37. (New) The implant of claim 31, wherein said implant includes at least one visualization aperture extending through at least one of said posterior side and said lateral side.

38. (New) The implant of claim 31, wherein a portion of said implant adjacent said distal side is tapered.

39. (New) The implant of claim 31, further including at least one anti-migration features comprising at least one of a set of ridges formed in the top surface, a set of ridges formed in the bottom surface, a set of ridges on the top and bottom surfaces, one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.

40. (New) The spinal fusion implant of claim 35, further including at least one receiving element at least partially defined along said proximal side.

41. (New) The spinal fusion implant of claim 40, wherein said receiving element is engageable with an insertion instrument.

42. (New) The spinal fusion implant of claim 41, wherein said receiving element comprises a threaded aperture.

43. (New) The spinal fusion implant of claim 42, wherein said receiving implant further comprises a slot extending from said threaded aperture.

REMARKS

Claims 1-5 and 31-43 are currently pending in the application. Through this response claims 1-5 are amended, new claims 31-43 are added, and claims 6-30 are cancelled without prejudice. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

In an effort to advance prosecution on the merits, the Applicants have amended independent claim 1 and cancelled independent claim 14 in order to define more particularly the subject matter sought to be patented. The amendments are made without prejudice and the Applicants reserve the right to further pursue the original subject matter, for example, in a continuation application.

Claim Rejections

A. 35 U.S.C. 102(b) – Lin

Claims 1-5, 27 and 28 were rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (US Pub. 2002/0116008 A1). With the cancellation of claims 27 and 28 the rejections of those claims are now moot. The Applicants respectfully traverse the remaining rejections as set forth below.

In order for a reference to anticipate the present claimed invention under 35 U.S.C. 102(b), it must be shown that each and every element of the claim can be found in the reference. If it can be shown that one element of the claim is missing or not met by the cited reference, the rejection must be withdrawn as inappropriate.

Claim 1, as currently amended, is directed to a spinal fusion implant positionable within an interbody space between a first vertebral endplate and a second vertebral endplate, said interbody space being at least partially defined by a posterior aspect, and anterior aspect, and opposing lateral aspects. The implant comprises a top surface including a plurality of ridges to engage said first vertebral endplate when said implant is positioned within the interbody space, a bottom surface including a plurality of ridges to engage said second vertebral endplate when said

implant is positioned within the interbody space, a distal side, a proximal side, a first side wall defining an anterior side when said implant is positioned within the interbody space, and a second side wall defining a posterior side when said implant is positioned within the interbody space; wherein said implant has a length extending from said proximal side to said distal side, a width extending from said first side wall to said second side wall, and a height extending from said top surface to said bottom surface; wherein said length is so dimensioned as to extend between said lateral aspects of said interbody space when said implant is positioned within the interbody space and is at least two and a half times greater than said width; wherein said width is greater than said height; said implant further including first and second fusion apertures that each extend between the top and bottom surfaces and permit bone growth between the first vertebral endplate and the second vertebral endplate when said implant is positioned within the interbody space, said first and second fusion apertures being adjacent to one another and separated by a medial support; said implant further including at least one radiopaque marker situated between said top and bottom surfaces.

The Lin reference is silent with regard to at least one element found in amended claim 1, such that the rejection for anticipation should be withdrawn. By way example, Lin is silent as to the claim 1 element of having a length that is at least two and a half times greater than the width, as well as having a length dimensioned to extend between the lateral aspects of the interbody space. By way of further example, Lin also fails to disclose, among other things, an implant where the width is greater than the height, an implant having first and second fusion apertures separated by a medial support, and an implant with at least one radiopaque marker situated between top and bottom surfaces.

Because the Lin reference is silent to at least one element of amended Claim 1, Applicants respectfully submit that the rejection under 35 USC 102(b) should be withdraw in favor of an indication of allowance, which is hereby earnestly solicited. Furthermore, claims 2-5 are dependent upon independent claim 1 and should be allowable at least for the reasons set forth for the allowability of claim 1, as well as the additional limitations they contain. New claims 31-

34 also depend from claim 1 and should also be allowable for the reasons set forth for the allowability of claim 1 and the additional limitations they contain. The Applicants believe claims 1-5 and 31-34 are in condition for allowance and respectfully request a favorable indication to that effect.

The Applicants respectfully submit that Lin also fails to disclose at least one element of new claim 35. By way of example, Lin fails to disclose the claim 35 element of having an implant with a generally rectangular shape. Lin also fails to disclose at least the additional elements of having an implant with a length extending from a proximal side to a distal side that is at least 40mm, an implant having first and second fusion apertures separated by a medial support, and an implant with at least one radiopaque marker situated between top and bottom surfaces, among others. Claim 35 is believed to be in condition for allowance and an indication to that effect is earnestly solicited. Claims 36-43 depend from claim 35 and are also believed to be in condition for allowance and an indication to that effect is respectfully requested.

B. 35 U.S.C. 103(a) – Lin in view of Steffee

Claims 11-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lin in view of Steffee (US Pat. 5,716,415). The rejection is now moot in light of the cancellation of claims 11-13.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Reconsideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

NUVASIVE, INC.

/roryschermerhorn/

By: _____

Rory Schermerhorn, Esq.
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January 21, 2008

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (12-08)
Approved for use through 01/31/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	11/093,409	Filing Date	2005-03-29	Docket Number (if applicable)	104US1	Art Unit	3733
First Named Inventor	Matthew Curran			Examiner Name	Jerry L. Cumberledge		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 502040

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (12-08)
Approved for use through 01/31/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/roryschermerhorn/	Date (YYYY-MM-DD)	2009-01-21
Name	Rory Schermerhorn	Registration Number	58148

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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

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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/093,409	03/29/2005	Matthew Curran	104US1	6640

30328 7590 09/17/2008

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EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

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

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

Office Action Summary	Application No.	Applicant(s)	
	11/093,409	CURRAN ET AL.	
	Examiner	Art Unit	
	JERRY CUMBERLEDGE	3733	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *20 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,11-18 and 24-30* is/are pending in the application.

4a) Of the above claim(s) *14-18,24-26,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11-13,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

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

DETAILED ACTION

Claim Rejections - 35 USC § 102

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

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

Claims 1-5, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (US Pub. 2002/0116008 A1).

Lin discloses a spinal fusion system comprising an interbody spinal fusion implant (Fig. 9, ref. 100), including at least in part a top surface for contacting a first vertebral endplate (Fig. 9), a bottom surface for contacting a second vertebral endplate (Fig. 9), at least one fusion aperture (Fig. 9, ref. 104) extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side (Fig. 9, lower portion), a proximal side (Fig. 9, upper portion) having a pair of receiving apertures (Fig. 9, ref. 106a,b) separated by a distance (Fig. 9)(Fig. 14) and situated within the boundaries of the proximal side (Fig. 9) for engaging an insertion instrument, and two lateral sides (Fig. 9); and an insertion instrument (Fig. 17, ref. 200), including a generally elongated tubular member (Fig. 17, ref. 212) having a distal opening (Fig. 17) and a proximal opening (Fig. 17), a generally elongated shaft member having a distal end and a proximal end (Fig. 17, ref. 214) and being generally dimensioned to be inserted through the elongated tubular member (Fig. 17) such that the distal end extends beyond the distal opening (Fig. 17, i.e. ref. 210) and

the proximal end extends beyond the proximal opening (Fig. 17, near ref. 230), and the distal end including an implant engagement feature (Fig. 18, ref. 232); and a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant (paragraph 0036). The implant is substantially radiolucent and composed of non-bone material (paragraph 0039). The implant includes at least one visualization aperture (e.g. Fig. 26, ref. 310) extending through at least one of the lateral sides. The top and bottom surfaces of the implant are at least one of generally parallel with respect to each other, and generally angled with respect to each other to better match the natural curvature of the spine (Fig. 9). The implant further includes anti-migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement (Fig. 1, ref. 12). The anti-migration features are at least one of a set of ridges formed in the top surface, a set of ridges formed in the bottom surface, and a set of ridges on the top and bottom surfaces (Fig.1). The anti-migration features are at least one of one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surfaces (Fig. 1).

Claim Rejections - 35 USC § 103

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

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

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (US Pub. 2002/0116008 A1) in view of Steffee (US Pat. 5,716,415).

Lin et al. discloses the claimed invention except for the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant. The elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature. The securing mechanism is, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device. Lin, however, does disclose a mechanism that comprises a threaded engagement (paragraph 0035) that includes

prongs that extend into apertures of an implant in order to grip and manipulate an implant (paragraph 0035)(paragraph 0036).

Steffee discloses a spinal fusion system that comprises a generally elongated tubular member which comprises a tubular lock member (Fig. 5, near ref. 100, ref. 102), the generally elongated shaft member comprises an elongated fork member (Fig. 4, ref. 86), and the engagement feature comprises two prongs (Fig. 4, ref. 136) extending from a pair of clamping arms (Fig. 4, ref. 130) and dimensioned to engage the two receiving apertures of the implant (Fig. 4)(Fig. 15)(Fig. 10). The elongate fork member includes a taper feature (Fig. 7, ref. 132) situated between the clamping arms (Fig. 7, ref. 130) and the proximal end (Fig. 7, near ref. 128) of the elongate fork member and the tubular lock member (Fig. 5, near ref. 100), ref. 102) includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature (Fig. 5, ref. 100). The securing mechanism includes, at least in part, a threaded region situated near the proximal end of the elongated fork member (Fig. 7, ref. 128), and a complimentary threaded region (Fig. 4, ref. 120) near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening (Fig. 4), wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions (Fig. 4), advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the

receiving aperture and releasably securing the implant to the insertion device (Fig. 4). Steffee discloses that this mechanism is used to grip and manipulate an implant (column 4, lines 36-60).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted a mechanism as taught by Lin et al, with a mechanism as taught by Steffee, in order to achieve the predictable result of gripping and manipulating an implant.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

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 http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

Notice of References Cited	Application/Control No. 11/093,409	Applicant(s)/Patent Under Reexamination CURRAN ET AL.	
	Examiner JERRY CUMBERLEDGE	Art Unit 3733	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2002/0116008 A1	08-2002	Lin et al.	606/99
*	B	US-2003/0109928 A1	06-2003	Pasquet et al.	623/17.11
*	C	US-6,159,211	12-2000	Boriani et al.	606/279
*	D	US-2005/0203538 A1	09-2005	Lo et al.	606/099
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11093409	CURRAN ET AL.
	Examiner	**Art Unit**
	Cumberledge, Jerry	3733

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	02/12/2007	02/27/2008	09/12/2008						
	1	÷	✓	✓						
	2	÷	✓	✓						
	3	÷	✓	✓						
	4	÷	✓	✓						
	5	÷	✓	✓						
	6	÷	✓	-						
	7	÷	✓	-						
	8	÷	✓	-						
	9	÷	✓	-						
	10	÷	✓	-						
	11	÷	✓	✓						
	12	÷	✓	✓						
	13	÷	✓	✓						
	14	÷	N	N						
	15	÷	N	N						
	16	÷	N	N						
	17	÷	N	N						
	18	÷	N	N						
	19	÷	N	-						
	20	÷	N	-						
	21	÷	N	-						
	22	÷	N	-						
	23	÷	N	-						
	24	÷	N	N						
	25	÷	N	N						
	26	÷	N	N						
	27			✓						
	28			✓						
	29			N						
	30			N						

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11093409	CURRAN ET AL.
	Examiner	Art Unit
	JERRY CUMBERLEDGE	3733

SEARCHED

Class	Subclass	Date	Examiner
623	17.11-17.16	2/27/2008	JLC
606	99	2/27/2008	JLC
	Updated Search	9/12/2008	JLC

SEARCH NOTES

Search Notes	Date	Examiner
Inventor Name Search Performed	2/27/2008	JLC

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of	)	
	)	
MATTHEW CURRAN	)	Group Art Unit: 3733
	)	
App. Ser. No. 11/093,409	)	
	)	Examiner: Jerry L. Cumberledge,
Filed: March 29, 2005	)	
	)	
For: SYSTEMS FOR METHODS FOR SPINAL FUSION	)	

Certificate of Transmission: I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on June 19, 2008:

Signature: /rory schermerhorn/
Name: Rory Schermerhorn

RESPONSIVE AMENDMENT

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

Dear Sir:

In response to the Office Action mailed on March 18, 2008, having a three-month shortened period for response that expires on June 18, 2008, please amend the application as follows:

IN THE CLAIMS:

1. (Currently amended) A spinal fusion system comprising;

an interbody spinal fusion implant, including at least in part a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having ~~at least one~~ a pair of receiving apertures separated by a distance and situated within the boundaries of the proximal side for engaging an insertion instrument, and two lateral sides; and

an insertion instrument, including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature; and

a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant.

2. (Original) The spinal fusion system of Claim 1, wherein the implant is substantially radiolucent and composed of non-bone material.

3. (Original) The spinal fusion system of Claim 1, wherein the implant includes at least one visualization aperture extending through at least one of the lateral sides.

4. (Original) The spinal fusion system of Claim 1, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other, and generally angled with respect to each other to better match the natural curvature of the spine.

5. (Currently amended) The spinal fusion system of Claim 1, wherein the implant further includes anti-migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement_~~, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface~~.

6. – 10. (Cancelled)

11. (Currently amended) The spinal fusion system of Claim 1~~0~~, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.

12. (Original) The spinal fusion system of Claim 11, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.

13. (Original) The spinal fusion system of Claim 12, wherein the securing mechanism is, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device.

14. (Withdrawn - Currently Amended) A method of spinal fusion, comprising the steps of:

(a) releasably securing a spinal fusion implant to an insertion instrument, the spinal fusion implant including a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture

extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having ~~at least one~~ a pair of receiving apertures separated by a distance and situated within the boundaries of the proximal side for engaging an insertion instrument, and two lateral sides, and the insertion instrument including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature;

(b) introducing the spinal fusion implant to a prepared space between adjacent vertebral end plates and properly positioning the implant within the space;

(c) releasing the insertion instrument from the properly positioned implant and withdrawing the insertion instrument from the surgical corridor.

15. (Withdrawn) The spinal fusion method of Claim 14, wherein the implant is substantially radiolucent and composed of non-bone material

16. (Withdrawn) The spinal fusion method of Claim 14, wherein the implant includes at least one visualization aperture extending through at least one of the lateral sides.

17. (Withdrawn) The spinal fusion method of Claim 14, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other, and generally angled with respect to each other to better match the natural curvature of the spine.

18. (Withdrawn - Currently Amended) The spinal fusion method of Claim 14, wherein the implant further includes anti-migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement. ~~, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.~~

19. – 23. (Cancelled)

24. (Withdrawn - Currently Amended) The spinal fusion method of Claim ~~24~~14, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.

25. (Withdrawn) The spinal fusion method of Claim 24, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.

26. (Withdrawn) The spinal fusion method of Claim 24, including a securing mechanism for releasbly securing the engagement features in the receiving apertures of the implant, the securing mechanism including, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device.

27. (New) The spinal fusion system of Claim 5, wherein the anti-migration features are at least one of a set of ridges formed in the top surface, a set of ridges formed in the bottom surface, and a set of ridges on the top and bottom surfaces.

28. (New) The spinal fusion system of Claim 5, wherein the anti-migration features are at least one of one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surfaces.

29. (Withdrawn - New) The spinal fusion method of Claim 18, wherein the anti-migration features are at least one of a set of ridges formed in the top surface, a set of ridges formed in the bottom surface, and a set of ridges on the top and bottom surfaces.

30. (Withdrawn - New) The spinal fusion method of Claim 18, wherein the anti-migration features are at least one of one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surfaces.

REMARKS

Claims 1-5, 11-13, 27, and 28 are currently pending in this application. Through this response claims 1, 5 and 11 are amended, claims 6-10, and 19-23 are cancelled without prejudice, and claims 27-28 are added. No new matter has been introduced. Claims 14-18, 24-26 and 29-30 currently stand as withdrawn. Withdrawn claims 14, 18, and 24 are amended, and new claims 29-30 were added and withdrawn. In the Office Action mailed on March 18, 2008 ("Office Action"), claims 1-13 were rejected and the drawings were objected to. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

In order to advance prosecution on the merits, Applicants have amended the pending independent claim 1 in order to define more particularly the subject matter sought to be patented, without prejudice to pursue the original subject matter, for example, in a continuation application.

Drawings

On page 3 of the Office Action, the Examiner objected to Figures 17-23, stating the figures were blurry and indistinct. In response, applicants have submitted replacement figures, including Figures 17-23 on 4 replacements sheets, and respectfully ask the Examiner to remove the objection of the figures.

Claim Rejections

A. 35 U.S.C. 102(b) - Steffee

Claims 1-5 and 10-13 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,716,415 to Steffee. The rejection of claim 10 is moot as claim 10 is now cancelled. Applicants respectfully traverse the remaining rejections as set forth below.

In order for a reference to anticipate the present claimed invention under 35 U.S.C. 102(b), it must be shown that each and every element of the claim can be found in the reference.

If it can be shown that one element of the claim is missing or not met by the cited reference, the rejection must be withdrawn as inappropriate.

Claim 1, as presently amended, describes a spinal fusion system comprising: an interbody spinal fusion implant, including at least in part a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having *a pair of receiving apertures separated by a distance and situated within the boundaries of the proximal side for engaging an insertion instrument*, and two lateral sides; and an insertion instrument, including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature; and
a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant.

The Steffee reference appears to be silent with regard to at least one element found in amended claim 1, such that the rejection for anticipation should be withdrawn. The Steffee reference does not disclose at least the claim 1 element of having "a pair of receiving apertures separated by a distance and situated within the boundaries of the proximal side." On the contrary, Steffee discloses an implant that includes a pair of recesses in which an engagement instrument grasps the exterior side surfaces of the implant. The implant described in Steffee includes end surfaces (30, 32), side surfaces (20, 22), and upper and lower surfaces (24, 26). The end surfaces 30 and 32 of Steffee correlate to the proximal and distal sides of the implant of claim 1, respectively. Side surfaces 20, 22 and upper and lower surfaces 24, 26, correlate to the lateral sides and top and bottom surfaces of the implant of claim 1. Again, claim 1 requires a pair of receiving apertures to be situated in the proximal side. Steffee however, teaches that the recesses (60, 62) (for engaging an insertion instrument) are situated in the side surfaces of the implant.

Col. 3, lns. 26-28; col. 3, ln. 37-38. "The recesses 60 and 60 may be located anywhere on the [side] surfaces 20 and 22." Col. 3, ln. 35, 35. To hold the implant, Steffee describes an insertion instrument with a pair of extensions (136) that clamp along the exterior of the implant and engaging the side surfaces 20, 22 in the recesses 60, 62. Assuming, *arguendo*, that the recesses 60, 62 are considered by the examiner to be included in the proximal side simply because they extend along the side surface and meet the end surface 30, the Applicants submit that this still lacks any teaching of the claim1 element of being situated "**within** the boundaries of the proximal side." Instead, each recess would only form a part of the outer boundary of the end surface.

The configuration of the implant of claim 1 with a pair of receiving apertures "situated within the boundaries of the proximal end" may provide significant advantages over that shown in Steffee. For example, by having the apertures of the implant located within the boundaries of the proximal side, the distal end of the insertion instrument can be created with a smaller profile than the implant (e.g. the engagement features of the insertion instrument do not need to have dimensions at least as big or bigger than an entire side of the implant), thus allowing the clinician to better visualize the implant and the surrounding tissue while inserting the implant. In comparison, the implant of Steffee requires an insertion instrument with a larger distal profile (see figures 10 and 12 in which the clamping extensions protrude from each side surface of the implant) in order to allow for the extensions to clamp the side surfaces. The smaller profile, with engagement features engaging the interior of the implant as opposed to the exterior (as in Steffee), provides further advantage in that it decreases the possibility of interference (such as, for example, friction between the engagement features and the adjacent vertebra during either insertion of the implant or removal of the insertion tool) or inadvertent contact between insertion instrument and surrounding body tissue (such as, for example, delicate nerves or blood vessels that may be proximate to the target site).

Because Steffee fails to teach or disclose at least one claimed feature in the independent claim 1, Applicants respectfully submit that the rejection under 35 USC 102(b) should be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.

Furthermore, claims 2-5,10-13, and 27-28 are dependent upon claim 1 and should be allowable at least for the reasons set forth for the allowability of claim 1, as well as the additional limitations they contain. The Applicants believe these claims to be in condition for allowance and respectfully request a favorable indication in that regard.

B. 35 U.S.C. 103(a) - Steffee in view of Boyd

Claims 6-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Steffee in view of US Patent No. 5,797,917 to Boyd. The rejection is now moot in light of the cancellation of claims 6-9.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Reconsideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

NUVASIVE, INC.

/rory schermerhorn/

By: _____

Rory Schermerhorn, Esq.
Registration No. 58,148

4545 Towne Centre Court
San Diego, CA 92121
Tel.: (858) 243-0029

June 19, 2008

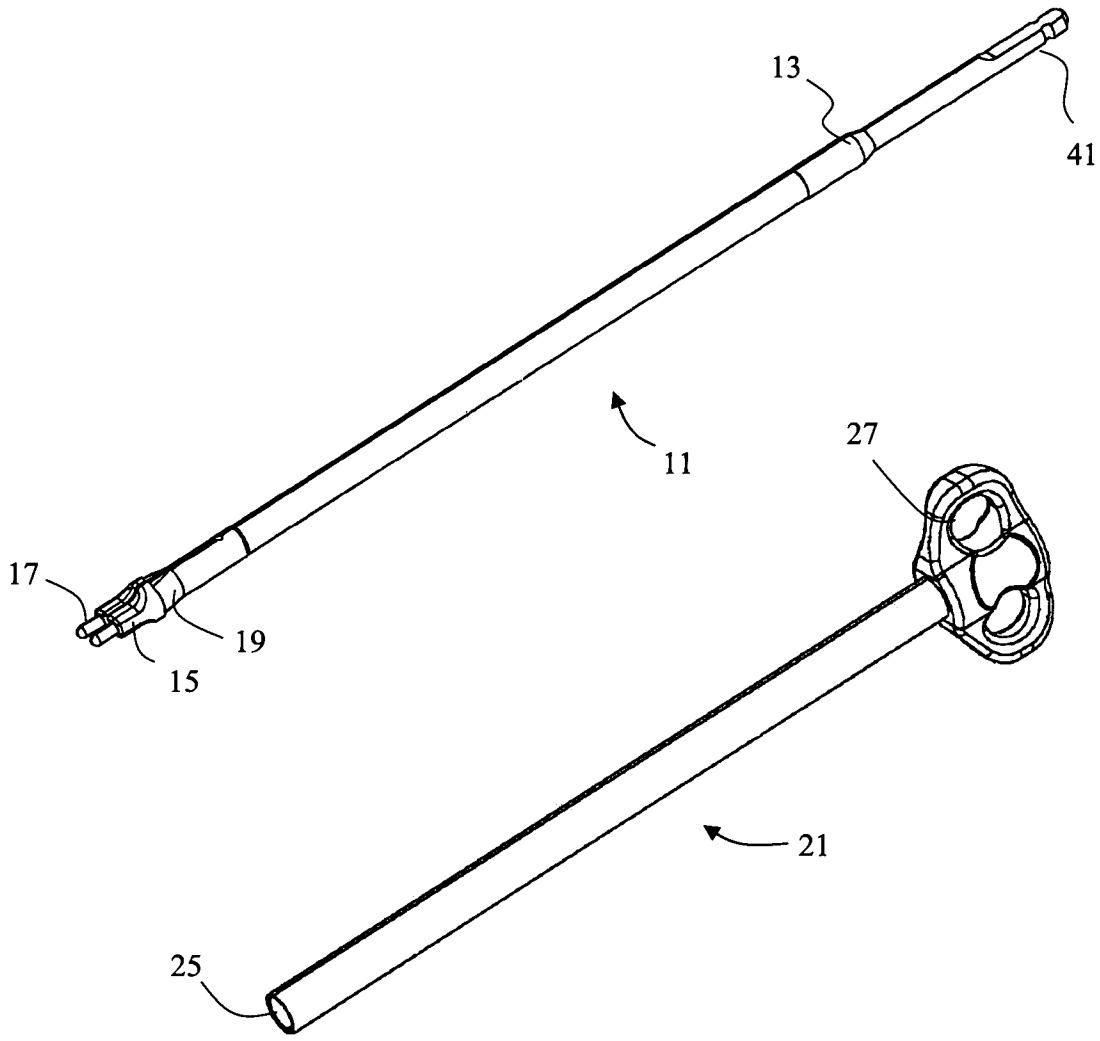


FIG. 17

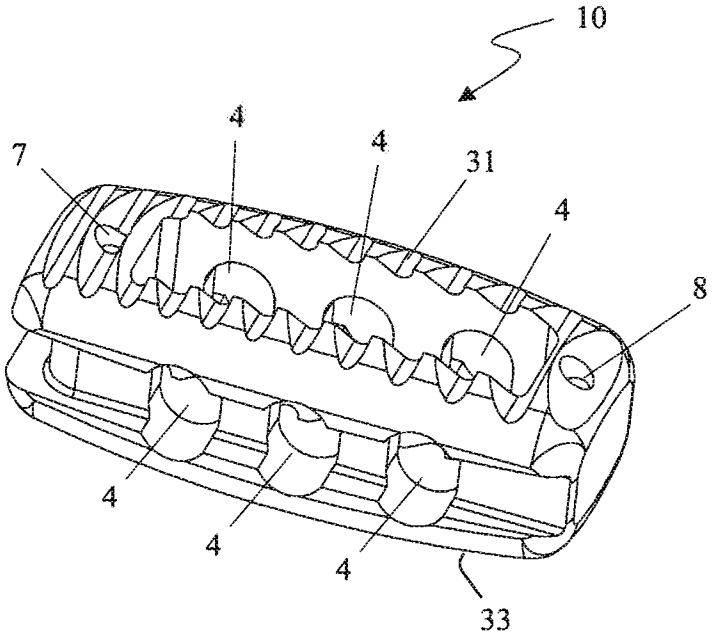


FIG. 18

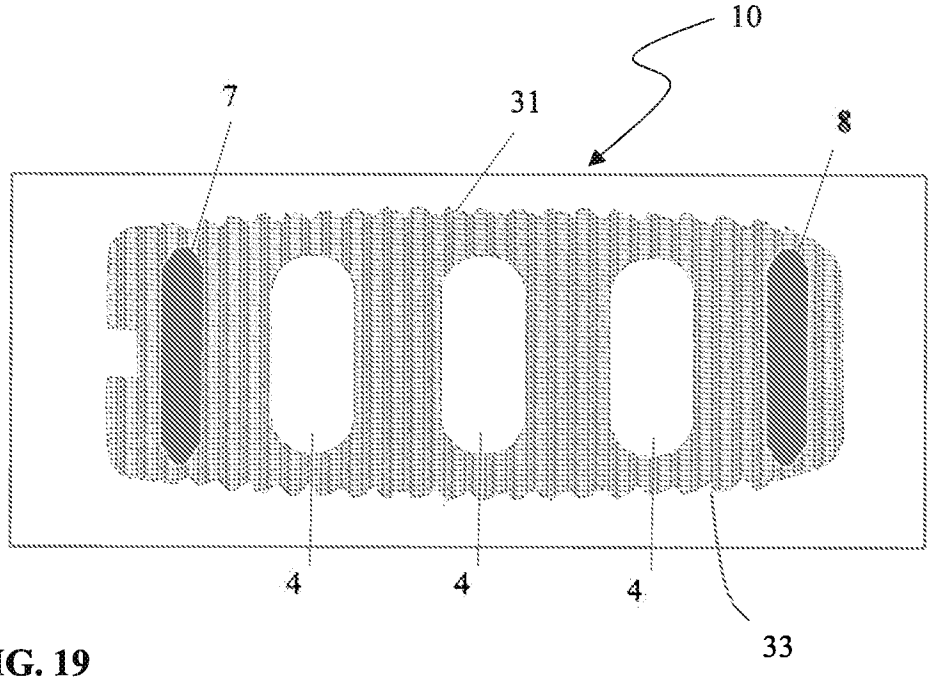
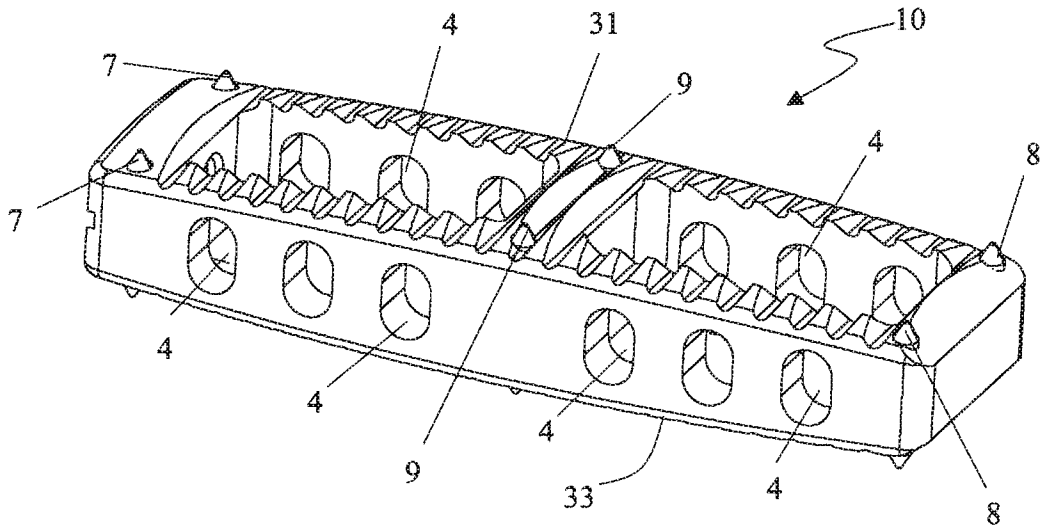


FIG. 19

FIG. 20



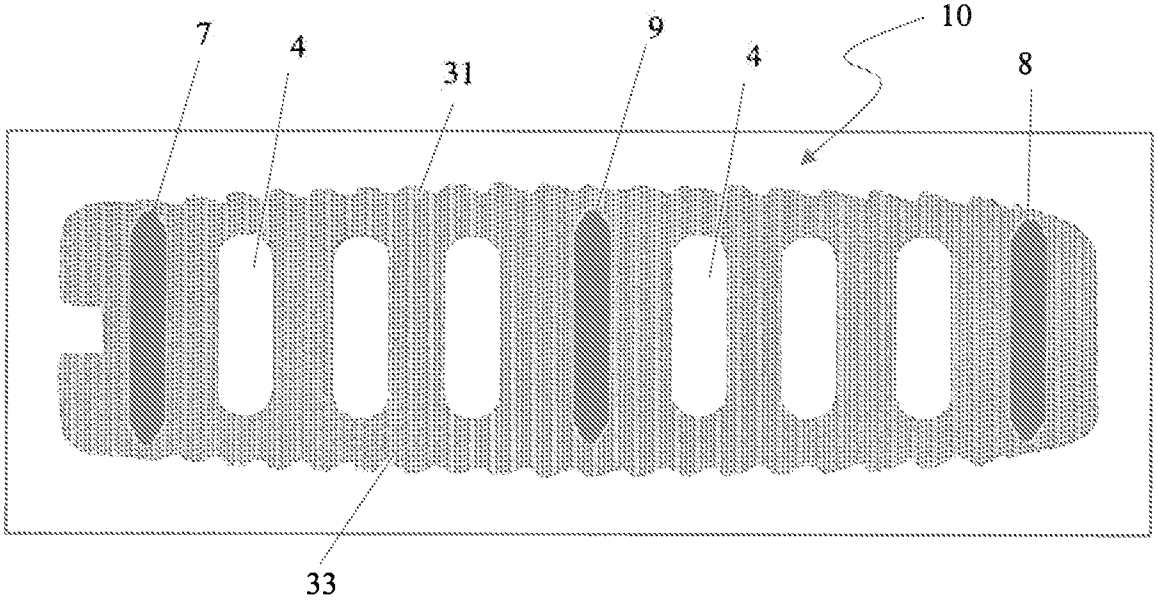


FIG. 21

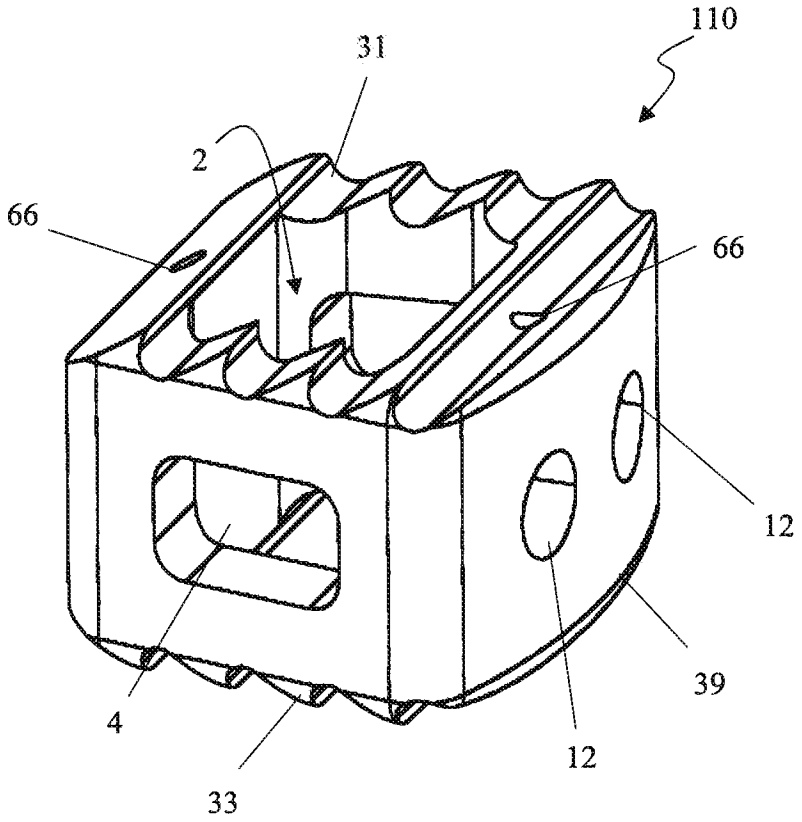


FIG. 22

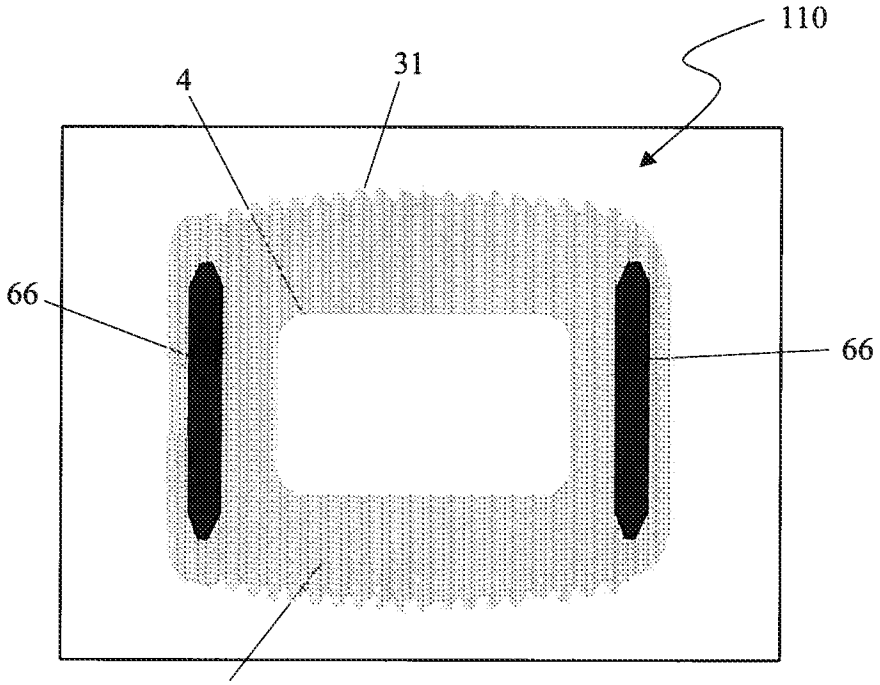


FIG. 23

Electronic Patent Application Fee Transmittal

Application Number:	11093409
Filing Date:	29-Mar-2005
Title of Invention:	Systems and methods for spinal fusion
First Named Inventor/Applicant Name:	Matthew Curran
Filer:	Rory A. Schermerhorn
Attorney Docket Number:	104US1

Filed as Small Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	60	60

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		60

Electronic Acknowledgement Receipt

EFS ID:	3489512
Application Number:	11093409
International Application Number:	
Confirmation Number:	6640
Title of Invention:	Systems and methods for spinal fusion
First Named Inventor/Applicant Name:	Matthew Curran
Customer Number:	30328
Filer:	Rory A. Schermerhorn
Filer Authorized By:	
Attorney Docket Number:	104US1
Receipt Date:	20-JUN-2008
Filing Date:	29-MAR-2005
Time Stamp:	01:48:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$60
RAM confirmation Number	4820
Deposit Account	502040
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		104US1-RA-efile-6-19-08.pdf	456875 a60a58dc3f23662fc03f3b1e26e033bcfd4bba9e	yes	13
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment - After Non-Final Rejection		1	1	
	Claims		2	8	
	Applicant Arguments/Remarks Made in an Amendment		9	13	
Warnings:					
Information:					
2	Drawings-only black and white line drawings	104US1-RA-efiledrawings-6-19-08.pdf	143220 d92df90149f2771a0210114ac4ed040bc45a6000	no	4
Warnings:					
Information:					
3	Fee Worksheet (PTO-06)	fee-info.pdf	8130 0fdb8f8b374abdb97f94b653c20502badd764abd	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	608225		

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/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/093,409	03/29/2005	

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			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	06/20/2008	(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 ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 26	= 0	X $25 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $105 =	0	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	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
	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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/LINDA W. BADIE/

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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/093,409	03/29/2005	Matthew Curran	104US1	6640

30328 7590 03/18/2008

JONATHAN SPANGLER
NU VASIVE, INC.
4545 TOWNE CENTRE COURT
SAN DIEGO, CA 92121

EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
03/18/2008	PAPER

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

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

Office Action Summary	Application No.	Applicant(s)	
	11/093,409	CURRAN ET AL.	
	Examiner	Art Unit	
	JERRY CUMBERLEDGE	3733	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *14-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner Comment

On 10/01/2007 a miscellaneous office communication was sent to Applicant's representative indicating that Applicant's response to the restriction requirement (mailed on 02/20/2007) was incomplete. During a brief conversation with Applicant's representative in January 2008, Applicant's representative pointed out how the response was a complete response and the examiner confirmed that the response was fully responsive. As such, the miscellaneous letter mailed 10/01/2007 was mistakenly sent and is vacated. An office action responsive to Applicant's election filed 03/19/2007 follows.

Election/Restrictions

Applicant's election with traverse of claims 1-13 (Group 1) in the reply filed on 03/19/2007 is acknowledged. The traversal is on the ground(s) that the claimed invention cannot be used to distract adjacent vertebrae. This is not found persuasive because the claimed invention can be used to distract vertebrae by placing the end of the device between adjacent vertebrae which would cause them to separate or distract.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected method of spinal fusion, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/19/2007.

Drawings

The drawings are objected to because Figs. 17-23 are blurry and indistinct. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Rejections - 35 USC § 102

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

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

Claims 1-5 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Steffee (US Pat. 5,716,415).

Steffee discloses a spinal fusion system comprising; an interbody spinal fusion implant (Fig. 15), including at least in part a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate (Fig. 1, surfaces contacting the vertebral endplates), at least one fusion aperture (Fig. 15, ref. 160) extending between the top surface and the bottom surface (Fig. 15, ref. 160) to allow bony fusion between the first vertebral end plate and the second vertebral endplate (Fig. 15), a distal side (Fig. 15, ref. 32a), a proximal side (Fig. 15, ref. 30b) having at least one receiving aperture (Fig. 15, ref. 60b) for engaging an insertion instrument, and two lateral sides (Fig. 15, ref. 20b and opposite side); and an insertion instrument (Fig. 4), including a generally elongated tubular member (Fig. 4, ref. 108) having a distal opening and a proximal opening (Fig. 4, near ref. 96 and ref. 104), a generally elongated shaft

member (Fig. 4, ref. 118) having a distal end and a proximal end (Fig. 4) and being generally dimensioned to be inserted through the elongated tubular member (Fig. 4) such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening (Fig. 4), and the distal end including an implant engagement feature (Fig. 4, near ref. 136); and a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant (column 4, lines 24-35). The implant is substantially radiolucent and composed of non-bone material (column 7, lines 13-22). The implant includes at least one visualization aperture extending through at least one of the lateral sides (Fig. 15, ref. 156b). The top and bottom surfaces of the implant are at least one of generally parallel with respect to each other to better match the natural curvature of the spine (Fig. 15). The implant further includes anti-migration features (Fig. 15. ref. 36b) to increase friction between the implant and vertebral endplate minimizing unwanted movement (Fig. 15), the anti-migration features including at least one of ridges formed in the top surface (Fig. 15), ridges formed in the bottom surface (Fig. 15), one or more spike elements protruding from the top surface (Fig. 15), one or more spike elements protruding from the bottom surface (Fig. 15), and one or more spike elements protruding from the top and bottom surface (Fig, 15). The securing mechanism includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member (Fig. 4, ref. 84) such that turning the rotation device causes the generally elongated shaft member to turn (Fig. 4), releasably securing the implant to the insertion instrument (Fig. 4) (column 4, lines 24-35) . The proximal end of the implant further includes at least one purchase

region (Fig. 15, any of the portions near the receiving aperture) adjacent to the receiving aperture and wherein the distal opening of the generally elongated tubular member is situated in a distal head (Fig. 4, portion near ref. 104), the distal head including at least one distal head slot (Fig. 4, slot between refs. 130), adjacent to the distal opening (Fig. 4), for engaging the purchase region on the implant (Fig. 4)and enhancing the engagement between the implant and the insertion instrument (Fig. 4). The implant includes two receiving apertures (Fig. 15, ref. 60b and ref. 62b) positioned adjacent to each other on the proximal side of the implant (Fig. 15). The generally elongated tubular member comprises a tubular lock member (Fig. 5, near ref. 100, ref. 102), the generally elongated shaft member comprises an elongated fork member (Fig. 4, ref. 86), and the engagement feature comprises two prongs (Fig. 4, ref. 136) extending from a pair of clamping arms (Fig. 4, ref. 130) and dimensioned to engage the two receiving apertures of the implant (Fig. 4)(Fig. 15)(Fig. 10). The elongate fork member includes a taper feature (Fig. 7, ref. 132) situated between the clamping arms (Fig. 7, ref. 130) and the proximal end (Fig. 7, near ref. 128) of the elongate fork member and the tubular lock member (Fig. 5, near ref. 100), ref. 102) includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature (Fig. 5, ref. 100). The securing mechanism includes, at least in part, a threaded region situated near the proximal end of the elongated fork member (Fig. 7, ref. 128), and a complimentary threaded region (Fig. 4, ref. 120) near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary

threaded regions to meet as the tapered region enters the central bore at the distal opening (Fig. 4), wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions (Fig. 4), advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device (Fig. 4)

Claim Rejections - 35 USC § 103

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

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

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffee (US Pat. 5,716,415) in view of Boyd et al. (US Pat. 5,797,917).

Steffee discloses the claimed invention except for the receiving aperture of the implant comprises a singular threaded aperture. The insertion instrument engagement feature comprises a threaded connector dimensioned to engage the threaded receiving aperture of the implant and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture. Steffe does disclose an engagement feature that is used to engage and manipulate a spinal implant (Steffee, column 4, lines 24-35).

Boyd et al. disclose a receiving aperture (Fig. 4, ref. 20) of a spinal implant (Fig. 4) that comprises a singular threaded aperture (Fig. 4, ref. 20). The insertion instrument

engagement feature comprises a threaded connector (Fig. 5, ref. 64) dimensioned to engage the threaded receiving aperture of the implant and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture (Fig. 4). The connector is used to engage and manipulate a spinal implant (Boyd et al., column 8, lines 22-31).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the engagement feature of Steffee with the engagement feature Boyd et al., in order to achieve the predictable result of using the connector to engage and manipulate a spinal implant.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

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 http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733

Notice of References Cited	Application/Control No. 11/093,409	Applicant(s)/Patent Under Reexamination CURRAN ET AL.	
	Examiner JERRY CUMBERLEDGE	Art Unit 3733	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,716,415	02-1998	Steffee, Arthur D.	623/17.16
*	B	US-5,797,917	08-1998	Boyd et al.	606/99
*	C	US-5,192,327	03-1993	Brantigan, John W.	623/17.11
*	D	US-6,206,922	03-2001	Zdeblick et al.	623/17.11
*	E	US-2003/0149438 A1	08-2003	Nichols et al.	606/99
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11093409	CURRAN ET AL.
	Examiner	Art Unit
	Cumberledge, Jerry	3733

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	02/12/2007	02/27/2008							
	1	÷	✓							
	2	÷	✓							
	3	÷	✓							
	4	÷	✓							
	5	÷	✓							
	6	÷	✓							
	7	÷	✓							
	8	÷	✓							
	9	÷	✓							
	10	÷	✓							
	11	÷	✓							
	12	÷	✓							
	13	÷	✓							
	14	÷	N							
	15	÷	N							
	16	÷	N							
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	22	÷	N							
	23	÷	N							
	24	÷	N							
	25	÷	N							
	26	÷	N							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11093409	CURRAN ET AL.
	Examiner	Art Unit
	JERRY CUMBERLEDGE	3733

SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	2/27/2008	JLC
606	99	2/27/2008	JLC

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search Performed	2/27/2008	JLC

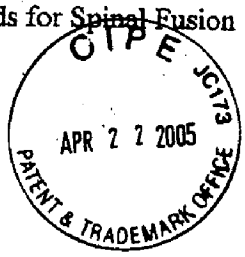
INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Matthew Curran et al.

Title: System and Methods for Spinal Fusion



Docket No.: 104US1
Filed: March 29, 2005
Examiner: Unknown

Serial No.: 11/093,409
Due Date: N/A
Group Art Unit: Unknown

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

We are transmitting herewith the following attached items (as indicated with an "X"):

X A return postcard and this transmittal document.
X An Information Disclosure Statement (2 pgs.), Form 1449 (6 pgs.), and copies of 37 cited documents.

Customer Number: 30328

By _____
Jonathan Spangler
Reg. No. 40,182

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20 day of April, 2005.

MEREDITH MESCHER
Name

Meredith Mescher
Signature

(GENERAL)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JC/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Matthew Curran et al.	Examiner:	Unknown
Serial No.:	11/093,409	Group Art Unit:	Unknown
Filed:	March 29, 2005	Docket:	104US1
Title:	System and Methods for Spinal Fusion		

INFORMATION DISCLOSURE STATEMENT

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

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the referenced materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 50-2040 in order to have this Information Disclosure Statement considered.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office. Notification of this change was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004. Thus, Applicant has not included copies of any US Patents or Published Applications cited with this submission. Should the Office require copies to be provided, Applicant respectfully requests that notice of such requirement be directed to Applicant's below-signed representative. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JC/

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

MATTHEW CURRAN ET AL.

By their Representatives,

CUSTOMER NUMBER: 30328
858-909-1807

Date 4-19-05 By _____
Jonathan Spangler
Reg. No. 40,182

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20 day of April, 2005.

MEREDITH MESCHER
Name

Meredith Mescher
Signature

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JC/

PTO/SB/08A(08-03)
Approved for use through 07/31/2006. OMB 0651-0031
US Patent & 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.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 1 of 6

Attorney Docket No: 104US1

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines,Where Relevant Passages or Relevant Figures Appear
	US-2002/0058950 A1	05/16/2002	Winterbottom, et al.	
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EXAMINER /Jerry Cumberledge/ **DATE CONSIDERED** 02/27/2008

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JC/

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 2 of 6

Attorney Docket No: 104US1

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EXAMINER /Jerry Cumberledge/ **DATE CONSIDERED** 02/27/2008

Substitute Disclosure Statement Form (PTO-1449)

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JC/

PTO/SB/08A(08-03)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 3 of 6

Attorney Docket No: 104US1

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EXAMINER /Jerry Cumberledge/ **DATE CONSIDERED** 02/27/2008

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 4 of 6

Attorney Docket No: 104US1

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EXAMINER /Jerry Cumberledge/ **DATE CONSIDERED** 02/27/2008

Substitute Disclosure Statement Form (PTO-1449)

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 5 of 6

Attorney Docket No: 104US1

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines, Where Relevant Passages or Relevant Figures Appear	T[2]
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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
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EXAMINER /Jerry Cumberledge/ **DATE CONSIDERED** 02/27/2008

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JC/

PTO/SB/08A(08-03)
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Substitute for form 1449A/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*	*Complete if Known*	
	Application Number	11/093,409
	Filing Date	March 29, 2005
	First Named Inventor	Matthew Curran
	Group Art Unit	Unknown
	Examiner Name	Unknown
Sheet 6 of 6	Attorney Docket No: 104US1	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	**Cite No [1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T[2]**
		BENINI, et al., "Undercutting decompression and posterior fusion with translaminar facet screw fixation in degenerative lumbar spinal stenosis: Technique and results", Neuro-Orthopedics, (1995),159-172	
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EXAMINER /Jerry Cumberledge/ **DATE CONSIDERED** 02/27/2008

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

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BIB DATA SHEET

CONFIRMATION NO. 6640

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/093,409	03/29/2005	623	3733	104US1

APPLICANTS

Matthew Curran, Carlsbad, CA;
Mark Peterson, Medford, OR;

**** CONTINUING DATA ***************************

This appln claims benefit of 60/557,536 03/29/2004

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

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
04/23/2005

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /JERRY L CUMBERLEDGE/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	20	26	2

ADDRESS

JONATHAN SPANGLER
NU VASIVE, INC.
4545 TOWNE CENTRE COURT
SAN DIEGO, CA 92121
UNITED STATES

TITLE

Systems and methods for spinal fusion

FILING FEE RECEIVED		
715	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/093,409	03/29/2005	Matthew Curran	104US1	6640

30328 7590 10/01/2007

JONATHAN SPANGLER
NU VASIVE, INC.
4545 TOWNE CENTRE COURT
SAN DIEGO, CA 92121

EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	**PAPER NUMBER**
3733	

MAIL DATE	DELIVERY MODE
10/01/2007	PAPER

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

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

UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
11093409	3/29/2005	CURRAN ET AL.	104US1

JONATHAN SPANGLER
NU VASIVE, INC.
4545 TOWNE CENTRE COURT
SAN DIEGO, CA 92121

EXAMINER	
Jerry Cumberledge	
ART UNIT	**PAPER**
3733	20070919B

DATE MAILED:

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

Commissioner for Patents

The reply filed on 03/19/2007 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Applicant has not included an election of invention with the response to the restriction requirement mailed on 02/20/2007. It is noted that the requirement to be complete must include (i) an election of species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

See 37 CFR 1.111.Since the above-mentioned reply appears to be bona fide, applicant is given ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER

09/21/07

PATENT APPLICATION FEE DETERMINATION RECORD
Effective December 8, 2004

11093409

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	26	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	26 minus 20=	* 6
INDEPENDENT CLAIMS	2 minus 3 =	* —
MULTIPLE DEPENDENT CLAIM PRESENT		☐

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

SMALL ENTITY TYPE ☑ OR OTHER THAN SMALL ENTITY

RATE	FEE	OR	RATE	FEE
BASIC FEE	150.00	OR	BASIC FEE	300.00
X$ 25=	150	OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL	300	OR	TOTAL	

CLAIMS AS AMENDED - PART II

SMALL ENTITY OR OTHER THAN SMALL ENTITY

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 26	Minus	** 26	= 0
Independent	* 2	Minus	*** 3	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

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

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 26	Minus	** 26	=
Independent	* 2	Minus	*** 3	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

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

1,141

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

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

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

JFW

PTO/SB/21 (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	9

Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Art Unit	3733
Examiner Name	Jerry L. Cumberledge
Attorney Docket Number	104US1

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  Return Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	NuVasive, Inc.		
Signature			
Printed name	Jonathan Spangler		
Date	July 13, 2007	Reg. No.	40,182

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Jonathan Spangler	Date	July 13, 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of	
Matthew Curran	Group Art Unit: 3733
App. Ser. No. 11/093,409	Examiner: Jerry L. Cumberledge
Filed: 03/29/2005	
For: SYSTEMS AND METHODS FOR SPINAL FUSION	

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria VA 22313-1450 on July 13, 2007:

Signature: _____
Jonathan Spangler

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT (37 CFR 1.121)

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Non-Compliant Amendment (37 CFR 1.121) mailed on July 9, 2007, which relates to a non-final amendment, thus having a one month shortened period for response that expires on August 9, 2007, Applicants submit herewith a corrected section entitled IN THE CLAIMS, which contains a corrected claims listing believed to now be fully compliant with 37 CFR 1.121.

IN THE CLAIMS:

1. (Original) A spinal fusion system comprising;

an interbody spinal fusion implant, including at least in part a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having at least one receiving aperture for engaging an insertion instrument, and two lateral sides; and

an insertion instrument, including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature; and

a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant.

2. (Original) The spinal fusion system of Claim 1, wherein the implant is substantially radiolucent and composed of non-bone material.

3. (Original) The spinal fusion system of Claim 1, wherein the implant includes at least one visualization aperture extending through at least one of the lateral sides.

4. (Original) The spinal fusion system of Claim 1, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other to better match the natural curvature of the spine.

5. (Original) The spinal fusion system of Claim 1, wherein the implant further includes anti-migration features to increase friction between the implant and vertebral endplate

minimizing unwanted movement, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.

6. (Original) The spinal fusion system of Claim 1, wherein the receiving aperture of the implant comprises a singular threaded aperture.

7. (Original) The spinal fusion system of Claim 6, wherein the insertion instrument engagement feature comprises a threaded connector dimensioned to engage the threaded receiving aperture of the implant.

8. (Original) The spinal fusion system of Claim 7, wherein the securing mechanism includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member such that turning the rotation device causes the generally elongated shaft member to turn, and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture, releasably securing the implant to the insertion instrument.

9. (Original) The spinal fusion system of Claim 8, wherein the proximal end of the implant further includes at least one purchase region adjacent to the receiving aperture and wherein the distal opening of the generally elongated tubular member is situated in a distal head, the distal head including at least one distal head slot, adjacent to the distal opening, for engaging the purchase region on the implant and enhancing the engagement between the implant and the insertion instrument.

10. (Original) The spinal fusion system of Claim 1, wherein the implant includes two receiving apertures positioned adjacent to each other on the proximal side of the implant.

11. (Original) The spinal fusion system of Claim 10, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.

12. (Original) The spinal fusion system of Claim 11, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.

13. (Original) The spinal fusion system of Claim 12, wherein the securing mechanism includes, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device.

14. (Original) A method of spinal fusion, comprising the steps of:

(a) releasably securing a spinal fusion implant to an insertion instrument, the spinal fusion implant including a top surface for contacting a first vertebral endplate, a

bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having at least one receiving aperture for engaging an insertion instrument, and two lateral sides, and the insertion instrument including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature

(b) introducing the spinal fusion implant to a prepared space between adjacent vertebral end plates and properly positioning the implant within the space;

(c) releasing the insertion instrument from the properly positioned implant and withdrawing the insertion instrument from the surgical corridor.

15. (Original) The spinal fusion method of Claim 14, wherein the implant is substantially radiolucent and composed of non-bone material

16. (Original) The spinal fusion method of Claim 14, wherein the implant includes at least one visualization aperture extending through at least one of the lateral sides.

17. (Original) The spinal fusion method of Claim 14, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other, and generally angled with respect to each other to better match the natural curvature of the spine.

18. (Original) The spinal fusion method of Claim 14, wherein the implant further includes anti-migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike

elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.

19. (Original) The spinal fusion method of Claim 14, wherein the receiving aperture of the implant comprises a singular threaded aperture.

20. (Original) The spinal fusion method of Claim 19, wherein the insertion instrument engagement feature comprises a threaded connector dimensioned to engage the threaded receiving aperture of the implant.

21. (Original) The spinal fusion method of Claim 20, wherein the means for releasably securing the threaded connector to the threaded receiving aperture of the implant includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member such that turning the rotation device causes the generally elongated shaft member to turn, and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture, releasably securing the implant to the insertion instrument.

22. (Original) The spinal fusion method of Claim 21, wherein the proximal end of the implant further includes at least one purchase region adjacent to the receiving aperture and wherein the distal opening of the generally elongated tubular member is situated in a distal head, the distal head including at least one distal head slot, adjacent to the distal opening, for engaging the purchase region on the implant and enhancing the engagement between the implant and the insertion instrument.

23. (Original) The spinal fusion method of Claim 14, wherein the implant includes two receiving apertures positioned adjacent to each other on the proximal side of the implant.

24. (Original) The spinal fusion method of Claim 23, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.

25. (Original) The spinal fusion method of Claim 24, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.

26. (Original) The spinal fusion method of Claim 25, including a securing mechanism for releasably securing the engagement features in the receiving apertures of the implant, the securing mechanism including, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device.

Respectfully submitted,

NUVASIVE, INC.

By: _____

Jonathan Spangler, Esq.
Registration No. 40,182

4545 Towne Centre Court
San Diego, CA 92121
Tel.: (858) 243-0029

July 13, 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/093,409	03/29/2005	Matthew Curran	104US1	6640

30328 7590 07/09/2007

JONATHAN SPANGLER
NU VASIVE, INC.
4545 TOWNE CENTRE COURT
SAN DIEGO, CA 92121

EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	**PAPER NUMBER**
3733	

MAIL DATE	DELIVERY MODE
07/09/2007	PAPER

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

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

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No. 11093409	Applicant(s)
	Examiner Cumberledge	Art Unit 3733

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

The amendment document filed on _____ is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
  - ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other _____.
- ☐ 2. Abstract:
  - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: Claims can not depend on 0. (15-26)
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):

_____

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.

2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

   Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

   Failure to timely respond to this notice will result in:
   Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or
   Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Legal Instruments Examiner (LIE), if applicable

571.272.1064
Telephone No.

IFW

PTO/SB/21 (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	10

Application Number	11/093,409
Filing Date	03/29/2005
First Named Inventor	Matthew Curran
Art Unit	3733
Examiner Name	Jerry L. Cumberledge
Attorney Docket Number	104US1

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Remarks

Return Postcard

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Jonathan Spangler		
Signature			
Printed name	Jonathan Spangler		
Date	03/15/2007	Reg. No.	40182

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Jonathan Spangler	Date	03/15/2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of	
Matthew Curran	Group Art Unit: 3733
App. Ser. No. 11/093,409	
Filed: 03/29/2005	Examiner: Jerry L. Cumberledge
For: SYSTEMS AND METHODS FOR SPINAL FUSION	

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria VA 22313-1450 on 03/15/2007:

Signature: _____
Jonathan Spangler

RESTRICTION RESPONSE

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

Dear Sir:

In response to the Office Action mailed February 20, 2007, having a one month shortened period for response that expires on March 20, 2007, Applicants hereby respectfully submit that the apparatus cannot be used to distract adjacent vertebra and therefore Group I (claims 1-13) and Group II (claims 14-26) form an indivisible invention and therefore no election or restriction is required.

IN THE CLAIMS:

1. (Original) A spinal fusion system comprising;

an interbody spinal fusion implant, including at least in part a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having at least one receiving aperture for engaging an insertion instrument, and two lateral sides; and

an insertion instrument, including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature; and

a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant.

2. (Original) The spinal fusion system of Claim 1, wherein the implant is substantially radiolucent and composed of non-bone material.

3. (Original) The spinal fusion system of Claim 1, wherein the implant includes at least one visualization aperture extending through at least one of the lateral sides.

4. (Original) The spinal fusion system of Claim 1, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other to better match the natural curvature of the spine.

5. (Original) The spinal fusion system of Claim 1, wherein the implant further includes anti-migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.

6. (Original) The spinal fusion system of Claim 1, wherein the receiving aperture of the implant comprises a singular threaded aperture.

7. (Original) The spinal fusion system of Claim 6, wherein the insertion instrument engagement feature comprises a threaded connector dimensioned to engage the threaded receiving aperture of the implant.

8. (Original) The spinal fusion system of Claim 7, wherein the securing mechanism includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member such that turning the rotation device causes the generally elongated shaft member to turn, and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture, releasably securing the implant to the insertion instrument.

9. (Original) The spinal fusion system of Claim 8, wherein the proximal end of the implant further includes at least one purchase region adjacent to the receiving aperture and wherein the distal opening of the generally elongated tubular member is situated in a distal head, the distal head including at least one distal head slot, adjacent to the distal opening, for engaging the purchase region on the implant and enhancing the engagement between the implant and the insertion instrument.

10. (Original) The spinal fusion system of Claim 1, wherein the implant includes two receiving apertures positioned adjacent to each other on the proximal side of the implant.

11. (Original) The spinal fusion system of Claim 10, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.

12. (Original) The spinal fusion system of Claim 11, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.

13. (Original) The spinal fusion system of Claim 12, wherein the securing mechanism includes, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device.

14. (Original) A method of spinal fusion, comprising the steps of:

(a) releasably securing a spinal fusion implant to an insertion instrument, the spinal fusion implant including a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having at least one receiving aperture for engaging an insertion instrument, and two lateral sides, and the insertion instrument including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature

(b) introducing the spinal fusion implant to a prepared space between adjacent vertebral end plates and properly positioning the implant within the space;

(c) releasing the insertion instrument from the properly positioned implant and withdrawing the insertion instrument from the surgical corridor.

15. (Original) The spinal fusion method of Claim 0, wherein the implant is substantially radiolucent and composed of non-bone material

16. (Original) The spinal fusion method of Claim 0, wherein the implant includes at least one visualization aperture extending through at least one of the lateral sides.

17. (Original) The spinal fusion method of Claim 0, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other, and generally angled with respect to each other to better match the natural curvature of the spine.

18. (Original) The spinal fusion method of Claim 0, wherein the implant further includes anti-migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.

19. (Original) The spinal fusion method of Claim 0, wherein the receiving aperture of the implant comprises a singular threaded aperture.

20. (Original) The spinal fusion method of Claim 0, wherein the insertion instrument engagement feature comprises a threaded connector dimensioned to engage the threaded receiving aperture of the implant.

21. (Original) The spinal fusion method of Claim 0, wherein the means for releasably securing the threaded connector to the threaded receiving aperture of the implant includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member such that turning the rotation device causes the generally elongated shaft member to turn, and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture, releasably securing the implant to the insertion instrument.

22. (Original) The spinal fusion method of Claim 0, wherein the proximal end of the implant further includes at least one purchase region adjacent to the receiving aperture and wherein the distal opening of the generally elongated tubular member is situated in a distal head, the distal head including at least one distal head slot, adjacent to the distal

opening, for engaging the purchase region on the implant and enhancing the engagement between the implant and the insertion instrument.

23. (Original) The spinal fusion method of Claim 0, wherein the implant includes two receiving apertures positioned adjacent to each other on the proximal side of the implant.

24. (Original) The spinal fusion method of Claim 0, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.

25. (Original) The spinal fusion method of Claim 0, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.

26. (Original) The spinal fusion method of Claim 0, including a securing mechanism for releasably securing the engagement features in the receiving apertures of the implant, the securing mechanism including, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and

releasably securing the implant to the insertion device.

REMARKS

Claims 1-26 are currently pending in this application. In the Office Action mailed on February 20, 2007 ("Office Action"), claims 1-26 were subject to restriction and/or election. The restriction alleged that the present application contains an invention needing election of certain claims because the apparatus can also be used to distract adjacent vertebrae.

The apparatus cannot be used to distract adjacent vertebrae because a separate distracter is needed before the apparatus can insert the implant. The system and method in the Application claims of inserting the implant between two vertebrae, but does not claim, nor is the apparatus designed to be a distracter of adjacent vertebrae since a separate distracter is needed for proper distraction of the vertebrae before insertion of the apparatus. Applicants respectfully request favorable consideration of the present application in light of the restriction to the claims and the following remarks.

In the event the Examiner disagrees with the Applicants characterization of a single indivisible invention, the Applicants hereby provisionally elect – with traverse – a spinal fusion system, Group I (claims 1-13), as originally set forth in the Application.

CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. No other fees are deemed necessary at this time. However, in the event that there are any additional fees to be charged or payments to be credited, the applicant hereby request that any charges are credits be made to Deposit Account No.: 50-2040 for Customer No.: 30,328. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

NUVASIVE, INC.

By: _____

Jonathan Spangler, Esq.
Registration No. 40,182

4545 Towne Centre Court
San Diego, CA 92121
Tel.: (858) 243-0029

March 15, 2007

PATENT APPLICATION FEE DETERMINATION RECORD
Effective December 8, 2004

11093409

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	26	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	26 minus 20=	* 6
INDEPENDENT CLAIMS	2 minus 3 =	* —
MULTIPLE DEPENDENT CLAIM PRESENT		☐

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

SMALL ENTITY TYPE ☑ OR OTHER THAN SMALL ENTITY

RATE	FEE	OR	RATE	FEE
BASIC FEE	150.00	OR	BASIC FEE	300.00
X$ 25=	150	OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL	300	OR	TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 26	Minus	** 26	=
Independent	* 2	Minus	*** 3	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐				

SMALL ENTITY OR OTHER THAN SMALL ENTITY

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

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐				

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

1,141

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐				

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

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/093,409	03/29/2005	Matthew Curran	104US1	6640

30328 7590 02/20/2007

JONATHAN SPANGLER
NU VASIVE, INC.
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EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	PAPER NUMBER
3733	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/20/2007	PAPER

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

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	11/093,409	CURRAN ET AL.	
	Examiner	Art Unit	
	Jerry Cumberledge	3733	

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

Period for Reply

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

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

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

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

DETAILED ACTION

Election/Restrictions

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

I. Claims 1-13, drawn to a system, classified in class 606, subclass 90.

II. Claims 14-26 drawn to a method of spinal fusion, classified in class 623, subclass 17.16.

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

Inventions of Group I and Group II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to distract adjacent vertebrae.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

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

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

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 http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC

JCC

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11093409	CURRAN ET AL.
	Examiner	Art Unit
	Cumberledge, Jerry	3733

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	02/12/2007								
	1	+								
	2	+								
	3	+								
	4	+								
	5	+								
	6	+								
	7	+								
	8	+								
	9	+								
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	24	+								
	25	+								
	26	+								

80100.104US1

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/093,409	03/29/2005	Matthew Curran	104US1

30328
ATTN: LEGAL DEPARTMENT
NU VASIVE, INC.
4545 TOWNE CENTRE COURT
SAN DIEGO, CA 92121

CONFIRMATION NO. 6640
FORMALITIES LETTER
"OC000000015847518"

Jun. 25, 2005 - 2mo
DV Nov. 25, 2005 - 7mo Date Mailed: 04/25/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

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

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

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is $65 for a Small Entity

- $65 Late oath or declaration Surcharge.

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

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

08/05/2005 NNGUYEN1 00000040 502040 11093409

01 FC:2051 65.00 DA

M-MAILE

Office of Initial Patent Examination (703) 308-1202

PART 1 - ATTORNEY/APPLICANT COPY

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	11

Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Art Unit	3738
Examiner Name	n/a
Attorney Docket Number	104US1

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☑ Reply to Missing Parts/ Incomplete Application
  - ☑ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  1. Return Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	NuVasive, Inc.		
Signature			
Printed name	Jonathan Spangler		
Date	August 1, 2005	Reg. No.	40,182

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Jonathan Spangler	Date	August 1, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of	)	
	)	
Matthew Curran, et al.	)	
	)	Group Art Unit: 3738
	)	
App. Ser. No. 11/093,409	)	
	)	Examiner: TBD
Filed: March 29, 2005	)	
	)	
For: SYSTEMS AND METHODS FOR SPINAL FUSION	)	
	)	
	)	
	)	

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on August 1, 2005.

Signature: _____
Jonathan Spangler

RESPONSE TO NOTICE TO FILE MISSING PARTS

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

Dear Sir or Madam:

In response to a Notice to File Missing Parts mailed on April 25, 2005, having a two-month period for response that expired June 25, 2005, the applicant respectfully submits the following:

(A) A copy of the Notice to File Missing Parts;

(B) A signed declaration by the inventors as required by the Notice to File Missing Parts; and

(C) A Petition for Extension of Time for 2 months.

Furthermore, Applicant hereby authorizes a payment of $65.00 fee for the late filed declaration and $225.00 fee for the Extension of Time for a total of $290.00. No other fees are deemed necessary at this time. However, in the event that there are any additional fees to be charged or payments to be credited, the applicant hereby request that any charges or credits be made to Deposit Account No.: 50-2040 for Customer No.: 30,328. In the event that there are any questions concerning the remarks above or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,
NUVASIVE, INC.

By: _____
Jonathan Spangler, Esq.
Registration No. 40,182

4545 Towne Centre Court
San Diego, CA 92121
Tel.: (858) 243-0029

August 1, 2005

PTO/SB/22 (12-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2005** *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)*	Docket Number (Optional) 104US1
Application Number 11/093,409	Filed MARCH 29, 2005
For SYSTEMS AND METHODS FOR SPINAL FUSION	
Art Unit 3738	Examiner N/A

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$120	$60	$
☑ Two months (37 CFR 1.17(a)(2))	$450	$225	$ 225.00
☐ Three months (37 CFR 1.17(a)(3))	$1020	$510	$
☐ Four months (37 CFR 1.17(a)(4))	$1590	$795	$
☐ Five months (37 CFR 1.17(a)(5))	$2160	$1080	$

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-2040. I have enclosed a duplicate copy of this sheet.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

08/05/2005 NNGUYEN1 00000040 502040 11093409
02 FC:2252 225.00 DA

I am the
☐ applicant/inventor.
☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).
☑ attorney or agent of record. Registration Number 40,182
☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature	August 1, 2005 Date
Jonathan Spangler Typed or printed name	858-243-0029 Telephone Number

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

☐ Total of _____ forms are submitted.

PTO/SB/01 (04-05)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing **OR** ☑ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	104US1
First Named Inventor	Matthew Curran
COMPLETE IF KNOWN	
Application Number	11/093,409
Filing Date	March 29, 2005
Art Unit	3738
Examiner Name	n/a

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Systems and Methods for Spinal Fusion

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☑ was filed on (MM/DD/YYYY) 03/29/2005 as United States Application Number or PCT International Application Number 11/093,409 and was amended on (MM/DD/YYYY) _____ (if applicable).

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

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

PTO/SB/01 (04-05)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☑ The address associated with Customer Number: 30,328 OR ☐ Correspondence address below

Name			
Address			
City	State	ZIP	
Country	Telephone	Email	

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 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Matthew	Curran

Inventor's Signature [signature] Date 7/26/05

Residence: City	State	Country	Citizenship
Carlsbad	CA	USA	US

Mailing Address: 3218 Rancho Quartillo

City	State	Zip	Country
Carlsbad	CA	92009	USA

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Mark	Peterson

Inventor's Signature | Date

Residence: City	State	Country	Citizenship
Medford	OR	USA	US

Mailing Address: 840 Royal Avenue Suite #1

City	State	Zip	Country
Medford	OR	97504	USA

☐ Additional inventors or a legal representative are being named on the _____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

PTO/SB/01 (04-05)
Approved for use through 07/31/2006. OMB 0651-0032
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.

DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☑ The address associated with Customer Number:	30,328	OR ☐	Correspondence address below

Name			
Address			
City	State	ZIP	
Country	Telephone	Email	

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 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])		Family Name or Surname	
Matthew		Curran	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Carlsbad	CA	USA	US
Mailing Address			
3218 Rancho Quartillo			
City	State	Zip	Country
Carlsbad	CA	92009	USA

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])		Family Name or Surname	
Mark		Peterson	
Inventor's Signature	Mark Peterson	Date	7/26/05
Residence: City	State	Country	Citizenship
Medford	OR	USA	US
Mailing Address			
840 Royal Avenue Suite #1			
City	State	Zip	Country
Medford	OR	97504	USA

☐ Additional inventors or a legal representative are being named on the ____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/093,409	03/29/2005	Matthew Curran	104US1

CONFIRMATION NO. 6640

30328
ATTN: LEGAL DEPARTMENT
NU VASIVE, INC.
4545 TOWNE CENTRE COURT
SAN DIEGO, CA 92121

FORMALITIES LETTER

OC000000015847518

Date Mailed: 04/25/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

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

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

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$65** for a Small Entity

- **$65** Late oath or declaration Surcharge.

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

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

M-HAILE

Office of Initial Patent Examination (703) 308-1202

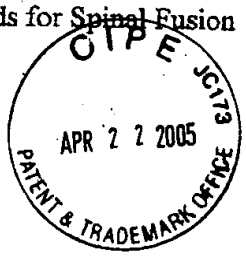
PART 3 - OFFICE COPY

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Matthew Curran et al.

Title: System and Methods for Spinal Fusion



Docket No.: 104US1
Filed: March 29, 2005
Examiner: Unknown

Serial No.: 11/093,409
Due Date: N/A
Group Art Unit: Unknown

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

We are transmitting herewith the following attached items (as indicated with an "X"):

X A return postcard and this transmittal document.
X An Information Disclosure Statement (2 pgs.), Form 1449 (6 pgs.), and copies of 37 cited documents.

Customer Number: 30328

By _____
Jonathan Spangler
Reg. No. 40,182

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20 day of April, 2005.

MEREDITH MESCHER
Name

Meredith Mescher
Signature

(GENERAL)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Matthew Curran et al.	Examiner:	Unknown
Serial No.:	11/093,409	Group Art Unit:	Unknown
Filed:	March 29, 2005	Docket:	104US1
Title:	System and Methods for Spinal Fusion		

INFORMATION DISCLOSURE STATEMENT

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

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the referenced materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 50-2040 in order to have this Information Disclosure Statement considered.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office. Notification of this change was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004. Thus, Applicant has not included copies of any US Patents or Published Applications cited with this submission. Should the Office require copies to be provided, Applicant respectfully requests that notice of such requirement be directed to Applicant's below-signed representative. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

MATTHEW CURRAN ET AL.

By their Representatives,

CUSTOMER NUMBER: 30328
858-909-1807

Date 4-19-05

By _____
Jonathan Spangler
Reg. No. 40,182

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known	
Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 1 of 6

Attorney Docket No: 104US1

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Group Art Unit	Unknown
Examiner Name	Unknown

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Examiner Name	Unknown

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Group Art Unit	Unknown
Examiner Name	Unknown

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Examiner Name	Unknown

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Attorney Docket No: 104US1

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Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/44 | A1

(11) International Publication Number: WO 99/08627

(43) International Publication Date: 25 February 1999 (25.02.99)

(21) International Application Number: PCT/US98/16650

(22) International Filing Date: 11 August 1998 (11.08.98)

(30) Priority Data:

60/055,291	13 August 1997 (13.08.97)	US
60/074,076	9 February 1998 (09.02.98)	US
60/074,197	10 February 1998 (10.02.98)	US
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(74) Agents: HEINE, Holliday, C. et al.; Weingarten, Schurgin, Gagnebin & Hayes LLP, Ten Post Office Square, Boston, MA 02109 (US).

(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
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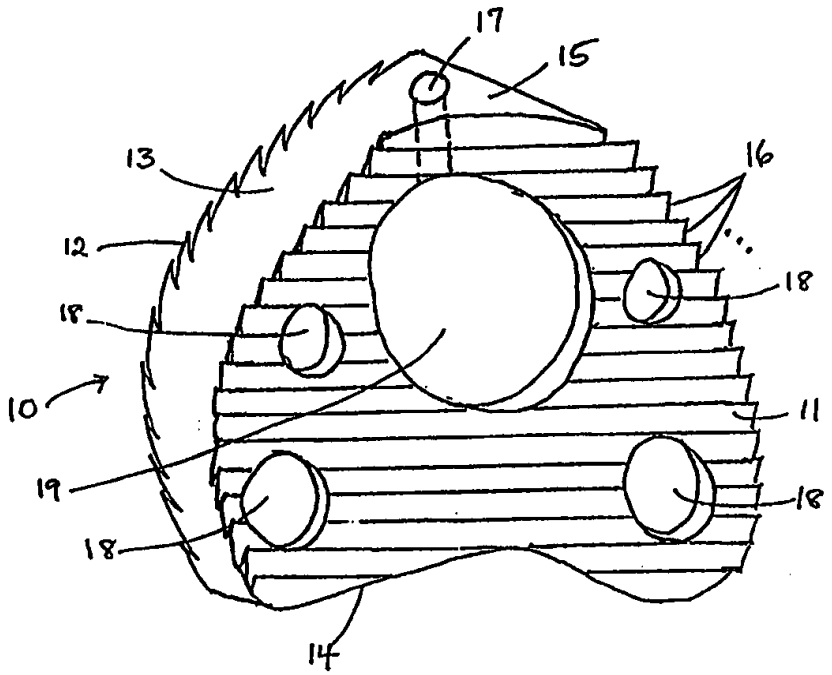
(54) Title: RESORBABLE INTERBODY SPINAL FUSION DEVICES



(57) Abstract

A resorbing interbody fusion device (10) for use in spinal fixation is disclosed. The device (10) is composed of 25 % to 100 % bio-resorbing or resorbing material. A preferred resorbing spinal fusion device (10) is in the shape of a tapered wedge having a top face (11), a bottom face (12), side faces (13), a front end (14), and a back end (15). The surfaces of the top (11), and bottom (12) faces each have serration (16) to aid in anchoring the device (10) to the surrounding bone. The fusion device (10) preferably has holes (17) of convenient diameter to facilitate resorption of the polymer from which the device has been made.

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TITLE OF THE INVENTION

Resorbable Interbody Spinal Fusion Devices

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority from U.S. Provisional Patent Application Nos. 60/055,291, filed August 13, 1997; 60/074,076, filed February 9, 1998; 60/074,197, filed February 10, 1998, and 60/081,803, filed April 15, 1998, the entire disclosures of which are incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable

BACKGROUND OF THE INVENTION

The present invention relates to the field of interbody spinal fusion devices.

In the structure of the spine of vertebrates including humans, the space between adjacent vertebrae is referred to as the interbody space. In normal spines, this space is occupied by the structure commonly referred to as a disc. This intervertebral structure separates and cushions the vertebrae.

Various pathologic and traumatic conditions require excision of a spinal disc and stabilization of the superior and inferior vertebrae while bony fusion develops. In 1995, approximately 225,000 new spinal fusions were performed in the United States alone, and of these about one half were performed in the thoracic and cervical spine, with the remaining spinal fusions focused on the lumbar spine. To stabilize the spine where the surgery has occurred, an internal fixation device is frequently used. Such implants provide the ability to improve spinal alignment and maintain the developing alignment while fusion develops. Fixation of the spine can further correct deformity and provide immediate stability, thereby facilitating spinal fusion, early

mobilization, and, when necessary, entry into rehabilitative programs.

The use of fixation devices is beneficial in several ways. First, the avoidance of long-term bed rest, thought by many to decrease non-neurological morbidity, is achieved. Additionally, fixation devices are thought to promote fracture healing and therefore reduce the need for rigid and cumbersome post-operative bracing.

While a number of commercially available implants for spinal stabilization are known, these devices are not resorbable and therefore, remain permanently at the implant site. Meticulous bone preparation and grafting is essential for successful long-term stability using current devices. Metallic and graphite implants have been known to fatigue and will eventually fail if the desired solid bony fusion is not achieved. Thus, it would be advantageous to obtain successful bony fusion and spinal development while avoiding the use of devices having the aforementioned drawbacks.

SUMMARY OF THE INVENTION

The present invention is directed to resorbable interbody fusion devices for use as spacers in spinal fixation, wherein the device is composed of 25-100% bioresorbable or resorbable material. The devices can be in any convenient form, such as a wedge, screw or cage. In one embodiment, the interbody fusion device of the invention further desirably incorporates structural features such as serrations to better anchor the device in the adjoining vertebrae. In another embodiment, the device comprises a plurality of peripheral voids and more desirably a central void space therein, which may desirably be filled with a grafting material for facilitating bony development and/or spinal fusion, such as an autologous grafting material. In addition, void spaces increase the surface area of the device, thereby providing multiple sites for resorption to occur.

In yet another embodiment, the interbody fusion device of the invention further includes reinforcing fibers to enhance the structural properties thereof. These fibers may be made of the same polymeric material as the resorbable material from which the interbody fusion device is made, from a neutralization compound or, alternatively, from another biocompatible polymer, which may be crosslinked with a suitable crosslinking agent to yield an interpenetrating network for increased strength and stability. In another alternative embodiment, the reinforcing fibers are incorporated into the device, e.g., during the molding process, being placed in the mold under tension and released after the process of molding is complete.

Bioerodible polymers that are useful in the invention include polydioxanone, poly(ϵ-caprolactone); polyanhydride; poly(ortho ester); copoly(ether-ester); polyamide; polylactone; poly(propylene fumarate) ($H[-O-CH(CH_3)-CH_2-O-CO-CH=CH-CO-]_nOH$); and combinations thereof. In a preferred embodiment, the polymer poly(lactide-co-glycolide) (PLGA: $H[-OCHR-CO-]_nOH$, R=H, CH_3), with a lactide to glycolide ratio in the range of 0:100% to 100:0% inclusive, is used.

As many of the preferred bioerodible polymers from which the resorbable interbody fusion device is manufactured are polymers that can produce acidic products upon hydrolytic degradation, the device preferably further includes a neutralization compound, or buffer. The neutralization compound is included in sufficiently high concentration to decrease the rate of pH change as the device degrades, in order to prevent sterile abscess formation caused by the accumulation of unbuffered acidic products in the area of the implant. Most preferably, the buffering or neutralizing agent is selected from a group of compounds wherein the pKa of the conjugate acids of the buffering or neutralization compound is greater than the pKa of the acids produced by hydrolysis of the polymers from which the device is prepared.

The neutralization compound, or buffer, included in the bioerodible material of the invention may be any base, base-

containing material or base-generating material that is capable of reacting with the acidic products generated upon hydrolysis of the bioerodible polymer. Polymeric buffers which preferably include basic groups which neutralize the acidic degradation products may also be used as buffering compounds. Another class of useful buffering compounds are those which, on exposure to water, hydrolyze to form a base as one reaction product.

In another alternative embodiment, the resorbable interbody fusion device of the invention preferably includes a biological growth factor, e.g., bone morphogenic protein, to enhance bone cell growth. To protect the growth factor and to provide for controlled delivery, the biological growth factor may itself be compounded with a resorbable polymer in some of the many techniques available and prepared as a growth factor/polymer composite in pellet form, in small particle form or within the interstices or pores of a polymeric foam or low-density polymer and this polymer/growth factor composite is deposited into void spaces of the resorbable spinal fusion device. Alternatively, the growth factor, or protected growth factor, may simply be directly incorporated into the component formulation of the resorbable spinal fusion device.

Active periosteum cells may also be incorporated into a foam, e.g., deposited into void spaces of the resorbable spinal fusion device, in order to facilitate bone cell fusion. Further, the resorbable spinal fusion device of the invention may be prepared in such a manner as to exhibit a piezoelectric effect, to enhance bone wound healing.

As used herein, the terms "resorbable" and "bioresorbable" are defined as the biologic elimination of the products of degradation by metabolism and/or excretion and the term "bioerodible" is defined as the susceptibility of a biomaterial to degradation over time, usually months. The terms "neutralization compound" or "buffer" are defined as any material that limits or moderates the rate of change of the pH in the implant and its near environment upon

exposure to acid or base. The term "acidic products" is defined herein as any product that generates an aqueous solution with a pH less than 7.

DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings in which:

Figs. 1A, 1B and 1C are perspective top, side and front views, respectively, of an interbody spinal fusion device according to the present invention;

Figs. 2A, 2B and 2C are top, side and perspective views, respectively, of another embodiment of an interbody spinal fusion device of the invention;

Figs. 3A, 3B and 3C are top, side and perspective views, respectively, of another embodiment of an interbody spinal fusion device of the invention;

Figs. 4A and 4B are side and top views, respectively, of another embodiment of an interbody spinal fusion device of the invention;

Figs. 5A and 5B are side and top views, respectively, of another embodiment of an interbody spinal fusion device of the invention;

Fig. 6A is a perspective view of a mold and ram assembly for preparing an interbody spinal fusion device of the invention;

Figs. 6B and 6C are edge and plan views, respectively, of the front face plate of the mold of Fig. 6A;

Fig. 6D shows a disc with serrated slots for use in the mold of Fig. 6A;

Figs. 6E and 6F are front and side views, respectively, of a threaded tension tube used with the mold of Fig. 6A;

Fig. 6G is a section through a mold assembly fitted with reinforcing fibers and associated holder assemblies;

Fig. 7 is a plot of displacement versus load for an interbody spinal fusion device of the invention; and

Fig. 8 shows compression strength with load for interbody spinal fusion devices of the invention with and without the incorporation of a buffering or neutralizing compound.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides, in one embodiment, an interbody spinal fusion device (IFD) comprising a resorbable spinal wedge for vertebral spacing as an adjunct to spinal fusion. Made from a biodegradable, biocompatible polymer, preferably poly(lactic-co-glycolic) acid (PLGA), discussed further below, this resorbable spacer incorporates peripheral voids and central voids, which can be filled with autologous grafting material to facilitate bony development and spinal fusion, and serrated or threaded faces to stabilize and align vertebral bodies. The spinal fusion device of the invention is used as an adjunct to fusions of the cervical, thoracic or lumbar vertebrae, the configuration and dimensions of the device depending on the site of use.

A preferred embodiment of a spinal implant, fabricated from a biocompatible and biodegradable polyester and intended to replace a cervical disc, C4, 5, or 6, is shown in Figs. 1A, 1B and 1C. A rod molded from a suitable material, as described below, is machined to the desired configuration and dimensions. Relatively complex geometries can be readily fabricated in this manner. Suitable biocompatible extraneous materials such as plasticizers or other machining aids, can be included in the material if desired.

As shown in Fig. 1A, a preferred resorbable interbody spinal fusion device of the invention 10 is in the shape of a tapered wedge, having a top face 11, a bottom face 12, side faces 13, a front end 14 and a back end 15. The surfaces of top and bottom faces 11 and 12 each have serrations 16 to aid in anchoring the device to the surrounding bone. Wedge 10 preferably contains holes 17 of convenient diameter, which may be drilled through the wedge to facilitate resorption of the polymer from which the device has been made. A plurality

of channels or ports 18 through the wedge or a larger center hole 19 in the wedge are useful for the introduction of autologous bone. As illustrated in Figs. 1B and 1C, the spinal wedge is preferably machined to have a taper from back end 15 to front end 14, such that the front end 14 is narrower than the back end 15.

In another embodiment, as shown in Figs. 2A-2C resorbable spinal fusion device 20 is shaped like a tapered rod having ridges 22 with threads 21. Device 20 functions as a screw and contains a cylindrical axially extending hole 23 and slots 24 to facilitate screwing the device into the spine of the patient. The device also contains recesses 26 between ridges 22 to facilitate ingrowth of tissue that would aid in anchoring the device in place.

As shown in Figs. 3A-3C, in a further embodiment, the device 30 is of cruciform shape having arms 33. Threads 31 extend the length of the outer surfaces of arms 33. In another embodiment, shown in Figs. 4A-4B, the device is shaped like a threaded screw having a continuous thread 41 provided around the surface of the tapered body. Cylindrical holes 43 and 44 are provided through the body, the holes being orthogonal to each other and to screw axis 42. A cylindrical hole 45 is provided coaxially with axis 42. Slots 46 in the top 48 serve to position and retain a tool that can be used to screw the device into place.

As shown in Figs. 5A and 5B, a further embodiment of a threaded screw contains flat side areas 52 alternating with threaded corner areas 51. Slots 53 can be machined or otherwise provided in the flat areas, to facilitate ingrowth of tissue, and can be of a constant width or can be tapered. A slot 56 in top 58 of the device accommodates a suitable tool to facilitate insertion.

For replacement of one of the cervical discs C4, C5, or C6, the device shown in Figs. 1A-1C preferably measures 15 mm laterally by 12 mm sagittally. The flattened side, positioned posterially, is 6-8 mm thick, enlarging to about 7-9 mm at the anterior edge; thus the device has a taper of

approximately 4.8 degrees. Both surfaces are serrated, the serrations directed laterally. The serrations may be either square cut or cut at an angle with one face vertical and the other sloping upward anteriorly.

The thickness of the device of the invention will govern the rate at which it degrades and total degradation time. Thus, interbody spinal fusion devices can be prepared with multiple thicknesses, but all having the same approximately 5° taper. For example, the anterior thickness could range from 7 to 9 mm and the posterior thickness from 6 to 8 mm. The taper provides the correct orientation to the vertebrae with which the device is in contact and can also serve to keep the device in place.

The vertebral body is a fairly cylindrical mass consisting of cancellous bone surrounded by a thin layer of cortical bone. Thus, the mechanical properties of the device should preferably match those of the cancellous bone of the vertebrae in regard to proportional limit stress, compression at proportional limit, modulus of elasticity, failure stress and compression at failure (See, e.g., Lindahl, Acta Orthop. Scand. 47:11, 1976; Hansson et al., Spine 12:56, 1987).

Bioerodible polymers that are useful in the spinal fusion device of the invention include polydioxanone, poly(ε-caprolactone); polyanhydride; poly(ortho ester); copoly(ether-ester); polyamide; polylactone; poly(propylene fumarate) ($H[-O-CH(CH_3)-CH_2-O-CO-CH=CH-CO-]_nOH$); poly(lactic acid); poly(glycolyic acid); poly(lactide-co-glycolide); and combinations thereof. Selection of a particular polymer is based primarily on the known properties of the polymer, such as the potentiality for cross-linking, polymer strength and moduli, rate of hydrolytic degradation, etc. One of ordinary skill in the art may take these and/or other properties into account in selecting a particular polymer for a particular application. Thus, the selection of a particular polymer is within the skills of the ordinary skilled practitioner.

In a preferred embodiment, the polymer poly(lactide-co-glycolide) ($H[-OCHR-CO-]_nOH$, R=H, CH_3) (PLGA) is used. The

PLGA polymers used according to the invention desirably have a lactide to glycolide ratio in the range of 0:100% to 100:0%, inclusive, i.e., the PLGA polymer can consist of 100% L- or D,L-lactide (PLA), 100% glycolide (PGA), or any combination of lactide and glycolide residues. These polymers have the property of degrading hydrolytically *in vivo* to form organic acids (lactic acid and glycolic acid) which accumulate in the region surrounding the implant. These acids are metabolized and eventually excreted as carbon dioxide and water or enter the citric acid cycle.

The process by which alpha polyesters such as PLA, PGA, and PLGA biodegrade is primarily by non-specific hydrolytic scission of the ester bonds. The L-lactic acid that is generated when PLA or PLGA degrades becomes incorporated into the tricarboxylic acid cycle and is excreted from the lungs as carbon dioxide and water. Glycolic acid, produced both by random hydrolytic scission and by enzymatically mediated hydrolysis, may be excreted in the urine and also can enter the TCA cycle and eventually be oxidized to carbon dioxide and water (Hollinger et al., Clin. Orthop. Rel. Res. 207: 290-305, 1986).

A particularly preferred polymer for use in the device of the invention is poly(d,l-lactide-co-glycolide)-85:15 (Boehringer-Ingelheim: distributor, Henley Chemicals, Inc., Montvale, NJ), the 85:15 designation referring to the lactide to glycolide mole ratio. The particularly preferred polymer is Resomer™ RG 858, with an inherent viscosity of approximately 1.4 corresponding to a weight average molecular weight of 232,000 as measured by gel permeation chromatography (GPC).

The polymer can be used as received or purified by precipitation from tetrahydrofuran solution into isopropanol, air dried and then exhaustively vacuum dried. Polymer data (composition and molecular weight) can be confirmed by nuclear magnetic resonance and by GPC (Hsu et al., J. Biomed. Mater. Res. 35:107-116, 1997).

Spinal fusions require interbody fusion devices that will maintain significant structural rigidity for 6-12 months. Strength requirements depend on the location of the disc to be replaced. When a person is standing, the forces to which a disc is subjected are much greater than the weight of the portion of the body above it. Nachemson et al. (Acta. Orthop. Scand. 37:177, 1966; J. Bone Joint Surgery 46:1077, 1964; Clin. Orthop. 45:107, 1966) has determined that the force on a lumbar disc in a sitting position is more than three times the weight of the trunk. Daniels et al. (J. Appl. Biomater. 1:57-78, 1990) have reviewed much of the mechanical data of PGA, PLA, and PLGA.

As a bioerodible polymer undergoes hydrolysis in the body, any acidic degradation products formed may be implicated in irritation, inflammation, and swelling (sterile abscess formation) in the treated area. To counteract this effect, a neutralization compound, or buffer, is desirably included in the bioerodible material to neutralize the acidic degradation products and thereby reduce the sterile abscess reaction, as described in copending U.S. Application No. 08/626,521, filed April 3, 1996, the whole of which is hereby incorporated by reference herein.

The buffering compound included in the bioerodible material of the invention may be any base, base-containing or base-generating material that is capable of reacting with the acidic products generated upon hydrolysis of the bioerodible polymer. Exemplary buffering materials include salts of inorganic or organic acids, salts of polymeric organic acids or polymeric bases such as polyamines. Preferably calcium salts of weak acids such as, e.g., tribasic calcium phosphate, dibasic calcium phosphate, or calcium carbonate are use. To be useful, the conjugate acids from which the buffering materials are derived must have a pKa greater than those of L-lactic acid (pKa = 3.79), D, L-lactic acid (pKa = 3.86), or glycolic acid (pKa = 3.83), if a PLGA is the polymer which is undergoing hydrolysis. Thus,

for example, salts of acetic acid (pKa = 4.74), or succinic acid (pK_1 = 4.19, pK_2 = 5.64) may also be used.

Buffer compositions of lower solubility are preferred because buffer loss from the polymer by diffusion will be slower (Gresser and Sanderson, "Basis for Design of biodegradable Polymers for Sustained Release of Biologically Active Agents" in Biopolymeric Controlled Release Systems, Ch. 8, D.L. Wise, Ed., CRC Press, 1984). Preferably, the buffering compound has an acid dissociation constant that is smaller than the acid dissociation constant of the acidic products generated upon hydrolysis of the bioerodible polymer. Ionic buffers will, in general, be the salts of weak acids. The acid, of which the buffer is a salt, should have an ionization constant (acid dissociation constant, K_a) which is less than the K_a for the acid products of polymer hydrolysis. Alternatively, the buffering compound has a hydrolysis constant that is greater than the hydrolysis constant of the acidic products.

Hydroxyapatite (HA) and calcium carbonate (CC) were each investigated as buffering fillers. Results demonstrate that the inclusion of CC or HA in a, e.g., PLGA fixture can effectively moderate the rate of pH decline as the fixture degrades. Further, the rapid decline in pH can be offset without considering 100% neutralization of the lactic and glycolic components. Thus, even given that the polymeric fixture will be filled with an inorganic buffer, the mechanical characteristics of the fixture can be stabilized since the loading requirements for the buffer will not be nearly as compromising as expected at the outset.

While both CC and HA can ameliorate the rate of decline in pH in the region of polymer hydrolysis, the use of hydroxyapatite as a filler also supports osteoconductivity. Thus, HA not only promotes bony ingrowth and obviates loosening of the fixture, but also acts as a buffer thereby preventing the formation of sterile abscesses that have been attributed to the acidic degradative products of PLGA implants. The resulting resorbable fixture should be capable

of a buffered hydrolytic degradation and induction of bony ingrowth as resorption of the implant progresses. A resorbable buffered bone fixture with such properties could provide structural support to stabilize and support a spinal repair over the period of time required for natural healing to occur.

According to the invention a preferred buffering compound is hydroxyapatite. The formula $Ca_{10}(OH)_2(PO_4)_6$ may be written as $Ca(OH)_2 \circ 3Ca_3(PO_4)_2$. When written in this manner it is seen that the following neutralization reactions may be written:

$$2RCO_2H + Ca(OH)_2 \circ 3Ca_3(PO_4)_2 \rightarrow 2RCO_2^- + Ca^{+2} + 2H_2O + 3Ca_3(PO_4)_2$$

$$12RCO_2H + 3Ca_3(PO_4)_2 \rightarrow 6H_2PO_4^- + 9Ca^{+2} + 12RCO_2^-$$

The dissociation constant of water (the conjugate acid of the hydroxyl ion) is $K_w=10^{-14}$. The basic phosphate ion, PO_4^{-3}, can neutralize two protons forming the following acids, for which dissociation constants are given:

$$RCO_2H + PO_4^{-3} \rightarrow RCO_2^- + HPO_4^{-2}$$

$$RCO_2H + HPO_4^{-2} \rightarrow RCO_2^- + H_2PO_4$$

K_2 of $H_2PO_4^{-1} = 6.2 \times 10^{-8}$

K_3 of $HPO_4^{-2} = 4.2 \times 10^{-13}$

Buffers included in the polymer in solid form preferably have a relatively small particle size, for example, between less than 1.0 and 250 μm. Particle size reduction can be accomplished by any standard means known in the art, such as ball milling, hammer milling, air milling, etc. If buffer and polymer are to be blended by the dry mixing method (described below), the polymer particle size must also be considered. Polymers such as the PLGAs have relatively low glass transition temperatures and melting temperatures. Thus, polymer particle size reduction must be accompanied by cooling, for example using a Tekmar A-10 mill with a cryogenic attachment.

Following milling, the desired particle size range of the buffer and the polymer may be recovered by sieving through, for example, U.S. Standard sieves. Particles in the

size ranges of <45, 45-90, 90-125, 125-180, 180-250 μm may be conveniently isolated.

In selection of particle size range, it is sometimes desirable to combine two or more ranges, or to use a wide range of sizes, for instance all sizes less than 250 μm. Larger particles may be preferred in some applications of the invention because larger particles take longer to be eroded by the acids and will therefore extend the useful lifetime of the buffer. In some cases particle size reduction will not be necessary, such as when commercially available precipitated calcium carbonate is used (e.g., Fisher Scientific, Inc., Catalog No. C-63).

The effectiveness of substances such as calcium carbonate and hydroxyapatite in neutralizing the acid products of polymer hydrolysis depends not only on the quantity of the substance in the matrix, but also on particle size and distribution, total surface area in contact with the polymer, and solubility.

The presence of calcium ions in the buffered device has advantages with respect to the physical properties of the device as it undergoes erosion. It has been shown that calcium ions form ionic bridges between carboxylate terminal polymer chains (Domb et al., J. Polymer Sci. A28, 973-985 (1990); U.S. Pat. No. 4,888,413 to Domb). Calcium ion bridges between carboxylate anions increase the strength of the composite in which the polymer chains are terminated by carboxylate anion end groups over similar chains terminated by the hydroxyl groups of, e.g., terminal glycol moieties or terminal α-hydroxy acids. In an analogous manner, the polyesters comprising the family of PLGA's are expected to be strengthened by calcium bridges between carboxylate anion terminated chains. As shown in Fig. 8 PLGA-85:15 wedges reinforced with 40% HA showed an increase in compressive strength of approximately 5% over the nonreinforced controls.

Another class of useful buffering compounds are those which, on exposure to water, hydrolyze to form a base as one reaction product. The generated base is free to neutralize

the acidic products produced upon hydrolysis of the bioerodible polymer. Compounds of this type include aryl or alkyl carbamic acids and imines. These "base-generating compounds" offer the advantage that the rate of hydrolysis of the base generator may be selected to correlate to the rate of hydrolysis of the bioerodible polymer.

Necessarily, the conjugate acid of the buffering compound has an acid dissociation constant that is smaller than the acid dissociation constant of the acidic products generated upon hydrolysis of the bioerodible polymer. Alternatively, the buffering compound preferably has a hydrolysis constant that is greater than the hydrolysis constant of the acidic products.

Furthermore, the buffering compound preferably is only partially soluble in an aqueous medium. In general, buffers of lower solubility are preferred because buffer loss from the polymer by diffusion will be minimized (Gresser and Sanderson, supra). The quantity of buffer to include depends on the extent of neutralization desired. This may be calculated as shown below, using a PLGA of any composition buffered with calcium carbonate as an example.

The average residue molecular weight, RMW, for a PLGA is given by

$$RMW = 14.03x + 58.04$$

where x = mole fraction of lactide in the PLGA. The term "residue" refers to the repeating lactide or glycolide moiety of the polymer. For example, if x = 0.85 (PLGA=85:15), RMW = 69.96. Thus, 1.0 gram of PLGA=85:15 contains 0.01429 moles of residues which, on hydrolysis of the polymer, will yield 0.01429 moles of lactic and/or glycolic acid. If, e.g., calcium carbonate is the buffering agent, and it is desired to neutralize, e.g., 50 mole % of the acids by the reaction

$$CaCO_3 + 2HA \rightarrow CaA_2 + H_2O + CO_2$$

where A = lactate or glycolate, then the weight of calcium carbonate needed is (0.25)(0.01429)(100.09) = 0.358 gram, and the required loading is (0.358)(1 + 0.358)(100) = 26.3% by weight.

Several methods may be used to incorporate the buffer into the polymer. These methods include solution casting coupled with solvent evaporation, dry mixing, incorporating the buffer into a polymer foam, and the polymer melt method.

Solution casting coupled with solvent evaporation may be used with buffers which are either soluble or insoluble in the solvent. The bioerodible polymer is dissolved in any suitable volatile solvent, such as acetone, tetrahydrofuran (THF), or methylene chloride. The buffer, which may be soluble or insoluble in this solvent, is added to give the final desired ratio of polymer to buffer. If particle size reduction of the buffer is necessary, it may be accomplished by ball milling the suspension of buffer in the polymer solution. In contrast, if the buffer is soluble in the chosen solvent, particle size reduction at any stage is not necessary.

The suspension or co-solution is cast as a film on a glass or other inert surface, and the solvent is removed by air drying. Residual solvent remaining in the film may be further removed by subjecting the film to vacuum drying at elevated temperatures. As an example, if calcium carbonate is to be used as a buffering compound and it is desired to neutralize 50% of the acid formed by hydrolysis of PLGA-50:50, the buffer content of the composition should be 27.8%.

In an exemplary embodiment, to prepare 50 grams of composite, 36.1 grams of PLGA-50:50 are dissolved in approximately 250 ml of tetrahydrofuran, and 13.9 grams of calcium carbonate of the desired particle size range is added to the solution mixture. After distributing the calcium carbonate homogeneously by mixing, the suspension is dried to a film as described above.

The resulting film may be processed by compaction under high pressure, extruded through a die, injection molded, or other method known in the art. Further definition of the final shape may be accomplished at this point by any desirable machining process, such as lathing.

In the dry-mixing method, a polymer of appropriate particle size range is mixed with the buffer, also of chosen particle size range, in proportions to give the desired stoichiometric buffering capacity. The dry mixture is thoroughly blended by rotating the mixture in a ball mill jar from which the grinding balls have been omitted, or other suitable mixing device. The blended mixture may then be processed by compaction, extrusion, injection molding, etc., as described above.

In the polymer melt method, a known weight of the buffer is incorporated by mixing into a known weight of a suitable melted polymer. A quantity of polymer is heated to a temperature above its melting point, and a suitable buffer is blended into the melted polymer. The resulting polymer/buffer composite is solidified by cooling, and may be processed as described above, or ground and sieved prior to processing.

In some applications, it may be desirable to protect the buffering compound, for example, during processing according to the melt method, or to make the buffering compound available at the later stages of polymer degradation. In such cases, it is desirable to coat the buffering compound particles with a material that degrades at a slower rate than the material chosen for the fixation devices. Thus, the buffering compound is exposed only after the body of the device and the coating material have partially degraded. Exemplary materials used to coat the buffering compound particles include high molecular weight poly(L-lactide) or poly(ϵ-caprolactone).

The particles of buffering compound may be coated with the protective material by any method that coats particles, such as spray coating with a solution of protecting polymer or micro-encapsulation. Alternatively, a chosen protective polymer may be made in a melted state and buffer particles are added. The melt is cooled and ground and milled to the desired particle size range. Alternatively, the buffering compound may be added to a solution of the protective polymer

and removing the solvent by evaporation. The dried mass is compacted in a mold under high pressure and grinding or milling the compacted mass to the appropriate particle size range.

The resorbable spinal fusion device of the invention optionally includes a biological growth factor, e.g., bone morphogenic protein, to enhance bone cell growth. To protect the growth factor and to provide for controlled delivery, the biological growth factor may be itself compounded with a resorbable polymer by one of the many techniques available and prepared as a growth factor/polymer composite in pellet form, in small particle form or within the interstices or pores of a polymeric foam or low-density polymer and this polymer/growth factor composite deposited into void spaces of the resorbable spinal fusion device. Alternatively, the growth factor may simply be directly incorporated into the component formulation of the resorbable spinal fusion device.

Active periosteum cells, or other bony cells, may be also incorporated into a foam surrounding, or deposited in, the resorbable spinal fusion device so that the cells may facilitate bone cell fusion. To carry out such an incorporation, the periosteum surrounding a human bone is removed and cultured following standard cell culturing techniques. The scaffold for such periosteum cell growth is a resorbable polymer foam or mesh. This scaffolding is prepared by dipping the completed device in a polymer/solvent (such as PLGA dissolved in acetic acid). The so-wetted device is then frozen and subsequently freeze-dried (lyophilized) resulting in a foam layer (or coating) of polymer surrounding the device. After the periosteum cells have been grown in this foam layer, the device is incorporated into the spine for the enhancement of spinal fusion.

In another embodiment, the resorbable spinal fusion device may be prepared in such a manner as to exhibit a piezoelectric effect. It is known that oriented (molecularly aligned) biopolymers such as PLGA have piezoelectric

characteristics. In addition, the oriented biopolymer poly-l-lactic acid (PLLA) has been shown to promote bone wound healing (Shimono et al., *In Vivo* 10:471-476, 1996 and Ikada et al., J. Biomed, Mater. Res. 30:553-558, 1996). To take advantage of this phenomenon, the resorbable polymer is first aligned, by drawing, for example, such that all polymer chains are essentially parallel. The spinal fusion device is then cut from this aligned polymeric material such that the polymer chains are at approximately a 45° angle to the surface of the device, this angle being known to produce the optimal piezoelectric effect. Buffers, reinforcement materials, growth factors, etc., may also be included in processing of the spinal fusion device to exhibit this phenomenon.

As described by White et al. (Clinical Biomechanics of the Spine, 2nd edition, 1990), there are four stages of maturation of the arthrodesis (spinal fusion): I, fibrous healing; II, mixed fibrous and osseous healing; III, immature osseous healing; and IV mature osseous healing. Stage I requires maximum protection with restricted activity and perhaps a protective orthosis. During stage II relatively less protection is required although with restricted activity. During stage III the patient is allowed normal but nonvigorous activity. In stage IV, maximum healing will be reached. For clinically stable patients the first three stages require about six weeks each, and stage IV, a minimum of six weeks. Clinically unstable patients require more time, especially for the first two stages. Thus the goals for duration and strength may be estimated.

A prototype device has been prepared for *in vitro* determination of weight loss and failure strength as a function of time. Due to the asymmetric design of the IFD, it is not feasible to measure the compressive modulus over time of the *in vitro* prototypes. This parameter, as well as failure and ultimate strength over time *in vitro*, has been measured on cylindrical discs of the same overall dimensions. *In vitro* experiments permit monitoring of the change in

molecular weight in time for correlation with the mechanical measurements. Devices are tested for mechanical properties, e.g., compressive strength, compressive modulus, with equipment such as, e.g., the TA-XT2 Texture Analyzer (Texture Technologies Corporation) or the Instron 8511 Servo-Hydraulic System (Instrom Corp.).

PLGA-85:15 (Resomer RG 858) including reinforcing fibers and HA buffer was molded at approximately 50°C under a force of 7-9 tons to form a translucent cylindrical rod 1.6 cm in diameter and 5.0 cm in length. Devices were then machined to the appropriate final dimensions, as discussed earlier. White and Panjabi (p. 29) report dimensions and stresses to which thoracic vertebrae are subject. The average area of the upper and lower end plates of T1 is about 340 mm^2, and is subject to a loading force of about 2000 N. The compressive strengths of exemplary buffered and reinforced devices were, in all cases, greater than 13,000 N. Thus, the initial strength of these PLGA-85:15 devices is in excess of the stress to which cervical vertebrae will be subject and greater also than clinical targets of 10,000 N. Devices so made do not fracture at failure but rather irreversibly compress.

Figure 7 illustrates this phenomenon. Failure at 13 kN is indicated by a slowly rising load at displacements greater than about 1.5mm. If the tested device had failed by fracture, a rapid drop in load would have resulted. The design of the IFD and the PLGA comonomer ratio (i.e., lactide:glycolide ratio) enable the device to function through the four stages of healing with progressive loss of mass and strength. In clinically stable situations, at the end of stage I, the device should retain 70-80% of its mechanical strength, and at the end of stage II, 50% of its strength should be retained. During stages III and IV, further slow degradation will occur with complete resorption by one year.

Prototype devices have been prepared for feasibility trials with goats as the animal model. A viable model for

testing fusion materials in the cervical spine is the *in vivo* goat model. Unlike most quadrupeds, the goat holds its head erect, thus loading the cervical vertebrae in a manner similar to humans. Although there are geometric differences, the relative sizes of the disc and vertebral bodies are similar to those of the human. (Pintar et al., Spine 19:2524-2528, 1994; Zdeblick et al., Spine 17(105):5418-5426, 1992.) The goat is thus the animal model of choice for testing the spinal fusion device of the invention.

The experimental procedure followed in the *in vivo* goat model is as follows. Anesthetized animals undergo implantation via a surgery to the anterior cervical spine (Pintar et al., Spine 19:2524-2528, 1994). After exposing the lower 5 cervical segments, discectomy is performed at four levels. Two resorbable IFD's filled with cancellous bone are placed in two of these spaces, the others receive a piece of tricortical iliac bone graft in place. The bone graft and cancellous bone are harvested from the goat iliac crest through a separate incision over the hip bone. Placement of the IFD or the graft in upper or lower sites is alternated for each animal with an intact disc space between implants. The operative sites are closed, and the animals allowed to recover.

At sacrifice, the spinal column of the goat is excised leaving the intact ligamentous column. The cervical and lumbar sites are separated and radiographed before mounting for biomechanical (as described above) or histological analyses for resorptive activity and new bone formation. The fusion rate and biomechanical stiffness are evaluated for spinal units harvested from the goats. Spinal units undergo radiographic imaging to assess fusion, biomechanical testing to assess strength, and histological analysis to assess tissue changes. The results are compared to conventional graft-based spacers and fusion devices.

PLGA implants can be effectively reinforced by the use of degradable scaffolds which are molecularly dispersed in the host PLGA polymer. For example, a solid solution

containing PLGA, poly(propylene fumarate)(PPF), and vinyl pyrrolidinone(VP) as a crosslinking agent (or other vinyl monomer) may be heated with an initiator (such as benzoyl peroxide). The PPF chains are crosslinked by VP to form an interpenetrating network of crosslinked PPF and PLGA polymer chains. Following heating, further crosslinking is possible using γ-irradiation, e.g. 2.5 mrad.

Several reinforcement techniques described in the literature include self-reinforcement using aligned PLGA fibers (Vainionpaa et al., Biomaterial 8:46-48, 1987; Pihlajamaki et al., J. Bone and Joint Surgery 74:13:853-857, 1992; Ashammakhi et al., J. Biomedical Materials Research 29: 687-694, 1995) and reinforcement with calcium phosphate glass fibers (R.A. Casper et al., Polym. Mater. Sci. Eng. 53:497-501, 1985).

Reinforcement can also be achieved according to the invention by molding a rod of rectangular or other suitable cross-section that contains fibers under tension using the mold and ram assembly of the invention, as shown in Figs. 6A-6G. Referring to Fig. 6A, mold cavity 61 and ram 62 are rectangular in cross- section in the illustrated embodiment. The mold illustrated is constructed of five plates (front face plate 63, rear face plate 64, side plates 65 and bottom plate 66), suitably fastened or bonded together. The front and rear face plates 63, 64 are machined or otherwise formatted, as will be described below, with key holes 60 to receive holder assemblies for the reinforcing fibers, which comprise front and rear tension tubes, front and rear tension tube caps, serrated discs, and a front tension tube threaded nut.

Referring to Fig. 6B (an edge view of front face plate 63) and Fig. 6C (a plan view of front face plate 63), the inside face 67 of plate 63 contains a circular recess 68, with associated slots 69. Recess 68 adjoins a larger recess 70 that extends to the outside face 71 of front face plate 63. Recess 70 includes associated slots 72. The axis between slots 72 is perpendicular to the axis between slots

69. A smaller diameter recess stop 73 separates recess 68 from recess 70. Rear face plate 64 is similarly configured.

Referring now also to Figs. 6D-G, the mold is assembled for use as follows. A disc 75 (Fig. 6D) having serrated slots 76 is threaded with polymer fibers 88, which are distributed throughout the serrated slots. The distribution of the fibers is spatially maintained by the serrations. Referring also to Fig. 6G, discs 75 with fibers in place are mounted in recesses 68 in the front and rear face plates 63, 64 of the assembled mold. Orientation of discs 75 is maintained by vanes 77 on the sides of the discs, which fit into slots 69. Alternatively, discs 75 may be mounted first in face plates 63, 64 and threaded in place. The protruding fiber bundles are then threaded through front and rear tension tube assemblies 78, 79, which are positioned in recesses 70 in the front and rear face plates 63, 64, respectively. Tension tube assemblies 78, 79 consist of tension tubes 80, each having vanes 82 which fit into slots 72 in the front and rear face plate recesses 70, respectively, thus maintaining the orientation of the tubes. The tension tubes are closed with caps 83 to complete assemblies 78, 79. The fiber bundles are threaded additionally through holes 84 in the front and rear tension tube caps, as they exit the tension tubes. Holes 84 are off-center and below the axis of the tension tubes. This configuration holds the fibers against the serrations of the discs. Outside the caps, the fibers may be knotted to keep them from slipping back through the holes. Other methods of anchoring the fibers may be used. For example, a bead of cement (such as epoxy or cyanoacrylate adhesives) may be built up on the outside of the caps to keep the fibers from slipping through. Also referring to Figs. 6E and 6F, it can be seen that the tension tube 80 of front tension tube assembly 78 is exteriorly threaded 85 along its length and equipped with a nut 86 which, when tightened against the face plate, pulls the tension tube partially out of the face plate, thus putting the fibers under tension.

To prepare a reinforced resorbable spinal fusion device, mold cavity 61 of the assembled mold is then filled with the appropriate powdered formulation. The powdered formulation may be evenly distributed among the fibers by placing the mold on a vibrator. Ram 62 is put in place, in the opening of the mold, and pressure is exerted. The mold may be heated externally with heating tapes, or it may be so machined as to have recesses for cartridge heaters. When the molding process is complete, the tension on the reinforcing fibers is released, and the completed device is removed from the mold.

While the present invention has been described in conjunction with a preferred embodiment, one of ordinary skill, after reading the foregoing specification, will be able to effect various changes, substitutions of equivalents, and other alterations to the compositions and methods set forth herein. It is therefore intended that the protection granted by Letters Patent hereon be limited only by the definitions contained in the appended claims and equivalents thereof.

CLAIMS

What is claimed is:

1. A resorbable interbody spinal fusion device for spinal fixation, said device comprising 25-100% resorbable material.

2. The resorbable interbody spinal fusion device of claim 1, further comprising one or more void spaces therein.

3. The resorbable interbody spinal fusion device of claim 2, wherein one of said one or more void spaces contains a grafting material for facilitating bony development and/or spinal fusion.

4. The resorbable interbody spinal fusion device of claim 3, wherein said grafting material is an autologous grafting material.

5. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a tapered wedge or cone.

6. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a threaded screw.

7. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a threaded rod of cruciform configuration.

8. The resorbable interbody spinal fusion device of claim 5, further comprising at least one serrated or threaded outer face.

9. The resorbable interbody spinal fusion device of claim 1, wherein said resorbable material is a polymer producing

acidic products or low molecular weight resorbable fragments upon hydrolytic degradation.

10. The resorbable interbody spinal fusion device of claim 9, wherein said resorbable material further comprises a buffering or neutralizing agent in sufficiently high concentration to moderate the rate of change of pH of said resorbable material during resorption.

11. The resorbable interbody spinal fusion device of claim 1, wherein said resorbable material is a polymer selected from the group consisting of polydioxanone, poly(ϵ-caprolactone), polyanhydride, polyester, copoly(ether-ester), polyamide, polylactone, poly(propylene fumarate), and combinations thereof.

12. The resorbable interbody spinal fusion device of claim 11, wherein said bioerodible polymer comprises poly(lactide-co-glycolide) with a lactide to glycolide ratio in the range of 0:100% to 100:0% inclusive.

13. The resorbable interbody spinal fusion device of claim 10, wherein said buffering or neutralizing agent is a polymer comprising at least one basic group.

14. The resorbable interbody spinal fusion device of claim 13, wherein said polymer comprising at least one basic group is selected from the group consisting of polyamines, polyesters, vinyl polymers, and copolymers of acrylic acid.

15. The resorbable interbody spinal fusion device of claim 10, wherein said buffering or neutralizing agent is a compound that, on exposure to water, hydrolyzes to form a base.

16. The resorbable interbody spinal fusion device of claim 10, wherein said buffering or neutralizing agent is selected

from the group consisting of carbonates, phosphates, acetates, succinates and citrates.

17. The resorbable interbody spinal fusion device of claim 1 wherein said resorbable material further comprises reinforcing fibers.

18. The resorbable interbody spinal fusion device of claim 17, wherein said reinforcing fibers are made of said resorbable material.

19. The resorbable interbody spinal fusion device of claim 10, wherein said resorbable material further comprises reinforcing fibers.

20. The resorbable interbody spinal fusion device of claim 19, wherein said reinforcing fibers are made of said buffering or neutralizing agent.

21. A substantially wedge shaped resorbable interbody spinal fusion device, wherein said device is substantially manufactured from a resorbable material poly(d,l-lactide-co-glycolide), said device further comprising a buffering or neutralizing agent wherein said buffering or neutralizing agent is hydroxyapatite, and wherein said device further comprises one or more void spaces therein.

22. A resorbable interbody spinal fusion device, said device shaped substantially as a threaded screw, wherein said device is substantially manufactured from a resorbable material poly(d,l-lactide-co-glycolide), said device further comprising a buffering or neutralizing agent wherein said buffering or neutralizing agent is hydroxyapatite, and wherein said device further comprises one or more void spaces therein.

23. A method of making a resorbable interbody spinal fusion device, comprising the steps of:

providing a mold for said resorbable interbody spinal fusion device;

orienting reinforcing fibers under tension in said mold;

introducing a resorbable material into said mold;

molding said resorbable material under pressure; and

releasing tension on said reinforcing fibers prior to removing said device from said mold.

24. The method of claim 23 wherein said resorbable reinforcing fibers are made of the same material as said resorbable interbody material.

25. The method of claim 23 wherein said resorbable reinforcing fibers do not contain a buffer.

26. The resorbable interbody spinal fusion device of claim 10 wherein said buffering or neutralizing agent is selected from the group consisting of compounds wherein the pKa of the conjugate acids of said compounds is greater than the pKa of acids produced by hydrolysis of the polymer(s) from which said device is prepared.

27. The resorbable interbody spinal fusion device of claim 1, wherein said device is fabricated from at least two resorbable polymers.

28. The resorbable interbody spinal fusion device of claim 27, wherein one of said resorbable polymers is poly (propylene fumarate).

29. The resorbable interbody spinal fusion device of claim 27, wherein one of said resorbable polymers has been cross-linked in the presence of a crosslinking agent and an initiator, whereby said crosslinked resorbable polymer forms a reinforcing interpenetrating network.

30. The resorbable interbody spinal fusion device of claim 29, wherein said crosslinking agent is vinyl pyrrolidone.

31. The resorbable interbody spinal fusion device of claim 29, wherein said initiator is benzoyl peroxide.

32. The resorbable interbody spinal fusion device of claim 1, wherein said device is fabricated from a polymer wherein molecular chains of said polymer have been aligned to be essentially parallel.

33. The resorbable interbody spinal fusion device of claim 32, wherein said device has been cut such that the aligned polymer molecular chains are at approximately a 45° angle to a surface of said device.

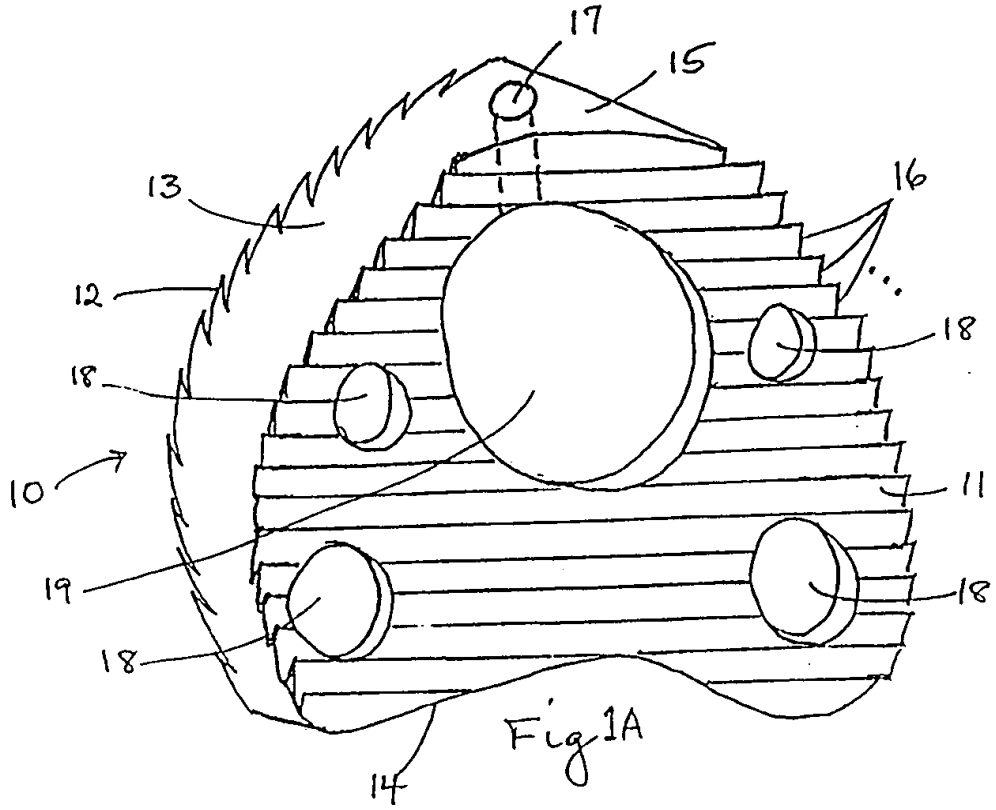

Fig.1A

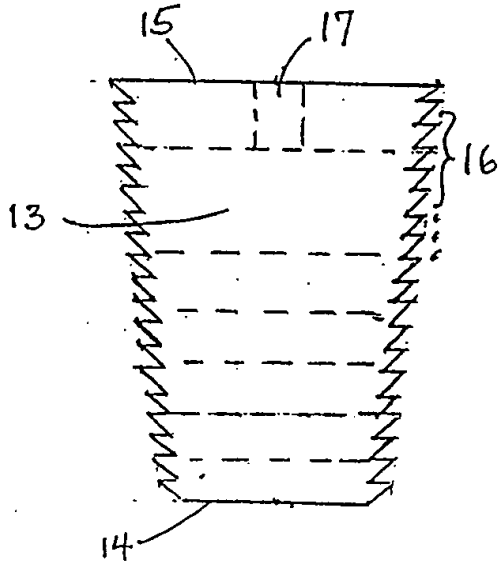

Fig.1B

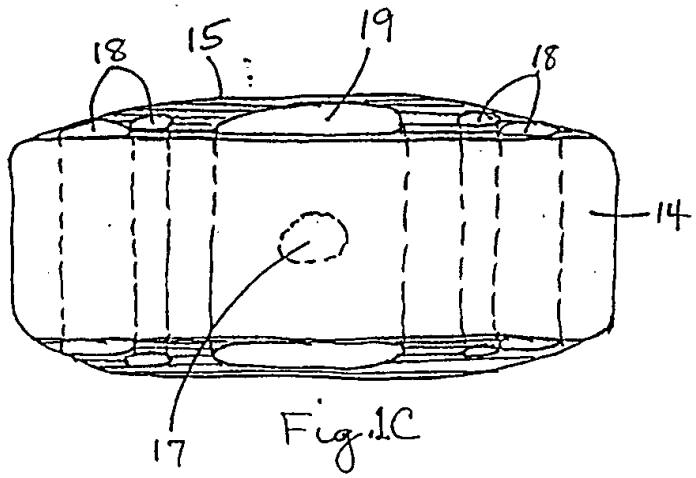

Fig.1C

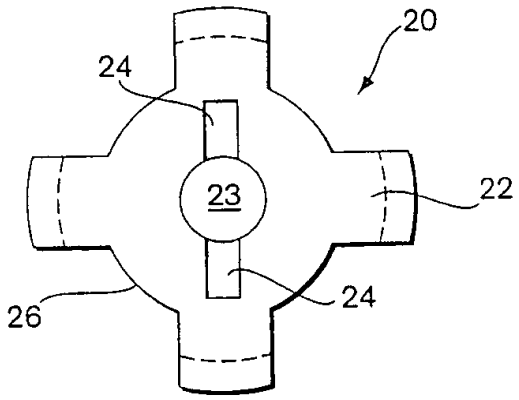

Fig. 2A

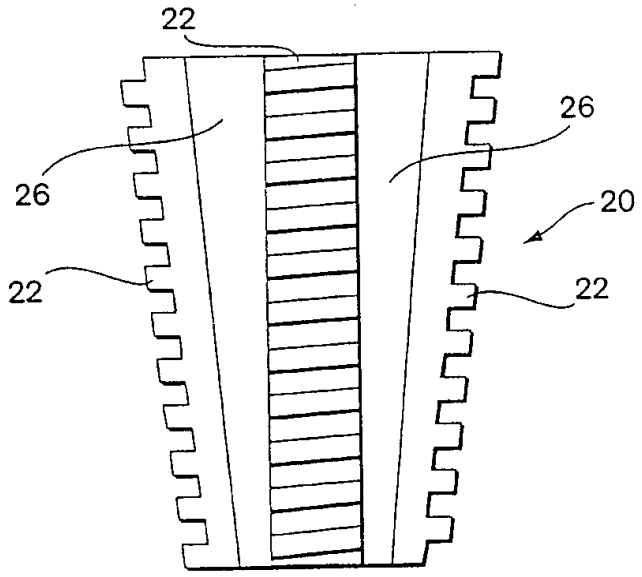

Fig. 2B

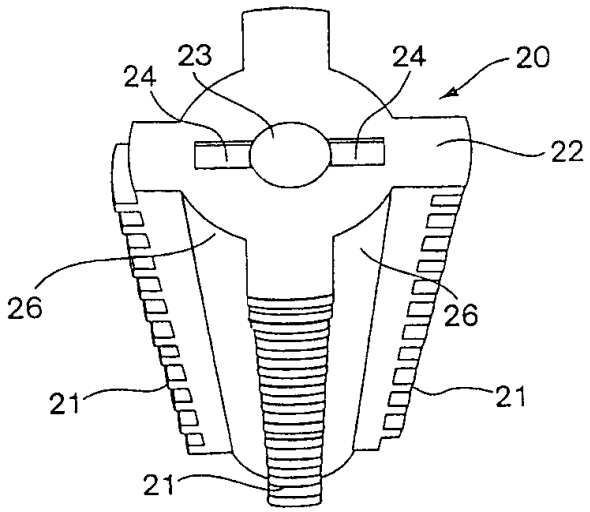

Fig. 2C

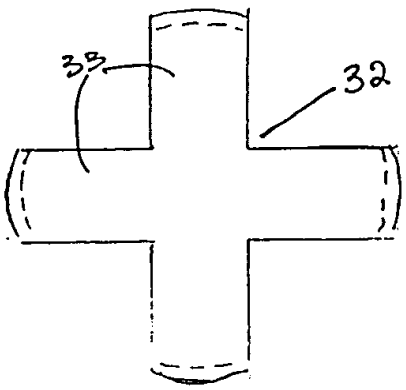

Fig. 3A

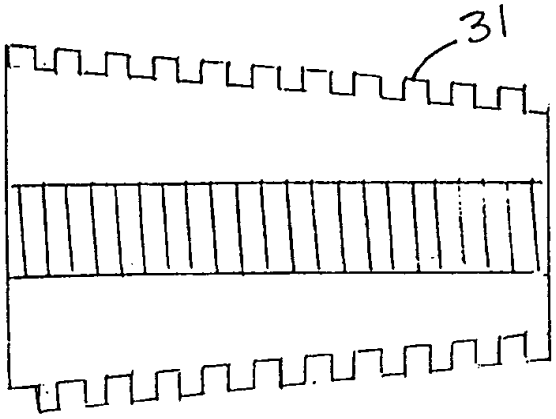

Fig. 3B

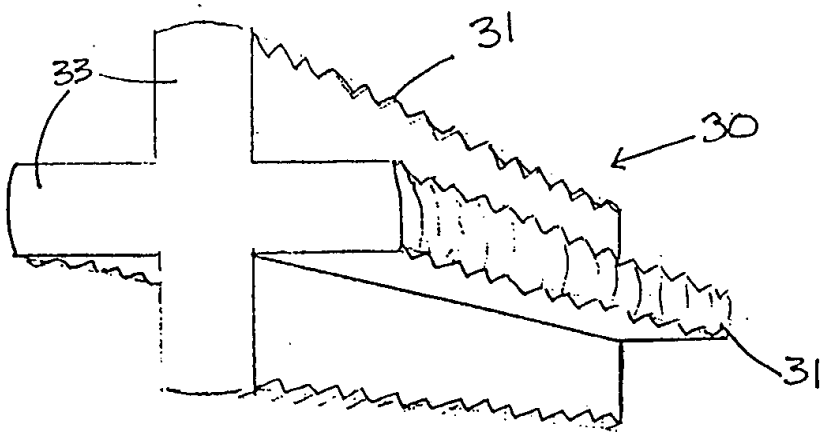

Fig. 3C

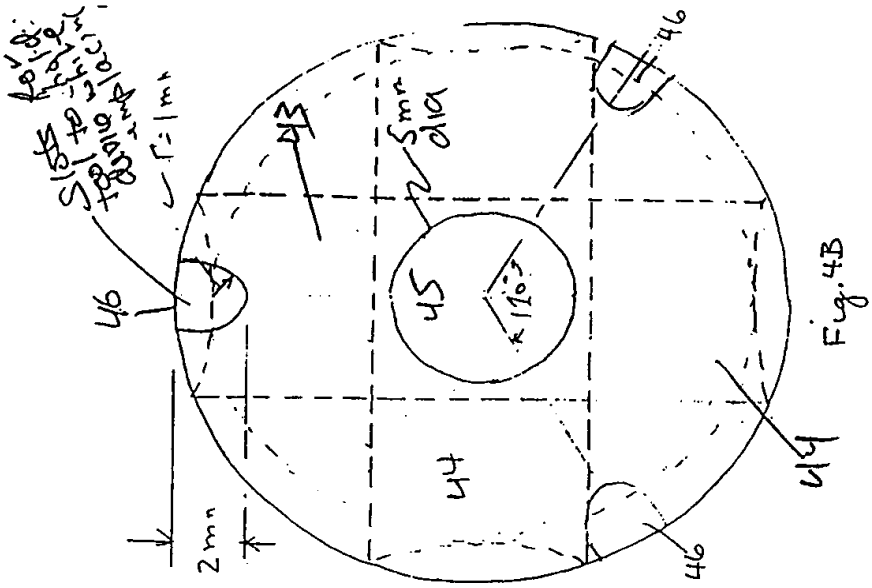

Fig. 4B

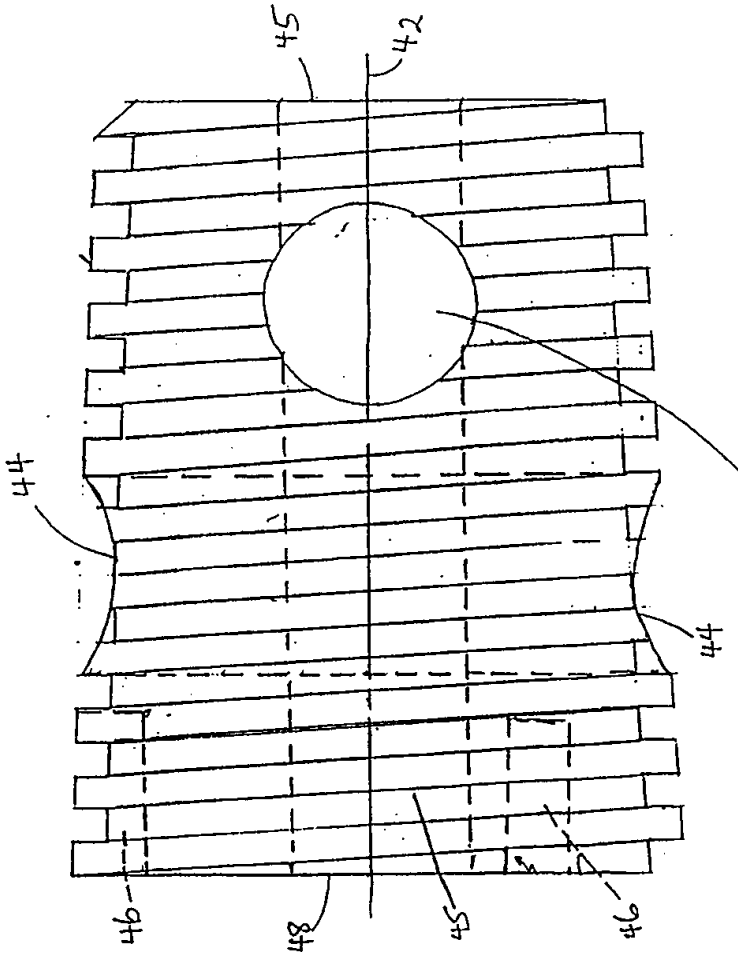

Fig. 4A

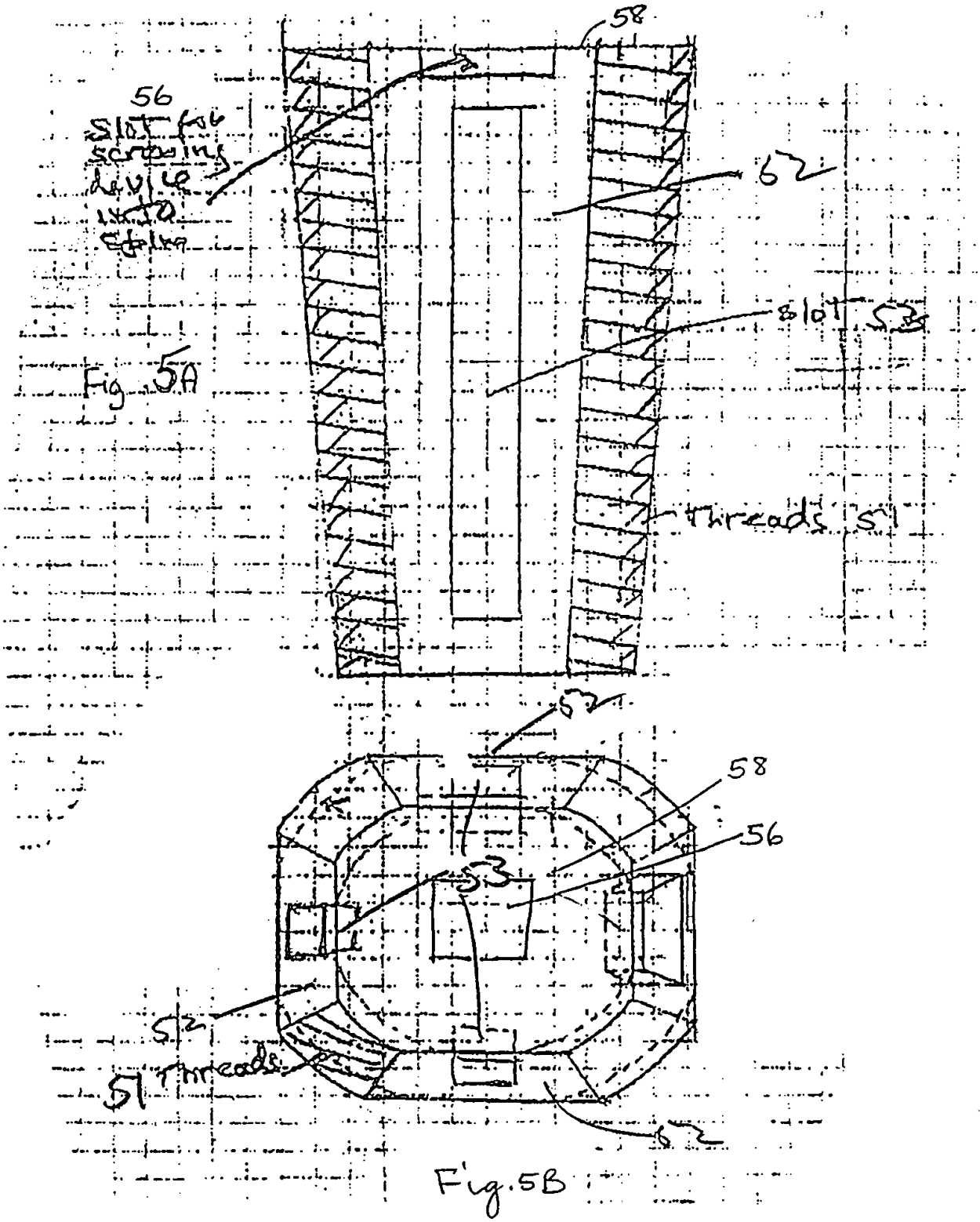

Fig. 5A

Fig. 5B

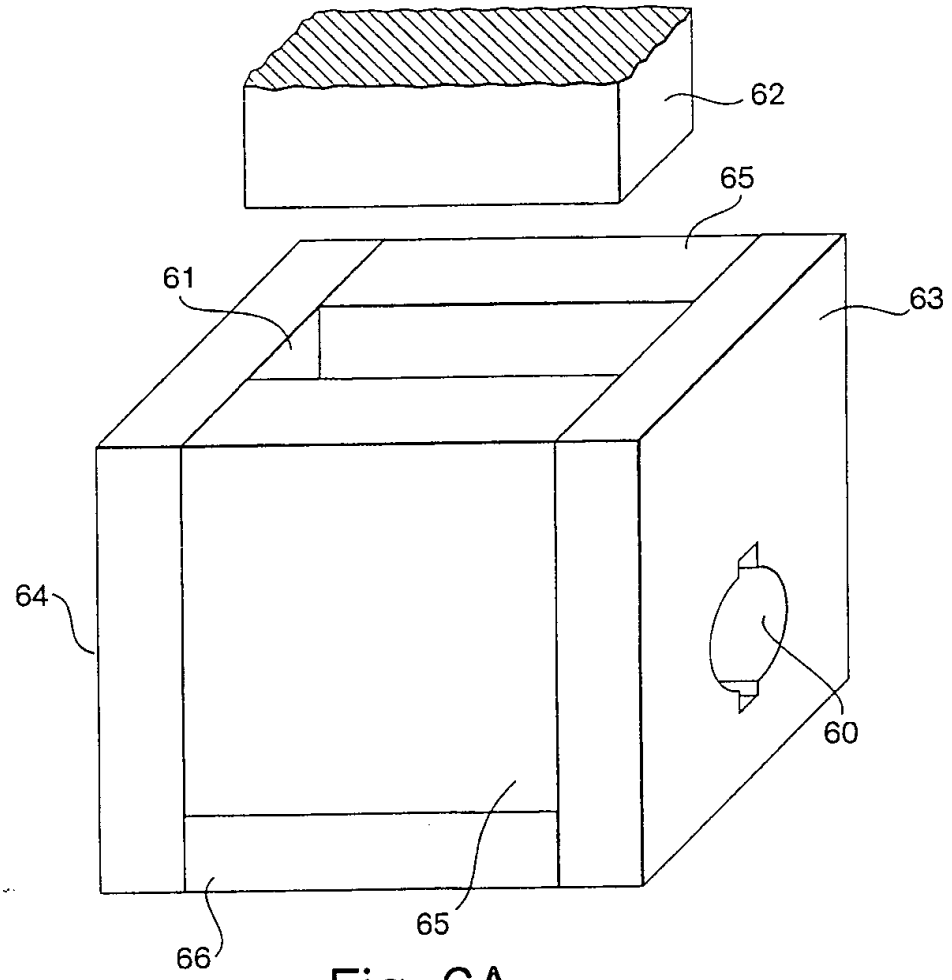

Fig. 6A

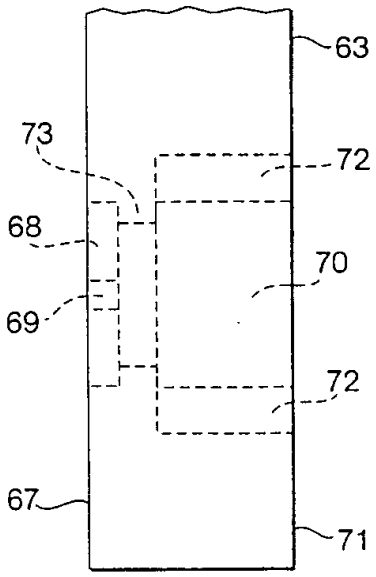

Fig. 6B

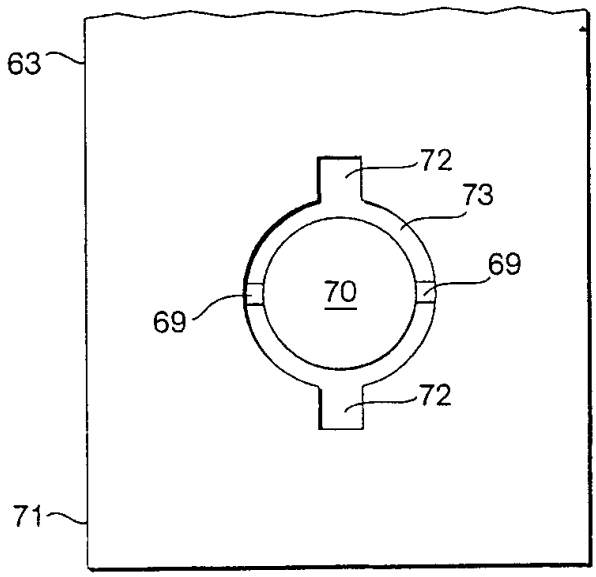

Fig. 6C

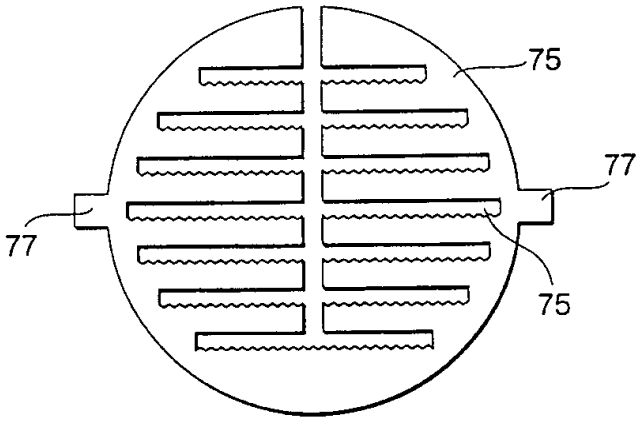

Fig. 6D

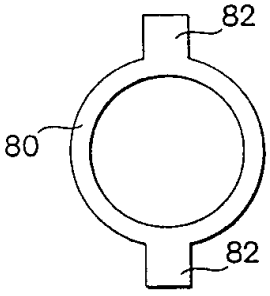

Fig. 6E

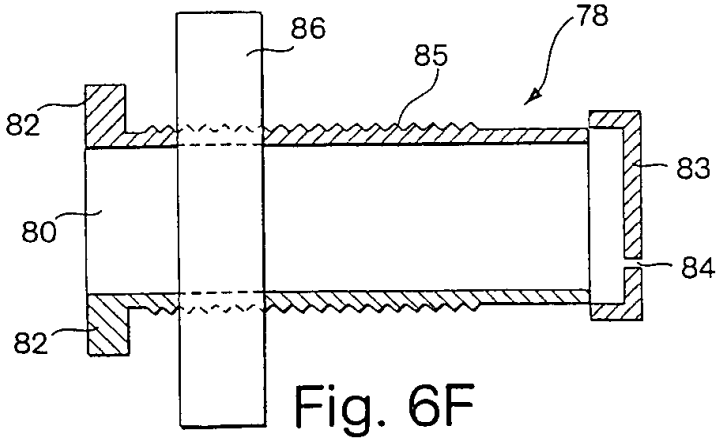

Fig. 6F

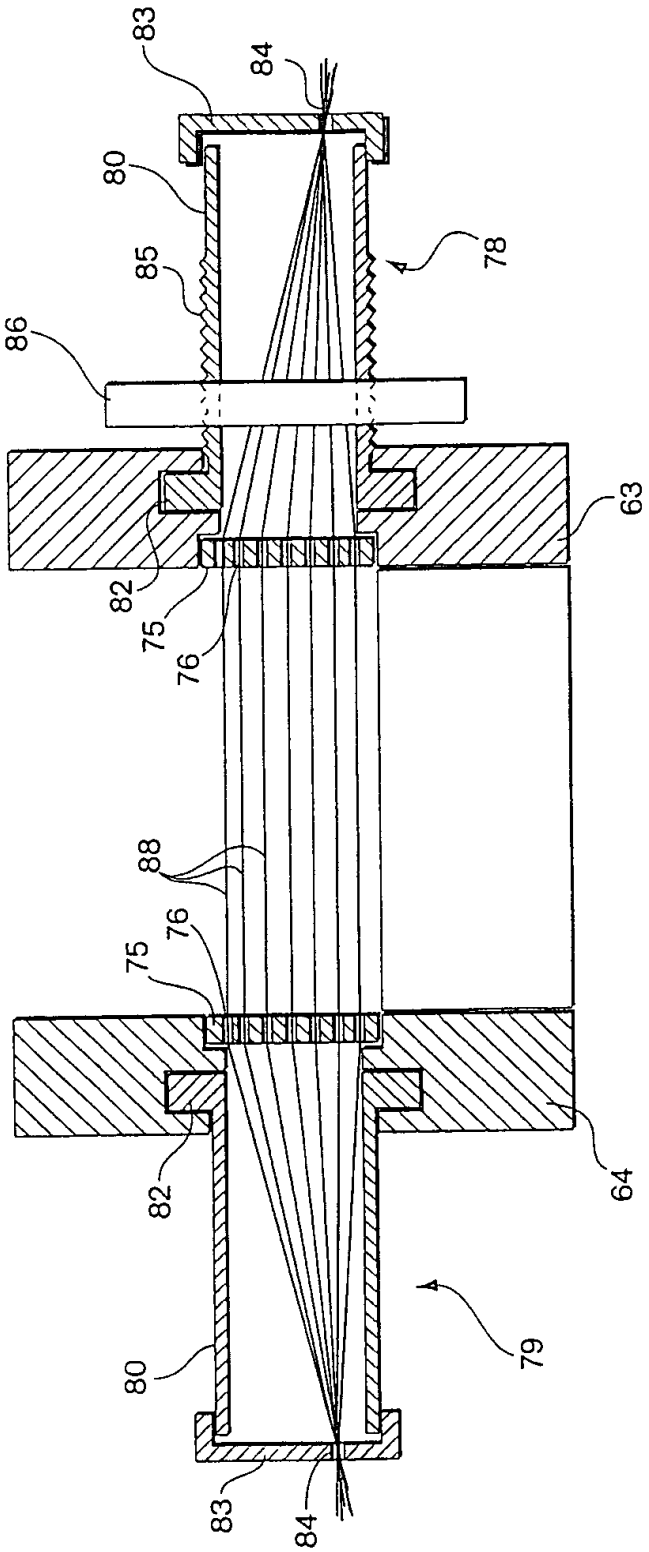

Fig. 6G

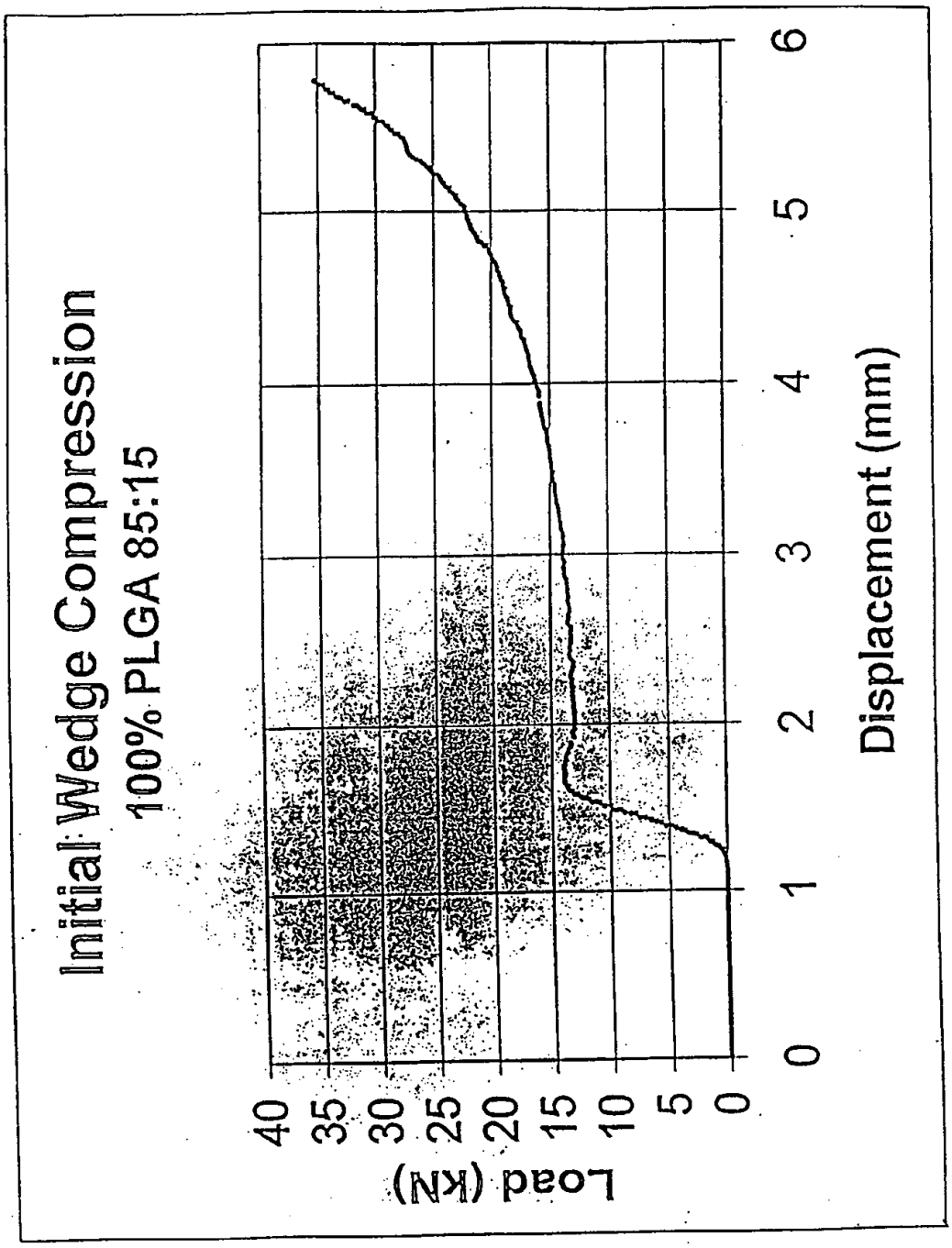

Fig. 7

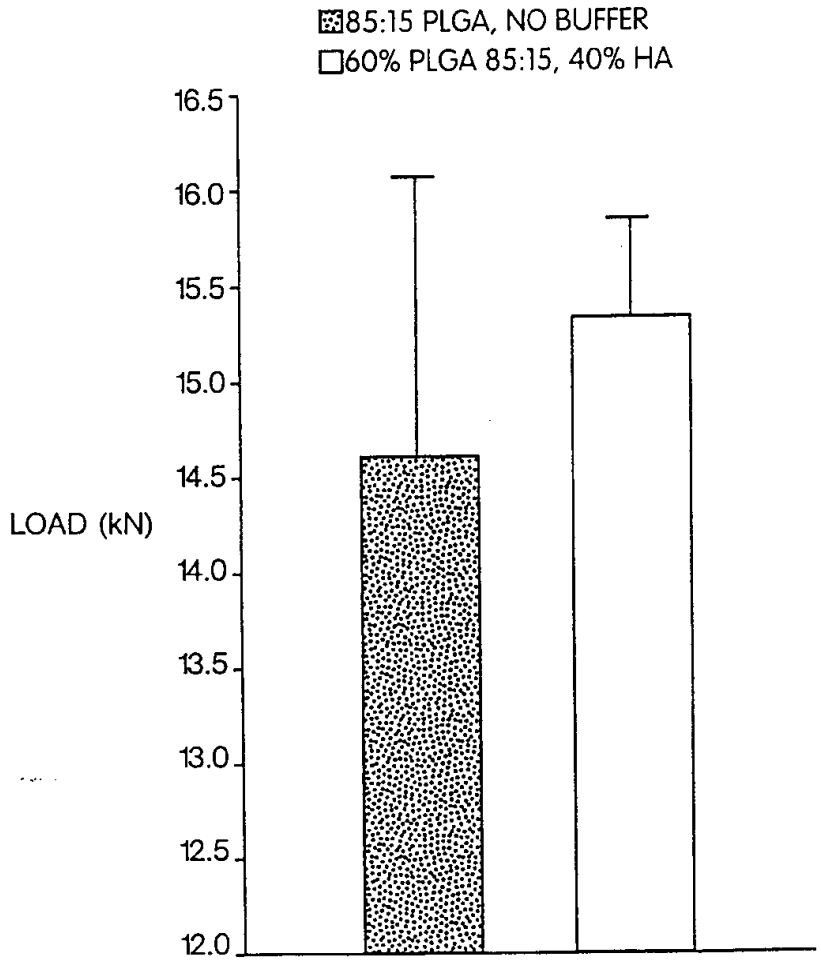
85:15 PLGA, NO BUFFER
60% PLGA 85:15, 40% HA
LOAD (kN)
16.5
16.0
15.5
15.0
14.5
14.0
13.5
13.0
12.5
12.0

Fig. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/16650

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/44
US CL :623/17

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. : 606,65, 77; 623/17

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)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,225,129 A (VAN DEN BERG) 06 July 1993, entire document especially col. 6 lines 21-49, and claims 19-24.	23-25
X	US 5,527,864 A (SUGGS et al) 18 June 1996, entire document.	1, 27-31
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Y		32, 33
X	US 5,522,895 A (MIKOS) 04 June 1996, entire document.	1-3, 9, 11, 12
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Y		5-8
Y	US 4,349,921 A (KUNTZ) 21 September 1982, entire document.	5-8

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 14 SEPTEMBER 1998	Date of mailing of the international search report 19 OCT 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer PAUL PREBILIC Telephone No. (703) 308-2905

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/16650

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,655,777 A (DUNN et al) 07 April 1987, entire document.	1, 9-13, 15-20, 26, 27 ---------- 33
Y	US 4,968,317 A (TORMALA et al) 06 November 1990, entire document.	32

B. FIELDS SEARCHED
Electronic data bases consulted (Name of data base and where practicable terms used):

APS
Search Terms: (resorbable or bioresorbable or absorbable or bioabsorbable or degradable or biodegradable) and buffer? and (glycoli? or lacti? or polyglycol? or polylacti?); and propylene fumarate. search terms: 264/257/ccls and (resorbable or bioresorbable or absorbable or bioabsorable or degradable or biodegradable).

PCT

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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/44

A2

(11) International Publication Number: WO 99/38461

(43) International Publication Date: 5 August 1999 (05.08.99)

(21) International Application Number: PCT/EP99/00433

(22) International Filing Date: 22 January 1999 (22.01.99)

(30) Priority Data:

60/073,271	30 January 1998 (30.01.98)	US
60/095,425	5 August 1998 (05.08.98)	US

(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

Without international search report and to be republished upon receipt of that report.

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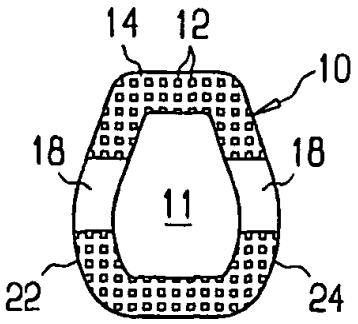
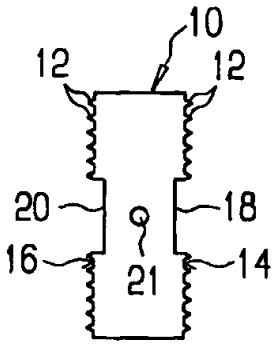
(54) Title: ALLOGENIC INTERVERTEBRAL IMPLANT





(57) Abstract

An allogenic intervertebral implant (10) for fusing vertebrae is disclosed. The implant (10) is an annular plug conforming in size and shape with end plates of vertebrae. The implant has either an exterior surface identical to that of the harvest bone or an exterior surface machined to have a uniform shape such as an oval or a rectangle. The top and bottom surfaces (14, 16) of the implant (10) have a plurality of teeth (12) to resist expulsion and provide initial stability. The top and bottom surfaces (14, 16) can be either flat planar surfaces or curved surfaces. Preferably, the anterior height of the implant is greater than the posterior height so that the implant is wedge–shaped profile to help restore disc height and the natural curvature of the spine. In one embodiment, the top and bottom surfaces each have a channel oriented in the anterior, lateral, or antero–lateral direction for receiving a surgical instrument. The implant can also have a hole for attachment of an inserter. Although the interior space formed by the annular plug can be the natural shape defined by the medullary canal, the medullary canal walls can be machined so that the implant has a uniform interior space.

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ALLOGENIC INTERVERTEBRAL IMPLANT

This invention concerns a device in accordance with the pre-characterising portion of Claim 1. More particularly, it refers to an allogenic intervertebral implant for use in the treatment of back pain.

A number of medical conditions such as compression of spinal cord nerve roots, degenerative disc disease, and trauma can cause severe back pain. Intervertebral fusion is a surgical method of alleviating back pain. In intervertebral fusion, two adjacent vertebral bodies are fused together by removing the affected intervertebral disc and inserting an implant that would allow for bone to grow between the two vertebral bodies to bridge the gap left by the disc removal.

A number of different implants and implant materials have been used for fusion with varying success. Current implants used include titanium cages and allografts. Titanium cages suffer from the disadvantage of requiring drilling and tapping of the vertebral endplates for insertion. In addition, the incidence of subsidence in long term use is not known. Due to MRI

incompatibility of titanium, determining fusion is problematic. Finally, restoration of lordosis, i.e., the natural curvature of the cervical and lumbar spine is very difficult when a titanium cage is used.

Allografts are sections of bone taken from the diaphysis of a long bone, such as the radius, ulna, fibula, humerus, tibia, or femur of a donor. A cross section of the bone is taken and processed using known techniques to preserve the allograft until implantation and reduce the risk of an adverse immunological response when implanted. For example, U.S. Patent No. 4,678,470 discloses a method for processing a bone grafting material which uses glutaraldehyde tanning to produce a non-antigenic, biocompatible material. Allografts have mechanical properties which are similar to the mechanical properties of vertebrae even after processing. This prevents stress shielding that occurs with metallic implants. They are also MRI compatible so that fusion can be more accurately ascertained and promote the formation of bone, i.e., osteoconductive. Although the osteoconductive nature of the allograft provides a biological interlocking between the allograft and the vertebrae for long term mechanical strength, initial and short term mechanical strength of the interface between the allograft and the vertebrae are lacking such that there is a possibility of the allograft being expelled after implantation.

U.S. Patent No. 5,728,159 discloses an allograft having grooves on end faces in an attempt to try to promote stability, but there are more effective ways for resisting expulsion.

For example, WO 98/17209, published April 30, 1998, is directed to a spinal spacer and has one embodiment which is an allograft cortical ring having teeth on superior and/or inferior surfaces. These teeth provide the initial, secure interlocking with the vertebrae.

Most allografts are simply sections of bone which, although cut to the approximate height of the disc being replaced, have not been sized and/or machined on the exterior surface to have a uniform shape. As a result, the fusion of the vertebral bodies does not occur in optimal anatomic position in a consistent manner along the surface of the endplates. While a surgeon may do some minimal intraoperative shaping and sizing to customize the allograft for the patient's anatomy, significant shaping and sizing of the allograft is not possible due to the nature of the allograft. Even if extensive shaping and sizing were possible, a surgeon's ability to manually shape and size the allograft to the desired dimensions is severely limited.

As the discussion above illustrates, there is a need for an improved allogenic implant for fusing vertebrae and relieving back pain. The invention as claimed aims at solving the above described problems.

The present invention provides an allogenic intervertebral implant for use when surgical fusion of vertebral bodies is indicated as defined in Claim 1.

The annular plug of allogenic bone is dimensioned in such a way that it conforms in size and shape with end plates of adjacent vertebrae, i.e. a rounded or appriximately circular form.

In a preferred embodiment the three-dimensional structure of the intervertebral implant includes a plurality of teeth. Preferably the three-dimensional structure has a minimum height of 0,5 mm and a maximum height of 1,5 mm relative to the top and bottom surfaces of the implant.

The teeth preferably have a pyramid shape or a saw-tooth shape. In one embodiment, the implant has an exterior surface machined to have a uniform shape, such as an oval or a rectangle. The interior space delineated by the annular plug also can have a machined wall to provide the implant with a uniform interior space. The interior space delineated by the annular plug can be filled with spongiosa, bone graft substitutes or artificial bone material.

The top and bottom surfaces may be flat planar surfaces or curved surfaces to mimic the topography of the end plates of the adjacent vertebrae. In a preferred embodiment, the anterior

height of the implant is greater than the posterior height of the implant so that the implant has a wedge-shaped profile to help restore disc height and the natural curvature of the spine.

In one embodiment, the implant has channels on the top and bottom surfaces for receiving a surgical tool, e.g. a distractor. These channels can run in the anterior, lateral, or antero-lateral direction to accommodate a variety of different tools used in surgical procedures. Finally, a threaded hole on the anterior, antero-lateral, or lateral side can be provided for receiving a threaded arm of an insertion tool.

The allogenic bone is preferably in the form of a cross section transverse to the longitudinal axis a human long bone, typically with a height of 5 to 8 mm. Preferably the allogenic bone has been process frozen or freeze dried. The allogenic bone may also be treated with an antiseptic solution.

In the drawings:

FIG. 1 is a top view of a first embodiment of the implant according to the present invention;

FIG. 2 is a front view of the implant of FIG. 1;

FIG. 3 is a top view of a second embodiment of the implant;

FIG. 4 is a side view of the implant of FIG. 1;

FIG. 5 is a side view of a third embodiment of the implant;

FIG. 6 is a close up of region A from FIG. 4 and FIG. 8;

FIG. 7 is a top view of a fourth embodiment of the implant according to the present invention;

FIG. 8 is a side view of the implant of FIG. 7;

FIG. 9 is a top view of a sixth embodiment of the implant; and

FIG. 10 shows an alternative tooth configuration.

FIG. 1 shows a top view of a first embodiment of an allogenic intervertebral implant 10 according to the present invention. Implant 10 is annular and conforms in size and shape with the end plates of the vertebrae between which implant 10 is to be implanted. Because implant 10 is annular, new bone can form in interior 11. Interior 11 can be filled with bone chips or any other osteoconductive material to promote the formation of bone. Although implant 10 will probably be predominantly used in the lumbar region of the spine, implant 10 can be configured for implantation in any region of the spine. Implant 10 has a plurality of teeth 12 on superior and inferior surfaces 14, 16 which provide a mechanical interlock between implant 10 and the end plates. These teeth 12 provide the mechanical interlock by

penetrating the end plates. The initial mechanical stability afforded by teeth 12 minimizes the risk of post-operative expulsion of implant 10. Preferably, teeth 12 are pyramid-shaped in which the angle formed from the tip to the base may be between about 45 and 75° and is preferably about 60°. The details of teeth 12 are best seen in FIG. 6. The teeth provide an enhanced interlock with the adjacent vertebrae compared to the use of channels, because the teeth impale the vertebrae surfaces. In comparison, channels impart grooves into the vertebrae surfaces and the implant can slide out along the direction of the channels or grooves. In an alternative embodiment, teeth 12 have a saw-tooth shape (FIG. 10).

As shown in FIG. 1 and FIG. 2, superior surface 14 has a channel 18 and inferior surface 16 has a channel 20 which is parallel to channel 18. Channels 18, 20 are sized to receive a surgical instrument such as an inserter and/or distractor. As the names imply, an inserter is a surgical instrument used to insert implant 10 and a distractor is a surgical instrument used to separate the adjacent vertebrae so that the surgeon has access to the intervertebral space. If the inserter has a threaded arm, implant 10 can be provided with optional threaded hole 21. In FIG. 1 and FIG. 2, channels 18 and 20 are oriented in the anterior/posterior direction. This orientation is useful if the surgeon prefers an anterior surgical approach.

FIG. 3 shows a second embodiment of an allogenic intervertebral implant 110 according to the present invention. In general, most of the structure of implant 110 (as well as the embodiments described below) is like or comparable to the structure of implant 10 and, accordingly the same reference numeral is used for like components and discussion of those like components is not believed necessary. As shown in FIG. 3, channels 18, 20 can run in the antero-lateral direction to facilitate use of implant 110 with an antero-lateral surgical approach. As another alternative embodiment, channels 18, 20 could run in the lateral direction for a lateral approach. Similarly, a threaded hole 21 optionally can be located on the lateral or antero-lateral side of implant 10.

In order to restore the natural curvature of the spine after the affected disc has been removed, implant 10 is provided with a wedge-shaped profile. As shown in FIG. 4, one way to achieve this wedge shape results from a gradual decrease in height from the anterior side 22 to the posterior side 24. In anatomical terms, the natural curvature of the lumbar spine is referred to as lordosis. When implant 10 is to be used in the lumbar region, angle α should be approximately 4,2° so that the wedge shape is a lordotic shape which mimics the anatomy of the lumbar spine. Furthermore, when used in the lumbar region, the ratio of the height of anterior side 22 (h_1) to the height of posterior side 24 (h_2) should be approximately 1,1-2 with the length of implant 10 (l) being approximately 22 - 30 mm.

In FIG. 4, superior and inferior surfaces 14, 16 are flat planar surfaces so that if the surgeon prepares the endplates to be parallel surfaces with a burr, implant 10 fits tightly between the bone surfaces.

FIG. 5 illustrates that superior and inferior surfaces 14, 16 of a third embodiment of an allogenic intervertebral implant 210 can be curved surfaces and still retain the wedge-shaped profile. The curved surface of superior and inferior surfaces 14, 16 is a mirror-image of the topography of the vertebral end plates. Thus, the curved surfaces conform to the contours of the end plates.

FIG. 7 shows a top view of a fourth embodiment of an allogenic intervertebral implant 310 according to the present invention. Although implant 310 will probably be predominantly used in the cervical region of the spine, implant 310 can be configured for implantation in any region of the spine. Interior 11 can be defined by the natural shape of the medullary canal as was the case for implant 10, 110, 210. Alternatively, the medullary canal can be machined so that the wall that formed interior 11 are uniform in shape and texture.

As previously noted, teeth 12 are preferably pyramid-shaped in which the angle formed from the tip to the base is preferably about 60°. Pyramid-shaped teeth help prevent expulsion of the implant in all directions. The prevention of movement between

implant 310 and the vertebrae is particularly important when the surgeon removes all of the annulus fibrosis, as may be the case for cervical vertebrae.

Most allografts are processed and used without significant machining of the exterior surface. In other words, the allografts have substantially the shape of the bone from which the allograft was harvested. As shown in FIG. 7, an exterior surface 26 of implant 310 has been machined to have a uniform shape. The uniform shape promotes initial stability until biological fixation is achieved with bony fusion.

As shown in FIG. 7, the exterior surface 26 has an oval shape. The oval shape preferably is arranged to have lateral sides 28 along the smaller oval axis and anterior and posterior sides 22, 24 along the longer axis. In another embodiment of the invention shown in FIG. 9, the exterior surface 26 of implant 410 is rectangular in shape with lateral sides 28 shorter in length than anterior and posterior sides 22, 24. The oval and rectangle shape and size of implants 310, 410 can be made to closely match the shape and size of the affected vertebrae. Typically, lateral sides 28 and anterior and posterior sides 22, 24 would be approximately 8-18 mm in length.

In order to restore the intervertebral space to the proper size after the affected disc has been removed, implant 310 has a height, h, sized to match the height of the removed disc, as shown in FIG. 8. The matched height helps promote fusion by

providing direct contact between the bone and implant 310. Typically, h would be approximately 4-20 mm for cervical vertebrae. Implant 310 has a uniform height so that the profile of implant 310 is rectangular. Alternatively, as shown in FIG. 4 and FIG. 5, implant 310 can have a wedge shaped profile with either flat planar surfaces or curved surfaces.

It should be noted that implants 310, 410 can be configured so that h would be approximately 10-100 mm. These larger sizes could be used in corpectomy, a surgical procedure in which a section of several vertebrae is removed. Implants 310, 410 would be inserted in the space created by the removed section of bone. Due to the nature of corpectomy, an accurate preoperative determination of the size of the implant needed is not possible. Thus, implant 310, 410 can be cut to the proper size by the surgeon. In such cases, the implants 310, 410 would only have teeth on either superior surface 14 or inferior surface 16.

CLAIMS

1. Intervertebral implant (10) comprising an annular plug of allogenic bone conforming in size and shape with end plates of vertebrae, wherein top and bottom surfaces (14,16) of the implant (10) include a three-dimensional structure (12) positioned thereon for interlocking with adjacent vertebrae.

2. Intervertebral implant (10) according to claim 1, wherein said three-dimensional structure (12) includes a plurality of teeth.

3. Intervertebral implant (10) according to claim 1 or 2, wherein said three-dimensional structure (12) has a minimum height of 0,5 mm relative to the top and bottom surfaces (14,16).

4. Intervertebral implant (10) according to one of the claims 1 to 3, wherein said three-dimensional structure (12) has a maximum height of 1,5 mm relative to the top and bottom surfaces (14,16).

5. Intervertebral implant (10) according to one of the claims 1 to 4, wherein said allogenic bone has been obtained from a human long bone, preferably from a femur, humerus, radius, ulna or fibula.

6. Intervertebral implant (10) according to claim 5, wherein said allogenic bone is a cross section transverse to the longitudinal axis of said long bone, preferably with a height of 5 to 8 mm.

7. Intervertebral implant (10) according to one of the claims 1 to 6, wherein said allogenic bone is treated with an antiseptic solution.

8. Intervertebral implant (10) according to one of the claims 1 to 7, wherein said allogenic bone has been process frozen or freeze dried.

9. Intervertebral implant (10) according to one of the claims 1 to 8, wherein the allogenic bone comprises glutaraldehyde.

10. Intervertebral implant (10) according to one of the claims 1 to 9, wherein the interior space delineated by the annular plug is filled with spongiosa, bone graft substitutes or artificial bone material.

11. Intervertebral implant (10) according to one of the claims 1 to 10, wherein the top and bottom (14,16) surfaces each have a channel (18,20) for receiving a surgical instrument.

12. Intervertebral implant (10) according to claim 11, wherein the channels (18,20) run in an anterior-posterior direction.

13. Intervertebral implant (10) according to claim 11, wherein the channels (18,20) run in an antero-lateral direction.

14. Intervertebral implant (10) according to claim 11, wherein the channels (18,20) run in a lateral direction.

15. Intervertebral implant (10) according to one of the claims 1 to 14, wherein the implant has a wedge-shaped profile to help restore disc height and spine curvature.

16. Intervertebral implant (10) according to claim 15, wherein said implant has an anterior height which is greater than a posterior height to produce the wedge-shaped profile.

17. Intervertebral implant (10) according to one of the claims 1 to 16, wherein the teeth (12) have a pyramidal shape.

18. Intervertebral implant (10) according to one of the claims 1 to 17, wherein at least one side of the implant (10) has at least one hole for attachment of an inserter.

19. Intervertebral implant (10) according to claim 18, wherein the at least one hole is threaded.

20. Intervertebral implant (10) according to claim 19, wherein the at least one hole is provided in an anterior, antero-lateral, or lateral side.

21. Intervertebral implant (10) according to one of the claims 1 to 20, wherein the top and bottom surfaces (14,16) are flat planar surfaces.

22. Intervertebral implant (10) according to one of the claims 1 to 20, wherein the top and bottom surfaces (14,16) are curved surfaces which are contoured to mimic the end plates of the adjacent vertebrae.

23. Intervertebral implant (10) according to one of the claims 1 to 22, wherein the exterior surface of said implant has a uniform shape.

24. Intervertebral implant (10) according to claim 23, wherein the exterior surface has an oval shape.

25. Intervertebral implant (10) according to claim 23, wherein the exterior surface has a rectangular shape.

26. Intervertebral implant (10) according to one of the claims 1 to 25, wherein the annular plug includes an interior surface of a machined wall.

27. Intervertebral implant (10) according to one of the claims 1 to 26, wherein, the teeth have a saw tooth shape.

FIG. 1

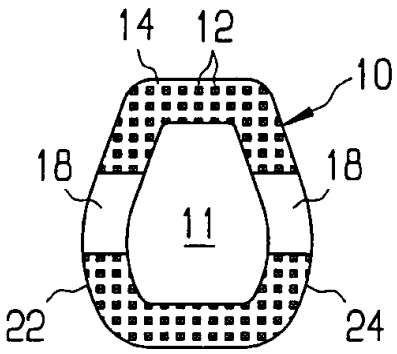


FIG. 2

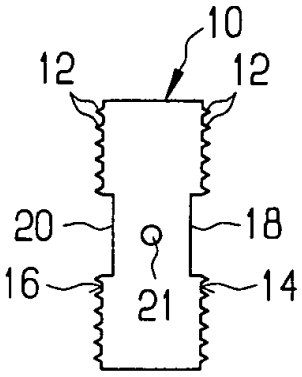


FIG. 3

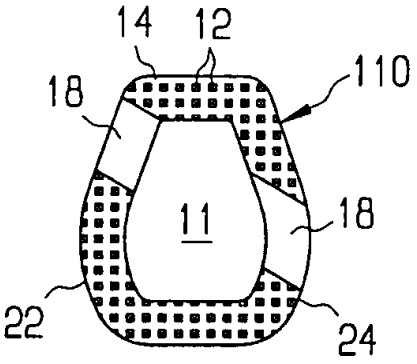


FIG. 4

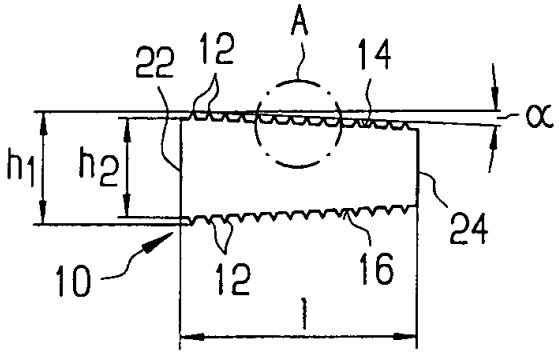


FIG. 5

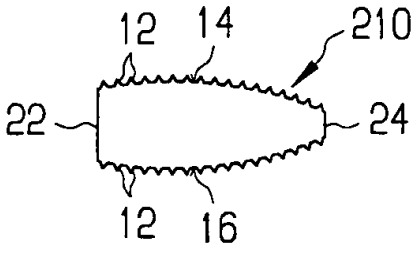


FIG. 6

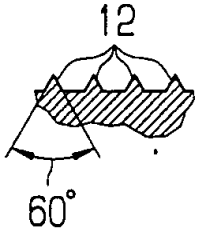


FIG. 7

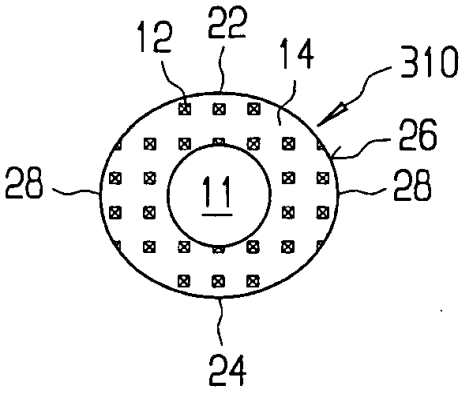


FIG. 8

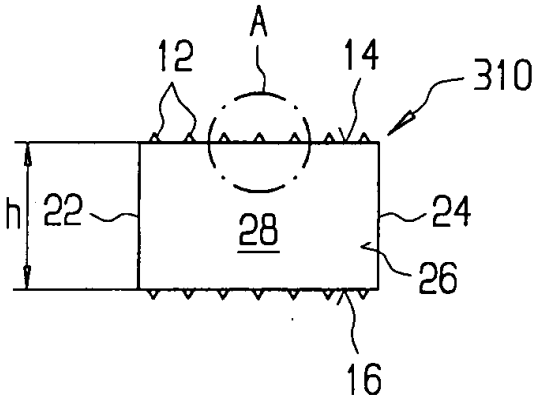


FIG. 9

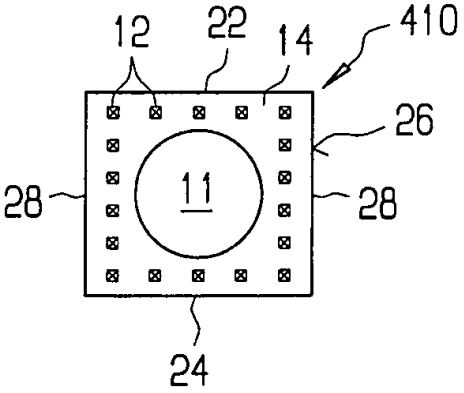
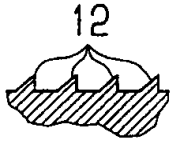


FIG. 10



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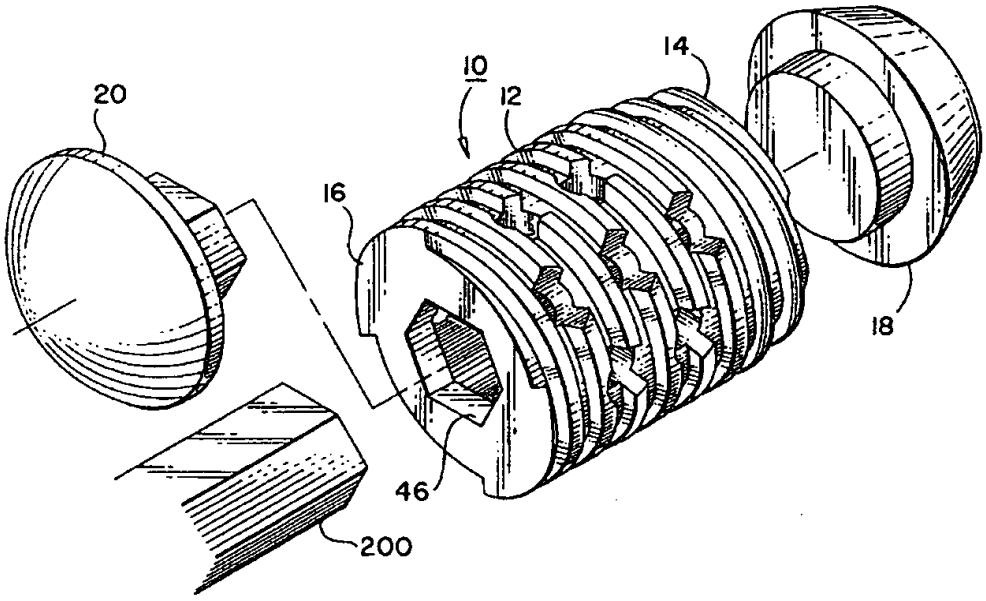
(12) (19) (CA) **Brevet-Patent**

(11) (21) (C) **2,015,507**
(22) 1990/04/26
(43) 1991/01/06
(45) 1999/01/05

(72) Kuslich, Stephen D., US
(72) Corin, James D., US
(72) Bagby, George W., US
(73) Spine-Tech, Inc., US

(51) Int.Cl.[6] A61B 17/70
(30) 1989/07/06 (376,657) US
(30) 1989/09/08 (405,564) US

(54) **IMPLANT RACHIDIEN**
(54) **SPINAL IMPLANT**



(57) L'invention porte sur un implant pour la stabilisation rachidienne. Dans un modèle privilégié, l'implant est décrit comme un corps cylindrique creux ayant un filetage externe et une série d'ouvertures formées radialement sur tout le corps et communiquant avec l'intérieur de ce dernier. Des bouchons, dont au moins un est fait d'un matériau perméable aux rayons X, sont prévus aux extrémités avant et arrière du corps.

(57) An implant is disclosed for use in spinal stabilization. In one preferred embodiment, the implant is described as including a hollow, cylindrical body having external threading and a plurality of openings formed radially through the body in communication with the body interior. End caps are provided on the leading and trailing ends of the body, with at least one of the end caps formed from a radiolucent material.

SPINAL IMPLANT

ABSTRACT OF THE DISCLOSURE

An implant is disclosed for use in spinal stabilization. In one preferred embodiment, the implant is described as including a hollow, cylindrical body having external threading and a plurality of openings formed radially through the body in communication with the body interior. End caps are provided on the leading and trailing ends of the body, with at least one of the end caps formed from a radiolucent material.

SPINAL IMPLANT

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains a surgical procedures for stabilizing the spine. More particularly, this invention pertains to a novel implant for use in such a procedure.

2. Description of the Prior Art

Chronic low back pain is one of the most common and perplexing problems facing the field of orthopedic surgery. In addition to patient discomfort, chronic low back pain has severe adverse societal impacts including lost income, possible chronic dependence on drugs, alcohol and public relief programs.

In many cases, low back pain can be avoided by preventing relative motion between spinal vertebrae (commonly referred to as intervertebral stabilization). To abate low back pain, stabilization is directed to

A

stabilizing contiguous vertebrae in the lumbar region of the spine.

Surgical techniques are known for use in spinal stabilization. Surgical techniques seek to rigidly join vertebrae which are separated by a degenerated disk. Ideally, the surgery effectively replaces the vertebra-disk-vertebra combination with a single rigid vertebra. Various surgical techniques have developed which attempt to approach or approximate this ideal.

One technique known in the art is to partially remove a degenerated disk and to insert a bone graft into the void formed by the removed disk. Other techniques involve the use of an implant which, acting alone or in combination with bone fragments, replace the use of bone grafts. An example of such implant is shown in U.S. Pat. No. 4,501,269 to Bagby dated February 26, 1985. In Bagby, a large, cylindrical basket is driven into a hole formed between bones which are to be joined. The basket is hollow and is filled with bone fragments which are produced during a boring step. Bone-to-bone fusion is achieved through and about the basket. In Bagby, the hole for the Bagby is slightly smaller than the diameter of the basket. This structure results in the spreading of the opposing bone segments upon insertion of the basket. This results in taughtness, which provides initial stabilization. Eventual

fusion of the opposing bone segments results from bone growth through the basket.

Prostheses such as that shown in U.S. Pat. No. 4,501,269 are promising. However, improved implant design is necessary to enhance patient safety and the probability of a satisfactory recovery.

III.

SUMMARY OF THE INVENTION

According to a preferred embodiment of the present invention, an implant is disclosed for insertion into a bore formed between opposing vertebrae of an animal's spine. The implant includes a rigid body having a leading end and a trailing end spaced apart along a longitudinal axis of the body. The body has exposed threads which are disposed between the leading and trailing ends. The threads are selected to engage vertebra material and draw the body along the direction of the axis upon rotation of the body about the axis. The body defines a chamber which is exposed through the body by a plurality of radially extending openings. The chamber may be filled with bone fragments which can fuse with the vertebra bone material through the openings.

In an alternative embodiment of the invention disclosed herein, a generally oval-shaped implant is disclosed which is hammered into an elongated bore between

two opposing vertebrae. The oval-shaped implant has enhanced surface area contact between the vertebrae and provides greater integrity against rotational motion between opposing vertebrae.

Other aspects of this invention are as follows:

An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:

a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;

said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;

said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;

said body having means defining a chamber disposed within said body and said body is provided with a rib disposed within said cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib dividing said chamber into a leading end chamber and a trailing end chamber, and said rib including at least a rigid extension extending between and connecting diametrically opposed sides of said body;

said body having means defining at least one opening formed through said body in communication with said chamber and with said

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opening extending generally radially to said axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae.

An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:

a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;

said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;

said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;

said body having means defining a chamber disposed within said body;

said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis, said opening comprising a hole having a

hole axis extending generally perpendicular to a plane defined by said opening at an exterior surface of said shell, said hole formed through said shell with said hole disposed with said hole axis offset from said longitudinal axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae.

An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:

a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;

said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;

said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;

said body having means defining a chamber disposed within said body and said body is provided with a rib disposed within said

cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib including at least a rigid extension extending between and connecting diametrically opposed sides of said body;

said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae;

said rib is disposed between said leading and trailing ends, said implant further including a first flange at said leading end and a second flange at said trailing end, said first and second flanges extending radially into said chamber.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective exploded of view of an implant according to a preferred embodiment of the present invention;

Fig. 2 is a side elevation view of a body portion of the implant of Fig. 1;

Fig. 2A is a side elevation view of an alternative embodiment of a body portion of an implant according to the present invention;

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Fig. 3 is an end view taken in elevation of the trailing end of the body portion of Fig. 2 taken along line 3-3 of Fig. 2;

Fig. 3A is the same view as Fig. 3 showing an alternative embodiment;

Fig. 4 is a view taken along lines 4-4 of Fig. 2;

Fig. 4a is the same view as Fig. 4 showing an alternative embodiment;

Fig. 5 is a view taken along line 5-5 of Fig. 2;

Fig. 6 is a view taken along lines 6-6 of Fig. 3;

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Fig. 7 is an enlarged view, taken in section, of the threads of the body of Fig. 2 adjacent the trailing end;

Fig. 7A is a view, taken in section, of the threads of the body portion of Fig. 2 adjacent a leading end of the body;

Fig. 8 is a side sectional view of a leading end cap of the implant of Fig. 1;

Fig. 9 is an inside end elevation view of the end cap of Fig. 8 taken along line 9-9 of Fig. 8;

Fig 10 is a side sectional view of a trailing end cap of the implant of Fig. 1;

Fig. 11 is an end elevation view of the end cap of Fig. 10 taken along line 11-11 of Fig 10;

Fig. 12 is a top plan view showing insertion of a single implant of Fig. 1 into an intervertebral space;

Fig. 12A is a view taken along lines 12A-12A of Fig. 12;

Fig. 13 is a top plan view showing an alternative embodiment of the present invention in place in a vertebra;

Fig. 13A is a view taken along lines 13A-13A of Fig. 13;

Fig. 14 is a perspective view of an alternative embodiment of the present invention showing an implant body leading end, side and top;

Fig. 15 is a perspective view of the body of Fig. 14 showing a trailing end, side and top;

Fig. 16 is a top plan view of the embodiment of Figs. 14 and 15;

Fig. 17 is a side sectional view taken along lines 17-17 of Fig. 16;

Fig. 18 is a side elevation view of a trailing end cap for use with the embodiment of Figs. 14 and 15;

Fig. 19 is an end view taken in elevation of the end cap of Fig. 18;

Fig. 20 is an elevation view a trailing end of the embodiment of Figs. 14 and 15;

Fig. 21 is an elevation view of a leading end of the body of the embodiment of Figs. 14 and 15;

Fig. 22 is a side elevation view of the body portion of Figs. 14 and 15;

Fig. 23 is a top plan view of an assembled implant including body portion and end cap shown in place in a vertebra body;

Fig. 24 is an anterior elevation view showing a bore drilling sequence prior to insertion of the implant as shown in Fig. 23;

Fig. 25 is a view taken along lines 25-25 of Fig. 23;

V.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A. General.

Reference is now directed to Figs. 1 and 12. Fig. 1 is an exploded perspective view of an implant according to a preferred embodiment of the present invention. The implant is shown generally at 10. Fig. 12 shows the implant 10 inserted within a bore 102 formed in a human vertebra body 100.

For ease of description, the implant 10 (as well as alternative embodiments of the invention) will be described for use in a human spine. Further, dimensions, when given, will be preferred dimensions for use in a specific spinal location of a particular class of humans -- notably, the L-5 vertebra of a typical adult male. It will be appreciated that the present invention is intended for use in a wide variety of vertebra sizes and a wide variety of animal species. The dimensions of the implant 10 (as well as the dimensions of the alternative embodiments) will vary necessarily with the size of the vertebra in which the implant 10 is to be used. However, making variations to the dimensions and sizes in order to accommodate differing sizes of vertebrae will be well within the skill of the art.

B. First Preferred Embodiment.

With reference now directed to Figs. 1-12, a first preferred embodiment of the present invention will now be described. Identical elements are numbered identically throughout.

The implant 10 includes a body 12 (shown separately in Figs. 2, 3-6) having a leading end 14 and a trailing end 16 which are spaced apart along a longitudinal axis X-X of the body 12. The implant also includes a leading end cap 18 and a trailing end cap 20 (shown separately in Figs. 8-9 and Figs. 10-11, respectively).

Body 12 is integrally constructed from a rigid, biocompatible material. While any rigid, biocompatible material (such as a ceramic) could be used, body 12 is preferably formed from titanium and/or its alloys. Titanium and/or its alloys is preferred since it is noncorrosive and fatigue resistent. Also, titanium is widely used in prosthetic devices and the material has a proven record of satisfactory performance.

With best reference to Figs. 2-7 and 7A, the body 12 includes a hollow cylindrical shell 22 of predetermined diameter D_1 (see Fig. 3). For reasons that will be later described D_1 is selected to be about .5 inches.

The shell 22 surrounds and defines an interior chamber 24. Chamber 24 has a diameter D_3 of preferably about .384 inches.

Threads 26 and 28 are formed on the exterior surface of shell 22 spirally wound around shell 22 and integral therewith. While double threading is shown, single threading or multiple threading in excess of double threading could be applied. Threads 26, 28 are disposed and selected for the threads 26, 28 to engage the bone material of opposing vertebrae and draw the body 12 in the direction of axis X-X upon rotation of the body 12 about axis X-X.

In a preferred embodiment, body 12 is self-tapping. Mainly, the threading 26, 28 (see Fig. 2) adjacent leading end 14 is tapered as shown by angle A_1 (which is preferably about 15°, see Fig. 2). Away from the tapered end 14, and adjacent the trailing end 16, the threads 26, 28 present flat, annular surfaces 30 which are in alignment and parallel to shell 22. Accordingly, the thread profile presents a generally bullet-shaped profile which is cylindrical along the majority of the body 12 and tapers inwardly toward axis X-X at the leading end 14.

The tapered portion of body 12 preferably has a length L_1 of about .198 inches. The overall length of body 12, L_2, is preferably about .740 inches. (See Fig. 2).

To assist in the self-tapping, the threads 26, 28 experience a change in profile from the leading end 14 to the trailing end 16. At the leading end 14, the threads are sharp, as shown in Fig. 7A. When the taper portion of

body 12 is passed, the threads 26, 28 assume a profile which is generally rectangular as shown in Fig. 7. For ease of discussion, the sharp portions of threads 26, 28 are numbered 26a, 28a in the drawings.

The changing thread profiles are selected to assist in advancing the implant 10 into an intervertebral space and to a hold the implant 10 securely in place when fully advanced. The sharp portion of threads 26, 28 (thread portions 26a, 28a shown in Fig. 7A) cut bone better and assist in advancing the implant 10. The generally rectangular thread profile (Fig. 7) has greater cross-sectional area and better opposes bone surfaces to hold the implant 10 in place.

Preferred dimensions of the threading 26, 28 are shown in Figs. 7 and 7A with a pitch, P, (distance between opposing threads) equaling about .10 inch for both the rectangular and sharp threading of Figs. 7 and 7A. The bevel B_1, of the sharp threading (Fig. 7A) is preferably about 57°. The bevel, B_2, of the rectangular thread portion (Fig. 7) is preferably about 5°. The height, H, of the rectangular thread is about .10 inches. This, together with the diameter D_1 (see Fig. 3) of the shell 22 results in overall diameter of the body 12 being about .6 inches. It will be appreciated that these dimensions as well as remaining dimensions given throughout this application are preferred dimensions and may be varied while retaining the

structure and function of the present invention. The scope of the claims of the present invention is not intended to be limited by dimensions which are set forth only to illustrate a preferred embodiment.

The body 12 has a plurality of holes 32 formed radially through the shell 22 and threads 26, 28. The holes 32 provide communication between interior chamber 24 and an exterior of the body 12.

The holes 32 are identical and each is preferably about .125 inches in diameter. Shown best in Fig. 4, each of the holes 32 includes a countersunk portion 34 at the radially outer surface of threads 26, 28. Preferably, the countersunk portion 34 has a diameter of about .155 inches.

The countersunk portion 34 creates cutting a beveled edge 33 on the rectangular threads 26, 28 in the location of the holes 32. This cutting edge 33 is best shown in Fig. 6. The cutting edges 33 chip away bone as the body 12 is rotated. The bone chips will migrate through the holes 32 into chamber 24. As will be described, it is anticipated that this chipping action will enhance the bone-to-bone fusion sought with the present invention.

In the region of the self-tapping sharp threads 26a, 28a (Fig. 7A), the threads 26a, 28a are shown self-tapping in Fig. 5 to present self-tapping cutting edges 36

set at a 90° cutting angle A_3. The cutting edges 36 are shown spaced apart by an angle A_4 of about 120°.

In the preferred embodiment as shown, holes 32 extend through the threads 26 and 28. An alternative embodiment would have the threads 26 and 28 spaced apart a distance greater than that shown in the present drawings, with the holes 32 extending through the shell 22 and not passing through threads 26 and 28. Such a design presents enhanced structural integrity since the more massive threads 26 and 28 are not being broken. However, such an alternative design forgoes the anticipated benefits which may be attributed to the chipping action of the cutting edges 33 of the threads adjacent holes 32.

The number of holes 32 in the body 12 as shown is twenty. This number may vary. The number is selected to be as many and as large as possible (to enhance bone fusion), while not compromising the strength of the body 12.

As previously indicated, the body 12 extends from a leading end 14 to a trailing end 16. Leading end 14 has a circular axial opening 40 formed therethrough in communication with chamber 24. Disposed inwardly from leading end 14 is an annular groove 42 (see Fig. 6) provided to facilitate attachment of leading end cap 18 as will be described.

Trailing end 16 has an inwardly projecting flange 44. Opposing surfaces of flange 44 define a centrally located hexagon-shaped axial opening 46.

When the implant 10 is in place in an intervertebral space, circular axial opening 40 and hexagon axial opening 46 are covered by caps 18 and 20. Shown best in Figs. 8 and 9, the leading end cap 18 includes a cylindrical hub portion 50 and an annular flange 52 extending from hub portion 50. Also extending from hub portion 50 on the side opposite flange 52 is a tapered cap portion 54 which extends from a large diameter 55 and tapers inwardly to a smaller diameter terminal end 56. An angle of taper A_3 (Fig. 8) is preferably about 15° to correspond with the angle of taper A_1 (Fig. 2) of body 12. The large diameter 55 is preferably selected to equal the diameter of body 12 at leading end 14. Flange 52 is selected to be snap received into annular groove 42. So received, cap 18 is permanently attached to the leading end 14 covering axial opening 40.

Trailing end cover 20 (Figs. 10 and 11) includes an arcuate cap 58 sized to cover end 16 with a flat surface portion 59 of cap 20 abutting trailing end 16. Six flexible retaining clips 60 are provided centrally extending from surface 59. Clips 60 are sized to be snap received within hexagon-shaped opening 46. Accordingly, the cooperation of surface 59 and the barbed portion 61 of

clips 60 capture flange 44 to thereby hold trailing end cap 20 securely against trailing end 16. For reasons that will be described, each of caps 18 and 20 are preferably formed from high-density polyethylene.

C. Method of Use.

Referring to Figs. 12 and 12A, the method of use of the implant 10 will now be described. In use of the implant 10, a surgeon forms a bore 102 through the intervertebral space in a disk 114 separating two opposing vertebral bodies 100 and 100a. The bore 102 is sized to be as large as possible to remove disk material 114 and to at least partially cut into opposing surfaces of the bone of vertebra bodies 100, 100a. It will be appreciated that it is well within the skill of the art to form bores such as bore 102.

Fig. 12 and 12A show a bore 102 formed through a posterior approach through a spine. In a posterior approach, a surgeon approaches the vertebra through the back of the patient. Preferably, the axis of the bore 102 is formed an angle with the anterior-posterior axis, A-P, of the vertebra body 100, 100a. As shown in the preferred surgical approach, the angle A_6 between the A-P axis and the bore axis is about 10°.

It is recognized that there are limits on the maximum size of a bore 102 that can directly drilled in a vertebra body via a posterior approach. Limitations on the

diameter of the bore 102 include location of important nerves and blood vessels which can be damaged by excessively large bore drilling operations. The maximum size bore that can be cut will depend on the particular location of the spine, the species of the animal, age and sex. A common safe maximum for an adult male spine in the L-5 area would be a bore diameter of about .5 inches.

For reasons that will be described, it is preferred that the bore diameter will be smaller than the diameter, D_1, of body shell 22. Specifically, it is anticipated that a bore diameter of about 3 millimeters less than diameter D_1 will be preferred. With such structure, the body 12 spreads apart opposing vertebrae upon insertion. By virtue of the spreading effect, the disk annulus becomes taught, thereby providing for the initial stabilization between the opposing vertebrae. (Those skilled in the art will recognize the annulus as being the fibrous outer circumferential portion of the disk). In the drawings, the implant is shown spreading apart the vertebrae and stretching the annulus. Eventual fusion of the opposing vertebrae results from bone growth through body 12, as will be described.

The implant 10 is partially assembled with leading end cap 18 snapped onto leading end 14. With trailing end cap 20 removed, the implant 10 is partially placed within bore 102 with the tapered leading end 14 received within

bore 102. An advancing tool (the tip of which is shown in Fig. 1) is provided having a hexagon-shaped tip 200 complementarily sized to be received within opening 46. The tip 200 is inserted by the surgeon into opening 46. The surgeon then turns the tool and, hence, the body 12, in a clockwise direction (from the perspective of the surgeon). The turning action of the body 12 causes the sharp threads 26a, 28a (Fig. 7A) to cut into the bone of the opposing vertebrae bodies 100, 100a to advance the body 12 into bore 102 to the fully inserted position shown in Fig. 12. The rectangular threads 26, 28 (Fig. 7) retain the body 12 in the desired axial position relative to bore 102. Leading end cap 18 covering axial opening 40 prevents disk material from migrating through axial opening 40 into chamber 24 during insertion of implant 10 as well as during the patient's recovery phase.

With the implant body 12 fully inserted as shown in Fig. 12, the trailing end cap 18 has not yet been installed. Accordingly, axial opening 46 exposes chamber 24 to the surgeon once the tool tip 200 is removed. With opening 46 still exposing chamber 24, a surgeon can impact a graft medium 202 (preferably bone chips) into chamber 24 (see Fig. 12A). Any impacted bone chips will supplement bone chips that may migrate through holes 32 as a result of the cutting action of cutting edges 33 against the vertebra bone surfaces.

With the graft medium fully applied to chamber 24, the surgeon snaps cap 20 into hole 46 to cover the trailing end 16. Figs. 12 and 12A show such a fully assembled and inserted implant 10. The surgeon can then close the patient through any suitable technique. With the completed implant 10 installed in the manner indicated, the bone graft 202 within chamber 24 and openings 32 fuses together with the bone of the opposing vertebrae 100, 100a to thereby join the vertebrae 100, 100a together.

As previously indicated, end caps 18, 20 are preferably formed from high density polyethylene. Such material is nonabrasive and inert, and has a slippery touch. This latter feature is particularly valuable for trailing end cap 20, which may oppose the epidural tissue. To avoid damage or irritation of the dura, the slippery, inert, nonabrasive polyurethane trailing end cap 20 is provided. Trailing end cap 20 is intended to cover axial opening 46 and retain the bone chips within chamber 24 while providing a nonabrasive and nonirritating surface opposing the epidura. Also, like leading end cap 18, trailing end cap 20 prevents disk material from entering chamber 24.

In a preferred embodiment, the end caps 18, 20 formed of polyethylene which is radiolucent. Radiolucent material permits X-rays to pass. Accordingly, with radiolucent end caps 18, 20, an attending physician can

study the growth of bone within chamber 24 without the need for exploratory surgery.

It will be appreciated that radiolucent end cap 18, 20, while desirable in a preferred embodiment, are not necessary to the practice of the full scope of the present invention. For example, the leading end 14 could taper completely as an integral portion of the solid body 12 as shown in Fig. 2A. In such an embodiment, the body 12' assumes a more complete hollow bullet-shaped profile where the leading edge 14' includes a sharp point 15' to better assist the insertion and advancement of the body 12' into the intervertebral space.

In Figs. 12 and 12A, the implant 10 is shown installed on the left side (from the patient's perspective) of the anterior-posterior axis, A-P. For a posterior approach as shown in Fig. 12, it is anticipated that two prostheses 10 will be used, with a second implant disposed on the right side of the anterior-posterior axis, A-P, and installed in a manner identical to that of implant 10 on the left side. However, for ease of illustration, the right side implant is not shown installed. When installed, such prostheses would be positioned with the right and left prostheses being symmetrically disposed about axis A-P.

D. Alternative Design

Figs. 3A and 4A show an alternative. The implant 10''' of the embodiment of Figs. 3A and 4A is identical to

that discussed above except as to the placement of holes 32'''. For ease of understanding the comparison between implant 10''' and implant 10, the reader will note that Figs. 3A and 4A are the same view of implant 10''' as Figs. 3 and 4 are of implant 10.

Unlike implant 10, implant 10''' does not have holes 32''' circumferentially spaced about body 12'''. Instead, as best shown in Fig. 4A, holes 32''' are placed on diametrically opposed sides of body 12'''.

Upon insertion of the implant 10''', the surgeon positions the implant 10''' with holes 32''' opposing the bone material of the vertebra bodies 100, 100a. As a result, no disc material 114 may enter into chamber 24'''. This prevents possible interference of disc material with the bone fusion process.

To assist a surgeon, indicia markings 15''' are placed on flange 44'''. The markings 15''' are aligned with the axis of holes 32'''. The surgeon turns body 12''' into position until markings 15''' are aligned pointing to bodies 100, 100a. So positioned, the surgeon knows the holes 32''' are opposing bone and not disc material.

E. Alternative Method and Apparatus for Anterior Approach.

The foregoing description and illustration describe the insertion of an implant 10 through a posterior approach. Figs. 13 and 13A show an alternative embodiment

of the invention for use in an anterior approach where a bore 102' is formed from the front of the spine and axially aligned with the anterior-posterior axis, A-P. Since the bore 102' is formed from an anterior approach, the size restrictions of a posteriorly formed bore (namely, locations of nerves and blood vessels) are largely avoided. As a result, a large diameter bore 102' can be formed. A comparison of Figs. 12A and 13A show the relative increase of bore diameter. This increase results in an enhanced surface area of exposed vertebra bone and an increased amount of graft material in an implant.

The implant 10'' shown in Figs. 13 and 13A may be identical in proportional dimensions to that of implant 10, only enlarged to be received within the larger bore 102'. However, the implant 10'' shown in Figs. 13 and 13A differs from that shown in Figs. 12 and 12A. Namely, the implant 10'' shown in Figs. 13 and 13A does not include a tapered leading end. Instead, the entire implant body 12" is cylindrical-shaped to illustrate that, while a tapered leading end is preferred, it is not necessary to practice the teachings of the present invention.

F. Further Alternative Embodiments.

Figs. 15-25 illustrate yet a further embodiment of an implant for use in spinal stabilization. As shown in those figures, the implant 120 (shown assembled in Figs. 23 and 25) includes a body portion 122 (shown in perspective

in Figs. 14 and 15) which is generally oval-shaped in cross section and formed from rigid, biocompatible material (preferably titanium). The body 122 includes generally flat side walls 124, 126 joined by upper and lower semi-cylindrical arcuate ribs 128. Arcuate ribs 128 are spaced apart to define a plurality of upper and lower semi-circular arcuate openings 130 which provide communication between a hollow interior 132 of body 122 and an exterior. The ribs 128 define upper and lower walls of the implant 120 with the walls having openings 130 therethrough.

Body 122 extends from a leading or anterior end 133, and a trailing or posterior end 134. Anterior end 133 has a centrally positioned cover plate 136 which partially covers end 132 but leaves upper and lower semi-circular axial openings 138 exposing interior 132 through end 133.

Shown best in Fig. 16, body 122 is tapered at the leading end 133, with the side walls 124, 126 tapering inwardly at an angle A_7 of preferably 10° each. Also, the upper and lower planar of the ribs 128 are tapered inwardly as best shown in Fig. 22 at a preferred taper angles, A_8, of about 3°. The edges defined by the juncture of walls 124, 126, ribs 128 and end 133 are rounded to facilitate insertion of implant 120 as will be described.

The posterior end 134 (shown in Fig. 14) has an axial opening 142 which communicates with the body interior 132. A pair of opposing retaining ribs 146 are shown

partially extending from the side walls 124, 126 into opening 142. A posterior end cap 147 is provided with an arcuate, smooth cap 149 sized to cover end 134 and opening 142. End cap 147 has retaining clips 148 selected to snap behind ribs 146 to thereby attach cap 147 against end 144.

G. Method of Use of Alternative Embodiment.

Implant 120 is intended for use in a posterior approach with two prostheses 120 being inserted on opposite sides of the anterior-posterior axis of a vertebra. For ease of illustration, only one prosthetic device is shown inserted in Figs. 23-25.

Fig. 24 shows a method for drilling the bore 154 to receive the oval-shaped implant 120. As shown in Fig. 24, three circular bores 150, 151, 152 are drilled in vertical alignment in opposing vertebra bodies 100', 100a' and separating disk 114'. The three bores 150, 151, 152 cooperate to form a generally oval-shaped bore 154.

Bore 154 is sized to be slightly smaller than the dimensions of body 122. The surgeon inserts the tapered leading end 133 into bore 154. With any suitable hammering mechanism, the surgeon then impacts on the uncapped posterior end 134 to drive the implant 120 into the bore 154 as shown in Figs. 23 and 25. The tapers A_7 and A_8

(Figs. 16 and 22) and the rounded corners on leading end 133 assist in the insertion.

With the implant fully inserted, the surgeon fills the chamber 132 with graft medium 155 (again, preferably bone chips), the surgeon then installs the polyethylene posterior cap 147 to cover posterior end 134 and provide a non-abrasive surface opposing the epidura.

The implant 120 of Figs. 14-25 greatly enhances the depth of insertion into opposing vertebrae 100', 100a' through a posterior approach. Namely, an oval bore 154 can be formed having a height, H_2 (see Fig. 24) equal to about three times the diameter of bores 102 described in previous embodiments. This added depth directly into the bone material of the vertebra body 100', 100a' increases the surface area available for grafting to thereby enhance the probability of a successful graft. Also, the increased depth into each of the vertebra bodies provides increased surface to prevent relative rotation of the opposing vertebrae 100', 100a' about the axis of the spine.

The side walls 124, 126 of the implant do not have openings and, therefore prevent disk material from penetrating into the chamber and thereby interfering with the bone fusion. The implant 120 is sized for the upper and lower openings 133 to be located completely above and below, respectively, the disk layer 114'. Also, plate 136 on end 133 is sized to be about the thickness of layer 114'

(or slightly greater) to prevent disk material from entering the interior 132 of implant 120. Openings 138 are positioned to oppose only bone of vertebra 100', 100a'.

From the foregoing detailed description of the present invention, it has been shown how the invention has been attained in a preferred embodiment, including alternative embodiments. However, modifications and equivalents of these concepts are intended to be included within the scope of this invention.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:

a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;

said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;

said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;

said body having means defining a chamber disposed within said body and said body is provided with a rib disposed within said cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib dividing said chamber into a leading end chamber and a trailing end chamber, and said rib including at least a rigid extension extending between and connecting diametrically opposed sides of said body;

said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae.

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2. An implant according to Claim 1 wherein said implant includes means spaced away from said trailing end for receiving an advancing tool for advancing said implant into said bore.

3. An implant according to Claim 1 wherein said rib has a rib opening formed therein, said rib opening sized to receive a distal end of an insertion tool for insertion of said distal end into said rib opening and for turning said implant upon turning of said tool.

4. An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:

a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;

said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;

said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;

said body having means defining a chamber disposed within said body;

said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis, said opening comprising a hole having a hole axis extending generally perpendicular to a plane defined by said opening at an exterior surface of said shell, said hole formed through said shell with said hole disposed with said hole axis offset from said longitudinal axis; and

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said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae.

5. An implant according to Claim 4 wherein

said body has a plurality of walls defining a plurality of holes each having a hole axis extending generally parallel to said walls and perpendicular to a plane defined by said holes at an exterior surface of said body, said holes formed through said body in communication with said chamber, said holes disposed with said hole axes not intersecting said longitudinal axis;

said holes have cutting edges positioned to oppose said vertebrae to chip bone from said vertebrae into said holes.

6. An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:

a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;

said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;

said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;

said body having means defining a chamber disposed within said body and said body is provided with a rib

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disposed within said cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib including at least a rigid extension extending between and connecting diametrically opposed sides of said body;

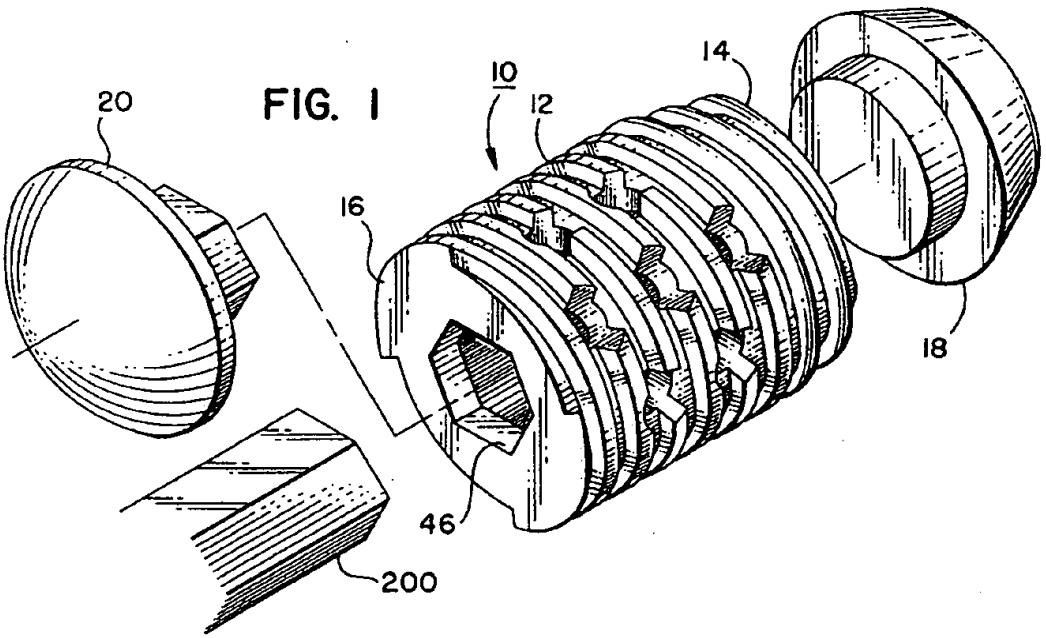
said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae;

said rib is disposed between said leading and trailing ends, said implant further including a first flange at said leading end and a second flange at said trailing end, said first and second flanges extending radially into said chamber.

A

FIG. 1



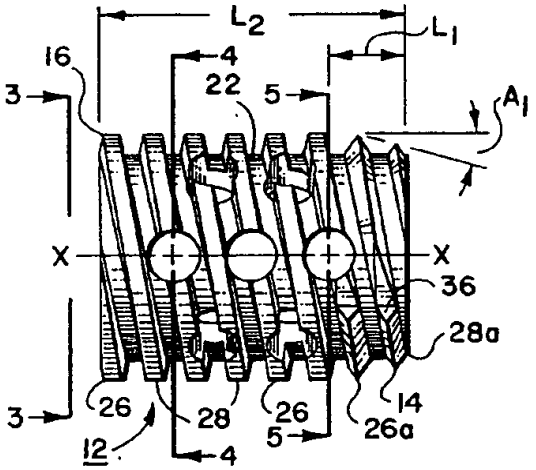


FIG. 2

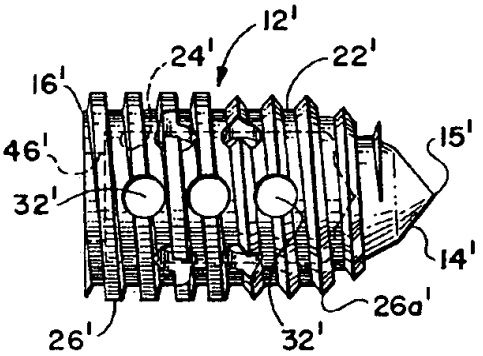


FIG. 2A

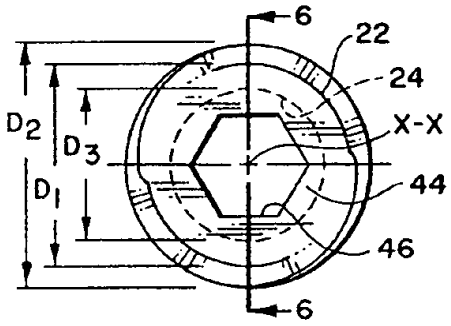


FIG. 3

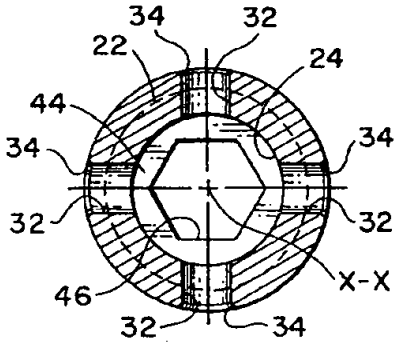


FIG. 4

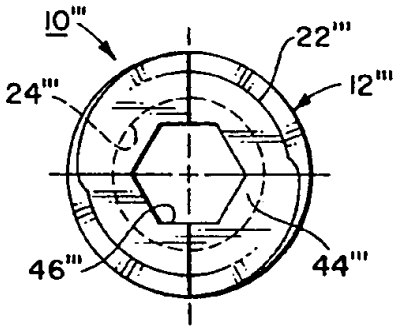


FIG. 3A

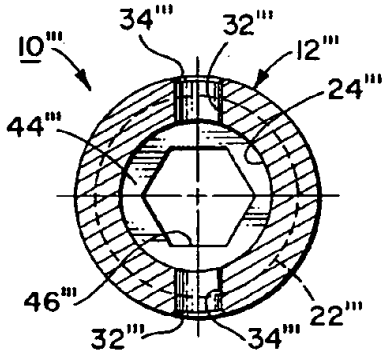


FIG. 4A

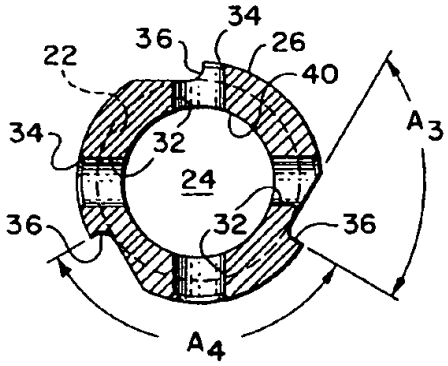


FIG. 5

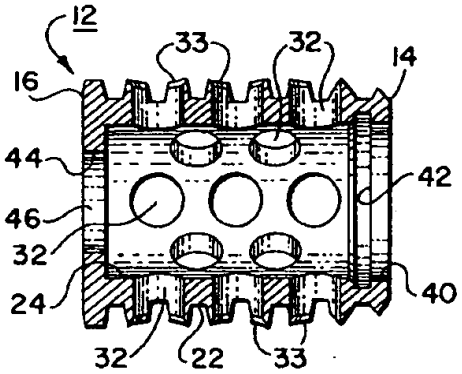


FIG. 6

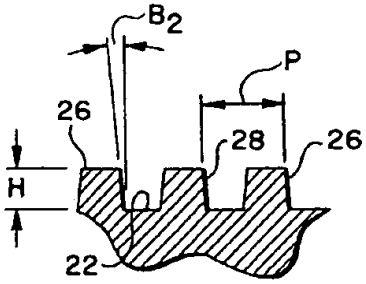


FIG. 7

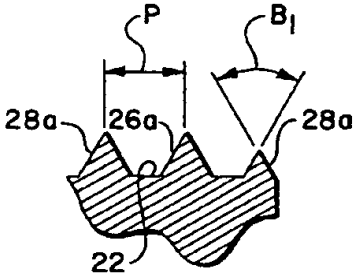


FIG. 7A

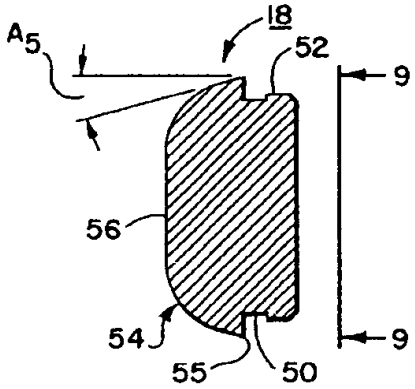


FIG. 8

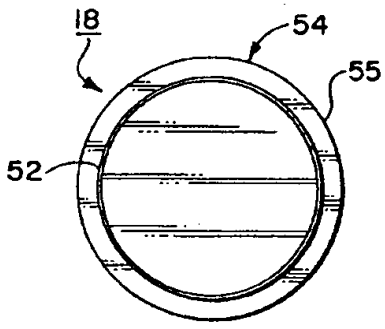


FIG. 9

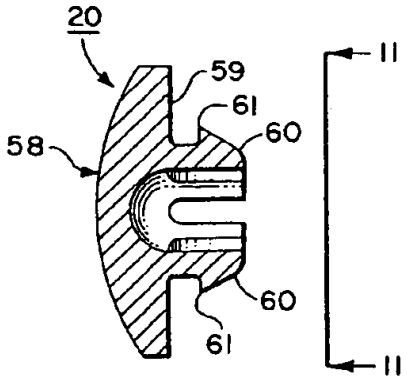


FIG. 10

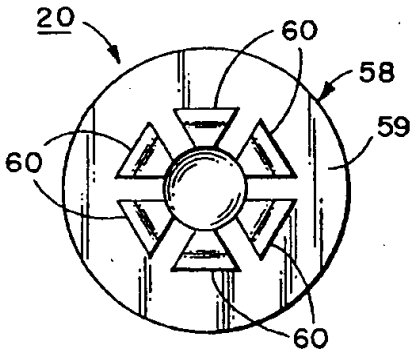


FIG. 11

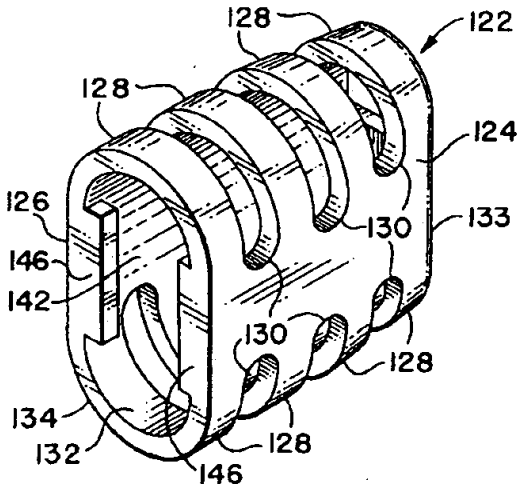


FIG. 14

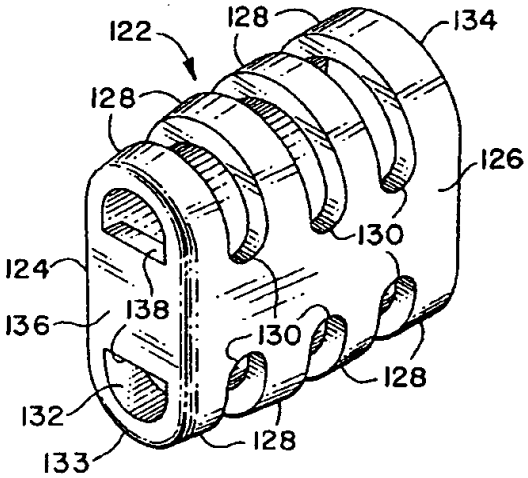


FIG. 15

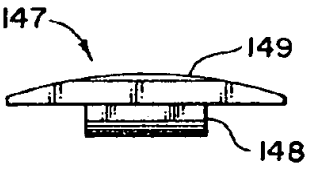


FIG. 18

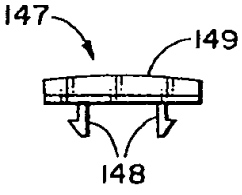


FIG. 19

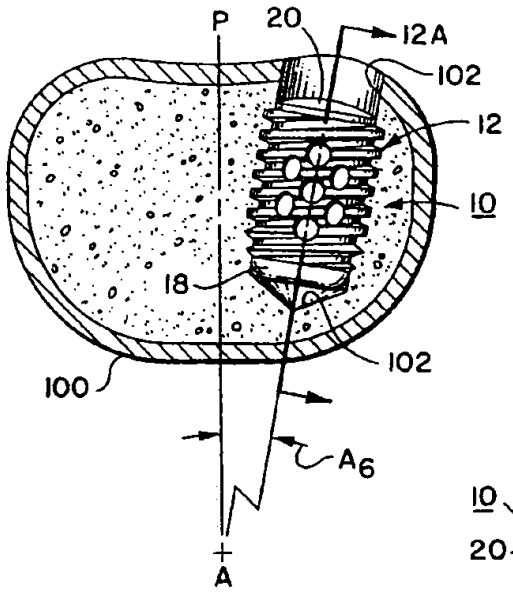


FIG. 12

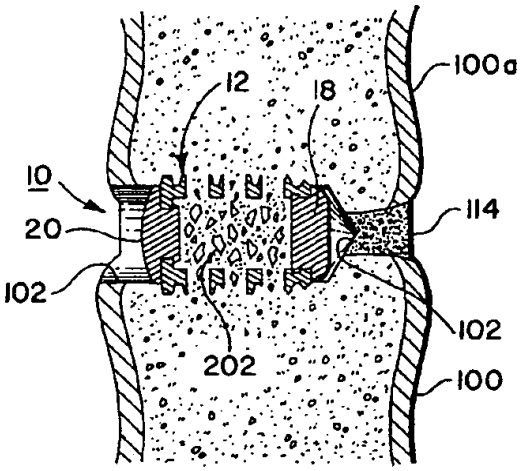


FIG. 12A

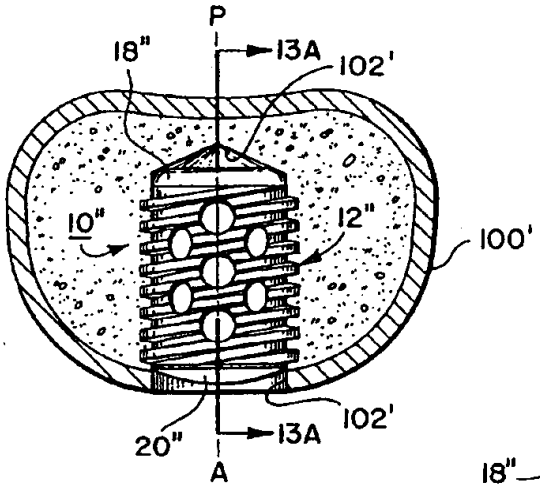


FIG. 13

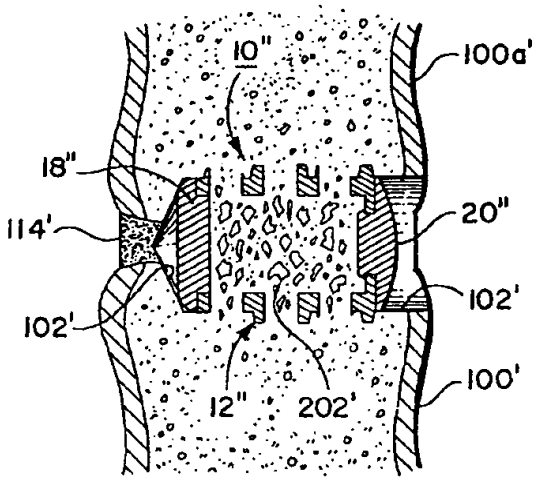


FIG. 13A

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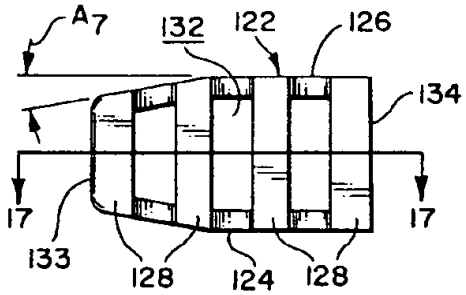

FIG. 16

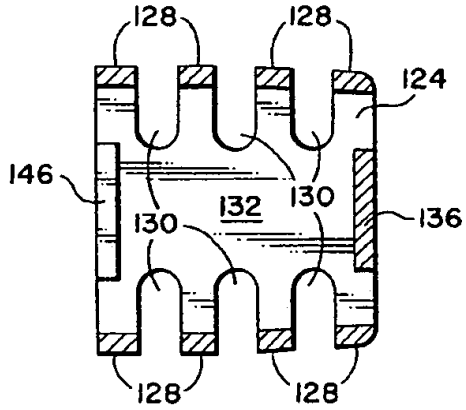

FIG. 17

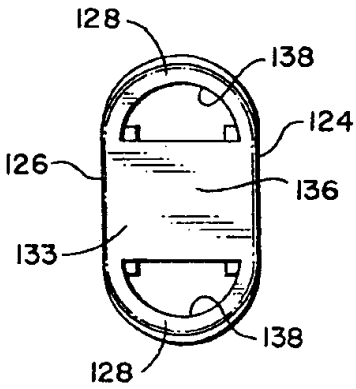

FIG. 21

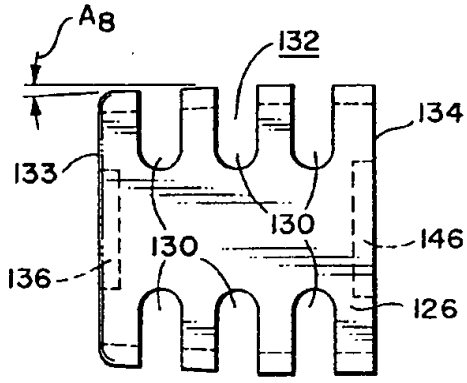

FIG. 22

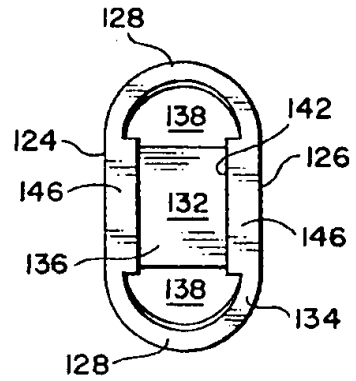

FIG. 20

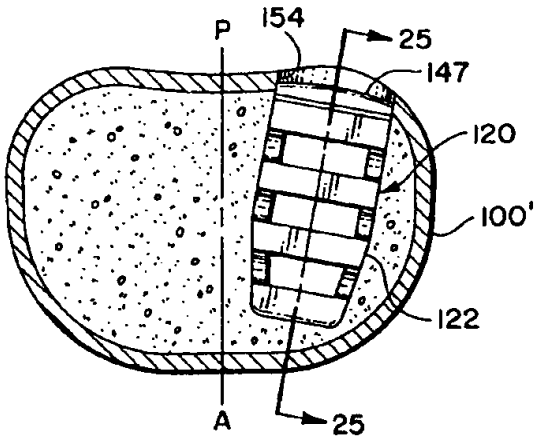

FIG. 23

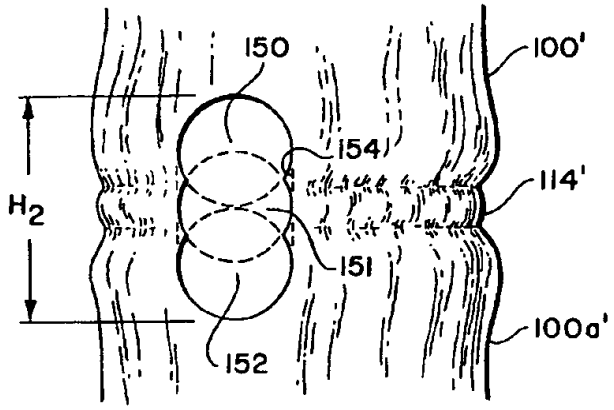

FIG. 24

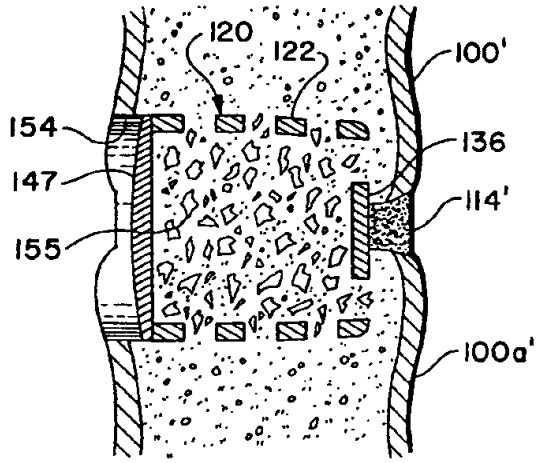

FIG. 25

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 369 603 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **89310572.6**

(51) Int. Cl.5: **A61F 2/44**

(22) Date of filing: **16.10.89**

The title of the invention has been amended (Guidelines for Examination in the EPO, A-III, 7.3).

(30) Priority: **17.10.88 US 259031**

(43) Date of publication of application: **23.05.90 Bulletin 90/21**

(84) Designated Contracting States: **DE FR GB NL SE**

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(54) Fusion cage for bone joints.

(57) A fusion basket (10) having an external, substantially continuous helical V-thread (12) by which it can be screwed into a bore after first forming in the bore mating female threads that bite into the cancellous regions.. Mating of the threads ensures that the fusion basket remains securely in place without compressing or splitting the recipient bone. Eventually, the ingrowth of bone through perforations (13) in the valley (14) of the thread forms a permanent interconnection between the two bony structures. When used to create bone ingrowth between adjacent vertebrae, the V-thread fusion basket is implanted in pairs on opposite sides of the disc space.

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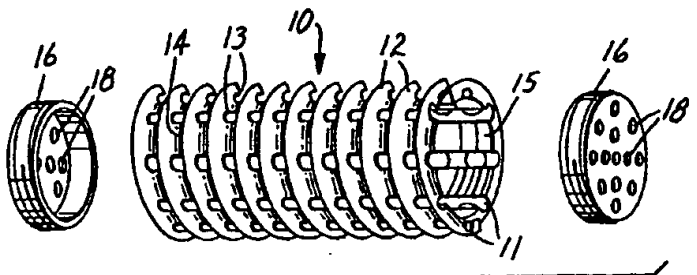

FIG.1

FUSION CAGE

The invention concerns method and apparatus for fusing two adjacent bony structures such as a bone joint, especially adjacent vertebrae of the spine.

BACKGROUND OF THE INVENTION

Subsequent to injury, disease or other degenerative disorder, the disc, a ligamentous cushion between vertebrae, may undergo a painful deterioration. The disc shrinks and flattens out, and the distance between the vertebral bodies begins to collapse. Subsequently, there may be a progressive degeneration leading to mechanical instability, where painful translocations occur between adjacent vertebrae. The movement-induced pain may be so disabling that in many such cases, the segmental motion must be eliminated. Thus, rigid fusions may be the only present means to stop the translocations and relieve the pain.

It is generally held that successful fusions demand a contiguous growth of bone to create a solid mass that will unite the movable elements into one unit. Otherwise, the fusion cannot achieve the tasks of pain reduction, maintenance of intervertebral height, and immobility of the segment. When fusion bone is first placed, it is soft and movable, having no cohesive strength. Therefore a variety of appliances have been developed that attempt to hold the segments quite still under conditions of normal spinal activity and daily stress. Bone graft material is placed between the segments, the outer or cortical surfaces of which have been removed or deeply scarified so as to promote the ingrowth of the graft into these recipient sites. Thus positioned, the bone graft slowly unites the segments. Such an appliance is not meant to permanently secure immobility of the segments. Bone ingrowth is required for this.

Dependency upon such an appliance as the sole stabilizer is ultimately unsuccessful due to the development of a mechanical gap or transition between the bone and the appliance, leading to structural failure of the bone and adjacent connective tissue. Such failure is seen in fractures, erosion, and absorption of bone with potential further collapse. The pain may also become progresively disabling.

Approximately 150,000 lumbar spinal fusions were performed in the USA during 1987, as reported by the American Hospital Association. There are many methods for intervertebral fusion. The most successful have achieved a success rate of about 90% in random cases. However, several of these techniques, especially those requiring complex appliances, are difficult to master and are hazardous to nerve and vessel structures normally lying close to the involved bones.

From a biomechanical point of view, the most important location of a spinal fusion is at the mechanical center of rotation between the vertebrae. This point is centered within the disc space. Therefore, an interbody fusion is the most rigid and thus the most sought after method among surgeons. Current methods of interbody fusions are, however, the most hazardous of all spinal fusion methods.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions. Typically, a plug, dowel, or segment of bone is driven tightly into a cavity carved inside the interbody, intradiscal space. Since there must be a bone-to-bone bridge created during the fusion process, connective tissue and discal tissue must be removed. Therefore, deep cuts within the bone must penetrate into the softer, cancellous region to promote bone growth across the space.

Intervertebral fusions using circular bone grafts have been reported in the orthopedic and neurosurgical literature for some years. B. R. Wiltberger in a paper published in Clinical Orthopedics, Vol. 35, pp. 69-79, 1964, reviewed various methods of intervertebral body fusion using posterior bone dowels driven firmly into a suitably smaller hole between the adjacent vertebrae. Upon doing so the dowel can split or crack or collapse. The stretched bone might also split and it can be compressed by the dowel to the point that it will not grow normally due to collapse of formerly open pores or vascular channels. If this occurs, there may be a late absorption of surrounding bone and the dowel might loosen, with a renewed danger of expulsion. See also a two-page brochure from Neurological Surgery Associates of Cincinnati, Inc. entitled "Posterior Lumbar Interbody Fusion Made Simple" which shows, after the bone dowel placement, the "(a)pplication of 5 mm dacron suture around spinous processes."

U.S. Patent 4,501,269 (Bagby) describes a surgical procedure for stabilizing the cervical spine of a horse and says that the procedure "is applicable to any human or animal joint formed by opposed contiguous bony surfaces which are covered and separated by intervening cartilage and are surrounded by ligaments which resist expansion of the joint. Specific examples of such joints are a spinal joint between adjacent vertebrae or the ankle joint. The process was developed to immediately stabilize the joint and to further promote ultimate

bone-to-bone fusion...The implanted structure is in the form of a perforated cylincrical bone basket which can be filled with bone fragments produced during the preparation of the joint. These bone fragments provide autogenous tissue to promote bone growth through the basket, as well as around it.

"The process involves the initial steps of surgically accessing the joint and removing intervening cartilage located between the contiguous bony surfaces. A transverse cylindrical opening is then bored across the contiguous bony surfaces. Immediate stabilization is achieved by driving into the cylindrical opening a hollow basket having a rigid perforated cylindrical wall whose outside diameter is slightly greater than the inside diameter of the cylindrical opening. The implanting of the basket spreads the bony surfaces apart in opposition to the resistance to expansion of the joint provided by the surrounding ligaments." (Col. 2, lines 26-55).

Vich, J. Neurosurg Vol. 63, pp. 750-753 (1983) describes a means for cervical spine fusion, using an anterior approach, by surgically implanting a cylindrical bone graft. "Screw threads are placed in the graft with a small, previously sterilized die. The grooves of the thread can be made as deep as required. The vertebral cervical bodies are prepared according to Cloward's technique. After a cylindrical bed has been drilled in the appropriate intervertebral bodies, the graft is screwed into place with instruments especially developed for this purpose." (P. 750). The Fig. 2 legend points out that a threaded graft dowel has a larger contact surface than a plain dowel and a greater resistance to pressure and sliding.

An additional desirable effect of an intervertebral fusion is the restoration or maintenance of a normal intervertebral spacing. Spreading devices are generally required in order to restore all or a part of the normal intradiscal height, in the process of placing the fusion material or applicance. When the procedure is performed using the commonly employed posterior approach, a variety of spreaders may be placed between various posterior bony elements normally attached to he vertebrae, such as, dorsal spinous processes or laminas. Using such spreaders, a forward tilt or wedging of the discal space occurs, with the posterior aspect of the space becoming more open than the anterior. When a bone graft of any shape is driven into a cavity that is wedged more open posteriorly between two opposing movable vertebrae, there is a strong propensity for the graft to be retropulsed during the postoperative recovery period as a result of to and fro movement between the opposing vertebrae. Thus, to aid in the prevention of graft expulsion, it would be desirable to have the cavity either maintain parallelism or be slightly narrower at its most posterior portion. Ventral to this cavity, the stout ligamentous disc anulus remains and prevents ventral migration of the graft into the retroperitoneal space. Further, there is value in restoring the original spinal lordotic curve, as the fusion grows; this requires that the cavity and the interbody fusion element be placed to promote a normal spinal anatomical position, that is, without wedging of the space in either direction.

BRIEF SUMMARY OF THE INVENTION

The invention provides a fusion basket or cage which, like the fusion basket of Bagby, is a perforate rigid cylinder that can be surgically inserted into a bore that has been formed in two adjacent bony structures such as two vertebrae. The fusion cage is then packed with bone chips or other bone-inducing substance, thus inviting ingrowth of live bone. The fusion cage of the invention differs from the fusion basket of Bagby by an external, substantially continuous helical V-thread by which it can be screwed into the bore, after first forming mating female threads in the bore. Mating of the threads ensures that the fusion basket remains securely in place, there being much less danger of splitting or compression atrophy of the recipient bone. Eventally, the ingrowth of bone through perforations in the valley of the thread forms a permanent interconnection between the two bony structures.

By V-thread is meant that the crown of the thread is sharp, although its valley preferably is blunt or rounded to permit the mating peaks of the female threads to have adequate strength. When the angle of the V-thread at its crown is about 60°, a preferred range of radii for the fillet in the valley is from 0.35 to 0.75 mm. The angle at the crown of the V-thread should be no more than 90°, because a sharper thread would increase the exposed interface surface of bone relative to the implant, thus increasing the opportunity for ingrowth. However, the angle at the crown should be at least 45°, because the pitch would be undesirably small if the angle were smaller. An unduly small pitch would entail weak female bone threads and create a danger of cross threading.

The perforations should be as large as possible as long as the fusion basket has adequate structural strength. When the surface of the fusion basket is projected onto the inner face of a cylinder, the projected perforations should comprise from 30% to 60% of the projected area, preferably about 50%. Individual apertures should be at least one mm both axially and transversely to permit good ingrowth of fresh bone, whereas the fusion basket might be unduly weakened if the apertures were

substantially more than 2 mm axially and 3 mm transversely when the angle of the V-thread at its crown is about 60°.

The novel fusion basket preferably is fitted with end caps, a first of which may be in place before the fusion basket is screwed into the recipient bone, and thus should have a maximum diameter no greater than the minor diameter of the V-thread of the fusion basket. The first end cap retains the bone-inducing sustance when it is packed into the fusion basket. The open end of the fusion basket may then be closed with a second end cap to hold the bone chips securely in place. The end caps may be imperforate but preferably have substantially the same perforation as does the fusion basket to permit bone or other tissue ingrowth through the end caps. However, end caps may not be necessary or, if used, they can be made of biodegradable material, even when the fusion basket is not.

Currently the novel V-thread fusion basket preferably is made of implantable-grade stainless steel. Titanium and ceramics are also useful, as are super-strength polymers or composites of polymers and high-strength filaments such as super-high-density polyethylene, glass, or graphite. Non-metallic composites have the preferred ability to pass x rays or magnetic beams without distortion, thus enhancing the preparation of scan images as compared to metallic fusion baskets. The fusion basket can be biodegradable, because it no longer is needed after the bone ingrowth has matured. When the fusion basket is not biodegradable, it can remain in place permanently after the ingrowth has taken place, in contrast to the need to remove many types of metallic supports or appliances that have heretofore been used to promote rigid fusions.

Useful bone-inducing substances include bone chips and bone substitutes or synthetic material, with or without bone activating matter, such as hydroxyapatite, bone morphologic protein, bone growth factor, or cartilage activation factor. Instead of being mixed with the bone-inducing substance, bone-activating matter can be coated onto the novel fusion basket, e.g., after being microencapsulated in a wax. When the fusion basket is made of an organic material, bone activating matter can be combined with the organic material before it is formed into the fusion basket.

For implantation between vertebrae of a person's lower back, two sizes of the novel fusion basket should suffice, one having a V-thread major diameter of 16 mm and the other a major diameter of 12 mm. Because the anterior-posterior dimension of a typical lower lumbar vertebra is about 30 mm, the length of the fusion basket preferably does not exceed 25 mm but is at least 20 mm in length to give sufficient contact as well as a good platform when implanted in pairs.

The crown of the V-thread of the novel fusion basket preferable is continuous, both for strength and for ease of insertion into the threaded bore. Preferably the V-thread has from 3 to 8 turns per cm. A smaller turn ratio may result in an undesirably large thread depth, penetrating too deeply into the cancellous bone. A larger turn ratio may unduly restrict the size of the performations.

The novel V-thread fusion basket can be implanted for fusing adjacent bony structures by the following method: (a) forming ain said bony structures a bore with a female thread that penetrates into their cancellous regions, (b) forming a rigid, perforate, cylindrical basket to have an external, substantially continuous helical V-thread that can mate with said female thread, (c) screwing the basket into said threaded bore, and (d) packing the basket with bone-inducing substance. When the bore to be formed in step (a) is to extend between adjacent vertebrae, there should be prior to step (a) the added step of spreading the vertebrae apart, preferably in a manner that maintains their parallelism, the fusion basket is implanted in pairs on opposite sides of the disc space.

The novel fusion basket should have a modulus of elasticity approximating that of the recipient bone, thus permitting it to flex along its length, consequently minimizing stresses at the bony interface between the graft and recipient bone. Although a fusion basket of substantially lower modulus of elasticity would provide the same desirable result, it might not have adequate structural strength.

The bore into which the V-thread fusion basket is to be inserted preferably is tapped by hand, using a slow motion to ensure against burning the bone. This freshens the bone margins of the bore so that if any bone had been burned by drilling to form the bore, it is now cut away slowly by hand. The tapping process is quite safe, in that the surgeon can feel the progress of the technique.

The V-thread fusion basket preferably is screwed by hand into the threaded bore, again permitting the surgeon to feel if the resistance is too great and that rethreading of the bore might be required. In contrast, a bone dowel typically is driven into a bore using a hammer, and in order to guard against an overly tight fit, the surgeon listens to the sound of the striking hammer and also monitors the degree of resistance.

When using the noval fusion basket to créat bone ingrowth between adjacent vertebrae, the fusion basket should be implanted in pairs on opposite sides of the disc space. Each is held in place by its V-thread, biting into female threads that penetrate into the cancellous bone of the inter-

posed vertebral bodies. Gravity, muscle pull, and elastic recoil of the spread (or stretched) outer disc anulus together exert force against each of the fusion baskets. Thus the fusion baskets are held in place by compression forces between the adjacent vertebrae.

To prevent distraction froces from possibly dislodging the fusion baskets, e.g., when the patient forward flexes, thus separating the posterior margins of the adjacent vertebrae, the dorsal processes may be tied or wrapped together. By another technique, screws placed through the appropriate facet jackets limit both flexion and extension motions.

A novel interbody spreader in the form of a scissors jack has been developed to maintain a desirable parallel attitude between the adjacent vertebrae while the bore is drilled and then tapped by a novel instrument. Another instrument that has been developed for use in the implantation of the novel fusion basket is a tapping instrument for forming helical threads in a bore in reciplent bone. This noval tapping instrument comprises

a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and

a pilot rod that slidably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus remvoed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the the hollow shaft.

The portion of the pilot rod that projects beyond said other end of the hollow shaft preferably is threaded to carry detritus upwardly to the reservoir.

When using the novel tapping instrument to form female threads for an interbody fusion, the hollow shaft should have an odd number of scallops and cutting edges, preferably three because an odd number provides more equal removal of recipient bone on both sides of the bore than would an even number.

The novel tapping instrument and a novel wrench are illustrated in the drawing that also illustrates two V-thread fusion baskets of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawing, all figures of which are schematic,

Fig. 1 is an exploded isometric view of a first V-thread fusion basket of the invention and two perforated end caps;

Fig. 2 is an isometric view illustrating the formation of a body that can be cut to form a series of second V-thread fusion baskets of the invention;

Fig. 3 is an isometric view of a tap (partly cut away to reveal details of construction) for forming female thread in bores into which a V-thread fusion basket is to be inserted; and

Fig. 4 is an isometric view of a wrench for screwing a V-thread fusion basket into a threaded bore.

The fusion basket 10 of Fig. 1 was formed from a solid steel cylinder by drilling eight small, equally-spaced holes 11 in the axial direction, each hole being centered on a circle concentric with the axis of the cylinder. Then a large hole was drilled centered on the axis and having a radius substantially identical to that of the aforementioned circle. A V-thread 12 was then machined in the external surface of the cylinder, thus opening through that surface a perforation 13 extending through the rounded valley 14 of the V-thread at each crossing of the valley and one of the small holes 11. A screw thread 15 was then machined in the internal surface of the fusion basket to threadably receive an end cap 16 that has apertures 18 similar to those of a salt shaker. Snap-on end caps would also be useful.

In making a fusion basket by the technique described in the preceding paragraph, the small holes 11 could be enlarged to intersect each other, thus making it unnecessary to drill a central hole. Enlarged small holes would result in larger perforations 13.

Referring to Fig. 2, a series of fusion baskets can be made from a plurality of rods 22 of rectangular cross-section that can be continuously extruded and fed into each of eight keyways 23 in the surface of a mandrel 24. Simultaneously, a rod 26 of triangular cross-section is extruded, wrapped helically around the rectangular rods 22, and soldered or welded to each of the rectangular rods 22 at every crossing to provide an external V-thread. Upon emerging from the keyways, the resulting body is cut into individual fusion baskets each of which has a perforation 28 between adjacent turns of the V-thread-forming rod 26 wherever it bridges a gap between adjacent rectangular rods 22.

A fusion basket identical to that of Fig. 2 can be made from a hollow cylinder by machining an external V-thread and broaching a plurality of rectangular internal keyways.

Each of the fusion baskets of Figs. 1 and 2 could be made from a model by the lost-wax process.

The tapping isntrument 30 of Fig. 3 has a hollow cylindrical shaft 31 with a T-handle 32 at one end and an external thread 33 at the other end.

Slidably received within the hollow shaft is a pilot rod 34, one end 35 of which protrudes beyond the hollow shaft 31 and slidably fits into a bore that has been drilled into the recipient bone. At the other end of the pilot rod is a knurled cap 35A. Projecting from the threaded end of the hollow shaft 31 are cutting teeth 36 that enlarge the bore to the minor diameter of the external thread 33 of the hollow shaft 31. The threaded end of the hollow shaft also is formed with three symmetrical scallops 37 (one shown) to expose a cutting edge 38 at the leading edge of the external thread 33, which cutting edge forms female bone threads in the bore upon rotation of the hollow shaft.

Detritus created by tapping instrument 30 is deposited through the scallops 37 into a reservoir provided by a central recess 39 in the pilot rod 34. The end 35 of the pilot rod which extends from the recess 39 into the bore has external threads which, when the threaded pilot rod 34 is turned, carry detritus upwardly to be deposited through the scallops into the reservoir.

Upon rotating the hollow shaft 3I to form female bone threads in the bore, the surgeon can feel increased back pressure when the reservoir becomes full and should grasp the knurled cap 35A to remove and clean out the pilot rod. If the gummy nature of the detritus were to prevent the pilot rod from being easily pulled out of the hollow shaft, the knurled cap 35A could be removed to permit the hollow shaft 31 to be unscrewed from the threaded bore, leaving the pilot rod in place. The pilot rod then serves. as a guide if the bore has not yet been completely tapped and it is necessary to reinsert the hollow shaft to complete the tapping.

The wrench 40 of Fig. 4 has a cylindrical shaft 41 with a T-handle 42 at one end and an octagonal protuberance 44 at the other end. The corners of the protuberance 44 fit into recesses in the fusion basket to permit the fusion basket to be rotated by rotating the wrench. A spring-loaded ball 46 frictionally holds the protuberance in place when it is inserted into the fusion basket.

Implanting the Fusion Basket

In order to implant the novel fusion basket between adjacent vertebrae, soft, collagenous disc material is first removed from the intervertebral space. A small window is created in the overlying laminas of each side, namely, standard laminotomies. The neural tissues, dural sac and nerves, are retracted medially. The intervertebral space is cleaned of disc material in a standard surgical fashion. If the disc space has narrowed as a result of degeneration, a scissors-jack type vertebral spreader or a hydraulically inflated bladder is inserted on one (the first) side inside the disc space and opened until the space approximates the normal. This may be confirmed by a lateral x ray. The height of the disc space is measured on the x ray so that the proper sizes of drills, tap, and fusion basket may be chosen.

The opposite (second) side of the same disc space is then addressed. The nerve tissues on the first side are relaxed and then retracted medialward on the second side. A pilot drill (e.g., 5 mm or 8 mm diameter depending upon discal space height) cuts a small channel in the face of each of the vertebrae, penetrating the interdiscal space to a depth of about mm (the normal disc space is about 30 mm deep and 50 mm wide). A drill stop may be applied to the drill to prevent overboring the hole. A solid rod pilot is then inserted into the pilot hole and a pilot cutter (7 mm or 10 mm) is passed over it and brought downward to enlarge the pilot channels to slidably receive the pilot rod 35 of the tapping instrument 30 of Fig. 3. The cutting thread 33 (12 mm or 16 mm major diameter) cuts female bone threads through the opposing vertebral end plates and into both cancellous regions that will invite the ingrowth of new bone.

A V-thread fusion basket of the invention, with one end cap in place, is snapped onto the wrench 40 of Fig. 4 by which it is screwed by hand into the threaded intradiscal bore to its full depth. After removing the wrench, the basket is packed with bone chips or other bone-inducing substance, and the second end cap is applied to hold the bone chips securely in place.

After removing the vertebral spreader, the dura and nerves on the second side are relaxed and attention is once again directed to the first side which is drilled and tapped to receive a second fusion basket by the same procedure.

Over a period of several weeks, the bone from the vertebral bodies will grow through the perforations in the fusion baskets and unite with the bone-inducing substance inside them, creating a solid fusion.

It is believed that the novel fusion baskets will primarily be implanted by a posterior approach to the spine, although an anterior approach may be utilized, especially when applied to the cervical spine.

Example 1

The fusion basket of Fig. 1 has been machined from a cylinder of surgically implantable stainless steel to have the following dimensions:

diameter of starting cylinder 16 mm
length of cylinder 25 mm
diameter of each small hole 11 3 mm
diameter of circle on which holes 11 are centered 11.5 mm
diameter of central hole 11 mm
pitch of V-thread 12 2.5 mm/turn
angle at crown of thread 12 60°
fillet radius in valley of thread 12 0.4 mm
axial width of perforations 13 1.6 mm
circumferential breadth of perfs. 13 2.8 mm
when projected onto interior of a cylinder, % of area perforated 25%

A V-thread fusion basket identical in appearance to one produced as in Fig. 2 can be made from a hollow cylindrical tube. After machining an external thread, a plurality of rectangular keyways are broached in the inner surface to form perforations through the valley of the thread. A continuous technique for making a novel fusion basket starts with a continuous helical spring made from a triangular rod such as the rod 26 used in Fig. 2, then welding or soldering the inner-facing surface of the spring to a plurality of cylindrical wires, each extending parallel to the axis of the spring.

Claims

1. A fusion cage which is a hollow perforate rigid cylinder that can be surgically inserted into a bore that has been formed in two adjacent bony structures and filled and packed with bone chips, thus inviting ingrowth of live bone, wherein the improvement comprises: the fusion cage (a) has an extenal, substantially continuous helical V-thread by which it can be screwed into mating female threads formed in the bore and (b) is perforated in the valley between adjacent turns of the thread.

2. A fusion cage as defined in claim 1 wherein the V-thread is continuous and the angle at the crown of the V-thread is no more than 90°, but not less than 45°.

3. A fusion cage as defined in claim 2 wherein the angle at the crown of the V-thread is about 60°.

4. A fusion cage as defined in claim 2 wherein the V-thread has from 3 to 8 turns per cm.

5. A fusion cage as defined in claim 2 wherein the valley of the V-thread has a fillet, the radius of which is from 0.35 to 0.75 mm.

6. A fusion cage as defined in claim 1 wherein, when the surface of the fusion cage is projected onto the inner face of a cylinder, the perforations comprise from 30% to 60% of the projected area.

7. A fusion cage as defined in claim 1, which is fitted with removable perforated end caps.

8. A fusion cage as defined in claim 1, the major diameter of which is from 12 to 16 mm.

9. A fusion cage as defined in claim 1, made of implantable-grade stainless steel.

10. A fusion cage as defined in claim 1, made of biodegradable material.

11. A fusion cage as defined in claim 1, made of x-ray-transparent material.

12. A fusion cage that is a hollow rigid cylinder that is suitable for insertion during surgery into a bore that has been formed in adjacent bony structures and can contain bone inducing substances, thus inviting ingrowth of live bone, the fusion cage having an external, substantially continuous screw thread by which it can be screwed into mating female threads formed in the bore, and, having openings in the valley between turns of the thread.

13. A fusion cage as claimed in claim 12 having any one or more of the features as defined in claims 2 to 11.

14. A fusion cage as claimed in claim 12 or 13, wherein the screw thread is a V-thread.

15. A fusion cage as claimed in any one of the preceding claims for use in fusing adjacent bony structures.

16. A tapping instrument comprising a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and a pilot rod that slidably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus removed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the hollow shaft.

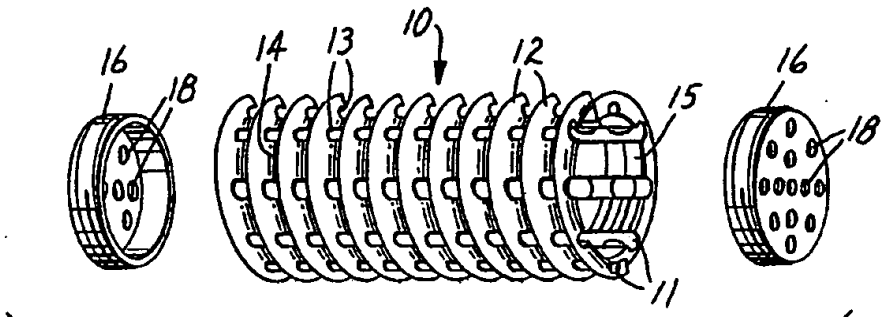

FIG.1

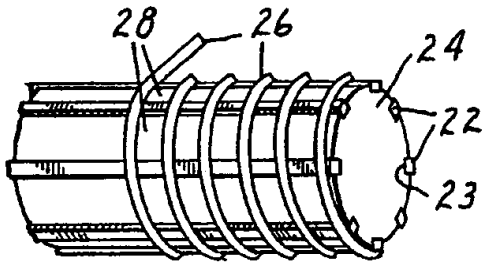

FIG.2

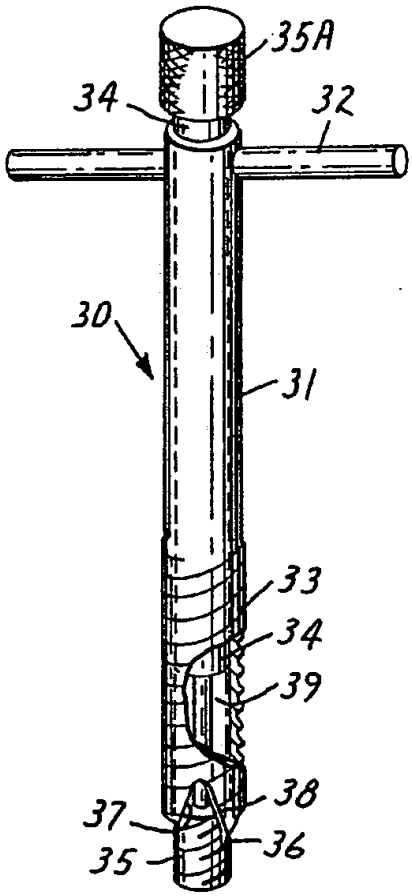

FIG.3

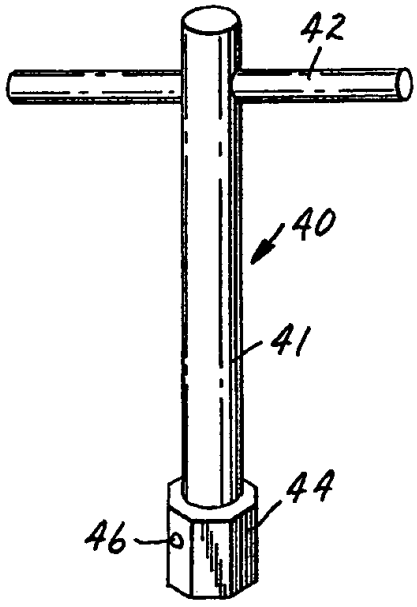

FIG.4

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 31 0572

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
D,Y	US-A-4 501 269 (BAGBY) * Complete document *	1,7,9, 10,12, 15	A 61 F 2/44
Y	DE-A-3 505 567 (VICH) * Claims; figures *	1,7,9, 10,12, 15	
A		16	
A	WO-A-8 707 827 (S + G IMPLANTS)		
A	EP-A-0 268 115 (BIEDERMANN)		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	16-01-1990	SANCHEZ Y SANCHEZ J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P0401)

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Veröffentlichungsnummer: **0 517 030 A3**

(12) # EUROPÄISCHE PATENTANMELDUNG

(21) Anmeldenummer: **92108405.9**

(51) Int. Cl.5: **A61F 2/44**

(22) Anmeldetag: **19.05.92**

(30) Priorität: **04.06.91 DE 4118316**
08.05.92 DE 4215137

(43) Veröffentlichungstag der Anmeldung:
09.12.92 Patentblatt 92/50

(84) Benannte Vertragsstaaten:
CH DE FR GB IT LI

(88) Veröffentlichungstag des später veröffentlichten Recherchenberichts: **14.04.93 Patentblatt 93/15**

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(54) **Wirbelkörperimplantat.**

(57) Als Implantat für Wirbelsäulen wird eine Scheibe (11) vorgeschlagen, die alleine oder zu mehreren gestapelt (11 bis 14) zwischen Wirbelkörper einsetzbar sind. Einzelne Scheiben werden nach Bedarf von einem Strang abgeschnitten, wobei die Scheibendikke dem Einzelfall genau angepaßt werden kann. Diese Implantate eignen sich insbesondere für Halswirbel sowie als Ersatz nach der Entfernung von Bandscheiben. Für die Bildung eines Implantats aus mehreren übereinandergestapelten Scheiben kann ein entsprechendes Sortiment von Scheiben bereitgestellt werden, die sich sowohl im Durchmesser als auch in der Höhe unterscheiden. Für den jeweiligen Anwendungszweck werden demzufolge Scheiben mit entsprechender Dicke ausgesucht und zusammengesetzt, so daß sie insgesamt die erforderliche Höhe des Implantats ergeben. Verschraubungen und insbesondere längere Handhabungen im eingesetzten Zustand des Implantats sind bei dem erfindungsgemäßen Implantat nicht erforderlich.

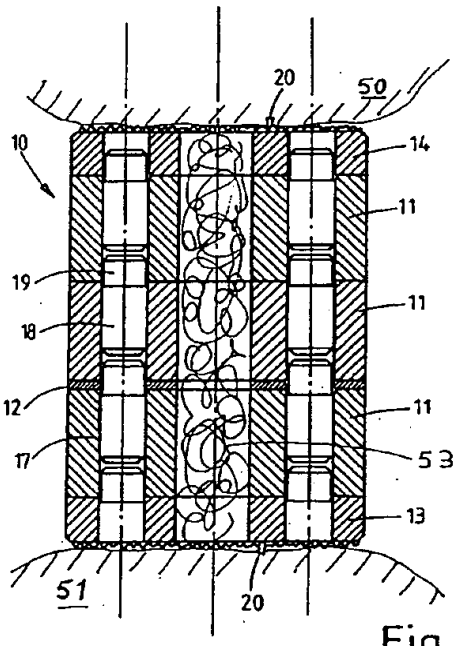

Fig.1

EP 0 517 030 A3

Europäisches Patentamt

EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung

EP 92 10 8405

EINSCHLÄGIGE DOKUMENTE

Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int. Cl.5)
X,D A	WO-A-9 000 037 (MICHELSON) * Seite 11, Zeile 28 - Seite 16, Zeile 25; Abbildungen *	1,3,4 5	A61F2/44
X A	US-A-4 743 256 (BRANTIGAN) * Spalte 5, Zeile 33 - Zeile 65; Abbildungen 11,12 *	1,4 2,3	
A	US-A-3 867 728 (STUBSTAD) * Spalte 11, Zeile 3 - Zeile 27; Abbildung 18 *	1	
A	EP-A-0 307 241 (BRANTIGAN) * Spalte 11, Zeile 35 - Zeile 53; Abbildungen 18,19 *	3,5	
A	WO-A-8 805 312 (M. C. OY) * Abbildung 8C; Beispiel 8 *	6,8	
A	EP-A-0 197 441 (M.A.N. TECHNOLOGIE) * Seite 6, Zeile 20 - Seite 7, Zeile 4; Ansprüche 1,2; Abbildungen *	6,8	RECHERCHIERTE SACHGEBIETE (Int. Cl.5)
A	DE-A-2 426 814 (U.S. A. E. C.) * Abbildung; Beispiel 3 *	7	A61F
A	EP-A-0 302 719 (A.W. SHOWELL)		
A,D	DE-A-3 023 942 (WALDEMAR LINK)		

Der vorliegende Recherchenbericht wurde für alle Patentansprüche erstellt

Recherchenort	Abschlußdatum der Recherche	Prüfer
DEN HAAG	02 FEBRUAR 1993	KLEIN C.

KATEGORIE DER GENANNTEN DOKUMENTE

X : von besonderer Bedeutung allein betrachtet
Y : von besonderer Bedeutung in Verbindung mit einer anderen Veröffentlichung derselben Kategorie
A : technologischer Hintergrund
O : nichtschriftliche Offenbarung
P : Zwischenliteratur

T : der Erfindung zugrunde liegende Theorien oder Grundsätze
E : älteres Patentdokument, das jedoch erst am oder nach dem Anmeldedatum veröffentlicht worden ist
D : in der Anmeldung angeführtes Dokument
L : aus andern Gründen angeführtes Dokument

& : Mitglied der gleichen Patentfamilie, übereinstimmendes Dokument

EPO FORM 1503 03.82 (P0403)

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 667 127 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **95200317.6**

(51) Int. Cl.[6]: **A61B 17/58**

(22) Date of filing: **09.02.95**

(30) Priority: **10.02.94 NL 9400210**

(43) Date of publication of application:
16.08.95 Bulletin 95/33

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IE IT LI LU NL PT SE

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(54) Device for implantation for the purpose of limiting the movements between two vertebrae.

(57) The invention relates to a device for implantation for the purpose of limiting movements between two vertebrae, comprising at least two vertebra engaging elements each having a free end, and an elastic coupling element which is connected with the free ends of the vertebra engaging elements, the elastic coupling element being designed in such a manner that upon an increase of the distance between the free ends of the vertebra engaging elements starting from a neutral position the coupling element generates a force counteracting the increase and upon a decrease of the distance between the free ends of the vertebra engaging elements starting from the neutral position the coupling element generates a force counteracting the decrease.

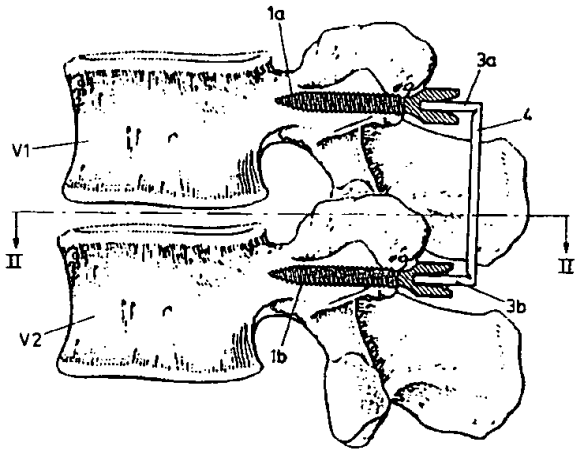

FIG.1

EP 0 667 127 A1

This invention relates to a device to be implanted for the purpose of limiting movements between two vertebrae.

Heretofore, there have been only two forms of treating back complaints in the lower part of the back caused by an unstable vertebral column segment. Characteristic of an unstable vertebral column segment is that a slight displacement from the neutral position results in too great a change or an abnormal change in the shape of the vertebral column segment. The complaints of pain are treated on the one hand with conservative methods such as physiotherapy and anti-inflammatory injections and on the other with relatively aggressive methods based on arthrodesis, i.e. fusion of the unstable vertebral elements. Between these two treatment options lies a wide gap which could not be filled heretofore. This gap could very suitably be filled by implantation of a device permitting limited movement between the vertebrae.

Movement-limiting devices for vertebrae could also be very suitably fitted at the transition between vertebral column segments fused by arthrodesis and the non-fused vertebral column parts adjacent to these segments. The vertebrae located at the transition between a fused and a non-fused vertebral column part are loaded extra heavily since these vertebrae attempt to take up the movements which were previously taken up by the fused vertebral column part. In order to relieve these vertebrae and the surrounding muscles to some extent, a movement-limiting device could very effectively be employed at precisely that point.

In the case of knee joints, for instance, it is known to use elastic tensioning bands which are tensioned around the free ends of two joint engaging elements, such as for instance screws, which are each fitted in a joint member whose relative movements are to be limited. Such a device is described in EP-A-0 260 970. The drawback of devices functioning on the basis of elastic tensioning bands is that the movements of the joint members are counteracted in only one direction by a force produced by the tensioning bands, viz. in that direction in which the band is pulled taut. Movements by which the tension on the elastic bands is reduced are, of course, not limited and even promoted. Since vertebrae can move relative to each other in all directions, the principle of limiting the movements by means of elastic bands cannot successfully be transferred to the vertebral column.

Another drawback of the known devices equipped with elastic tensioning bands is that the tensioning bands, even when the joint members are disposed in the neutral position relative to each other, are under stress and therefore draw the joint members toward each other. The element which is to produce the counterpressure to keep the joint members spaced apart is formed by a cartilage part or a connective tissue structure such as, for instance, a meniscus or, when the device is applied to the vertebral column, an intervertebral disk. This cartilage part loses its elasticity under the influence of the continuous load and moreover becomes thinner in the course of time. As a result, the tension on the tensioning bands lessens, so that the device allows greater movement again and the chances of the tensioning bands coming off the free ends of the screws increase.

Further, the durability of the tensioning bands, typically made of rubber or plastic, is not sufficient to function satisfactorily for the rest of the patient's life under the fatigue loads exerted thereon.

The object of the invention is to provide a device for limiting movements between two vertebrae without the above-described disadvantages.

To that end, the device comprises at least two vertebra engaging elements each having a free end, and an elastic coupling element which is connected with the free ends of the vertebra engaging elements, the elastic coupling element being designed in such a manner that upon an increase of the distance between the free ends of the vertebra engaging elements starting from a neutral position the coupling element generates a force counteracting the increase, and upon a decrease of the distance between the free ends of the vertebra engaging elements starting from the neutral position the coupling element generates a force counteracting the decrease.

Such a device has the advantage that also in the case where the free ends of the vertebra engaging elements move towards each other, the coupling element will produce a force counteracting this movement. This provides the advantage that in the event of such movements the intervertebral disk is loaded to a lesser extent. Moreover, the coupling element need not exert any force on the vertebra engaging elements when they are in the neutral position. This prevents an additional force being exerted continuously on the intervertebral disk, so that the extent of thinning of the intervertebral disk over a particular period of time will be slight.

According to a further elaboration of the invention, it is particularly advantageous if the force counteracting the increase or decrease of the distance between the free ends of the vertebra engaging elements increases progressively with the amount of increase or decrease. Such progressive increase of the force upon an increase or decrease of the distance between the free ends of the vertebra engaging elements provides that the movement ends in a damped manner against a kind of end stop. Thus shock loads to which the vertebrae are

exposed are minimized.

In further elaboration of the invention, the device is characterized in that the counteractive force increases exponentially with the amount of increase or decrease of the distance between the free ends of the vertebra engaging elements.

Tests show that such exponential increase is highly satisfactory and that the occurrence of shock loads is thereby minimized.

The vertebra engaging elements will mainly be arranged on the dorsal side of the vertebral column. Accordingly, upon forward bending, also referred to as flexion, the distance between the free ends of the vertebra engaging elements increases while, conversely, upon straightening of the vertebral column, also referred to as extension, the distance between the free ends of the vertebra engaging elements decreases.

According to a further elaboration of the invention, it is particularly advantageous if the counteractive force arising upon a particular increase of the distance between the free ends of the vertebra engaging elements is smaller than the counteractive force arising upon an equally large decrease of that distance. The consequence of this is that unbending the vertebral column will require more effort than bending it, which corresponds with the natural situation in the case of a healthy vertebral column.

A first embodiment of the above-described device is characterized in that the coupling element comprises two flexible pins which are each rigidly connected by one end to the free end of a vertebra engaging element and are each connected at their other end to a rigid connecting member, each vertebra engaging element comprising at the free end thereof an internal cavity in which the pin extends at least partly, the internal surface of the cavity serving to support the pin during the bending thereof.

Such a device provides the advantage that all parts can be made of metal. Metal presents few problems in the natural environment in which the device is disposed. Rubber and plastic have a more limited resistance to fatigue than metal does, which is unfavorable in particular when they are employed as an elastic element. Accordingly, the first embodiment, in which no rubber or plastic is used, is particularly advantageous.

Preferably, the internal surface of the cavity in the vertebra engaging element is designed in such a manner that upon a greater amount of increase or decrease of the distance between the free ends of the vertebra engaging elements, i.e. upon a stronger bending of the pins, the pins abut against the internal surface over a greater part of their length.

Because upon the bending of the pin the pin abuts against the internal surface of the internal cavity over an increasingly greater part of its length, the force counteracting the bending increases progressively upon an increase of the bending. This is the result of the shortening of the flexible part of the pin. Through an appropriate design of the internal surface of the cavity in which the pin extends, it is, for instance, possible to obtain an exponential increase of the counteractive force upon an increase or decrease of the distance between the vertebra engaging elements starting from the neutral position thereof.

The flexible pin is preferably manufactured from memory metal, such as for instance a TiNi alloy. Such material provides the advantage that it can resist an elongation of approximately 8% in the elastic range. With a relatively short pin, which is necessary to limit the required overall space for the device, such an amount of elongation still enables a relatively large displacement of the free pin end relative to the clamped pin end.

In order to limit the undesirable build-up of moment in the memory metal pins and the rigid connecting member of the coupling element, it is particularly advantageous, in accordance with a further elaboration of the invention, when the rigid connecting member is pivotally connected to the free ends of the two flexible pins.

To limit the maximum elongation in the pins, it can be particularly advantageous, according to a further elaboration of the invention, if the pins are designed as a bundle of substantially parallel wire-shaped elements. Such bundle of wire-shaped elements can be bent to a considerable extent without the elongation in the individual wire-shaped elements becoming inadmissibly large. This provides that even in the case of extreme bending, the deformations still take place within the elastic range of the material.

A first alternative embodiment of the invention is characterized in that the coupling element comprises a rigid connecting member and two ball-and-socket joints, of which each ball in mounted condition is rigidly connected with an associated vertebra engaging element, while each socket is slidably connected with the rigid connecting member and in the neutral position is urged in an end position by biassed springing means.

Over the known device, this device has an important advantage in that both with flexion and with extension of the vertebral column, a force counteracting this flexion or extension is generated by the device.

In order to effect a progressive increase of the force counteracting the change in the distance between the free ends of the vertebra engaging elements, it is possible, in accordance with a further

elaboration of the invention, for the springing means to be formed by blocks made from rubber or plastic and accommodated in a chamber of the rigid connecting member. As long as the rubber or plastic blocks can still deform freely, the counteractive force will increase approximately linearly with the change in the distance between the free ends of the vertebra engaging elements. However, as soon as the blocks contact the walls of the chamber, the force counteracting the change in the distance will increase progressively due to the fact that the rubber blocks can no longer expand freely in particular directions.

In this connection, according to a further elaboration of the invention, the two sockets can each be positioned relative to the springing means in such a manner that upon an increase of the distance between the free ends of the vertebra engaging elements one socket is urged into the associated end position and the other socket moves from the end position against the spring pressure of the springing means associated with that socket, while upon a decrease of the distance between the free ends of the vertebra engaging elements the other socket is urged into the end position and the one socket moves from the end position against the spring pressure of the springing means associated with that one socket. Thus, both for an increase and for a decrease of the distance between the vertebra engaging elements, in each case only one of the blocks made of rubber or plastic is operative. By choosing, for instance, blocks having different spring characteristics, in this way the counteractive force upon a particular decrease of the distance can simply be different from the counteractive force upon an equally large increase of the distance between the free ends of the vertebra engaging elements. It can thus be provided that for flexion, for instance, less resistance has to be overcome than for a similar extension, which corresponds with the natural situation in the case of a healthy vertebral column.

In a third embodiment according to the invention, the coupling element comprises at least one spring element, manufactured from springing wire or sheet material, which is provided with a curvature, the or each spring element being connected at the free end thereof with the free ends of the vertebra engaging elements. Such element, manufactured from springing wire or sheet material and provided with a curvature, upon an increase of the distance between the free ends of the vertebra engaging elements, exerts on the vertebra engaging elements a force counteracting the increase of the distance. According as the distance between the free ends of the vertebra engaging elements increases, the curvature in the spring element is straightened, so that the spring arm becomes smaller and the force needed to further extend the spring increases progressively.

In order to provide that the counteractive force increases progressively also in the case where the free ends of the vertebra engaging elements move toward each other, it is particularly advantageous, in accordance with a further elaboration of the invention, if the coupling element comprises two spring elements, the curvatures of the two elements being so designed that upon a decrease of the distance between the free ends of the vertebra engaging elements the spring elements butt against each other. Owing to the fact that the springs butt against each other upon a particular reduction of the distance between the free ends of the vertebra engaging elements, much more counteractive force will have to be overcome to achieve a further reduction of the distance. Through the interaction between the two spring elements, in particular in that the spring elements must bend over a shorter part of their length, the spring characteristic will change markedly. This change of the spring characteristic results in a progressive increase of the counteractive force upon the decrease of the distance between the free ends of the vertebra engaging elements.

When the spring elements are designed as leaf springs, the chances of the spring elements sliding past each other rather than butting against each other are minimized.

To clarify the invention two exemplary embodiments of the device are described with reference to the drawing.

Fig. 1 is a lateral view of a part of the lumbar part of the vertebral column in which a first exemplary embodiment of the device is fitted;

Fig. 2 is a cranial view taken on line II-II of Fig. 1;

Fig. 3 is a side elevation of a first embodiment of the device in the neutral position;

Fig. 4 is a side elevation of the device, similar to that shown in Fig. 3, where the distance between the free ends of the vertebra engaging elements is reduced;

Fig. 5 is a side elevation of a second embodiment of the device according to the invention;

Fig. 6 is a top plan view of a third embodiment of the device;

Fig. 7 is a top plan view of a fourth embodiment of the device; and

Fig. 8 is a side elevation of the device shown in Figs. 6 and 7.

Fig. 1 shows the position of vertebra engaging elements 1a, 1b of the device according to the first exemplary embodiment, which is preferred, in two lumbar vertebrae V1, V2, located one above the other, while Fig. 2 shows the position of a vertebra engaging element 1b in cranial view.

In the exemplary embodiments shown, the vertebra engaging elements 1a, 1b are each designed as pedicle screws. It will be clear, however, that for the vertebra engaging elements other engagement constructions to be rigidly connected to the vertebrae can be used as well, such as for instance the transversal hook proposed in applicant's patent application EP-A-0 564 046.

Figs. 3 and 4 respectively show the device attached to the vertebrae in Figs. 1 and 2 in the neutral position and in a position where the distance between the free ends 2a, 2b of the pedicle screws 1a, 1b is reduced. When the vertebral column is in the natural position, the free ends 2a, 2b of the pedicle screws 1a, 1b are spaced apart a specific distance. In this situation the pedicle screws 1a, 1b are in the neutral position.

According to the invention, the device includes a coupling element which comprises two flexible pins 3a, 3b and a rigid connecting member 4. The flexible pins 3 are each rigidly connected by a first end to a pedicle screw 1 and connected by a second end to the rigid connecting member 4. The pedicle screws 1a, 1b are both provided, at the free end 2a, 2b thereof, with an internal cavity 5a, 5b in which the pin 3a, 3b extends at least over a part of its length. The internal surface of the cavity 5a, 5b is of such design that the pin 3a, 3b, upon being bent, abuts against and is supported by the internal surface of the cavity 5a, 5b. Preferably, the surface is so designed that upon a greater extent of increase or decrease of the distance between the free ends 2a, 2b of the pedicle screws 1a, 1b, i.e. upon a stronger bending of the pins 3a, 3b, the pins 3a, 3b abut against the internal surface of the cavities 5a, 5b over a greater part of their lengths.

Because the pins 3a, 3b, upon being bent further, abut against the internal surface of the cavities 5a, 5b over an increasingly greater part of their length, the length of the part of the pin 3a, 3b that can bend still further becomes increasingly shorter, so that the force which is required to effect such further bending increases progressively. A suitable internal surface of the cavity 5, in a sectional plane coinciding with the longitudinal centerplane of the pin 3a, 3b, can follow the contour of, for instance, a segment of a circle, a segment of a parabola or a like continuous contour.

It is clear that the contour of the internal surface need not be rotation-symmetrical with respect to the longitudinal axis of the pin 3. By choosing a non-rotation symmetrical contour, it can for instance be provided that the increase of the counteractive force upon a decrease of the distance between the free ends 2a, 2b of the pedicle screws 1a, 1b has a different curve than in the case where the distance is increased. Accordingly, it can thus be provided that more force is required for extension than for flexion.

The pin 3 can be secured in the cavity 5 by means of a securing bolt (not shown) extending transversely to the longitudinal axis of the pin 3. The pin 3 can also be connected with the free end 2 of the pedicle screw 1 by means of a press fit. Of course, other securing methods are possible as well.

In the exemplary embodiment shown, the pins 3 and the rigid connecting member 4 are constructed in one piece. The constriction 6 at the transition between the rigid connecting member 4 and the pins 3 creates the possibility of pivotal movement of the pins 3a, 3b relative to the rigid connecting member 4. It is clear that this possibility of pivotal movement can also be created in a different manner. Thus, the pins 3a, 3b may at the second end thereof be provided with a spherical body and the rigid connecting member 4 may be provided with cup-shaped cavities in which the spherical bodies are receivable. When placing the rigid connecting member 4, the spherical bodies are received in the cup-shaped cavities and thus form a ball-and-socket joint.

By manufacturing the pins 3 from memory metal, in particular from a TiNi alloy, a relatively short pin 3 yet enables a considerable elastic deformation of the pin and hence a relatively large displacement of the second end of the pins 3a, 3b through bending of the pins 3a, 3b. This is possible in that the memory metal features an elongation in the elastic range of 8%. For this application, no use is made of the mnemonic properties of the material.

In order to implant the device, first the pedicle screws 1a, 1b are fitted at the appropriate points in two adjacent vertebrae V1, V2 (see Figs. 1, 2). Then the vertebral column is brought into the equilibrium or neutral position and the distance between the free ends 2a, 2b of the pedicle screws is accurately determined. Then a coupling element comprising the rigid connecting member 4 and the two pins 3a, 3b of the proper length is placed in the pedicle screws and secured, for instance by means of securing bolts or by tapping it home into a press fit.

Fig. 5 shows an alternative embodiment of a device according to the invention, which comprises two vertebra engaging elements in the form of pedicle screws 11a, 11b and a coupling element 12. The coupling element 12 comprises a rigid connecting member 13 and two ball-and-socket joints 14a, 14b, each comprising a ball 15a, 15b and a socket 16a, 16b. In mounted condition, each ball 15 is rigidly connected with the associated pedicle screw 11. Both sockets 16 are slidably connected with the rigid connecting member 13 and in a neutral position are urged in an end

position by biassed springing means 17a, 17b. Fig. 5 shows the device in the neutral position. In the exemplary embodiment shown, the springing means 17a, 17b are formed by blocks 17a, 17b manufactured from rubber or plastic and accommodated in a chamber 18a, 18b. A block 17 accommodated in the chamber 18 can initially deform freely, until the block contacts the walls of the chamber 18 and the deformation is influenced. Because of this influence, the force required for further deformation of the rubber block 17 increases progressively.

In the exemplary embodiment shown in Fig. 5 the two sockets 16a, 16b are each positioned relative to the springing means 17a, 17b in such a manner that upon an increase of the distance between the free ends 15a, 15b of the pedicle screws 11a, 11b one socket 16b is urged into the associated end position and the other socket 16a moves from the end position against the spring pressure of the springing means 17a associated with that socket 16a. Conversely, upon a decrease of the distance between the free ends 15a, 15b of the pedicle screws 11a, 11b, the above-mentioned other socket 16a is urged into the end position while the above-mentioned one socket 16b moves from the end position against the spring pressure of the springing means 16b associated with the one socket 16b.

Optionally, the elasticity of one rubber block 17a may be chosen differently from that of the other rubber block 17b. Thus it can be provided that a greater force is required for moving the free ends 15a, 15b of the pedicle screws 11a, 11b towards each other than for moving them apart.

In this embodiment, the pedicle screws 11a, 11b are each provided with a conical nut 19a, 19b, formed thereon, which facilitates tightening the pedicle screws 11a, 11b and which also serves as a stop. In the embodiment of Figs. 3 and 4, this conical stop is integrated into the free end 2a, 2b of the pedicle screw 1a, 1b.

In a third embodiment, which is shown in Figs. 6 and 8, the coupling element comprises a leaf spring 22 which is provided with a curvature. The leaf spring 22 is clamped in a slot in the free ends 23a, 23b of the vertebra engaging elements, which in this exemplary embodiment are designed as pedicle screws 21a, 21b. In the exemplary embodiment shown, the clamping is effected by means of locking screws 26. It will be clear that a press fit, soldering, welding or other jointing techniques also qualify for this purpose. Upon an increase of the distance between the free ends 23a, 23b of the pedicle screws 21a, 21b, the leaf spring 22 exerts on the pedicle screws a force counteracting the distance increase. According as the distance between the free ends 23a, 23b of the pedicle screws 21a, 21b increases, the curve in the leaf spring 22 is straightened, so that the spring arm becomes smaller and the force required to further extend the leaf spring increases progressively.

In order to effect the progressive increase of the counteractive force also in the case where the free ends 23a, 23b of the pedicle screws 21a, 21b move towards each other, in the fourth embodiment, shown in Fig. 7, the coupling element is made up of two leaf springs 24, 25. The curvatures of the two leaf springs 24, 25 are of such design that upon a decrease of the distance between the free ends 23a, 23b of the pedicle screws 21a, 21b the leaf springs 24, 25 butt against each other. Owing to the fact that the leaf springs 24, 25 will butt against each other upon a particular decrease of the distance between the free ends 23a, 23b of the pedicle screws 21a, 21b, a much greater counteractive force will have to be overcome for any further reduction of the distance. Through the interaction between the two leaf springs 24, 25 the spring characteristic thereof will change markedly, in particular because the leaf springs 24, 25 must bend over a shorter part of the length thereof. This change of the spring characteristic results in a progressive increase of the counteractive force upon a decrease of the distance between the free ends 23a, 23b of the pedicle screws 21a, 21b. It will be clear that the invention is not limited to the exemplary embodiments described but that various modifications are possible within the purview of the invention.

Claims

1. A device for implantation for the purpose of limiting movements between two vertebrae (V1, V2), comprising at least two vertebra engaging elements (1a, 1b; 11a, 11b) each having a free end (2a, 2b; 15a, 15b), and an elastic coupling element (3a, 3b, 4; 12) which is connected with the free ends (2a, 2b; 15a, 15b) of the vertebra engaging elements (1a, 1b; 11a, 11b), the elastic coupling element (3a, 3b, 4; 12) being designed in such a manner that upon an increase of the distance between the free ends (2a, 2b; 15a, 15b) of the vertebra engaging elements (1a, 1b; 11a, 11b) starting from a neutral position the coupling element (3a, 3b, 4; 12) generates a force counteracting the increase and upon a decrease of the distance between the free ends (2a, 2b; 15a, 15b) of the vertebra engaging elements (1a, 1b; 11a, 11b) starting from the neutral position the coupling element (3a, 3b, 4; 12) generates a force counteracting the decrease.

2. A device according to claim 1, characterized in that the force counteracting the increase or decrease of the distance between the free ends (2a, 2b; 15a, 15b) of the vertebra engaging elements (1a, 1b; 11a, 11b) increases progressively with the extent of increase or decrease.

3. A device according to claim 2, characterized in that the counteractive force increases exponentially with the extent of increase or decrease.

4. A device according to claim 2 or 3, characterized in that the counteractive force arising upon a particular increase of the distance between the free ends (2a, 2b; 15a, 15b) of the vertebra engaging elements (1a, 1b; 11a, 11b) is smaller than the counteractive force arising upon an equally large decrease of that distance.

5. A device according to any one of claims 1-4, characterized in that the coupling element (3a, 3b, 4) comprises two flexible pins (3a, 3b) which are each rigidly connected by one end with the free end (2a, 2b) of a vertebra engaging element (1a, 1b) and are each connected at the other end with a rigid connecting member (4), each vertebra engaging element (1a, 1b) at the free end (2a, 2b) thereof comprising an internal cavity (5) in which the pin (3a, 3b) extends at least partly, the internal surface of the cavity (5) serving to support the pin (3a, 3b) during the bending thereof.

6. A device according to claim 5, characterized in that the internal surface of the cavity (5) in the vertebra engaging element (1a, 1b) is designed in such a manner that upon a greater extent of increase or decrease of the distance between the free ends (2a, 2b) of the vertebra engaging elements (1a, 1b), i.e. upon stronger bending of the pins (3a, 3b), the pins (3a, 3b) abut against the internal surface over a greater part of their length.

7. A device according to claim 5 or 6, characterized in that the flexible pin (3a, 3b) is manufactured from memory metal, such as, for instance, a TiNi alloy.

8. A device according to any one of claims 5-7, characterized in that the rigid connecting member (4) is pivotally connected to the free ends of the two flexible pins (3a, 3b).

9. A device according to any one of claims 5-8, characterized in that the pins are designed as a bundle of substantially parallel wire-shaped elements.

10. A device according to any one of claims 1-4, characterized in that the coupling element (12) comprises a rigid connecting member (13) and two ball-and-socket joints (14a, 14b) each comprising a ball (15a, 15b) and a socket (16a, 16b), each ball (15a, 15b) in mounted condition being rigidly connected with an associated vertebra engaging element (11a, 11b), while each socket (16a, 16b) is slidably connected with the rigid connecting member (13) and in a neutral position is urged into an end position by biassed springing means (17a, 17b).

11. A device according to claim 10, characterized in that the springing means (17a, 17b) are formed by blocks (17a, 17b) made of rubber or plastic and accommodated in a chamber (18a, 18b) of the rigid connecting member (13).

12. A device according to claim 10 or 11, characterized in that the two sockets (16a, 16b) are each positioned relative to the springing means (17a, 17b) in such a manner that upon an increase of the distance between the free ends (15a, 15b) of the vertebra engaging elements (11a, 11b) one socket (16b) is urged into the associated end position and the other socket (16a) moves from the end position against the spring pressure of the springing means (17a) associated with that socket (16a), while upon a decrease of the distance between the free ends (15a, 15b) of the vertebra engaging elements (11a, 11b) said other socket (16a) is urged into the end position and said one socket (16b) moves from the end position against the spring pressure of the springing means (17b) associated with said one socket (16b).

13. A device according to any one of claims 1-4, characterized in that the coupling element comprises at least one spring element, manufactured from springing wire or sheet material, which is provided with a curvature, the or each spring element being connected at free ends thereof with the free ends of the vertebra engaging elements.

14. 14. A device according to claim 13, characterized in that the coupling element comprises two spring elements, the curvatures of the two elements being so designed that upon a decrease of the distance between the free ends of the vertebra engaging elements the spring

elements butt against each other.

15. 15. A device according to any one of claims 13 or 14, characterized in that the spring elements are designed as leaf springs.

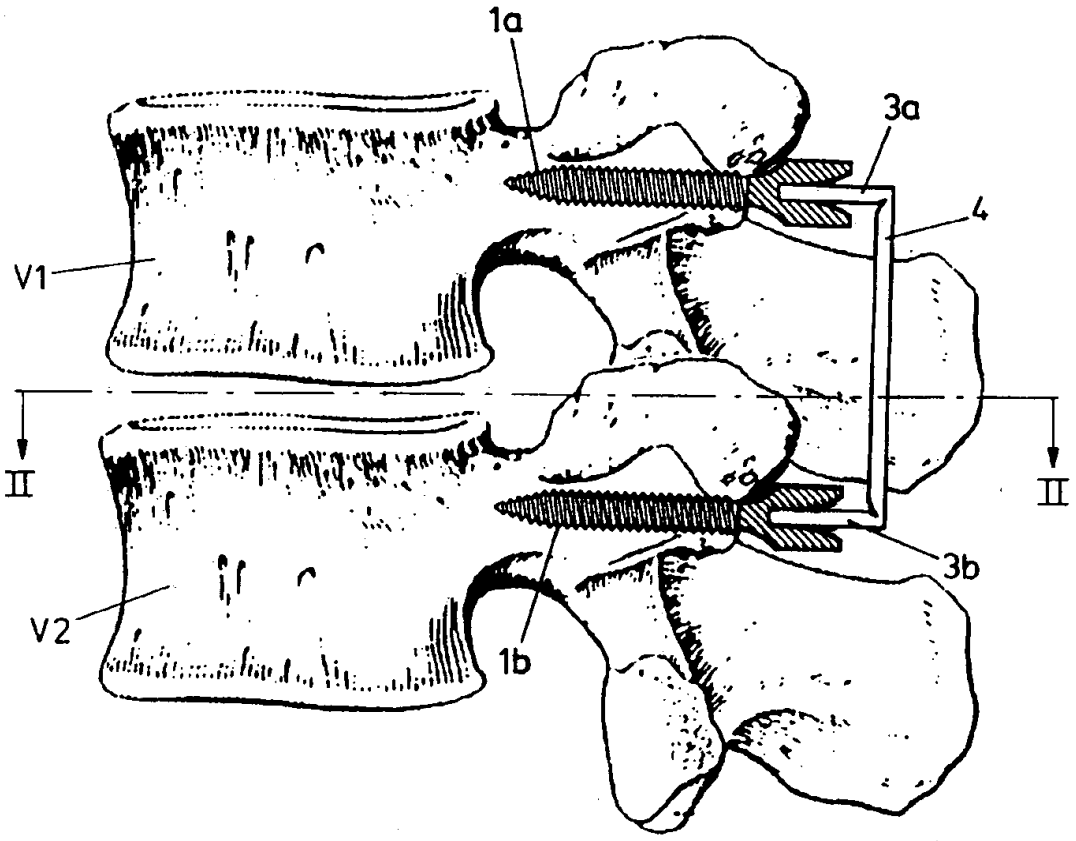

FIG.1

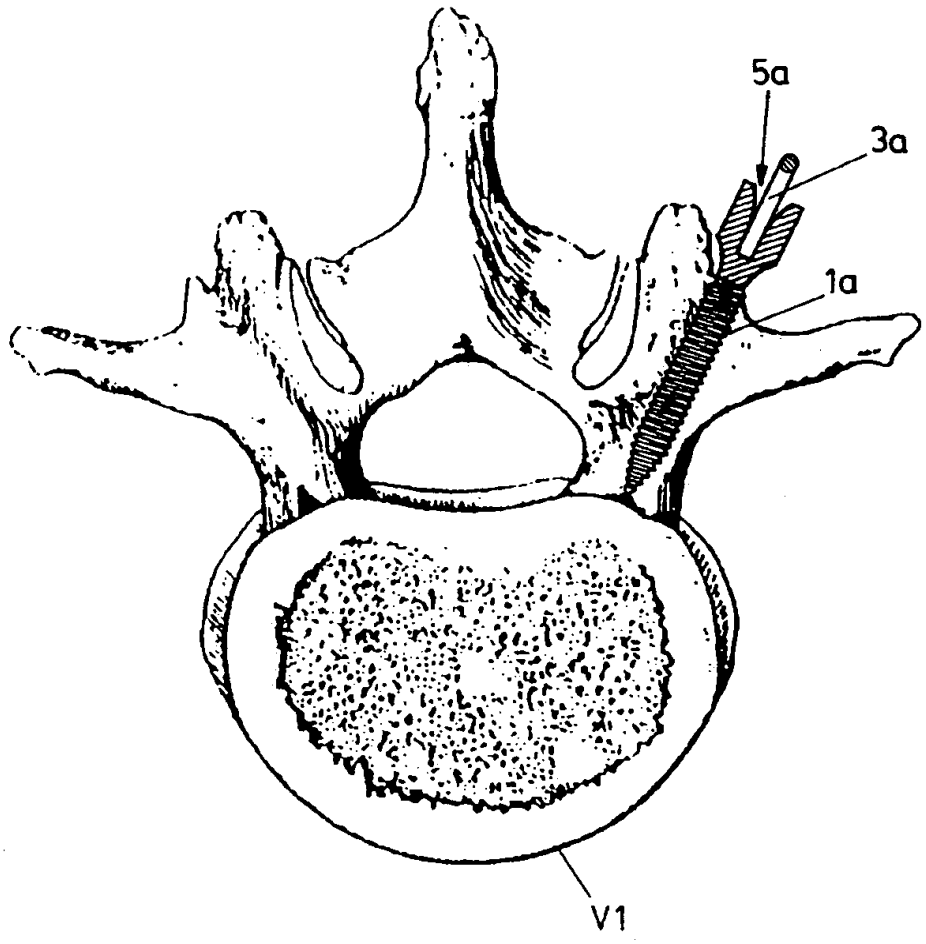

FIG.2

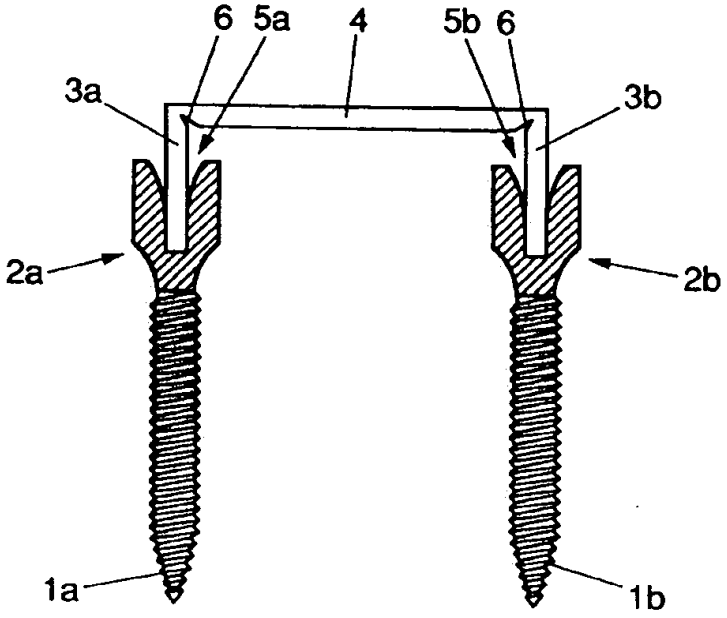

FIG. 3

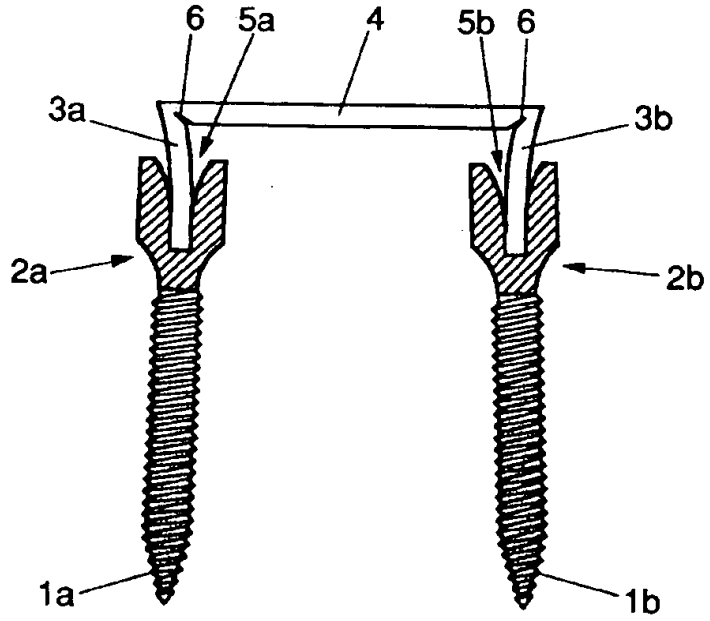

FIG. 4

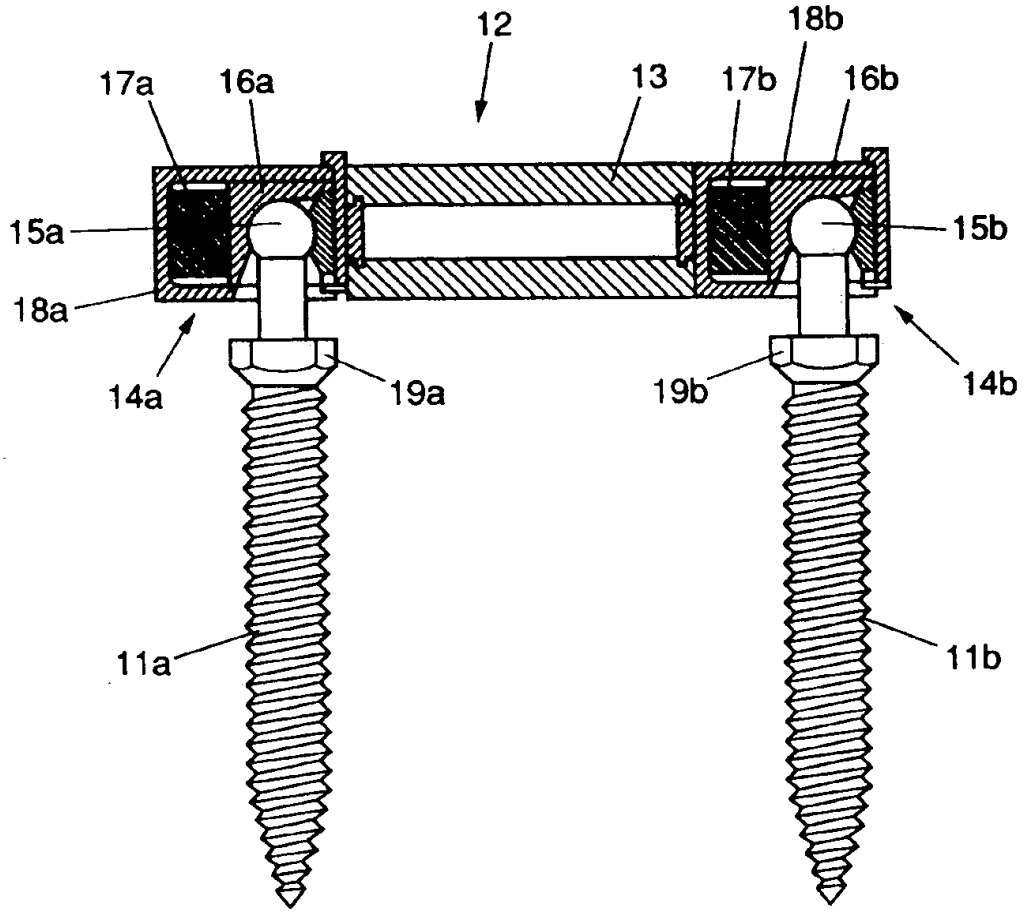

FIG. 5

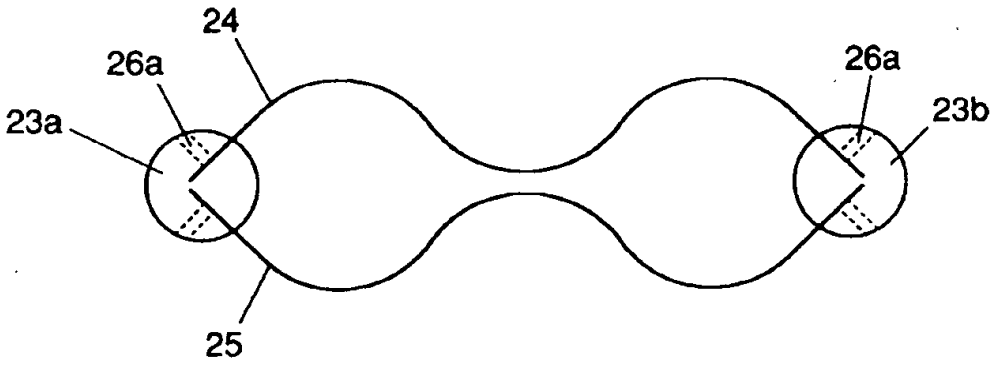

FIG. 7

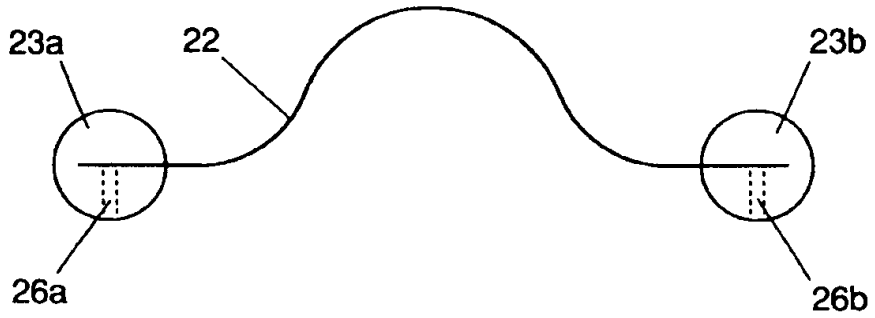

FIG. 6

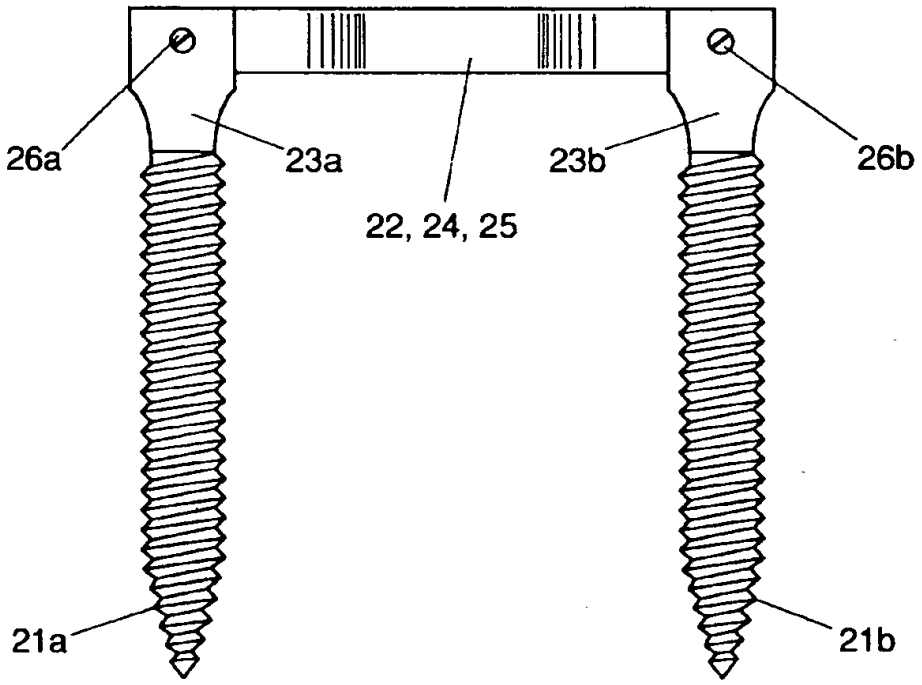

FIG. 8

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 20 0317

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	EP-A-0 576 379 (PSI) * abstract; figure 4 * * column 3, line 36 - line 44 * * column 4, line 10 - line 23 *	1-4, 10-12	A61B17/58
X	EP-A-0 516 567 (PSI) * column 5, line 41 - line 48 * * column 7, line 4 - line 6 * * figures 3,8-10 *	1,2,4,10	
X	EP-A-0 322 334 (COTE) * claim 1; figure 1 *	1,2,4	
X	FR-A-2 681 525 (MEDICAL OP) * abstract; figures *	1,2,13	
A	EP-A-0 140 790 (W.PEZE) * abstract; figures 1,3,9 * * page 10, line 8 - line 12 * * page 12, line 22 - line 28 *	7,9	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
P,X	FR-A-2 697 428 (A.ALBY) * abstract; figures 5,9 *	1-3, 10-12	A61B
P,X	EP-A-0 611 554 (PSI) * figures 3,4 *	1-3, 10-12	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	18 May 1995	Nice, P

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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EPO FORM 1503 03.82 (P04C01)

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 706 876 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
17.04.1996 Bulletin 1996/16

(51) Int. Cl.[6]: **B29C 70/34**, B29C 70/22, B29B 11/16

(21) Application number: **95114530.9**

(22) Date of filing: **15.09.1995**

(84) Designated Contracting States:
AT BE CH DE ES FR GB IT LI NL SE

(30) Priority: **14.10.1994 US 323251**

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(54) Composite structure and method of forming same

(57) A method of forming a composite structure (60) comprises the steps of forming a radially inner portion (64) of a preform with braided reinforcing fibers extending substantially transverse to an axis of the preform and forming a radially outer portion (68) of the preform circumscribing the inner portion with braided reinforcing fibers extending substantially parallel to the axis of the preform. The preform is heated and consolidated in a mold into the composite structure. The composite structure has braided reinforcing fibers extending throughout a radially inner portion (60) substantially transverse to an axis of the structure along which the structure is subject to splitting to resist splitting of the composite structure along the axis and braided reinforcing fibers extending throughout a radially outer portion (68) substantially parallel to the axis to resist bending of the composite structure. The composite structure is particularly suitable for manufacturing a bone plate.

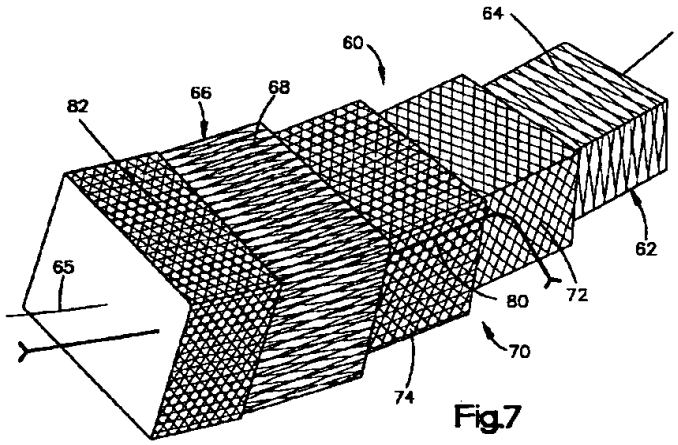

Fig.7

EP 0 706 876 A1

Description

Background of the Invention

The present invention relates to a composite structure, and in particular relates to a composite structure comprising matrix material with braided reinforcing fibers and a method of making the structure.

There are many known composite structures which comprise a fiber reinforced matrix material. A known composite structure comprises a laminated stack of layers of matrix material containing linearly oriented reinforcing fibers. The direction of orientation of the reinforcing fibers in one layer may be at a different angle relative to the direction of orientation of the reinforcing fibers in an adjacent layer. A disadvantage of a laminated stack of layers of a matrix material containing linearly oriented reinforcing fibers is that there is no fiber reinforcement in a direction perpendicular to the layers. A known way to strengthen the structure in the direction perpendicular to the layers is to stitch the layers together. A disadvantage in stitching the layers together is that the stitching process is labor and equipment intensive. Also, known fiber reinforced composite structures are made from knitted fibers and woven fibers which form a three-dimensional structure. However, the making of these composite structures is also labor and equipment intensive.

Summary of the Invention

In accordance with the present invention, a composite structure is made by a method which comprises the steps of braiding reinforcing fibers of a radially inner portion of a preform to extend substantially transverse to an axis of the preform along which the composite structure is subject to splitting. Reinforcing fibers of a radially outer portion circumscribing the radially inner portion are braided to extend substantially parallel to the axis of the preform. The preform is placed in a mold and heated to a temperature at which fibers which are to become the matrix material melt but the reinforcing fibers do not melt. The preform is consolidated in the mold. After heating and consolidating the preform, the composite structure is cooled so that a device such as a bone plate can be machined from the composite structure.

The composite structure comprises a radially inner portion of matrix material with braided reinforcing fibers extending throughout the inner portion substantially transverse to an axis of the composite structure along which the composite structure is subject to splitting to resist splitting of the composite structure. A radially outer portion of matrix material circumscribes the inner portion and has braided reinforcing fibers extending throughout the outer portion substantially parallel to the axis to resist bending of the composite structure.

The composite structure is similar to an I-beam in bending. The radially outer portions, like the outer webs of an I-beam, need the strength to resist bending of the composite structure because the stresses due to the bending are concentrated in the radially outer portions. The radially inner portion, like the connecting web of the I-beam, does not need to resist bending. The radially inner portion can be used to resist splitting of the composite structure.

The composite structure is machined into a bone plate for maintaining adjacent bone members, such as vertebrae or pieces of a broken bone, in a desired spatial relationship. When fasteners extend through openings in the bone plate to connect the bone plate to bone, the bone plate is subjected to clamping forces which could cause the bone plate to split along an axis. The braided reinforcing fibers in the radially inner portion of matrix material resist splitting of the bone plate due to the clamping forces applied to the bone plate by the fasteners. Furthermore, the braided reinforcing fibers extending through the radially outer portion resist bending of the bone plate and prevent movement between adjacent bone members which the bone plate is connected to.

A composite bone plate, as compared to a metal bone plate, is advantageous because it does not block the image of tissue on X-ray films and computerized tomography scans. A doctor can easily see if the pieces of a broken bone to which the composite bone plate is connected are healing properly or if adjacent vertebrae to which the composite bone plate is connected are fusing together properly. An X-ray marker, such as a titanium wire, may be braided into the composite bone plate so that a doctor may determine the position of the bone plate.

Another advantage of the composite bone plate is that the plate can be designed to prevent stress shielding. The stress-strain curve for bone has an initial region where some strain is achieved with very little stress. This initial region of the stress-strain curve is often called the "toe" of the stress-strain curve. At higher stresses, the curve becomes linear or proportional. The "toe" region allows for some deformation of the bone at low stress levels, while becoming more rigid at higher stresses, protecting against higher loads. The low stress deformation of bone is important in bone remodeling since the bone remodels to support applied loads.

When stiff metallic implants are connected to bone, the surrounding bone is shielded from applied stresses and the bone resorbs. If flexible implants are used, at high loads, the bone is deformed too much and damaged. The composite structure of the present invention is well suited for use as a bone plate since it can be made to have a stress-strain curve similar to that of bone, that is, with a low-stress "toe" region.

Contorted reinforcing fibers may be used in the composite structure to increase the size of the "toe" region. Twisted commingled yarn may be used in braiding the preform or the reinforcing fibers may be coiled, wavy, or kinked. With these

structures, the matrix material of the bone plate deforms at low stress levels while the reinforcing fibers begin to straighten out. At higher stress levels, the reinforcing fibers straighten out to pick up the load and the composite plate becomes stiffer.

Brief Description of the Drawings

The foregoing and other features of the present invention will become apparent to one skilled in the art upon consideration of the following description of the preferred embodiments of the invention with reference to the accompanying drawings, wherein:

Fig. 1 is a fragmentary view of a portion of a spinal column on which a composite bone plate constructed in accordance with the present invention has been installed to maintain vertebrae in a desired spatial relationship;
Fig. 2 is a sectional view, taken generally along the line 2-2 of Fig. 1, illustrating the manner in which fasteners are used to connect the composite bone plate with the vertebrae;
Fig. 3 is a plan view of the composite bone plate of Fig. 1;
Fig. 4 is a sectional view of the composite bone plate of Fig. 3 taken along the line 4-4 of Fig. 3;
Fig. 5 is a schematic view of a preform, partially cut away to show various layers of the preform, used in forming the composite bone plate of Fig. 1;
Fig. 6 is an enlarged plan view of a portion of a layer of the preform of Fig. 5;
Fig. 7 is a schematic perspective view of a composite structure, partially cut away to show various portions of the structure, from which the bone plate of Fig. 1 is machined; and
Fig. 8 is a graph showing the relationship between stress and strain for the composite structure of Fig. 7.

Description of the Preferred Embodiments of the Invention

A pair of surgically implantable composite bone plates 10 (Fig. 1) for correcting deformation and/or degeneration of a spinal column C are connected with several vertebrae V of the spinal column by fasteners 20. Each composite bone plate 10 is elongate and has a rectangular cross-section taken in a plane extending perpendicular to a longitudinal central axis 12 of the plate (Fig. 2). Each composite plate 10 is preferably curved to conform to a desired curvature of the spinal column C, as illustrated in Fig. 4. The composite bone plates 10 have sufficient strength and rigidity to maintain the vertebrae V in the desired relationship. Although the composite bone plates are shown maintaining vertebrae in a desired spatial relationship, they may be used for maintaining pieces of a broken bone in a desired relationship.

The composite bone plates 10 are connected to respective vertebrae V by fasteners 20 (Fig. 2) made of a suitable biocompatible material, such as titanium or stainless steel. Each of the fasteners 20 has a threaded inner end portion 22 having a coarse helical thread convolution 24 which engages the vertebra V. An outer end portion 26 of the fastener 20 is provided with a relatively fine thread which engages an internal thread convolution on a clamp nut 28 preferably made of a suitable biocompatible material, such as titanium coated with titanium nitride. Wrenching flats (not shown) are provided on the outermost end of the outer end portion 26 of the fastener 20. Torque is applied to these wrenching flats to turn the relatively coarse helical thread convolution 24 into the vertebra V. Once the fastener 20 has been connected to the vertebra and the composite bone plate 10, the outer end portion of the fastener may be cut away to minimize the overall length of the fastener.

An intermediate portion 32 is provided with wrenching flats which can be engaged to hold the fastener 20 against rotation when the clamp nut 28 is tightened. In addition, the intermediate portion 32 of the fastener has a flat outer side surface which abuttingly engages the composite bone plate 10. When the clamp nut 28 is tightened, the composite bone plate 10 is securely gripped between the clamp nut 28 and the intermediate portion 32 of the fastener 20.

Although it is contemplated that the fastener 20 could have many different constructions, it is preferred to construct the fastener 20 in accordance with U.S. Patent No. 4,854,311 which is assigned to the assignee of the present invention. Another possible fastener would include a piece with a plurality of ridges that mates with a plurality of ridges on the plate to prevent movement of the plate relative to the fastener.

Each of the composite bone plates 10 has a length which is at least sufficient to enable the bone plate to span at least two of the vertebrae V. In the embodiment of the invention illustrated in Fig. 1, the bone plates 10 span two vertebrae V. Of course, the length of the composite bone plates in any particular installation will depend upon the condition to be corrected and the number of vertebrae V to be held in a desired spatial relationship relative to each other by the composite bone plates. Preferably, each of the composite bone plates includes a titanium wire 80 (Fig. 2) extending along the longitudinal extent of the bone plate as an X-ray marker.

Each of the composite bone plates 10 is identical and includes at least one slot 40 (Figs. 3 and 4) and may include a circular opening 42 located adjacent an end portion of the bone plate. The bone plate 10 may have any number of slots for receiving fasteners depending on the length of the bone plate. The bone plate 10 has an upper surface 44 provided with spherical recesses 46 along the slot 40 defining a plurality of locations for receiving the fastener 20. If the bone plate 10 includes a circular opening 42, then upper surface 44 also includes a spherical recess 48 surrounding

the opening 42 for receiving a fastener 20. The spherical recesses 46 and 48 have a radius that is the same as a radius of a spherical surface of the clamp nut 28 and is approximately 16mm. The spherical recesses extend approximately 145° to help prevent splitting of the plate along the longitudinal axis 12 by directing most of the clamping forces applied to the plate in a direction normal to the surface 44 instead of transverse to the axis 12.

Preferably, a composite structure 60 from which the bone plate 10 is machined is formed by heating and consolidating a cylindrical braided preform 100 (Fig. 5) having a longitudinal axis 101. The preform 100 has a cross-section that forms a cross-section of a single composite structure 60 upon heating and consolidating the preform. The preform 100 may have any desired length to form one or a plurality of composite structures 60.

The preform 100 comprises a plurality of concentric layers of braided commingled yarn. The layers have varying braid angles with the inner layers having a large braid angle and the outer layers having a relatively small braid angle. The braid angle X is defined as half of the interlacing angle between yarns such as A and B, as shown in Fig. 6.

Preferably, the yarn is a commingled yarn known as Ultrapek/AS-4 Commingled Yarn manufactured by Cytec Inc., Anaheim, CA. Ultrapek/AS-4 Commingled Yarn comprises Ultrapek polymer fibers made from poly(ether ketone ether ketone ketone) by BASF Inc., Charlotte, NC commingled with AS-4 carbon fibers made from a polyacrylonitrile percurser by Hercules Advanced Materials and Systems Company, Magna, UT. The carbon fibers are the reinforcing fibers and the polymer fibers become matrix material when melted. Preferably, the reinforcing fibers are between 55% and 75% of the weight of the preform 100.

Alternatively, the material of which the yarn is made may be carbon fibers that have firmly adhering polymer powder bonded to the carbon fibers. Also, the material of which the yarn is made may be carbon fibers having a thin coating of polymer material. Also, the carbon fibers may be replaced with other carbon or graphite fibers or with glass fibers, silicon carbide fibers, or any other structural fibers. Also, the Ultrapek polymer may be replaced with other high performance and biocompatible polymers. These include, but are not limited to, other poly (aryl ether ketone)s such as PEEK, PEKK, and PEK, as well as poly (amide imide)s, poly (aryl sulfone)s, nylon, poly (butylene phthalate), poly (ethylene phthalate) and liquid crystal polymers or other similar polymers.

The preform 100 includes a radially inner plurality of concentric layers 102, one of which is shown in Figs. 5 and 6, of biaxially braided commingled yarn. The braid angle X of each of the layers 102 is between approximately 60° and 90°. It is desirable to have the braid angle as close to 90° as possible. Preferably, the inner plurality of concentric layers 102 comprises approximately one third of the thickness of the preform 100. The number of layers and the actual braid angle may vary depending on the braiding process.

An intermediate plurality of concentric layers 104 and 106 of braided yarn circumscribes the radially inner plurality of concentric layers 102. The braid angle of each of the layers of the intermediate plurality of concentric layers 104 and 106 is between approximately 40° and approximately 55°. The intermediate plurality of layers includes a first plurality of concentric layers 104, one of which is shown in Fig. 5, of biaxially braided yarn and a second plurality of concentric layers 106, one of which is shown in Fig. 5, of triaxially braided yarn circumscribing the first plurality of layers. Triaxially braided yarn has a pattern similar to the pattern of biaxially braided yarn shown in Fig. 6 with another system of yarn extending parallel to the longitudinal axis 101 of the preform 100 braided between the yarn extending transverse to the longitudinal axis.

The titanium wire 80 is braided into one of the second plurality of layers 106. Preferably, the intermediate plurality of layers 104 and 106 comprises approximately one third of the thickness of the preform 100. The actual number of intermediate layers 104 and 106 and the braid angle of the intermediate layers 104 and 106 may vary depending on the braiding process.

A radially outer plurality of concentric layers 110, one of which is shown in Fig. 5, of triaxially braided yarn circumscribes the intermediate plurality of layers 104 and 106. The braid angle of each of the layers of the outer plurality of concentric layers 110 is between approximately 0° and approximately 45°. It is desirable to have the braid angle as close to 0° as possible. Preferably, the outer plurality of concentric layers 110 comprises approximately one third of the thickness of the preform 100. The number of outer layers 110 and the actual braid angle of outer layers 110 may vary depending on the braiding process.

A radially outermost concentric layer 112 of triaxially braided yarn circumscribes the radially outer plurality of concentric layers 110. The outermost layer 112 has a braid angle of between approximately 40° and approximately 65°. The outermost layer 112 is tightly braided together so it does not come apart easily to provide for easy handling of the preform 100. Preferably, approximately half of the bias ends of the outermost layer 112 comprises a polymer yarn, the other half of the bias ends comprises Ultrapek/AS-4 commingled yarn and the axial ends comprise Ultrapek/AS-4 commingled yarn to provide a polymer rich surface of the composite structure 60.

Preferably, at least some of the reinforcing fibers are contorted prior to braiding the preform. The commingled yarn may be twisted, or coils, waves, or kinks may be formed in the reinforcing fibers. Therefore, the stress-strain curve (Fig. 7) of the composite structure has a "toe" region 200 and a linear region 202. At low stress levels the stress-strain curve is non-linear and at higher stress levels the stress and strain are approximately proportional. At low stresses the matrix material of the composite structure 60 deforms while the reinforcing fibers straighten out and at higher stresses the reinforcing fibers straighten and pick up the load.

EXAMPLES

Two examples of braided preforms from which composite bone plates have been formed are set forth below in Tables 1 and 2. The tables set out each concentric layer of the preform numbered from the radially innermost layer to the radially outermost layer. The braid angle and the picks per inch (ppi) for each layer are given in the tables. The picks per inch is defined as the distance between interlacing points and is labeled Y in Fig. 6.

TABLE 1

Layer	Braid Angle (deg.)	ppi
1	14	14
2	47	13
3	54	12
4	64	14
5	60	9
6	62	9
7	65	9
8	65	8
9	66	8
10	70	9
11	71	9
12	70	8
13	71	8
14	72	8
15	73	8
16	65	5
17	66	5
18	47	10
19	45	8
20	48	8.5
21	43	7
22	45	7
23	45	6.25
24	46	6.25
25	45	5.75
26	45	5.25
27	45	5
28	60	5

Layers 1-17 are biaxially braided with 4 bias ends. Layers 18-21 are biaxially braided with 16 bias ends. Layers 22 and 23 are triaxially braided with 16 bias ends and 16 axial ends. Layer 22 includes a bias end of titanium wire. Layers

24-27 are triaxially braided with 16 bias ends and 32 axial ends. Layer 28 is triaxially braided with 8 bias ends of commingled yarn, 24 bias ends of polymer yarn, and 48 axial ends of commingled yarn.

TABLE 2

Layer	Braid Angle (deg.)	ppi
1	33.4	14
2	50.8	13
3	65.5	14
4	71.4	14
5	72.2	12
6	74	12
7	75.8	12
8	77.8	12
9	59.1	4
10	60.1	4
11	54.7	4
12	44.1	2
13	44.8	2
14	45.1	8
15	26.6	3.5
16	25	3
17	26.6	3
18	30.1	3
19	22.2	2
20	28.8	2.5
21	30.2	2.5
22	64.2	7

Layers 1-13 are biaxially braided with 4 bias ends. Layers 14 and 15 are triaxially braided with 16 bias ends and 16 axial ends. Layer 14 includes an axial end of titanium wire. Layers 16-21 are triaxially braided with 16 bias ends and 32 axial ends. Layer 22 is triaxially braided with 8 bias ends of commingled yarn, 8 bias ends of polymer yarn, and 48 axial ends of commingled yarn.

In both examples the first few radially innermost layers have braid angles from 14° to 54°. These braid angles are a result of the braiding process and machinery. It is preferred that these innermost layers have a braid angle as close to 90° as possible.

After the preform 100 is formed, it is heated and consolidated into an elongate composite structure 60 from which the bone plate 10 is machined. The preform 100 may be cut into a plurality of lengths to form a plurality of composite structures 60. The preform 100 is placed into a mold and the mold is placed into a high temperature consolidation press with vacuum capability. The vacuum chamber of the press is evacuated, the temperature is set to 800°F, and the pressure is set to 500 lbs. closing force. It requires approximately one hour for the press to reach 800°F. As the press displacement decreases, showing consolidation of the preform, the pressure is increased to 7,000 lbs. The temperature and pressure are maintained for 45 minutes and then the heat is turned off and the press cooling is turned on. After the mold has reached ambient temperature, the press is opened, the mold is removed, and the consolidated composite structure 60

is removed from the mold. The composite structure 60 is then machined to form a desired bone plate 10. After the bone plate 10 is machined it is placed in an ultrasonic bath with acetone to remove any residual particulate debris.

The composite bone plate 10 is machined from the composite structure 60 (Fig. 7) comprising matrix material and reinforcing fibers. Preferably, the composite structure 60 is curved if the bone plate 10 is to be curved. The matrix material is the polymeric material, Ultrapek, and the reinforcing fibers are the AS-4 carbon fibers. Preferably, the reinforcing fibers make up between 55% and 75% of the weight of the composite structure 60.

The composite structure 60 includes a radially inner portion of matrix material 62 with a plurality of concentric layers 64, one of which is shown in Fig. 7, of biaxially braided reinforcing fibers extending throughout the inner portion. The reinforcing fibers in the radially inner portion of matrix material 62 extend substantially transverse to a longitudinal axis 65 of the composite structure 60 to resist splitting of the structure along the longitudinal axis 65 when connected to bone as a bone plate. The axis 65 of the composite structure 60 becomes the axis 12 of the bone plate 10. The reinforcing fibers in the radially inner portion 62 have a braid angle between approximately 60° and 90°. It is desirable to have the braid angle as close to 90° as possible.

The composite structure 60 has a radially outer portion of matrix material 66 which circumscribes the radially inner portion of matrix material 62. A plurality of concentric layers 68, one of which is shown in Fig. 7, of triaxially braided reinforcing fibers extend throughout the radially outer portion of matrix material 66 substantially parallel to the longitudinal axis 65 to resist bending of the composite structure. The reinforcing fibers in the outer portion 66 have a braid angle between 0° and approximately 45°. It is desirable to have the braid angle as close to 0° as possible.

The composite structure 60 also includes an intermediate portion of matrix material 70 circumscribing the inner portion of matrix material 62 and circumscribed by the outer portion of matrix material 66. A plurality of concentric layers 72 and 74 of braided reinforcing fibers extend throughout the intermediate portion 70 and have a braid angle between approximately 40° and approximately 55°. A first plurality of concentric layers 72, one of which is shown in Fig. 7, of braided reinforcing fibers of the intermediate portion 70 are biaxially braided. A second plurality of concentric layers 74, one of which is shown in Fig. 7, of braided reinforcing fibers of the intermediate portion 70 circumscribes the first plurality of concentric layers 72 of the intermediate portion and are triaxially braided. The titanium wire 80 extends through the intermediate portion 70 and substantially parallel to the longitudinal axis 65 of the composite structure 60 to act as an X-ray marker.

The composite structure 60 has a radially outermost layer 82 of braided reinforcing fibers. The radially outermost layer 82 circumscribes the radially outer portion of matrix material 66. The radially outermost layer 82 is triaxially braided and has a braid angle between approximately 40° and approximately 60°.

From the above description of the invention, those skilled in the art will perceive improvements, changes and modifications. Such improvements, changes and modifications within the skill of the art are intended to be covered by the appended claims.

Claims

1. A composite structure comprising:
   a radially inner portion of matrix material;
   a radially outer portion of matrix material circumscribing said inner portion;
   braided reinforcing fibers extending throughout said inner portion substantially transverse to an axis along which said composite structure is subject to splitting to resist splitting of said composite structure along said axis; and
   braided reinforcing fibers extending throughout said outer portion substantially parallel to said axis to resist bending of said composite structure;
   said directions of said reinforcing fibers resulting from heating and consolidating a preform made of matrix material and braided reinforcing fibers.

2. A composite structure as set forth in claim 1 wherein said reinforcing fibers in said inner portion have a braid angle between approximately 60° and 90° and said reinforcing fibers in said outer portion have a braid angle between 0° and approximately 45°.

3. A composite structure as set forth in claim 2 further including an intermediate portion of matrix material circumscribed by said outer portion of matrix material and circumscribing said inner portion of matrix material and braided reinforcing fibers extending throughout said intermediate portion, said reinforcing fibers in said intermediate portion having a braid angle between approximately 40° and approximately 55°.

4. A composite structure as set forth in claim 3 wherein each of said inner, intermediate, and outer portions includes a plurality of concentric layers of braided reinforcing fibers.

5. A composite structure as set forth in claim 4 wherein said plurality of concentric layers of reinforcing fibers in said inner portion are biaxially braided.

6. A composite structure as set forth in claim 5 wherein said intermediate portion includes a first plurality of concentric layers of biaxially braided reinforcing fibers and a second plurality of concentric layers of triaxially braided reinforcing fibers, said second plurality of concentric layers of reinforcing fibers circumscribing said first plurality of concentric layers of reinforcing fibers in said intermediate portion.

7. A composite structure as set forth in claim 6 wherein said plurality of concentric layers of reinforcing fibers in said outer portion are triaxially braided.

8. A composite structure as set forth in claim 3 further including a titanium wire extending through said intermediate portion.

9. A composite structure as set forth in claim 2 further including a radially outermost portion circumscribing said outer portion, said outermost portion including braided reinforcing fibers with a braid angle between approximately 40° and approximately 65°.

10. A composite structure as set forth in claim 1 including a plurality of openings for receiving fasteners.

11. A composite structure as set forth in claim 10 wherein said openings are defined by spherical recesses in a side surface of said composite structure which define a plurality of locations for receiving fasteners, each of said recesses defining a spherical arc extending approximately 145°.

12. A composite structure as set forth in claim 11 wherein at least one of said openings is a slot, said recesses defining a plurality of locations along said slot for receiving fasteners.

13. A composite structure as set forth in claim 12 further including a round opening located at an axial end portion of said structure.

14. A composite structure as set forth in claim 1 wherein said reinforcing fibers are between 55% and 75% of the weight of said composite structure.

15. A composite structure as set forth in claim 1 wherein at least some of said reinforcing fibers are contorted.

16. A composite structure as set forth in claim 15 wherein said at least some of said reinforcing fibers are coiled.

17. A composite structure as set forth in claim 15 wherein said at least some of said reinforcing fibers are twisted.

18. A method of forming a composite structure which in use is subject to splitting along an axis and bending, said method comprising the steps of:

providing a radially inner portion of a preform with a first plurality of braided reinforcing fibers extending substantially transverse to the axis;

providing a radially outer portion of the preform circumscribing the inner portion with a second plurality of braided reinforcing fibers extending substantially parallel to the axis; and

heating and consolidating the preform to form a matrix with the first and second plurality of braided reinforcing fibers extending through inner and outer portions of the matrix material, respectively.

19. A method as set forth in claim 18 including braiding the first plurality of reinforcing fibers of the inner portion of the preform with a braid angle between approximately 60° and 90° and braiding the second plurality of reinforcing fibers of the outer portion with a braid angle between 0° and approximately 45°.

20. A method as set forth in claim 19 including providing an intermediate portion of the preform circumscribed by the outer portion and circumscribing the inner portion with a third plurality of braided reinforcing fibers having a braid angle between approximately 40° and approximately 55°.

21. A method as set forth in claim 20 including providing a radially outermost portion of the preform circumscribing the outer portion with braided reinforcing fibers having a braid angle between approximately 40° and approximately 65°.

22. A method as set forth in claim 21 including braiding approximately 50% of bias ends of the radially outermost portion with matrix yarn, approximately 50% of the bias ends of the radially outermost portion with commingled matrix and reinforcing fiber yarn, and axial ends of the radially outermost portion with commingled matrix and reinforcing fiber yarn.

23. A method as set forth in claim 20 including forming each of the inner, intermediate, and outer portions to be approximately one third the thickness of the preform.

24. A method as set forth in claim 20 including forming each of the inner, intermediate, and outer portions out of a plurality of concentric layers of braided fibers.

25. A method as set forth in claim 24 including biaxially braiding the plurality of concentric layers of the inner portion.

26. A method as set forth in claim 24 including biaxially braiding a first plurality of concentric layers of the intermediate portion and triaxially braiding a second plurality of concentric layers of the intermediate portion circumscribing the first plurality of concentric layers of the intermediate portion.

27. A method as set forth in claim 24 including triaxially braiding the plurality of concentric layers of the outer portion.

28. A method as set forth in claim 24 including braiding a titanium wire into the intermediate portion.

29. A method as set forth in claim 18 including contorting at least some of the reinforcing fibers prior to braiding.

30. A method as set forth in claim 29 wherein said step of contorting the reinforcing fibers includes forming coils in the reinforcing fibers.

31. A method as set forth in claim 29 including forming the preform with commingled yarn.

32. A method as set forth in claim 31 wherein the step of contorting the reinforcing fibers includes twisting the commingled yarn.

33. A method as set forth in claim 18 including forming a plurality of openings in the composite structure for receiving fasteners.

34. A method as set forth in claim 33 including forming spherical recesses extending approximately 145° in a side surface of the composite structure to define a plurality of locations for receiving fasteners.

35. A method as set forth in claim 34 including forming a slot with at least two recesses defining locations for receiving fasteners.

36. A method as set forth in claim 35 including forming a round opening at an axial end portion of the composite structure for receiving one fastener.

37. A method as set forth in claim 18 further including forming the composite structure with the reinforcing fibers making up between 55% and 75% of the weight of the composite structure.

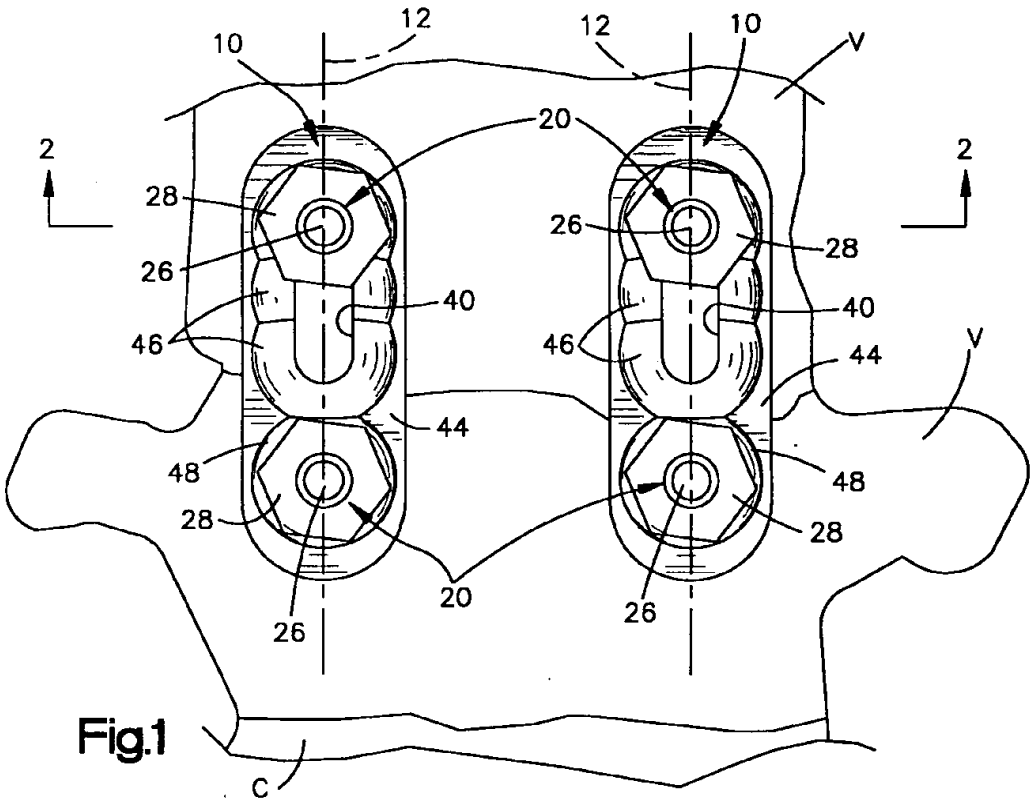

Fig.1

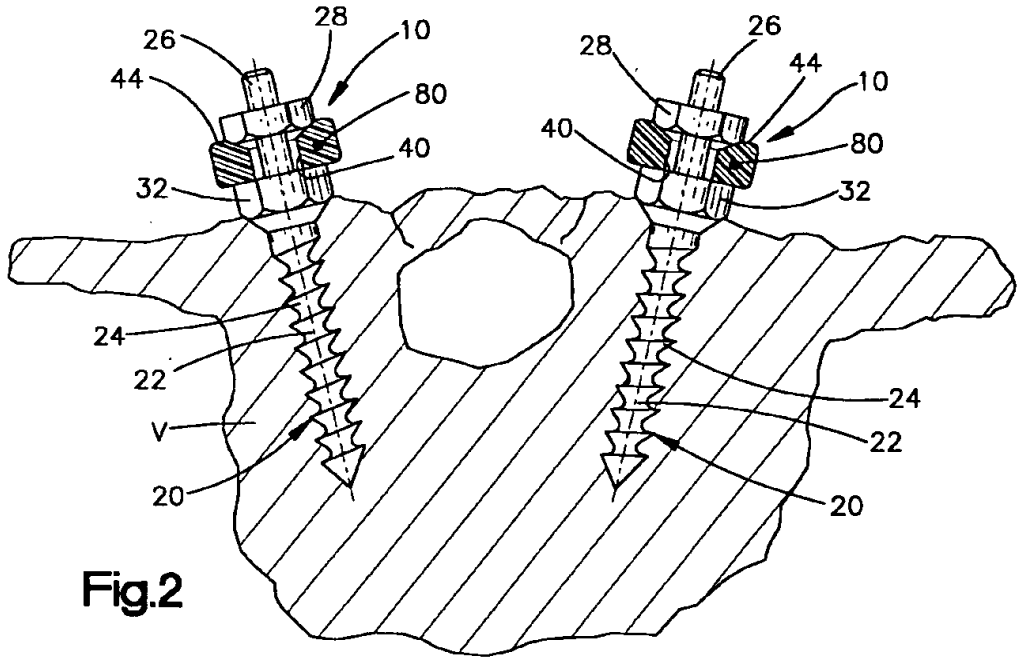

Fig.2

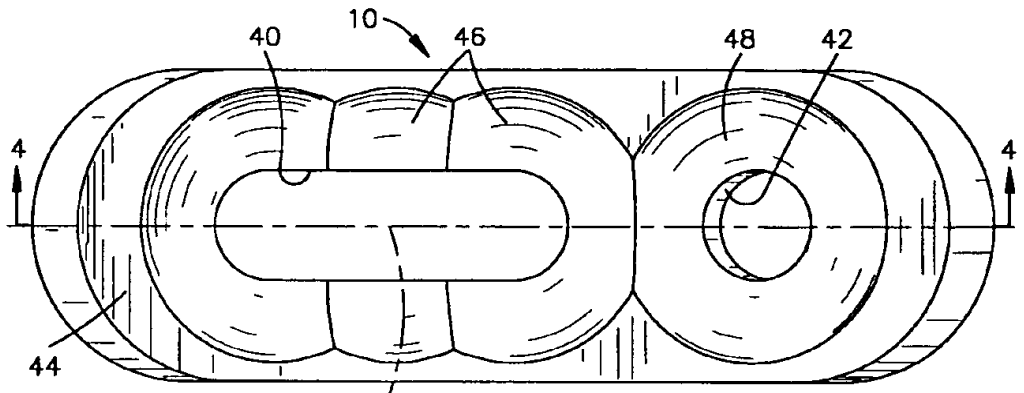

Fig.3

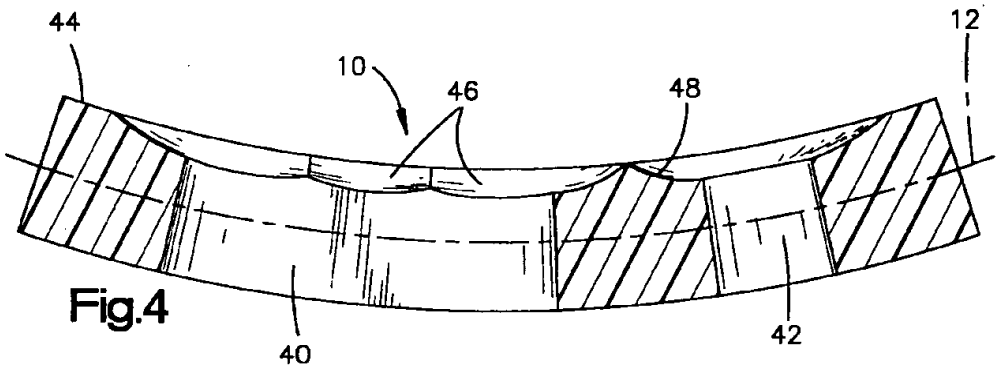

Fig.4

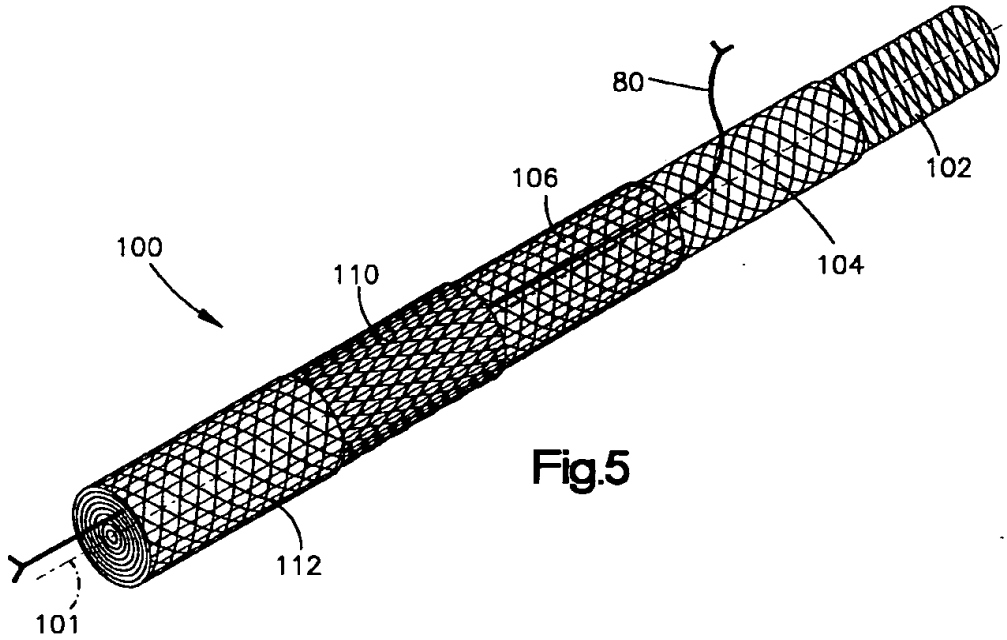

Fig.5

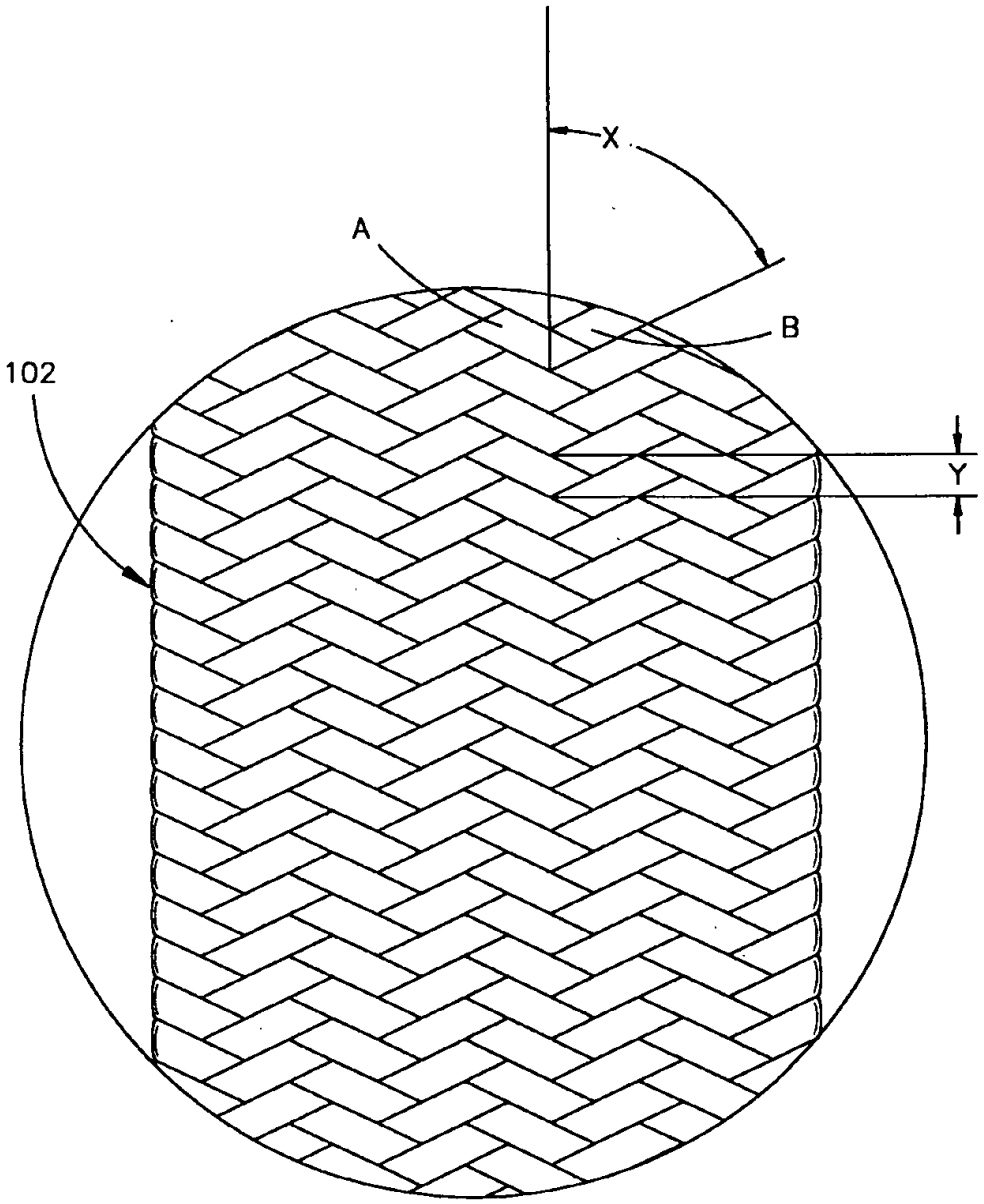

Fig.6

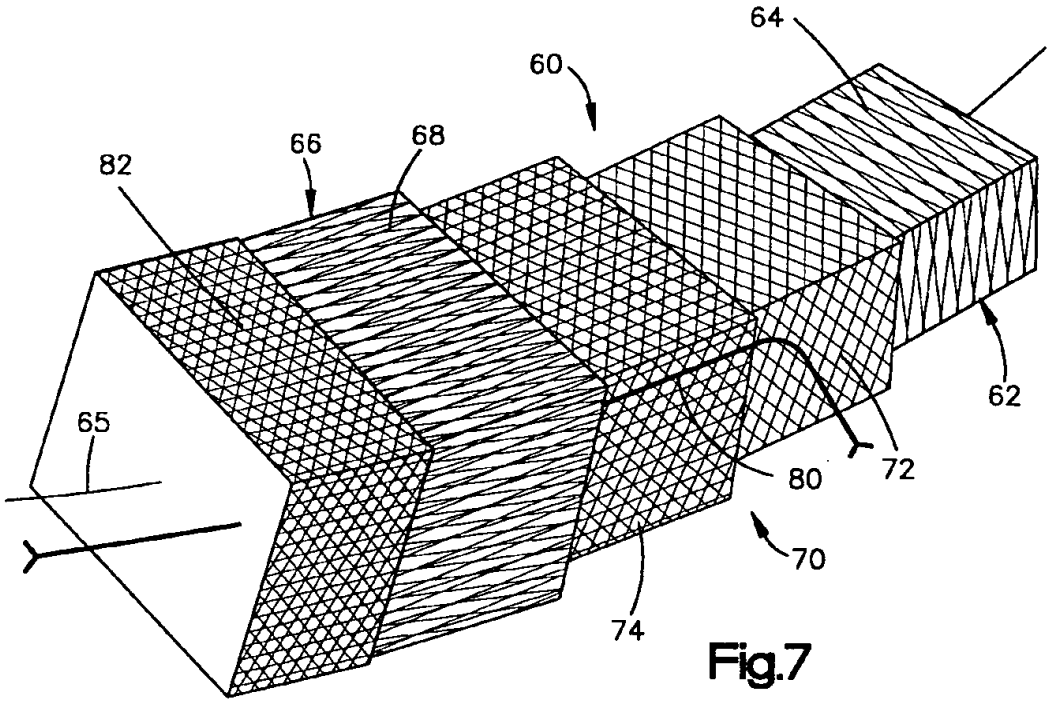

Fig.7

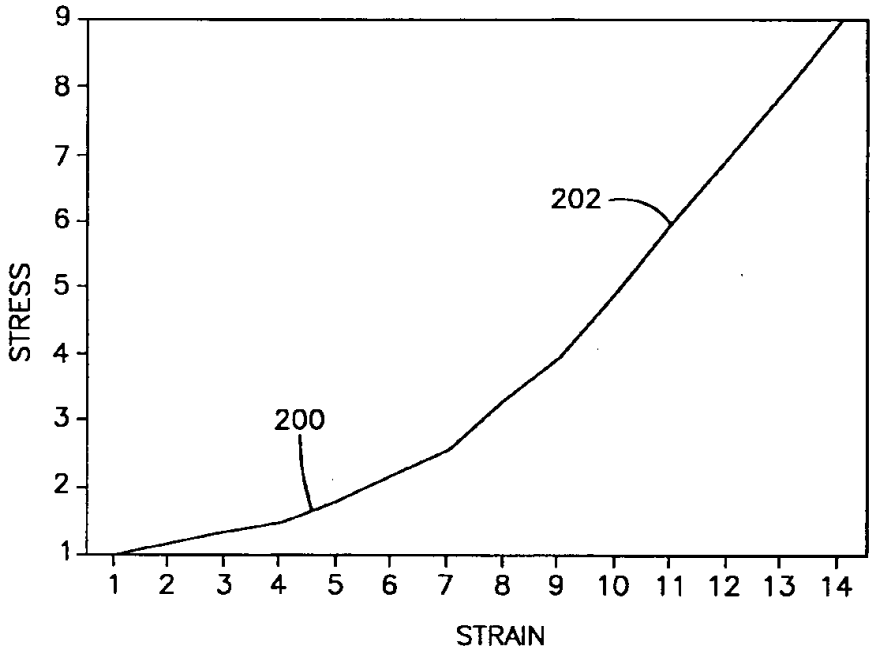

Fig.8

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 11 4530

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y	EP-A-0 285 156 (DU PONT) 5 October 1988 * example 1 *	18-21, 23-27,37	B29C70/34 B29C70/22 B29B11/16
X Y	WO-A-93 13733 (DU PONT) 22 July 1993 * page 19, line 29 - page 21, line 5; claims 20,21 *	1-5,9,14 18-21, 23-27,37	
X Y	WO-A-93 19699 (HOWMEDICA) 14 October 1993 * page 9, line 17 - line 34 * * page 3, line 29 - line 31 *	1-5,9,14 18-21, 23-27,37	
X	EP-A-0 127 553 (VERRE TISSE SA) 5 December 1984 * the whole document *	1-5,9,14	
A	WO-A-92 11128 (ALLIED SIGNAL INC) 9 July 1992 * the whole document *	6,7,26, 27	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6) B29C B29B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	30 January 1996	Van Wallene, A

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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EPO FORM 1503 03.82 (P04C01)

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 716 840 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
19.06.1996 Bulletin 1996/25

(51) Int. Cl.[6]: **A61F 2/44**

(21) Application number: **95119558.5**

(22) Date of filing: **12.12.1995**

(84) Designated Contracting States:
DE ES FR GB IT

(30) Priority: **12.12.1994 US 354364**

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(54) Conically-shaped fusion cage and method of implantation

(57) A fusion cage 20 for vertebral body fusion is conically-shaped. A thread 40 is formed as part of the external conical surface of the fusion cage. Apertures 54 are defined through the fusion cage in order to provide for contact between the engaged vertebral bone structures and bone growth inducing substances packed within the fusion cage. The fusion cage is introduced and maintains or increases the lordosis between adjacent vertebral bone structures.

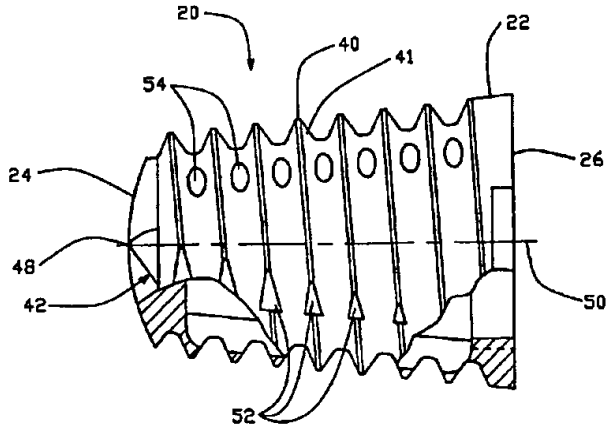


FIG.—1

EP 0 716 840 A2

Printed by Rank Xerox (UK) Business Services
2.12.3/3.4

Description

BACKGROUND

Field of the Invention

The present invention is directed to devices and methods for facilitating the fusing of bone structures and more particularly the fusing together of adjacent vertebral bodies or bone structures.

Background of the Invention

Technical literature and patent documents disclose a number of devices and methods for fusing bones together. One such device which has proven to be successful is disclosed in U.S. Patent 4,961,740, entitled "V-THREAD FUSION CAGE AND METHOD OF FUSING A BONE JOINT," which patent has been assigned the present assignee and which patent is incorporated herein by reference. The referenced patent discloses a fusion cage which is preferably cylindrical and has a thread formed as part of the external cylindrical surface. The fusion cage defines an internal cavity and apertures through the wall of the cage which communicate the external cylindrical surface with the internal cavity. The apertures are formed in the valleys of the thread. Normally two such cages are used to stabilized and fuse together adjacent vertebral bodies or bone structures.

In practice, using a posterior approach, a patient's vertebral bone structures are exposed and degenerate disk material located between the vertebral bone structures is removed. A threaded tap is used to tap a complementary thread in the upper and lower vertebral bone structures preparatory to the insertion of the above fusion cage. Once such tapping has been accomplished, using an introduction tool, the fusion cage is screwed into the space between the adjacent vertebral bone structures. The thread bites into the bone of the upper and lower vertebral bone structures, stabilizing the bone structures, and preventing the fusion cage from working out of this position due to patient movement. Generally two such fusion cages are applied using this technique. Once the two implants have been positioned, then bone growth inducing substances, such as bone chips, are packed into the internal cavity of the fusion cages. These bone growth inducing substances come into immediate contact with the bone from the vertebral bone structures which project into the internal cavity through the apertures. Such projection of bone is due to the fact that the apertures are formed in the valleys of the external thread of the fusion cage. Such immediate bone to bone contact between the vertebral bone structures and the bone pack within the fusion cages results in more rapid propagation of bone cells between the adjacent vertebral bone structures and thus a more rapid fusion of the adjacent vertebral bone structures.

It is to be understood that in the above method, bone growth inducing substances can be prepacked into the cages before the cages are implanted between the vertebral body structures.

Summary of the Invention

The present invention is directed to a fusion cage which has been designed to be implanted using principally a posterior approach to the vertebral bone structures.

In a first embodiment of the present invention, the fusion cage includes a cage body having a proximal end and a distal end, said distal end having a diameter which is larger than the diameter of the proximal end. The distal end further is rounded with for example a bull nose in order to facilitate the insertion of the cage body relative to one or more bone structures. The distal end could alternatively have a snub nose with or without a starter turn of a thread. The snub nose has a starter diameter that is smaller than the diameter of the distal end. The cage body is preferably conically-shaped. This shape is particularly advantageous due to the fact that the normal lordosis of the vertebral bone structures defines a wedged-shape space for a vertebral disk between, for example, lumbar vertebrae. Accordingly, the conically-shaped body cage can be sized and selected in order to maintain or enlarge upon the normal lordosis.

In a second embodiment of the present invention the cage body can include a cylindrically-shaped portion and a conically-shaped portion. The cylindrically-shaped portion is located adjacent to the distal end and the conically-shaped portion extends from the cylindrically-shaped portion and tapers toward the proximal end.

In a third embodiment of the present invention, a fusion cage includes a cage body having a proximal end and a distal end with the proximal end having a diameter which is smaller than the diameter of the distal end. The distal end has a flute formed therein. Additionally, the cage body has an outer surface and at least one flute formed in the outer surface. These flutes act as a relief much as the flute placed on self-tapping screws in order to facilitate the insertion of the fusion cage using a twisting motion between two vertebral bone structures.

In a fourth embodiment of the invention, a fusion cage includes a cage body having a proximal end and a distal end, the proximal end having a diameter which is smaller than the diameter of the distal end. The cage body has an outer surface and a thread formed as part of the outer surface. The thread aids the cage body in being inserted. As the cage is inserted, it gradually spreads apart the vertebral bone structures in order to regain or enlarge the natural lordosis of the adjacent vertebral bone structures. As with other embodiments of the present invention, flutes can be provided in the thread in order to allow for enhanced thread tapping by the cage and for a smoother insertion of the fusion cage between the vertebral bone structures. Preferably two or three flutes would be formed spaced about the fusion cage in order that one flute would be engaging with or adjacent to an upper vertebral bone structures with another flute

being engaging with or adjacent to a lower vertebral bone structure. Such a relationship maintains alignment of the fusion cage and prevent wandering as the fusion cage is introduced between the two vertebral bone structures. Without two or more flutes, wandering might occur due to the fact that the thread is only substantially engaged with the vertebral bone structures and not with the disk material between the vertebral bone structures, which disk material does not provide support to the thread.

In a further aspect of the invention, any of the above embodiments can be provided with a plurality of apertures through the fusion cage and an internal cavity with the apertures communicating between the internal cavity and the external surface of the fusion cage. Bone growth inducing substances, such as bone chips, can be packed into the internal cavity either before the fusion cage is inserted or after the fusion cage has reached a final insertion position, or packed in both before and after. The bone chips come in contact with the vertebral bone structures through the apertures in order to facilitate fusion between the adjacent vertebral bone structures.

In another aspect of the invention which can be included in any of the above embodiments, the cage body can have a round or bull nose distal end with one or more flutes formed in the round or bull nose distal end in order to enhance the self-tapping nature of the fusion cage and to prevent the cage from wandering.

In yet another aspect of the invention, introduction tools allow the fusion cage to be accurately positioned between the vertebral bone structures. A preferred introduction tool allows for the cage to be implanted and thereafter allows an end cap of the cage to be conveniently removed, if desired, in order to place bone growth inducing substances in the cage.

The method of the present invention affords access to adjacent vertebral bone structures using an posterior approach and procedure. Such posterior approach and procedure can be performed percutaneously using a minimally invasive technique with an introduction set including cannulas. Such a procedure is minimally invasive as the tissues can be spread using a set of cannula of increasing size and a small opening thereby developed through which a fusion cage can be inserted. Such a procedure is less traumatic to the tissue than an alternate posterior approach and procedure, also known as an posterior lumbar interbody fusion, where an incision is made, through the tissues. It is to be understood however that either posterior approach and procedure can be used with the fusion cage and fall within the scope of the invention.

After such access, using preferably a minimally invasive technique, degenerate disk material can be removed and, using a cannula and insertion tool, an appropriately shaped fusion cage can be screwed into place between the vertebral bone structures in order to stabilize the vertebral bone structures and allow for fusion. Either preparatory to insertion of the fusion cage or after it has been inserted, bone chips or other bone growth inducing substances can be inserted into the fusion cage to promote bone to bone contact and subsequent fusion.

It is to be understood that although the above-embodiments have been described with respect to the fusion of adjacent vertebral bodies or bone structures, that the present invention can be used (1) to fuse together a variety of bone structures, in addition (2) to being fused to one bone structure and used as, for example, a base for an implant or (3) to being used to reunite the pieces of a broken bone.

Other objects and advantages of the invention can be obtained through a review of the specification and the figures.

Brief Description of the Figure

Anterior Fusion Cage:

Figure 1 is a partially sectional side view of an embodiment of the anterior fusion cage of the invention.

Figure 2 depicts a left end (distal end) view of the fusion cage of Figure 1.

Figure 3 depicts a right end (proximal end) view of the fusion cage of Figure 1.

Figure 4 depicts a view through line 4-4 of the fusion cage of Figure 1.

Figure 5 depicts the fusion cage of Figure 1 in conjunction with an introduction tool.

Figure 6 depicts an alternative embodiment of the introduction tool.

Figures 7, 8, and 9 depict progressive stages in the method of inserting the anterior fusion cage between adjacent vertebral bone structures.

Figure 10 depicts a side view of an alternative embodiment of the anterior fusion cage of the invention.

Figure 11 depicts the left end (distal end) view of the fusion cage of Figure 10.

Figure 12 depicts the right end (proximal end) view of the fusion cage of Figure 10.

Figure 13 depicts a side view of yet another embodiment of the anterior fusion cage of the present invention.

Figure 14 depicts a left distal end (distal end) view of the fusion cage of the invention of Figure 13.

Figure 15 depicts a right end (proximal end) view of the fusion cage of the invention of Figure 13.

Figure 16 depicts a sectional view taken through line 16-16 of Figure 13.

Posterior Fusion Cage:

Figure 17 is a partially sectional side view of an embodiment of the posterior fusion cage of the invention.

Figure 18 depicts a left end (distal end) view of the fusion cage of Figure 17.

Figure 19 depicts a right end (proximal end) view of the fusion cage of Figure 17.

Figure 20 depicts a view through line 20-20 of the fusion cage of Figure 17.

Figures 21, 22, and 23 depict progressive stages in the method of inserting the posterior fusion cage between adjacent vertebral bone structures using the cage depicted in Figure 25.

Figure 24 depicts a side view of an alternative embodiment of the posterior fusion cage of the invention.

Figure 25 depicts a side view of another embodiment of the posterior fusion cage of the invention.

Figure 26 depicts a left end (distal end) view of the embodiment of the fusion cage of Figure 25.

Figure 27 depicts the fusion cage of Figure 25 in conjunction with a new preferred insertion tool that can preferably be used with the anterior fusion cages of Figure 1, 10 and 13, and with the posterior fusion cages of Figure 17 and 25.

Figure 28 depicts an end view of the insertion tool of Figure 27 along line 28-28.

Figure 29 depicts a partially broken away view of the fusion cage and the insertion tool of Figure 27 connected together.

Figure 30 depicts a perspective view of the end of the insertion tool depicted in Figure 28.

Figure 31 depicts a partially sectional view of the handle of the insertion tool of Figure 27.

Detailed Description of the Preferred Embodiment

Anterior Fusion Cage:

With respect to the figures in a particular Figure 1, a side view of the preferred embodiment of the fusion cage 20 is depicted. Fusion cage 20 includes a fusion cage body 22 which in this preferred embodiment is provided in the shape of a cone. Fusion cage 20 includes a distal end 24 and a proximal end 26. The distal end 24 in a preferred embodiment is rounded or bull nosed in order to facilitate the insertion of the fusion cage 20 relative to one or more bone structures. The proximal end 26 includes an opening 28 which communicates with an internal cavity 30 defined by the fusion cage 20. The opening 28 in a preferred embodiment is threaded so that it can receive an end cap or plug 32 (Figure 5). End cap 32 is used to close off the proximal end 26 and retain bone growth inducing substances packed therein as described herein-below. As can be seen in Figure 5, end cap 32 includes a threaded bore 34 which is designed to receive an insertion tool. The threaded bore 34 has an initial unthreaded, square or hex-shaped section 35 which can be used with a socket wrench to tightly position end cap 32 in opening 28 and which can be engaged by a preferred insertion tool of Figure 27. Further the unthreaded portion of bore 34 could equally be cylindrical with an irregularity to allow for mating with an insertion tool, as well as having a variety of other shapes. The proximal end 26 further define first and second peripheral indentations 36, 38. These peripheral indentations 36, 38 receive tangs from an insertion tool as described hereinbelow for facilitating the insertion of the fusion cage 20.

A thread 40 is defined as part of the outer cylindrical surface 41 of the body 22. It is to be understood that the thread can be replaced with a plurality of discrete threads or a plurality of projections, ridges, protrusions, barbs, or spurs and be within the spirit and scope of the invention.

The rounded distal end 24, and at least some of the turns of thread 40 defined flutes or relief grooves 42, 44, and 46. (Figures 1, 2.) In a preferred embodiment, flutes 42, 44, and 46 meet at a central point 48 of the distal end 24 on the longitudal axis 50 of the fusion cage 20. In other embodiments the flutes can be smaller and not extend all the way to the central point 48 on the longitude axis 50. Still in other embodiments, the flutes can be eliminated from the distal end 24 and such embodiments are still within the spirit and scope of the invention.

The flutes extend from the distal end 24 toward the proximal end 26 as shown in Figure 1 with respect to flute 42. These flutes are defined by the sections 52 which are removed from the thread. In a preferred embodiment, the flutes become narrower as they approach the proximal end 26 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position. As shown in other embodiments, the flutes can be deeper and extend from the distal end completely to the proximal end. Still further in other embodiments the flutes can be confined to the first several turns of the thread adjacent to the distal end and/or to just the distal end.

As can be seen in Figures 1, 4, a plurality of apertures 54 are provided through wall 56 of the fusion cage 20. In a preferred embodiment, these apertures 54 are formed by broaching grooves 58 in the internal surface 60 of the internal cavity 30. The effect of such broaching is to remove material from the valleys between the turns of the thread 40, thus defining the aperture 54. The advantages of such an arrangement are taught by the above-referenced U.S. Patent No. 4,961,740, which patent is incorporated herein by reference and allows for immediate bone to bone contact between the vertebral bodies or bone structures and the bone packed within the internal cavity 30 of the fusion cage 20.

The apertures 54 in a preferred embodiment increase in size from smaller apertures closer to the distal end 24 to a larger aperture closer to the proximal end 26. This increase in size allows for more bone to bone contact. Alternatively in the embodiment as shown in Figure 1, all the apertures are of the same size.

As can be seen in Figure 4, the apertures are clustered about a transverse axis 51, both at the upper and lower end of the axis. This is so that in position, the apertures come into contact with the upper and lower vertebral bone structures (Figure 9) to encourage bone growth through the fusion cage from the vertebral bone structures. The lateral section of the fusion cage found along the other transverse access 53 do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process.

A preferred embodiment of the conically-shaped fusion cage 20 includes a fusion cage which is 23 mil-

limeters in length having a distal end 24 with a diameter of 14 millimeters and a proximal end 26 with a diameter of 18 millimeters. The cage body is a right circular cone. The thread has a pitch of 30° and there are ten turns per inch with a thread depth of .053 inches. Further the cage is made of a titanium metal or alloy such as Ti64. Preferably this and the other disclosed fusion cages disclosed are machined. However, the processes such as molding, casting, or sintering can be used to accomplished formation of the fusion cages.

The cage is inserted between vertebral bodies using an insertion tool 62 (Figure 5). Insertion tool 62 includes an inner handle 64 and an outer handle 66. The outer handle includes a bore 68 for receiving the inner handle 64. Handles 64, 66 include knobs 70, 72 respectively. The distal end of inner handle 64 defines a threaded shaft 74, having a reverse thread to facilitate easy removal, and the distal end of handle 66 define a cylindrical disk 76 which has first and second tangs 78, 80, projecting from the peripheral edge of the cylindrical disk 76. These tangs 78, 80 are designed to mate with the peripheral indentation 36, 38 of the fusion cage 20. For purposes of inserting the fusion cage between the vertebral bodies, the end cap 32 is inserted into the fusion cage 20 as shown in Figure 5. Then the threaded shaft 74 of the inner handle is introduced into the threaded bore 34 of the end cap 32. After this is accomplished, the outer handle 66 is slid over the inner handle 64 and the tangs 78, 80 are positioned into engagement with the indentations 36, 38. In this arrangement, the fusion cage 20 can be anteriorly inserted into the space between the vertebral body structure using the insertion tool 62.

An alternative embodiment of the insertion tool is shown in Figure 6. In this figure, insertion tool 82 includes a handle 84 with a knob 86. At the end of the insertion tool 82 distal from the knob 86 is a cylindrical disk 88 which has first and second tangs 90, 92, which have the same function as the above tangs 78, 80. Extending from the center of the cylindrical disk 88 along the centerline of the insertion tool 82 is a shaft 94 which has a ball detent 96. For use with insertion tool 82, the threaded bore 34 of the end cap 32 would be replaced with a bore having a lip which could engage with the ball detent 96 of the insertion tool 82.

It is to be understood that the insertion tool depicted in Figure 27 and described below is preferable to the above described insertion tools for both the anterior fusion cages and the below described posterior fusion cages.

The method for inserting the fusion cage 20 of Figure 1 using an anterior approach and procedure to the vertebral bodies is as follows. It is to be understood that although the focus of this discussion is on a laparoscopic procedure, that the anterior approach and procedure can also include a more invasive procedure where a long incision is made in the abdomen wall.

With an anterior approach, using an introduction set such as described by way of example only, in U.S. Patent 4,863,430, entitled "INTRODUCTION SET WITH FLEXIBLE TROCAR WITH CURVED CANNULA," which is incorporated by reference, but however with larger diameter instruments, an amount of disk material is removed between the two vertebral bodies or bone structures which are to be fused together. This procedure is accomplished through a cannula position adjacent to the vertebral bone structures. With the same or a larger diameter cannula, the fusion cage 20 can be introduced adjacent to the vertebral bone structures. In a first procedure, the fusion cage is packed with bone growth substances and the end cap 32 is affixed to the fusion cage 20. Insertion tool 62 is then secured to the fusion cage 20 and the fusion cage is guided through the cannula to a location adjacent to the upper and lower vertebral body such as presented schematically in Figures 7, 8, 9, by upper body 98 and lower body 100. In the initial position as shown in Figure 7, the fusion cage 20 is adjacent to the anterior surfaces 102, 104 of the vertebral bodies 98, 100. As the introduction tool is turned, the thread 40 of the fusion cage 20 bites into the vertebral bodies 98, 100. Further turning of the introduction tool causes the fusion cage to move through the position shown in Figure 8 to the final resting position shown in Figure 9, where the distal end 24 is moved adjacent to the posterior sections 106, 108 of the vertebral bone structures 98, 100. As this occurs, the fusion cage 20 increases the lordosis or spacing between the vertebral bodies, basically distracting the vertebral bodies and causing the vertebral bodies to pivot about the posterior sections 106, 108, with such posterior sections acting like a hinge. It is noted that most of the distraction occurs adjacent to the anterior sections, but that distractions also occur at the posterior sections where the hinged effect is exhibited. Preferably, the lordosis is increased over the normal lordosis in order to stabilize the vertebral bone structures prior to fusion occurring. Stabilization occurs due to the fact that increased lordosis places additional stress on the anterior longitudinal ligaments which are part of the anatomy holding the vertebral bodies in place.

Once the fusion cage 20 is appropriately positioned, the handle 64 of the insertion tool 62 is unscrewed from the cap 32 and the fusion handle 62 is pulled away from the fusion cage.

An alternative embodiment of a fusion cage 200 is shown in Figures 10, 11, and 12. Fusion cage 200 includes a distal end 202 and an a proximal end 204. Fusion cage 200 includes an internal cavity 206. End caps not shown can be used to close the ports 208, 210 of distal and proximal ends 202, 204. A thread 212 is defined on the external conical surface 214 of the fusion cage 200. Defined by the thread 212 are first and second flutes 216, 218, which in this embodiment extend from the distal end 202 to the proximal end 204. These flutes provide thread relief allowing the fusion cage 200 to be self-tapping.

The fusion cage 200 includes a plurality of elongated apertures 220 which are formed through the side walls of a fusion cage 200. The elongated apertures 202 are formed in such a way that the internal conical surface

214 is spaced away from the internal surface 224 of the internal cavity 206 by the thickness of the sidewall 222.

A further embodiment of the invention is shown in Figures 13, 14, 15 and 16. In Figure 16 the fusion cage 300 has distal and proximal ends 302 and 304 respectively. The fusion cage 300 defines an internal cavity 306, and ports 308 and 310 defined through the distal and proximal ends 302 and 304 respectfully. A thread 312 is defined as part of the external conical surface 314 of the fusion cage 200. First, second and third flutes 316, 318, and 320, are defined in the thread 312 from the distal end 302 to the proximal end 304. These flutes give the fusion cage 300 an enhanced self-tapping advantage. These flutes are equally spaced about the fusion cage 300 in a manner similar to the flutes of the fusion cage embodiment 20 in Figure 1.

A plurality of aperture 322 is provided through the external conical surface 314 of the fusion cage 300 and through the side wall 324 opening into the internal cavity 306. Accordingly, at the location of the aperture 322 the external surface 314 is held away from the internal surface 326 by the thickness of the side wall 324.

Posterior Fusion Cage:

With respect to the figures in a particular Figure 17, a side view of the preferred embodiment of the posterior fusion cage 420 is depicted. Fusion cage 420 includes a fusion cage body 422 which in this preferred embodiment is provided with a conically-shaped portion 423 and a cylindrically-shaped portion 425. It is to be understood that alternatively the entire body 422 can be conically-shaped. Further, as appropriate the shape of the cage body 422 can be more complex with various conical and/or cylindrical configurations. Fusion cage 420 includes a distal end 424 and a proximal end 426. The distal end 424 in a preferred embodiment is rounded or bull nosed in order to facilitate the insertion of the fusion cage 420 relative to one or more bone structures. The proximal end 426 includes an opening 428 (Figure 19) which communicates with an internal cavity 430 (Figure 20) defined by the fusion cage 420. The opening 428 in a preferred embodiment is threaded so that it can receive an end cap or plug such as 32 of the embodiment in Figure 5. End cap is used to close off the proximal end 426 and retain bone growth inducing substances, such as bone chips, packed therein as described herein-below. As can be seen in the embodiment of Figure 5, end cap 32 includes a threaded bore 34 which is designed to receive an insertion tool. The threaded bore 34 has an initial unthreaded, square or hex-shaped portion 35 which can be used with a socket wrench to tightly position end cap 32 in opening 428 and which can also be engaged by the insertion tool of Figure 27 described below. Portion 35 can be otherwise shaped as described above.

The proximal end 426 of the embodiment of Figure 19 further define first and second peripheral indentations 436, 438 which are centered about transverse axis 453. These peripheral indentations 436, 438 receive tangs from an insertion tool as described below for facilitating the insertion of the fusion cage 420. These identifications are also used to line up the cage 420 for proper insertion between the vertebral bodies as discussed below.

A thread 440 is defined as part of the outer cylindrical surface 441 of the body 422. It is to be understood that the thread can be replaced with a plurality of interrupted or discrete threads or a plurality of projections, ridges, protrusions, barbs, or spurs and be within the spirit and scope of the invention.

The rounded distal end 424, and at least some of the turns of thread 440 can in a preferred embodiment can define flutes or relief grooves 442, 444, and 446 (Figures 24, 25). It is to be understood that in alternative embodiments the flutes can be eliminated from the distal end 424 and the thread 440, since for example, the bore for the insertion of the fusion cage 420 between the vertebral bodies can be pre-tapped. Still in alternative embodiment, the flutes on the distal end can remain to assist in the insertion of the cage 420 between the vertebral bodies. In a preferred embodiment, flutes 442, 444, and 446 meet at a central point 448 of the distal end 424 on the longitudal axis 450 of the fusion cage 420. In other embodiments the flutes can be smaller and not extend all the way to the central point 448 on the longitude axis 450. Still as indicated above in other embodiments, the flutes can be eliminated from the distal end 424 and the thread 440 and such embodiments are still within the spirit and scope of the invention.

The flutes can extend from the distal end 424 toward the proximal end 426 as shown in the alternative embodiment in Figure 24 with respect to flute 542. These flutes are defined by the sections 552 which are removed from the thread. In this embodiment, the flutes become narrower as they approach the proximal end 526 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position. As shown in other embodiments, the flutes can be deeper and extend from the distal end completely to the proximal end. Still further in other embodiments the flutes can be confined to the first several turns of the thread adjacent to the distal end and/or to just the distal end.

With respect to Figures 17, 20, a plurality of apertures 454 are provided through wall 456 of the fusion cage 420. In a preferred embodiment, these apertures 454 are formed by broaching grooves 458 in the internal surface 460 of the internal cavity 430. The effect of such broaching is to remove material from the valleys between the turns of the thread 440, thus defining the aperture 454. The advantages of such an arrangement are taught by the above-referenced U.S. Patent No. 4,961,740, which patent is incorporated herein by reference and allows for immediate bone to bone contact between the vertebral bodies or bone structures and the bone packed within the internal cavity 430 of the fusion cage 420.

The apertures 454 in a preferred embodiment increase in size from smaller apertures closer to the

proximal end 426 to a larger aperture closer to the distal end 424. This increase in size allows for more bone to bone contact. Alternatively in the embodiment as shown in Figure 17, all the apertures are of the same size.

As can be seen in Figure 20, the apertures are clustered about a transverse axis 451, both at the upper and lower end of the axis. This is so that in position, the apertures come into contact with the upper and lower vertebral bone structures (Figure 23) to encourage bone growth through the fusion cage from the vertebral bone structures. The lateral sections of the fusion cage found along the other transverse axis 453 do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process. As can be seen viewing both Figures 19 and 20 together, the indentation 436 and 438 are centered on the axis 453 with the aperture 454 centered on axis 451. Axis 451 is preferably perpendicular to axis 453. The insertion tool has tangs that are inserted in indentation 436 and 438. Accordingly, the position of the insertion tool defines the position of the apertures 454 in that upon insertion the apertures 454 can be put in contact with the upper and lower vertebral bodies to allow bone ingrowth and prevent lateral ingrowth of disk material.

A preferred embodiment of the conically-shaped fusion cage 420 includes a fusion cage which is 28 millimeters in length having a distal end 424 with a diameter of 16 millimeters and a proximal end 426 with a diameter of 14 millimeters. The cage body is a right cylinder from the distal end 424 extending toward the proximal end 426 for four turns of thread 440. Then the cage 420 becomes a right cone from the remaining five turns of thread 440 until thread 440 terminates at proximal end 426. This conically-shaped portion is defined by relief 455 of 3.2°.. The thread has a pitch of 30° and there are ten turns per inch with a thread depth of .053 inches. Further the cage is made of a titanium metal or alloy such as Ti64. Preferably this and the other disclosed fusion cages disclosed are machined. However, the processes such as molding, casting or sintering can be used to accomplished formation of the fusion cages.

The cage is inserted between vertebral bodies using a preferred insertion tool 700 shown in Figure 27. Insertion tool 700 includes a handle 702 with an outer shaft 704 extending therefrom. The handle 702 includes first and second wings 706, 708 which make the handle easier to grab. The outer shank 704 is hollow and disposed within the outer shaft is an intermediate shaft 710 which can be seen extending from the cage engaging in 712 of the shaft 704. The cage engaging end 712 includes first and second tangs 714, 716 which can be inserted in the indentation of the cage such as for example indentations 436, 438, as shown in Figure 19, and indentations 636 and 638 shown in Figure 27. The end of shaft 710 includes a square-shaped drive 718 which engages the square-shaped unthreaded portion of the otherwise threaded bore such as bore 34 of an end cap such as end cap 32 as shown in Figure 5. This same end cap can be used in the end of fusion cage 620. Alternatively, the square drive can be hexagonal shape with the unthreaded portion of the bore 34 being hexagonal shaped to provide the necessary mating arrangement. Other mating shapes can also be used. A first knurled knob 720 is secured to immediate shaft 710 in order to provide a mechanism for rotating intermediate shaft 710 inside of outer shank 704. As can be seen in Figure 31, the intermediate shank 710 is spring biased relative to the handle 702 with a spring 722. Spring 722 is imbedded in a bore 724 of handle 702. In Figure 31, the first knurled knob 720 and the shank 710 are pulled back and thus compress the spring 722. In Figure 27, the first knurled knob 720 is released and the spring (not shown) is uncompressed.

An inner shaft 726 is located within a bore 728 of the intermediate shaft 710. The inner shaft 726 ends in a threaded portion 730 (Figure 30). The other end of inner shaft 726 is secured to the second knurled knob 732. Inner shaft 726 is free to rotate, through the use of the second knurled knob 72, within the bore 728 of the intermediate shaft 710. In addition the inner shaft 728 has limited freedom of motion along the longitudinal axis of the inner shaft 726.

The operation of the insertion tool 700 is as follows. With the insertion tool 700 not secured to a fusion cage, the insertion tool is as depicted in Figure 27 with the threaded portion 730 being either received entirely within bore 728 or extending a minimal amount out of bore 728. With the end cap secured in the fusion cage, the exposed square drive 718 is mated with the square portion of the bore in the end cap. The tangs 712, 714 are aligned with the indentations 636 and 638 and the tool is pushed in so that the tang 712, 714 are received in the indentations 636, 638. As this occurs, the knurled knob 730 moves up to the position as shown in Figure 29 and 31, compressing the spring. After this occurs, the second knurled knob 732 can be turned clockwise in order to engage the threaded portion 730 of the inner shaft 726 with the threaded portion of the bore of the end cap. This draws the fusion cage securely to the insertion tool 700 as shown in Figure 29. In this position, the cage is ready for insertion between the vertebral bodies. The handle 702 is then used to screw the cage between the vertebral bodies into the final resting position. Once the cage is in the final resting position, second knurled knob 732 is turned counter-clockwise in order to back the threaded 730 out of the threaded portion of the bore of the end cap. As this occurs, the spring 722 causes the square drive 718 to push against the end cap maintaining the end cap in its position relative to the fusion cage until the threaded portion 730 disengages itself from the threaded portion of the end cap, and the insertion tool 700 is disengaged from the fusion cage and can be removed. Thus the square drive, which is spring loaded, prevents the end cap on the cage from screwing out when the insertion tool is removed from the cage.

Should it be desired to move the end cap with the fusion cage in place, the square drive 718 can be inserted into the square portion of the threaded bore.

The threaded portion 730 of the inner shaft 726 can then be screwed into engagement with the threaded portion of the threaded bore of the end cap, preferably with the tangs unaligned with the indentations. The first knurled knob 720 can then be turned in order to back the cap out of the fusion cage. A reverse of this operation can be used to insert the end cap into the fusion cage after additional bone growth inducing substances are packed into the fusion cage.

The method for inserting the fusion cage 420 of Figure 17 using a posterior approach and procedure to the vertebral bodies is as follows. Both a minimally invasive procedure and a more invasive procedure where a long incision is made in the back can be used.

With a posterior approach, using an introduction set such as described by way of example only, in U.S. Patent 4,863,430, entitled "INTRODUCTION SET WITH FLEXIBLE TROCAR WITH CURVED CANNULA," which is incorporated by reference, but however with larger diameter instruments, an amount of disk material is removed between the two vertebral bodies or bone structures which are to be fused together. This procedure is accomplished through a cannula position adjacent to the vertebral bone structures. Then if required a thread is tapped in the upper and lower vertebral bodies. With the same or a larger diameter cannula, the fusion cage 420, or alternatively the preferred fusion cage 620 of Figure 25, can be introduced adjacent to the vertebral bone structures. In a first procedure, the fusion cage is packed with bone growth substances and the end cap is affixed to the fusion cage 620. Insertion tool 700 is then secured to the fusion cage 620 and the fusion cage is guided through the cannula to a location adjacent to the upper and lower vertebral body such as presented schematically in Figures 21, 22, 23, by upper body 498 and lower body 500. In the initial position as shown in Figure 21, the fusion cage 620 is adjacent to the posterior sections 502, 504 of the vertebral bodies 498, 500. As the introduction tool is turned, the thread 640 (Figure 25) of the fusion cage 620 bites into the vertebral bodies 498, 500. Further turning of the introduction tool causes the fusion cage to move through the position shown in Figure 22 to the final resting position shown in Figure 23, where the distal end 624 is moved adjacent to the anterior sections 506, 508 of the vertebral bone structures 498, 500. As this occurs, the fusion cage 620 increases the lordosis or spacing between the vertebral bodies, basically distracting the vertebral bodies. It is noted that most of the distraction occurs adjacent to the anterior sections, but that distraction also occur at the posterior sections. Preferably, the lordosis is increased over the normal lordosis in order to stabilize the vertebral bone structures prior to fusion occurring. Stabilization occurs due to the fact that increased lordosis places additional stress on the anterior longitudinal ligaments which are part of the anatomy holding the vertebral bodies in place.

Once the fusion cage 620 is appropriately positioned, the insertion tool 700 is unscrewed from the cap and the insertion tool 700 is pulled away from the fusion cage.

It is to be understood that the cage can be implanted without the use of a cannula by making a larger incision in the back. With this arrangement the bone chips would more often be packed into the cage after the cage reaches its final position and then an end cap would be secured t the cage. In the final position apertures 454 or 654 (embodiment of Figure 25) would be positioned adjacent vertebral bodies 498 and 500. No matter which procedure is used to insert the cage 420 or 620, it is advantageous to provide a bore between the vertebral bodies that is less than the diameter of the distal end 424. Thus, for a cage 420 or a cage 620 with a distal end having an 18 diameter, the bore would be 14 millimeters. Inserting the cage 420 or the cage 620 would cause the vertebral bodies to be distracted (Figure 22) and then rock back (Figure 23) onto the conically-shaped portion of the fusion cage 420.

An alternative embodiment of a fusion cage 520 is shown in Figures 24. Fusion cage 520 includes a distal end 524 and an a proximal end 526. A thread 540 is defined on the external surface of the fusion cage 520. Defined by the thread 540 are flutes 542, 544, 546, which in this embodiment extend from the distal end 524 toward the proximal end 526. These flutes provide thread relief 552 allowing the fusion cage 520 to be self-tapping

Still an alternative and preferred embodiment of the invention as mentioned above is shown in Figure 25. In this embodiment the fusion cage 620 includes a blunt or flat distal end 624 and a proximal end 626. As in the other embodiments, the fusion cage is conically-shaped, and includes a thread 640 and aperture 654.

Figure 26 includes a view of the distal end 624 of the fusion cage 620. This distal end 624 uses a snub nosed portion that is closed. The diameter of the snub nosed portion 660 is smaller than the largest root of the thread 640 at the distal end 624. As can be seen in Figure 26, the thread 640 has a starter portion or starter turn 641 which includes approximately the first half turn of the thread 640. The diameter of the starter portion 641, as can be seen Figure 26, is substantially less than the outside diameter of the four turns of thread 640 which comprised the cylindrical portion 625. From the cylindrical portion 625, the cage 620 and the thread 640 taper off to the proximal end 626 and define the conically-shaped portion 623.

The starter turn 641 of thread 640, as the name implies, assist in promoting the proper engagement of the thread 640 with the upper and lower vertebral bodies. In this embodiment, as in prior embodiments, the distal end has a diameter of approximately 16 millimeters. The diameter of the snub nosed portion 660 is about 10 millimeters.

Industrial Applicability

The present invention affords the advantages of a fusion cage which can be introduced through a posterior

approach in order to maintain or increase lordosis between adjacent vertebral bodies. The fusion cage has the advantage of being conically-shaped and self-tapping through the use of external flutes. The flutes additionally assist in keeping the fusion cage aligned and centered as the cage is being inserted between the vertebral bone structures.

Other advantages, aspects, and objects of the invention can be obtained through a review of the claims and the appended figures.

Additional embodiments of the invention can be constructed and fall within the scope of the claims.

Claims

1. A fusion cage for promoting fusion with one or more bone structures comprising:
   a cage body having a proximal end and a distal end, said proximal end having a diameter which is smaller than a diameter of said distal end; and
   said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

2. A fusion cage for promoting fusion with one or more bone structures comprising:
   a cage body having a proximal end and a distal end, said proximal end having a diameter which is smaller than a diameter of said distal end; and
   said cage body having an outer surface and at least one flute formed in the outer surface.

3. A fusion cage for promoting fusion with one or more bone structures comprising:
   a cage body having a proximal end and a distal end, said proximal end having a diameter which is smaller than a diameter of said distal end; and
   said cage body having a outer surface and a thread formed into said outer surface.

4. The fusion cage of claims 1, 2 or 3 wherein:
   said cage has a cylindrically-shaped portion located adjacent to the distal end and a conically-shaped portion located adjacent to the proximal end.

5. The fusion cage of claim 4 wherein:
   a thread is defined by the cylindrically-shaped portion and the conically-shaped portion.

6. The fusion cage of any of the preceding claims wherein:
   said cage body has a thread formed on an outer surface and at least one flute formed in the thread.

7. The fusion cage of claim 6 wherein the flute is formed in the distal end in order to facilitate the insertion of the fusion cage in the one or more bone structures, the flute extending from the distal end toward the proximal end.

8. The fusion cage of any of the preceding claims including:
   at least three flutes formed in the outer surface being equally spaced about said distal end.

9. The fusion cage of any of preceding claims wherein:
   said cage body has an outer surface and an internal cavity; and
   a plurality of apertures are formed through the cage body which communicate said outer surface with said internal cavity.

10. The fusion cage of any of the preceding claims wherein said cage body is a right circular cone.

11. The fusion cage of any of the preceding claims further comprising a thread with a plurality of turns found on the outer surface, and the flute is formed in at least one of said turns.

12. The fusion cage of any of the preceding claims in combination with an insertion tool, said fusion cage including:
   said proximal end having an opening which communicates with an internal cavity;
   an end cap which can fit into said opening in order to close off said internal cavity;
   said proximal end including at least one insertion tool receiving indentation;
   said end cap including an insertion tool receiving threaded bore with an unthreaded portion with an irregularity; and
   said insertion tool including:
   a tang for being received in said indentation and a threaded shaft for being received in said threaded bore, and a shaft for mating with the unthreaded portion, said insertion tool for being engaged with said fusion cage for inserting said fusion cage relative to the one or more bone structures.

13. The fusion cage of claim 9 including:
   said apertures increase in size from the distal end toward the proximal end.

14. A fusion cage for promoting fusion with one or more bone structures comprising:
   a cage body having a proximal end and a distal end;
   said cage body having a longitudinal axis, and a first transverse axis which is perpendicular to the longitudinal axis and a second transverse axis which is perpendicular to both the longitudinal axis and the first transverse axis;
   a position indicator located at said proximal end, which position indicator is located along the first

transverse axis; and

said cage body having a plurality of apertures for promoting bone growth into the cage body, which apertures are located only substantially along the second transverse axis between the proximal end and the distal end.

15. The fusion cage of claim 14 wherein:

said position indicator includes an indentation into said proximal end.

16. The fusion cage of claim 15 wherein:

said distal end has a snub nose extending therefrom in order to facilitate insertion relative to one or more bone structures the snub nose having a diameter which is less than the diameter of the distal end.

17. The fusion cage of claims 14, 15 or 16 wherein:

the cage body includes a thread which has a starter turn located at the distal end, the starter turn of the thread extends from the snub nose in order to facilitate insertion relative to the one or more bone structures.

18. A fusion cage in combination with an insertion tool comprising:

said fusion cage having a cage body with a distal end and a proximal end, said proximal end including at least one insertion tool receiving indentation;

said proximal end including an insertion tool receiving threaded bore having an unthreaded portion with at least one irregularity; and

said insertion tool having a first shaft with a tang that can be received in said indentation, a second shaft with a portion which can mate with the unthreaded portion of the bore with the irregularity, and a third shaft with a threaded portion which can mate with the threaded bore.

19. The fusion cage and insertion tool combination of claim 18 wherein:

said second and said third shafts can rotate relative to the first shaft and relative to each other.

20. The fusion cage and insertion tool combination of claim 19 wherein:

one of said second and third shafts is biased relative to the other of said second and third shafts.

21. The fusion cage and insertion tool combination of claim 20 wherein:

said fusion cage includes an end cap which in part comprises said proximal end, and wherein said end cap includes said threaded bore, and wherein said end cap can be selectively removed from the remainder of the proximal end.

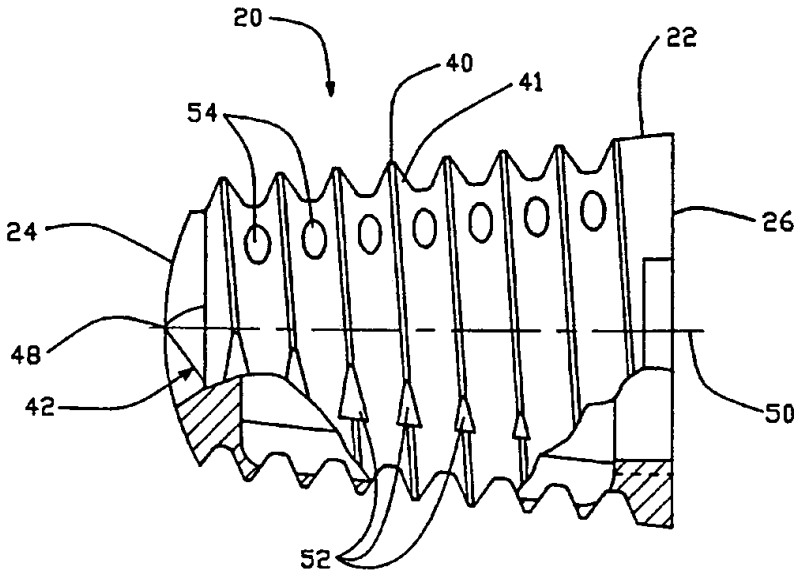


FIG.—1

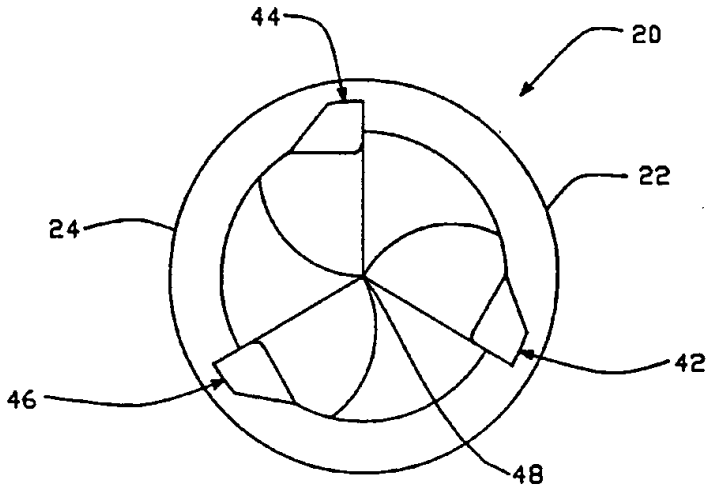


FIG.—2

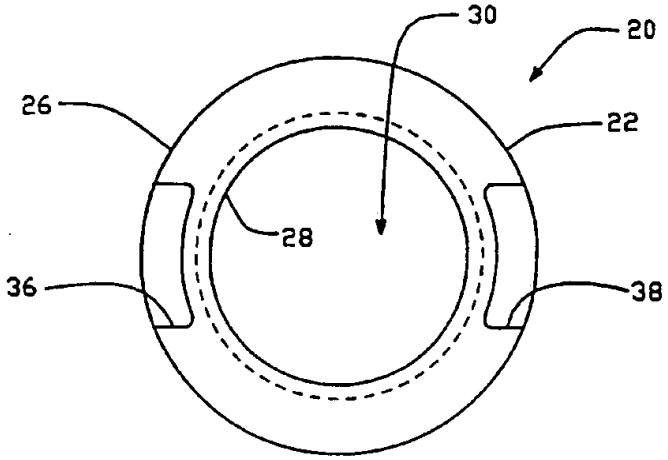


FIG.—3

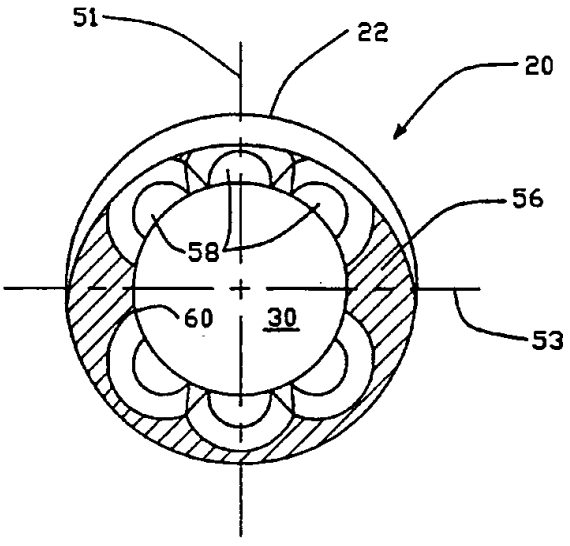


FIG.—4

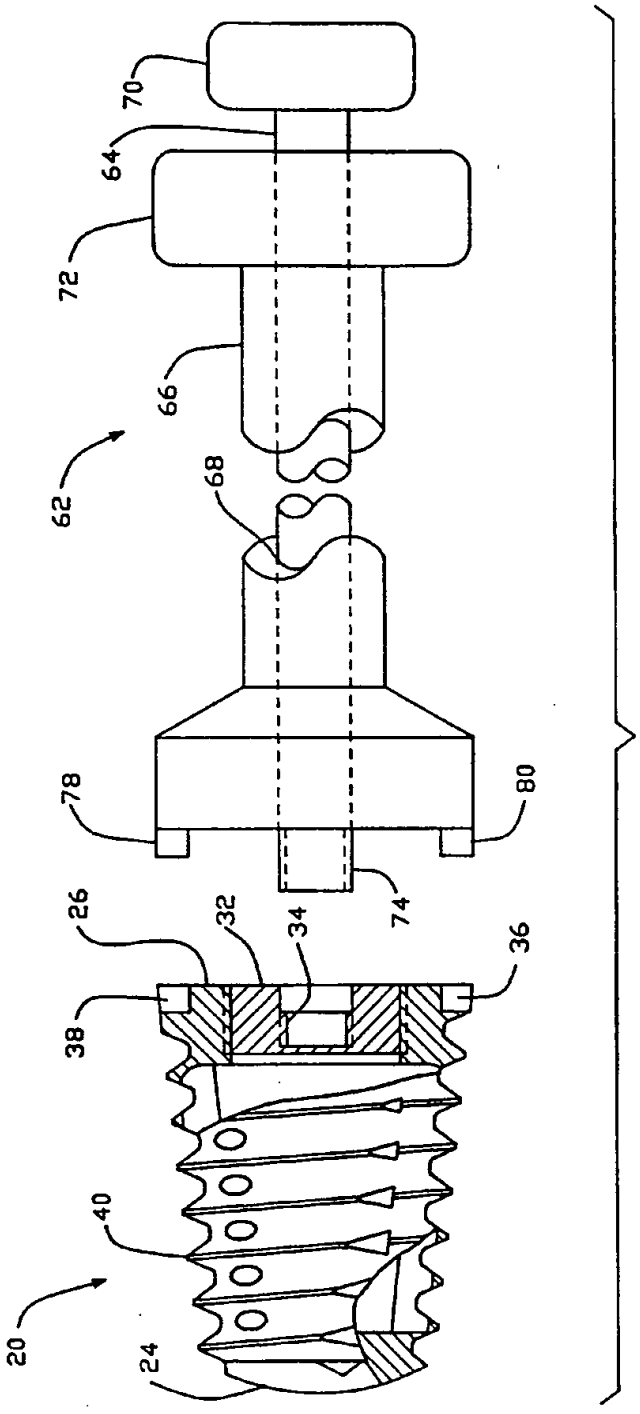


FIG.—5

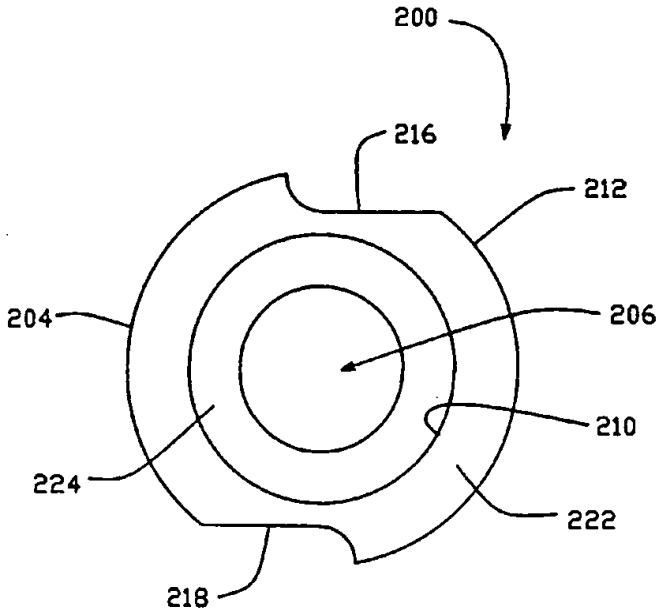


FIG.—12

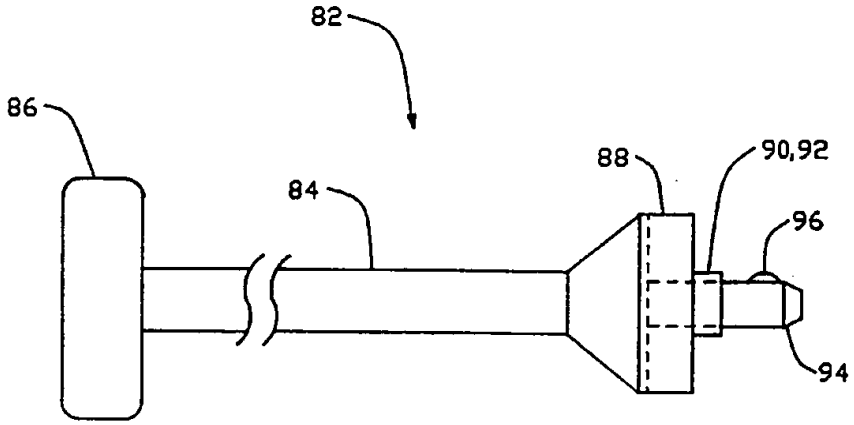


FIG.—6

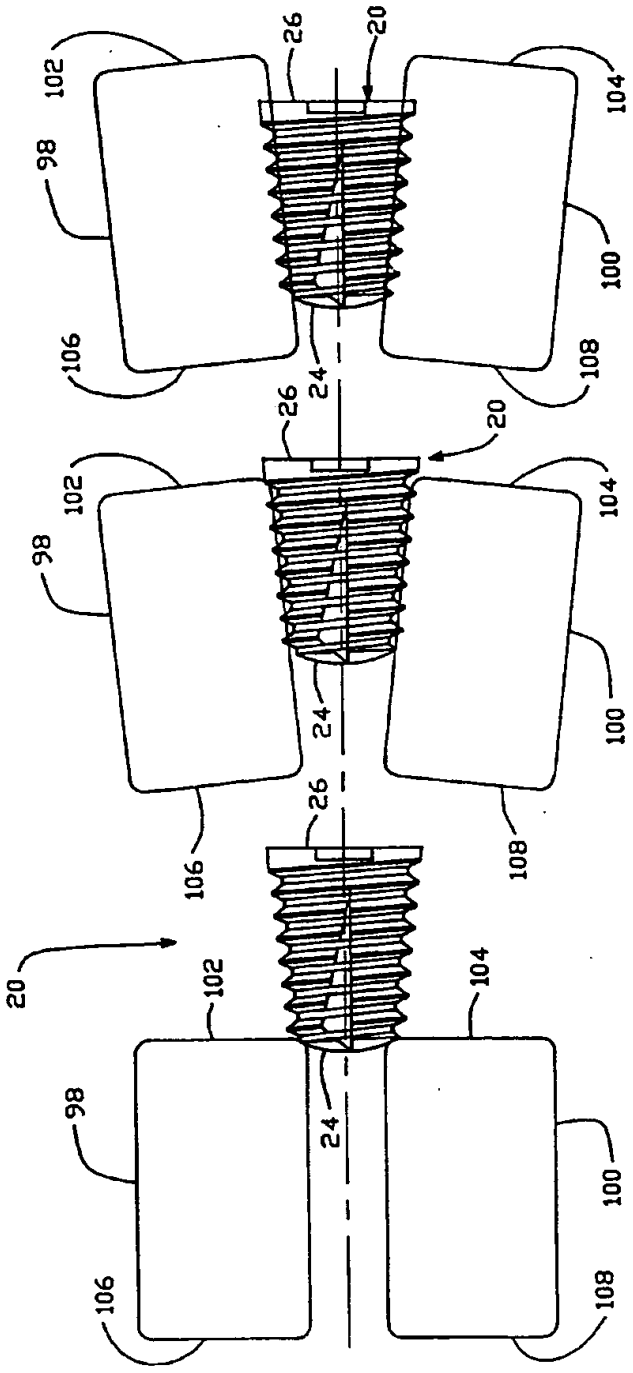


FIG.—9

FIG.—8

FIG.—7

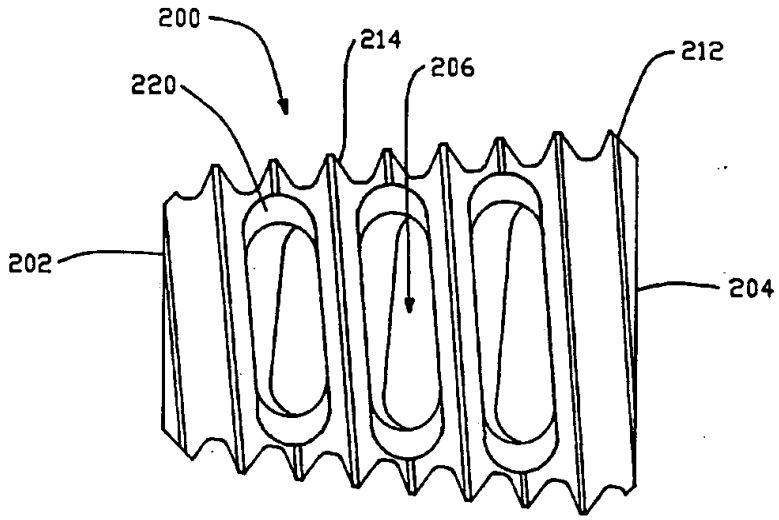


FIG.—10

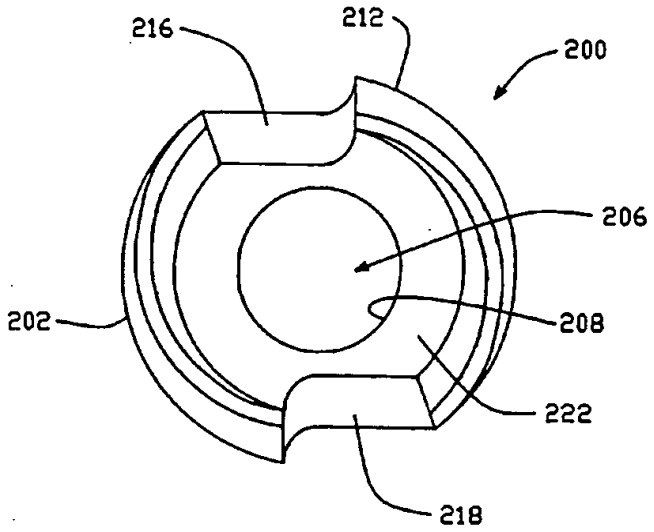


FIG.—11

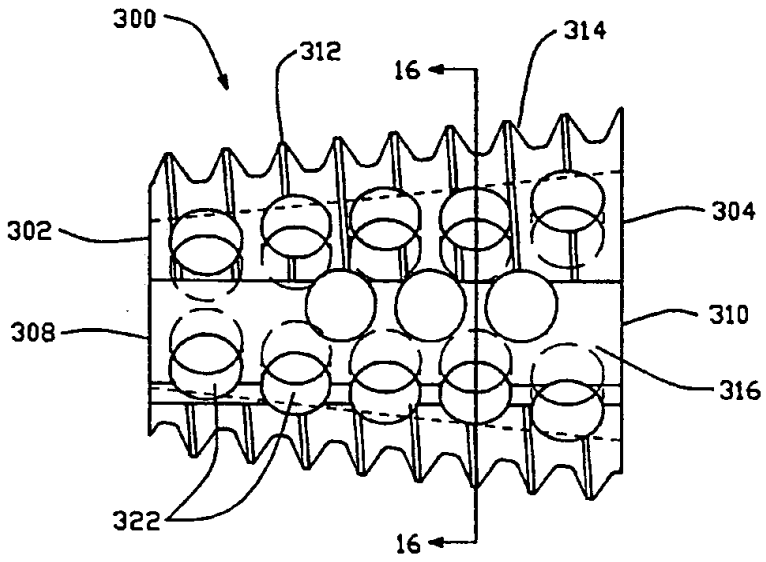


FIG.—13

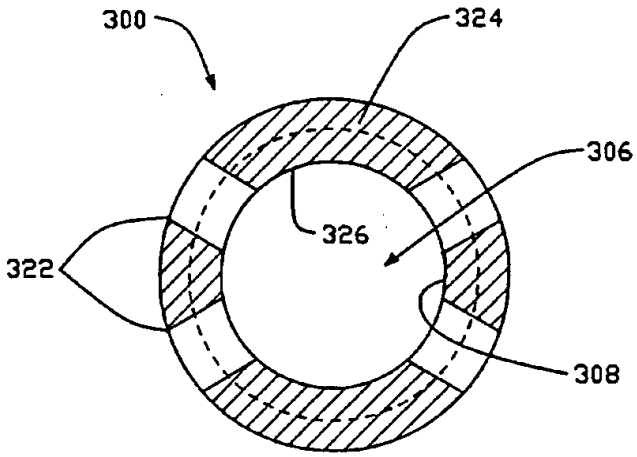


FIG.—16

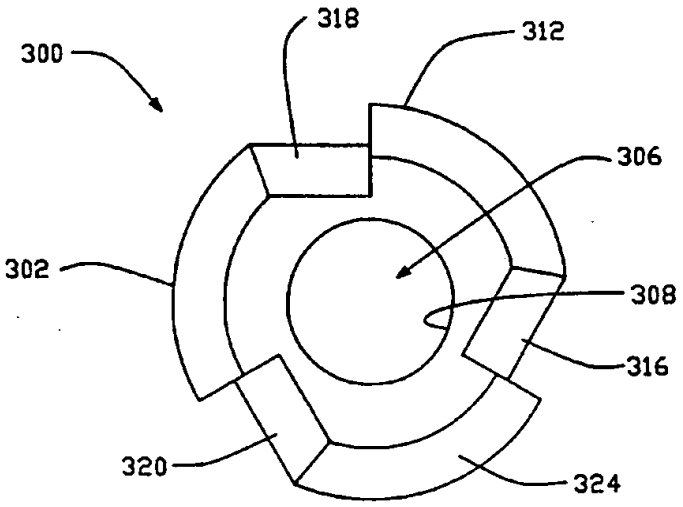
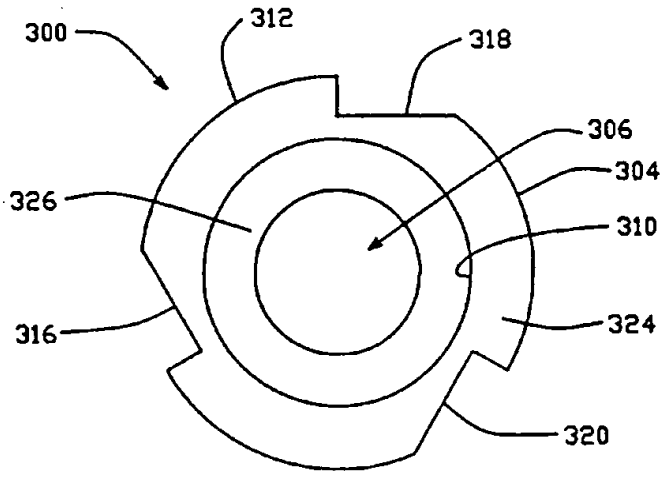


FIG.—14



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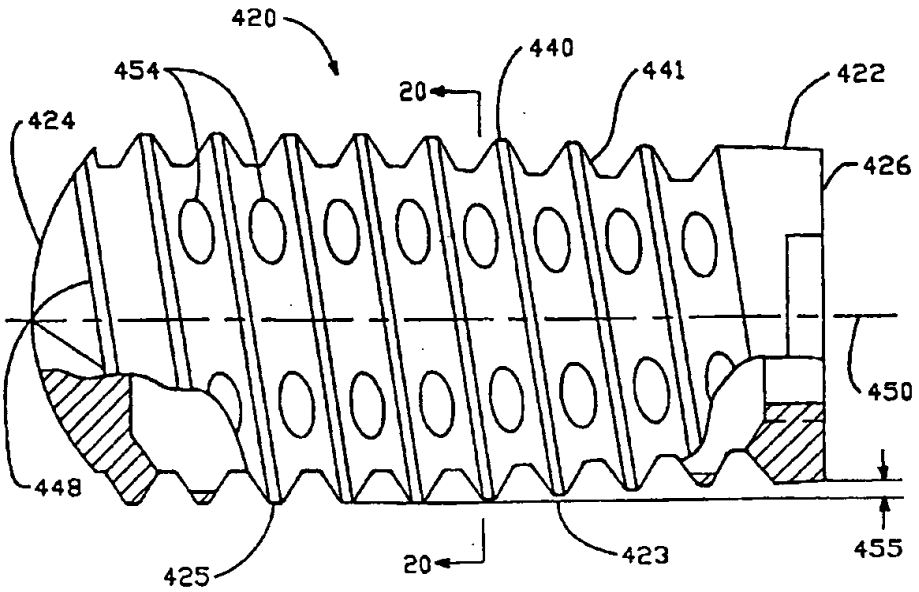

FIG.—17

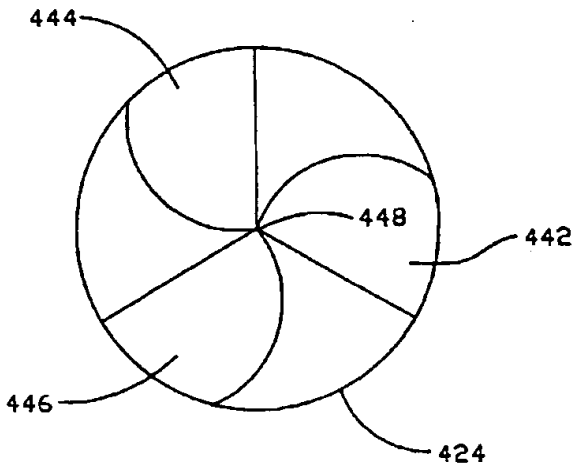

FIG.—18

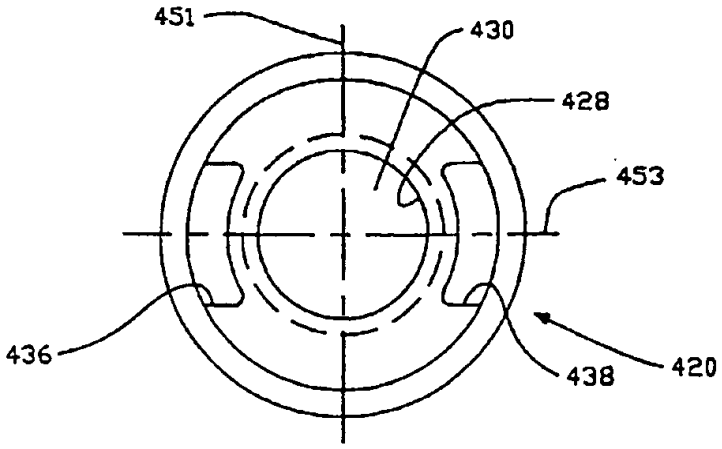

FIG.—19

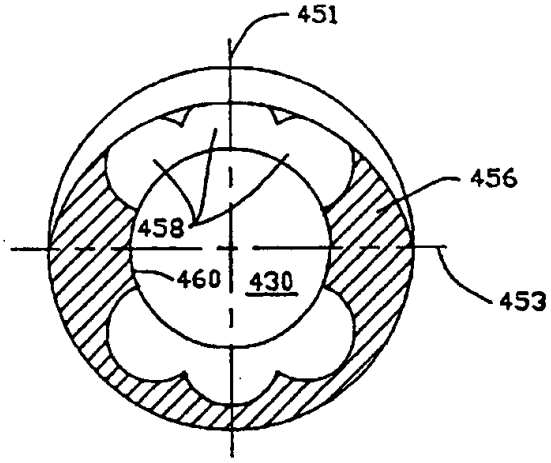

FIG.—20

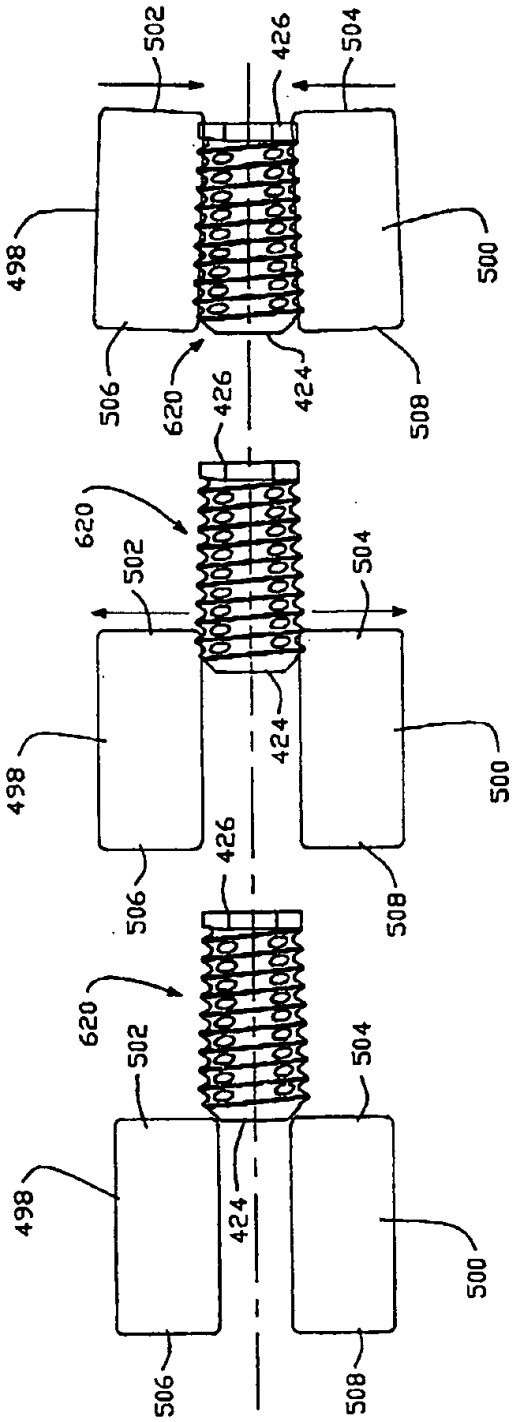

FIG.—23

FIG.—22

FIG.—21

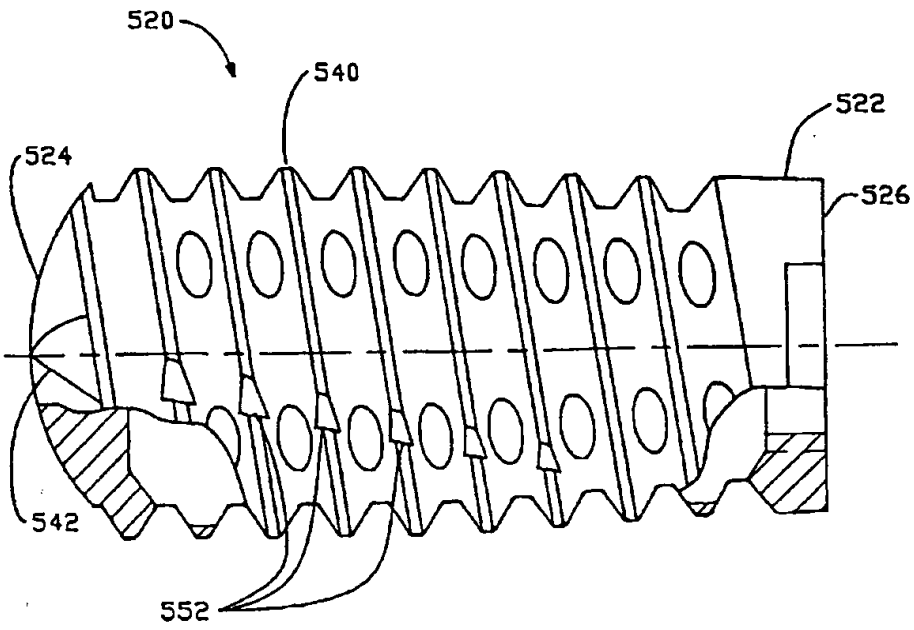

FIG.—24

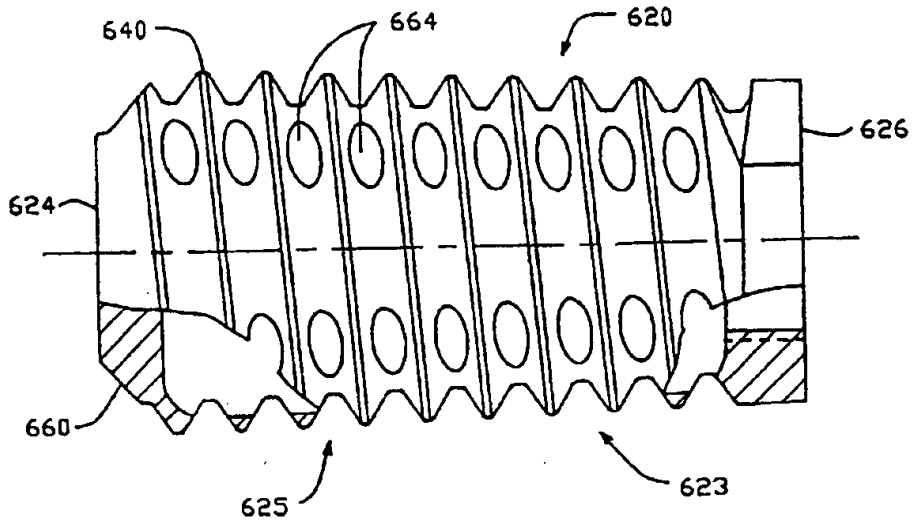

FIG.—25

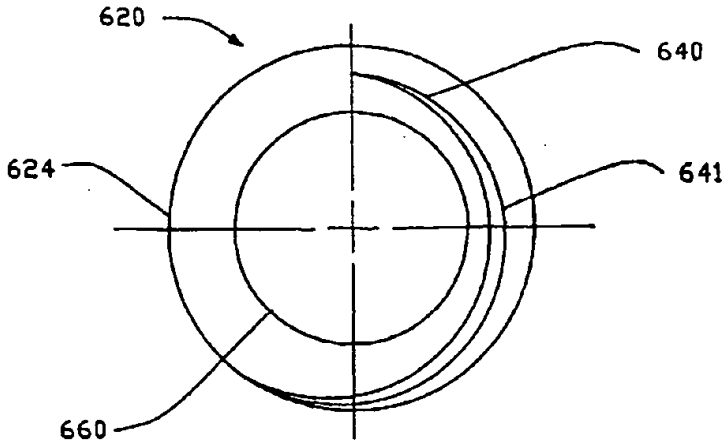

FIG.—26

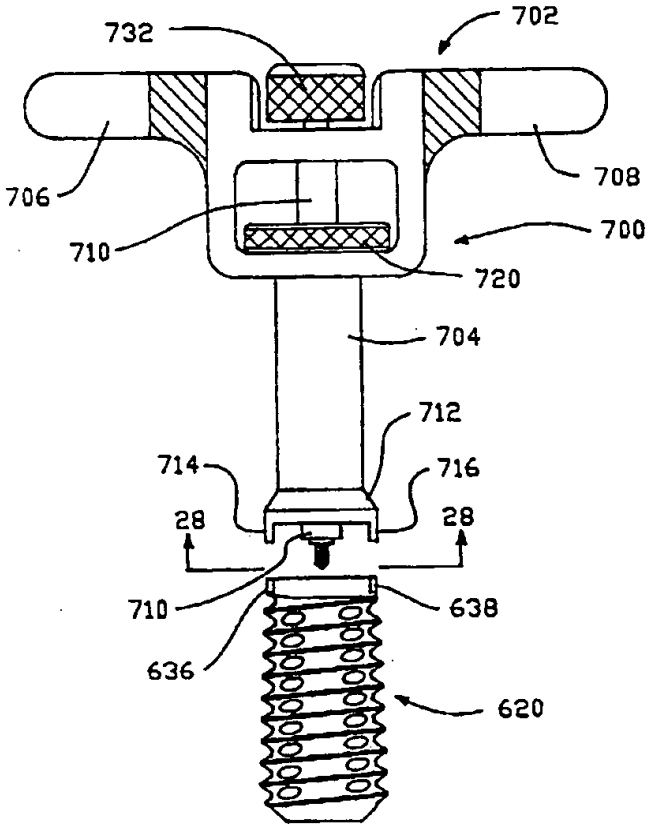

FIG.—27

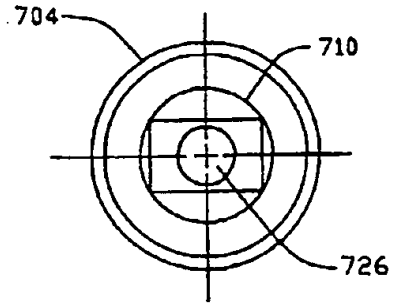

FIG.—28

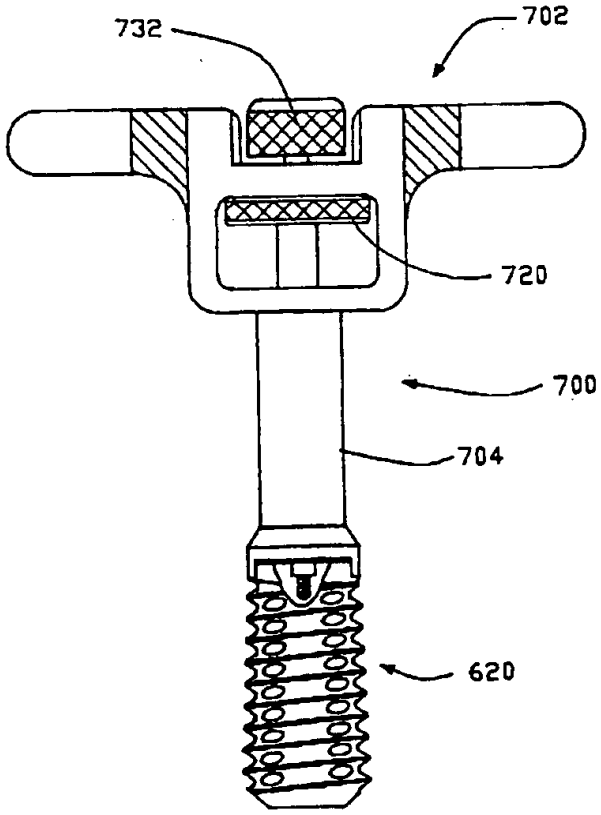

FIG.—29

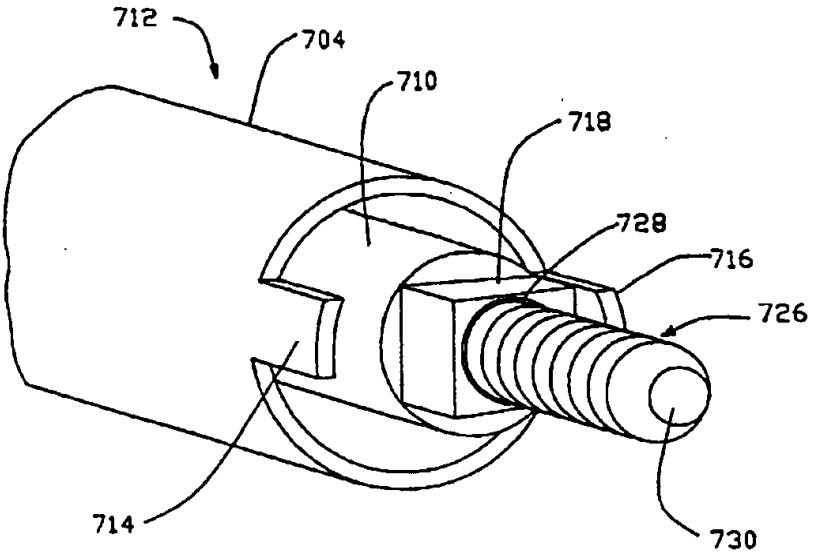

FIG.—30

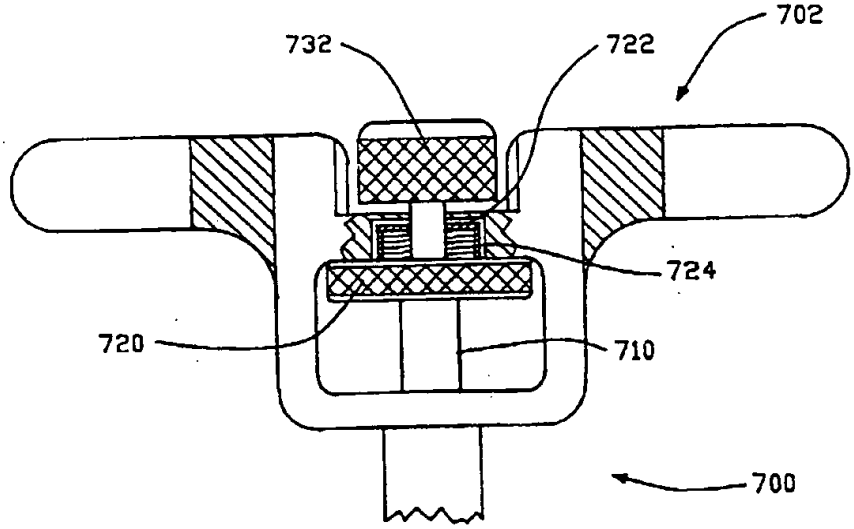

FIG.—31

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 737 448 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
16.10.1996 Bulletin 1996/42

(51) Int. Cl.[6]: **A61B 17/70**

(21) Application number: **96301739.7**

(22) Date of filing: **14.03.1996**

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

(30) Priority: **10.04.1995 US 419100**

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(54) Transverse connection for spinal jobs

(57) Four versions of clamps originally slidable along two generally parallel spinal rods (12,13) are swivel connected to three versions of transverse connectors (19) located between the rods (12,13). Set screws (31) lock the transverse connectors (19) to the clamps (22). Two of the clamp versions use interfitting rotational index locking detents at the swivel connections to fix the final orientation of the transverse connector (19) relative to the spinal rods (12,13). The other two clamp versions use locking tapers to lock the rotational index positions at the swivel connections to fix the final orientation of the transverse connector (19) relative to the spinal rods (12,13). One clamp version uses a separate set screw to fix the clamp on the spinal rod. One transverse connector has an open clamping head for installation directly onto the spinal rod without sliding it onto the rod from one end or the other.

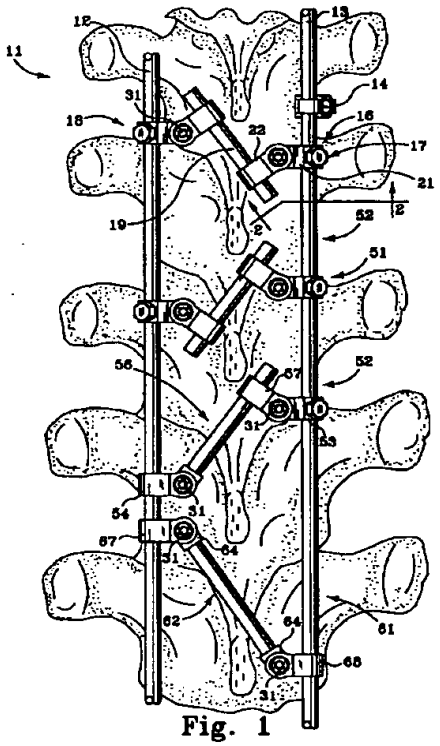

Fig. 1

EP 0 737 448 A1

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Description

BACKGROUND OF THE INVENTION

Field of the Invention:

This invention relates generally to spinal osteosynthesis, and more particularly to a system for making connections between two spinal rods.

Description of the Prior Art:

In spinal osteosynthesis, there are many cases in which implanted apparatus include laterally spaced implanted rods. Usually the positioning of the rods relative to each other must be stabilized, and various devices are used for that purpose. In U. S. Patent No. 5,005,562 issued April 9, 1991 to Yves Cotrel, transverse threaded rods 22 have hooks 23 screwed onto them. The hooks are fixed to the spinal rods 3 by hexagonal headed set screws or bolts. In U. S. Patent No. 5,261,907 issued November 16, 1993 to Vignaud et al., the pedicular screw 3 is anchored in bone and is attached to ring 9 by screwing down screw 6 which simultaneously spreads the screw head 5 to lock on ring 9, and also clamps the rod 2. Transverse rods 10, fixed in the rings 9, are received in clamping collar 11 and, when oriented in desired position, are fixed in collar 11 by the common clamping screw 12. There has remained a need for a device enabling rigid connection between two rods and which accommodates some variation in initial relative positioning of the rods, does not require mounting directly to screws such as in Vignaud et al., enables passage between vertebrae, and has minimal bulk. The present invention is addressed to that need.

SUMMARY OF THE INVENTION

Described briefly, according to a typical embodiment of the present invention, clamps originally slidable along two generally parallel spinal rods are swivel connected to a transverse connector located between the rods. Set screws lock the transverse connector to the clamps. One embodiment of clamp uses a separate set screw to fix the clamp on the spinal rod. The clamps use interfitting rotational index locking detents at the swivel connections to fix the final orientation of the transverse connector relative to the spinal rods. Other embodiments use locking tapers to lock the rotational index positions at the swivel connections to fix the final orientation of the transverse connector relative to the spinal rods.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a fragmentary posterior view of a spinal column with a corrective implant system incorporating transverse connection devices according to various embodiments of the present invention.

FIG. 2 is a view taken at line 2--2 in FIG. 1 and viewed in the direction of the arrows.

FIG. 3 is a view of a portion of one of the pivot assemblies.

FIG. 4 is a view similar to FIG. 1 but showing a still further embodiment.

FIG. 5 is a sectional view taken at line 5--5 in FIG. 4 and viewed in the direction of the arrows.

FIG. 6 is a fragmentary section of the assembly of FIG. 5.

FIG. 7A is an elevational view of one connector rod embodiment.

FIG. 7B is a top plan view of the FIG. 7A component.

FIG. 8 is an elevational view of another connector rod embodiment.

FIG. 9 is a view similar to FIG. 6 but of a still further connector assembly.

FIG. 10 is a much enlarged view of a break-off set screw used in the system.

FIG. 11 is a view similar to FIGS. 1 and 4 but showing a lateral connector with an open clamp to one of the spinal rods.

FIG. 12 is an exploded view of the lateral connector with the open clamp.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now to the drawings in detail, in FIG. 1 there is the spinal column shown generally at 11 with two spinal rods 12 and 13 thereon and, for purposes of illustration, one hook assembly 14 securing the rod 13 to one of the bones. It should be understood that the rods can be secured in several additional places to the spinal column by appropriate hooks such as are well known in the art, some examples of which are shown in the above-mentioned Cotrel patent and others in the TSRH Spinal Implant System described in the "Surgical Technical Manual" of Danek Medical, Inc. published in 1990, the disclosure of which is incorporated herein by reference. That particular literature describes CROSSLINK devices to provide fixed spacing between rods 12 and 13.

Several different embodiments of the present invention are illustrated in FIG. 1 herein, and another embodiment is shown in FIG. 2. Conditions to be treated in

different cases may indicate the desirability of using only one embodiment or other combinations of various embodiments of the present invention.

The first embodiment to be described will be the transverse connector assembly 16 which includes two pivot assemblies 17 and 18 which are identical although differently oriented, and a transverse connector rod 19. The pivot assembly 17, which will be described as exemplary, includes the connector pivot base 21 and the U-clamp 22. The components are better shown in FIGS. 2 and 3. The pivot base 21 includes the aperture through which the spinal rod 13 extends. The set screw 23 is threaded into the boss 24 of the pivot base 21. There are axially extending serrations or teeth 26 in the spinal rod receiving aperture in the pivot base to assist in securing the pivot base on the rod when the screw 23 is tightened onto the rod.

The other portion of the pivot base has an aperture through it receiving a set screw 31 which serves first as a pivot pin, and then as a clamping screw. On the upper and lower faces 27 and 28, respectively, there are grooves extending radially from the axis 29 of the pin receiving aperture, thus providing a rotary indexing detent system.

The other portion of the pivot assembly 17 is the U-clamp 22. This clamp is secured to the transverse connector rod 19 and to the pivot base by set screw 31 which, as shown in FIG. 10, has a hexagonal head 32, a peripheral notch 33 immediately below the head, a flange 34, a smooth shank 36 and threaded distal lower end 37. The notch provides a break-off feature to prevent excessive tightening. A circular aperture 38 through the head provides access to a number 10 TORX socket 41 in the top of that portion of the set screw immediately below the notch 33. In the assembly, the threaded portion is passed freely through the aperture 42 in the top of the U-clamp (FIG. 3) and threaded into the threaded portion 43 in the bottom of the U-clamp to thereby assemble the U-clamp to the pivot base. The U-clamp has two sets of axially extending teeth 44 and 46, similar to the teeth in the spinal rod receiving bore of the pivot base. These U-clamp teeth 44 and 46 grip transverse connector rod 19 when the clamp is tightened.

Once the orientation of the clamp on the pivot base has been established and deemed acceptable by the surgeon, it is essential that the orientation remain constant. For that purpose, there are four ribs 47 on the U-clamp. Two of these, spaced diametrically apart, face downward from the top of the clamp, and two of them face upward from the bottom of the clamp. These ribs or ridges seat in the grooves in the upper and lower faces 27 and 28, respectively, of the pivot base. The grooves are in a sunburst array around the axis 29 of the pin receiving aperture in the pivot base. The ability to interfit the ridges 47 of U-clamp 22 in the grooves in the top and bottom surfaces of the pivot base enables locking these two parts in any of many possible rotational index positions chosen by the surgeon.

The pivot assembly 18 on the spinal rod 12 is exactly the same as assembly 17 just described on spinal rod 13. The orientation is different as shown in FIG. 1, with the transverse connector rod 19 spanning the gap between the two U-clamps on the respective pivot assemblies. It is a feature of this invention that there is great freedom of discretion in the location and orientation of the pivot assemblies and the transverse connector. The assembly allows for the necessary degrees of tilt, rotation and angulation in three planes to make connections possible regardless of what the anatomy instrumented or deformity treated might be. It allows for dynamic diagonal transverse connections with both distraction and compression force applications. The sequence of tightening the set screws 23 for the pivot bases to the spinal rods and screws 31 for the U-clamps to the pivot bases can be selected in accordance with the preferences of the surgeon, to provide the best possible relationship of the parts. At such time as the desired relationship of the U-clamps to the pivot bases has been determined, the set screws 31 can be tightened by a hexagonal wrench on the heads 32. They are designed to break at the notch 33 to avoid excessive application of tightening torque. If, at some later time, it is desired to remove the set screws, a suitable TORX wrench can be used in the socket 41 for that purpose.

Referring further to FIG. 1, there is a second transverse connector assembly 51 shown connected between the two rods 12 and 13. The components of this connector assembly are exactly the same as those for the assembly 16, the only difference being that the pivot base on the right-hand rod is above that on the left-hand rod.

Referring still further to FIG. 1, there is a third transverse connector assembly 52. This one is different from the first two in several respects. A pivot base and U-clamp assembly 53 is secured to the rod 13 in the same manner as described above with reference to the assembly 17. But on the other rod 12, the pivot assembly has only the U-clamp portion 54 of an assembly such as 53. The U-clamp 54 is exactly like U-clamp 22. Instead of the transverse connector rod 19 previously described, the transverse connector 56 as shown in FIG. 7A and 7B has a cylindrical rod portion 58 and, at one end of it, there is a double faced swivel head portion 59 having an upper surface 61 and lower surface 62, both of which have the radially extending grooves in a sunburst array as was described above for the pivot base 21. These are received in the U-clamp 54 just as the comparable portion of the pivot base 21 is received in the U-clamp 22. This swivel connection is secured in the same way with the same type of set screw 31 as described above. The cylindrical portion 58 of the rod is received through the U-clamp 57 (which is exactly like U-clamps 54 and 22) and is secured in the same way as described above for the rod 19 in U-clamp 22.

Referring further to FIG. 1, a fourth transverse connector assembly 61 is shown connected between the rods 12 and 13. In this example, the transverse connec-

tor 62 is as shown in FIG. 8 and is similar to connector 56 described above, but the cylindrical rod portion 63 has swivel head portions 64 at both ends. These are like the swivel head 59 at the end of the rod 58 and are received in U-clamps 67 and 68 on rods 12 and 13, respectively. Set screws 31 are used in both of the U-clamps to clamp them to the swivel heads 64 of the rod 62 when the desired spacing and location of the rod 62 have been determined. U-clamps 67 and 68 are like U-clamp 22 and the clamping is the same as described above for fixing the U-clamp 22 to pivot 21.

Referring now to FIG. 4, spinal rods 72 and 73 are shown. It should be understood that the spinal rods in FIGS. 1 and 2 can be closer together or farther apart, and the only resulting change would be the orientation of the connector assemblies and the transverse rod between them. Therefore, any of the three different connector assemblies in FIG. 1 can be used with a greater or lesser spacing between the spinal rods. This is true of the embodiment shown in FIG. 4. The transverse connector assembly in FIG. 4 appears very similar to and is similarly oriented to that shown at the top of FIG. 1., but there are some differences, as can be better understood by reference to FIGS. 5 and 6. In this case, the transverse rod 76 can be the same as rod 19 in FIG. 1. But the pivot assembly 77 includes two clamps 78 and 79. In a sense, both of these clamps 78 and 79 might be considered U-clamps. But to distinguish them, the clamp 78 will be referred to as split clamp and 79 as a U-clamp. Clamp 78 has the longitudinally or axially extending alternate ridges or grooves or (teeth) 81 therein to tightly engage the spinal rod 73 when clamped shut. Similarly, clamp 79 has the axially extending alternate ridges and grooves 82 for gripping tightly on transverse rod 76 when the assembly is clamped together. For clamping the assembly together, a set screw 83 is used and is provided with a Morse taper on its exterior surface 84 received in a matching Morse taper 85 in the upper finger of clamp 79, and matching Morse taper 86 in the clamp 78. The threads 87 on the lower end of the set screw 83 are threaded into the threads 88 of the clamp 79. A Morse taper is also provided on surface 91 of the clamp 78 so that it does not matter whether the clamp is used as shown or upside down, as the set screw 83 will lock in whichever of the apertures 86 or 91 is at the top. The set screw 83 can be provided with a break off head as described above with reference to the set screw 31, or with simply a TORX or hexagonal socket 92 therein. Upon reception of the clamps 78 and 79 on rods 73 and 76, respectively, and upon suitable orientation of the rods with respect to each other and the suitable orientation of the clamps on the rods, the set screws can be tightened to clamp both of the clamps onto their respective rods, with the set screws locking in their respective tapers such as 86 in the upper finger of clamp 78 and surface 85 in the upper finger of clamp 79. The connector clamp assembly 93 on rod 72 is exactly the same as clamp assembly 77 on rod 73 and is clamped to rod 72 and rod 76 in the same way. A shallow, semi-circular channel 94, half of which is on the lower finger of clamp 78 and half on the upper finger of clamp 78, extends around the entire exposed surface of the two fingers so as to accommodate the rod 76 during the swiveling of the clamp 79 on clamp 78 before locking the two together with the set screw.

Referring now to FIG. 9, a variation of the embodiment of FIGS. 5 and 6 is shown. In this pivot assembly example, the spinal rod 97 and the transverse rod 76 are associated with two clamps, one being clamp 78 as previously described with reference to FIGS. 5 and 6, but the other being a U-clamp 99 which is different from clamp 79. One of the differences is the fact that the upper finger 101 thereof has the aperture 102 which is a straight walled cylindrical aperture and does not lock on the taper 84 of the locking screw 83. Another difference is that there is a tapered aperture with a Morse taper at 103 in the lower finger of the clamp. The locking screw 83 is the same as that in the previously described embodiment, except that in this embodiment it has an upper flange 104 to engage and bear on the upper surface of the upper finger 101. The threaded end of this screw is received in a lock nut 106 which has a tapered external surface 107, and a flange 108 on its lower end. Therefore, when this assembly is to be clamped on the rods 97 and 76, the screw 83 is turned down to engagement of the threads thereon with the threads in the bore of the nut 106 which then jams in the Morse taper in the lower finger of the clamp 99 and, upon sufficient tightening, the flange 104 on the head of screw 83 will pull the clamp 99 into clamping engagement with rod 76. The engagement of the Morse taper 84 on the screw 83 with the taper 86 in the clamp 78 will pull that clamp tightly onto rod 97 and lock the screw in the clamp. The edges 109 at the bottom of the aperture in the lower finger of clamp 99 can be bent over to trap the flange 108 of the lock nut in the assembly so that it does not fall out before the screw threads engage it.

Referring now to Figs. 11 and 12, the spinal rods 112 and 113 can be considered comparable and situated similarly to those in Figs. 1 and 4, for example. A U-clamp 114 is secured to rod 113. This clamp can be identical to clamp 22 shown in Figs. 1-3 but, instead of being secured to the transverse rod as in those figures, it is secured directly to the spinal rod 113. A pivot base 116 is mounted to the U-clamp 114. This pivot base is identical to pivot base 21 in Figs. 1 and 2. It is mounted to the U-clamp 114 in exactly the same way and secured by the set screw 117, which simultaneously secures the U-clamp 114 to the spinal rod 113. In this example, in contrast to the Fig. 1 illustration, the U-clamp and the pivot base are shown at 90° with respect to each other but, as in the previous example, the angle between the parts, once established as desired, is fixed by the ribs on the U-clamp received in the grooves in the pivot base to securely maintain that angular relationship.

The transverse connector rod 118 is received and fixed in the aperture of the pivot base 116 by the set

screw 119 in exactly the same manner as the spinal rod 13 is secured in pivot base 21 by set screw 23 in Fig. 2. This transverse connector rod 118 is integral with the connector base 121 of the open-type connector clamp assembly 122 which includes a connector cap 123 secured to the base and to the spinal rod 112 by the set screw 124.

Referring now to Fig. 12, the transverse connector rod-base and clamp assembly 122 is shown in three pieces, with the connector rod 118 and base 121 separate from the cap 123 and set screw 124. The rod 118 itself has a knurled surface as does the groove 126 in the base. Similarly, although not shown, the groove 127 in the cap is knurled. As may be evident from the description to this point, the base is open so that it can be installed on the spinal rod in a transverse direction without having to slide it axially down the length of the rod. In other words, the entrance gap to the spinal rod receiver channel is wide enough for the spinal rod to be received in it in the direction of arrow 129. Grooves 131 are provided at each side of the spinal rod receiver channel. The lower surface of each groove has a slight concave curve to it, and the flange 132 at the top of the base at each side of the channel entrance has a convex curve to it. Similarly, the cap 123 has a flange 133 at each side which extends parallel to the axis of the rod receiving channel 127, whereby the cap can be installed into the base in the direction of arrow 136, with the flanges on the cap received in the grooves 131 outboard of the flanges 132 on the base, the flanges 132 of the base being received in the grooves 134 in the cap. Because of the fact that the top of flange 133, bottom of flange 132 and the bottom of the groove 134 in the cap and the bottom of the groove 131 in the base are all curved, so is the bottom 137 of the cap. Therefore a slight rocking motion of the cap as it is inserted in the direction of arrow 136 into the base, will occur. Therefore, the total clearance between the cylinder formed by the rod receiving channel 127 in the cap and the rod receiving channel 126 in the base will be enough to admit the cap into the base when the base has been positioned in place under the spinal rod. Following the installation, the set screw 124 is tightened in the threads 138 in the set screw receiver aperture in the cap. Accordingly, the set screw drives the spinal rod tightly against the bottom of channel 126 in the base. The bottom of the set screw is pointed as at 139 to avoid any axial slippage along the spinal rod. Axial movement of the base along the spinal rod is limited not only by the friction between the channel bottom and the rod but also by the fact that, due to the curvature in the flanges and receiver grooves in the base and the cap, axial movement of the base cannot take place without tending to rotate it about the axis of the rod 118. This movement is resisted not only by the rod 112 itself, but also by the clamping of the transverse rod 118 in the pivot base and by the pivot base being clamped in the U-clamp 114. Therefore, once the set screws 117, 119 and 124 are secured, movement is securely resisted in all directions.

The material for all of the components may be the same. For one example, connector 56 is a solid unit of 316L ASTM F138 grade 2 cold rolled 900/1050 MPa material. It is machined to provide the rod portion 58 and head portion 59. The spinal rods and transverse rods can be smooth, shot peened, or knurled. The transverse rods such as 19 and 58 can be cut off to a desired length.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

Claims

1. In a system for spinal osteosynthesis including two generally parallel spinal rods implanted adjacent a spinal column, apparatus for making a rigid connection between the rods and comprising:

   first and second connectors slidable along the first and second rods, respectively;

   a transverse connector located between the rods and swivel connected to the first and second connectors;

   two fasteners;

   one of the fasteners connecting the first connector to the transverse connector, the other of the fasteners connecting the second connector to the transverse connector;

   and

   swivel orientation locks at the locations of the connection of the transverse connector to the first and second connectors for locking said connector at variable orientations.

2. The apparatus of claim 1 and further comprising: third and fourth fasteners, the third fastener clamping the first connector to the first rod, and the fourth fastener clamping the second connector to the second rod.

3. The apparatus of claim 1 and wherein:

   the first connector is a pivot base having upper and lower indexing detent recesses circularly-spaced around a pivot aperture, the apparatus further comprising:

   a U-clamp pivotally mounted to the pivot base and having detent projections thereon receivable in the detent recesses,

   one of the fasteners being a set screw operable to drive at least one of the detent projections into one of the detent recesses to thereupon prevent the U-clamp from pivoting on the pivot about the aperture.

4. The apparatus of claim 3 and wherein:
the U-clamp has upper and lower arms,
the detent recesses are grooves extending radially outward from the pivot aperture
the upper arm having an aperture therein receiving the one set screw therein, and the lower arm having screw threads therein receiving threads of the one set screw,
the upper arm having a lower surface with at least one of the detent projections thereon projecting downward therefrom into one of the detent recesses of the pivot base,
the lower arm having an upper surface with at least one of the detent projections thereon projecting upward therefrom into one of the detent recesses of the pivot base.

5. The apparatus of claim 4 and wherein:
the U-clamp has a semicylindrical portion thereof with a cylindrical axis, and has a plurality of teeth therein extending parallel to the axis thereof and gripping a rod.

6. The apparatus of claim 5 and wherein:
the one set screw is a break-off set screw.

7. The apparatus of claim 1 and wherein:
the first connector is a pivot base in the form of a split clamp having upper and lower arms, the apparatus further comprising:
a U-clamp having a portion received on the split clamp and a portion receiving the transverse connector therein; and
the fastener connecting the pivot base to the transverse connector is a set screw which has a tapered portion and a threaded portion, and at least one of the split clamp and the U-clamp has a taper matching and locking on the tapered portion of the set screw.

8. The apparatus of claim 7 and wherein:
the matching taper is in the upper arm.

9. The apparatus of claim 8 and wherein:
the U-clamp has an upper arm and a lower arm, the upper arm having an aperture therein receiving a portion of the set screw therethrough, the aperture having a tapered internal wall matching the taper of the set screw, and the lower arm having an aperture therein with threads receiving the threaded portion of the set screw whereby, upon advancing the threaded portion of the set screw in the lower arm threads, the clamps are locked to each other and the split clamp is locked on the spinal rod and the U-shaped clamp is locked on the transverse connector.

10. The apparatus of claim 8 and wherein:
the set screw has an upper flange engageable with the top of the upper arm of the split clamp;
the U-clamp has an upper arm and a lower arm and an aperture in the lower arm and which has a taper therein, the apparatus further comprising:
a nut received in the aperture in the lower arm of the U-clamp, the nut having an external taper matching the taper in the lower arm of the U-clamp, and the nut having internal threads receiving the threaded portion of the set screw whereby the set screw is securable in the nut and the nut is lockable in the taper in the lower arm of the U-clamp and the taper on the set screw is lockable in the taper in the upper arm of the split clamp to thereby lock the clamps to each other and lock the split clamp on the spinal rod and lock the U-clamp on the transverse connector.

11. The apparatus of claim 1 and wherein:
the first and second connectors are pivot bases and the fasteners are set screws threaded through the pivot bases and operable to fix the pivot bases on their respective rods, the apparatus further comprising:
first and second swivel clamps pivotally mounted to the first and second pivot bases;
the transverse connector being a rod extending through the first and second clamps; and
third and fourth set screws serve as clamp set screws and connect the clamps to their respective pivot bases and lock the clamps on the pivot bases and on the transverse connector rod.

12. The apparatus of claim 11 and wherein:
the clamps and transverse connector rod are disposed between the first and second spinal rods.

13. The apparatus of claim 10 and wherein:
each of the clamps has an interface with the pivot base

14. The apparatus of claim 13 and wherein:
the interfaces between the clamps and pivot bases have interengaging detents providing interference between the clamp and respective pivot base when the clamp set screw is tightened, to prevent swiveling of the clamp on the pivot base.

15. The apparatus of claim 1 and wherein:
the first connector is a U-clamp having an upper arm and a lower arm;
the swivel orientation locks include detents on the transverse connector and on the U-clamp.

16. The apparatus of claim 15 and wherein:
the detents include detent ridges and grooves on the transverse connector and detent ridges on the U-clamp.

17. The apparatus of claim 16 and wherein:

the transverse connector has a rod portion and a head portion at an end of the rod portion, the head portion having top and bottom surfaces and an aperture through them, and

the detent ridges and grooves extend radially outward from the aperture on the top and bottom surfaces of the head portion.

18. The apparatus of claim 17 and wherein:

the one fastener is a set screw and has threads threaded into the lower arm of the U-clamp and has a bearing surface bearing downward on the upper arm of the U-clamp and holds at least one detent ridge of the U-clamp in at least one detent groove of the connector rod head to prevent swiveling of the rod about the aperture in the U-clamp.

19. In a system for spinal osteosynthesis including first and second generally parallel spinal rods implanted adjacent a spinal column, apparatus for making a rigid connection between the rods and comprising:

first and second connectors slidable along the first and second rods, respectively;

a transverse connector located between the rods and swivel connected to at least one of the first and second connectors;

two fasteners;

one of the fasteners connecting the first connector to the transverse connector, the other of the fasteners connecting the second connector to the transverse connector;

and

swivel orientation locks at the location of the connection of the transverse connector and the one of the connectors for locking said transverse connector at different orientations with respect to the second rod.

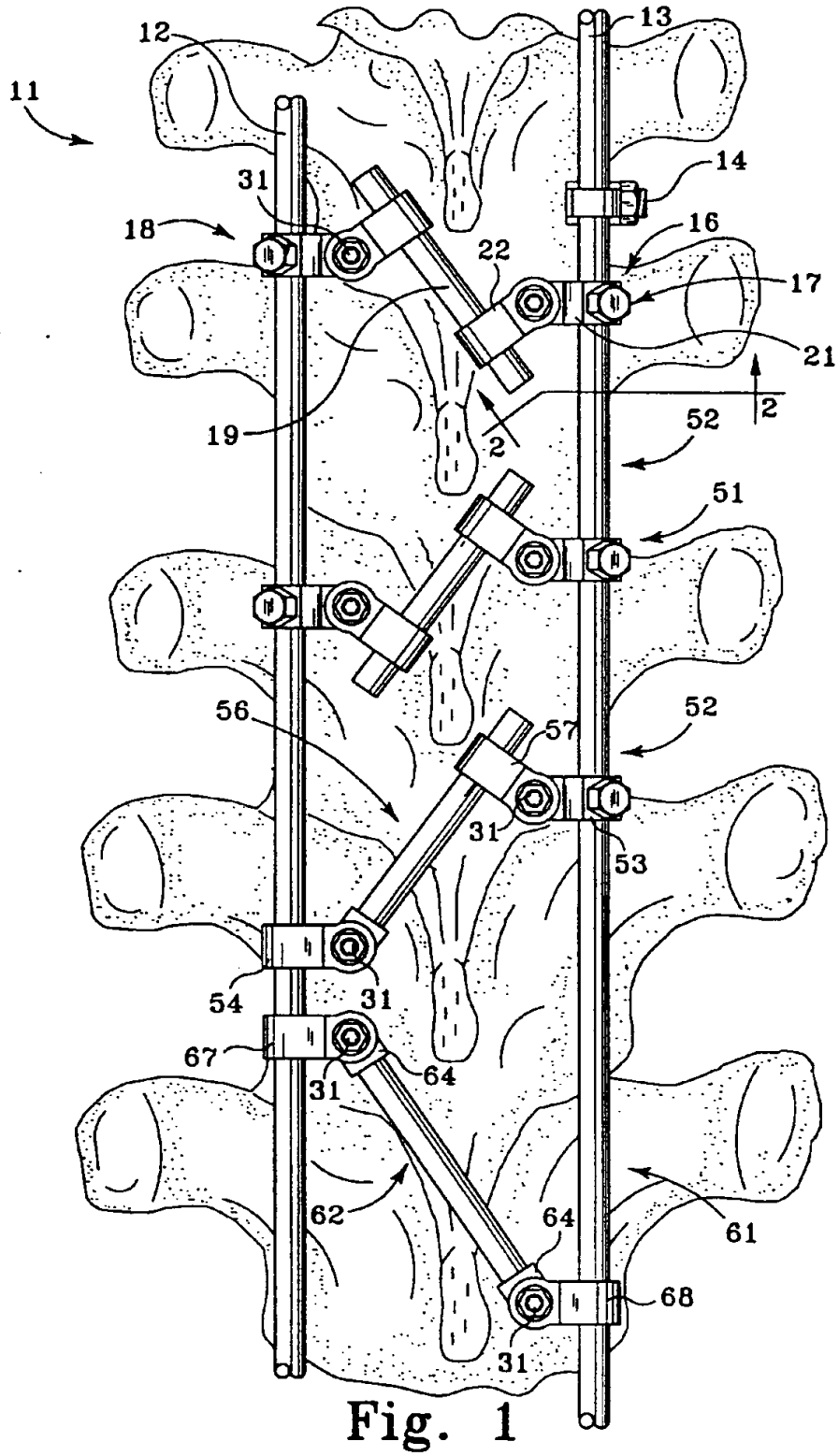

Fig. 1

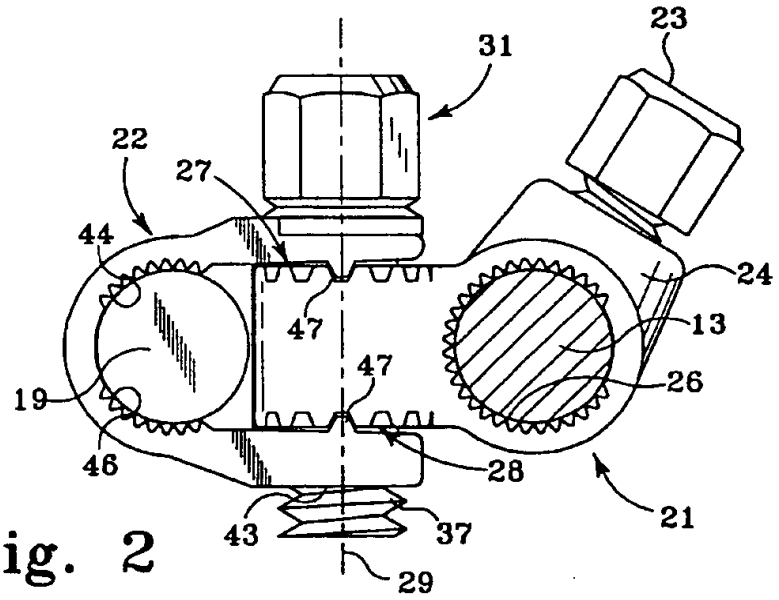

Fig. 2

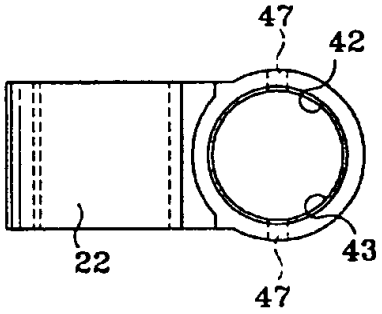

Fig. 3

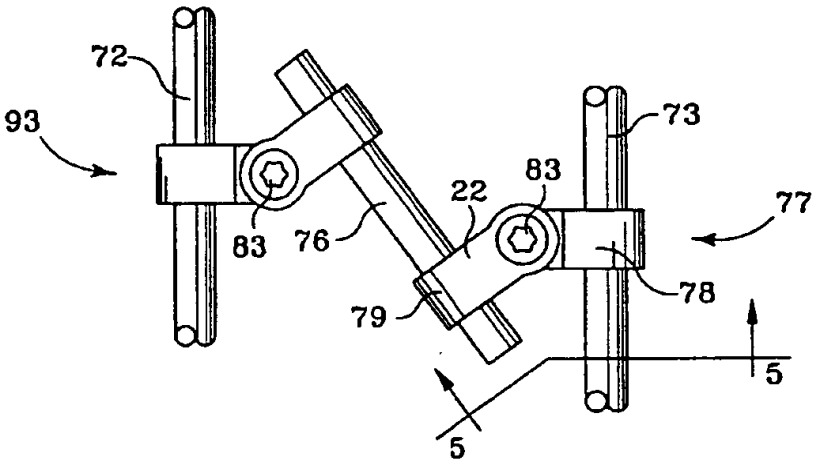

Fig. 4

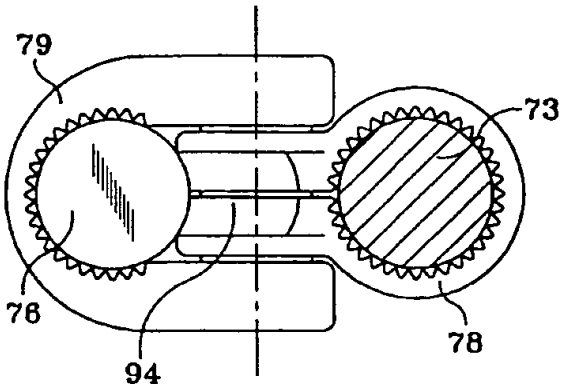

Fig. 5

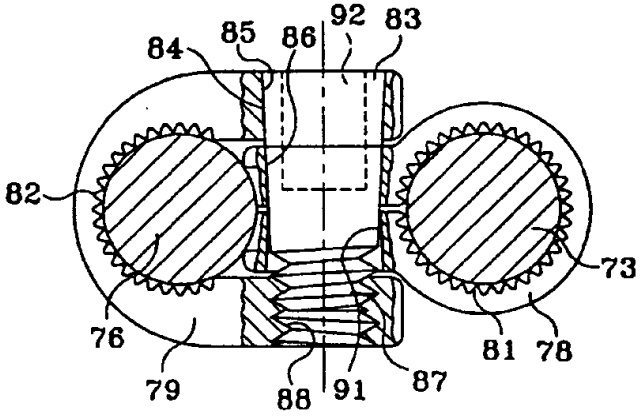

Fig. 6

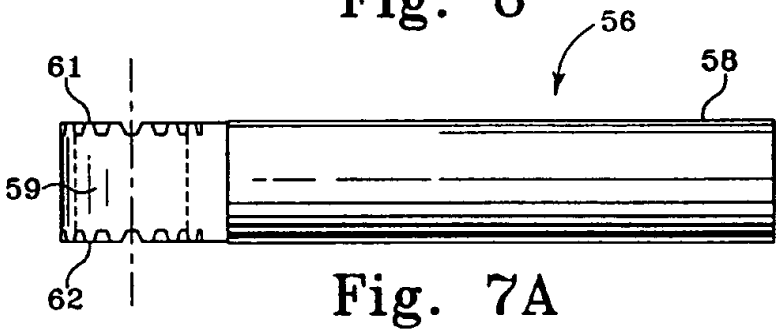

Fig. 7A

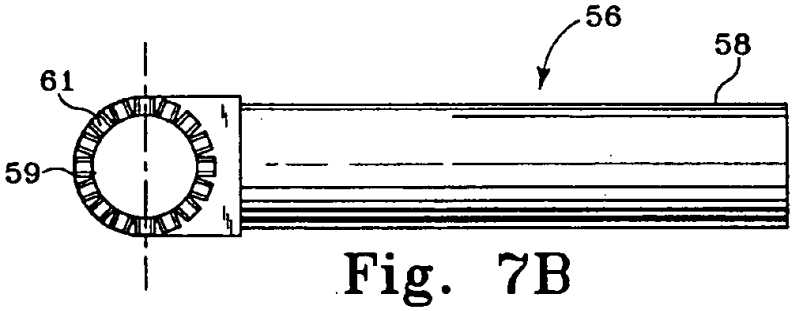

Fig. 7B

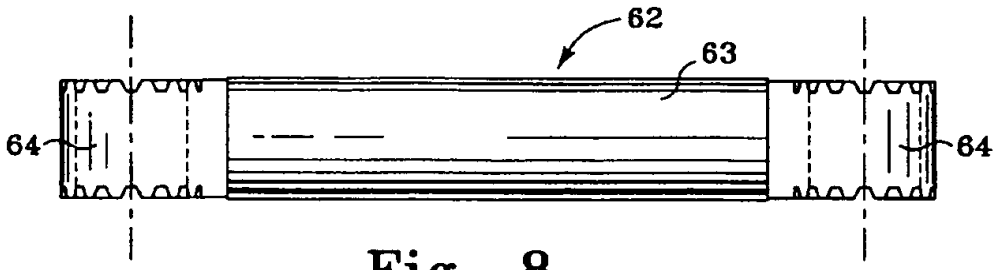

Fig. 8

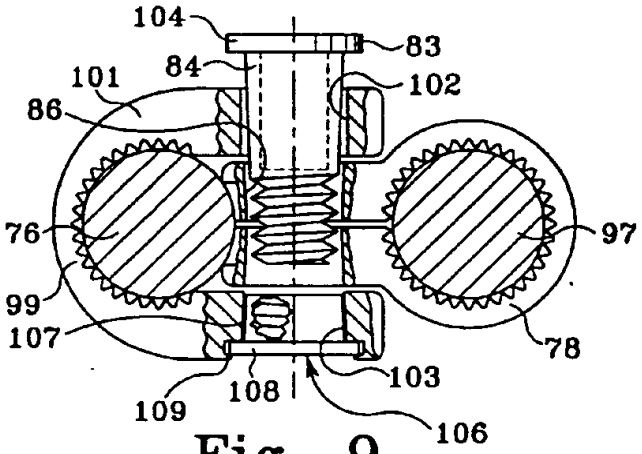

Fig. 9

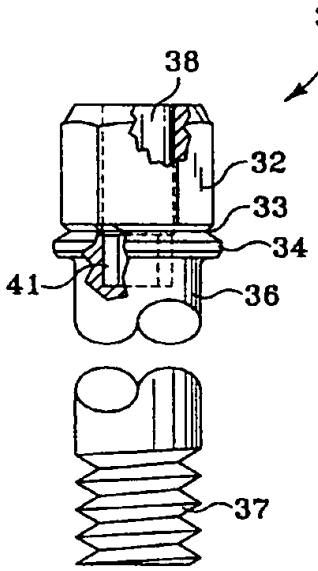

Fig. 10

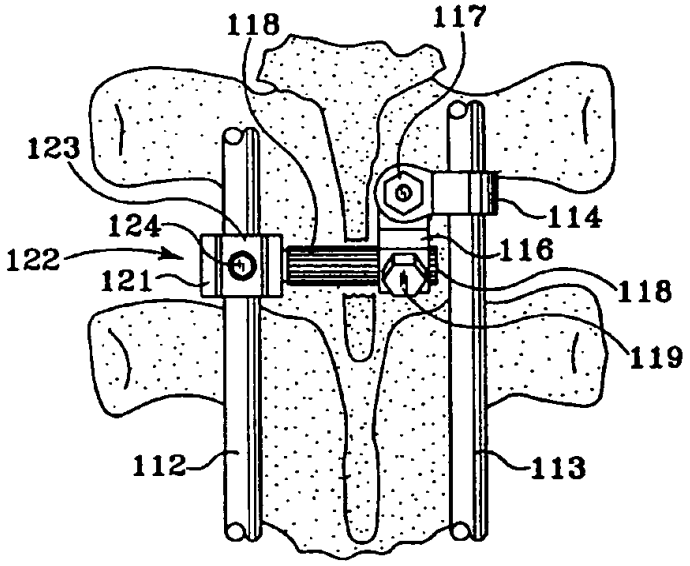

Fig. 11

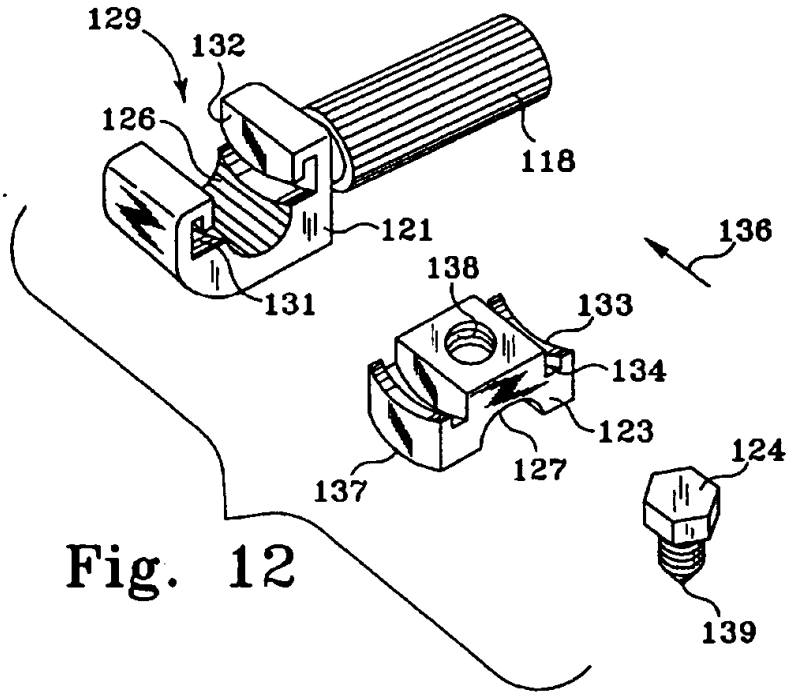

Fig. 12

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 30 1739

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	EP-A-0 418 387 (V KURGANSKY NAUCHNY TS VOSSTAN) 27 March 1991 * column 8, line 2 - line 17; claim 4; figure 7 *	1,19	A61B17/70
A	US-A-5 254 118 (MIRKOVIC SRDJIAN) 19 October 1993 * column 2, line 13 - line 26; figures *	1,15,19	
D,A	US-A-5 261 907 (VIGNAUD JEAN L ET AL) 16 November 1993 * column 3, line 10 - line 47; figures *	1,19	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	1 July 1996	Neumann, E

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
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EPO FORM 1503 03.82 (P04C01)

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 796 593 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
24.09.1997 Bulletin 1997/39

(51) Int. Cl.[6]: **A61B 17/02**, A61B 17/16, A61F 2/46

(21) Application number: **97104277.5**

(22) Date of filing: **13.03.1997**

(84) Designated Contracting States:
DE ES FR GB IT NL

(30) Priority: **14.03.1996 US 615379**

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(54) Method and instrumentation for surgical implant insertion

(57) A surgical retractor including a sleeve member having two opposed retractor arms (20) at its distal end portion. By inserting the retractor arms of the retractor within a space defined between adjacent bony structures, first and second supporting surfaces (20a, 20b) of each retractor arm respectively engage the opposed structures thereby distracting the structures, for performing a surgical procedure. A method for inserting a spinal implant is also disclosed. Instrumentation for performing the procedure is also disclosed.

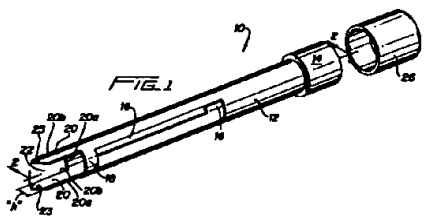

FIG. 1

EP 0 796 593 A2

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Description

BACKGROUND

1. Technical Field

The present disclosure generally relates to a method and associated instrumentation for implant insertion and, in particular, to a method and instrumentation for insertion of spinal implants to facilitate fusion of adjacent vertebral bodies.

2. Background of the Related Art

A large number of orthopedic procedures involve the insertion of either natural or prosthetic implants into bone or associated tissues. These procedures include, for example, ligament repair, joint repair or replacement, non-union fractures, facial reconstruction, spinal stabilization and spinal fusion. In a typical procedure, an insert, dowel or screw is inserted into a prepared bore formed in the bone or tissues to facilitate repair and healing. See, for example, U.S. Patent Nos.: 5,470,334 to Ross et al.; 5,454,811 to Huebner; 5,480,403 to Lee et al.; 5,40_,805 to Warren; 5,358,511 to Gatturna et al.; and 4,877,020 to Vich.

Some implants are particularly configured with cavities and bores to facilitate bony in growth and enhance anchoring of the implant at the insertion site. See, for example, U.S. Patent Nos.: 4,328,593 to Sutter et al.; 4,936,851 to Fox et al.; and 4,878,915 to Brantigan. Implants in the form of fusion cages having internal cavities to receive bone growth stimulation materials such as bone chips and fragments are disclosed, for example, in U.S. Patent Nos.: 4,501,269 to Bagby; 4,961,740 to Ray et al.; 5,015,247 to Michaelson; and 5,489,307 to Kuslich et al. These types of implants are particularly well suited for intervertebral spinal fusion procedures necessitated by injury, disease or some degenerative disorder of the spinal disc. Subsequently, there may be progressive degeneration leading to mechanical instability between adjacent vertebrae necessitating direct fusion of the vertebrae while maintaining a pre-defined intervertebral space. This fusion may be accomplished by the insertion of one or more of the specialized implants as discussed above and also discussed in commonly assigned U.S. Patent No. 5,026,373, the contents of which are incorporated herein by reference.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar spine. Fusions in the cervical area of the spine are primarily performed using a posterior approach. Typically, an implant such as a plug, dowel, prosthesis or cage is inserted into a preformed cavity inside the interbody, interdiscal space. Since it is desirable in these procedures to promote a "bone to bone" bridge, connective tissue and at least a portion of the distal tissue is removed. Preferably, relatively deep cuts are made in the adjacent bones in order to penetrate into the softer, more vascularized cancellous region to facilitate bone growth across the implant.

One of the more critical tasks performed in the insertion of a surgical fusion implant, particularly, in intervertebral spinal fusion, is the formation of the implant receiving cavity or bore between/within the adjacent vertebrae. More particularly, the drilled bore must be equally centered within the intervertebral space and preferably parallel to the vertebral end plates to ensure removal of equal portions of bone from the adjacent vertebrae throughout the length of the cut and subsequent appropriate seating of the implant relative to the vertebral bodies.

Surgical instruments for spinal fusion implant insertion are known. For example, U.S. Patent No. 5,484,437 to Michelson discloses a method and apparatus incorporating an outer and an inner sleeve arrangement. The outer sleeve is positioned over the spinal distractor and has teeth at one end which are driven directly into the posterior surface of the adjacent vertebrae. The inner sleeve is positioned within the outer sleeve and serves to guide instruments such as a drill used to form the implant receiving bore. U.S. Patent Nos.: 5,487,307 to Kuslich et al.; 5,015,247 to Michelson; and 4,878,915 to Brantigan also disclose outer sleeves with teeth mounted to the vertebrae. Other arrangements include the use of guide rods which are placed in pilot holes formed in the vertebral bodies. The guide rods guide a bore forming hollow drill into the intervertebrai space.

Although some current instrumentation and methods associated therewith for enhancing the placement of spinal fusion implants have been generally effective for their intended purposes, there exists certain limitations with the design of this instrumentation which detract from their usefulness. For example, the arrangement disclosed in the Michelson '437 patent and similar arrangements do not provide for automatic alignment of the outer sleeve to ensure that the bore formed by a drill introduced into the outer sleeve is in optimal alignment for a tapping procedure (if required) and reception of the spinal implant. Rather, such orientation is dependent directly upon the skill of the surgeon. Moreover, the outer sleeve, which is mounted via teeth only at its extreme distal end to the posterior surface of the adjacent vertebrae, is subject to disorientation or dislodgment during insertion and/or removal of the drill and/or tapping instrument. The use of guide rods increases the number of steps required to implant the fusion cage.

Accordingly, the present disclosure is directed to a method and associated instrumentation to facilitate the introduction of a fusion implant, which ensures optimal alignment of the drilled bore for reception of the fusion implant and, if appropriate, for bore tapping procedures. The instrumentation of the present disclosure also reduces the number of steps required for implantation of the fusion cage.