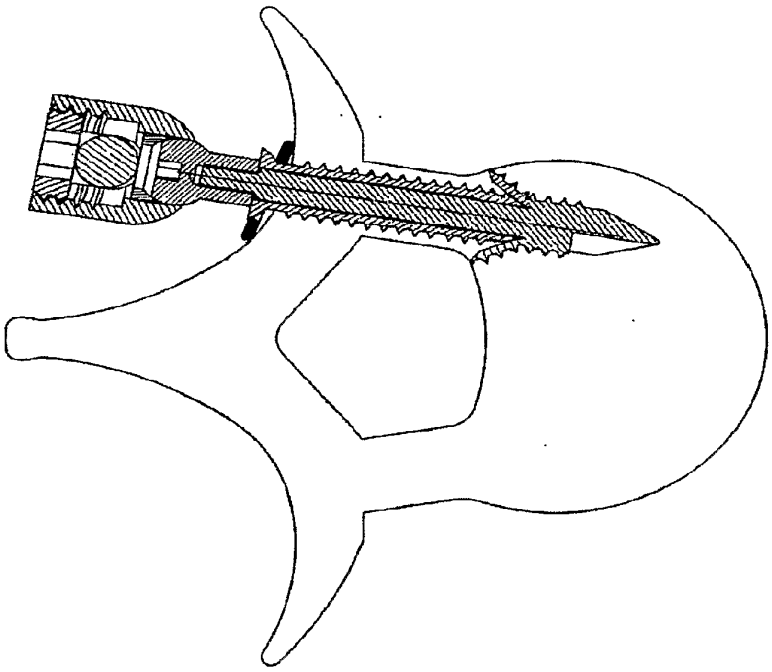


Fig. 11B

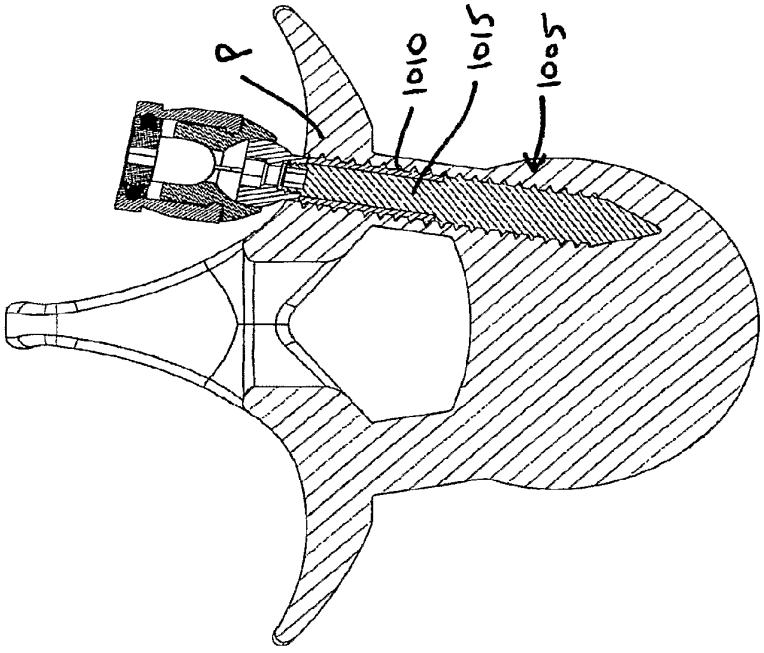


Fig. 11A

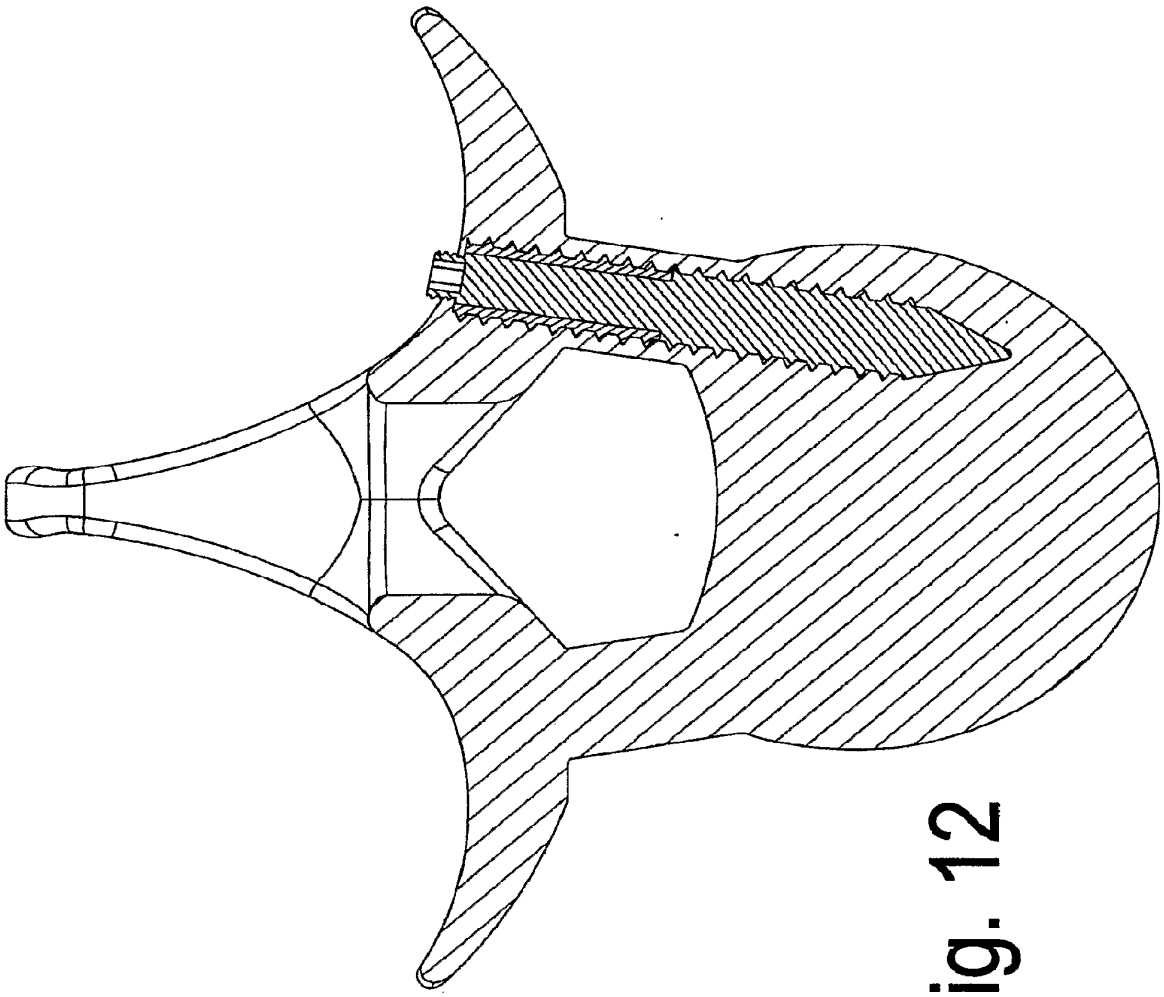


Fig. 12

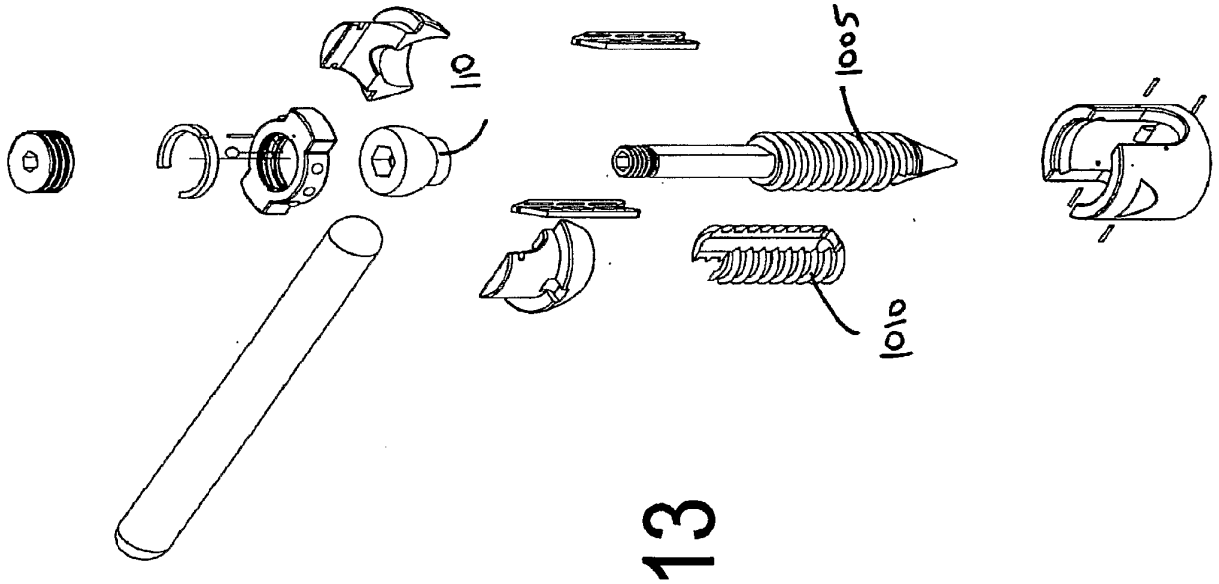


Fig. 13

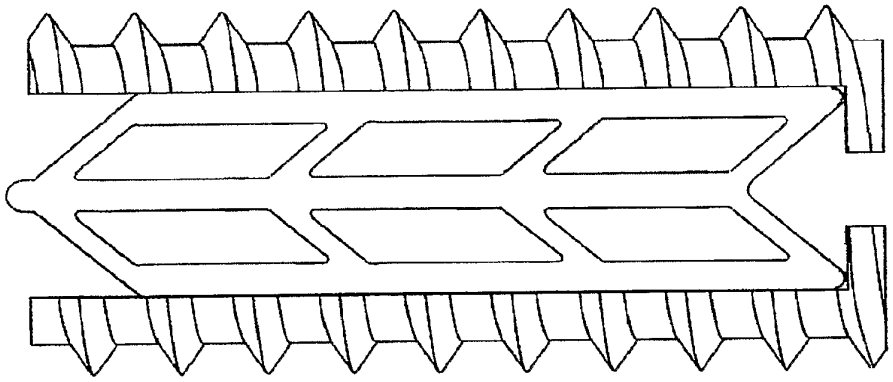


Fig. 14B

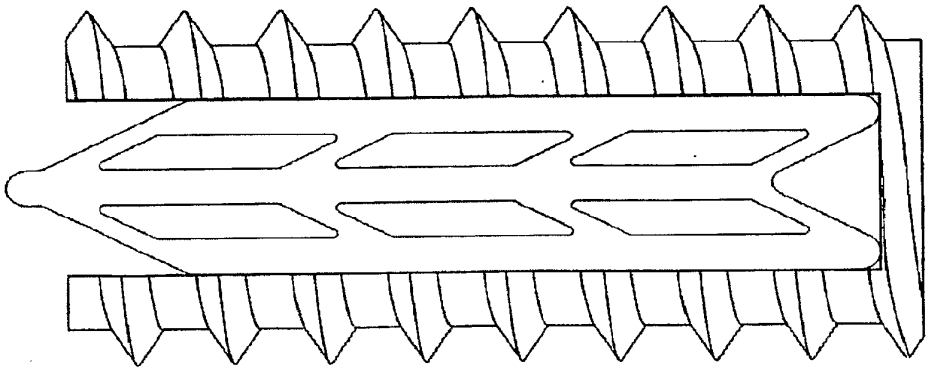


Fig. 14A

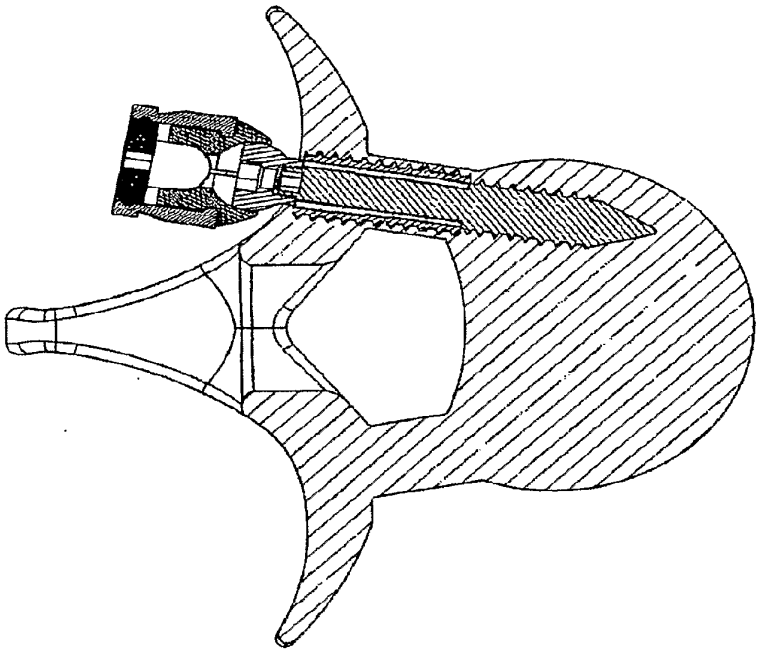


Fig. 15B

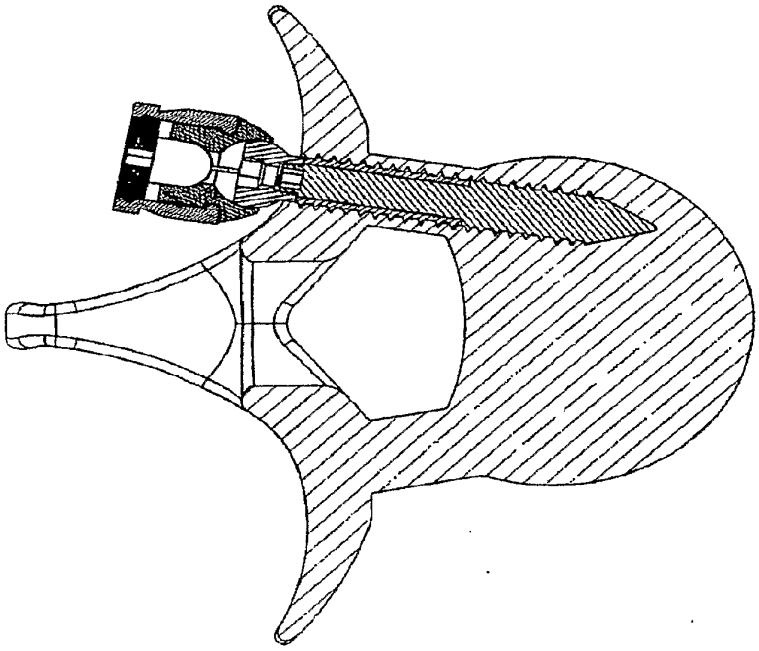


Fig. 15A

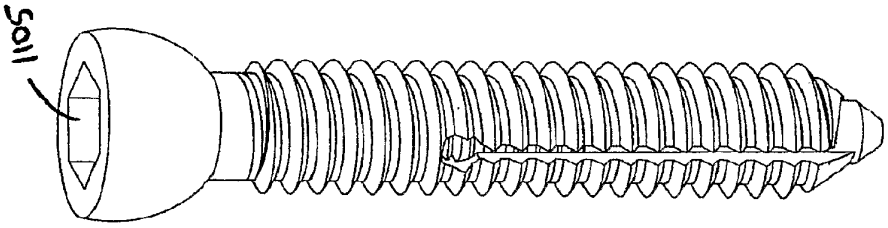


Fig. 16B

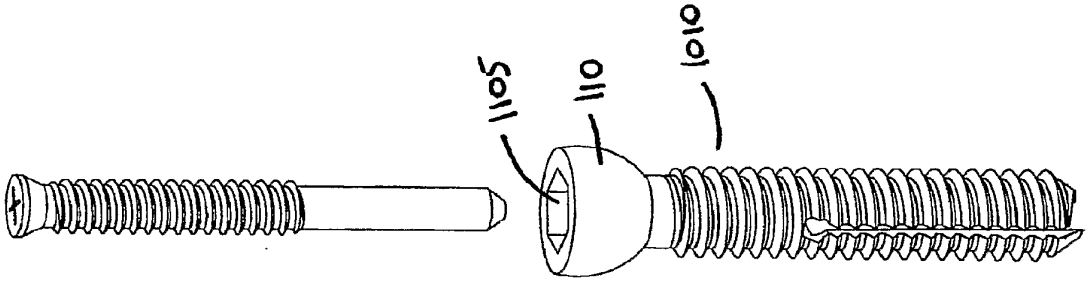


Fig. 16A

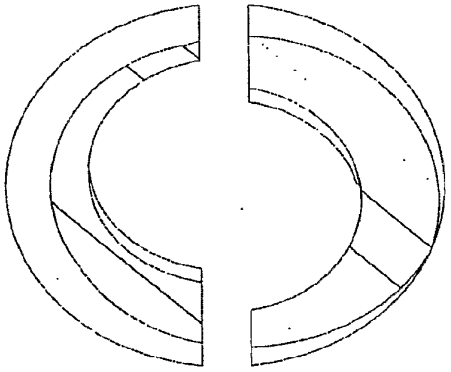


Fig. 18A

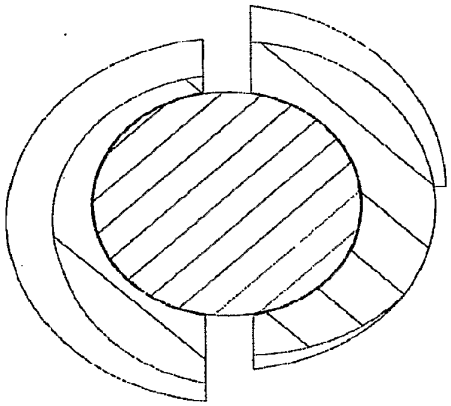


Fig. 18B

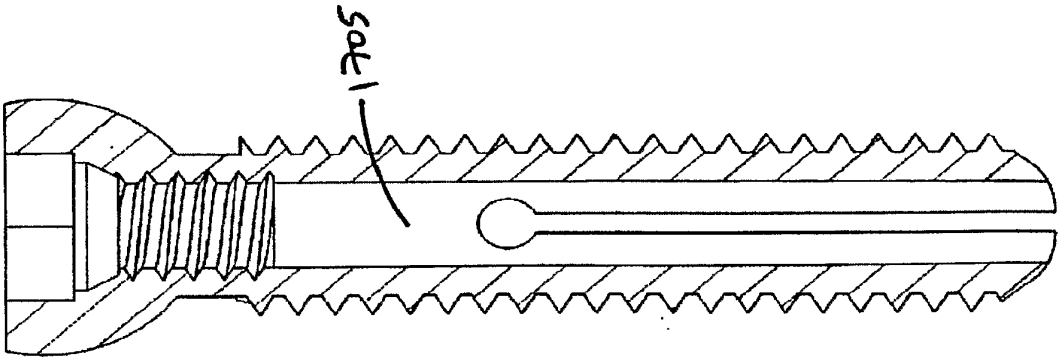


Fig. 17

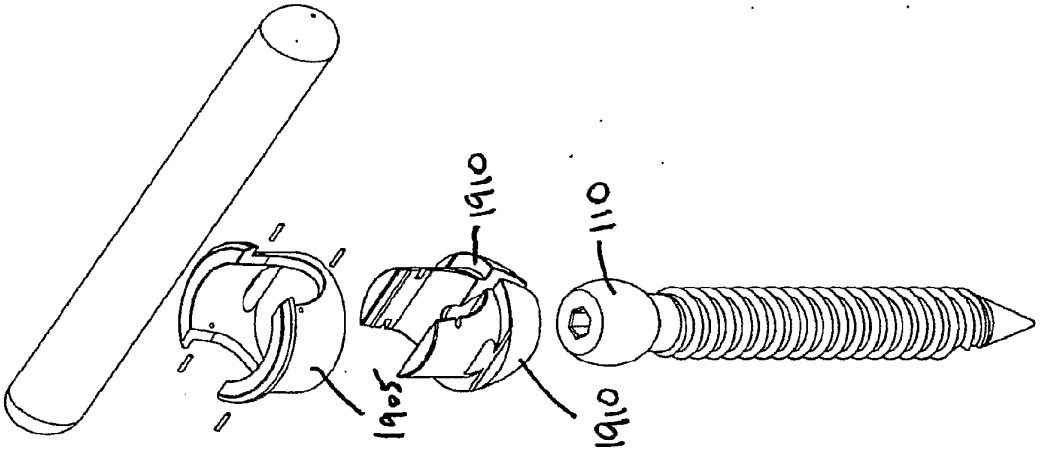


Fig. 20

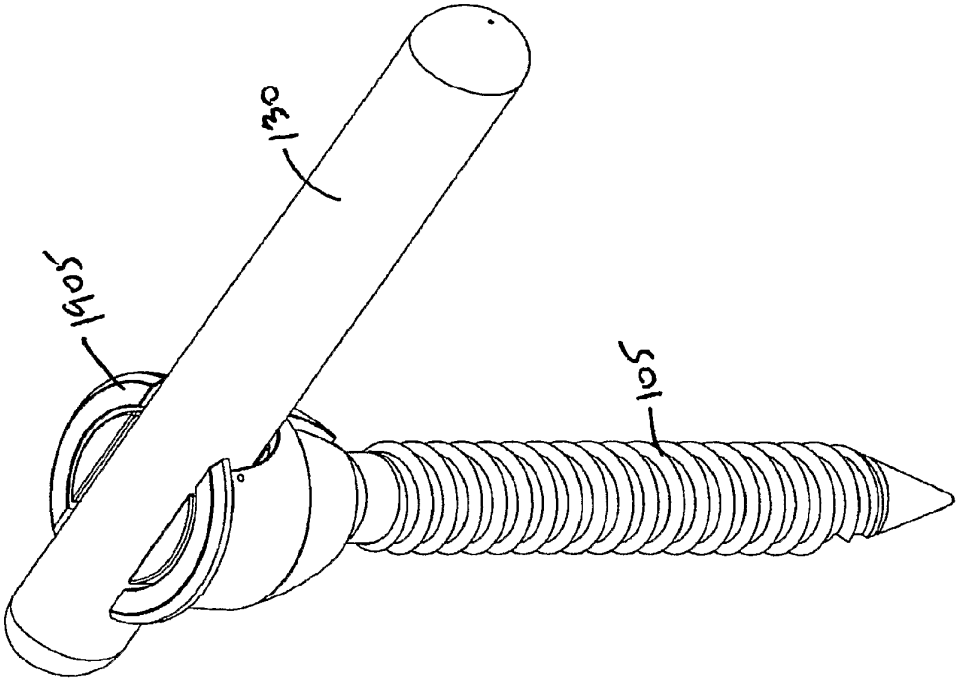


Fig. 19

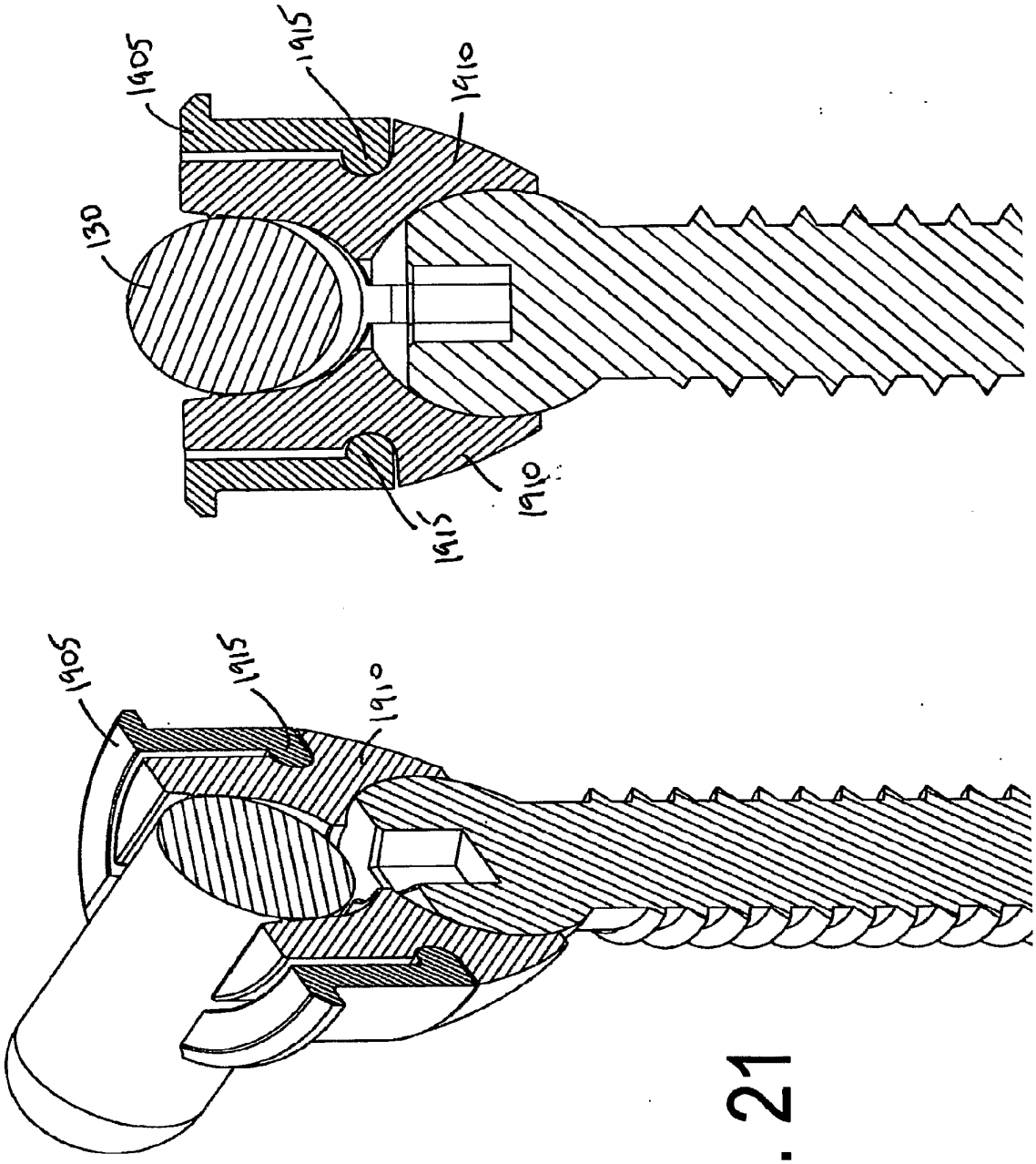


Fig. 21

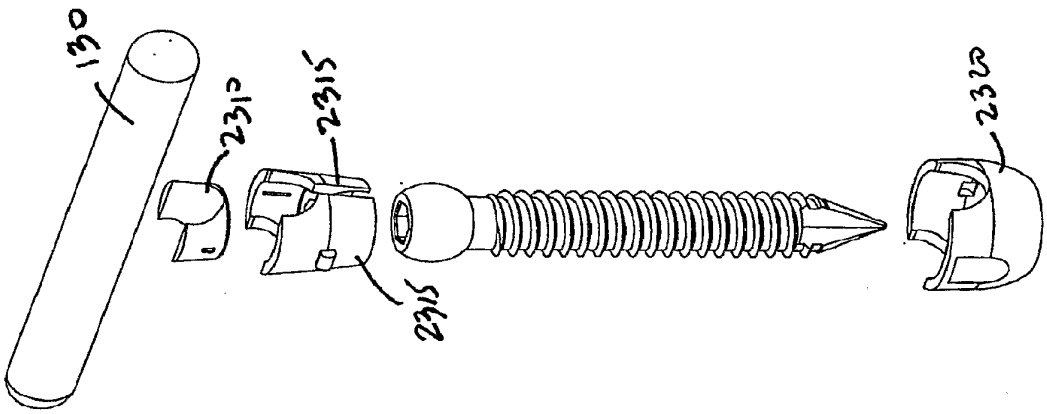


Fig. 23

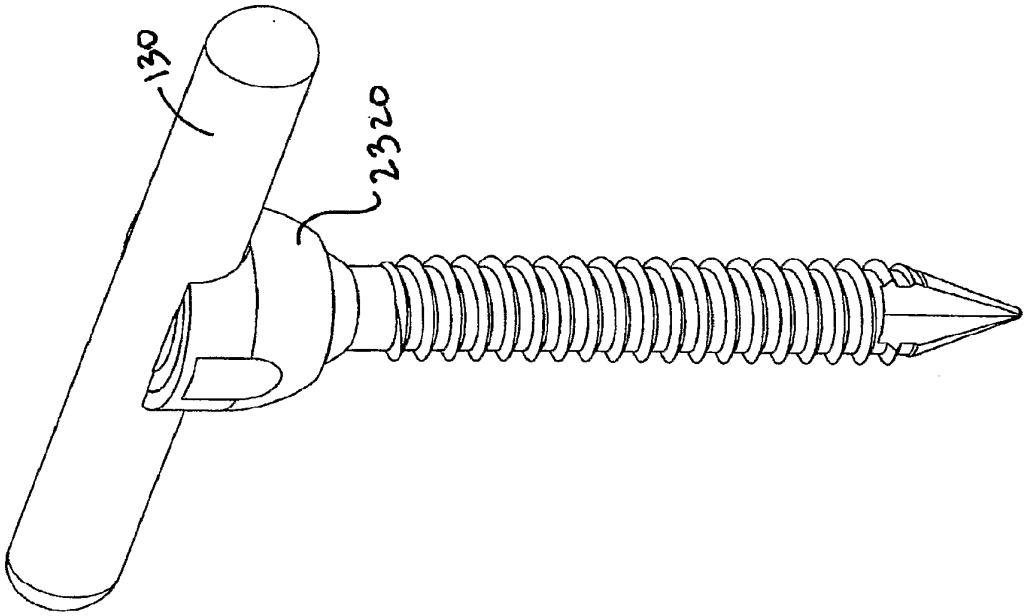


Fig. 22

Fig. 25

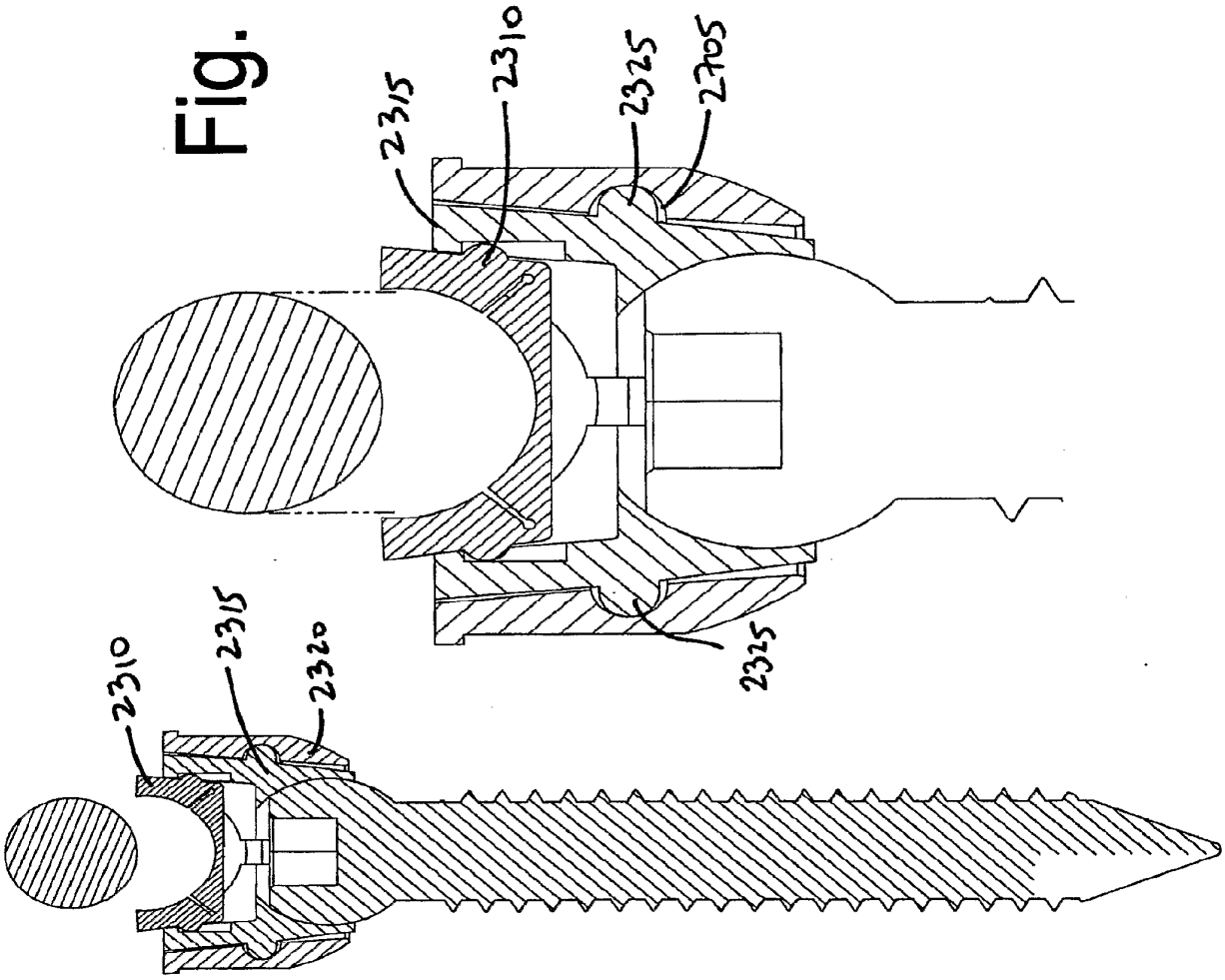


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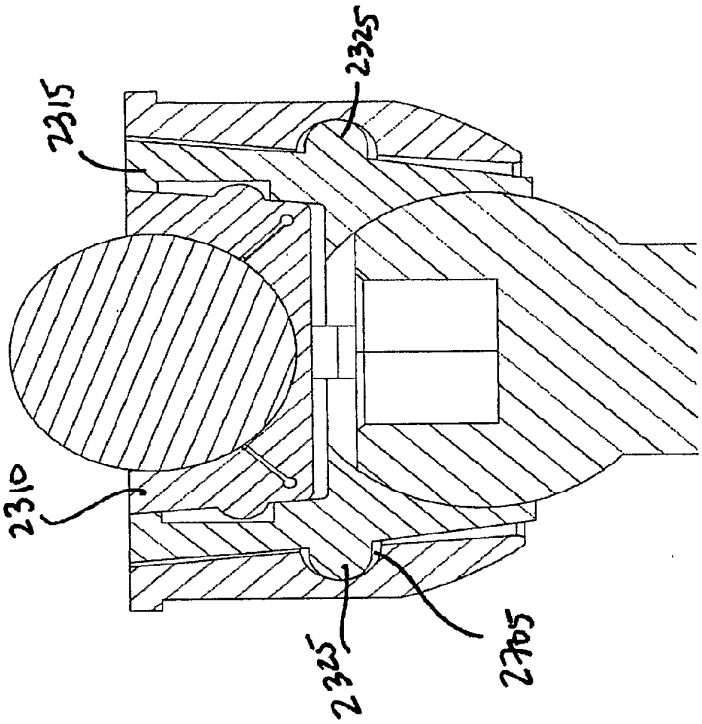


Fig. 27

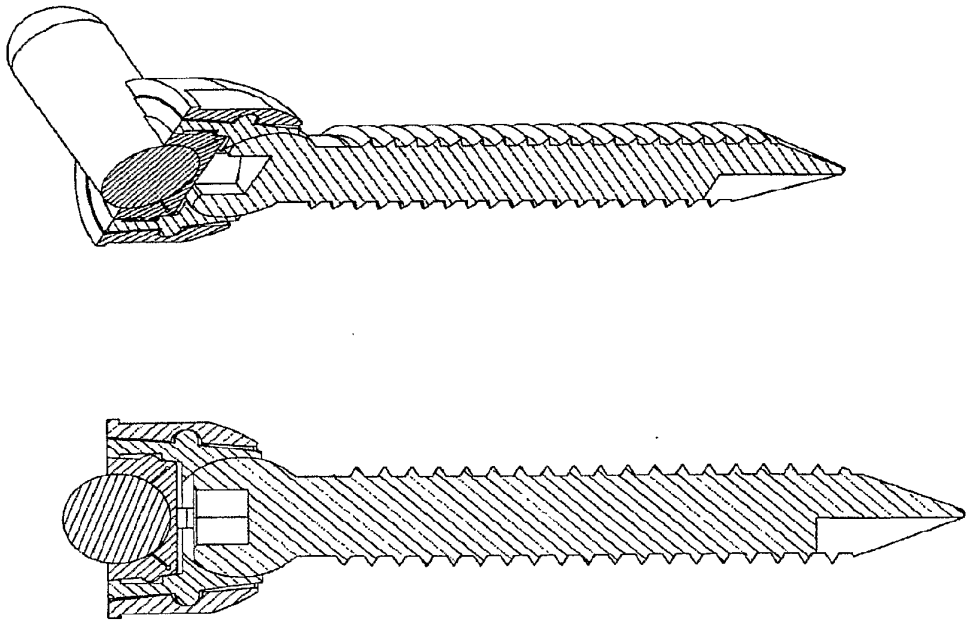


Fig. 26

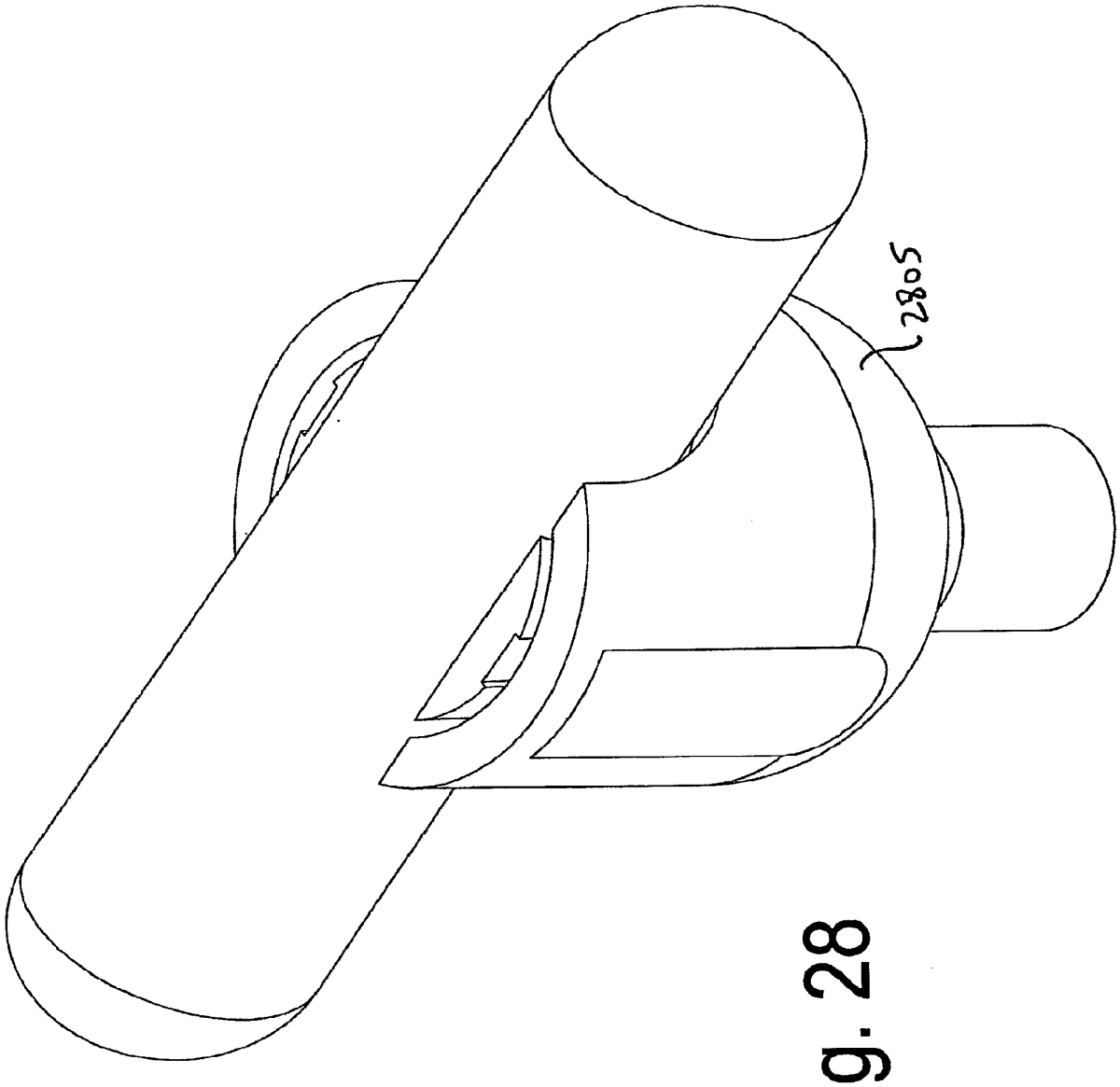
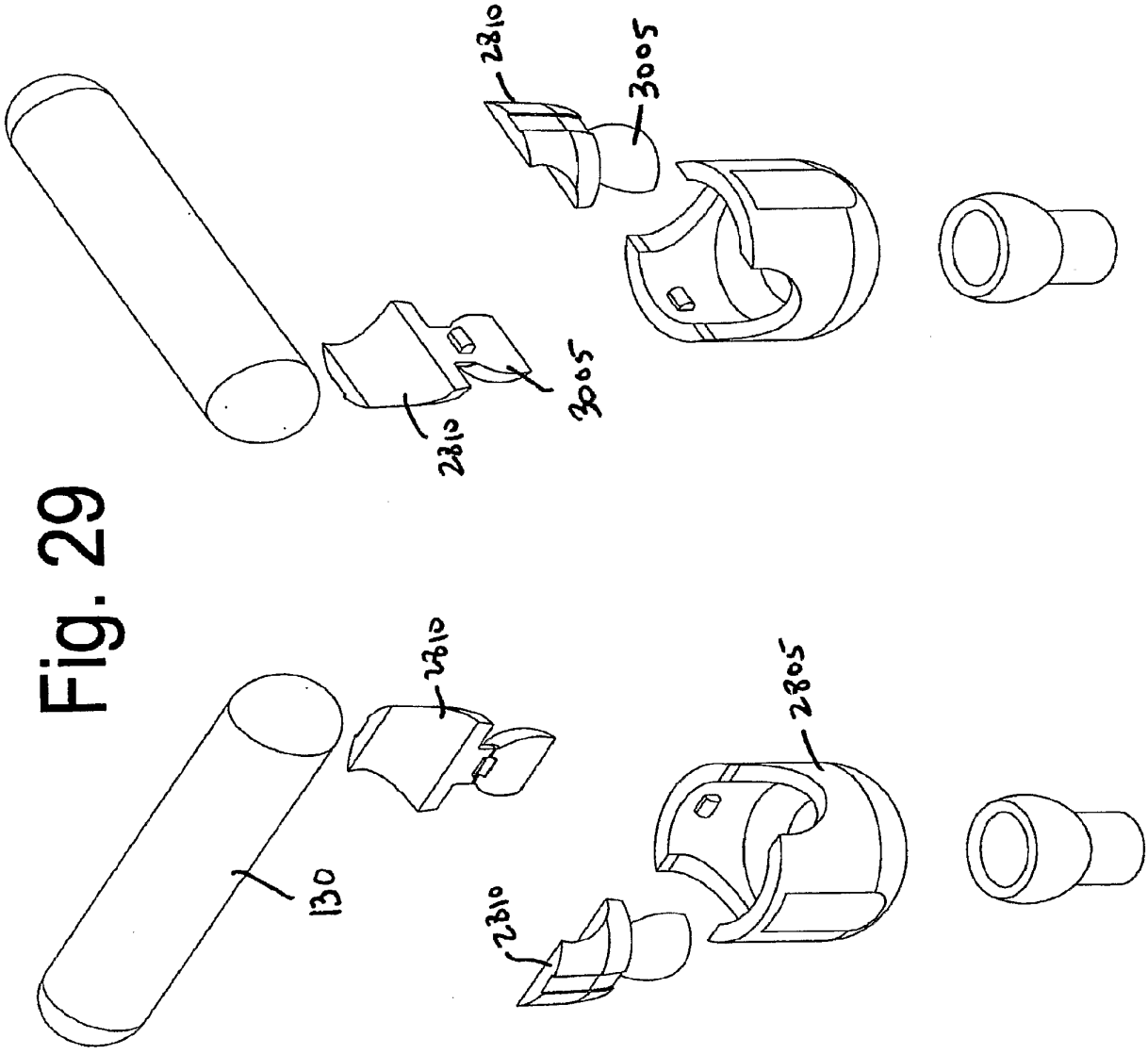


Fig. 28

Fig. 29



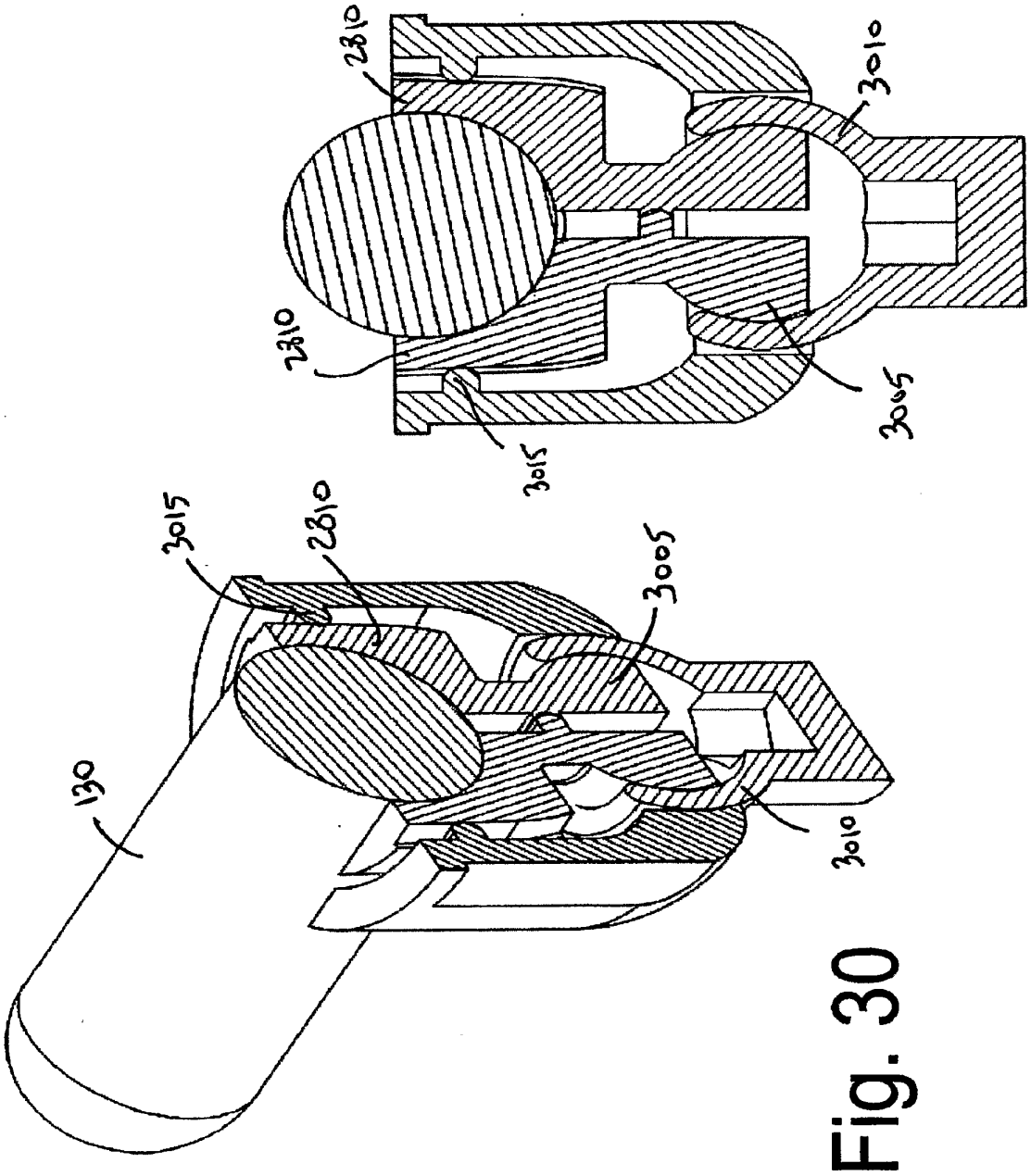


Fig. 30

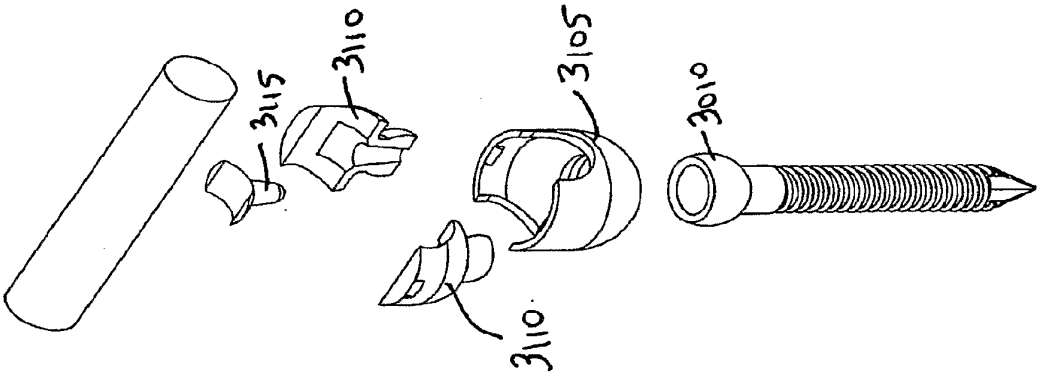


Fig. 32

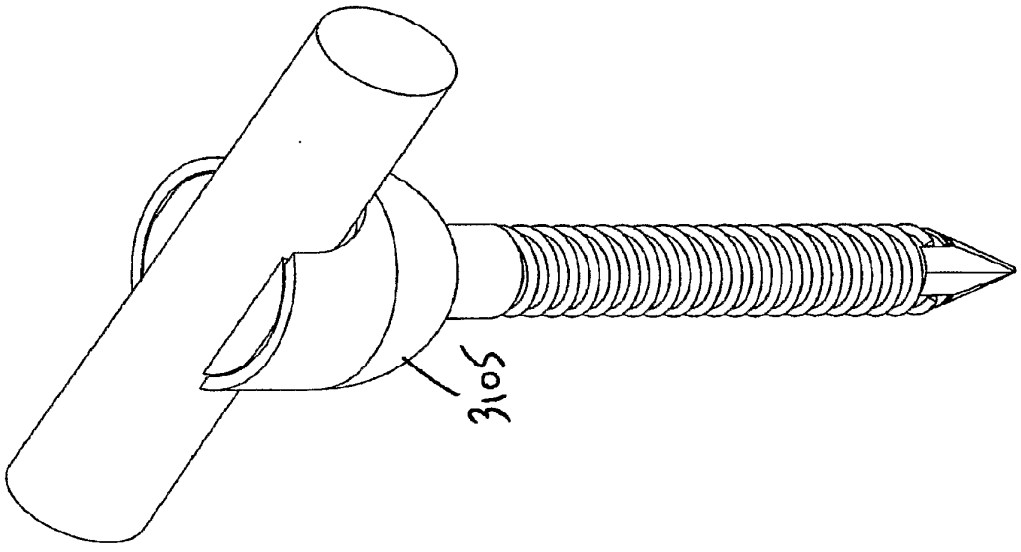
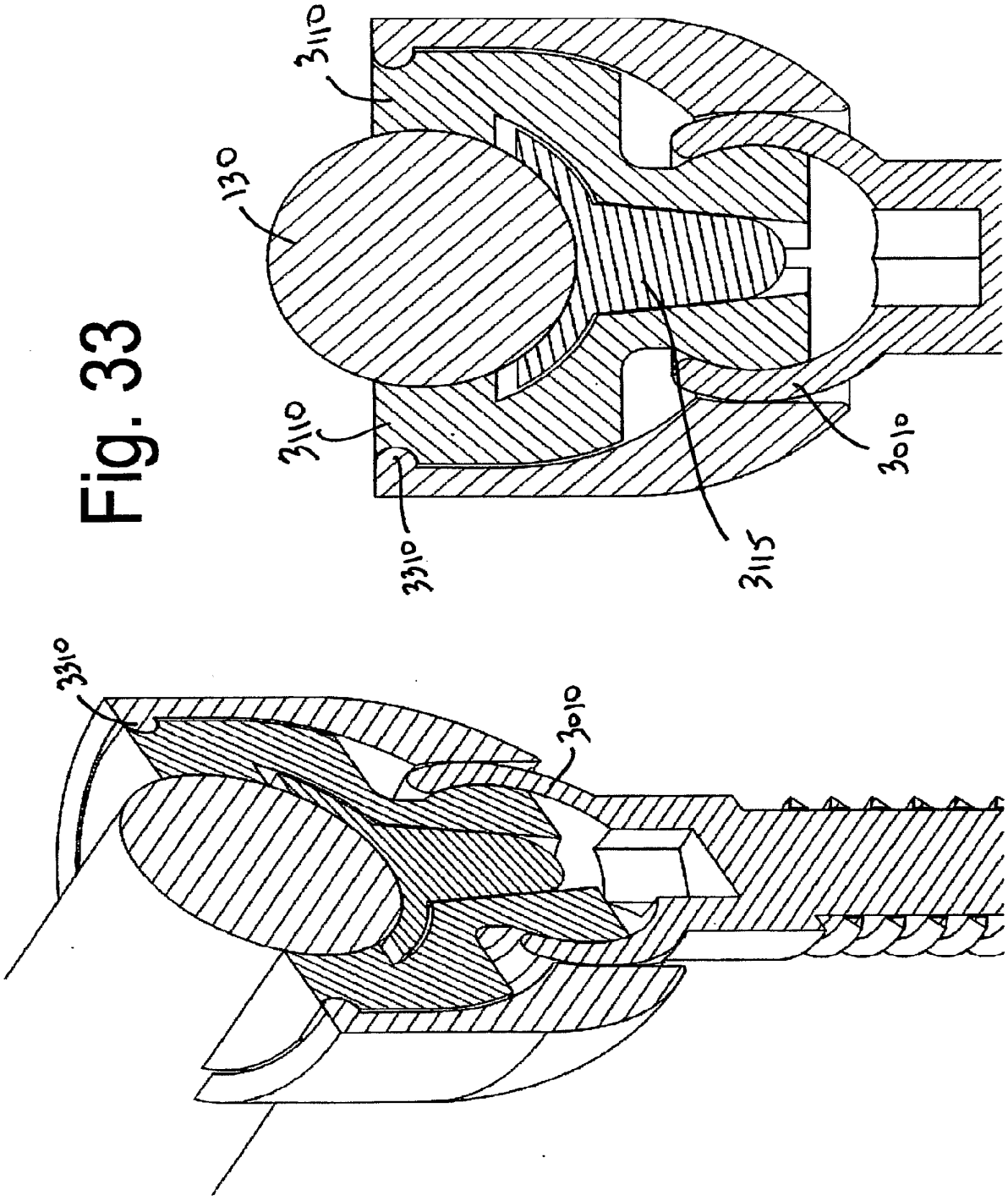


Fig. 31

Fig. 33



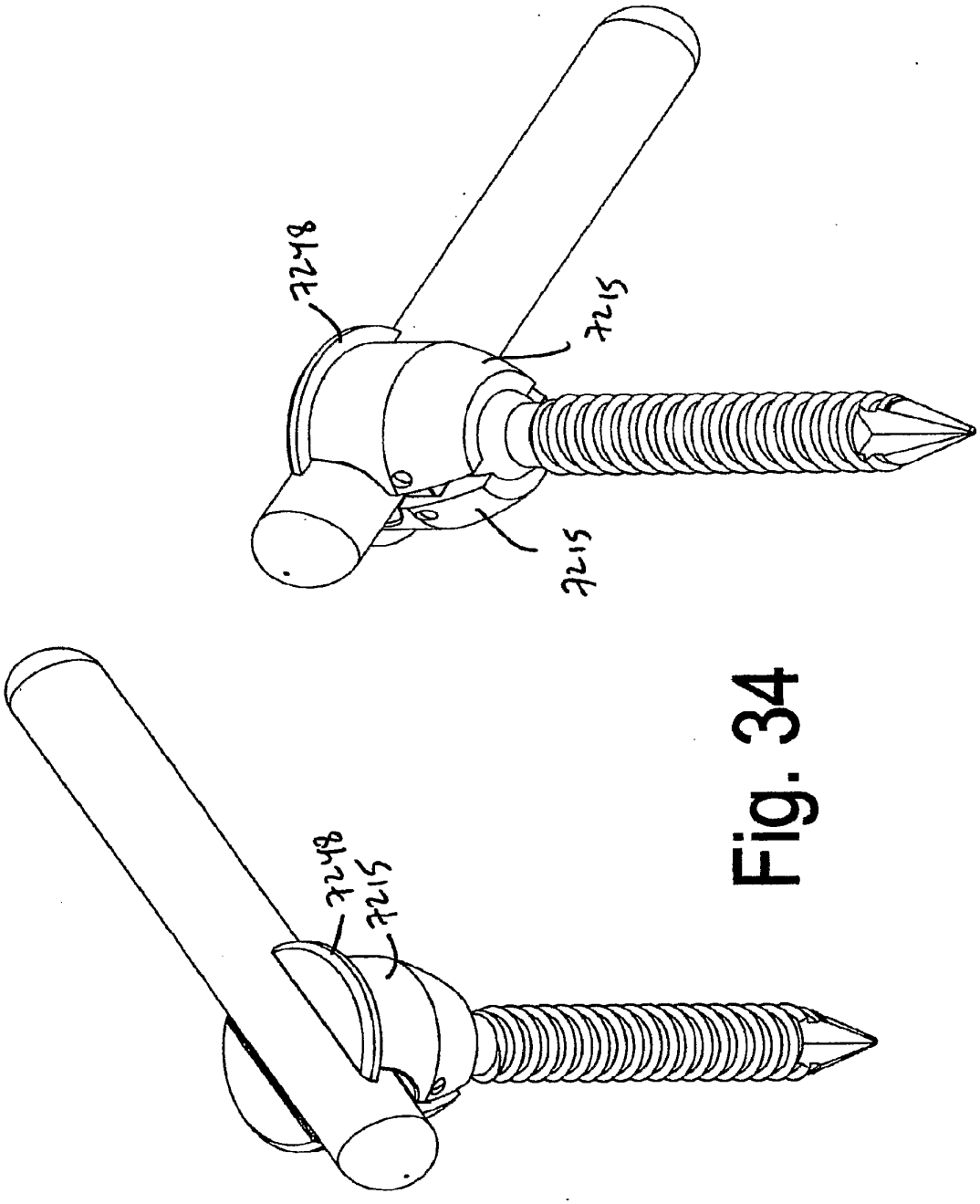


Fig. 34

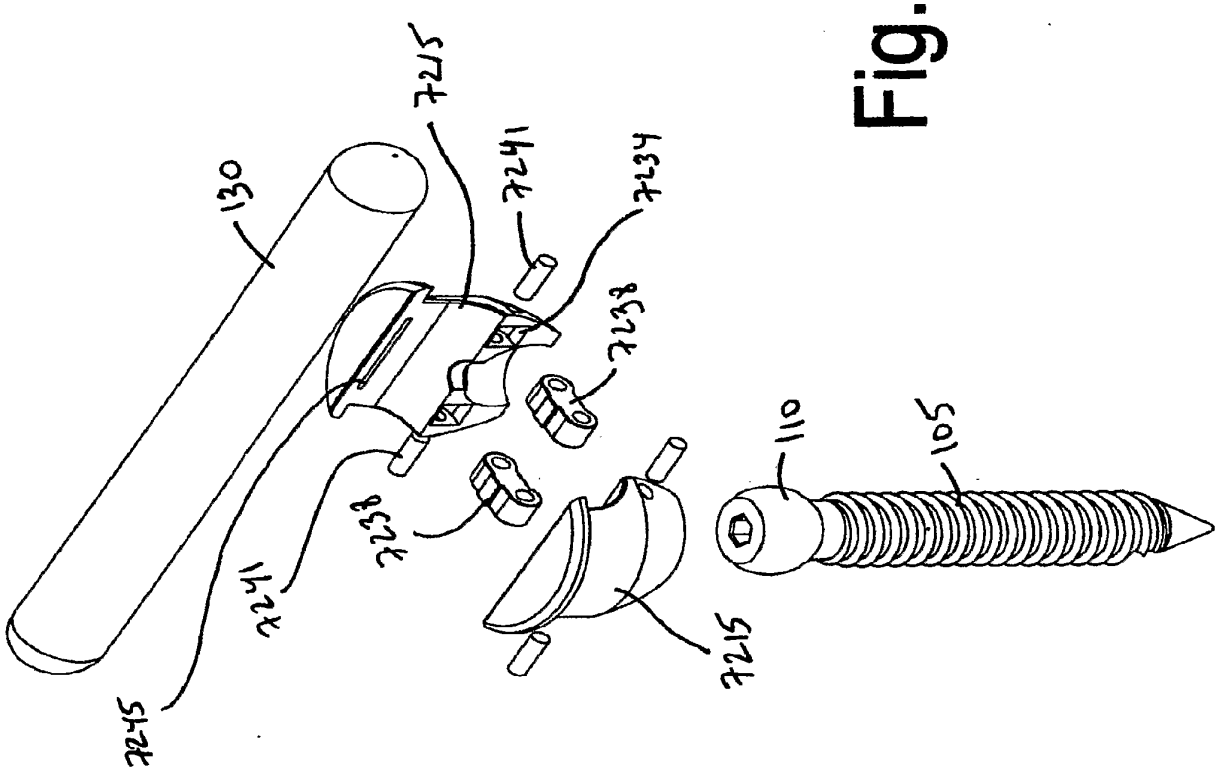


Fig. 35

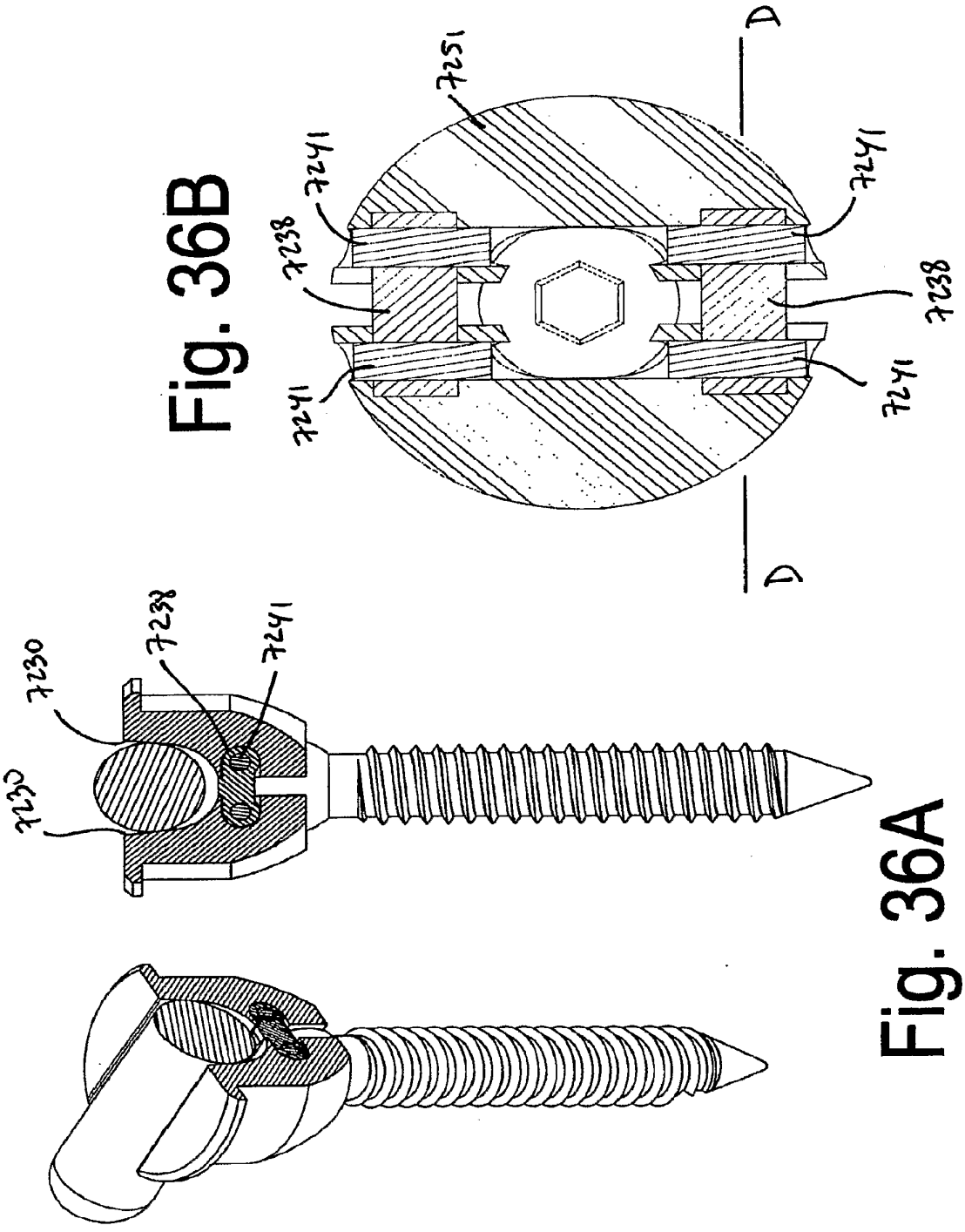


Fig. 36A

Fig. 36B

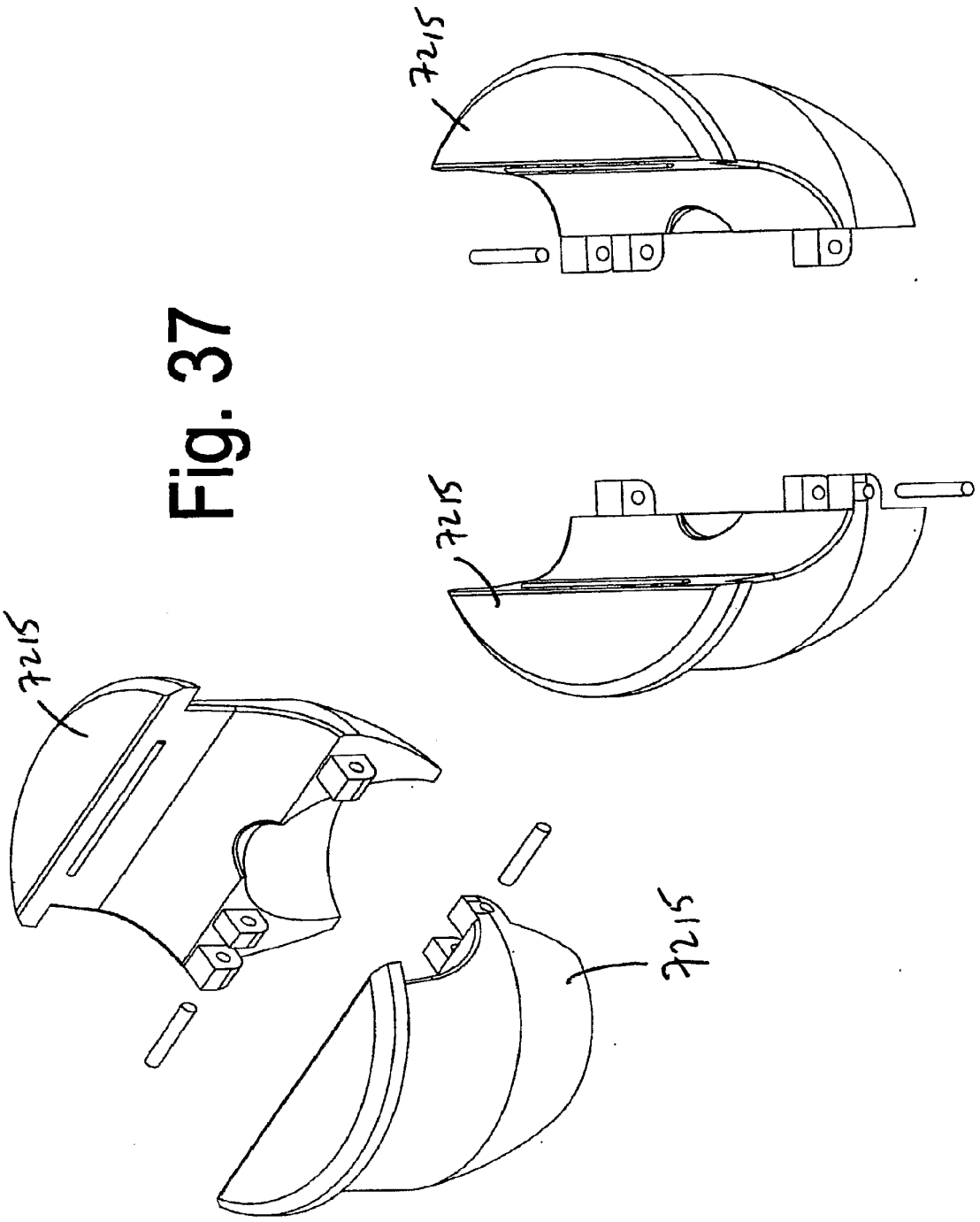


Fig. 37

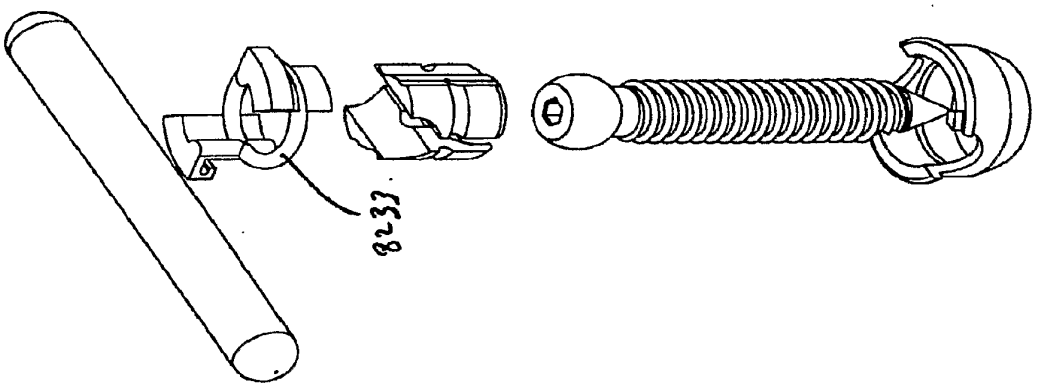


Fig. 38B

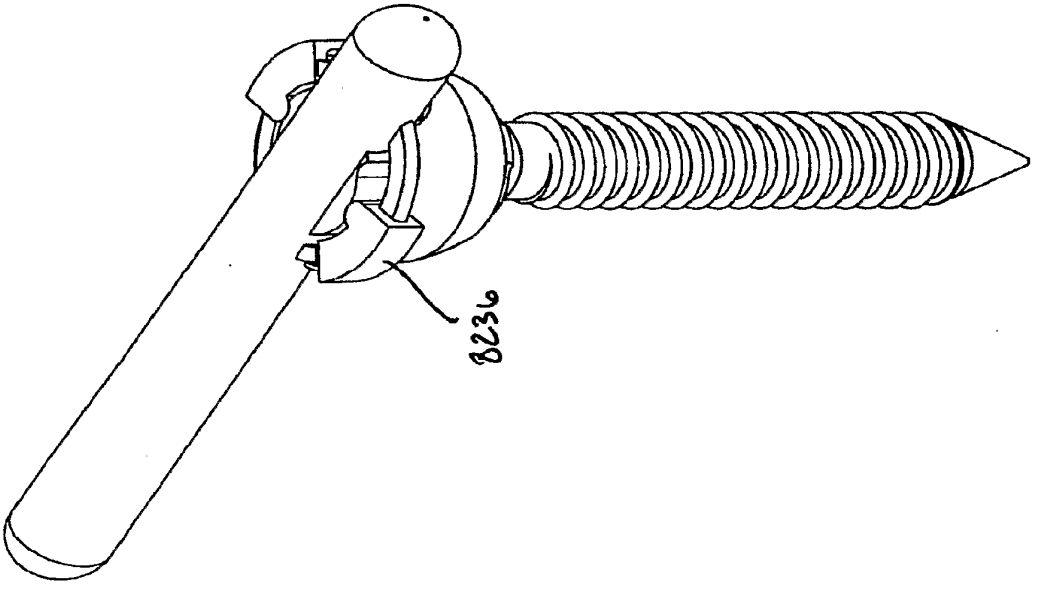


Fig. 38A

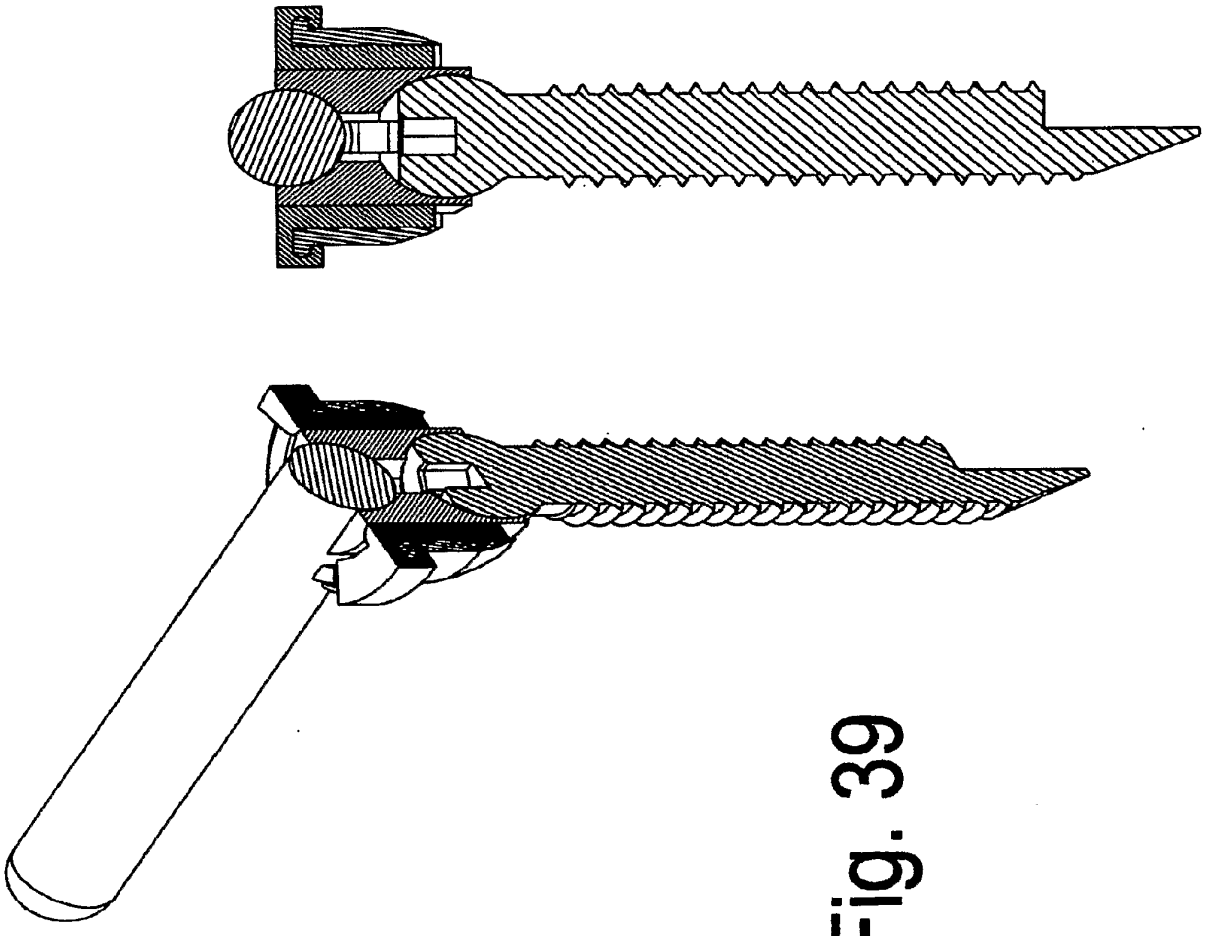


Fig. 39

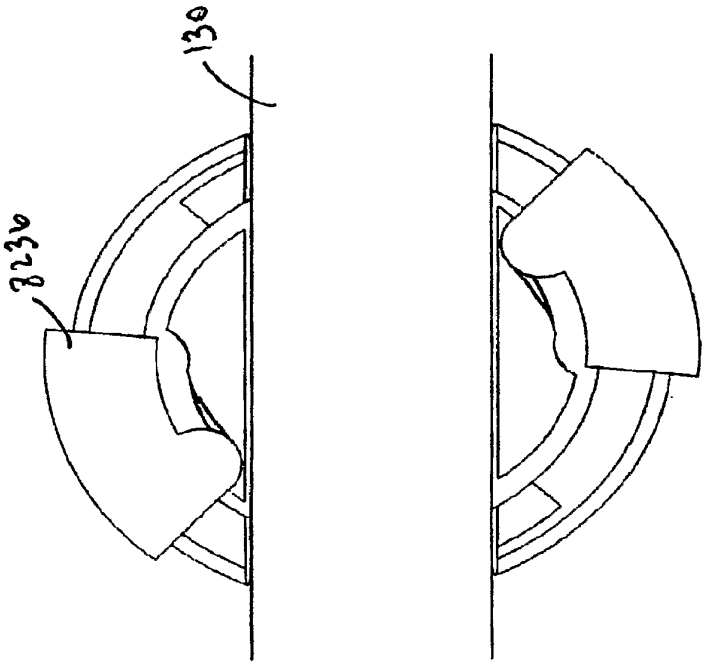


Fig. 40A

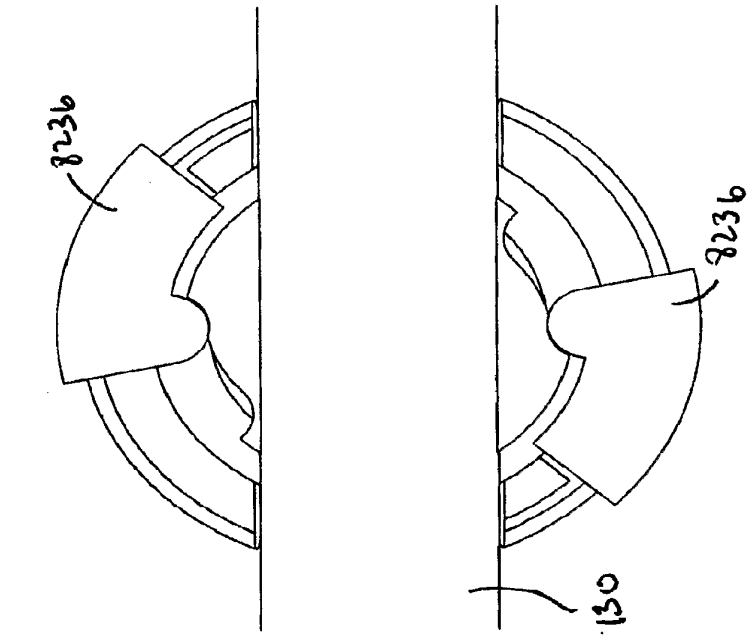


Fig. 40B

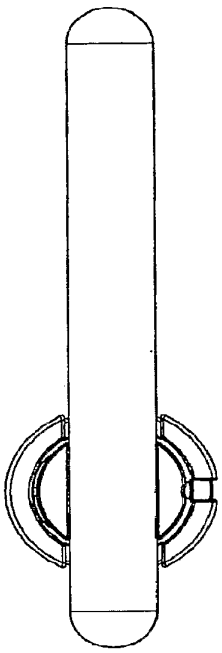


Fig. 41A

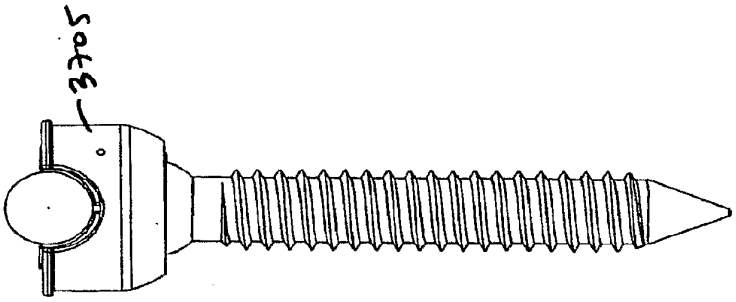


Fig. 41C

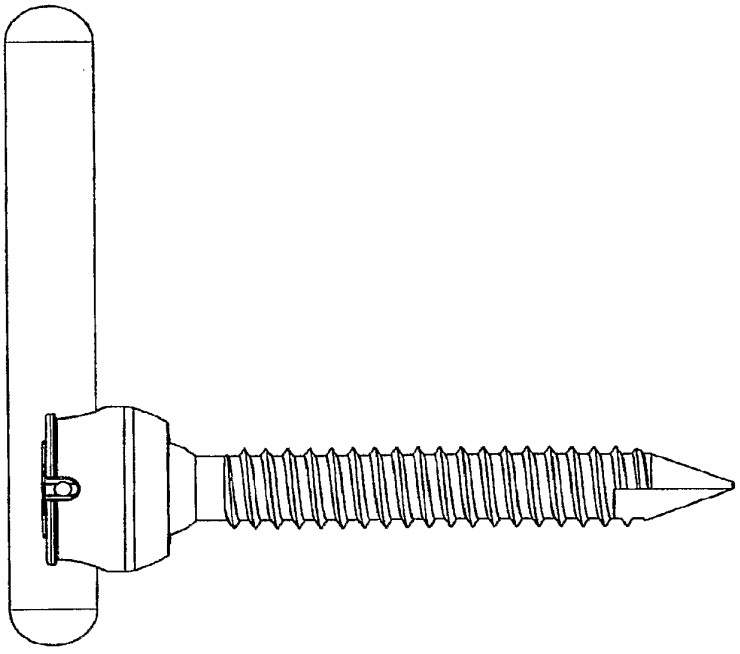


Fig. 41B

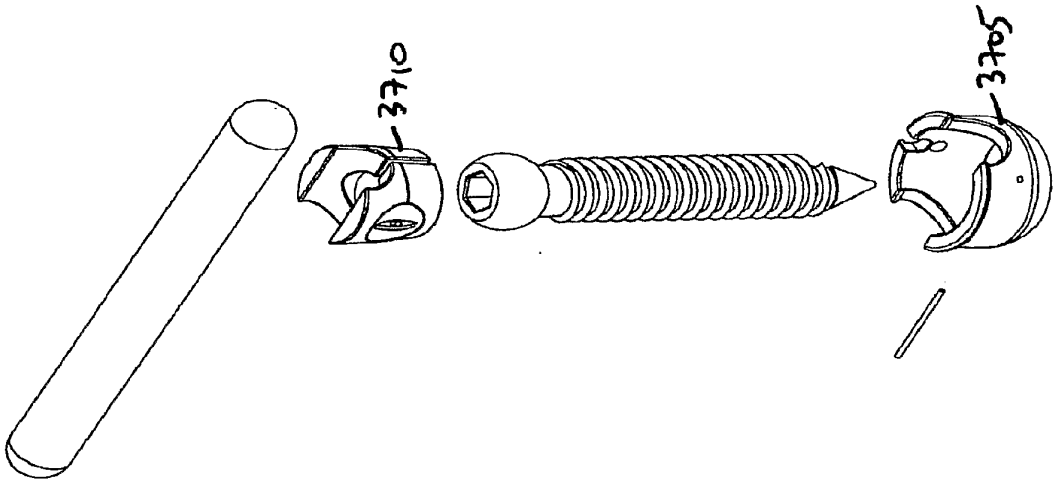


Fig. 42B

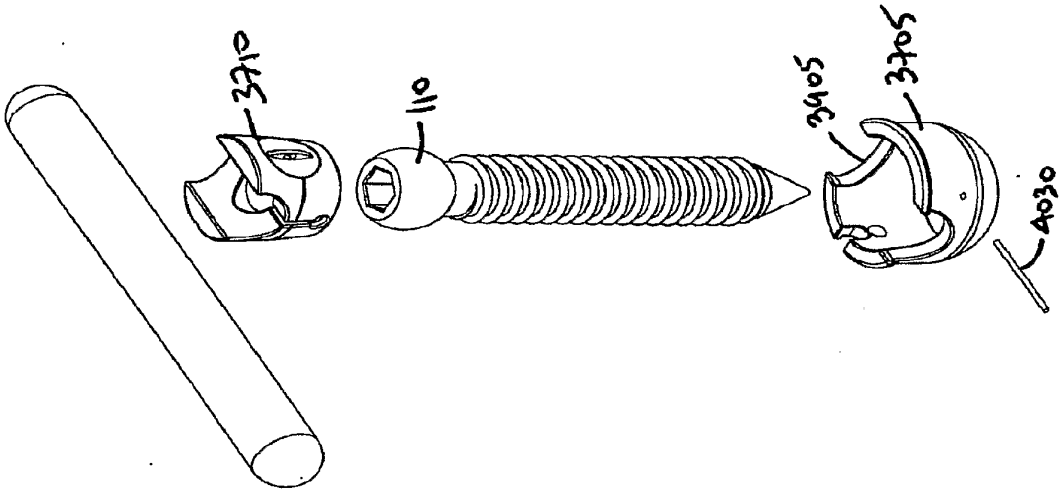


Fig. 42A

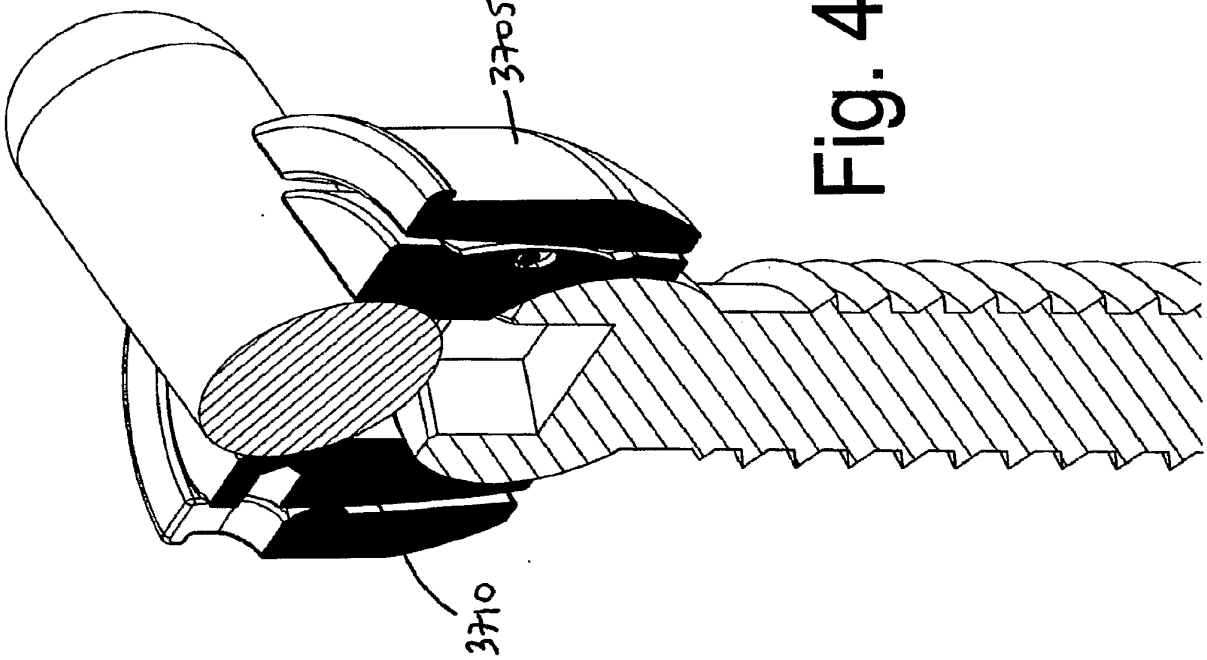


Fig. 43B

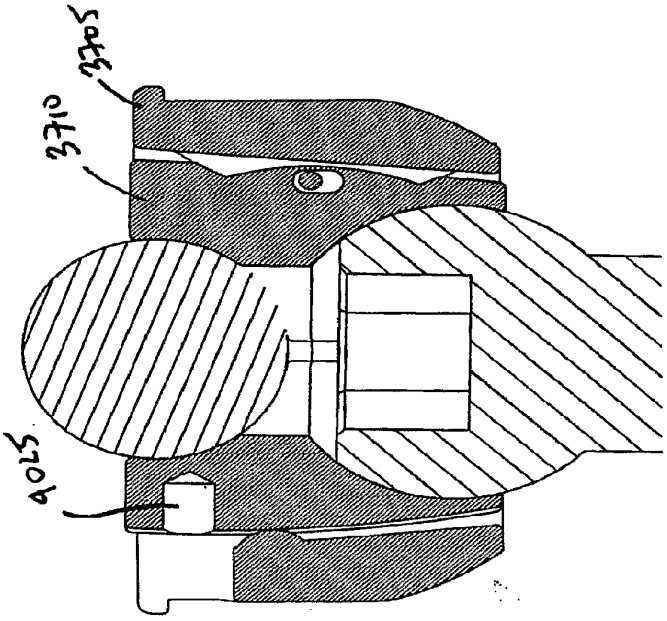


Fig. 43A

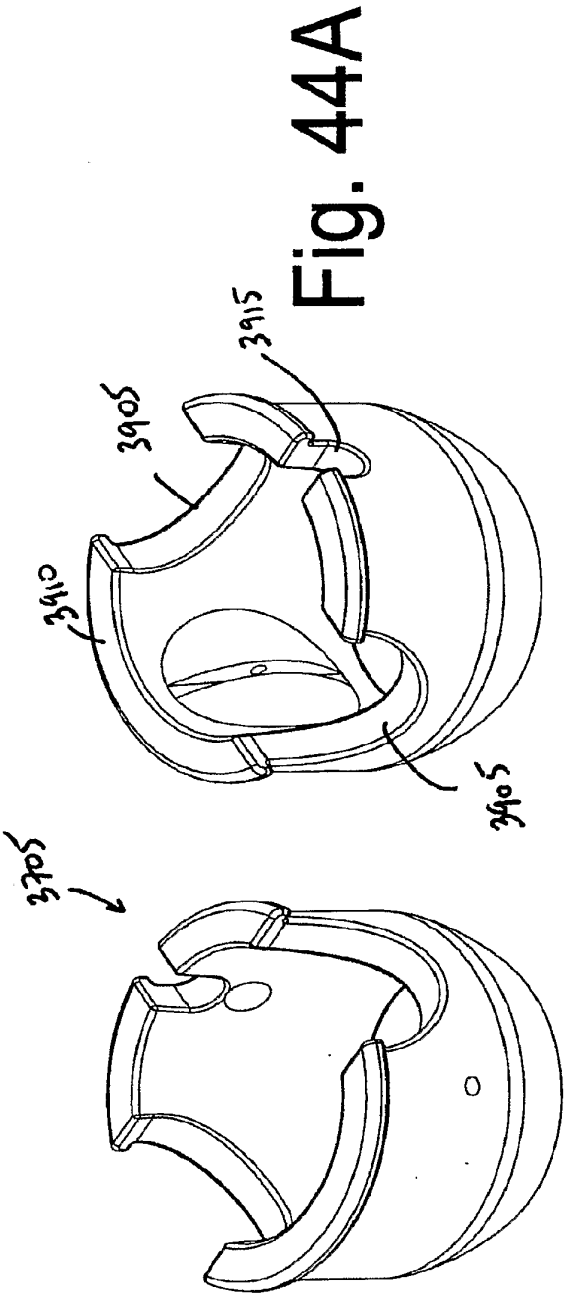


Fig. 44A

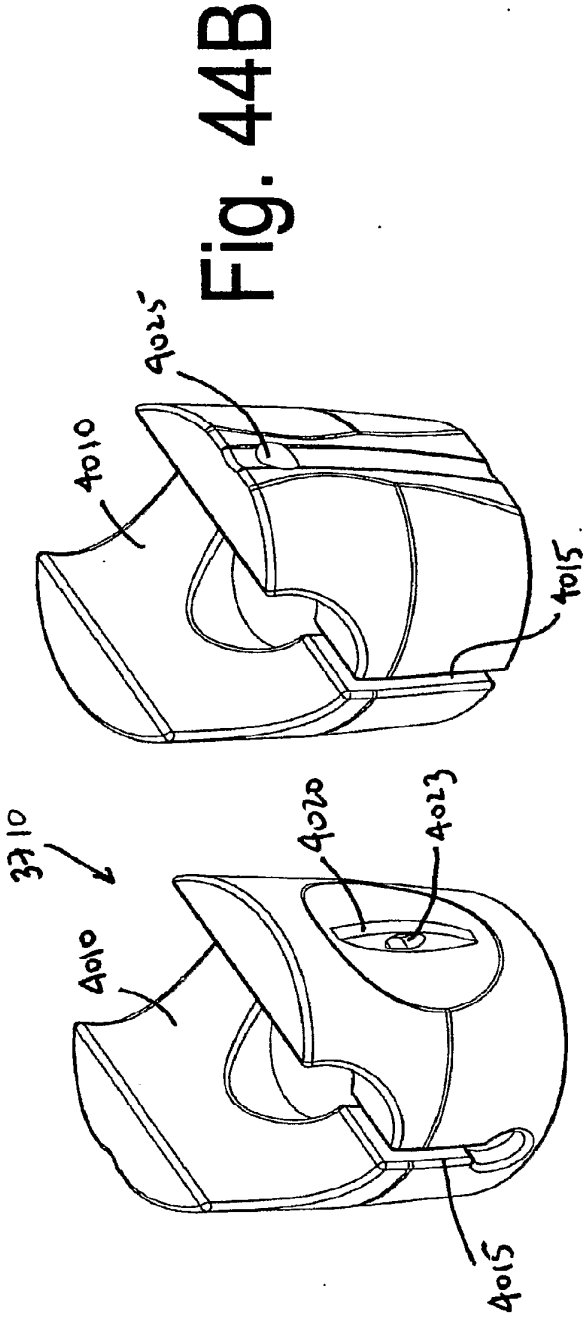


Fig. 44B

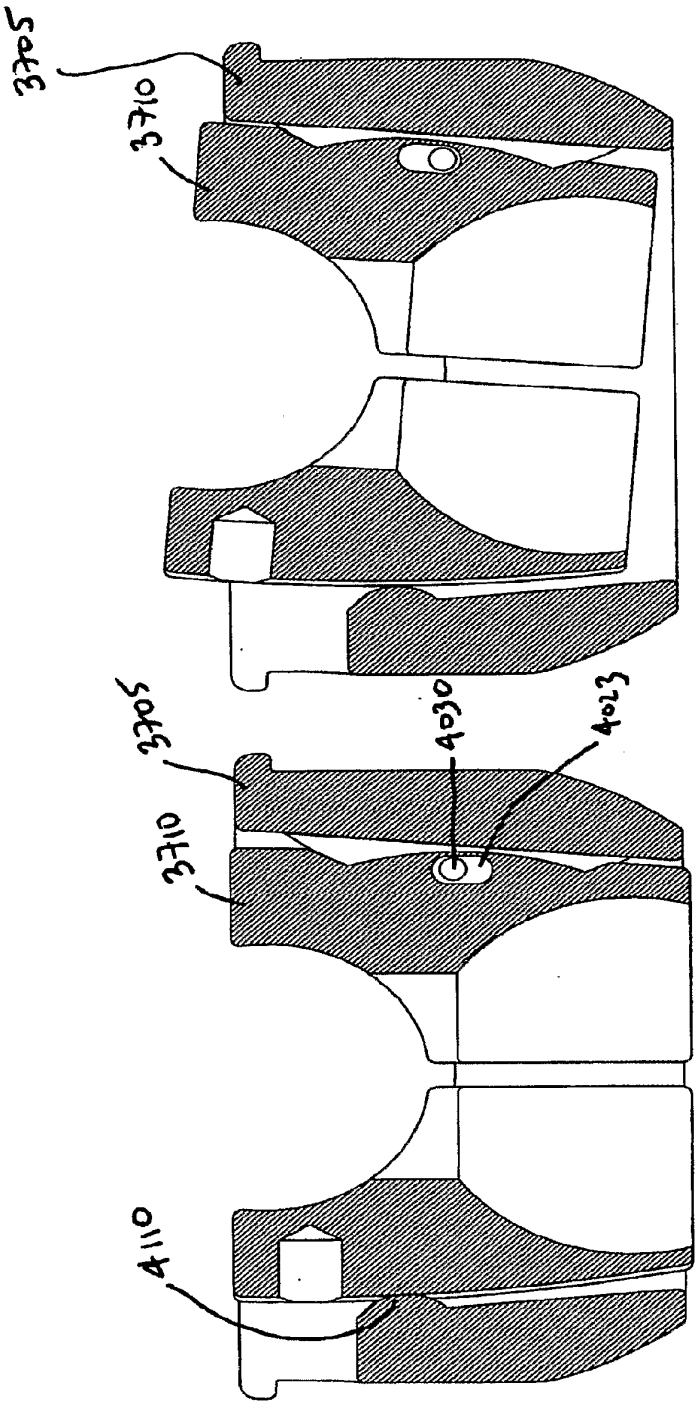


Fig. 45B

Fig. 45A

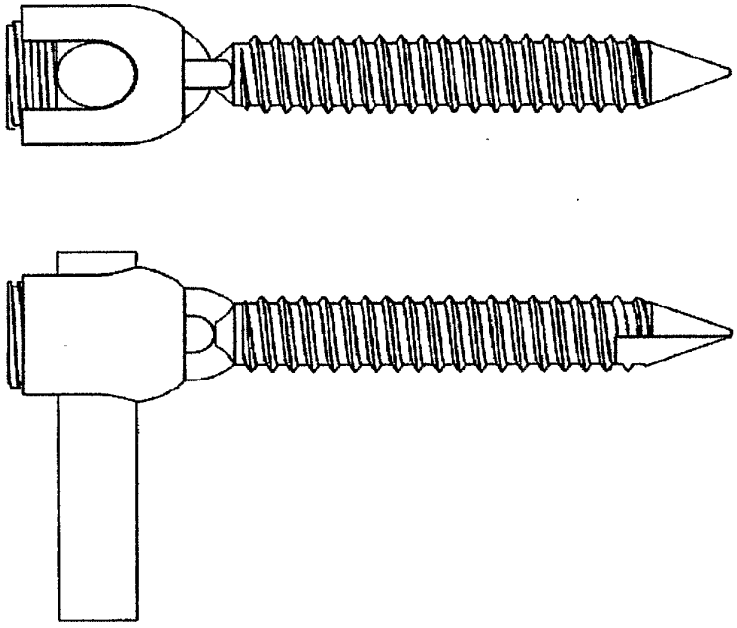


Fig. 46B

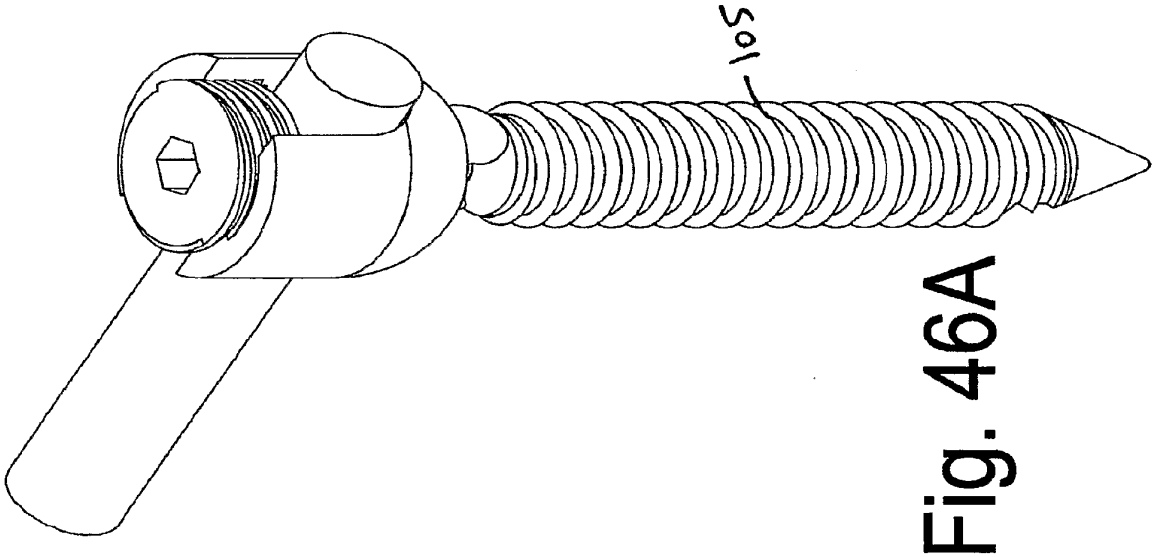


Fig. 46A

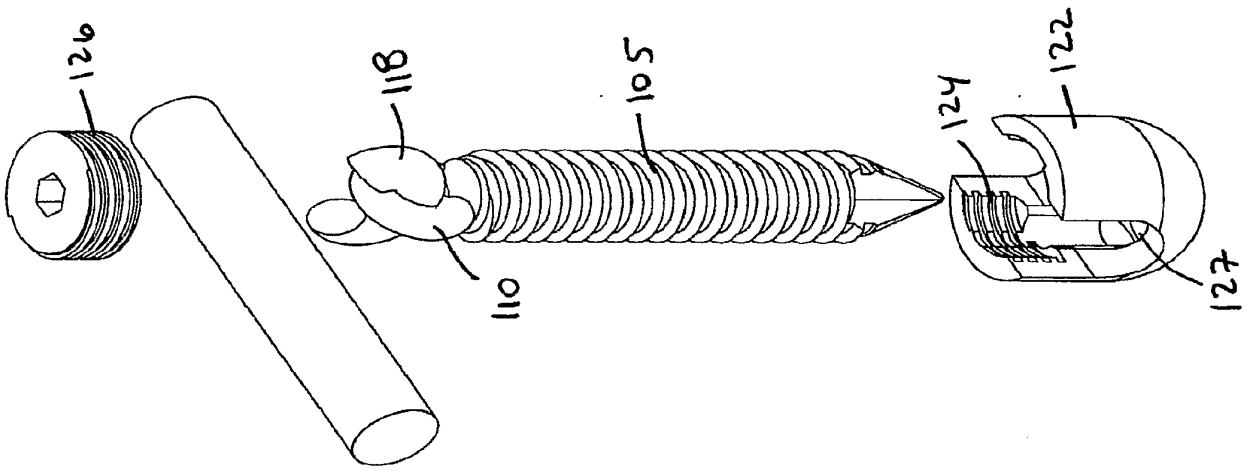


Fig. 47

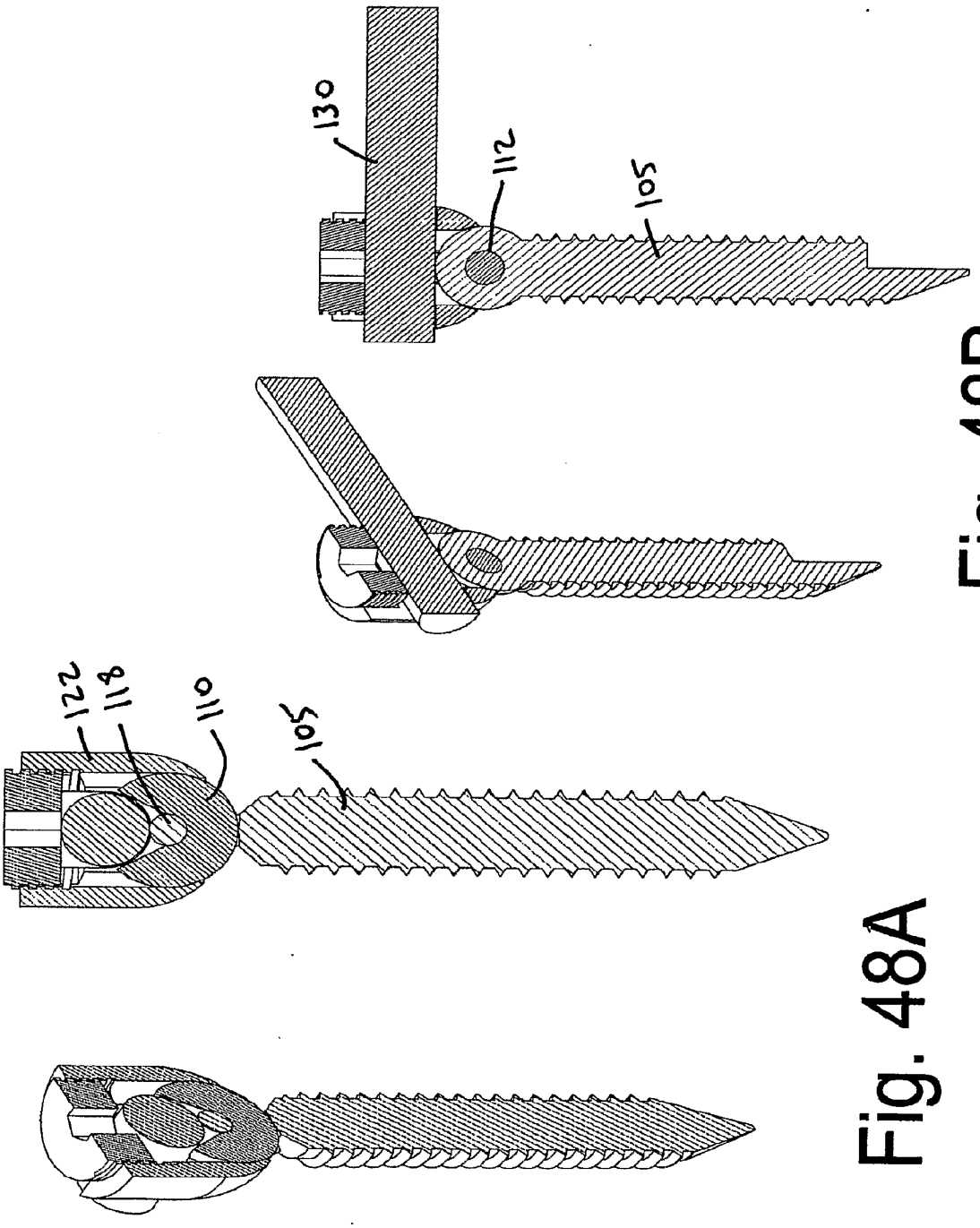


Fig. 48B

Fig. 48A

Fig. 49

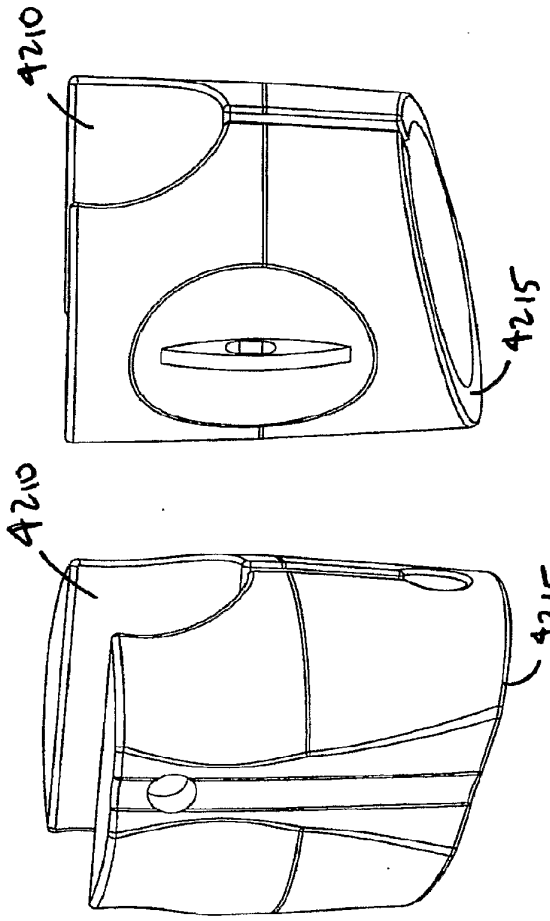
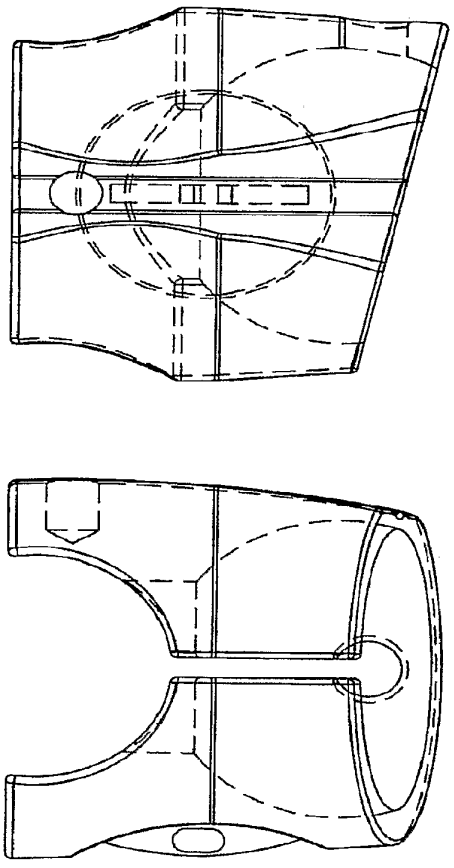


Fig. 50



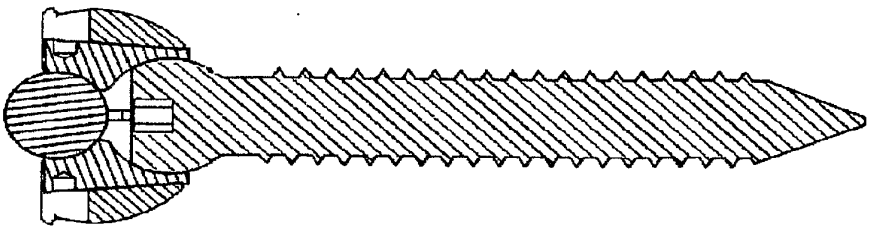


Fig. 51C

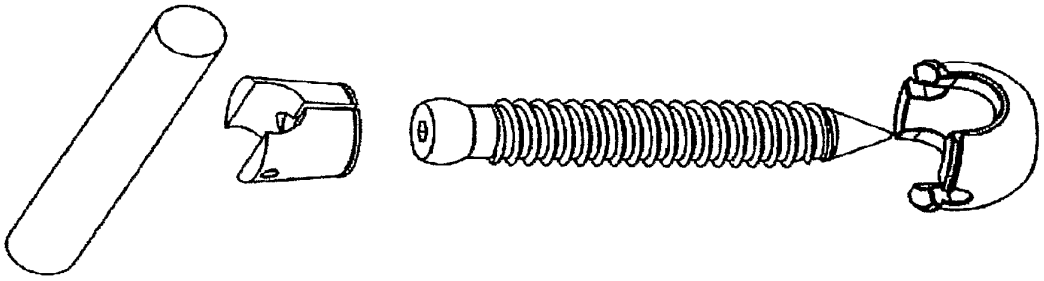


Fig. 51B

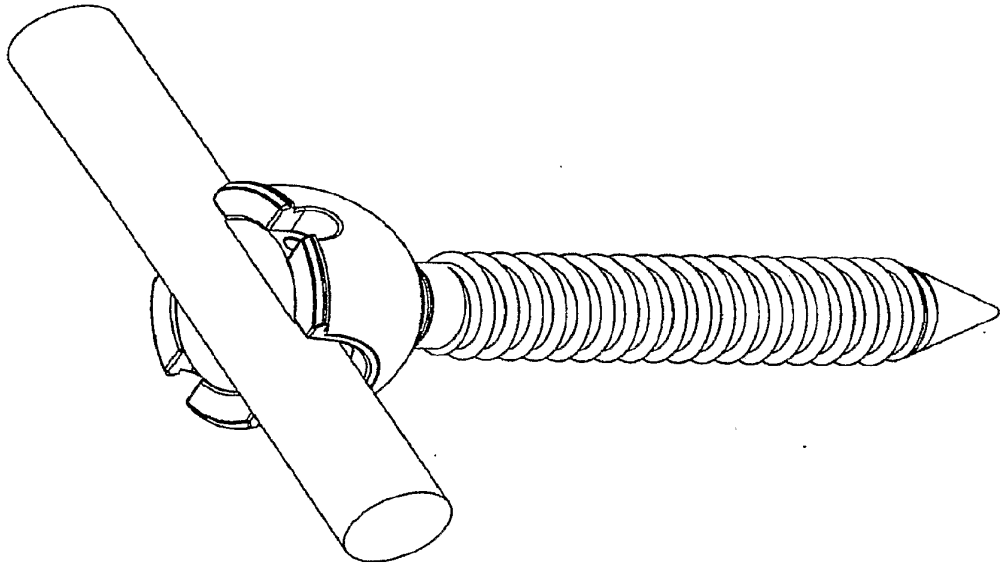


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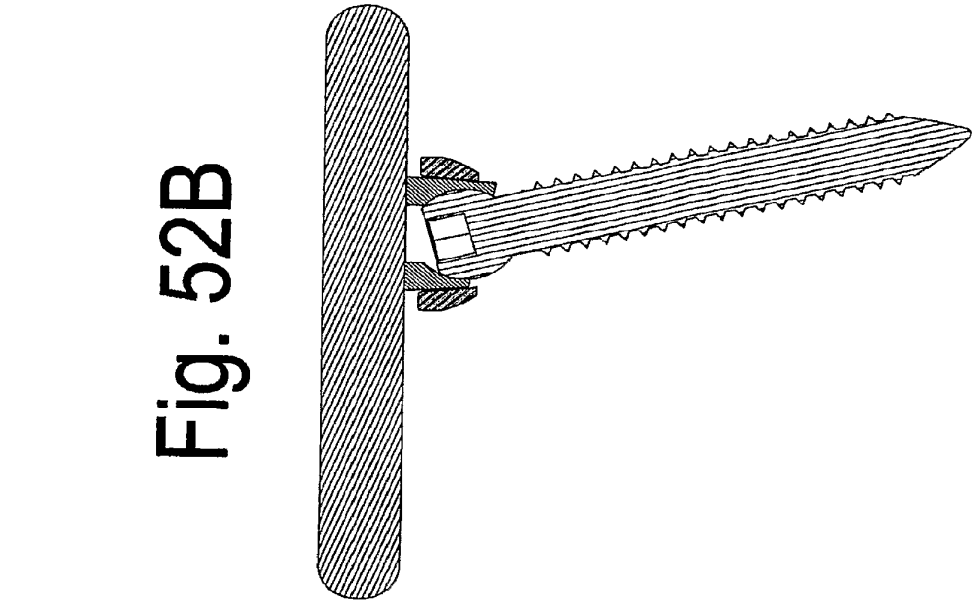


Fig. 52B

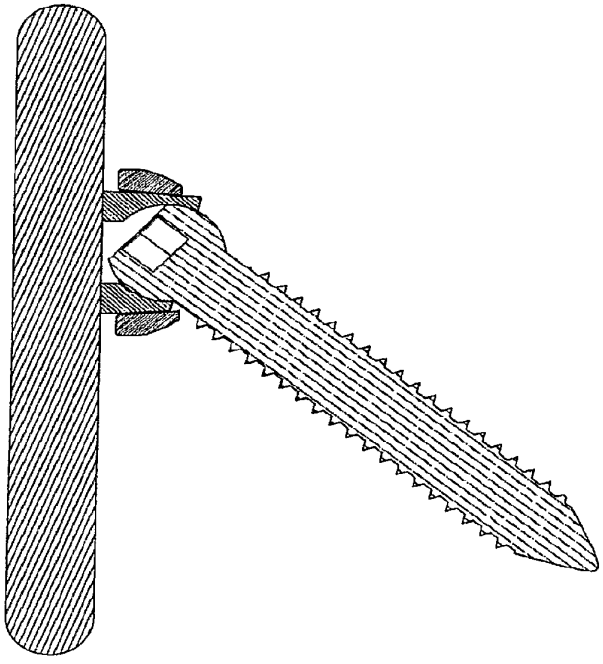


Fig. 52A

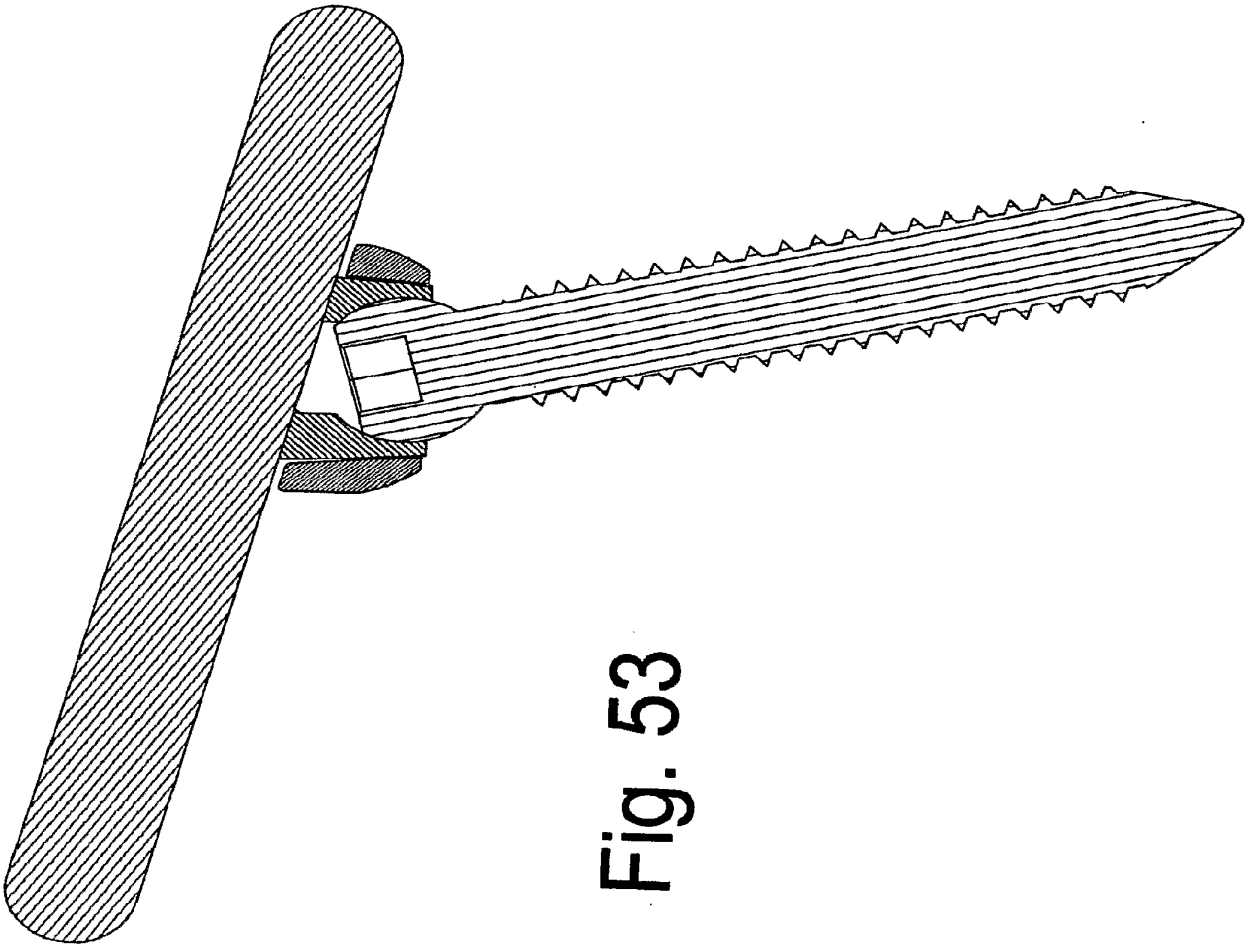


Fig. 53

(12) 按照专利合作条约所公布的国际申请

(19) 世界知识产权组织
国 际 局

(43) 国际公布日
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— 关于申请人有权要求在先申请的优先权(细则4.17(iii))
— 发明人资格(细则4.17(iv))

本国际公布:
— 包括国际检索报告。

(54) **Title:** CLEANING COMPOSITION FOR REMOVING RESIST

(54) **发明名称:** 一种光刻胶清洗剂

(57) **Abstract:** A cleaning composition for removing resist includes quaternary ammonium hydroxide, water, alkyl glycol aryl ether, dimethylsulfoxide and corrosion inhibitor of polyacrylic acid. The alkyl glycol of alkyl glycol aryl ether has 3-18 carbon atoms. The cleaning composition for removing resist may clean the resist on a metal, metal alloy or dielectric substrate and other residues, and has low etch rate for metals such as Al and Cu, and nonmetals such as SiO_2.

(57) **摘要:**

一种光刻胶清洗液, 其含有: 季铵氢氧化物、水、烷基二醇芳基醚、二甲基亚砜和聚羧酸类缓蚀剂; 烷基二醇芳基醚中烷基二醇的碳原子数目为 3－18。该清洗剂可用于去除金属、金属合金或电介质基材上的光刻胶和其它刻蚀残留物, 同时对铝和铜等的金属, 以及二氧化硅等非金属材料具有很低的腐蚀性。

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一种光刻胶清洗剂

技术领域

本发明涉及半导体制造工艺中一种清洗剂，具体的涉及一种光刻胶清洗剂。

技术背景

在通常的半导体制造工艺中，通过在二氧化硅、Cu（铜）等金属以及低k材料等表面上形成光刻胶的掩模，曝光后利用湿法或干法刻蚀进行图形转移。低温快速的清洗工艺是半导体晶片制造工艺发展的重要方向。20μm 以上厚度的负性光刻胶正逐渐应用于半导体晶片制造工艺中，而目前工业上大部分的光刻胶清洗剂对正性光刻胶的清洗能力较好，但不能彻底去除晶片上经曝光和刻蚀后的具有交联网状结构的负性光刻胶。另外，在半导体晶片进行光刻胶的化学清洗过程中，清洗剂常会造成晶片图案和基材的腐蚀。特别是在利用化学清洗剂除去光刻胶和刻蚀残余物的过程中，金属（尤其是铝和铜等较活泼金属）腐蚀是较为普遍而且非常严重的问题，往往导致晶片良率的显著降低。

目前，光刻胶清洗剂主要由极性有机溶剂、强碱和/或水等组成，通过将半导体晶片浸入清洗剂中或者利用清洗剂冲洗半导体晶片，去除半导体晶片上的光刻胶。

专利文献 WO03104901 利用四甲基氢氧化铵（TMAH）、环丁砜（SFL）、水和反-1,2-环己烷二胺四乙酸（CyDTA）等组成碱性清洗剂，将晶片浸入该清洗剂中，于 50~70℃下浸没 20~30min，除去金属和电介质基材上的光刻胶。

该碱性清洗剂对半导体晶片基材的腐蚀略高，且不能完全去除半导体晶片的光刻胶，清洗能力不足。

WO04059700 利用四甲基氢氧化铵（TMAH）、N-甲基吗啡啉-N-氧化物（MO）、水和 2-巯基苯并咪唑（MBI）等组成碱性清洗剂，将晶片浸入该清洗剂中，于 70℃下浸没 15~60min，除去金属和电介质基材上的光刻胶。该碱性清洗剂的清洗温度较高，对半导体晶片基材的腐蚀略高，且清洗速度相对较慢，不利于提高半导体晶片的清洗效率。

JP1998239865 利用 TMAH、二甲基亚砜（DMSO）、1,3'-二甲基-2-咪唑烷酮（DMI）和水等组成碱性清洗剂，将晶片浸入该清洗剂中，于 50~100℃下除去金属和电介质基材上的 20μm 以上的厚膜光刻胶。该碱性清洗剂在较高的清洗温度下对半导体晶片基材的腐蚀较严重。

JP2001215736 利用 TMAH、二甲基亚砜（DMSO）、乙二醇（EG）和水等组成碱性清洗剂，将晶片浸入该清洗剂中，于 50~70℃下除去金属和电介质基材上的光刻胶。该碱性清洗剂在较高的清洗温度下对半导体晶片基材的腐蚀较严重。

JP200493678 利用 TMAH、N-甲基吡咯烷酮（NMP）、水或甲醇等组成碱性清洗剂，将晶片浸入该清洗剂中，于 25~85℃下除去金属和电介质基材上的光刻胶。该碱性清洗剂随着清洗温度的升高，对半导体晶片基材的腐蚀明显增强。

以上清洗剂或者清洗能力不足，或者对半导体晶片基材腐蚀较强，不能满足工业需要。

发明概要

本发明的目的是为了解决现有技术中的光刻胶清洗剂对光刻胶的清洗能力不足和对半导体晶片基材的腐蚀性较强的问题，提供一种具有较高的光刻胶清洗能力和较低的基材腐蚀性的光刻胶清洗剂。

本发明的光刻胶清洗剂含有：季铵氢氧化物、水、烷基二醇芳基醚、二甲基亚砜和聚羧酸类缓蚀剂；烷基二醇芳基醚中烷基二醇的碳原子数目为3~18。

其中，所述的季铵氢氧化物较佳的为四甲基氢氧化铵、四乙基氢氧化铵、四丙基氢氧化铵、四丁基氢氧化铵或苄基三甲基氢氧化铵，更佳的为四甲基氢氧化铵、四乙基氢氧化铵或四丁基氢氧化铵，最佳的为四甲基氢氧化铵。所述的季铵氢氧化物的含量较佳的为质量百分比 0.1~15%，更佳的为质量百分比 0.5~10%。

其中，所述的水的含量较佳的为质量百分比 0.1~40%，更佳的为质量百分比 0.5~25%。

其中，所述的烷基二醇芳基醚较佳的为丙二醇单苯基醚、异丙二醇单苯基醚、二乙二醇单苯基醚、二丙二醇单苯基醚、二异丙二醇单苯基醚、三乙二醇单苯基醚、三丙二醇单苯基醚、三异丙二醇单苯基醚、六缩乙二醇单苯基醚、六缩丙二醇单苯基醚、六缩异丙二醇单苯基醚、丙二醇单苄基醚、异丙二醇单苄基醚或己二醇单萘基醚，更佳的为丙二醇单苯基醚、二丙二醇单苯基醚或丙二醇单苄基醚。所述的烷基二醇芳基醚的含量较佳的为质量百分比 1~50%，更佳的为质量百分比 5~30%。烷基二醇芳基醚可以提高四甲基氢氧化铵在二甲基亚砜中的溶解度，且对环境的危害低于乙二醇烷基醚和乙二

醇芳基醚等，更利于环境的保护。

其中，所述的二甲基亚砜的含量较佳的为质量百分比 1~98%，更佳的为质量百分比 50~90 %。

其中，所述的聚羧酸类缓蚀剂较佳的为聚丙烯酸（PAA）或其共聚物、聚甲基丙烯酸（PMAA）或其共聚物、聚丙烯酸醇胺盐、聚甲基丙烯酸醇胺盐、聚氧乙烯改性聚丙烯酸或其衍生物、聚氧乙烯改性聚甲基丙烯酸或其衍生物、聚环氧琥珀酸、聚天冬氨酸、含羧基的聚己内酯或含羧基的聚丙交酯，更佳的为聚丙烯酸、聚甲基丙烯酸、聚丙烯酸醇胺盐、聚甲基丙烯酸醇胺盐、含羧基的聚己内酯或含羧基的聚丙交酯。所述的聚羧酸类缓蚀剂的分子量较佳的为 500~20000，更佳的为 1000~10000。所述的聚羧酸类缓蚀剂的含量较佳的为质量百分比 0.01~5%，更佳的为质量百分比 0.05~2.5%。所述的聚羧酸类缓蚀剂对铝的腐蚀表现出很好的抑制作用。

本发明中，所述的光刻胶清洗剂还可含有极性有机共溶剂、表面活性剂和除聚羧酸类以外的其它缓蚀剂中的一种或多种。

其中，所述的极性有机共溶剂的含量较佳的为质量百分比 0~50%，更佳的为质量百分比 5~30%；所述的表面活性剂的含量较佳的为质量百分比 0~5%，更佳的为质量百分比 0.05~3%；所述的除聚羧酸类以外的其它缓蚀剂的含量较佳的为质量百分比 0~10%，更佳的为质量百分比 0.1~5%。

其中，所述的极性有机共溶剂较佳的为亚砜、砜、咪唑烷酮、醇胺和烷基二醇单烷基醚中的一种或多种；烷基二醇单烷基醚中烷基二醇的碳原子数目为 3~18。其中，所述的亚砜较佳的为二乙基亚砜或甲乙基亚砜；所述的砜较佳的为甲基砜、乙基砜或环丁砜，更佳的为环丁砜；所述的咪唑烷酮较佳

的为 2-咪唑烷酮、1,3-二甲基-2-咪唑烷酮或 1,3-二乙基-2-咪唑烷酮，更佳的为 1,3-二甲基-2-咪唑烷酮；所述的醇胺较佳的为一乙醇胺、二乙醇胺、三乙醇胺、异丙醇胺、甲基二乙醇胺、二甲基乙醇胺或羟乙基乙二胺，更佳的为一乙醇胺、三乙醇胺或甲基二乙醇胺；所述的烷基二醇单烷基醚较佳的为二乙二醇单甲醚、二乙二醇单乙醚、二乙二醇单丁醚、丙二醇单丁醚、二丙二醇单甲醚、二丙二醇单乙醚、二丙二醇单丁醚、三乙二醇单甲醚、三丙二醇单甲基醚、三丙二醇单乙醚、三丙二醇单丁醚、六缩乙二醇单甲醚、六缩丙二醇单甲醚、六缩异丙二醇单甲醚，更佳的为二乙二醇单甲醚或二丙二醇单甲醚。

其中，所述的表面活性剂较佳的为聚乙烯醇（PVG）、聚乙烯吡咯烷酮（PVP）或聚氧乙烯醚（POE）。所述的表面活性剂的分子量较佳的为 500~20000，更佳的为 1000~10000。

其中，所述的除聚羧酸类以外的其它缓蚀剂较佳的为醇胺类、唑类、羧酸类或膦酸类缓蚀剂。其中，所述的醇胺类缓蚀剂较佳的为一乙醇胺（MEA）、二乙醇胺（DEA）、三乙醇胺（TEA）、异丙醇胺、甲基二乙醇胺、二甲基乙醇胺或羟乙基乙二胺，更佳的为一乙醇胺、三乙醇胺或甲基二乙醇胺；所述的唑类缓蚀剂较佳的为苯并三氮唑（BTA）、甲基苯并三氮唑（TTA）、苯并三氮唑三乙醇胺盐（BTA-TEA）、1-苯基-5-巯基四氮唑（PMTA）、2-巯基苯并咪唑（MBI）、2-巯基苯并噻唑（MBT）、2-巯基苯并噁唑（MBO）、二巯基噻二唑（DMTDA）或 2-氨基-5-巯基-1,3,4-噻二唑（AMTDA），更佳的为苯并三氮唑、甲基苯并三氮唑、1-苯基-5-巯基四氮唑、2-巯基苯并噻唑或 2-氨基-5-巯基-1,3,4-噻二唑；所述的羧酸类缓蚀剂较佳的为邻苯二甲酸、没食

子酸、柠檬酸、苹果酸或乙醇酸，更佳的为柠檬酸或乙醇酸；所述的膦酸类缓蚀剂较佳的为 1,3-（羟乙基）-2,4,6-三膦酸、氨基三亚甲基膦酸、2-膦酸丁烷-1,2,4-三羧酸、乙二胺四亚甲基膦酸或二乙烯三胺五亚甲基膦酸，更佳的为 2-膦酸丁烷-1,2,4-三羧酸、乙二胺四亚甲基膦酸或二乙烯三胺五亚甲基膦酸。

本发明的光刻胶清洗剂由上面所述组分简单混合均匀即可制得。本发明所用试剂及原料均市售可得。本发明的光刻胶清洗剂可在较大的温度范围内使用（室温至 85℃之间）。清洗方法可参照如下步骤：将含有光刻胶的半导体晶片浸入清洗剂中，在室温至 85℃下利用恒温振荡器缓慢振荡，然后经去离子水洗涤后用高纯氮气吹干。

本发明的积极进步效果在于：本发明的清洗剂可以在室温至 85℃下较为迅速地清洗除去金属、金属合金或电介质基材上 20μm 以上厚度的光刻胶（光阻）和其它刻蚀残留物；同时，所含的烷基二醇芳基醚和聚羧酸类缓蚀剂能够在晶片图形和基材表面形成一层保护膜，阻止卤素原子、氢氧根离子等对晶片图形和基材的攻击，从而降低对晶片图形和对铝和铜等金属，以及二氧化硅等非金属基材的腐蚀，尤其是其含有的聚羧酸类缓蚀剂对金属铝的腐蚀表现出良好的抑制作用。本发明的光刻胶清洗剂在半导体晶片清洗等微电子领域具有良好的应用前景。

发明内容

下面通过实施例的方式进一步说明本发明，但并不因此将本发明限制在所述的实施例范围之中。

实施例 1~29

表 1 给出了光刻胶清洗剂实施例 1~29 的配方，按表 1 中所列组分及其含量，简单混合均匀，即制得各清洗剂。

表 1 光刻胶清洗剂实施例 1~29

实施例	季铵氢氧化物		水含量 wt%	烷基二醇芳基醚		二甲基亚砜含量 wt%	聚羧酸类缓蚀剂		其他	
	具体物质	含量 wt%		具体物质	含量 wt%		具体物质	含量 wt%	具体物质	含量 wt%
1	四甲基氢氧化铵	0.1	0.1	丙二醇单苯基醚	1.79	98	聚丙烯酸（分子量为 500）	0.01	\	\
2	四乙基氢氧化铵	0.5	0.5	异丙二醇单苯基醚	8.95	90	丙烯酸-马来酸共聚物（分子量为 1500）	0.05	\	\
3	四丙基氢氧化铵	10	25	二乙二醇单苯基醚	30	32.5	聚丙烯酸三乙醇胺盐（分子量为 20000）	2.5	\	\
4	四丁基氢氧化铵	15	40	二丙二醇单苯基醚	30	3.5	聚甲基丙烯酸三乙醇胺盐（分子量为 10000）	5	二乙基亚砜	1.4
									邻苯二甲酸	0.1
									柠檬酸	5
5	苄基三甲基氢氧化铵	8	15	二异丙二醇单苯基醚	50	1	聚甲基丙烯酸（分子量为 2500）	0.01	甲乙基亚砜	25.84
									聚乙烯醇（分子量为 500）	0.05
									羟乙基乙二胺	0.1
6	四甲基氢氧化铵	2	5	三乙二醇单苯基醚	1	88.85	甲基丙烯酸-马来酸共聚物（分子量为 1000）	0.05	聚乙烯吡咯烷酮（分子量为 20000）	3
									没食子酸	0.1
7	四乙基氢氧化铵	6	25.9	三丙二醇单苯基醚	8	50	聚氧乙烯改性聚丙烯酸（分子量为 5000）	0.1	苯并三氮唑	10

8	四丙基氢氧化铵	7	20	三异丙二醇单苯基醚	10	27.9	聚氧乙烯改性聚丙烯酸酯（分子量为5000）	0.1	甲基砜 一乙醇胺	30 5
9	四丁基氢氧化铵	9	28	六缩乙二醇单苯基醚	15	34.92	聚氧乙烯改性聚甲基丙烯酸（分子量为5000）	0.08	乙基砜 二乙醇胺 乙醇酸	5 7 1
10	四丙基氢氧化铵	1	10	六缩丙二醇单苯基醚	10	25.7	聚氧乙烯改性聚甲基丙烯酸酯（分子量为5000）	0.2	环丁砜 三乙醇胺 苹果酸	40 2 0.1
	四甲基氢氧化铵	1		六缩异丙二醇单苯基醚	10					
11	四丁基氢氧化铵	3	10	丙二醇单苄基醚	6	59.2	聚环氧琥珀酸（分子量为3000）	0.5	2-咪唑烷酮 异丙醇胺 邻苯二甲酸	20 1 0.3
12	四丙基氢氧化铵	3	6	异丙二醇单苄基醚	10	25.5	聚天冬氨酸（分子量为4500）	0.3	1,3-二甲基-2-咪唑烷酮 甲基二乙醇胺	50 0.2
13	四甲基氢氧化铵	5	10	己二醇单萘基醚	10	33	含羧基的聚己内酯（分子量为6500）	1	1,3-二乙基-2-咪唑烷酮 二甲基乙醇胺	35 6
14	四丙基氢氧化铵	4	8	丙二醇单苯基醚	15	56.5	含羧基的聚丙交酯（分子量为8000）	0.5	二乙二醇单甲醚 一乙醇胺 甲基苯并三氮唑	10 1 5
15	四丁基氢氧化铵	3	20	异丙二醇单苯基醚	20	45.4	聚氧乙烯改性聚甲基丙烯酸（分子量为5000）	0.5	二乙二醇单乙醚 二乙醇胺 苯并三氮唑三乙醇胺盐	10 1 0.1
16	四丙基氢氧化铵	5	18	二丙二醇单苯基醚	5	54.2	聚丙烯酸（分子量为500）	0.8	二乙二醇单丁醚 三乙醇胺 1-苯基-5-巯基四氮唑	10 2 5
17	四甲基氢氧化铵	5	12	丙二醇单苯基醚	5	56.5	聚丙烯酸三乙醇胺盐（分子量为20000）	1.5	丙二醇单丁醚 异丙醇胺 2-巯基苯并咪唑	10 2 8

18	四甲基氢氧化铵	5	15	丙二醇单苯基醚	8	57.4	聚丙烯酸（分子量为 500）	0.1	二丙二醇单甲醚	10
									甲基二乙醇胺	3
							聚丙烯酸三乙醇胺盐（分子量为 20000）	0.5	2-巯基苯并噻唑	1
19	苄基三甲基氢氧化铵	5	10	异丙二醇单苯基醚	8	58.2	聚甲基丙烯酸三乙醇胺盐（分子量为 10000）	2	二丙二醇单乙醚	15
									二甲基乙醇胺	1.5
									1,3-（羟乙基）-2,4,6-三膦酸	0.3
20	四乙基氢氧化铵	4	10	二丙二醇单苯基醚	10	65.4	聚氧乙烯改性聚丙烯酸（分子量为 5000）	0.5	二丙二醇单丁醚	10
									氨基三亚甲基膦酸	0.1
21	四甲基氢氧化铵	3	22	丙二醇单苯基醚	12	50	丙烯酸-马来酸共聚物（分子量为 1500）	1	三乙二醇单甲醚	10
									2-巯基苯并噁唑	2
22	四甲基氢氧化铵	3	10	二异丙二醇单苯基醚	15	60.95	聚甲基丙烯酸（分子量为 2500）	0.05	三丙二醇单甲基醚	10
									二巯基噻二唑	1
23	苄基三甲基氢氧化铵	5	15	丙二醇单苯基醚	15	53.5	聚丙烯酸（分子量为 500）	0.5	三丙二醇单乙醚	10
									2-氨基-5-巯基-1,3,4-噻二唑	1
24	四乙基氢氧化铵	5	10	二乙二醇单苯基醚	10	62.5	聚丙烯酸三乙醇胺盐（分子量为 20000）	2	三丙二醇单丁醚	10
									2-膦酸丁烷-1,2,4-三羧酸	0.5
25	四甲基氢氧化铵	2	6	二丙二醇单苯基醚	5	56.45	甲基丙烯酸-马来酸共聚物（分子量为 1000）	0.05	六缩乙二醇单甲醚	30
									乙二胺四亚甲基膦酸	0.5
26	四丁基氢氧化铵	6	15	二异丙二醇单苯基醚	10	50.5	聚甲基丙烯酸三乙醇胺盐（分子量为 10000）	3	六缩丙二醇单甲醚	15
									二乙烯三胺五亚甲基膦酸	0.5

27	四甲基氢氧化铵	5	10	异丙二醇单苯基醚	10	69.45	聚丙烯酸三乙醇胺盐（分子量为20000）	0.5	六缩异丙二醇单甲醚 聚氧乙烯醚（分子量为10000）	5 0.05
28	四甲基氢氧化铵	0.5	0.5	异丙二醇单苯基醚	8.95	70	丙烯酸-马来酸共聚物（分子量为1500）	0.05	甲基砜	20
29	四乙基氢氧化铵	10	25	二乙二醇单苯基醚	30	27.5	聚丙烯酸三乙醇胺盐（分子量为20000）	2.5	聚氧乙烯醚（分子量为10000）	5

效果实施例　对比清洗剂 1'~6'和本发明的光刻胶清洗剂 1~16

表 2 给出了对比清洗剂 1'~6'和本发明的光刻胶清洗剂 1~16 的配方，按表 1 中所列组分及其含量，简单混合均匀，即制得各清洗剂。

表 2 对比清洗剂 1'~6'和本发明的光刻胶清洗剂 1~16 的组分和含量

实施例	四甲基氢氧化铵	去离子水	丙二醇单苯基醚	二甲基亚砜	聚丙烯酸三乙醇胺盐	1,3-二甲基-2-咪唑烷酮	聚氧乙烯醚	单乙醇胺	三乙醇胺	苯并三氮唑	甲基苯并三氮唑	乙二胺四亚甲基膦酸
1'	1.00	5.00	\	94.00	\	\	\	\	\	\	\	\
2'	1.00	5.00	\	93.50	\	\	\	\	\	0.50	\	\
3'	1.50	8.50	\	89.50	\	\	\	\	\	\	0.50	\
4'	2.00	8.00	\	89.90	\	\	0.10	\	\	\	\	\
5'	2.50	12.00	\	84.90	\	\	0.10	\	\	0.50	\	\
6'	3.00	12.00	\	84.70	\	\	0.30	\	\	\	\	\
1	0.50	5.00	1.00	93.49	0.01	\	\	\	\	\	\	\
2	1.00	5.00	3.00	90.95	0.05	\	\	\	\	\	\	\
3	1.50	5.00	5.00	88.45	0.05	\	\	\	\	\	\	\
4	2.00	5.00	5.00	87.80	0.10	\	0.10	\	\	\	\	\
5	2.50	5.00	5.00	87.10	0.20	\	0.10	0.10	\	\	\	\
6	3.00	6.00	6.00	84.10	0.30	\	0.10	0.50	\	\	\	\
7	3.00	6.00	6.00	64.50	0.30	20.00	0.10	\	0.10	\	\	\

8	3.50	7.50	6.00	81.20	0.30	\	\	1.00	\	0.50	\	\
9	4.00	7.50	7.00	79.70	0.30	\	\	1.00	\	\	0.50	\
10	4.50	8.50	10.00	58.80	0.50	15.00	\	1.00	0.50	1.00	\	0.20
11	5.00	10.00	10.00	71.30	0.50	\	\	2.00	\	0.50	0.50	0.20
12	7.50	15.00	15.00	44.70	1.50	\	0.30	15.00	\	1.00	\	\
13	10.00	20.00	15.00	29.50	3.00	\	0.50	20.00	\	1.00	1.00	\
14	3.00	7.00	10.00	75.00	1.00	\	\	2.00	\	1.00	1.00	\
15	3.00	7.00	10.00	71.00	1.00	\	\	6.00	\	1.00	1.00	\
16	3.00	7.00	10.00	67.00	1.00	\	\	10.00	\	1.00	1.00	\

注：\ 是没有加入该组分。

将表 2 中的各组分按照比例混合均匀，制得对比清洗剂 1'~6'和清洗剂 1~16。其中，除对比清洗剂 6'中有少量四甲基氢氧化铵不能溶解以外，对比清洗剂 1'~5'和清洗剂 1~16 均为澄清透明的均相溶液。

将对比清洗剂 1'~5'和清洗剂 1~16 用于清洗空白 Cu 晶片，测定其对于金属 Cu 的腐蚀情况。测试方法和条件：将 4×4cm 空白 Cu 晶片浸入清洗剂，在 23~85℃下利用恒温振荡器以约 60 转/分的振动频率振荡 60 分钟，然后经去离子水洗涤后用高纯氮气吹干，利用四极探针仪测定空白 Cu 晶片蚀刻前后表面电阻的变化计算得到。结果如表 3 所示。

将对比清洗剂 1'~5'和清洗剂 1~16 用于清洗空白 Al 晶片，测定其对于金属 Al 的腐蚀情况。测试方法和条件：将 4×4cm 空白 Al 晶片浸入清洗剂，在 23~85℃下利用恒温振荡器以约 60 转/分的振动频率振荡 60 分钟，然后经去离子水洗涤后用高纯氮气吹干，利用四极探针仪测定空白 Al 晶片蚀刻前后表面电阻的变化计算得到。结果如表 3 所示。

将对比清洗剂 1'~5'和清洗剂 1~16 用于清洗空白的四乙氧基硅烷（TEOS）晶片，测定其对于非金属 TEOS 的腐蚀情况。测试方法和条件：将 4×4cm 空白 TEOS 晶片浸入清洗剂，在 23~85℃下利用恒温振荡器以约

60 转/分的振动频率振荡 60 分钟，然后经去离子水洗涤后用高纯氮气吹干。利用 Nanospec6100 测厚仪测定空白 TEOS 晶片清洗前后 TEOS 厚度的变化计算得到，结果如表 3 所示。

本发明中，利用光刻胶清洗剂清洗半导体晶片上光刻胶的方法如下：将含有负性丙烯酸酯类光刻胶（厚度约为 50 微米，且经过曝光和刻蚀）的半导体晶片（含有图案）浸入清洗剂中，在 23~85℃下利用恒温振荡器以约 60 转/分的振动频率振荡 1~30 分钟，然后经去离子水洗涤后用高纯氮气吹干。光刻胶的清洗效果和清洗剂对晶片图案的腐蚀情况如表 3 所示。

表 3 对比清洗剂 1'~5'和清洗剂 1~16 对金属 Cu 和 Al 以及非金属 TEOS 的腐蚀性及其对负性光刻胶的清洗情况

清洗剂	清洗温度 (℃)	金属 Cu 的腐蚀情况	金属 Al 的腐蚀情况	非金属 TEOS 的腐蚀情况	光刻胶清洗时间 (min)	光刻胶清洗结果	晶片图案的腐蚀情况
对比 1'	40	×	×	○	30	○	◎
对比 2'	35	×	×	○	30	○	◎
对比 3'	30	×	×	○	30	◎	○
对比 4'	23	×	×	△	25	◎	△
对比 5'	23	×	×	△	20	◎	×
1	40	○	○	◎	30	○	◎
2	35	◎	◎	◎	30	○	◎
3	30	◎	◎	◎	30	◎	◎
4	23	◎	◎	◎	25	◎	◎
5	23	◎	◎	◎	20	◎	◎
6	23	◎	◎	◎	15	◎	◎
7	23	◎	◎	◎	15	◎	◎
8	23	◎	◎	◎	10	◎	◎
9	23	◎	◎	◎	10	◎	◎
10	23	◎	◎	◎	10	◎	◎
11	23	◎	◎	◎	10	◎	◎

12	23	◎	○	◎	5	◎	◎
13	23	○	○	◎	5	◎	◎
14	45	◎	◎	◎	5	◎	◎
15	60	◎	◎	◎	5	◎	◎
16	85	○	○	◎	1	◎	◎

注：

腐蚀情况：	◎ 基本无腐蚀；	清洗情况：	◎ 完全去除；
	○ 略有腐蚀；		○ 少量残余；
	△ 中等腐蚀；		△ 较多残余；
	× 严重腐蚀。		× 大量残余。

从表 3 可以看出，与对比清洗剂 1'~5'相比，本发明的光刻胶清洗剂 1~16 对负性丙烯酸酯类光刻胶具有良好的清洗能力，使用温度范围广，同时对金属 Cu 和 Al 以及非金属 TEOS 的腐蚀性低，对晶片图案无损坏。

权利要求

1. 一种光刻胶清洗剂，其特征在于含有：季铵氢氧化物、水、烷基二醇芳基醚、二甲基亚砜和聚羧酸类缓蚀剂；烷基二醇芳基醚中烷基二醇的碳原子数目为 3~18。
2. 如权利要求 1 所述的光刻胶清洗剂，其特征在于：所述的季铵氢氧化物为四甲基氢氧化铵、四乙基氢氧化铵、四丙基氢氧化铵、四丁基氢氧化铵或苄基三甲基氢氧化铵。
3. 如权利要求 1 所述的光刻胶清洗剂，其特征在于：所述的季铵氢氧化物的含量为质量百分比 0.1~15%。
4. 如权利要求 3 所述的光刻胶清洗剂，其特征在于：所述的季铵氢氧化物的含量为质量百分比 0.5~10%。
5. 如权利要求 1 所述的光刻胶清洗剂，其特征在于：所述的水的含量为质量百分比 0.1~40%。
6. 如权利要求 5 所述的光刻胶清洗剂，其特征在于：所述的水的含量为质量百分比 0.5~25%。
7. 如权利要求 1 所述的光刻胶清洗剂，其特征在于：所述的烷基二醇芳基醚为丙二醇单苯基醚、异丙二醇单苯基醚、二乙二醇单苯基醚、二丙二醇单苯基醚、二异丙二醇单苯基醚、三乙二醇单苯基醚、三丙二醇单苯基醚、三异丙二醇单苯基醚、六缩乙二醇单苯基醚、六缩丙二醇单苯基醚、六缩异丙二醇单苯基醚、丙二醇单苄基醚、异丙二醇单苄基醚或己二醇单萘基醚。
8. 如权利要求 1 所述的光刻胶清洗剂，其特征在于：所述的烷基二醇芳基

醚的含量为质量百分比 1~50%。

9. 如权利要求 8 所述的光刻胶清洗剂，其特征在于：所述的烷基二醇芳基醚的含量为质量百分比 5~30%。

10. 如权利要求 1 所述的光刻胶清洗剂，其特征在于：所述的二甲基亚砜的含量为质量百分比 1~98%。

11. 如权利要求 10 所述的光刻胶清洗剂，其特征在于：所述的二甲基亚砜的含量为质量百分比 50~90 %。

12. 如权利要求 1 所述的光刻胶清洗剂，其特征在于：所述的聚羧酸类缓蚀剂为聚丙烯酸或其共聚物、聚甲基丙烯酸或其共聚物、聚丙烯酸醇胺盐、聚甲基丙烯酸醇胺盐、聚氧乙烯改性聚丙烯酸或其衍生物、聚氧乙烯改性聚甲基丙烯酸或其衍生物、聚环氧琥珀酸、聚天冬氨酸、含羧基的聚己内酯或含羧基的聚丙交酯。

13. 如权利要求 1 所述的光刻胶清洗剂，其特征在于：所述的聚羧酸类缓蚀剂的含量为质量百分比 0.01~5%。

14. 如权利要求 13 所述的光刻胶清洗剂，其特征在于：所述的聚羧酸类缓蚀剂的含量为质量百分比 0.05~2.5%。

15. 如权利要求 1 所述的光刻胶清洗剂，其特征在于：所述的光刻胶清洗剂还含有极性有机共溶剂、表面活性剂和除聚羧酸类以外的其它缓蚀剂中的一种或多种。

16. 如权利要求 15 所述的光刻胶清洗剂，其特征在于：所述的极性有机共溶剂的含量为质量百分比 0~50%；所述的表面活性剂的含量为质量百分比 0~5%；所述的除聚羧酸类以外的其它缓蚀剂的含量为质量百分比

0~10%。

17. 如权利要求 16 所述的光刻胶清洗剂，其特征在于：所述的极性有机共溶剂的含量为质量百分比 5~30%；所述的表面活性剂的含量为质量百分比 0.05~3%；所述的除聚羧酸类以外的其它缓蚀剂的含量为质量百分比 0.1~5%。

18. 如权利要求 15 所述的光刻胶清洗剂，其特征在于：所述的极性有机共溶剂为亚砜、砜、咪唑烷酮、醇胺和烷基二醇单烷基醚中的一种或多种；烷基二醇单烷基醚中烷基二醇的碳原子数目为 3~18；所述的表面活性剂为聚乙烯醇、聚乙烯吡咯烷酮或聚氧乙烯醚；所述的除聚羧酸类以外的其它缓蚀剂为醇胺类、唑类、羧酸类或膦酸类缓蚀剂。

19. 如权利要求 18 所述的光刻胶清洗剂，其特征在于：所述的亚砜为二乙基亚砜或甲乙基亚砜。

20. 如权利要求 18 所述的光刻胶清洗剂，其特征在于：所述的砜为甲基砜、乙基砜或环丁砜。

21. 如权利要求 18 所述的光刻胶清洗剂，其特征在于：所述的咪唑烷酮为 2-咪唑烷酮、1,3-二甲基-2-咪唑烷酮或 1,3-二乙基-2-咪唑烷酮。

22. 如权利要求 18 所述的光刻胶清洗剂，其特征在于：所述的醇胺为一乙醇胺、二乙醇胺、三乙醇胺、异丙醇胺、甲基二乙醇胺、二甲基乙醇胺或羟乙基乙二胺。

23. 如权利要求 18 所述的光刻胶清洗剂，其特征在于：所述的烷基二醇单烷基醚为二乙二醇单甲醚、二乙二醇单乙醚、二乙二醇单丁醚、丙二醇单丁醚、二丙二醇单甲醚、二丙二醇单乙醚、二丙二醇单丁醚、三乙二醇

单甲醚、三丙二醇单甲基醚、三丙二醇单乙醚、三丙二醇单丁醚、六缩乙二醇单甲醚、六缩丙二醇单甲醚、六缩异丙二醇单甲醚。

24. 如权利要求 18 所述的光刻胶清洗剂，其特征在于：所述的醇胺类缓蚀剂为一乙醇胺、二乙醇胺、三乙醇胺、异丙醇胺、甲基二乙醇胺、二甲基乙醇胺或羟乙基乙二胺。

25. 如权利要求 18 所述的光刻胶清洗剂，其特征在于：所述的唑类缓蚀剂为苯并三氮唑、甲基苯并三氮唑、苯并三氮唑三乙醇胺盐、1-苯基-5-巯基四氮唑、2-巯基苯并咪唑、2-巯基苯并噻唑、2-巯基苯并噁唑、二巯基噻二唑或 2-氨基-5-巯基-1,3,4-噻二唑。

26. 如权利要求 18 所述的光刻胶清洗剂，其特征在于：所述的羧酸类缓蚀剂为邻苯二甲酸、没食子酸、柠檬酸、苹果酸或乙醇酸。

27. 如权利要求 18 所述的光刻胶清洗剂，其特征在于：所述的膦酸类缓蚀剂为 1,3-（羟乙基）-2,4,6-三膦酸、氨基三亚甲基膦酸、2-膦酸丁烷-1,2,4-三羧酸、乙二胺四亚甲基膦酸或二乙烯三胺五亚甲基膦酸。

INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

See extra sheet

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: G03F7/; HO1L21/; C11D1/; C23G1/

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

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

WPI, EPODOC,CNPAT, PAJ,CNKI: +resist, semiconductor, clean+, remov+, peel+, detergent, pickl+, strip+

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CN1715389A (AIR PROD & CHEM INC) 04 Jan. 2006 (04.01.2006) claims 1-19, specification pages 3-7	1-27
Y	CN1982426A (ANJI MICROELECTRONIC SHANGHAI CO LTD) 20 Jun. 2007(20.06.2007) claims 1-11, specification pages 2-6	1-27
Y	US6440856B1(BESSHO, Keiichi et al.) 27 Aug. 2002 (27.08.2002) claims 1-18, specification pages 2-7	1-27

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"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

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"&"document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 Aug. 2008 (31.08.2008)	**23 Oct. 2008 (23.10.2008)**
Name and mailing address of the ISA/CN The State Intellectual Property Office, the P.R.China 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088 Facsimile No. 86-10-62019451	Authorized officer LI, Bin Telephone No. (86-10) 62085693

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2008/001258

Patent Documents referred in the Report	Publication Date	Patent Family	Publication Date
CN1715389A	04.01.2006	EP1612858 A2	04.01.2006
		US2006014656A1	19.01.2006
		JP2006049860A	16.02.2006
		SG118431 A1	27.01.2006
		KR20060048757A	18.05.2006
		CN1963678A	16.05. 2007
		SG136966A1	29.11.2007
		TW274968B1	01.03.2007
CN1982426A	20.06.2007	WO2007068176A1	21.06.2007
US6440856B1	27.08.2002	JP2001064685A	13.03.2001
		TW593674A	21.06.2004
		JP2001064679 A	13.03.2001

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INTERNATIONAL SEARCH REPORT

International application No.
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Continuation of : International Patent Classification (IPC) or both national classification and IPC

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H01L21/02(2006.01) i

C23G1/06(2006.01) n

C11D1/83(2006.01) n

国际检索报告

国际申请号
PCT/CN2008/001258

A. 主题的分类

参见附加页

按照国际专利分类表(IPC)或者同时按照国家分类和 IPC 两种分类

B. 检索领域

检索的最低限度文献(标明分类系统和分类号)

IPC: G03F7/; HO1L21/; C11D1/; C23G1/

包含在检索领域中的除最低限度文献以外的检索文献

在国际检索时查阅的电子数据库(数据库的名称，和使用的检索词（如使用））

WPI, EPODOC,CNPAT,PAJ,CNKI: +resist, semiconductor, clean+, remov+, peel+, detergent, pickl+, strip+, 清洗, 清除, 清洁

C. 相关文件

类　型*	引用文件，必要时，指明相关段落	相关的权利要求
Y	CN1715389A(气体产品与化学公司) 04. 1 月 2006（04.01.2006） 权利要求 1-19，说明书 3－7 页	1-27
Y	CN1982426A(安集微电子（上海）有限公司) 20.6 月 2007(20.06.2007) 权利要求 1-11，说明书 2－6 页	1-27
Y	US6440856B1(Keiichi Bessho 等) 27.8 月 2002(27.08.2002) 权利要求 1-18，说明书 2－7 页	1-27

☐ 其余文件在 C 栏的续页中列出。　　☒ 见同族专利附件。

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检索报告中引用的专利文件	公布日期	同族专利	公布日期
CN1715389A	04.01.2006	EP1612858 A2	04.01.2006
		US2006014656A1	19.01.2006
		JP2006049860A	16.02.2006
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		KR20060048757A	18.05.2006
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		SG136966A1	29.11.2007
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US6440856B1	27.08.2002	JP2001064685A	13.03.2001
		TW593674A	21.06.2004
		JP2001064679 A	13.03.2001

附加页

(当前面的任何一栏篇幅不够时使用本栏)

续　　栏：主题的分类

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(54) Title: UNIVERSAL ANCHOR FOR ATTACHING OBJECTS TO BONE TISSUE

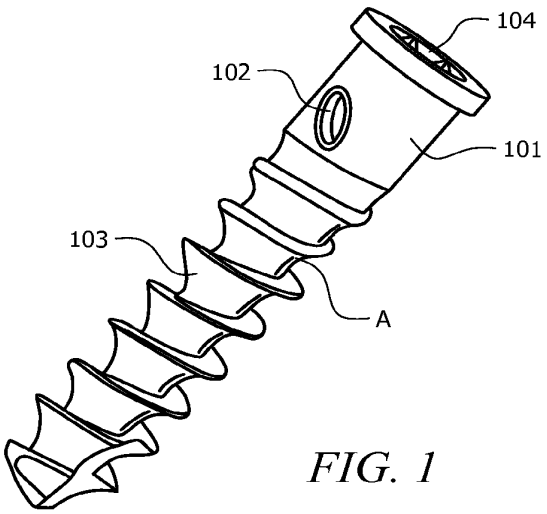


FIG. 1

(57) Abstract: An anchoring device and method for attaching an object to a bone comprises an anchoring member having proximal and distal ends, with the proximal end being adapted to hold the object to the bone while the distal end is in the bone, and a locking member having proximal and distal ends, with the proximal end adapted to secure the anchoring member into the bone and oppose its pull-out or loosening by stopping its backing or preventing its unscrewing while the distal end is in the bone. Also provided are first and second fasteners, with the first fastener adapted to fit to the proximal end of the anchoring member, and the second fastener adapted to fit to the proximal end of the locking member. The end of the second fastener can have an angle that matches an angle of the locking member.

UNIVERSAL ANCHOR FOR ATTACHING OBJECTS TO BONE TISSUE

[0001] The present invention claims priority to U.S. Provisional Application Serial No. 61/039,464, filed March 26, 2008, which is incorporated by reference herein in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to devices for attaching various objects, such as prostheses or implants, to bones, and in certain cases for anchoring spinal instruments to the vertebrae of the human rachis.

BACKGROUND OF THE INVENTION

[0003] The fast-growing aging population represents an important orthopedic market with a very specific need related to its low-quality cancelous or spongy bone (osteoporosis). Osteosynthesis procedures in such people are jeopardized by the risk of loosening in relation with the pullout or back-out of anchors in the bone. The reliability of an anchoring system depends on its ability to resist pulling out of the bone. Removal of an anchor may lead to extrusion, or even worse, loosening of any object attached to the bone. Known anchoring systems propose several solutions: Divergent or convergent screws have been proposed to oppose to pull out forces by increasing the grip. Locking mechanisms intended to secure the anchor within the object (such as locking screw or anti-reverse systems) avoid the pull out of the anchor but not the extrusion of the entire construct. Bicortical screwing may be dangcrous and can makc thc construct too rigid. This can lcad to thc brcakagc of thc implant itself. Special features like conical core, self-tapping profile and roughened surfaces of the anchor have been developed to increase the grip to the cancelous bone. Expandable mechanisms (such as threaded peg expanded with a coaxial inner member or "Molly screw") crush and split fragile bone tissue and then creates an empty room around the buried part of the anchor. This can lead the construct to toggle and therefore to a condition for pull out or loosening in response to physiological micro-motions.

[0004] U.S. Patent 6,695,844 to Bramlet et al discloses an expandable-winged fastener made up of an outer member and an inner mechanism able to protract or retract wings intended not only to increase the interface between the bone and the device but also to expand within the cancelous bone. Although the wings are blunted, the bone-implant interface is

weakened as the wings expand or retract because the expanded wings broach through the bone as they pivot and therefore require the bone to remodel.

[0005] Other solutions use an interlocking mechanism, such as a K-wire which intersect a bone screw ("An Interlocking Screw for Fixation in Osteoporotic Bone" described by McKoy and al. in "internal fixation in osteoporotic bone" authored by Yuehuei H. An in 2002) or two members connected by their ends through a threaded connection ("Anchoring System for Fixing Object to bones" US Patent Application Serial No. 10/275,710 to Lionel Sevrain).

[0006] Connecting solutions address some of the problems, and provide increased strength and reliability, but require an aiming system that may represent a hurdle not only from a marketing standpoint but also from an anatomical standpoint. There is therefore a need for an improved anchoring system and installation method for anchoring an object to bone.

[0007] It would be desirable to provide a novel anchoring system for securing various objects to bones, such as spinal devices or instrumentations to the rachis, and to provide an anchoring system well adapted to prevent a pull out of the anchor and therefore the extrusion and/or the loosening of the object over time. It would also be desirable to provide an anchoring system to bring the needed reliability in such osteoporotic bone, without the hassle of an additional aiming guide.

SUMMARY OF THE INVENTION

[0008] Therefore, in accordance with a first aspect, there is provided an anchoring device for attaching an object to a bone, comprising an anchoring member having proximal and distal ends, the proximal end being adapted to hold the object to the bone while the distal end is in the bone, and a locking member having proximal and distal ends, with the proximal end adapted to secure the anchoring member into the bone and oppose its pull-out or loosening by stopping its backing or preventing its unscrewing, while the distal end is in the bone.

[0009] Also in accordance with another aspect, there is provided first and second fasteners, the first fastener being adapted to fit to the proximal end of the anchoring member, and the second fastener being adapted to fit to the proximal end of the locking member. More specifically, the second fastener is adequately designed to match the angulation of the locking member.

[0010] Further in accordance with another aspect, there is provided a method for mounting an object to a bone, comprising the steps of: (a) providing anchoring member and locking member each having proximal and distal ends, (b) introducing the anchoring member in the bone wherein said proximal end holds an object to the bone, (c) positioning the locking member into the proximal end of the anchoring member, and (d) preventing the anchoring member of loosening.

[0011] In one embodiment of the invention, there is a system for attaching one or more objects to bone tissue, comprising: an anchoring member having proximal and distal ends, wherein the proximal end comprises a socket and an aperture, wherein the aperture is oblique to the axis of the length of the anchoring member; and a locking member having proximal and distal ends, wherein the proximal end comprises a socket; wherein the aperture of the anchoring member is adapted for insertion of the locking member therethrough. In a specific embodiment, the system further comprises at least one fastener, wherein the fastener is adapted to fit to a socket in the proximal end of the anchoring member, adapted to fit to a socket in the proximal end of the locking member, or both. In one specific embodiment, the system further comprises first and second fasteners, wherein the first fastener is adapted to fit to a socket in the proximal end of the anchoring member and the second fastener is adapted to fit to a socket in the proximal end of the locking member.

[0012] In another embodiment of the invention, the angle on the head of the second fastener corresponds to the angulation of the locking member inserted into the anchoring member. In other specific embodiments, the anchoring member, the locking member, or both have a rough surface. In certain aspects, the surface of the inner wall of the aperture is smooth, rough, or threaded. In particular aspects of the invention, the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 1 and 89 degrees, between 10 and 75 degrees, between 10 and 50 degrees, between 10 and 35 degrees, or between 25 and 30 degrees.

[0013] In a specific embodiment of the invention, the shape of the socket of the anchoring member and/or the shape of the socket of the locking member is hexagonal, pentagonal, square, triangular, cross-shaped, plus sign-shaped, linear, or star-shaped. In a particular aspects of the invention, the second fastener is a ball end hexagonal fastener.

[0014] In one embodiment of the invention, there is a method of affixing one or more objects to bone, comprising the step of anchoring the object to the bone using the system(s) or composition(s) of the invention. In another embodiment of the invention, there is a kit comprising the system(s) or composition(s) of the invention.

[0015] The foregoing has outlined rather broadly the features and technical advantages of the present invention in order that the detailed description of the invention that follows may be better understood. Additional features and advantages of the invention will be described hereinafter which form the subject of the claims of the invention. It should be appreciated by those skilled in the art that the conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present invention. It should also be realized by those skilled in the art that such equivalent constructions do not depart from the spirit and scope of the invention as set forth in the appended claims. The novel features which are believed to be characteristic of the invention, both as to its organization and method of operation, together with further objects and advantages will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended as a definition of the limits of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Having thus generally described the nature of the invention, reference will now be made to the accompanying drawings, showing by way of illustration a particular embodiment thereof.

[0017] Fig. 1 is a schematic perspective view of an anchoring member in accordance with the present invention.

[0018] Fig. 2a is a schematic cross-sectional plan view of an anchoring member.

[0019] Fig. 2b is a top plan schematic view of the proximal end of the anchoring member.

[0020] Fig. 3 is a schematic perspective view of an anchoring member with the locking member.

[0021] Fig. 4 is a schematic cross-sectional plan view of an anchoring member with the locking member

[0022] Fig. 5 is a perspective view of an anchoring member holding an object (plate).

[0023] Fig. 6a is a cross-sectional view of the shaft (Hex Key) of one embodiment of the first fastener Fl.

[0024] Fig. 6b is a schematic perspective view of the distal end (ball end hex tool) of the first fastener Fl.

[0025] Fig. 6c is a lateral view of the first fastener Fl.

[0026] Fig. 7 is a schematic perspective view of a differential that can be used for the second fastener F2.

[0027] Fig. 8a is an enlarged perspective view of the distal end (ball end hex tool) of the first fastener Fl.

[0028] Fig. 8b is an enlarged lateral view of the distal end (ball end hex tool) showing a 25 to 30 degree angle entry to the hex tool.

[0029] Fig. 8c is an example of oblique insertion.

[0030] Fig. 8d is a lateral view of the first fastener Fl engaged within a hex screw.

[0031] Fig. 9a is a lateral view of a cortical-type locking member L.

[0032] Fig. 9b is a lateral view of a cancelous-type locking member L.

[0033] Fig. 9c is a latcral vicw of a hcadlcss-typc locking mcmbcr L.

[0034] Fig. 10 illustrates various angulation patterns of the interlocking anchor and locking members.

[0035] Fig. 11 illustrates one embodiment of a locking member within an anchoring member, in addition to the respective fastener having a corresponding angulation to the angulation of the locking member within the anchoring member.

[0036] Fig. 12 illustrates an exemplary embodiment of a fastener and its corresponding locking member within the anchoring member.

[0037] From the foregoing disclosure and the following more detailed description of various particular embodiments it will be apparent to those skilled in the art that the present invention provides a significant advance in the art of bone anchoring devices. Additional features and advantages of various particular embodiments will be better understood in view of the detailed description provided below.

DETAILED DESCRIPTION OF THE INVENTION

[0038] The present invention incorporates by reference herein in its entirety U.S. Provisional Patent Application Serial No. 60/896,960, filed March 26, 2007.

[0039] The term "a" or "an" as used herein in the specification may mean one or more. As used herein in the claim(s), when used in conjunction with the word "comprising", the words "a" or "an" may mean one or more than one. As used herein "another" may mean at least a second or more. Some embodiments of the invention may consist of or consist essentially of one or more elements, method steps, methods and/or systems of the invention. It is contemplated that any system, method, or composition described herein can be implemented with respect to any other method or composition described herein.

I. The Present Invention

[0040] It will be apparent to those skilled in the art, that is, to those who have knowledge or experience in this area of technology, that many variations are possible for the system for anchoring bone disclosed herein. The following detailed discussion of various and particular features and embodiments will illustrate the general principles of the invention with reference to an improved bone anchoring device for use in mammalian bone, including vertebrae, for example. Other embodiments suitable for other applications will be apparent to those skilled in the art given the benefit of this disclosure.

[0041] Any mammalian bone, including human bone, may have the inventive systems, methods, and/or compositions of the present invention applied thereto. Examples include long, short, flat, irregular, accessory, and sesamoid bones. Particular examples include but are not limited to vertebrae, femur, humerus, radius, ulna, femur, tibia, fibula, clavicle, rib, metacarpals, metatarsals, phalanges, skull bones, sternum, scapulae, innominates, vertebrae, maxillae, sphenoid, carpus, tarsus, patella, interfrontal bone, epipteric bone, coronal ossicle, bregmatic ossicle, sagittal ossicle, lambdoid ossicle, and squame-parietal ossicle.

[0042] The materials of the components of the present invention may be of any suitable kind. Materials of the anchor and locking member are biocompatible, in certain embodiments. Examples of materials include biomedical metallic materials, including stainless steel; alloys (Al, Co, Ni, Ta, W, V, *etc.);* cobalt-based alloys; or titanium and its alloys. Other examples of materials include polymeric biomaterials, such as synthetic non-biodegradable polymers: polyethylene (high density polyethylene -HDPE-, ultrahigh molecular weight polyethylene -UHMWPE-), poly (ether ether ketone) or PEEK. Polymer matrix composite biomaterials may be employed and include fiber-reinforced composites (for example, carbon fiber or kevelar).

[0043] The shape, diameter, length, and any associated angles of the anchor, locking member, and, by extrapolation, fastener(s) of the invention maybe of any kind, so long as the locking member is able to be positioned within the anchor at an angle to generate a V-shaped (or L-shaped, in a 90 degree configuration) configuration and so long as the corresponding fastener(s) can be inserted in the respective socket 104 in the head of anchor and/or locking member to apply torque for affixing them into bone.

[0044] Referring now to Figs. 1 to 9, in accordance with an illustrative embodiment of the present invention, an anchoring device or implant, generally referred to using the numeral 100, will now be described. The anchoring system 100 is generally comprised of an anchoring member A and a locking member L (see Fig. 3)

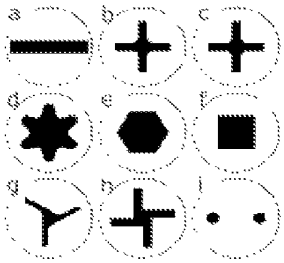
[0045] Fig. 1 illustrates an anchoring member A in accordance with a certain embodiment. The anchoring member A generally has cancelous screws' features such as a 2-portion shaft comprising an optionally coarse, self-tapping thread 103, designed to anchor in the softer medullary or cancelous bone, and topped by a smooth unthreaded portion 101 that allows

it to act as a lag screw. The unthreaded upper portion 101 presents an oblique aperture 102 having an angle (for example, of about 25°) with respect to an axial plane of the anchoring member's shaft. The proximal end of the anchoring member A has a proximal end socket 104 such that it can be engaged by a fastener like a key, screwdriver, or wrench (see Fig. 2b). In specific embodiments, the proximal end of the anchoring member A has a Hex (hexagonal) type's proximal end socket 104 such that it can be engaged by a Hex tip fastener like a key or wrench (see Fig. 2b).

[0046] The term "fastener" as used herein refers to a tool, such as a wrench, key, or screwdriver, that is employed to insert the corresponding anchor in the bone *via* the head of the anchor and/or to insert the corresponding locking member in the anchor *via* the socket 104 of the head of the locking member.

[0047] Although the socket 104 of the head of the anchor or locking member may be of any shape, the embodiment presented herein wherein both heads are hexagonal is merely illustrative. That is, the shape of the socket 104 for insertion of the respective fastener in the anchor or locking member may be of any shape, including hexagonal, pentagonal, square, triangular, cross-shaped, plus sign-shaped, linear, star-shaped, and so forth, for example. In a specific embodiment, the head of the locking member is smaller than the head of the anchor, although in other embodiments the head of the locking member is the same size as the head of the anchor. In another specific embodiment, the socket 104 of the proximal end of the anchor and the socket 104 of the proximal end of the locking member are identical in shape and/or size, whereas in other specific embodiments the socket 104 of the proximal end of the anchor and the socket 104 of the proximal end of the locking member are not identical in shape and/or size.

[0048] Fig. 2 shows a cross-sectional view of the anchoring member (Fig. 2a) and a top plan of the proximal end of the anchoring member (Fig. 2b). The shape of the socket 104 for insertion of the respective fastener in the anchor or locking member may be of any shape, including hexagonal, pentagonal, square, triangular, cross-shaped, plus sign-shaped, linear, star-shaped, and so forth, for example (see below); these may be referred to as slotted, Phillips, Pozidriv, torx, Hex key, Robertson, Tri-Wing, Torq-Set, or Spanner, for example.

[0049] 

[0050] However, an exemplary hexagonal (Hex) socket in the head (104) of the anchoring member brings the following advantage: a ball end hex key (or wrench) can be used for angulated screwing and insertion, the contact surfaces of the screw are protected from external damage, the tool can be used with a headless screw, there are six contact surfaces between screw and driver, the socket's depth are less prone to stripping, and this room can be used for cannulation, for example.

[0051] Fig. 3 illustrates the anchoring system 100 comprising the anchoring member A and the locking member L. The angle α between the two members is fixed and set up at 25 degrees in a certain embodiment. This angle allows using a standard hex second fastener F2 (wherein F1 fastener refers to the fastener for the anchor and F2 fastener refers to the fastener for the locking member) equipped with an end ball hex end since it can be used with an angulation up to 30 degrees. In other embodiments, the angle can be set up to another value comprised between 1 to 90 degrees. In a specific embodiment, the angle can be 15-25 degrees. Beyond 30 degrees angulation, another embodiment of the second fastener F2 with an inclinable hex tip end may be used (differential inner mechanism).

[0052] Fig. 4 is a schematic cross-sectional plan view of the anchoring system 100. In this representation, a headless locking member L is engaged into a oblique aperture (111) within the exemplary hex-shaped socket (104) of the head of the anchoring member A. The surface of the inner wall of the aperture may be threaded, smooth, or rough. One end of the aperture is at the proximal head of the anchor, and the opposite end is on one side of the anchor.

[0053] Fig. 5 is a perspective view of an anchoring member holding an exemplary object (plate) P.

[0054] Fig. 6 illustrates the first fastener F1 with its Hex type tip (112). In this representation, the fastener comprises a head or tip that engages with the socket of the anchor to apply torque by rotating the tip, such as but not limited to a screwdriver, key or wrench. The tip is not limited to hex type. The second fastener F2 in certain aspects comprises a ball end hex type end to allow screwing of the locking member. The second fastener F2 can have the same features as the first fastener F1 when used in a particular embodiment *e.g.* with an angle α between the two members equal at 25 degrees, or inferior at 30 degrees at the maximum, in accordance with the working angle (25 to 30 degrees) of such ball end hex tip. In this case, only the size differs from the first fastener F1, the second fastener F2 being thinner than the first fastener F1 in order to be able to slid within the inner socket 104 of the first fastener F1, in particular embodiments.

[0055] In another embodiment an angle β, higher than the angle α, *e.g.* superior at 30 degrees between the two members A and L, is set up. In this embodiment, the second fastener F2 presents an inclinable tip able to match the angle β and is equipped with an inner mechanism applying the torque in accordance with an oblique transmission of the rotating motion imparted to the handle of the fastener. Such mechanism can be but is not limited to a differential, a screw gear, or a set of gears. Fig. 7 illustrates the principle of such mechanism and shows a schematic conceptual view of a differential. Such a fastener can be rotated manually or by an electric or other motor.

[0056] Whatever the mechanism can be, it is intended to allow an oblique screwing while the handle of the fastener remains straight forward, in certain embodiments. Such a feature is useful when the local anatomical requirements forbid the tool to be tilted. For example, when a surgery using a minimally invasive approach through a small incision is performed, the instruments must go through this small cutaneous aperture, and therefore can not be angulated in order to avoid damaging soft tissue.

[0057] Fig. 8a is an enlarged perspective view of the distal end (ball end hex tool) of the fastener. The concept by which ball ends slide into a screw head is known as funnel insertion. Basically, it means that the sides of the ball end direct (funnel) it into place. This allows fast funnel entry, eliminates wasted time even in blind applications, and the full depth engagement reduces "stripping" problems.

[0058] Fig. 8b is an enlarged lateral view of the distal end (ball end hex tool) showing a 25 to 30 degree angle entry to hex. As maximum allowable angle increases, neck size decreases, and strength also decreases. By contrast, increasing the strength of a ball-end tool requires a corresponding increase in neck size and decrease in maximum allowable angle. Designing the perfect ball-end tool means choosing the ideal balance between strength and allowable angle. Fig. 8c is an example of oblique insertion. Fig. 8d is a lateral view of the first fastener F1 engaged within a hex screw.

[0059] Fig. 9 illustrates the three possible designs of the locking member L. In certain embodiments, the locking member L is thinner than the anchoring member A so that it can be slid through the oblique aperture and positioned within the empty room of the hexagonal socket of the anchoring member. Its length can be smaller, equal or bigger than the anchoring member. Its proximal end can be equipped with a head (105) or be wide-mouthed (106) to block within the anchoring member's head, or be headless (107). Whatever the type of the locking member L can be (headed 105, wide-mouthed 106 or headless 107), the socket has a hex type shape, in certain embodiments. The locking member can be a cortical type screw (Fig. 9a) with a fine thread (108) all along its shaft and therefore screwed into an oblique threaded canal within the anchoring member's head, or a cancelous type screw (Fig. 9b) with a coarser thread (109), designed to anchor the bone and a smooth, unthreaded portion (110), designed to slid within an oblique unthreaded canal within the anchoring member's head. Depending of its type, the locking member L can just act as an anti-rotational device and prevent the unscrewing of the anchoring member A in the cortical type design, or be both a blocking system as described above and an additional fastening device intended to secure and reinforce the grip within the medullary bone in the cancelous type design. Moreover, due to its divergent positioning, it brings to the construct a V-shaped design which opposes to pull-out forces. Whatever cancelous or cortical type design be used, the adjunction of a second divergent member (locking member L) advantageously increases both the grip and the purchase within the bone, especially in cancelous and/or osteoporotic bone and therefore opposes to pull-out and secures the fixation of any object to the bone.

[0060] Fig. 10 illustrates various angulation patterns of the interlocking anchor and locking members. Upon certain angulations of the locking member within the anchoring member, and therefore, certain angulations required for the corresponding fastener to screw the

locking member, the proximal end of the anchoring member requires a cavity at its socket to allow the fastener access to the locking member.

[0061] Fig. 11 illustrates one embodiment of a locking member within an anchoring member, in addition to the respective fastener having a corresponding angulation to the angulation of the locking member within the anchoring member. In this specific embodiment, the proximal end of the anchoring member has a cavity that allows insertion of the fastener for the locking member.

[0062] Fig. 12 illustrates an exemplary embodiment of a fastener and its corresponding locking member within the anchoring member. The proximal end of the anchoring member comprises a cavity that allows insertion of the fastener for the locking member.

[0063] In certain embodiments, the anchor and locking member are coated with antibiotic or other medicine useful upon implantation of an implant on and/or in a bone. In other embodiments, the surface of the anchor and/or locking member is rough for a better grip within the bone.

[0064] Any of the compositions described herein may be comprised in a kit. Where there are more than one components in the kit, the kit also may contain a second, third or other additional container into which the additional components may be separately placed. The kits of the present invention may include a means for containing the invention component(s) in close confinement for commercial sale. Such containers may include injection or blow molded plastic containers into which the components are retained, for example.

[0065] The kit may comprise the anchor, locking member, and/or fastener(s). In some cases, all components are sold separate, whereas in other cases all or a subset of components are sold together. Irrespective of the number and/or type of containers, the kits of the invention may also comprise, and/or be packaged with, an instrument other than a fastener(s) of the invention for assisting with placing the anchor/locking member within the body of an animal.

[0066] In particular embodiments of the invention, a variety of anchors, locking members, and/or fasteners may be provided in a kit. For example, a variety of lengths,

diameters, socket shapes, and/or angles of the corresponding anchors, locking members, and/or fastener(s) may be provided in a kit.

[0067] From the foregoing disclosure and detailed description of certain embodiments, it will be apparent that various modifications, additions and other alternative embodiments are possible without departing from the true scope and spirit of the invention. The embodiments discussed were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to use the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

CLAIMS

What is claimed is:

1. A system for attaching one or more objects to bone tissue, comprising:

an anchoring member having proximal and distal ends, wherein the proximal end comprises a socket and an aperture, wherein the aperture is oblique to the axis of the length of the anchoring member; and

a locking member having proximal and distal ends, wherein the proximal end comprises a socket;

wherein the aperture of the anchoring member is adapted for insertion of the locking member therethrough.

2. The system of claim 1, further comprising at least one fastener, wherein the fastener is adapted to fit to a socket in the proximal end of the anchoring member, adapted to fit to a socket in the proximal end of the locking member, or both.

3. The system of claim 1, further comprising first and second fasteners, wherein the first fastener is adapted to fit to a socket in the proximal end of the anchoring member and the second fastener is adapted to fit to a socket in the proximal end of the locking member.

4. The system of claim 3, wherein the angle on the head of the second fastener corresponds to the angulation of the locking member inserted into the anchoring member.

5. The system of claim 1, wherein the anchoring member, the locking member, or both have a rough surface.

6. The system of claim 1, wherein the surface of the inner wall of the aperture is smooth, rough, or threaded.

7. The system of claim 2, wherein the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 1 and 89 degrees.

8. The system of claim 2, wherein the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 10 and 75 degrees.

9. The system of claim 2, wherein the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 10 and 50 degrees.

10. The system of claim 2, wherein the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 10 and 35 degrees.

11. The system of claim 2, wherein the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 25 and 30 degrees.

12. The system of claim 1, wherein the shape of the socket of the anchoring member and/or the shape of the socket of the locking member is hexagonal, pentagonal, square, triangular, cross-shaped, plus sign-shaped, linear, or star-shaped.

13. The system of claim 3, wherein the second fastener is a ball end hexagonal fastener.

14. A method of affixing one or more objects to bone, comprising the step of anchoring the object to the bone using the system of claim 1.

15. A kit comprising the system of claim 1.

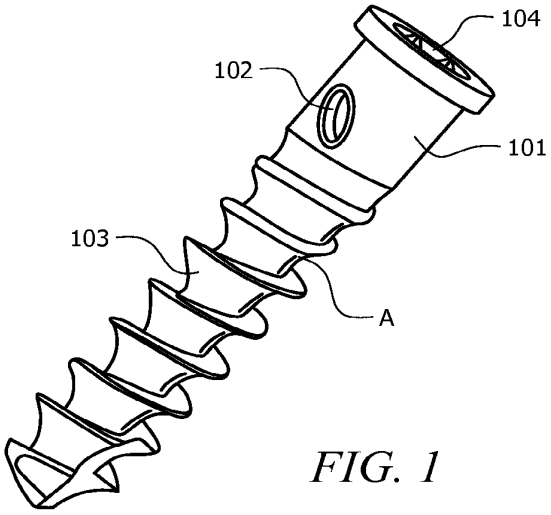


FIG. 1

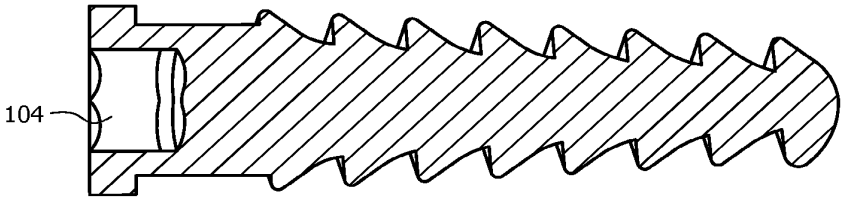


FIG. 2A

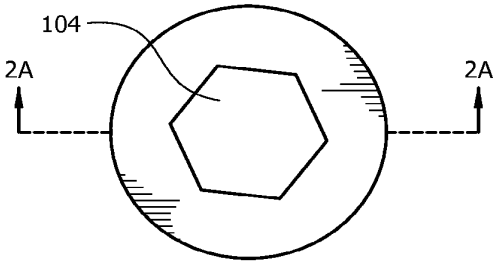


FIG. 2B

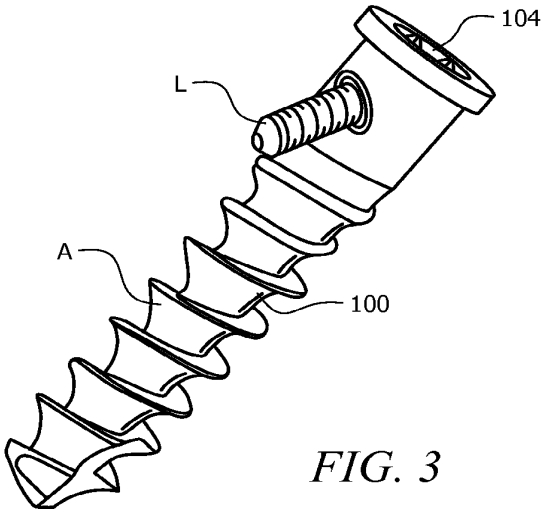


FIG. 3

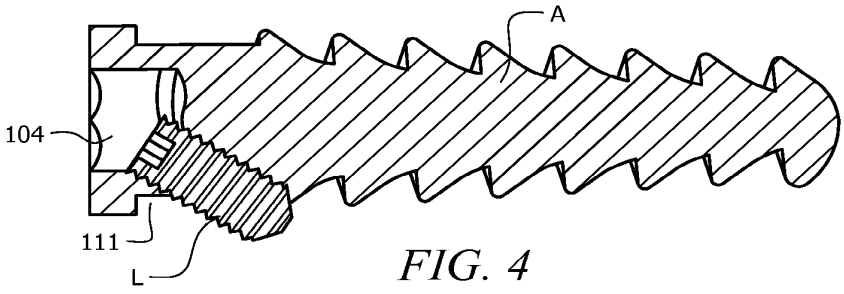


FIG. 4

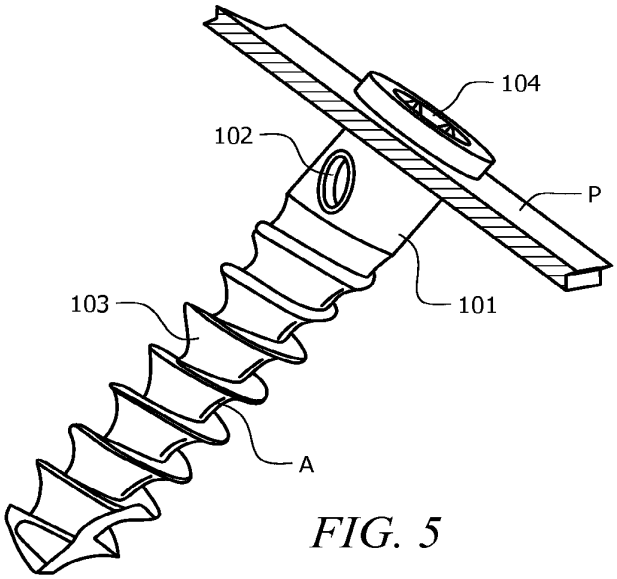


FIG. 5

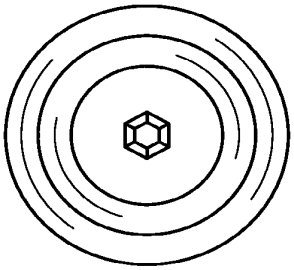


FIG. 6A

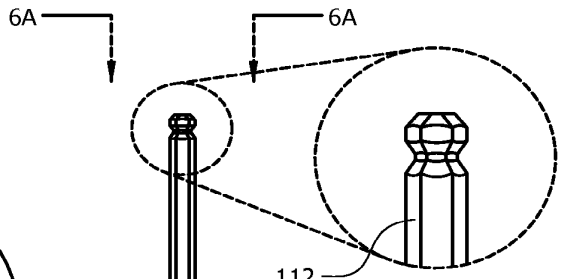


FIG. 6B

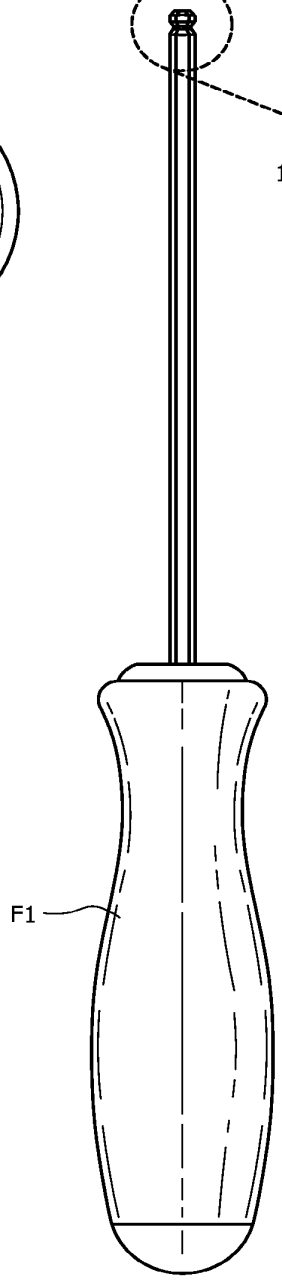


FIG. 6C

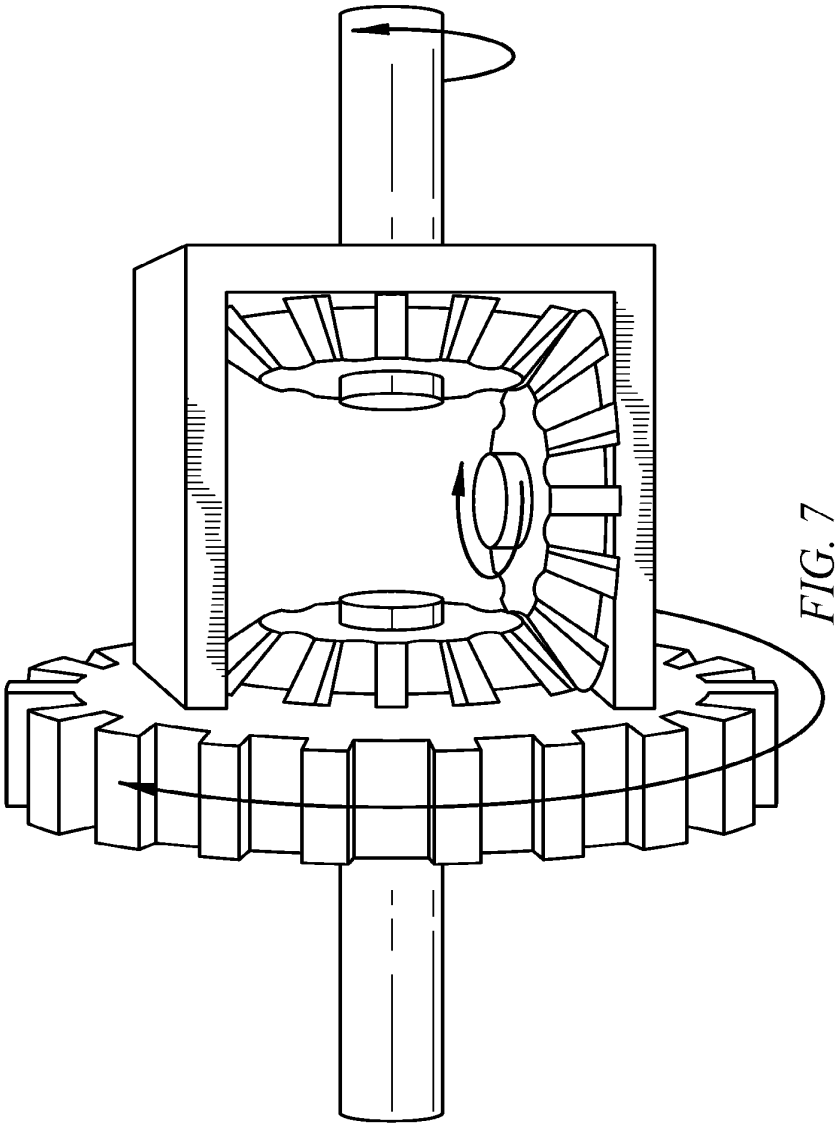


FIG. 7

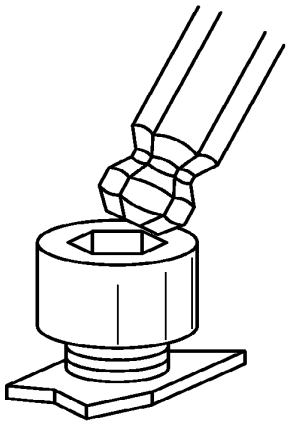


FIG. 8A

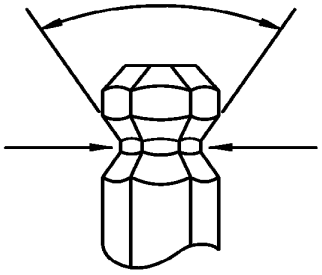


FIG. 8B

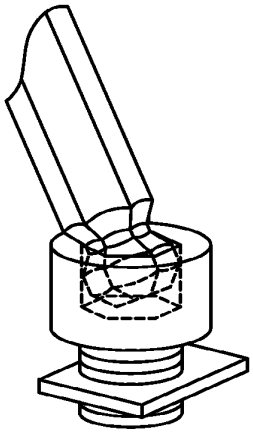


FIG. 8C

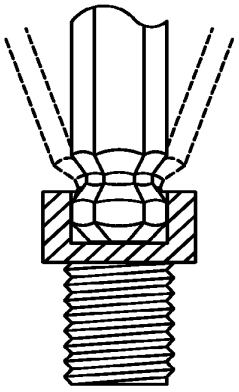


FIG. 8D

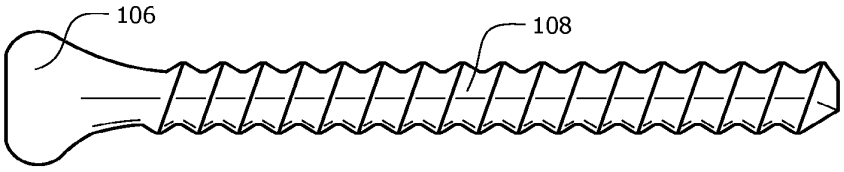


FIG. 9A

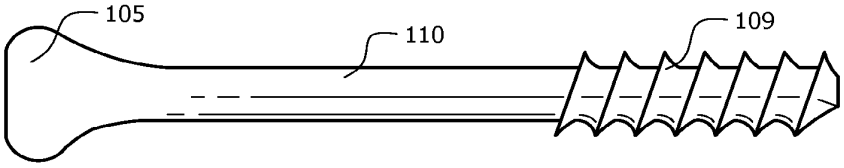


FIG. 9B

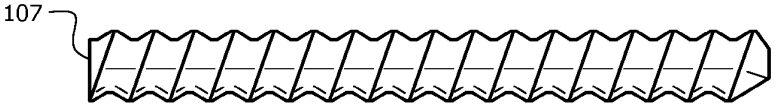


FIG. 9C

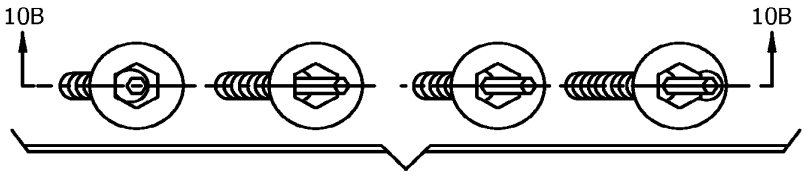


FIG. 10A

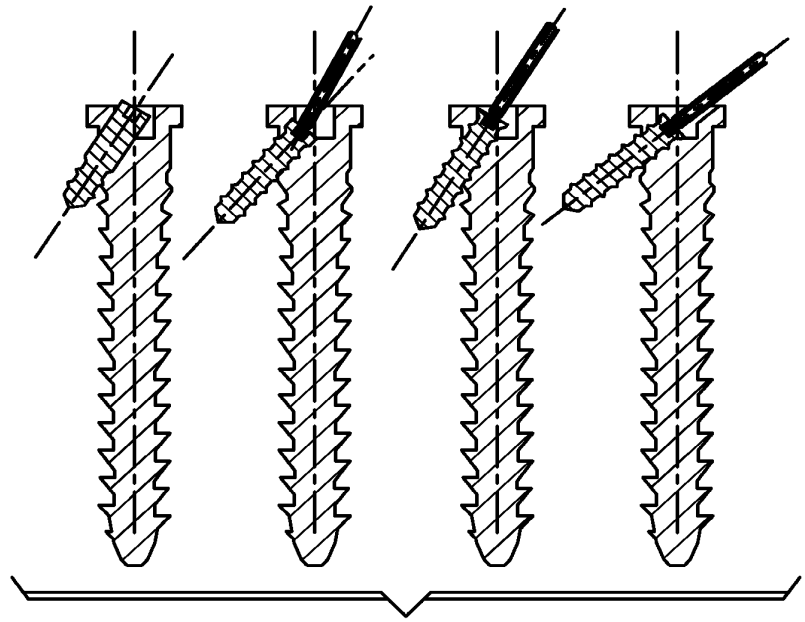


FIG. 10B

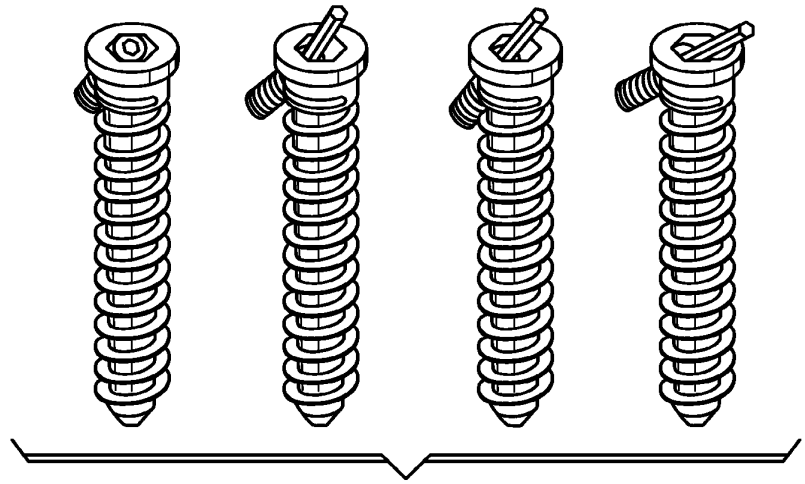


FIG. 10C

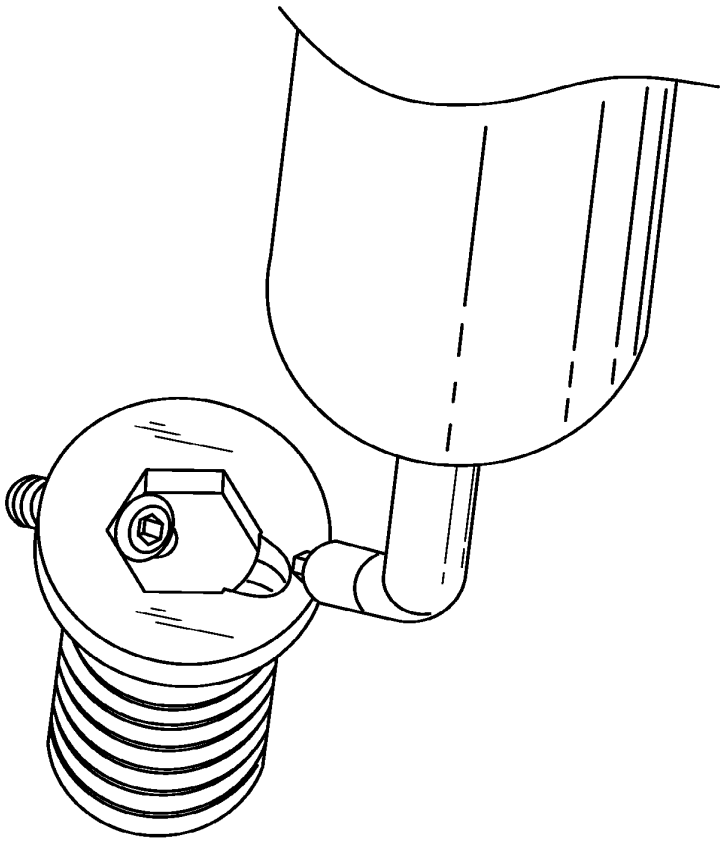


FIG. 11

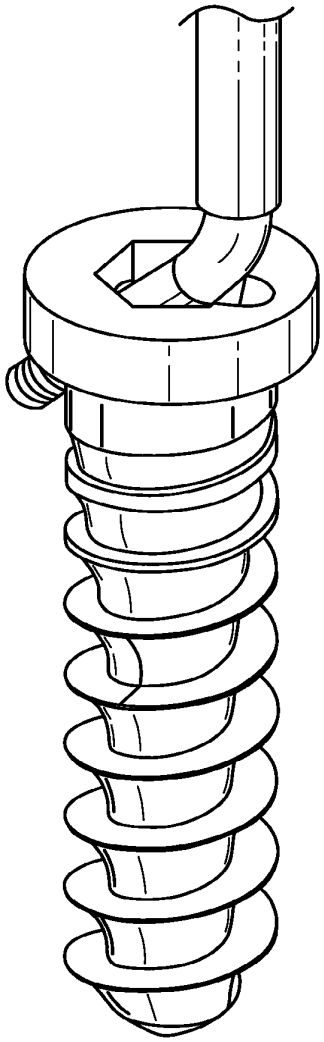


FIG. 12

Electronic Acknowledgement Receipt	
EFS ID:	42771421
Application Number:	17323923
International Application Number:	
Confirmation Number:	5684
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Customer Number:	27776
Filer:	David G. Lindenbaum
Filer Authorized By:	
Attorney Docket Number:	024664
Receipt Date:	20-MAY-2021
Filing Date:	
Time Stamp:	06:11:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	Cover.pdf	98665 8d83eb4a116107da4ec46c1a9022e9cb23d26f49	no	1

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	IDS.pdf	2978395 f8e6bb525e7ba39de793f2188d310a067b6d9913	no	31
Warnings:					
Information:					
3	Foreign Reference	CN2738745Y_PDF.pdf	1112948 0e599a188f6d9e5291182588699532 7a39b80ad9	no	18
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4	Foreign Reference	EP2151213A1.pdf	585053 0e30226655e8e89ad61983a29a53fc9dad22b560	no	31
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5	Foreign Reference	FR2861576A1.pdf	309175 1500ca98072a86ed543c24e562175ee50d8f7a2b	no	12
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6	Other Reference-Patent/App/Search documents	IN_Report.pdf	223035 b765d072194e414113e9b5f4652dfb078f1f941f	no	7
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7	Foreign Reference	WO1997022301A1.pdf	4061635 6686106238dab5165f1b89795058748fbfb9135d	no	120
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		Total Files Size (in bytes):	15268436		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Extremity Medical LLC	Confirmation No.: 5684
Application No.: 17/323,923	Group Art Unit: 2833
Filing Date: 05-18-2021	Examiner: TBD
For: Intraosseous Intramedullary Fixation Assembly and Method of Use	Atty. Doc. No.: 024664

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

COVER LETTER

Applicant submits herewith an Information Disclosure Statement pursuant to 37 CFR § 1.97(a). No admission is made that any of the references cited on the attached Information Disclosure Statement qualify as prior art or are material to patentability.

No fee is believed due for this submission. If any fees are due, however, the Patent and Trademark Office is specifically authorized to charge such fees to Deposit Account No. 502968 in the name of Kelley Drye & Warren LLP.

Respectfully submitted,

Date: May 20, 2021

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Parsippany, NJ 07054
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4848-1669-4762

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/323,923	05/18/2021	2833	830	024664	15	2

CONFIRMATION NO. 5684

27776
Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

FILING RECEIPT

OC000000125886390

Date Mailed: 05/27/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

Jeff Tyber, Bethlehem, PA;
Jamy Gannoe, West Milford, NJ;
Lawrence Kiefer, Lafayette, NJ;

Applicant(s)

Extremity Medical LLC, Parsippany, NJ;

Assignment For Published Patent Application

Extremity Medical LLC, Parsippany, NJ

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 17/002,005 08/25/2020
which is a CON of 15/884,048 01/30/2018 PAT 10751097
which is a CON of 15/181,435 06/14/2016 PAT 9877752
which is a CON of 14/599,671 01/19/2015 PAT 9364271
which is a DIV of 12/658,680 02/11/2010 PAT 9044282
which is a CIP of 12/456,808 06/23/2009 PAT 8303589
which claims benefit of 61/132,932 06/24/2008

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: No

Permission to Access Search Results: No

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 05/26/2021
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/323,923**
Projected Publication Date: 09/02/2021
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

Preliminary Class

439

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor

community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/323,923

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	15 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x 240 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	830		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

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

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

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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P.O. Box 1450
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/323,923	05/18/2021	Jeff Tyber	024664	5684

27776 7590 07/08/2021

Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

EXAMINER	
ART UNIT	PAPER NUMBER
3773	
NOTIFICATION DATE	DELIVERY MODE
07/08/2021	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

NJPatentGroup@kelleydrye.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/323,923	**Applicant(s)** Tyber et al.	
	Examiner CHERYL P GIBSON BAYLOR	**Art Unit** OPET	**AIA (FITF) Status** No

1. THE REQUEST FILED 18 May 2021 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET	

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/323,923	05/18/2021	Jeff Tyber	024664	5684

27776 7590 07/15/2021

Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

EXAMINER	
HARVEY, JULIANNA NANCY	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
07/15/2021	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

NJPatentGroup@kelleydrye.com

Office Action Summary	Application No. 17/323,923	Applicant(s) Tyber et al.	
	Examiner JULIANNA N HARVEY	Art Unit 3773	AIA (FITF) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

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

Status

1)☑ Responsive to communication(s) filed on May 18, 2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-15 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-15 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on May 18, 2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, 365(c), or 386(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of 35 U.S.C. 112(a) or the first paragraph of pre-AIA 35 U.S.C. 112, except for the best mode requirement. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994)

The disclosure of the prior-filed application, Application No. 12/456,808, fails to provide adequate support or enablement in the manner provided by 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph for one or more claims of this application. The aforementioned prior-filed application fails to provide support for an assembly comprising a third member that receives first and second members in the manner

recited in claims 1 and 12. Accordingly, the claims have been examined in view of the filing date of Application No. 12/658,680, which is February 11, 2010.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for

applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-3, 5-8, and 12-15 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 5-8, and 12-15 of U.S. Patent No. 10,751,097 B2. Although the claims at issue are not identical, they are not patentably distinct from each other. The difference between the claims of the patent and those of the application is that the claims of the patent are more specific (claims 1 and 12 of the patent recite that the second member includes a head portion having an external surface). Thus, the invention of the patent claims is in effect a species of the generic invention of the application claims. It has been held that the generic invention is anticipated by the species. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Because claims 1-3, 5-8, and 12-15 of the application are anticipated by claims 1-3, 5-8, and 12-15 of the patent, they are not patentably distinct from those claims.

Claims 4, 10, and 11 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 10,751,097 B2

in view of Overes et al. (US 2010/0145397 A1). See above regarding claims 1 and 3 of the application (the claims from which claims 4, 10, and 11 depend) in relation to claims 1 and 3 of the patent. The patent claims fail to include that the head portion of the first member comprises a torque transmitting feature (claim 4), that the first end of the first member includes a self-tapping edge for removing bone material (claim 10), and that the first end of the second member includes a self-tapping edge for removing bone material (claim 11). Overes et al. teach an assembly for bone fusion comprising: an inner member (bone anchor 24) received in an aperture of a receiving member (bone anchor 22), wherein the inner member includes a head portion (head 44) having a torque transmitting feature (inner surface 43) such that the inner member can be engaged by a tool to rotate the inner member during insertion (see para. 0073), and wherein the inner member includes a first end having a self-tapping edge (cutting flutes 25) for removing bone material such that a bore does not need to be pre-drilled into the bone (see para. 0070) (Figs. 1-4C). It would have been obvious to one of ordinary skill in the art to provide the head portion of the first member with a torque transmitting feature (claim 4), the first end of the first member with a self-tapping edge for removing bone material (claim 10), and the first end of the second member with a self-tapping edge for removing bone material (claim 11), as suggested by Overes et al., as the torque transmitting feature would allow the first member to be engaged by a tool to rotate the first member during insertion and the self-tapping edges would eliminate the need to pre-drill bores into the bone.

Claim 9 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10,751,097 B2 in view of Michelson (US

2002/0128712 A1). See above regarding claim 1 of the application (the claim from which claim 9 depends) in relation to claim 1 of the patent. The patent claims fail to include that the first bore axis and the second bore axis intersect outside the third member. Overes et al. teach an assembly for bone fusion comprising: a first member (bone screw 478); a second member (bone screw 478); and a third member (implant 400) that receives the first and second members, wherein the first member extends along a first bore axis (see Fig. 35 inset) and the second member extends along a second bore axis (see Fig. 35 inset) that intersects the first bore axis outside the third member (see Fig. 35 inset) (Fig. 35).

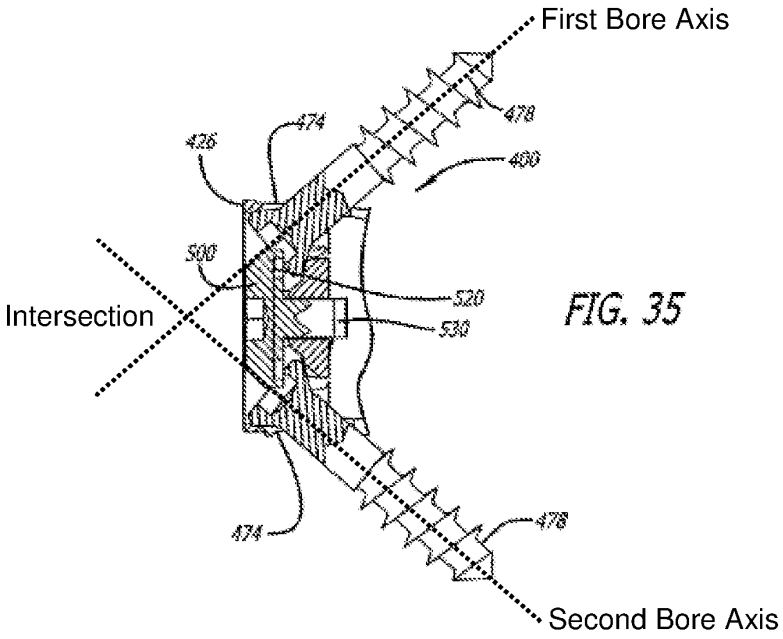


FIG. 35

It would have been obvious to one of ordinary skill in the art for the first bore axis and the second bore axis to intersect outside the third member, as suggested by Michelson, as such non-parallel axes will provide for better fixation in comparison to if the first and second members extended along parallel axes.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note that Krinke et al. (US 2011/0218585 A1) anticipate at least claim 1 (consider diagonal anchor 112 as the first member, anchor 106 as the second member, and subchondral member 102 as the third member). However, Krinke et al. does not constitute prior art as its earliest filing date is March 8, 2010.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIANNA NANCY HARVEY whose telephone number is (571)270-3815. The examiner can normally be reached on Mon.-Fri. 8:00-5:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JULIANNA N HARVEY/
Primary Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 17/323,923	Applicant(s)/Patent Under Reexamination Tyber et al.	
	Examiner JULIANNA N HARVEY	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20030208270-A9	11-2003	Michelson, Gary Karlin	A61F2/447	623/17.11
*	B	US-20100145397-A1	06-2010	Overes; Tom	A61B17/725	606/319
*	C	US-20110218585-A1	09-2011	Krinke; Todd A.	A61B17/17	606/86R
	D					
	E					
	F					
	G					
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	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/323,923	Tyber et al.
	Examiner	**Art Unit**
	JULIANNA N HARVEY	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/12/2021								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
	10	✓								
	11	✓								
	12	✓								
	13	✓								
	14	✓								
	15	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/323,923	Tyber et al.
	Examiner	Art Unit
	JULIANNA N HARVEY	3773

CPC - Searched*		
Symbol	Date	Examiner
a61b 17/7291, 17/744, 17/742, 17/74, 17/72, 17/7233, 17/7241	07/12/2021	jnh

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
inventor/applicant searches	07/12/2021	jnh

Interference Search			
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/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773	

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

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First Named Inventor	Jeff Tyber
Art Unit	2833
Examiner Name	TBD
Attorney Docket Number	024664

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.N.H/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17323923
Filing Date	2021-05-18
First Named Inventor	Jeff Tyber
Art Unit	2833
Examiner Name	TBD
Attorney Docket Number	024664

	84	20120109213		2012-05-03	Appenzeller, et al	
	85	20050125070		2005-06-09	Reiley	
	86	20060015123		2006-01-19	Fencl et al	
	87	20090118772		2009-05-07	Diederich	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.N.H/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17323923
	Filing Date	2021-05-18
	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

	95	20030229346		2003-12-10	Oribe, et al	
	96	20040006345		2004-01-08	Vlahos et al	
	97	20040097945		2004-05-20	Wolf	
	98	20050149030		2005-07-07	Serhan et al	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17323923
	Filing Date	2021-05-18
	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

	106	20100042167		2010-02-18	Nebosky et al	
	107	20100042164		2010-02-18	Lee et al	
	108	20100069970		2010-03-18	Lewis et al	
	109	20100057141		2010-03-04	Abdelgany et al	
	110	20110218580		2011-09-08	Schwager et al	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17323923
	Filing Date	2021-05-18
	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

	117	20020197134		2002-12-26	Huber	
	118	20030147716		2003-08-07	Nagawa	
	119	20060052787		2006-03-09	Re et al	
	120	20080221623		2008-09-11	Gooch	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17323923
	Filing Date	2021-05-18
	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

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	130	20090093813		2009-04-09	Elghazaly	
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	132	20110106172		2011-05-01	Wallenstein	
	133	20100121325		2010-05-13	Tyber, et al	
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	135	20030208270		2003-11-01	Michelson	
	136	20040049192		2004-03-01	Shimizu	
	137	20060149257		2006-07-01	Orbay	
	138	20100145397		2010-06-01	Overes	

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	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2738745	CN		2005-11-09	United Orthopedics Instr		
	2	21512134	EP		2010-02-10	Zhao Daguo		
	3	199722301	WO	A1	1997-06-01	Bramlet		
	4	2007131287	WO		2007-11-22	Slater		
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	7	2861576	FR	A1	2005-05-01	Cognet		
	8	200906783	WO	A1	2009-06-01	Klaue		
	9	2008024373	WO	A2	2008-02-01	Samy		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17323923
	Filing Date	2021-05-18
	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Examination Report issued December 12, 2018 for Indian Patent Application 355/MUMNP/2012.	

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EXAMINER SIGNATURE

Examiner Signature	/JULIANNA N HARVEY/	Date Considered	07/12/2021

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17323923
	Filing Date	2021-05-18
	First Named Inventor	Jeff Tyber
	Art Unit	2833
	Examiner Name	TBD
	Attorney Docket Number	024664

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any 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. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David G. Lindenbaum/	Date (YYYY-MM-DD)	2021-05-20
Name/Print	David G. Lindenbaum	Registration Number	51951

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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*** circled refs reviewed ***

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S115	115	(extremity medical).as,aanm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 07:09
S116	169	(tyber near2 jeff).in. or (gannoe near2 jamy).in. or (kiefer near2 lawrence).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 07:32
S117	2,601	a61b17/7291.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 07:42
S118	3,167	a61b17/744.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 07:42
S119	1,615	a61b17/742.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 07:42
S120	1,522	a61b17/74.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 07:42
S121	7,484	a61b17/72.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 07:42
S122	3,151	a61b17/7233.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 07:42
S123	1,533	a61b17/7241.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 07:42
S124	1,490	S119 not (S120)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 08:09
S125	2,694	S118 not (S120 or S119)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	ADJ	OFF	2021/07/12 08:10

			JPO; DERWENT; IBM_TDB			
S126	2,426	S117 not (S120 or S119 or S118)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 08:11
S127	869	S123 not (S120 or S119 or S118 or S117)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 08:12
S128	1,458	S122 not (S120 or S119 or S118 or S117 or S123)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 08:13
S129	4,388	S121 not (S120 or S119 or S118 or S117 or S123 or S122)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2021/07/12 08:13

EAST Search History (Interference)

<This search history is empty>

7/12/2021 4:29:18 PM
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Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
17/323,923	05-18-2021

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 27776

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

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OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
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I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Extremity Medical, LLC

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	Matthew Lyons		
Title	CEO		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Electronic Acknowledgement Receipt	
EFS ID:	43473112
Application Number:	17323923
International Application Number:	
Confirmation Number:	5684
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Customer Number:	27776
Filer:	David G. Lindenbaum
Filer Authorized By:	
Attorney Docket Number:	024664
Receipt Date:	10-AUG-2021
Filing Date:	18-MAY-2021
Time Stamp:	15:38:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	POA.pdf	90689 aec424d3788cbc4cb6d78276f60f61d51f56fd11	no	1
Warnings:					

Information:	
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/323,923	05/18/2021	Jeff Tyber	024664-0102

CONFIRMATION NO. 5684

27776
Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

POA ACCEPTANCE LETTER

OC000000127648419

Date Mailed: 08/13/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 08/10/2021.

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

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/dgela/

Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	17323923
Filing Date	18-May-2021
First Named Inventor	Jeff Tyber
Attorney Docket Number	024664-0102
Title of Invention	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Extremity Medical, LLC	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

10751097

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.	
Applicant claims the following fee status: ◉ Small Entity ○ Micro Entity ○ Regular Undiscounted I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.	
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number 51951 ○ A sole inventor ○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ○ A joint inventor; all of whom are signing this request	
Signature	/David G. Lindenbaum/
Name	David G. Lindenbaum

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	17323923
Filing Date:	18-May-2021
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Filer:	David G. Lindenbaum
Attorney Docket Number:	024664-0102

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**170**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 17323923

Filing Date: 18-May-2021

Applicant/Patent under Reexamination: Tyber

Electronic Terminal Disclaimer filed on August 13, 2021

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt	
EFS ID:	43503890
Application Number:	17323923
International Application Number:	
Confirmation Number:	5684
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Customer Number:	27776
Filer:	David G. Lindenbaum
Filer Authorized By:	
Attorney Docket Number:	024664-0102
Receipt Date:	13-AUG-2021
Filing Date:	18-MAY-2021
Time Stamp:	11:53:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$170
RAM confirmation Number	E20218CB53042800
Deposit Account	502968
Authorized User	David Lindenbaum
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	41234 bde0a9c540e9152f8e61601e77282dfc79245520	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37827 6a3e52618bc6ba8b5385c1164cdbd851115b13ef	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	79061		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Extremity Medical, LLC	Application No.: 17/323,923
Attorney Docket No.: 024664-0102	Filing Date: 05-18-2021
Examiner: HARVEY, JULIANNA NANCY	Group Art Unit: 3773
For: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE	Confirmation No.: 5684

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

RESPONSE TO JULY 15, 2021 OFFICE ACTION

A response to the Office Action mailed July 15, 2021 is set forth below. Based upon the remarks herein, the application is deemed to be in condition for allowance and action to that end is respectfully requested.

Remarks begin on Page 2.

REMARKS

This is a response to the Office Action mailed July 15, 2021 ("the Office Action"). Claims 1-15 are pending in this application. In the Office Action, Claims 1-15 were rejected on the ground of nonstatutory double patenting as unpatentable over Claims 1-15 of U.S. Patent No. 10,751,097. A terminal disclaimer addressing the nonstatutory double patenting rejection has been filed. In view of the terminal disclaimer, Applicant respectfully requests withdrawal of the nonstatutory double patenting rejection. The Application is believed to be in condition for allowance.

No fee is believed due for this Response. If, however, any fee is due, the Patent and Trademark Office is specifically authorized to charge such fees to Deposit Account No. 502968 in the name of Kelley Drye & Warren LLP.

Respectfully submitted,

Date: August 13, 2021

/David G. Lindenbaum/

David G. Lindenbaum
Reg. No. 51,951
KELLEY DRYE & WARREN LLP
One Jefferson Road
Parsippany, NJ 07054
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

Electronic Acknowledgement Receipt	
EFS ID:	43503972
Application Number:	17323923
International Application Number:	
Confirmation Number:	5684
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Customer Number:	27776
Filer:	David G. Lindenbaum
Filer Authorized By:	
Attorney Docket Number:	024664-0102
Receipt Date:	13-AUG-2021
Filing Date:	18-MAY-2021
Time Stamp:	11:55:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response.pdf	106242 8540524c9a4ab1474ec2b3907b073e3ff3469a1e	yes	2

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Applicant Arguments/Remarks Made in an Amendment	2	2
Warnings:			
Information:			
	Total Files Size (in bytes):	106242	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/323,923	05/18/2021	Jeff Tyber	024664-0102

CONFIRMATION NO. 5684

27776
Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

PUBLICATION NOTICE



Title:INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

Publication No.US-2021-0267648-A1
Publication Date:09/02/2021

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

27776 7590 01/12/2022

Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

EXAMINER	
HARVEY, JULIANNA NANCY	
ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 01/12/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/323,923	05/18/2021	Jeff Tyber	024664-0102	5684

TITLE OF INVENTION: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	04/12/2022

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27776 7590 01/12/2022
Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

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

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/323,923	05/18/2021	Jeff Tyber	024664-0102	5684

TITLE OF INVENTION: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	04/12/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
HARVEY, JULIANNA NANCY	3773	606-062000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

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

1_____
2_____
3_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

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

4a. Fees submitted: ❑Issue Fee ❑Publication Fee (if required) ❑Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/323,923	05/18/2021	Jeff Tyber	024664-0102	5684

27776 7590 01/12/2022

Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

EXAMINER	
HARVEY, JULIANNA NANCY	
ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 01/12/2022

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/323,923	Applicant(s) Tyber et al.	
	Examiner JULIANNA N HARVEY	Art Unit 3773	AIA (FITF) Status No

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the response filed on August 13, 2021.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-15 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

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

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/JULIANNA N HARVEY/
Primary Examiner, Art Unit 3773

EXAMINER'S COMMENT

Terminal Disclaimer

The terminal disclaimer filed on August 13, 2021 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of **U.S. Patent No. 10,751,097** has been reviewed and is accepted. The terminal disclaimer has been recorded.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: the claims in the instant application have not been rejected using prior art because no references, or reasonable combination thereof, could be found which disclose, or suggest, an assembly for bone fusion as claimed in claims 1 and 12, and specifically, the first angle in the range of 0° to 90° (claim 1), the second angle in the range of 0° to 90° (claims 1 and 12), and the second bore axis substantially perpendicular to the third longitudinal axis (claims 1 and 12).

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

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIANNA NANCY HARVEY whose telephone number is (571)270-3815. The examiner can normally be reached Mon.-Fri. 8:00-5:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JULIANNA N HARVEY/
Primary Examiner, Art Unit 3773

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/323,923	Tyber et al.
	Examiner	**Art Unit**
	JULIANNA N HARVEY	3773

CPC						
Symbol					**Type**	**Version**
A61B	/	17	/	7291	F	2013-01-01
A61B	/	17	/	1717	I	2013-01-01
A61B	/	17	/	72	I	2013-01-01
A61B	/	17	/	8605	I	2013-01-01
A61B	/	17	/	8625	I	2013-01-01
A61B	/	17	/	1775	I	2016-11-01
Y10S	/	411	/	954	A	2013-01-01
A61F	/	2002	/	4238	A	2013-01-01
A61B	/	17	/	1782	A	2016-11-01
A61B	/	2017	/	564	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	15	
/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773	04 January 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	18

U.S. Patent and Trademark Office — Part of Paper No.: 20220104

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/323,923	Tyber et al.
	Examiner	Art Unit
	JULIANNA N HARVEY	3773

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61B17/72	/	17	/	72

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE (Assistant Examiner)	(Date)	Total Claims Allowed: 15	
/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773 (Primary Examiner)	04 January 2022 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 18

U.S. Patent and Trademark Office

Part of Paper No.: 20220104

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/323,923	Tyber et al.
	Examiner	Art Unit
	JULIANNA N HARVEY	3773

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10												
2	2	11	11												
3	3	12	12												
4	4	13	13												
5	5	14	14												
6	6	15	15												
7	7														
8	8														
9	9														

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	15	
/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773	04 January 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	18

U.S. Patent and Trademark Office — Part of Paper No.: 20220104

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/323,923	Tyber et al.
	Examiner	**Art Unit**
	JULIANNA N HARVEY	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/12/2021	01/04/2022							
1	1	✓	=							
2	2	✓	=							
3	3	✓	=							
4	4	✓	=							
5	5	✓	=							
6	6	✓	=							
7	7	✓	=							
8	8	✓	=							
9	9	✓	=							
10	10	✓	=							
11	11	✓	=							
12	12	✓	=							
13	13	✓	=							
14	14	✓	=							
15	15	✓	=							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/323,923	Tyber et al.
	Examiner	Art Unit
	JULIANNA N HARVEY	3773

CPC - Searched*		
Symbol	Date	Examiner
a61b 17/7291, 17/744, 17/742, 17/74, 17/72, 17/7233, 17/7241	07/12/2021	jnh

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
inventor/applicant searches	07/12/2021	jnh
updated searches	01/04/2022	jnh

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	see EAST printout	01/04/2022	jnh

/JULIANNA N HARVEY/ Primary Examiner, Art Unit 3773	

circled refs reviewed

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	120	(extremity medical).as,aanm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2022/01/04 06:54
L2	171	(tyber near2 jeff).in. or (gannoe near2 jamy).in. or (kiefer near2 lawrence).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2022/01/04 06:54
L3	6	(L1 or L2) and @pd>"20210712"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2022/01/04 06:54
L4	2,758	a61b17/7291.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2022/01/04 07:00
L5	3,251	a61b17/744.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2022/01/04 07:00
L6	1,640	a61b17/742.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2022/01/04 07:00
L7	1,598	a61b17/74.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2022/01/04 07:00
L8	7,696	a61b17/72.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2022/01/04 07:00
L9	3,291	a61b17/7233.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2022/01/04 07:00
L10	1,593	a61b17/7241.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2022/01/04 07:00

L11	420	(L7 or L6 or L5 or L4 or L10 or L9 or L8) and @pd>"20210712"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2022/01/04 07:00

EAST Search History (Interference)

<This search history is empty>

1/4/2022 8:23:35 AM
C:\Users\jharvey2\Documents\EAST\Workspaces\17-323923.wsp

Bibliographic Data

Application No: 17/323,923

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /JULIANNA N HARVEY/ Examiner's Signature | Initials

Title: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
05/18/2021	606	3773	024664-0102
RULE			

APPLICANTS

Extremity Medical LLC, Parsippany, NJ,

INVENTORS

Jeff Tyber, Bethlehem, PA, UNITED STATES

Jamy Gannoe, West Milford, NJ, UNITED STATES

Lawrence Kiefer, Lafayette, NJ, UNITED STATES

CONTINUING DATA

This application is a CON of 17002005 08/25/2020

17002005 is a CON of 15884048 01/30/2018 PAT 10751097

15884048 is a CON of 15181435 06/14/2016 PAT 9877752

15181435 is a CON of 14599671 01/19/2015 PAT 9364271

14599671 is a DIV of 12658680 02/11/2010 PAT 9044282

12658680 is a CIP of 12456808 06/23/2009 PAT 8303589

12456808 has PRO of 61132932 06/24/2008

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

05/26/2021

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

Kelley Drye & Warren LLP

One Jefferson Road

Parsippany, NJ 07054

UNITED STATES

FILING FEE RECEIVED

$3,000

circled refs reviewed

EAST Search History

EAST Search History (Prior Art)

<This search history is empty>

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2,038	((aperture or hole or opening) near3 ((terminal end) or terminus)).clm.	USPAT	ADJ	ON	2022/01/04 10:47
L2	156,529	(perpendicular near5 (axis or axes)).clm.	USPAT	ADJ	ON	2022/01/04 10:47
L3	260,888	(thread$3).clm.	USPAT	ADJ	ON	2022/01/04 10:47
L4	27	L1 and L2 and L3	USPAT	ADJ	ON	2022/01/04 10:47
L5	17	L4 and screw	USPAT	ADJ	ON	2022/01/04 10:47

1/4/2022 10:59:43 AM
C:\Users\jharvey2\Documents\EAST\Workspaces\17-323923.wsp

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27776 7590 01/12/2022
Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

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

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/323,923	05/18/2021	Jeff Tyber	024664-0102	5684

TITLE OF INVENTION: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	04/12/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
HARVEY, JULIANNA NANCY	3773	606-062000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

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

1 Kelley Drye & Warren 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. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Extremity Medical LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Parsippany, NJ

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

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /David G. Lindenbaum/ Date 1/19/2022

Typed or printed name David G. Lindenbaum Registration No. 51951

PTOL-85 Part B (08-18) Approved for use through 01/31/2020 OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	17323923
Filing Date:	18-May-2021
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Filer:	David G. Lindenbaum
Attorney Docket Number:	024664-0102

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	600	600

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**600**

Electronic Acknowledgement Receipt	
EFS ID:	44774325
Application Number:	17323923
International Application Number:	
Confirmation Number:	5684
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Customer Number:	27776
Filer:	David G. Lindenbaum
Filer Authorized By:	
Attorney Docket Number:	024664-0102
Receipt Date:	19-JAN-2022
Filing Date:	18-MAY-2021
Time Stamp:	02:19:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$600
RAM confirmation Number	E20221I321073539
Deposit Account	502968
Authorized User	David Lindenbaum
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	IssueFee.pdf	118166 40093c0cbb7553f0646132b1f5d0c17a106a856a	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37986 6f9a11875b9df32c02c4369a8949c38f577d740f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	156152		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/323,923	05/18/2021	Jeff Tyber	024664-0102	5684

27776 7590 01/24/2022

Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

EXAMINER	
HARVEY, JULIANNA NANCY	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
01/24/2022	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

NJPatentGroup@kelleydrye.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 17323923
Applicant : Tyber
Filing Date : 05/18/2021
Date Mailed : 01/24/2022

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Ashley Gerstlauer/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 17323923 **Drawings filed: 05/18/2021**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 15
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as "New" or "Amended" or "Canceled" as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as "Canceled" but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as "Canceled." See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Extremity Medical, LLC	Application No.: 17/323,923
Attorney Docket No.: 024664-0102	Filing Date: 05-18-2021
Examiner: HARVEY, JULIANNA NANCY	Group Art Unit: 3773
For: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE	Confirmation No.: 5684

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

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

In response to the Notice to File Corrected Application Papers mailed January 24, 2022 ("the Notice") Applicant submits herewith Replacement Figure 15. The Replacement Figure corrects any data, reference number, or part of the drawing truncated or missing. Applicant also submits herewith a copy of the Notice as instructed therein.

No fee is believed due for this Response. If, however, any fee is due, the Patent and Trademark Office is specifically authorized to charge such fees to Deposit Account No. 502968 in the name of Kelley Drye & Warren LLP.

Respectfully submitted,

Date: January 27, 2022

/David G. Lindenbaum/
David G. Lindenbaum
Reg. No. 51,951
KELLEY DRYE & WARREN LLP
One Jefferson Road
Parsippany, NJ 07054
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

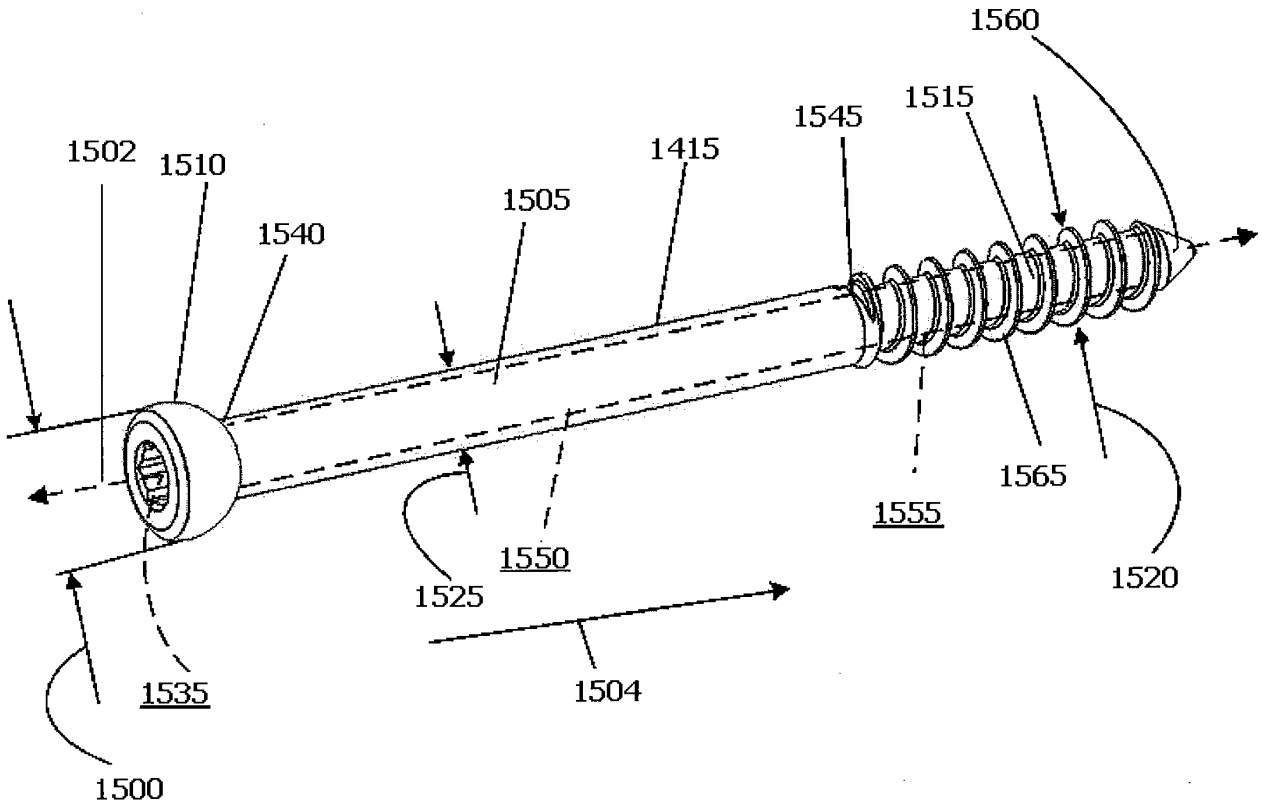

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FIG. 15

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/323,923	05/18/2021	Jeff Tyber	024664-0102	5684

27776 7590 01/24/2022

Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

EXAMINER	
HARVEY, JULIANNA NANCY	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
01/24/2022	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

NJPatentGroup@kelleydrye.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 17323923
Applicant : Tyber
Filing Date : 05/18/2021
Date Mailed : 01/24/2022

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Ashley Gerstlauer/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 17323923 **Drawings filed: 05/18/2021**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 15
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as "New" or "Amended" or "Canceled" as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as "Canceled" but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as "Canceled." See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

Electronic Acknowledgement Receipt	
EFS ID:	44854206
Application Number:	17323923
International Application Number:	
Confirmation Number:	5684
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Customer Number:	27776
Filer:	David G. Lindenbaum
Filer Authorized By:	
Attorney Docket Number:	024664-0102
Receipt Date:	27-JAN-2022
Filing Date:	18-MAY-2021
Time Stamp:	16:09:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response After Final Action	Response.pdf	99245 e4f3c9e97e38d86cdc831e476b8993f52761ed4b	no	1

Warnings:

Information:					
2	Drawings-only black and white line drawings	Figure15.pdf	46660 2ba1c3395db419536f5dec49dcddc39399e5ac8c	no	1
Warnings:					
Information:					
3	Examination support document	Notice.pdf	114308 0c39a038047a2568c50e27947fbc5dc3f9127654	no	3
Warnings:					
Information:					
			Total Files Size (in bytes):	260213	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17323923
Filing Date	2021-05-18
First Named Inventor	Jeff Tyber
Art Unit	2833
Examiner Name	TBD
Attorney Docket Number	024664

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5984681		1999-11-16	Huang Barney	
Change(s) applied to document, /J.T./ 1/13/2022	2	9289970		~~1989-07-27~~ 03/2016	~~Mueller, Emanuel~~ Seo et al.	
	3	5112333		1992-05-12	Fixel	
	4	6168595		2001-01-02	Durham, et al	
	5	7229448		2007-06-12	Goble, et al	
	6	5531748		1996-07-02	de la Carfiniere	
	7	6019761		2000-02-01	Gustillo	
	8	6106528		2000-08-22	Durham, et al	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.N.H/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/323,923	05/18/2021	Jeff Tyber	024664-0102	5684

27776 7590 02/28/2022

Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

EXAMINER	
HARVEY, JULIANNA NANCY	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
02/28/2022	ELECTRONIC

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

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Alexandria, VA 22313-1450
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Application No. : 17323923
Applicant : Tyber
Filing Date : 05/18/2021
Date Mailed : 02/28/2022

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See attachment(s).

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/Marty Willis/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 17323923 **Drawings filed: 05/18/2021**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
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- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 10
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
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- [ ] OTHER:
- [X] COMMENTS:
  Near the center of Figure 10, there is a reference number 2145 that appears to be missing its corresponding lead line.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/323,923	05/18/2021	Jeff Tyber	024664-0102	5684

27776 7590 02/28/2022

Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

EXAMINER	
HARVEY, JULIANNA NANCY	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
02/28/2022	ELECTRONIC

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www.uspto.gov

Application No. : 17323923
Applicant : Tyber
Filing Date : 05/18/2021
Date Mailed : 02/28/2022

NOTICE TO FILE CORRECTED APPLICATION PAPERS

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See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Marty Willis/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 17323923 **Drawings filed: 05/18/2021**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
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- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
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- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
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- [ ] OTHER:
- [X] COMMENTS:
  Near the center of Figure 10, there is a reference number 2145 that appears to be missing its corresponding lead line.

Electronic Acknowledgement Receipt	
EFS ID:	45178184
Application Number:	17323923
International Application Number:	
Confirmation Number:	5684
Title of Invention:	INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
First Named Inventor/Applicant Name:	Jeff Tyber
Customer Number:	27776
Filer:	David G. Lindenbaum
Filer Authorized By:	
Attorney Docket Number:	024664-0102
Receipt Date:	08-MAR-2022
Filing Date:	18-MAY-2021
Time Stamp:	19:01:37
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	Response.pdf	99253 4f9e58cbdcb5b1bfbb9ec339957a80bb3ea0bf64	no	1

Warnings:

Information:					
2	Drawings-only black and white line drawings	Figure_10.pdf	130395 e1b7d90457a3cedde2c47aae4fa64baf01617c5e	no	1
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	Notice.pdf	115892 8342714797a40a78a86c6703b699d748ea727787	no	3
Warnings:					
Information:					
		Total Files Size (in bytes):	345540		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Extremity Medical, LLC	Application No.: 17/323,923
Attorney Docket No.: 024664-0102	Filing Date: 05-18-2021
Examiner: HARVEY, JULIANNA NANCY	Group Art Unit: 3773
For: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE	Confirmation No.: 5684

Mail Stop Issue Fee
Honorable Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

In response to the Notice to File Corrected Application Papers mailed February 28, 2022 ("the Notice"), Applicant submits herewith Replacement Figure 10. The Replacement Figure omits reference number 2145 for which there was no lead line. Applicant also submits herewith a copy of the Notice as instructed therein.

No fee is believed due for this Response. If, however, any fee is due, the Patent and Trademark Office is specifically authorized to charge such fees to Deposit Account No. 502968 in the name of Kelley Drye & Warren LLP.

Respectfully submitted,

Date: March 8, 2022

/David G. Lindenbaum/
David G. Lindenbaum
Reg. No. 51,951
KELLEY DRYE & WARREN LLP
One Jefferson Road
Parsippany, NJ 07054
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

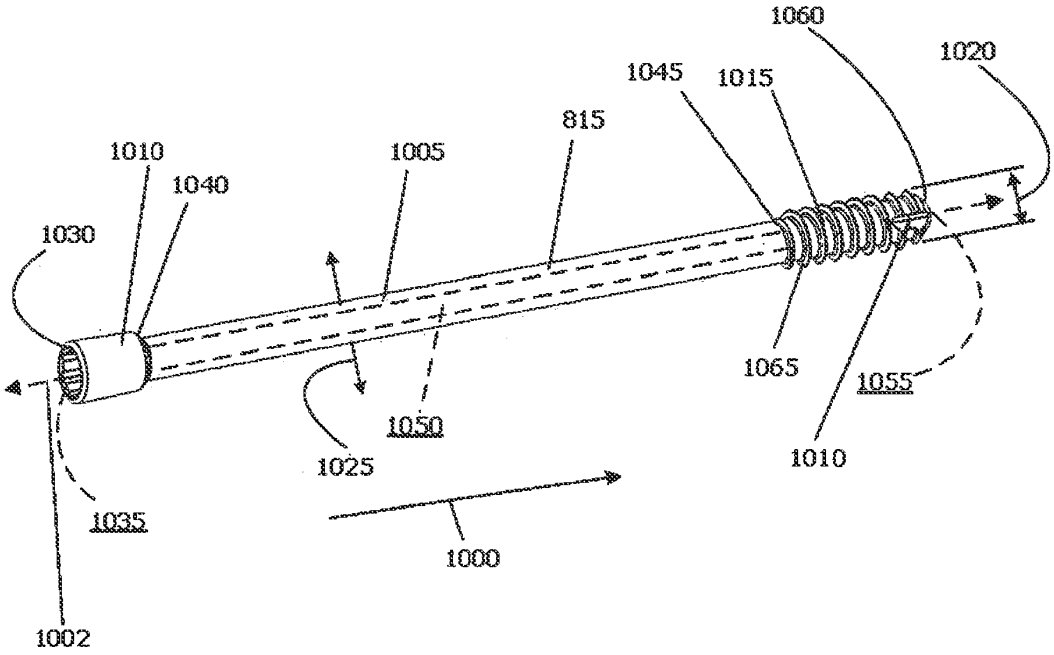

1060
1020
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1015
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FIG. 10

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

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AO 120 (Rev. 08/10)

TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of Arizona on the following

☐ Trademarks or ☐ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
CV 22-723-PHX-MTM	4/28/2022	for the District of Arizona

PLAINTIFF	DEFENDANT
Extremity Medical, LLC	Fusion Orthopedics, LLC

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	11,298,166	4/12/2022	Extremity Medical, LLC
2			
3			
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading		
	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1			
2			
3			
4			
5			

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
Debra D Lucas	Rebecca E Lubozyn	4/29/22

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

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Paper 15
Date: November 17, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSION ORTHOPEDICS, LLC,
Petitioner,

v.

EXTREMITY MEDICAL, LLC,
Patent Owner.

IPR2023-00894
Patent 11,298,166 B2

Before JEFFREY N. FREDMAN, ROBERT A. POLLOCK, and JAMIE T. WISZ, *Administrative Patent Judges.*

POLLOCK, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

A. Background and Summary

Fusion Orthopedics, LLC ("Fusion Orthopedics," "Petitioner") filed a Petition for an *inter partes* review of claims 1–15 of U.S. Patent No. 1,298,166 B2 ("the '166 patent," Ex. 1001). Paper 1 ("Pet."). Extremity Medical, LLC ("Extremity Medical," "Patent Owner") timely filed a Preliminary Response. Paper 12 ("Prelim. Resp."). With our authorization (*see* Exhibit 3001), Petitioner filed a Reply to the Preliminary Response (Paper 13, "Reply"); Patent Owner filed a corresponding Sur-reply (Paper 14, "Sur-reply").

We have authority under 35 U.S.C. § 314 and 37 C.F.R. § 42.4. After considering the Petition, the Preliminary Response, the Reply, the Sur-reply, and the evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of claims 1–15 of the '166 patent, based on all of the grounds identified in the Petition. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60 (2018); 37 C.F.R. § 42.108(a) ("When instituting post-grant review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.").

B. Real Parties-in-Interest

Petitioner identifies itself, Fusion Orthopedics, LLC, as the real party-in-interest. Pet. 1. Patent Owner identifies itself, Extremity Medical, LLC, as the real party-in-interest. Paper 5, 1.

C. Related Matters

The '166 patent is at issue in *Extremity Medical, LLC. v. Fusion Orthopedics, LLC*, No. 2:22-cv-00723-PHX-GMS (D. Ariz.) ("the related litigation"). *See* Pet. 1; Paper 5, 1; Exs. 1010, 1011, 2002.

D. Asserted Challenges to Patentability

Petitioner challenges the patentability of claims 1–15 on the following bases (Pet. 6):

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–7, 9, 12, 13	102(a), 102(b)	Cognet[1]
2	4, 8, 10, 14, 15	103	Cognet, Brumfield[2]
3	11	103	Cognet, Ferrante[3]
4	1, 4, 5, 8, 10–12, 14, 15	102(a), 102(b)	Simon[4]
5	4, 8, 10, 11, 14, 15	103	Simon, Ferrante
6	9	103	Simon, Cognet
7	2, 3, 6, 7, 13	103	Simon, Leu[5]

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Mr. Leonel Dominguez. Ex. 1002. Considering his background and experience, Mr. Dominguez is amply qualified to testify as

[1] Cognet, French Patent Appl. Publication No. FR 2,861,576 A1, pub. May 6, 2005. Exs. 1003, 1004 (Certified English Translation).

[2] Brumfield, US 4,827,917, issued May 9, 1989. Ex. 1006.

[3] Ferrante, US 2003/0187447 A1, pub. Oct. 2, 2003. Ex. 1007.

[4] Simon, US 2006/0206044 A1, pub. Sept. 14, 2006. Ex. 1008.

[5] Leu, US 6,270,499 B1, issued Aug. 7, 2001. Ex. 1009.

one of ordinary skill in the art as defined in section II.B, below. *See id.* ¶¶ 4–23, Attachment A.

E. The '166 Patent and Relevant Background

The '166 patent, titled "Intraosseous Intramedullary Fixation Assembly and Method of Use," is directed to orthopedic implant devices for correcting deformities and the fusion of angled joints and bones. Ex. 1001, code (57), 1:25–28. Orthopedic implant devices, such as intramedullary nails, plates, rods and screws are often used to repair or reconstruct hand and foot bones. *Id.* at 1:28–33.

Figure 18 of the '166 patent is reproduced below.

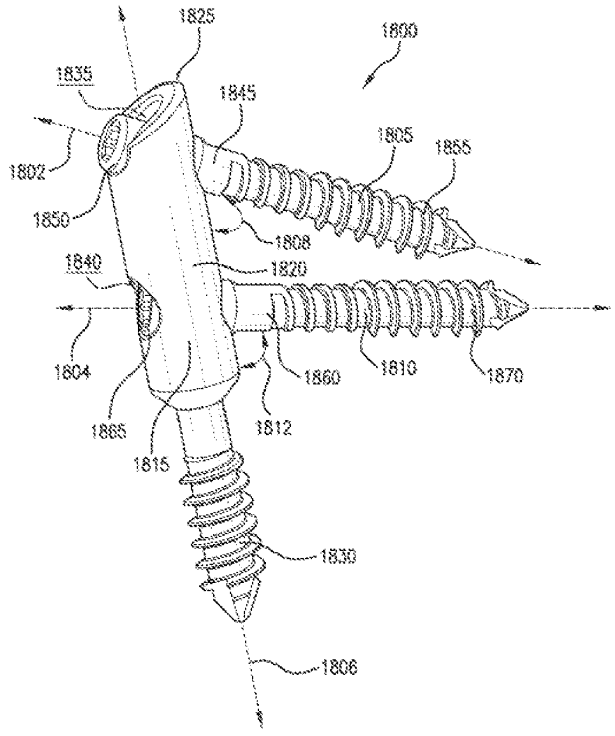


FIG. 18

Figure 18 shows a perspective view of an intramedullary fixation assembly 1800 having a plurality of lag screw members 1805, 1810. *Id.* at 4:11–14, 13:22–24. As assembled, "lag screw members **1805** and **1810** coupled to a tapered screw member **1815** . . . apply compression at multiple points on the bone fragment surface." *Id.* at 13:24–26.[6] "Each of the lag screw members **1805** and **1810** forms an [sic, a] fixed acute angle with the tapered screw member **1815,** with these angles being predetermined by, for example, a surgeon to fix the bones in a human body." *Id.* at 13:31–34. In some embodiments,

> end **1825** has a tapered aperture **1835**, which is aligned on axis **1802** and forms a fixed angle **1808** with axis **1806**. Fixed angle **1808** determines the angle for fixation of tapered screw member **1810** with respect to lag screw member **1805**. Also, tapered screw member **1815** has a second tapered aperture **1840**, aligned along axis **1804** and forms a fixed angle **1812** with axis **1804**. The fixed angle **1812** determines the angle for fixation of lag screw member **1810** with tapered screw member **1815.**

Id. at 13:38–47.

F. Challenged Claims

Petitioner challenges claims 1–15 of the '166 patent. Pet. 4. Challenged claims 1 and 12 are independent, and the remaining challenged claims depend, directly or indirectly, either from independent claims 1 or 12. Ex. 1001, 14:62–16:64. Claim 1, reproduced below, is illustrative of the subject matter challenged (paragraphing and labeling of limitations as added

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[6] With reference to challenged independent claims 1 and 2 (discussed below), we understand lag screw members 1805 and 1810 to map to claimed "first member" and "second member," respectively. Tapered screw member 1815 of Figure 18 maps to the claimed "third member."

in Petitioner's Specific Grounds; bolding added to indicate elements argued in the Patent Owner Preliminary Response).

1. An assembly for bone fusion, comprising:

1[a][i]: a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis

1[a][ii]: wherein the first member comprises a shaft portion having an external surface and **a head portion** having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;

1[b][i]: a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis,

1[b][ii]: wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;

1[c][i]: a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis,

1[c][ii]: wherein the third member comprises **a first aperture at a terminal end** of the first end of the third elongated body,

1[c][iii]: **a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member**

1[c][iv]: wherein the first bore comprises an interior surface at the first aperture

1[c][v]: wherein there are no threads adjacent to the second aperture on the exterior surface of the third member

1[c][vi]: wherein the third longitudinal axis and the first bore axis define a first angle

> 1[d]: wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle
>
> 1[e]: wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture
>
> 1[f]: wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture
>
> 1[g]: wherein the first angle is in the range of about 0 degrees to about 90 degrees
>
> 1[h]: wherein the second angle is in the range of about 0 degrees to about 90 degrees
>
> 1[i]: wherein the second bore axis is substantially perpendicular to the third longitudinal axis.

Ex. 1001, 14:62–15:44; *see* Pet. 8–23. Independent claim 12 is substantially similar to claim 1 but omits element 1[h], "wherein the second angle is in the range of about 0 degrees to about 90 degrees." *See* Ex. 1001, 16:7–56.

II. ANALYSIS

A. Legal Standards

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (2012) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l*

Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

Petitioner contends that the challenged claims are anticipated by the prior art. Pet. 6. To show anticipation under 35 U.S.C. § 102, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). The prior art need not, however, use the same words as the claims to find anticipation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). In evaluating anticipation, it is permissible to take into account not only the literal teachings of the prior art reference, but also the inferences the skilled artisan would draw from it. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. At Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017) (holding that the "dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from a prior art reference that every claim element is disclosed in that reference"). As such, "a reference can anticipate a claim even if it does not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination." *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (internal quotation and alteration marks omitted).

Petitioner also contends that the challenged claims are unpatentable as obvious under § 103. Pet. 6. A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary

skill in the art to which the claimed invention pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, if any.[7] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotation marks omitted).

[7] Patent Owner does not rely on secondary considerations in its Preliminary Response.

We address Petitioner's challenges with these standards in mind, and in view of the definition of the skilled artisan and the claim constructions discussed below.

B. Person of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner proposes that a person of ordinary skill in the art would possess

> a bachelor's degree in biomedical and/or mechanical engineering or similar training with at least five years of experience with the methods, processes, and implant devices used to stabilize fractures, correct deformities and fuse bone in small bone and/or long bone fractures using internal fixation, and preferably has experience in the operating room (OR) or cadaver labs to witness use and implementation.

Pet. 6–7 (citing Ex. 1002 ¶ 29). Patent Owner neither objects to the above definition nor offers a different definition of a person of ordinary skill in the art in its Preliminary Response. *See generally* Prelim. Resp. 1–37.

On the current record, and for the purposes of this decision, we accept Petitioner's proposed definition, as it appears consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the '166 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the prior art itself [may] reflect[] an appropriate level" as evidence of the

ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

C. Claim Construction

We construe claims "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100 (2021). Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.*

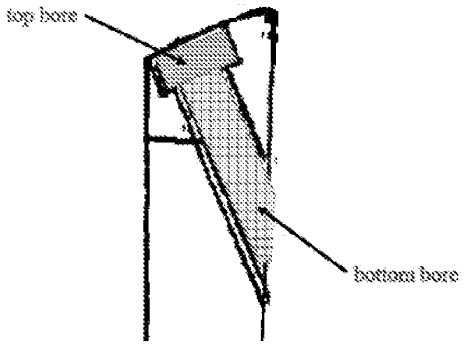
Petitioner bears the burden of stating "[h]ow the challenged claim is to be construed." 37 C.F.R. § 42.104(b)(3). But only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an AIA trial proceeding). For the purpose of this Decision, we need address only the terms "bore" and "at a terminal end."

1. "bore"

Claim 1, element 1[c][iii] and claim 12, element 12[c][iii] recite "a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member." Relying on the testimony of Mr. Dominguez, Petitioner proposes a construction of "bore" as "a usually cylindrical hole made by or as if by the turning or twisting

movement of a tool." Pet. 16 (citing Ex. 1002 ¶ 58). In this respect, Mr. Dominguez testifies that "[a] bore is a cylindrical hole made by the spinning rotation of a twist drill cutting tool. It is typically made by removing material from a solid or hollow object, similar to a tunnel or orifice." Ex. 1002 ¶ 58.

Referencing Figure 1 of Cognet, Patent Owner argues that the claim term "bore" excludes a tunnel made by "two adjacent bores." *See* Prelim. Resp. 21–25; Sur-reply 1–4. Patent Owner's position is illustrated by the following figure from its Preliminary Response. *See* Prelim. Resp. 23.



The above figure represents Patent Owner's interpretation of a portion of Cognet's Figure 1, in which a passage having two distinct diameters is labeled as having a "top bore" and a "bottom bore." *Id.* Patent Owner bases this interpretation on Mr. Dominguez's testimony that "[a] bore is a cylindrical hole. . . " (Sur-reply 2 (citing Ex. 1002 ¶ 58)), and further notes that in connection with claims 2 and 3, Petitioner refers to this portion of Cognet as comprising a "first bore" and "a smaller diameter tunnel." (Prelim. Resp. 23 (citing Pet. 23–24)).

In response, Petitioner argues that nothing in the Petition or Mr. Dominguez's declaration admits that a uniformly cylindrical shape is the only possible configuration for the claimed bore. Reply 3–4. Consistent with

this position, Petitioner argues that during prosecution of related applications, Patent Owner itself identified in the specification a "bore" that tapers along its length, and acknowledged that combination of "recess 8" and "hole 10" of the Dierks reference constituted a single bore despite having two distinct diameters. Reply 1–3 (citations omitted).[8]

On the limited record before us, and insofar as nothing in the plain language of the claims appears to limit the interior shape of a bore to a regular cylinder, as Patent Owner appears to argue, we preliminarily construe the term "bore" as a hole or passage made by or as if by the turning or twisting movement of a tool such that its interior walls have cylindrical lateral cross-sections, and which do not exclude holes or passages having tapered or stepped longitudinal cross-sections. The parties are, nevertheless, invited to further address this construction at trial.

2. "At a terminal end"

Claim 1, element 1[c][ii] and claim 12, element 12[c][ii] recite "wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body." Relying on the testimony of

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[8] Although not necessary to our determination, Patent Owner's position also appears inconsistent with the present claims. Dependent claims 8, 14, and 15 specify that "the head portion of the first member is tapered." *See* Ex. 1001, 15:61–62, 16:59–62. Given that "the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture," and/or "resides at least partially within the first bore [of the third member], we infer that the first bore of the third member may encompass a tapered or partially tapered interior aspect. *See* Ex. 1001, 15:48–50 (claim 3), 15:55–58 (claim 6). Admittedly, however, this reading of the dependent claims has not been addressed by experts for either party.

Mr. Dominguez, Petitioner argues that one of ordinary skill in the art would understand the claim phrase "at the terminal end" to indicate "a location nearer the terminal or proximal end, as opposed to merely along the shaft of the nail [(i.e., the third member)] at any location, or at the distal end." Pet. 15 (citing Ex. 1002 ¶ 55). Seeking to distinguish Simon (Ex. 1008), Patent Owner argues that Petitioner misconstrues "at a terminal end" to mean "*near* a terminal end." Prelim. Resp. 35; Sur-reply 4–5.

In support of its construction, Petitioner argues that, during prosecution of parent application serial No. 12/658,680, Patent Owner amended claim 1 to recite "a first aperture at a terminal end." Reply 4 (citing Ex. 1015, 21:10–11). According to Petitioner, "Patent Owner took the position during prosecution of the '680 patent that the separation between first aperture 1130 and terminal end 1120 illustrated in Figure 11 nevertheless provides written description support for 'the first aperture *at* a terminal end.'" Reply 5 (citing Ex. 1015, 78:12–13 (identifying "a first aperture [1130, Fig. 11, ¶ [0060] and/or 1630, Fig. 16, ¶ [0070]] at a terminal end [1120, Fig. 11, ¶ [0060]] of the second end of the second elongated body"), 108:11 (referencing "[t]he bone fusion assembly 800 of the present invention, as claimed in independent claim 1 and as shown in Figure . . . 11"), 109:10–11 ("The second elongated body further comprises a first aperture 1130 at a terminal end 1120 of the second end of the second elongated body, and a bore extending along a third axis 1102 from the first aperture 1130 to a second aperture on an exterior surface 1135 of the second screw member 810.")). According to Petitioner, "Figure 11 shows that terminal end 1120 is at the surface of element 1110, while aperture 1130 is recessed well below that surface, i.e., 'at some distance' away from it." *Id.*

Considering this prosecution history, Petitioner argues that "Patent Owner may not now argue that a comparable separation between Simon's end and hole 20 fails to do so as well." *Id.* In response, Patent Owner contends that Petitioner's argument fails because Mr. Dominguez did not expressly consider the prosecution history relied on by Petitioner. Sur-reply 4–5.[9] We do not, however, require Mr. Dominguez's guidance in reading the cited portions of the intrinsic record. In this respect, we note that claim construction is a legal determination and while expert testimony "'can shed useful light on the relevant art' . . . it is 'less significant than the intrinsic record in determining 'the legally operative meaning of claim language'." *Phillips v. AWH Corp.*, 415 f.3d 1303, 1317 (Fed. Cir. 2005) (citations omitted); *see id.* at 1318 ("a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'").

Taken as a whole, the record before us would appear to support Petitioner's contention that the aperture of claim elements 1[c][ii] and 12[c][ii] need not align precisely with the terminal end as Patent Owner argues. Consistent with our views here, we note that the District Court similarly rejected Patent Owner's construction of "terminal end" as meaning

[9] We also note Mr. Dominguez's somewhat opaque testimony seeming to suggest that, although in some circumstances the terms "nail head," "terminal end," and "nail termination" might be used synonymously, "[n]ail termination is more specific than that. It's really the very end of the nail before there's just air above it." *See* Ex. 2011.

"the very tip" of the third member, and declined to otherwise construe the term. *See* Ex. 3002, 13–15.

Further, and while we agree with Petitioner that the "at a terminal end" does not demand placement of the first aperture at the extreme proximal end of third member, the present record provides scant basis to determine the maximum distance the first aperture may be from the very tip of the third member and still fall within the scope of the asserted claims. Would the ordinarily skilled artisan understand the term to encompass a first aperture only within a few millimeters of the tip of the third member, the proximal 10% of the length of the third member, or some other value? Relatedly, we are unsure what basis one of ordinary skill would use to measure the distance between the tip of the third member and the first aperture—e.g., from the tip to the midline of the first aperture, or from the tip to the closest point of the first aperture. Accordingly, and absent a more robust discussion of the prosecution history and any other relevant evidence, we decline to further construe the meaning of this term as understood by one of ordinary skill in the art. *But see*, *e.g.*, *Micron Tech., Inc. v. Unification Techs. LLC*, IPR2021-00343, Paper 42 at 45–46, 57 (PTAB July 8, 2022) (declining to reach a final decision on the merits where the panel could not ascertain claim scope with reasonable certainty). The panel may revisit this issue on a fuller record.

D. Merits Analysis

Petitioner asserts seven grounds involving five references. Pet. 6. Patent Owner does not presently challenge the prior art status of any asserted reference. *See* Prelim. Resp. Grounds 1–3 are based on Cognet, either alone or with Brumfield or Ferrante. Grounds 4–7 are based on Simon, either

alone or with Ferrante, Cognet, or Leu. Patent Owner opposes Petitioner's reliance on Cognet and Simon in Grounds 1–3 and 4–7, respectively, for disclosing limitations recited in the independent claims. We focus below on Petitioner's anticipation grounds based on Cognet (Ground 1) and Simon (Ground 4).

1. Ground 1: Anticipation by Cognet

As Ground 1, Petitioner challenges independent claim 1 and its dependent claims 2–7 and 9 and independent claim 12 and its dependent claim 13 as anticipated by Cognet. Pet. 6, 8–32. Petitioner's challenge includes an element-by-element comparison of the claims to the cited art (*id.* at 9–32). Patent Owner opposes. Prelim. Resp. 20–25. We begin with an overview of the asserted reference and focus our analysis on the disputed elements of independent claim 1.

a) Overview of Cognet (Exhibit 1004)

Cognet discloses a device for the osteosynthesis of fractures. *See, e.g.*, Ex. 1004, code (57). Figure 1 of Cognet is reproduced below.

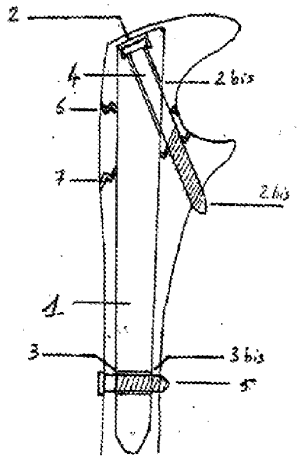
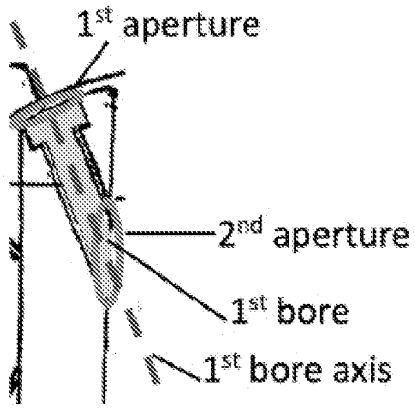


Figure 1 shows an exemplary device of Cognet in sagittal section. *Id.* at 3:21–23. According to Cognet, the device "consists of a nail (1) having a proximal orifice or tunnel (2) and at least two distal orifices facing one another or one distal tunnel (3) and into which screws are introduced, one in a proximal situation (4) and the other or others (5) in a distal situation." *Id.* at code (57).

b) Whether Cognet discloses "a first bore extending along a first bore axis from the first aperture to a second aperture"

Relying on the testimony of Mr. Dominguez, Petitioner argues that Cognet discloses each limitation of independent claim 1. Pet. 8–23; Ex. 1002 ¶¶ 38–71. Patent Owner contends that Petitioner's argument fails because Cognet fails to disclose claim element 1[c][iii]: a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member. Petitioner illustrates its position with respect to element 1[c][iii] with reference to the following illustration.



Pet. 16–17 (citing Ex. 1002 ¶ 59). The above figure shows a terminal portion of the nail member from Cognet's Figure 1 annotated to show a first bore having a first bore axis and first and second apertures. *See id.*

Patent Owner, however, contends that the illustrated portion of Cognet "discloses two bores—a top bore (the top of the 'T') with a larger diameter that may receive the head of the screw, and a smaller diameter bottom bore (the body of the 'T') through which the head of the screw cannot pass." Prelim. Resp. 24. According to Patent Owner:

> The two-bore construct of Cognet is significant here because Claims 1 and 12 require a single bore, i.e., a "first bore," that extends all the way along a first bore axis from a very specific location to another specific location: (1) from the first aperture at a terminal end of the first end to (2) a second aperture on an exterior surface of the third member. Ex. 1001 at 15:11–18, 16:24-31. But in Cognet, in order to get from the first aperture at the top of the "T" to the aperture at the bottom of the "T" (the only other aperture at the exterior surface), you must pass through *two* bores—the larger bore that represents the top portion of the "T" and the narrower bore that represents the body portion of the "T".

Id. at 24–25. So construed, Patent Owner contends that the Petition "does not show that Cognet discloses a 'first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member.'" *Id.* at 25.

Contrary to Patent Owner's analysis, we preliminarily construe a "bore" as "a hole or passage made by or as if by the turning or twisting movement of a tool such that its interior walls have a cylindrical cross-section, and which do not exclude and may include holes or passages having tapered or stepped longitudinal cross-sections." *See supra* Section II.C.1. As such, and on the limited record before us, Cognet discloses a bore and further satisfies all elements of claim phrase 1[c][iii].

c) Conclusion as to Ground 1

In view of the above preliminary construction, Petitioner establishes sufficiently that Cognet discloses claim element 1[c][iii]. Patent Owner does not dispute any other element of Ground 1 in its Preliminary Response. Having considered the evidence of record, we determine that Petitioner has established sufficiently that these remaining elements are also disclosed in Cognet. According, and solely for the purpose of institution, Petitioner has demonstrated a reasonable likelihood that Cognet anticipates claim 1.

2. Ground 4: Anticipation by Simon

As Ground 4, Petitioner challenges independent claim 1 and its dependent claims 4, 5, 8, 10, and 11 and independent claim 12 and its dependent claims 14 and 15 as anticipated by Simon. Pet. 6, 37–58. Petitioner's challenge includes an element-by-element comparison of the claims to the cited art (*id.* at 38–58). Patent Owner opposes. Prelim. Resp. 25–35. As above, we begin with an overview of the asserted reference and focus our analysis on independent claim 1.

a) Overview of Simon (Exhibit 1008)

Simon discloses a "device, method, and system for treatment or fixation of a fractured, damaged, or deteriorating bone or bones in a mid-foot region." Ex. 1008, code (57). According to Simon, the device is "an implant with both proximal and distal fastener holes, along with fastener slots in a central elongated body, for securing the implant to the appropriate osseous cortical structures of the foot." *Id.*

Figure 1 of Simon is reproduced below.

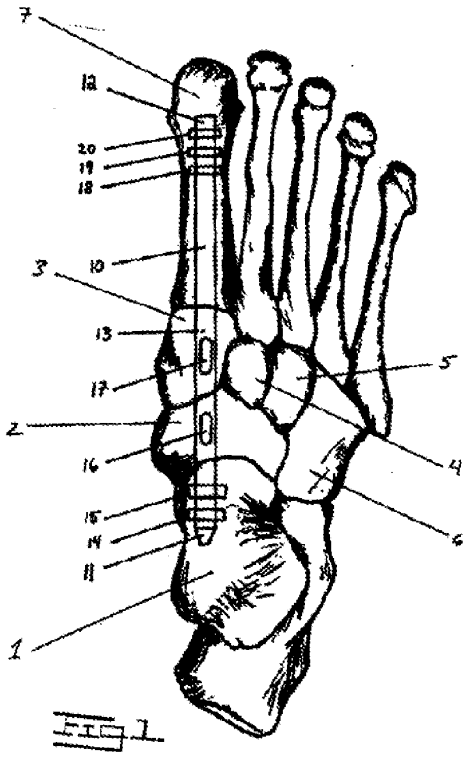


Figure 1 is a top-down view of a right human foot, depicting the bones and intramedullary nail 10 running through the mid-foot region. *Id.* ¶ 53. Simon discloses that "the proximal end **11** of the implant or intramedullary nail **10** is attached with at least one fastener []or locking screw, with two depicted in **FIG. 1**, **14** & **15**[]." *Id.* Intramedullary nail 10 includes fastener holes 16, 17, which transverse the axial central axis 13 of nail 10. *Id.* "[D]istal end **12** of the intramedullary nail **10** is attached by way of at least one fastener (or locking screw, with three depicted in **FIG. 1**, **20**, **19**, & **18**)." *Id.*

b) Whether Simon discloses "a head portion"

Relying on the testimony of Mr. Dominguez, Petitioner argues that Simon discloses each limitation of independent claim 1. Pet. 37–50; Ex. 1002 ¶¶ 111–132. Patent Owner first contends that Petitioner's argument

fails because Simon fails to disclose the head portion of claim element 1[a][ii] ("wherein the first member comprises a shaft portion having an external surface and **a head portion** having an exterior surface"). Prelim. Resp. 26–27; Sur-reply 4 (noting that Petitioner does not address the alleged failure to identify a head portion in its Reply).

As an initial matter, Petitioner appears to identify one or more of elements 18–20 of Simon's Figure 1 as the claimed first member. *See* Pet. 40. But Figure 1 of Simon is a low-resolution drawing that does not clearly differentiate elements 18–20 as having distinct head and shaft portions. *See* Ex. 1008, Fig. 1. However, as noted in the Preliminary Response, when discussing support for element 1[a][ii] in Simon, Petitioner references its parallel discussion regarding Cognet. *See* Prelim. Resp. 26; Pet. 40 (citing "section V.A.1.b" of the Petition). In this parallel discussion, Petitioner asserts that the Cognet's "screw comprises a head portion which has an exterior surface." Pet. 11 (citing Ex. 1002 ¶ 42a).

In contrast to its assertion regarding Cognet, Petitioner does not expressly state that Simon's screws have a head but, more generally, that the entirely of element 1[a][ii] is satisfied because "Simon discloses elements 18, 19, and 20 as being locking screws [Ex. 1008, [0053]), interlocking cortical screws, or transfixation screws (Ex. 1008, [0039])." *Id.* at 40 (further citing Ex. 1002 ¶ 116). And in a related discussion pertaining to the claimed second member (which does not recite a head), Petitioner further states that

> screws have an elongated body that extends from a first end (the tip of the screw) to a second end (the head of the screw) along a longitudinal axis. Ex. 1002 ¶ 42. Figure 1 of Simon discloses a second screw (second member) (elements 14 or 15 of Figure 1) (Ex. 1008, [0053]). Simon further discloses that the second screw is also a locking screw (Ex. 1008, [0053]),

> interlocking cortical screw, or transfixation screw (Ex. 1008, [0039]), and thus discloses this claim element. Ex. 1002 ¶ 117.

Id. at 40–41.

According to Patent Owner, the above statement fails to satisfy Petitioner's burden to "show 'each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference.'" Prelim. Resp. 26 (citing *Arbutus Biopharma Corp. v. Modernatx, Inc*, 65 F.4th 656, 662 (Fed. Cir. 2023)). Patent Owner further argues that any inherency argument is undercut by Mr. Dominguez's testimony that "[s]ome screws are 'headless' . . . ." *Id.* (citing Ex. 1002 ¶ 42a).

Petitioner has a better argument at this stage of the proceeding. First, on the present record, we do not read paragraph 42a of Mr. Dominguez's declaration as undercutting Petitioner's position. Paragraph 42 of his declaration generally discusses the geometry of bone screws used in orthopedic surgery. *See* Ex. 1002 ¶ 42. Quoted in full, the sentence relied on by Patent Owner states that "[s]ome screws are 'headless' or have a 'threaded conical taper' shape with threads running all the way to include the head *intended to be fully sunk in bone*." *Id.* ¶ 42a (emphasis added). Absent evidence to the contrary, we understand Mr. Dominguez's testimony to indicate that while headless screws are known, at least those at issue in his statement are used to drive the screw entirely into the bone. The quoted passage, however, does not appear to apply to screw heads that instead make contact with a fixation assembly. In the present case, for example, we understand the head of the first member to be in contact with the third member, rather than with bone. *See* claim element 1[e] ("wherein the first member couples to the third member by inserting the first end of the first

member into the first aperture, through the first bore, and out of the second aperture"); *see also* Ex. 1001, Fig. 18 (proximal end 1850 of lag screw members 1805 coupled to a tapered screw member 1815).

Second, while the Petition is not a model of clarity as to support for element 1[a][ii] in Simon, we find Petitioner's reference to Simon's Figure 1 and its disclosure of a second screw comprising "a locking screw (Ex. 1008, [0053]), interlocking cortical screw, or transfixation screw (Ex. 1008, [0039])," coupled with the testimony of Mr. Dominguez, sufficient—at least for the purpose of institution—to identify the screw head of claim element 1[a][ii]. *See* Pet. 40; Ex. 1002 ¶ 117.

c) Whether Simon discloses "a first aperture at a terminal end"

Patent Owner further argues that the Petition is defective for failing to show that Simon discloses element 1[c][ii], "wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body." Prelim. Resp. 32–36. For this element, Petitioner points to Simon Figure 2 and, in particular, fastener hole 20, which it contends "is at the terminal end [of the third elongated body] and not merely along the shaft." *See* Pet. 42–44 (citing Ex. 1008, Fig. 2, ¶ 54; Ex. 1002 ¶ 121). The parties' positions as to this element depend on their respective constructions of "at the terminal end." As discussed in section II.C.2, above, we do not agree with Patent Owner's position that "at a terminal end" demands placement of the first aperture at the extreme proximal end of third member, but note that the present record does not allow us to determine the maximum distance the first aperture may be from the very tip of the third member and still fall within the scope of the asserted claims. With this background, and solely for the purpose of institution, we credit Mr. Dominguez's presently

unopposed testimony that one of ordinary skill in the art would understand hole 20 in Simon's Figure 2 to be "at the terminal end of the third elongated body." Thus, and although Patent Owner's position might prove persuasive on a better developed record, we find that for the purpose of institution, Petitioner has sufficiently established that Simon discloses this element 1[c][ii].

d) Conclusion as to Ground 4

For the reasons set forth above, Petitioner establishes sufficiently that Simon discloses claim elements 1[a][ii] and 1[c][ii]. Patent Owner does not dispute any other elements of Ground 4 in its Preliminary Response. Having considered the evidence of record, we determine that Petitioner has established sufficiently that these remaining elements are also disclosed in Simon. According, and solely for the purpose of institution, Petitioner has established a reasonable likelihood that Simon anticipates claim 1.

3. Other Claims and Grounds

Other than the claim terms discussed above (elements 1[c][iii] with respect to Cognet, and elements 1[a][ii] and 1[c][ii] with respect to Simon), Patent Owner does not presently dispute Petitioner's argument that each element is found within the four corners of the primary references. Nor, with respect to its obviousness grounds, does Petitioner argue that any of elements 1[c][iii], 1[a][ii] or 1[c][ii] are obvious in view of Cognet or Simon combined with any other reference. Accordingly, and having considered the evidence of record, Petitioner has shown sufficiently a reasonable likelihood that the challenged claims are unpatentable for the reasons set forth in Grounds 1–7.

E. Discretionary Denial of Institution under 35 U.S.C. § 314(a)

Patent Owner contends that we should exercise our discretion to deny the Petition in favor of the related litigation taking place in the U.S District Court for the District of Arizona. Prelim. Resp. 5. Petitioner takes a contrary position, arguing that the Board should not deny institution. Pet. Reply 1–6.[10] We address the parties' arguments below.

1. Legal standard

Under our precedential decision in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12–17 (PTAB May 13, 2020), the Board, in deciding "whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding," should consider a variety of factors, and, in evaluating these factors, "takes a holistic view of whether efficiency and integrity of the system are best served." *Fintiv*, Paper 11 at 5–6; *see also Samsung Elecs. Am., Inc. v. Uniloc 2017 LLC*, IPR2020-00117, Paper 11 at 7–11 (PTAB May 28, 2020) (same). According to Patent Owner, granting the Petition for *inter partes* review would be an inefficient use of Board resources and is contrary to Congress's intent in establishing IPR proceedings.
Prelim. Resp. 17.

In *Fintiv*, the Board set forth six factors relating to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding:

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[10] The parties addressed discretionary denial in the Petition and Preliminary Response but did not request or provide further briefing on this issue. *See* Ex. 3001 (authorizing Petitioner's request for leave to file a Reply addressing Patent Owner's claim constructions); Reply; Sur-reply.

1. Whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. Proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
3. Investment in the parallel proceeding by the court and the parties;
4. Overlap between issues raised in the petition and in the parallel proceeding;
5. Whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. Other circumstances that impact the Board's exercise of discretion, including the merits.

Fintiv, Paper 11 at 6.

Particularly applicable to *Fintiv* factor 6, we are also guided by the USPTO's *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation*, June 21, 2022 (the "Guidance").[11] As stated by the Guidance, the Board will not rely on the *Fintiv* factors to discretionarily deny institution in view of parallel district court litigation when: (1) a petition presents compelling evidence of unpatentability; (2) a petitioner presents a stipulation (a "*Sotera* stipulation") not to pursue in a parallel proceeding the same grounds or any grounds that could have reasonably been raised before the PTAB[12]; and (3) if all other *Fintiv* factors weigh against exercising discretion to deny institution, or are

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[11] *Available at* https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf (last visited September 24, 2023).

[12] *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (PTAB December 1, 2020) (precedential).

neutral, the proximity to trial should not alone outweigh all of those other factors.[13] Guidance 1–8.

2. Analysis

We consider the above interrelated factors and Guidance, as they apply to the facts of the Petition.

a) *Fintiv* Factor 1: whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted

Under the first *Fintiv* factor, we consider "whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted." *Fintiv*, Paper 11 at 6. On August 3, 2023, Petitioner Fusion Orthopedics filed a motion for stay of the district court litigation. *See* Ex. 3003. On August 17, Patent Owner Extremity Medical filed a response in opposition, to which Petitioner filed an August 24 reply. *Id.* The district court has not acted on that motion. *Id.*

Patent Owner contends that "[i]t is not likely that a stay will be granted in the Parallel District Court Case." Prelim. Resp. 7. In support, Patent Owner cites the "timing and advanced stage of the Parallel District Court Case" (addressed in *Fintiv* Factor 3, *infra*) and the concluding paragraph of the court's case management order. *Id.* (citing Ex. 2003 ¶ 11). The referenced portion of the case management order states:

> 11. The Deadlines Are Real. **The parties are advised that the Court intends to enforce the deadlines set forth in this Order and should plan their litigation activities accordingly. Even if all parties stipulate to an extension, the Court will**

[13] The Guidance notes that the *Fintiv* factors do not apply to parallel litigation before the U.S. International Trade Commission (ITC). Guidance 2–3, 5–7.

> **not extend the deadlines, absent good cause to do so. The pendency of settlement discussions or the desire to schedule mediation does not constitute good cause, unless discovery is substantially complete and the extension requested is minimal**.

Ex. 2003 ¶ 11.

On the present record, we decline to speculate whether the pending motion to stay might be successful. Accordingly, *Fintiv* Factor 1 is neutral.

b) *Fintiv* Factor 2: proximity of the court's trial date to the Board's projected statutory deadline for a final written decision

Under the second *Fintiv* factor, we consider the "proximity of the court's trial date to the Board's projected statutory deadline for a final written decision." *Fintiv*, Paper 11 at 6. Petitioner argues that the Judge in the district court litigation has not yet set a trial date. Pet. 69. Patent Owner calculates a projected trial date of around August 28, 2024, more than two months before a Final Written Decision would be due if this case were instituted. Prelim. Resp. 9 (citing Ex. 2009).

Fintiv Factor 2 discusses consideration of a trial date. The Director's Guidance states that it may be useful to compare a trial date with evidence of a median time-to-trial. Guidance 8. The purpose is to ascertain the likelihood of the scheduled trial date actually occurring on or around that date. *Id.* at 8 ("Stakeholders correctly noted that scheduled trial dates are unreliable and often change[,]" and a "scheduled trial date . . . is not by itself a good indicator of [when] the district court trial will occur."). The Guidance does not state that median time-to-trial statistics are themselves a trial date, or otherwise replace consideration of a trial date under *Fintiv* Factor 2. In the

circumstances here, the usefulness of the median time-to-trial statistics is less clear and we will not speculate on when a trial may be scheduled.

We also note that, even if we were to consider the trial date statistics cited by Patent Owner, Exhibit 2009 does not support their argument. Although Patent Owner characterizes the "*median* time-to-trial" as 28 months, Exhibit 2009 actually shows 28 months as the "*average* time-to-trial," while the median time-to-trial is shown as being *34* months. Ex. 2009. The Director's Guidance states that, "when considering the proximity of the district court's trial date to the date when the PTAB final written decision will be due, the PTAB will consider the *median time* from filing to disposition of the civil trial for the district in which the parallel litigation resides." Guidance 3. Using the median time-to-trial statistics from Exhibit 2009 would project a trial date of around February 28, 2024, which is more than 3 months *after* our Final Written Decision date.[14]

Accordingly, *Fintiv* Factor 2 weighs against exercising discretion to deny institution.

c) *Fintiv* Factor 3: investment in the parallel proceeding by the court and the parties

Under the third *Fintiv* factor, we consider the "investment in the parallel proceeding by the court and the parties." *Fintiv*, Paper 11 at 6. Petitioner contends that this "case is in the early stages of discovery and a

[14] Further, the Director's Guidance cites to a particular website for determining median time-to-trial statistics (https://www.uscourts.gov/statistics-reports/analysis-reports/federal-court-management-statistics). Guidance 3, fn.4. These statistics report a median time-to-trial of 37.3 months, which would push the projected trial date even further past our Final Written Decision date.

claim construction hearing for the '166 patent has not yet occurred." Pet. 69. But as Patent Owner makes clear, Petitioner's assertion is outdated and incorrect. *See* Prelim. Resp. 9–11. In particular, Patent Owner presents a timeline illustrating that, as of the August 23, 2023, filing of the Preliminary Response,

> the Parallel District Court Case has been pending for almost 16 months, claim construction is over, document discovery is on the verge of completion, fact depositions are scheduled to be completed in just over a month, and expert reports (along with potentially some expert depositions) will be completed by the time the Board is expected to issue its Institution Decision.

Id. at 10–11 (including illustrated timeline); *see also id.* at 5 (further stating that "[a]ny Final Written Decision here (expected in November 2024), would come months after dispositive motions (due January 12, 2024) and also likely after trial)."

Petitioner has not contested Patent Owner's timeline, which appears generally consistent with our reading of the court's docket. *See generally* Ex. 3003. Considering the posture of the District Court proceeding and the investment by the court and parties, *Fintiv* Factor 3 weighs marginally in favor of exercising discretion to deny institution.

d) *Fintiv* Factor 4: overlap between issues raised in the petition and in the parallel proceeding

Under the fourth *Fintiv* factor, we consider the "overlap between issues raised in the petition and in the parallel proceeding." *Fintiv*, Paper 11 at 6. Upon filing the Petition, Petitioner asserted that "[a]t present, it is unclear how much overlap there will be between the two proceedings." Pet. 70. Petitioner has not, however, presented a *Sotera* stipulation, or any type of stipulation limiting the grounds it intends to pursue in the parallel

proceedings. *See, e.g.*, *Sand Revolution II, LLC v. Continental Intermodal Grp. – Trucking LLC*, IPR2019-01393, Paper 24 at 12 (PTAB June 16, 2020) (informative). To the contrary, Patent Owner asserts that "at trial . . . Petitioner has reserved its ability to present the exact same unpatentability arguments it is advancing here." Prelim Resp. 5. Moreover, Patent Owner explains, all 15 claims of the '166 patent are challenged in both proceedings based on similar citations to substantially the same references—Cognet, Simon, Brumfield, and Ferrante. *See id.* at 12–13 (citing Ex. 2007, 2, 3, 8–63). Although Patent Owner admits that Petitioner does not assert Leu in the related district court litigation, this reference is only raised here with respect to Ground 7. *See id.* at 13.

Considering the present record, we agree with Patent Owner that "the Petition asserts the same claims and uses substantially the same evidence as in the Parallel District Court Case. This factor . . . weighs in favor of denying the Petition." *Id.*

e) *Fintiv* Factor 5: whether the petitioner and the defendant in the parallel proceeding are the same party

Under the fifth *Fintiv* factor, we consider "whether the petitioner and the defendant in the parallel proceeding are the same party." *Fintiv*, Paper 11 at 6. Petitioner here is the defendant in the related District Court Litigation. Pet. 70; Prelim. Resp. 2. Although this factor may, standing alone, be neutral, under these circumstances in which the trial date is not set and may occur after our Final Written Decision date (see discussion of *Fintiv* factor 2, above), we determine that the fifth *Fintiv* factor weighs against discretionary denial of institution.

f) *Fintiv* Factor 6: other circumstances that impact the Board's exercise of discretion, including the merits

Under the sixth *Fintiv* factor, we consider "other circumstances that impact the Board's exercise of discretion, including the merits." *Fintiv*, Paper 11 at 6. In this respect, the Director's Guidance addresses "the potential for inefficiency and gamesmanship in AIA proceedings." Guidance 1. Possibly implying that Petitioner is engaging in the latter conduct, Patent Owner several times points out that Petition was filed on the last possible day permitted under 35 U.S.C § 315(b). *See* Prelim. Resp. 1, 5. While Petitioner's timing undoubtedly contributed to the advanced stage of the parallel district court proceeding, filing a petition within the statutory limit set by congress, in and of itself, does not weigh in favor of denying institution. *See* 35 U.S.C § 315(b) (stating that a petition must be filed no more than one year after "the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent").

As to the merits, we determined and have discussed above that Petitioner establishes a reasonable likelihood of prevailing with respect to the challenged claims based on the asserted grounds. As discussed in detail above, the evidence and arguments presented by Petitioner meet our standard for instituting an *inter partes* review. Under these circumstances, we determine that the sixth *Fintiv* factor is neutral.

3. Conclusion

Because *Fintiv* Factors 1–5, when weighed together, do not favor exercising our discretion to deny institution, there is no need to determine whether the Petition establishes compelling merits. *See* Guidance 4–5

(explaining that compelling merits can overcome what would otherwise warrant a discretionary denial under *Fintiv* analysis); *see also CommScope Techs. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 at 6 (PTAB Feb. 27, 2023) (precedential) ("[t]he Board should first assess *Fintiv* factors 1–5; if that analysis supports discretionary denial, the Board should engage the compelling merits question."). For the reasons stated above, the *Fintiv* factors do not support exercising our discretion to deny institution.

F. Discretionary Denial of Institution under 35 U.S.C. § 325(d)

In their arguments for *Fintiv* Factor 6, Patent Owner also appears to argue that the Petition should be denied under 35 U.S.C. § 325(d) because Cogent was considered during prosecution of the '166 patent. Prelim. Resp. 14–15 (citing Exs. 1001, 2010). Under the first prong of the *Advanced Bionics* framework, we consider "whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office." *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8 (PTAB Feb. 13, 2020) (precedential).

We agree that Cogent appears to have been cited to the Office during prosecution in an Information Disclosure Statement ("IDS"), along with hundreds of other references. *See* Ex. 2010. Notably, however, Patent Owner does not argue that Simon was previously disclosed to the Office. Nor is Simon listed on the face of the challenged patent. *See* Ex. 1001, code (56). That Simon—the primary reference in four of Petitioner's seven Grounds—does not appear to have been previously presented to the Office, thus indicating that part 1 of the *Advanced Bionics* framework is not satisfied for

those grounds and 35 U.S.C. § 325(d) is not sufficiently implicated. Nevertheless, for completeness, we briefly address part 2 of the analysis.

Under the second part of the *Advanced Bionics* framework, we consider "whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims." *Advanced Bionics*, Paper 6, 8. As discussed in Section II.D.1., however, we find that Petitioner has established a reasonable likelihood that Cogent discloses all the limitations of claim 1. Therefore, we find that, on the current record, the Examiner erred by overlooking the relevant disclosure from Cogent discussed *supra*.

Accordingly, and for the reasons discussed above, we decline to exercise our discretion to deny institution under 35 U.S.C. § 325(d).

III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review is instituted on claims 1–15 for all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, *inter partes* review of the '166 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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