IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Matthew Curran	Art Unit:	3733
Serial No.:	11/093,409	Examiner:	Elana Beth Fisher
Filing Date:	March 29, 2005		
Title:	Systems and Methods for Spinal Fusion		

Certificate of Transmission: I hereby certify that this paper or fee is being transmitted to the USPTO via EFS-Web on March 1, 2010.

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 Final Office Action mailed on August 27, 2009, having a three-month shortened period for response that expired on February 27, 2010, please amend the application as follows:

IN THE CLAIMS:

1. (Currently Amended) 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 being positionable from a lateral approach to extend from one lateral aspect to the other, said implant comprising:

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 extending parallel to said proximal and said distal sides and between said top and bottom surfaces;

said implant further including at least one radiopaque marker situated between said top and bottom surfaces.

2. (Previously Presented) The spinal fusion implant of Claim 1, wherein said implant is substantially radiolucent and composed of non-bone material.

3. (Previously Presented) The spinal fusion implant of Claim 1, wherein said implant includes at least one visualization aperture extending through at least one of said first side wall and said second side wall.

4. (Previously Presented) The spinal fusion implant 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. (Previously Presented) The spinal fusion implant of Claim 1, wherein said first and second fusion apertures are one of generally rectangular and generally oblong in shape.

6– 30. (Cancelled)

31. (Previously Presented) The Spinal fusion implant of claim 1, further including at least one receiving element at least partially defined along said proximal side.

32. (Previously Presented) The spinal fusion implant of claim 31, wherein said receiving element is engageable with an insertion instrument.

33. (Previously Presented) The spinal fusion implant of claim 32, wherein said receiving element comprises a threaded aperture.

34. (Previously Presented) The spinal fusion implant of claim 33, wherein said receiving implant further comprises a slot extending from said threaded aperture.

35. (Currently Amended) A spinal fusion implant of non-bone construction postionable via a lateral trans-psoas surgical approach to the spine into a position within an interbody space between a first vertebra and a second vertebra, ~~wherein~~ said interbody space being at least partially defined by a posterior aspect, and anterior aspect, and opposing lateral aspects, said implant comprising:

a top surface to contact said first vertebra when said implant is positioned within the interbody space, a bottom surface to contact said second vertebra when said implant is positioned within the interbody space, a distal side, a proximal side, a first side to face said anterior aspect of said disc space when said implant is positioned within the interbody space and a second side to face said posterior aspect of said disc space when said implant is positioned within the interbody space, wherein said implant is generally rectangular in shape having a length extending from said proximal side to said distal side of at least 40mm, a width extending from said first side to said second side of at least 15mm, and a height extending from said top surface to said bottom surface ranging from 8mm to 16mm, said implant further including a pair fusion apertures comprising one of a generally rectangular and generally oblong shape and extending between said top surface and bottom surface to permit bone growth between the first vertebra and the second vertebra, said pair of fusion apertures being separated by a medial support extending parallel to said proximal and said distal sides and between said top and bottom surfaces, said implant further including a at least one radiopaque marker situated between said top and bottom surfaces.

36. (Previously Presented) The implant of claim 31, wherein said non-bone material is one of PEEK and PEKK.

37. (Previously Presented) 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. (Previously Presented) The implant of claim 31, wherein a portion of said implant adjacent said distal side is tapered.

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

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

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

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

44. (New) The spinal fusion implant of claim 37, wherein said spinal fusion implant includes exactly four visualization apertures in communication with a first of said fusion apertures from said pair of fusion apertures and exactly four visualization apertures in communication with a second of said fusion apertures from said pair of fusion apertures.

45. (New) The spinal fusion implant of claim 44, wherein two of said visualization apertures in communication with said first fusion aperture are situated in said first side, two of said fusion apertures in communication with said first fusion aperture are situated in said second side, two of said visualization apertures in communication with said second fusion aperture are situated in

said first side, and two of said fusion apertures in communication with said second fusion aperture are situated in said second side.

46. (New) The spinal fusion implant of claim 37, wherein said spinal fusion implant includes exactly six visualization apertures in communication with a first of said fusion apertures from said pair of fusion apertures and exactly six visualization apertures in communication with a second of said fusion apertures from said pair of fusion apertures.

47. (New) The spinal fusion implant of claim 46, wherein three of said visualization apertures in communication with said first fusion aperture are situated in said first side, three of said fusion apertures in communication with said first fusion aperture are situated in said second side, three of said visualization apertures in communication with said second fusion aperture are situated in said first side, and three of said fusion apertures in communication with said second fusion aperture are situated in said second side.

48. (New) The spinal fusion implant of claim 1, wherein said spinal fusion implant includes exactly four visualization apertures in communication with said first fusion aperture and exactly four visualization apertures in communication with said second fusion aperture.

49. (New) The spinal fusion implant of claim 48, wherein two of said visualization apertures in communication with said first fusion aperture are situated in said first side, two of said fusion apertures in communication with said first fusion aperture are situated in said second side, two of said visualization apertures in communication with said second fusion aperture are situated in said first side, and two of said fusion apertures in communication with said second fusion aperture are situated in said second side.

50. (New) The spinal fusion implant of claim 1, wherein said spinal fusion implant includes exactly six visualization apertures in communication with said first fusion aperture and exactly six visualization apertures in communication with said second fusion.

51. (New) The spinal fusion implant of claim 50, wherein three of said visualization apertures in communication with said first fusion aperture are situated in said first side, three of said fusion apertures in communication with said first fusion aperture are situated in said second side, three of said visualization apertures in communication with said second fusion aperture are situated in said first side, and three of said fusion apertures in communication with said second fusion aperture are situated in said second side.

REMARKS

Claims 1 and 31 have been amended and new claims 44-51 have been added. The independent claims have been amended to expediently advance prosecution on the merits without prejudice to pursue the subject matter as originally presented, for example, in a continuation. No new subject matter has been added.

Accordingly, claims 1-5 and 31-51are currently pending. Applicants respectfully submit that all pending claims are in condition for allowance and an indication to that effect is respectfully requested.

Claim Rejections- 35 U.S.C. 103(a) Michelson, Frey, and Kuntz

Claims 1-5, 31-34, and 48-51

Claim 1 and particular dependents were rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,860,973 to Michelson ("Michelson") in view of US Patent 6,830,570 to Frey et al. ("Frey") and US Patent 4,349,921 to Kuntz et al. ("Kuntz"). The Applicants respectfully submit that even if there was an articulated reason that would have prompted a skilled artisan to combine these references as proposed in the Office Action (an issue that is not conceded herein), the proposed combination of Michelson, Frey, and Kuntz would nevertheless fail to disclose all the elements of claim 1.

Unlike claim 1, none of the Michelson, Frey, or Kuntz references discloses "first and second fusion apertures being adjacent to one another and separated by a **medial support extending parallel to said proximal and said distal sides and between said top and bottom surfaces**." Indeed, the Office Action does not contend that Michelson or Kuntz provides such teaching. Instead the Office Action relies on the Frey reference for disclosure of "fusion apertures (1018a, 1018b, 1020a, 1020b) that are adjacent each other and separated by a medial support (1019, 1024)." (*See* Office Action at pp. 3.) Applicants respectfully submit that Frey fails to disclose the claimed structure. Instead, Frey includes "upper openings 1018a and 1018b separated by an **upper strut** 1019," and "lower openings 1020a and 1020b separated by a **lower strut** 1021," neither of which extend between the top and bottom surfaces as required by claim 1. Furthermore, neither of the upper strut or lower strut are parallel to the proximal and distal

ends.

Accordingly, the subject matter of claim 1 is patentable over Michelson, Frey, Kuntz and all other references cited in the record. Dependent claims 2-5, 31-34, and 48-51 are patentable for at least the same reasons as claim 1 and for the additional inventive combinations described therein.

Claims 35-47

Claim 35 and particular dependents were rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Frey and Kuntz. The Applicants respectfully submit that even if there was an articulated reason that would have prompted a skilled artisan to combine these references as proposed in the Office Action (an issue that is not conceded herein), the proposed combination of Michelson, Frey, and Kuntz would nevertheless fail to disclose all the elements of claim 35.

Unlike claim 1, none of the Michelson, Frey, or Kuntz references discloses "first and second fusion apertures being adjacent to one another and separated by a "pair of fusion apertures being separated by a **medial support extending parallel to said proximal and said distal sides and between said top and bottom surfaces**." As noted above, the Office Action does not contend that Michelson or Kuntz provide such a teaching, relying instead upon on the Frey reference. (*See* Office Action at pp. 3.) Applicants respectfully submit that neither of the "**upper strut**" and "**lower strut**" which the Office Action points to for the teaching of a medial support extend between the top and bottom surfaces as required by claim 35. Furthermore, neither of the upper strut or lower strut are parallel to the proximal and distal ends as also required by claim 35.

Accordingly, the subject matter of claim 35 is patentable over Michelson, Frey, Kuntz and all other references cited in the record. Dependent claims 36-47 are patentable for at least the same reasons as claim 1 and for the additional inventive combinations described therein.

Conclusion

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. Applicants specifically reserve the right to pursue the subject matter of independent claims 1 and 35 (prior to amendment herein) in a continuing application.

The foregoing amendments have been submitted to place the present application in condition for allowance. Prompt allowance of claims 1-5 and 31-51 is earnestly solicited. Applicants hereby authorizes a payment of the $555.00 fee for the 3 month Extension of Time Request to be charged to Deposit Account No.: 50-2040 for Customer No.: 30,328. The Applicants have previously paid fees for a total of 26 claims. With the addition of 8 new claims the number of claims now stands at 26. As such, no other fees are believed to be due at this time, however, in the event that there are any additional fees to be charged or payments to be credited, the Applicants 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 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,

Date: March 1, 2010

/Rory Schermerhorn/
Rory Schermerhorn, Esq.
Registration No. 58,148

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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 under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with $0 paid	2253	1	555	555

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**555**

Electronic Acknowledgement Receipt

EFS ID:	7118168
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:	02-MAR-2010
Filing Date:	29-MAR-2005
Time Stamp:	01:12:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$555
RAM confirmation Number	8542
Deposit Account	502040
Authorized User	

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

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

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		104US1RA_3-1-10_f.pdf	53132 8069fa6697d52b08de5a007c3f55e1e6fbf25628	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	10

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	29367 0c3b64b140e2b512f3e8334afa3b8e7213e9dd4b	no	2

Warnings:

Information:

Total Files Size (in bytes):	82499

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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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 05/18/2010

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EXAMINER	
FISHER, ELANA BETH	

ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
05/18/2010	PAPER

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

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

Office Action Summary	Application No.	Applicant(s)	
	11/093,409	CURRAN ET AL.	
	Examiner	Art Unit	
	ELANA B. FISHER	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 *02 March 2010*.

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 and 31-51* is/are pending in the application.

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

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 31-51* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☒ 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 § 103

1. 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.

2. Claims 1-5 and 31-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. Patent 5,860,973) in view of Boriani et al. (U.S. Patent 6,159,211) and Kuntz (U.S. Patent 4,349,921).

Michelson discloses a spinal fusion implant (900) positionable from a lateral approach to extend from one lateral aspect to the other that is generally rectangular in shape and comprising parallel top and bottom surfaces (902, 904) comprising a plurality of ridges (FIG 16), a tapered distal side, a proximal side, and first and second sidewalls (see diagram provided), such that a length extends between the distal and proximal sides, a width extends between the first and second sidewalls, and a height extends between the top and bottom surfaces (902, 904). The length is at least 40mm, the width is at least 15mm and the height is in the range of 8mm to 16mm (Column 10, lines 42-47). Additionally, the implant includes at least one visualization aperture extending through at least one of the first and second sidewalls (FIG 16).

However, Michelson fails to disclose that the spinal fusion implant (900) includes first and second fusion apertures extending between the top and bottom surfaces. Boriani et al. disclose a spinal fusion implant (12) comprising top and bottom surfaces (14, 16)

including first and second fusion apertures (20) that are adjacent to one another and separated by a medial support (28) extending parallel to proximal and distal sides (18) and between the top and bottom surfaces (FIG 1). The apertures are generally rectangular and oblong in shape. It therefore would have been obvious to one skilled in the art to modify the spinal fusion implant taught by Michelson by adding fusion apertures that extend between the top and bottom surfaces, as is taught by Boriani et al., because the apertures and the medial support promote fusion of upper and lower vertebrae to one another via the addition of packed bone graft material (Boriani et al.; Column 4, line 10-13).

Michelson additionally discloses that the implant (900) includes exactly four or six visualization apertures (906) in communication with a first of said fusion apertures from said pair of fusion apertures and exactly four or visualization apertures (906) in communication with a second of said fusion apertures from said pair of fusion apertures. Two or three of said visualization apertures (906) in communication with said first fusion aperture are situated in said first side, two or three of said visualization apertures (906) in communication with said first fusion aperture are situated in said second side, two or three of said visualization apertures (906) in communication with said second fusion aperture are situated in said first side, and two or three of said visualization apertures (906) in communication with said second fusion aperture are situated in said second side (FIG 16; Column 10)

Michelson further fails to disclose that the implant (900) comprises a least one receiving element. Boriani et al. disclose a spinal fusion implant (12) that additionally

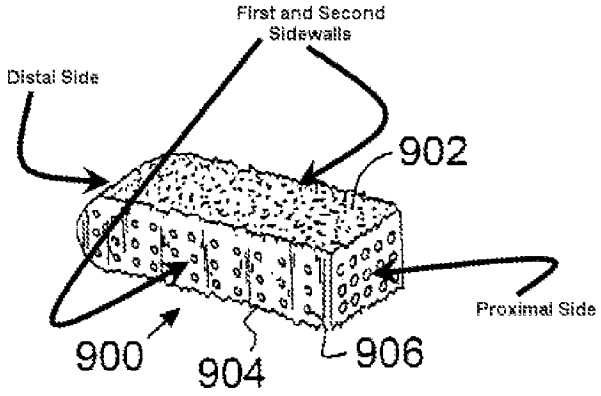
comprising a least one receiving element (22) comprising a threaded aperture engagable with an insertion instrument and a slot extending from the threaded aperture (FIG 7). It therefore would have been obvious to one skilled in the art to modify the implant taught by Michelson by having at least one receiving element along its proximal side, as is taught by Boriani et al., because it allows for an insertion instrument to securely attach to the implant for controlled insertion into the disc space.

Additionally, Michelson fails to disclose the specific material of the implant. Boriani et al. disclose a spinal implant (12) that is made of a radiolucent material (Column 2). Additionally, Kuntz discloses a spinal implant (10) made of a radiolucent material, such as high density polyethylene that additionally comprises a radiopaque marker (Column 7, lines 52-60). It therefore would have been obvious to one skilled in the art to modify the implant taught by Michelson such that it is made up of a radiolucent material and also comprises a radiopaque marker between the top and bottom surfaces, as is taught by Boriani et al. and Kuntz, because the radiolucent material has "high strength and durability" and the radiopaque marker allows for “the position of the posthesis be confirmed radiologically" (Kuntz; Column 7, lines 52-60).

Michelson in view of Boriani et al. and Kuntz further fail to disclose that the length of the implant is at least two and a half times greater that the width of the implant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the length be at least two and a half times greater than the width, since it has been held that discovering an optimum value of a result effective

variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Finally, Michelson in view of Kuntz et al. and Kuntz fail to disclose that the implant is made of one of PEEK and PEKK. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the material of the implant be one of PEEK and PEKK, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.



Response to Arguments

3. Applicant's arguments with respect to claims 1-5 and 31-43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

4. 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 ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

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.

/Elana B Fisher/
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 ELANA B. FISHER	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-5,860,973	01-1999	Michelson, Gary Karlin	606/247
*	B	US-4,349,921	09-1982	Kuntz, J. David	623/17.16
*	C	US-6,830,570	12-2004	Frey et al.	623/17.16
*	D	US-6,113,638	09-2000	Williams et al.	128/898
*	E	US-6,159,211	12-2000	Boriani et al.	606/279
	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	08/16/2009	05/15/2010				
	1	÷	✓	✓	✓	✓				
	2	÷	✓	✓	✓	✓				
	3	÷	✓	✓	✓	✓				
	4	÷	✓	✓	✓	✓				
	5	÷	✓	✓	✓	✓				
	6	÷	✓	-	-	-				
	7	÷	✓	-	-	-				
	8	÷	✓	-	-	-				
	9	÷	✓	-	-	-				
	10	÷	✓	-	-	-				
	11	÷	✓	✓	-	-				
	12	÷	✓	✓	-	-				
	13	÷	✓	✓	-	-				
	14	÷	N	N	-	-				
	15	÷	N	N	-	-				
	16	÷	N	N	-	-				
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	24	÷	N	N	-	-				
	25	÷	N	N	-	-				
	26	÷	N	N	-	-				
	27			✓	-	-				
	28			✓	-	-				
	29			N	-	-				
	30			N	-	-				
	31				✓	✓				
	32				✓	✓				
	33				✓	✓				
	34				✓	✓				
	35				✓	✓				
	36				✓	✓				

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11093409	CURRAN ET AL.
	Examiner	**Art Unit**
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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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CLAIM		DATE								
Final	Original	02/12/2007	02/27/2008	09/12/2008	08/16/2009	05/15/2010				
	37				✓	✓				
	38				✓	✓				
	39				✓	✓				
	40				✓	✓				
	41				✓	✓				
	42				✓	✓				
	43				✓	✓				
	44					✓				
	45					✓				
	46					✓				
	47					✓				
	48					✓				
	49					✓				
	50					✓				
	51					✓				

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
	Above Updated	08/16/2009	EF
	Above Updated	05/15/2010	EF

SEARCH NOTES

Search Notes	Date	Examiner
Inventor Name Search Performed	2/27/2008	JLC
EAST classification search	08/16/2009	EF
EAST citation search	08/16/2009	EF
EAST text search	08/16/2009	EF
IDS reference search in EAST	08/16/2009	EF
Above Updated	05/15/2010	EF

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

/ELANA B FISHER/
Examiner.Art Unit 3733

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Matthew Curran	Art Unit:	3733
Serial No.:	11/093,409	Examiner:	Elana Beth Fisher
Filing Date:	March 29, 2005		
Title:	Systems and Methods for Spinal Fusion		

AMENDMENT AFTER FINAL REJECTION

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

Dear Sir:

In response to the Office Action mailed May 18, 2010, please amend the above-identified application as set forth below. The shortened statutory period for reply was set to expire on August 18, 2010. A petition for extension of time for 1 month is submitted herewith, extending the period for reply to September 18, 2010 (which fell on a Saturday). Accordingly, this response is timely filed.

Amendments to the claims begin on page 2 of this paper.

Applicant Remarks begin on page 8 of this paper.

IN THE CLAIMS:

1. (Currently Amended) 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]] an anterior aspect, and opposing lateral aspects, the implant being positionable from a lateral approach to extend from one lateral aspect to the other, said implant comprising:

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 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 height extending from said top surface to said bottom surface;

wherein said length is at least two and 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 extending parallel to said promixal and said distal sides and between said top and bottom surfaces;

said implant further including at least ~~one~~ three radiopaque ~~marker~~ markers situated between said top and bottom surfaces; wherein a first of the at least three radiopaque markers is disposed within said distal side of the implant, a second of the at least three radiopaque markers

is disposed within said proximal side and a third of the at least three radiopaque markers is disposed within said medial support.

2. (Previously Presented) The spinal fusion implant of Claim 1, wherein said implant is substantially radiolucent and composed of non-bone material.

3. (Previously Presented) The spinal fusion implant of Claim 1, wherein said implant includes at least one visualization aperture extending through at least one of said first side wall and said second side wall.

4. (Previously Presented) The spinal fusion implant 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. (Previously Presented) The spinal fusion implant of Claim 1, wherein said first and second fusion apertures are one of generally rectangular and generally oblong in shape.

6.-30. (Canceled)

31. (Previously Presented) The spinal fusion implant of Claim 1, further including at least one receiving element at least partially defined along said proximal side.

32. (Previously Presented) The spinal fusion implant of Claim 31, wherein said receiving element is engageable with an insertion instrument.

33. (Previously Presented) The spinal fusion implant of Claim 32, wherein said receiving element comprises a threaded aperture.

34. (Previously Presented) The spinal fusion implant of claim 33, wherein said receiving implant further comprises a slot extending from said threaded aperture.

35. (Currently Amended) A spinal fusion implant of non-bone construction ~~postionable~~ positionable via a lateral trans-psoas surgical approach to the spine into a position within an interbody space between a first vertebra and a second vertebra, said interbody space being at least partially defined by a posterior aspect, [[and]] an anterior aspect, and opposing lateral aspects, said implant comprising:

a top surface to contact said first vertebra when said implant is positioned within the interbody space, a bottom surface to contact said second vertebra when said implant is positioned within the interbody space, a distal side, a proximal side, a first side to face said anterior aspect of said disc space when said implant is positioned within the interbody space and a second side to face said posterior aspect of said disc space when said implant is positioned within the interbody space, wherein said implant is generally rectangular in shape having a length extending from said proximal side to said distal side of at least 40mm, a width extending from said first side to said second side of at least 15mm, and a height extending from said top surface to said bottom surface ranging from 8mm to 16mm, said implant further including a pair of fusion apertures comprising one of a generally rectangular and generally oblong shape and extending between said top surface and bottom surface to permit bone growth between the first vertebra and the second vertebra, said pair of fusion apertures being separated by a medial support extending parallel to aid proximal and said distal sides and between said top and bottom surfaces, said implant further including [[a]] at least ~~one~~ three radiopaque ~~marker~~ markers situated between said top and bottom surfaces; wherein a first of the at least three radiopaque markers is disposed within said distal side, a second of said at least three radiopaque markers is disposed within said proximal side and a third of said at least three radiopaque markers is disposed within said medial support.

36. (Previously Presented) The implant of Claim 31, wherein said non-bone material is one of PEEK and PEKK.

37. (Previously Presented) 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. (Previously Presented) The implant of Claim 31, wherein a portion of said implant adjacent said distal side is tapered.

39. (Previously Presented) 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. (Previously Presented) The spinal fusion implant of Claim 35, further including at least one receiving element at least partially defined along said proximal side.

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

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

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

44. (Previously Presented) The spinal fusion implant of Claim 37, wherein said spinal fusion implant includes exactly four visualization apertures in communication with a first of said fusion apertures from said pair of fusion apertures and exactly four visualization apertures in communication with a second of said fusion apertures from said pair of fusion apertures.

45. (Previously Presented) The spinal fusion implant of Claim 44, wherein two of said visualization in communication with said first fusion aperture are situated in said first side, two of said fusion apertures in communication with said first fusion aperture are situated in said second side, two of said visualization apertures in communication with said second fusion

aperture are situated in said first side, and two of said fusion apertures in communication with said second fusion aperture are situated in said second side.

46. (Previously Presented) The spinal fusion implant of Claim 37, wherein said spinal fusion implant includes exactly six visualization apertures in communication with a first of said fusion apertures from said pair of fusion apertures and exactly six visualization apertures in communication with a second fo said fusion apertures from said pair of fusion apertures.

47. (Previously Presented) The spinal fusion implant of Claim 46, wherein three of said visualization apertures in communication with said first fusion aperture are situated in said first side, three of said fusion apertures in communication with said first fusion aperture are situated in said second side, three of said visualization apertures in communication with said second fusion aperture are situated in said first side, and three of said fusion apertures in communication with said second fusion aperture are situated in said second side.

48. (Previously Presented) The spinal fusion implant of claim 1, wherein said spinal fusion implant includes exactly four visualization apertures in communication with said first fusion aperture and exactly four visualization apertures in communication with said second fusion aperture.

49. (Previously Presented) The spinal fusion implant of claim 48, wherein two of said visualization apertures in communication with said first fusion aperture are situated in said first side, two of said fusion apertures in communication with said first fusion aperture are situated in said second side, two of said visualization apertures in communication with said second fusion aperture are situated in said first side, and two of said fusion apertures in communication with said second fusion aperture is situated in said second side.

50. (Currently Amended) The spinal fusion implant of Claim 1, wherein said spinal fusion implant includes exactly six visualization apertures in communication with said first fusion aperture and exactly six visualization apertures in communication with said second fusion aperture.

51. (Previously Presented) The spinal fusion implant of Claim 50, wherein three of said visualization apertures in communication with said first fusion aperture are situated in said first side, three of said fusion apertures in communication with said first fusion aperture are situated in said second side, three of said visualization apertures in communication with said second fusion aperture are situated in said first side, and three of said fusion apertures in communication with said second fusion aperture are situated in said second side.

REMARKS

In the Office Action mailed May 18, 2010, (the "Office Action"), claims 1-5 and 31-51 were rejected.

Claims 1-5 and 31-51 are currently pending. The independent claims have been amended to expediently advance prosecution on the merits without prejudice to pursue the subject matter as originally presented, for example, in a continuation. Applicants respectfully submit that all pending claims are in condition for allowance and an indication to that effect is respectfully requested.

Claim rejections – 35 U.S.C. § 103(a)

Claims 1-5 and 31-51 were rejected under 35 USC §103(a) as being unpatentable over Michelson (US Patent 5,860,973) in view of Boriani et al. (US Patent 6,159,211) and Kuntz (US Patent 4,349,921) for reasons as set forth in detail on pages 2-5 of the Office Action. The instant amendment addresses this issue.

The claims have been amended to include at least three radiopaque markers, a first disposed within the distal side of the implant, a second disposed within the proximal side of the implant and a third within the medial support portion of the implant. Support for the amendments can be found, for example, on pages 13-14 of the specification as filed and Fig. 21. Applicants respectfully submit that the Michelson reference does not teach a spinal fusion implant, positionable from a lateral approach to extend from one lateral aspect of an interbody space to the other, having at least three radiopaque markers disposed within the distal, proximal and medial portions of the implant, respectively. Further, neither the Boriani nor the Kuntz reference cures this defect. Therefore, Applicant respectfully requests that the rejection under 35 USC §103(a) be properly withdrawn.

CONCLUSION

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. 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 attorney of record so that prosecution may be expedited.

Respectfully submitted,
NUVASIVE, INC.

By: /Jennifer Risser/
Jennifer Risser, Esq.
Registration No. 60,059
Tel. (858) 320-4537

7475 Lusk Boulevard
San Diego, CA 92121

September 20, 2010

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:	Jennifer Lynn Risser
Attorney Docket Number:	104US1

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	65	65

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**65**

Electronic Acknowledgement Receipt

EFS ID:	8458355
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:	Jennifer Lynn Risser
Filer Authorized By:	
Attorney Docket Number:	104US1
Receipt Date:	20-SEP-2010
Filing Date:	29-MAR-2005
Time Stamp:	20:34:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$65
RAM confirmation Number	6387
Deposit Account	502040
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Transmittal Letter	2010-09-20-Transmittal104US1.pdf	262380 6a22bb5cb2864721afb79f6ff43bda127ff76c32	no	2
Warnings:					
Information:					
2	Extension of Time	2010-09-20-EOT104US1.pdf	302065 3cf477b4da855371a4ce41375643514be62a7c63	no	2
Warnings:					
Information:					
3		2010-09-20-RAF104US1.pdf	45731 2f0107523521acb861ffa11a29bdb17e54d51c3a	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment After Final	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	9

Warnings:					
Information:					
4	Fee Worksheet (PTO-875)	fee-info.pdf	29480 f5fe3a6da103a773a3c70ff89acbd284c3dc9e99	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	639656	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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 displays a valid OMB control number.

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	3733
Examiner Name	Elana Beth Fisher
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

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	NuVasive Inc.		
Signature	/Jennifer Risser/		
Printed name	Jennifer Risser		
Date	September 20, 2010	Reg. No.	60,059

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		Date	

Privacy Act Statement

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

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

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

PTO/SB/22 (07-09)
Approved for use through 07/31/2012. 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 2009** (*Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).*)	Docket Number (Optional)
Application Number	Filed
For	
Art Unit	Examiner

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))	$130	$65	$_____
☐ Two months (37 CFR 1.17(a)(2))	$490	$245	$_____
☐ Three months (37 CFR 1.17(a)(3))	$1110	$555	$_____
☐ Four months (37 CFR 1.17(a)(4))	$1730	$865	$_____
☐ Five months (37 CFR 1.17(a)(5))	$2350	$1175	$_____

☐ 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 _____.

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.

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 _____

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

_____ _____
Signature Date

_____ _____
Typed or printed name 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.

This collection of information is required by 37 CFR 1.136(a). 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 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Privacy Act Statement

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

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

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

PTO/SB/22 (07-09)
Approved for use through 07/31/2012. 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 2009** *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)*	Docket Number (Optional) 104451
Application Number 11/093,409	Filed
For Systems and methods for spinal fusion	
Art Unit 3733	Examiner

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))	$130	$65	$ 65
☐ Two months (37 CFR 1.17(a)(2))	$490	$245	$
☐ Three months (37 CFR 1.17(a)(3))	$1110	$555	$
☐ Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐ Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☐ 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.

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.

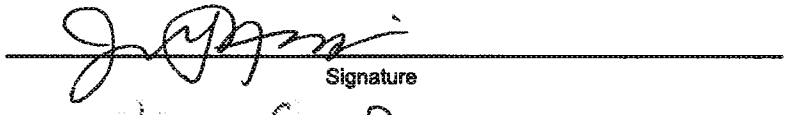
I am the

☐ 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 60,859

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____


Signature

9/20/2010
Date

Jennifer Risser
Typed or printed name

858-320-4537
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 1 forms are submitted.

Electronic Acknowledgement Receipt

EFS ID:	8458447
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:	Jennifer Lynn Risser
Filer Authorized By:	
Attorney Docket Number:	104US1
Receipt Date:	20-SEP-2010
Filing Date:	29-MAR-2005
Time Stamp:	20:57:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Extension of Time	2010-09-20-EOT104US1.pdf	40855 65e8593bfefbc152c79e521b5c531de16bcdabc9	no	1

Warnings:

The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing	
Information:	
Total Files Size (in bytes):	40855

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/093,409	Filing Date 03/29/2005	☐ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ 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	09/20/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 26	Minus	** 26	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	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 ($)	ADDITIONAL FEE ($)		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:
/DAWN BREWER/

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

30328 7590 10/08/2010

NuVasive
c/o CPA Global
P.O. Box 52050
Minneapolis, MN 55402

EXAMINER	
FISHER, ELANA BETH	

ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
10/08/2010	PAPER

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

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

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 11/093,409	**Applicant(s)** CURRAN ET AL.	
	Examiner ELANA B. FISHER	**Art Unit** 3733	

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

THE REPLY FILED 20 September 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

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

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-5 and 31-51*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

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

/Elana B Fisher/
Examiner, Art Unit 3733

Continuation of 3. NOTE: The amendments to claims 1 and 35 setting first that there are three radiopaque markers along with the positions of the three radiopaque markers on the implant raise new issues that require further search and considereation.

DO NOT ENTER: /E.F./

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Matthew Curran	Art Unit:	3733
Serial No.:	11/093,409	Examiner:	Elana Beth Fisher
Filing Date:	March 29, 2005		
Title:	Systems and Methods for Spinal Fusion		

AMENDMENT AFTER FINAL REJECTION

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

Dear Sir:

In response to the Office Action mailed May 18, 2010, please amend the above-identified application as set forth below. The shortened statutory period for reply was set to expire on August 18, 2010. A petition for extension of time for 1 month is submitted herewith, extending the period for reply to September 18, 2010 (which fell on a Saturday). Accordingly, this response is timely filed.

Amendments to the claims begin on page 2 of this paper.

Applicant Remarks begin on page 8 of this paper.

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. 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	11093409	Filing Date	2005-03-29	Docket Number (if applicable)	104US1	Art Unit	3733
First Named Inventor	Matthew Curran			Examiner Name	Elana Beth Fisher		

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 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Jennifer Risser/	Date (YYYY-MM-DD)	2010-11-18
Name	Jennifer Risser	Registration Number	60059

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.

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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 records.

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Matthew Curran	Art Unit:	3733
Serial No.:	11/093,409	Examiner:	Elana Beth Fisher
Filing Date:	March 29, 2005		
Title:	Systems and Methods for Spinal Fusion		

AMENDMENT AFTER FINAL REJECTION

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

Dear Sir:

In response to the Advisory Action mailed October 8, 2010 and the Office Action mailed May 18, 2010, please amend the above-identified application as set forth below. The shortened statutory period for reply was set to expire on August 18, 2010. A petition for extension of time for 3 month is submitted herewith, extending the period for reply to November 18, 2010. Accordingly, this response is timely filed.

Amendments to the claims begin on page 2 of this paper.

Applicant Remarks begin on page 8 of this paper.

IN THE CLAIMS:

1. (Currently Amended) 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]] an anterior aspect, and opposing lateral aspects, the implant being positionable from a lateral approach to extend from one lateral aspect to the other, said implant comprising:

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 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 height extending from said top surface to said bottom surface;

wherein said length is at least two and 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 extending parallel to said promixal and said distal sides and between said top and bottom surfaces;

said implant further including at least ~~one~~ three radiopaque ~~marker~~ markers situated between said top and bottom surfaces; wherein a first of the at least three radiopaque markers is disposed within said distal side of the implant, a second of the at least three radiopaque markers

is disposed within said proximal side and a third of the at least three radiopaque markers is disposed within said medial support.

2. (Previously Presented) The spinal fusion implant of Claim 1, wherein said implant is substantially radiolucent and composed of non-bone material.

3. (Previously Presented) The spinal fusion implant of Claim 1, wherein said implant includes at least one visualization aperture extending through at least one of said first side wall and said second side wall.

4. (Previously Presented) The spinal fusion implant 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. (Previously Presented) The spinal fusion implant of Claim 1, wherein said first and second fusion apertures are one of generally rectangular and generally oblong in shape.

6.-30. (Canceled)

31. (Previously Presented) The spinal fusion implant of Claim 1, further including at least one receiving element at least partially defined along said proximal side.

32. (Previously Presented) The spinal fusion implant of Claim 31, wherein said receiving element is engageable with an insertion instrument.

33. (Previously Presented) The spinal fusion implant of Claim 32, wherein said receiving element comprises a threaded aperture.

34. (Previously Presented) The spinal fusion implant of claim 33, wherein said receiving implant further comprises a slot extending from said threaded aperture.

35. (Currently Amended) A spinal fusion implant of non-bone construction ~~postionable~~ positionable via a lateral trans-psoas surgical approach to the spine into a position within an interbody space between a first vertebra and a second vertebra, said interbody space being at least partially defined by a posterior aspect, [[and]] an anterior aspect, and opposing lateral aspects, said implant comprising:

a top surface to contact said first vertebra when said implant is positioned within the interbody space, a bottom surface to contact said second vertebra when said implant is positioned within the interbody space, a distal side, a proximal side, a first side to face said anterior aspect of said disc space when said implant is positioned within the interbody space and a second side to face said posterior aspect of said disc space when said implant is positioned within the interbody space, wherein said implant is generally rectangular in shape having a length extending from said proximal side to said distal side of at least 40mm, a width extending from said first side to said second side of at least 15mm, and a height extending from said top surface to said bottom surface ranging from 8mm to 16mm, said implant further including a pair of fusion apertures comprising one of a generally rectangular and generally oblong shape and extending between said top surface and bottom surface to permit bone growth between the first vertebra and the second vertebra, said pair of fusion apertures being separated by a medial support extending parallel to aid proximal and said distal sides and between said top and bottom surfaces, said implant further including [[a]] at least ~~one~~ three radiopaque ~~marker~~ markers situated between said top and bottom surfaces; wherein a first of the at least three radiopaque markers is disposed within said distal side, a second of said at least three radiopaque markers is disposed within said proximal side and a third of said at least three radiopaque markers is disposed within said medial support.

36. (Previously Presented) The implant of Claim 31, wherein said non-bone material is one of PEEK and PEKK.

37. (Previously Presented) 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. (Previously Presented) The implant of Claim 31, wherein a portion of said implant adjacent said distal side is tapered.

39. (Previously Presented) 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. (Previously Presented) The spinal fusion implant of Claim 35, further including at least one receiving element at least partially defined along said proximal side.

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

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

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

44. (Previously Presented) The spinal fusion implant of Claim 37, wherein said spinal fusion implant includes exactly four visualization apertures in communication with a first of said fusion apertures from said pair of fusion apertures and exactly four visualization apertures in communication with a second of said fusion apertures from said pair of fusion apertures.

45. (Previously Presented) The spinal fusion implant of Claim 44, wherein two of said visualization in communication with said first fusion aperture are situated in said first side, two of said fusion apertures in communication with said first fusion aperture are situated in said second side, two of said visualization apertures in communication with said second fusion

aperture are situated in said first side, and two of said fusion apertures in communication with said second fusion aperture are situated in said second side.

46. (Previously Presented) The spinal fusion implant of Claim 37, wherein said spinal fusion implant includes exactly six visualization apertures in communication with a first of said fusion apertures from said pair of fusion apertures and exactly six visualization apertures in communication with a second fo said fusion apertures from said pair of fusion apertures.

47. (Previously Presented) The spinal fusion implant of Claim 46, wherein three of said visualization apertures in communication with said first fusion aperture are situated in said first side, three of said fusion apertures in communication with said first fusion aperture are situated in said second side, three of said visualization apertures in communication with said second fusion aperture are situated in said first side, and three of said fusion apertures in communication with said second fusion aperture are situated in said second side.

48. (Previously Presented) The spinal fusion implant of claim 1, wherein said spinal fusion implant includes exactly four visualization apertures in communication with said first fusion aperture and exactly four visualization apertures in communication with said second fusion aperture.

49. (Previously Presented) The spinal fusion implant of claim 48, wherein two of said visualization apertures in communication with said first fusion aperture are situated in said first side, two of said fusion apertures in communication with said first fusion aperture are situated in said second side, two of said visualization apertures in communication with said second fusion aperture are situated in said first side, and two of said fusion apertures in communication with said second fusion aperture is situated in said second side.

50. (Currently Amended) The spinal fusion implant of Claim 1, wherein said spinal fusion implant includes exactly six visualization apertures in communication with said first fusion aperture and exactly six visualization apertures in communication with said second fusion aperture.

51. (Previously Presented) The spinal fusion implant of Claim 50, wherein three of said visualization apertures in communication with said first fusion aperture are situated in said first side, three of said fusion apertures in communication with said first fusion aperture are situated in said second side, three of said visualization apertures in communication with said second fusion aperture are situated in said first side, and three of said fusion apertures in communication with said second fusion aperture are situated in said second side.

REMARKS

In the Office Action mailed May 18, 2010, (the "Office Action"), claims 1-5 and 31-51 were rejected.

Claims 1-5 and 31-51 are currently pending. The independent claims have been amended to expediently advance prosecution on the merits without prejudice to pursue the subject matter as originally presented, for example, in a continuation. Applicants respectfully submit that all pending claims are in condition for allowance and an indication to that effect is respectfully requested.

Claim rejections – 35 U.S.C. § 103(a)

Claims 1-5 and 31-51 were rejected under 35 USC §103(a) as being unpatentable over Michelson (US Patent 5,860,973) in view of Boriani et al. (US Patent 6,159,211) and Kuntz (US Patent 4,349,921) for reasons as set forth in detail on pages 2-5 of the Office Action. The instant amendment addresses this issue.

The claims have been amended to include at least three radiopaque markers, a first disposed within the distal side of the implant, a second disposed within the proximal side of the implant and a third within the medial support portion of the implant. Support for the amendments can be found, for example, on pages 13-14 of the specification as filed and Fig. 21. Applicants respectfully submit that the Michelson reference does not teach a spinal fusion implant, positionable from a lateral approach to extend from one lateral aspect of an interbody space to the other, having at least three radiopaque markers disposed within the distal, proximal and medial portions of the implant, respectively. Further, neither the Boriani nor the Kuntz reference cures this defect. Therefore, Applicant respectfully requests that the rejection under 35 USC §103(a) be properly withdrawn.

CONCLUSION

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. 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 attorney of record so that prosecution may be expedited.

Respectfully submitted,
NUVASIVE, INC.

By: /Jennifer Risser/
Jennifer Risser, Esq.
Registration No. 60,059
Tel. (858) 320-4537

7475 Lusk Boulevard
San Diego, CA 92121

November 18, 2010

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:	Jennifer Lynn Risser
Attorney Docket Number:	104US1

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with $65 paid	2253	1	490	490

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**895**

Electronic Acknowledgement Receipt

EFS ID:	8871978
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:	Jennifer Lynn Risser
Filer Authorized By:	
Attorney Docket Number:	104US1
Receipt Date:	18-NOV-2010
Filing Date:	29-MAR-2005
Time Stamp:	21:26:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$895
RAM confirmation Number	7957
Deposit Account	502040
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Transmittal Letter	2010-11-18-Transmittal104US1.pdf	262867 e567d5e1cabd243aeaed42b009637b30e3f14f64	no	2
Warnings:					
Information:					
2	Extension of Time	2010-11-18-EOT104US1.pdf	312838 aada0834477ffb8412774b19a0941493f7585542	no	2
Warnings:					
Information:					
3	Request for Continued Examination (RCE)	2010-11-18-RCERequest104US1.pdf	797439 a8057427f27f20d04dbfacca544c936919397055	no	3
Warnings:					
Information:					
4		2010-11-18-RCEResponse104US1.pdf	45226 d8910359c2426392b5bba05e6b6df331808ed828	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment After Final	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	9

Warnings:					
Information:					
5	Fee Worksheet (PTO-875)	fee-info.pdf	31533 d193c6d197f66b2eb799d447056a950d45252b8a	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1449903	

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	12

Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Art Unit	3733
Examiner Name	Elana Beth Fisher
Attorney Docket Number	104US1

ENCLOSURES (*Check all that apply*)

- [x] Fee Transmittal Form
  - [x] Fee Attached
- [x] Amendment/Reply
  - [x] After Final
  - [ ] Affidavits/declaration(s)
- [x] 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
- [x] Other Enclosure(s) (please Identify below):

Request for Continued Examination

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	NUVASIVE INC.		
Signature	/Jennifer Risser/		
Printed name	Jennifer Risser		
Date	November 18, 2010	Reg. No.	60,059

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		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

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

PTO/SB/22 (07-09)
Approved for use through 07/31/2012. 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 2009** (*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 3733	Examiner Elana Beth Fisher

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))	$130	$65	$
☐	Two months (37 CFR 1.17(a)(2))	$490	$245	$
☑	Three months (37 CFR 1.17(a)(3))	$1110	$555	$ 555
☐	Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐	Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☑ 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.

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.

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 60,059

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/Jennifer Risser/ — Signature

November 18, 2010 — Date

Jennifer Risser — Typed or printed name

858-320-4537 — 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 1 forms are submitted.

Privacy Act Statement

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

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

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

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/093,409	Filing Date 03/29/2005	☐ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ 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))							
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Filing Date	2005-03-29
First Named Inventor	Matthew Curran
Art Unit	3733
Examiner Name	Elana Beth Fisher
Attorney Docket Number	104US1

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	2	4501269		1985-02-26	Bagby	
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	4	5015247		1991-05-14	Michelson	
	5	5047055		1991-09-10	Bao et al.	
	6	5192327		1993-03-09	Brantigan	
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	9	5489307		1996-02-06	Kuslich et al.	
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	11	4545374		1985-10-08	Jacobson	
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	1	90/00037	WO		1990-01-11	Michelson		☐
	2	92/14423	WO		1992-09-03	Pisharodi		☐

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	1	BAULOT et al. "Complementary anterior spondylodesis by thoracoscopy. Technical note regarding an observation," Technical Designs and Experimental Research, 90(5):347-351 (1994).	☐
	2	BERRY et al. "A morphometric study of human lumbar and selected thoracic vertebrae, study of selected vertebrae" (1986)	☐
	3	CROCK, H.V., "Anterior Lumber Interbody Fusion" Clinical Orthopaedics & Related Research (1982)	☐
	4	CROCK, H.V., "A short practice of spinal surgery," Published 1993 by Spinger-Verlag/Wien, New York	☐
	5	EDELAND, H.G. "Some additional suggestions for a intervertebral disck prosthesis" 7 Journal of Biomedical Engineering 57 (1985)	☐
	6	KEMP, H.B.S. "Anterior fusion of the spine for infective lesions in adults" 55B Journal of Bone & Joint Surgery 715 (1973)	☐
	7	NUVASIVE, INC. Corrected Final Invalidity Contentions Regarding US Patent Nos. 5,860,973, 6,592,586 and 6,945,933 filed in the United States District Court Southern District of California on June 14, 2010 (and 23 Appendices)	☐

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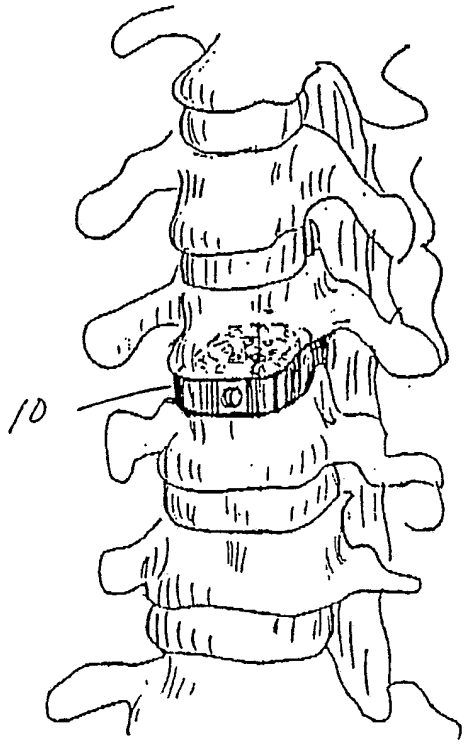

(57) Abstract

A spinal implant (10) is disclosed which when placed within the spinal disc space stabilizes that spinal segment and materially participates in, and is incorporated in the ensuing fusion.

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ARTIFICIAL SPINAL FUSION IMPLANTS

Background

The present invention relates to an artificial fusion implant to be placed into the intervertebral space left after the removal of a damaged spinal disc.

The purpose of the present invention is to provide an implant to be placed within the intervertebral disc space and provide for the permanent elimination of all motion at that location. To do so, the device is space occupying within the disc space, rigid, self-stabilizing to resist dislodgement, stabilizing to the adjacent spinal vertebrae to eliminate local motion, and able to intrinsically participate in a vertebra to vertebra bony fusion so as to assure the permanency of the result.

At present, following the removal of a damaged disc, either bone or nothing is placed into the spacea left. If nothing is placed in the space the space may collapse which may result in damage to the nerves; or the space may fill with scar tissue and eventually lead to a reherniation. The use of bone is less than optimal in that the bone obtained from the patient requires additional surgery and is of limited availability in its most useful form, and if obtained elsewhere, lacks living bone cells, carries a significant risk of infection, and is also limited in supply as it is usually obtained elsewhere, lacks living bone cells, carries a significant risk of infection, and is also limited in supply as it is usually obtained from young accident victims. Furthermore, regardless of the source of the bone, it is only marginal structurally and lacks a means to either stabilize itself, against dislodgement, or to stabilize the adjacent vertebrae.

A review of all possibly related prior art will demonstrate the novelty of the present invention.

There have been an extensive number of attempts to develop an acceptable disc prothesis (an artificial

disc). Such devices by design would be used to replace a damaged disc and seek to restore the height of the interspace and to restore the normal motion of that spinal joint. No such device has been found that is medically acceptable. This group of prosthetic or artificial disc replacements seeking to preserve spinal motion which are different from the present invention include:

Patent No. 3,867,728 STUBSTAD - describing a flexible disc implant.

Patent No. 4,349,921 KUNTZ - describing a flexible disc replacement with rope or file like surface projections to discourage device dislocation.

Patent No. 4,309,777 PATIL - describing motion preserving implant with spike outer surfaces to resist dislocation and containing a series of springs to urge the vertebrae away from each other.

Patent No. 3,875,595 FRONING - describing a motion preserving bladder like disc replacement with two opposed stud like projections to resist dislocation.

Patent No. 2,372,622 FRENCH (FASSIO) - describing a motion preserving implant comprising complimentary opposed convex and concave surfaces.

In summary then, these and other similar devices resemble the present invention only in that they are placed within the intervertebral space following the removal of a damaged disc. In that thy seek to preserve spinal motion, they are diametrically different from the present invention which seeks to permanently eliminate all motion at that spinal segment.

A second related area of prior art includes those devices utilized to replace essentially wholly removed vertebrae. Such removal is generally necessitated by extensive vertebral fractures, or tumors, and is not associated with the treatment of disc disease, or therefore related to the present invention. While the present invention is to be placed within the disc space, these prior devices cannot be placed within the disc space as at least one vertebrae has already been removed and there no longer remains a "disc space." Furthermore, all of these devices are limited in that they seek to perform as

temporary structural members mechanically replacing the removed vertebrae (not a removed disc), and do not intrinsically participate in supplying osteogenic material to achieve cross vertebrae bony fusion. Therefore, again unlike the present invention which provides for a source of osteogenesis, use of this group of devices must be accompanied by a further surgery consisting of a bone fusion procefure utilizing conventional technique. This group consisting of vertebral struts rather than disc replacements would include the following:

Patent No. 4,553,273 WU - describing a turnbuckle like vertebral strut.

Patent No. 4,401,112 REZAIAN - describing a turnbuckle like vertebral strut with the addition of a long stabilizing staple that spans the missing vertebral body.

Patent No. 4,554,914 KAPP - describing a large distractible spike that elongates with a screw mechanism to span the gap left by the removal of a entire vertebrae and to serve as an anchor for acrylic cement which is then used to replace the missing bone (vertebrae).

Patent No. 4,636,217 OGILVIE - describing a vertebral strut mechanism that can be implanted after at least one vertebrae has been removed and which device consists of a mechanism for causing the engagement of screws into the vertebrae above the vertebrae below the one removed.

In summary then, this group of devices differs from the present invention in that they are vertebral replacements struts, do not intrinsically participate in the bony fusion, can only be inserted in the limited circumstances where an entire vertebrae has been removed from the anterior approach, and are not designed for, or intended to be used for the treatment of disc disease.

A third area of prior art related to the present invention includes all devices designed to be applied to one of the surfaces of the spine. Such devices include all types of plates, struts, and rods which are attached by hooks, wires, and screws. These devices differ significantly from the present invention in that they are not inserted within the disc space, and furthermore do not

intrinsically participate in supplying osteogenic material for the fusion.

Therefore, with these devices where permanent spinal immobilization is desired an additional surgery consisting of a spinal fusion performed by conventional means or the use of supplemental methylmethacrylate cement is required. Such devices, applied to the spine but not within the disc space, would include the following:

Patent No. 4,604,995 - STEPHENS - describing a "U" shaped metal rod attached to the posterior elements of the spine with wires to stabilize the spine over a large number of segments.

Patent No. 2,677,369 - KNOWLES - describing a metal column device to be placed posteriorly along the lumbar spine to be held in position by its shape alone and to block pressure across the posterior portions of the spinal column by locking the spine in full flexion thereby shifting the miximum weight back onto the patient's own disc.

Other devices are simply variations on the use of rods (e.g. Harrington, Luque, Cotrel-Dubosset, Zielke), wires or cables (Dwyer), plates and screws (Steffee), or struts (Dunn, Knowles).

In summary, none of these devices are designed for or can be used within the disc space, do not replace a damaged disc, and do not intrinsically participate in the generation of a bony fusion.

Other prior art possibly related to the present invention and therefore, to be considered related to "Bony Ingrowth". Patents related to this feature describe either methods of producing materials or devices to achieve the same. Such patents would include:

Patents No. 4,636,526 (DORMAN), No. 4,634,720 (DORMAN), No. 4,542,539 (ROWE), No. 4,405,319 (COSENTINO), No. 4,439,152 (SMALL), No. 4,168,326 (BROEMER), No. 4,535,485 (ASHMAN), No. 3,987,499 (SCHARBACH), No. 3,605,123 (HAHN), No. 4,655,777 (DUNN), No. 4,645,503 (LIN), No. 4,547,390 (ASHMAN), No. 4,608,052 (VAN KAMPEN), No. 4,698,375 (DORMAN), No. 4,661,536 (DORMAN), No. 3,952,334 (BOKROS), No. 3,905,047 (LONG), No. 4,693,721

(DUCHEYNE), No. 4,070,514 (ENTHERLY).

However, while the present invention would utilize bone ingrowth technology, it would do so with conventional technology.

The final area of related prior art to be considered is that of devices designed to be placed within the vertebral interspace following the removal of a damaged disc, and seeking to eliminate further motion at that location.

Such a device is contained in Patent No. 4,501,269 BAGBY describing an implantable device, limited instrumentation, and a method; whereby a hole is bored transversely across the joint and then a hollow metal basket of larger diameter is then pounded into the hole and then filled with the bone debris generated by the drilling. The present invention differs from the prior art devices in the following ways:

1. UNIVERSAL APPLICABILITY WITHOUT CONTOURING OF THE INTERSPACE. The present device will fit any patient, anywhere throughout the spine, in any intervertebral disc space, and without alteration of that interspace regardless of its natural size or shape.

2. RESTORATION AND PRESERVATION OF THE INTERSPACE. The present invention will restore the intervertebral space to its premorbid dimensions, and do so by having the implant fit the space rather than having to modify the interspace, by bone removal from the vertebrae, to accommodate the implant.

3. END PLATE PRESERVATION. Preservation of the highly specialized weight bearing cortical bone is allowed and end plate perforation into the highly vascular cancellous bone marrow with its attendant bleeding is avoided. Such bleeding, when it occures, bears all the risks of blood loss (e.g. hypoglycemic shock, transfusion transmitted diseases such as hepatitis and acquired immune deficiency syndrome, etc.), and all the complications arising from the resultant impaired visualization of the vital structures (e.g. nerves, blood vessels, and organs due to such bleeding.

4. TECHNIQUE. The technique for insertion of

these implants is consistent with the established methods of disc removal, and requires neither specialized instrumentation nor specialized surgical technique.

5. EXTENT OF DISC REMOVAL. The extent of disc removal can be determined by the surgeon at the time surgery and can be individualized for each patient.

6. NO DRILLING. No drilling is involved with the use of the present invention.

7. ELIMINATION OF INCORRECT IMPLANT SIZE SELECTION. In those implant systems where a drill is used and significant bone is removed then an estimate of the implant size must first be made, and then, regardless of the fit, an implant at least as large as the space created by the drilling must be utilized, regardless of the quality of that fit. With the present invention no significant bone is removed, and the correct size implants are fitted directly to the interspace eliminating the need to guess at the correct implant size before the fact.

8. MODULAR DESIGN. The present implants are available in varying lengths to accommodate the changing depths of the interspace from central to lateral. The devices are available in varying heights or are infinitely adjustable as to the height within the physiological range. The widths are standardized, and the various embodiments can be used in any combination (e.g. in the lumbar spine two auto-expanding implants could be used in conjunction with two anchor deploying implants to completely fill the interspace).

9. AVOIDANCE OF SIZE LIMITATIONS. Because in one embodiment the system is modular, component parts can be inserted through a very small opening until a much larger implant is reconstituted completely filling the available interspace; and yet much larger when assembled than the opening through which the component modular sections were introduced. For example, in the lumbar spine four implants introduced one at a time and measuring 8mm in width, would when reconstituted within the interspace constitute a 32mm wide implant. Implantation of a single implant of those dimensions from a posterior approach in the lumbar spine would otherwise be impossible because of

the presence of the dural sac and spinal nerves.

10. THE AVOIDANCE OF INTERSPACE COLLAPSE. The device is many times stronger than bone and will not collapse. The implantation of the device allows preservation of the very strong vertebral cortex, which is resistant to compression preventing the migration of the implant into the vertebrae. The large surface area of the assembled modular implant, minimizes the load per unit area. For example, a reconstituted lumbar implant of four modular components would have the weight distributed over approximately 8 sq. cm. per vertebral interface.

11. REMOVABILITY. Because the present invention is an interspace implant and not a "through vertebrae" cross interspace implant, removal of the implant, should that become necessary, would not result in iatrogenic destruction of the adjacent vertebrae.

12. SELF-STABILIZING. The implant is self-stabilizing without the use of threads. All of the implants are surface configured to resist dislodgement and the preferred embodiments contain active, mechanical means to assure permanent anchoring. Long term stability begins with the above and is further enhanced by surface treating of the implant for bone ingrowth (by known conventional means) and osteogenically loading the implants.

13. SPINE REDUCING. Various embodiments of the present invention such as the ones with the 180 degree opposed ratcheted surface, and the auto-expanding type, are capable of reducing a vertebral listheses (a forward or backward translation of one vertebrae upon another).k

14. SPINAL STABILITY. These implants are capable of stabilizing a spial segment following disc removal, and do so without the use of threads (threads would be design need to violate the vertebrae themselves extensively).

15. SAFETY. The entire procedure is performed under direct vision and with complete visualization of the adjacent vital structures (e.g. organs, neural structures and blood vessels).

In summary then, the present invention is an interspace implant utilized to replace a damaged disc, which unlike an artificial disc, seeks to permanently

eliminate rather than to preserve spinal motion, and to do so by a bony fusion. The present invention is clearly an improvement over the prior art providing an interspace implant intrinsically participating in the fusion process, self-stabilizing, stabilizing to the spinal segment, consistent with conventional methods of discectomy, and uniquely consistent with the preservation of the integrity of the adjacent vertebrae.

BRIEF SUMMARY OF THE PRESENT INVENTION

The present invention comprises an artificial implant, the purpose of which is to participate in, and directly cause bone fusion across an intervertebral space following the excision of a damaged disc. Said implants are structurally load bearing devices, stronger than bone, capable of withstanding the substantial forces generated within the spinal interspace. Such devices have a plurality of macro sized cells and openings of 1-3mm, which can be loaded with fusion promoting materials, such as autogenous bone, for the purpose of materially influencing the adjacent vertebrae to perform a bony bond to the implants and to each other. The implant casing may be surface textured or otherwise treated by any of a number of known technologies to achieve a "bone ingrowth surface" to further enhance the stability of the implant and to expedite the fusion. Further, said devices are so configured and designed so as to promote their own stability within the vertebral interspace to resist dislodgement, and furthermore, to stabilize the adjacent vertebrae.

To use the implant of the present invention a conventional discectomy is performed and the vertebral endplates scraped, but not perforated. The appropriately sized implants are loaded with autogenous bone and implanted within the interspace.

For example for an anterior cervical device implantation, a short transverse incision is made across the front of the neck and to the right of the midline directly over the diseased disc. The platysma muscle is split, and the sternocleidomastoid muscle with is split, and the sternocleidomastoid muscle with the carotid sheath

is protected and retracted laterally. The esophagus, trachea and associated midline structures are protected and retracted medically, thus exposing the anterior aspect of the cervical spine. The diseased disc is identified and removed by conventional surgical methods. The adjacent vertebral endplates are gently scraped free of any remaining cartilage until diffuse fine punctuate decortication is achieved. The dimensions of the interspace are then measured in mild distraction, and the appropriate implant selected. Cancellous bone, obtained from the patient's iliac crest or the equivalent, is loaded into the implant. The safety driver is then utilized to insert the implant behind the anterior lips of the vertebrae. The wound is then closed in the routine manner.

Objects of the Present Invention

It is an object of the present invention to provide for means of achieving interspace fusion and stabilization as a single procedure by a means consistent with the conventional method of discectomy.

It is another object of the present invention to provide for a means of achieving an interspace fusion and stabilization that is quicker, safer, and entails less blood loss than by any other known means.

It is another object of the present invention to provide for means of achieving a one stage interspace fusion and stabilization without significant violation or removal of the adjacent vertebral bone stock.

It is another object of the present invention to provide for method of intervertebral arthrodesis and stabilization of enhanced safety where the entire procedure is performed under direct vision.

It is another object of the present invention to provide for a method of intervertebral arthrodesis and stabilization of greater simplicity and requiring minimal specialized instrumentation or technique not already possessed by those doing such procedures by conventional means.

It is another object of the present invention to provide for modular prosthesis, allowing complimentary

subunits to be inserted individually through a small opening and to then be reassembled within the interspace, so as to reconstitute an interspace occupying device much larger than would be insertable as a whole.

It is another object of the present invention to to provide for a modular impant system such that it is possible to precisely fit the contours of any interspace without the need to sacrifice any vertebral bone to accommodate the prosthesis. These and other objects of the present invention will be apparent from review of the following specifications and the accompanying drawings.

Brief description of the Drawings

Figure 1 is a top right perspective view of the implant (cervical type).

Figure 1a is a front view of the implant of Fig. 1.

Figure 1b is a rear view of the implant of Fig. 1.

Figure 1c is a top view of the implant of Fig. 1.

Figure 1d is a side view of the implant of Fig. 1.

Figure 1e is a bottom view of the implant of Fig. 1.

Figure 2 is a side sectional view of the implant viewed along lines 2-2 of Fig. 1d.

Figure 3 is the implant Figure 1 showing the attachment to the driver and driver.

Figure 4 is a front perspective view showing the implant being driven into the disc space.

Figure 4a is a front perspective view of the implant located in the spine.

Figure 5 is a side view of the implant in the spine attached to the driver.

Figure 5a is a close up partial sectional view of the implant and driver.

Figure 6 is a perspective view of a series of implants placed in the cervical intervertebral space.

Figure 6A is an alternative embodiment of a rectangular solid implant.

Figure 7 is a side sectional view of the vertebrae and implant viewed along lines 7-7 of Figure 6.

Figure 7A is a side sectional view of the vertebrae structure showing a third embodiment of the rectangular solid implant in place.

Figure 8 is an exploded perspective view of another embodiment of the present invention.

Figure 9 is a side sectional view of the vertebrae structure and implant viewed along lines 9-9 of Fig. 8.

Figure 10 is a side sectional view of the implant of Figure 8, in a contracted position.

Figure 11 is a side sectional view of the implant of Figure 10, in an expanded position.

Figure 12 is a perspective view of an alternative embodiment of the implant of Figure 9.

Figure 13 is an alternative embodiment of a hollow rectangular solid implant.

Figure 14 is a cross sectional view of the hollow rectangular solid implant of Figure 13 viewed along lines 14-14 of Fig. 13.

Figure 15 is an alternative embodiment of an expandable implant in its extended position.

Figure 16 is an expandable implant of Figure 15 in its retracted position.

Figure 17 is an expandable implant of Figure 16 located in the disc space.

Referring to Figures 1 through 5 an implant for use in the disc space and associated apparatus used for inserting the implant 10 is shown. The implant 10 is shown as a substantially rectangular hollow configuration, having a tapered forward portion.

The implant 10 has an upper surface 12 and a parallel lower surface 14. The two side walls 16 and 18 are parallel to one another and have a series of small sized openings 20 of 1mm-3mm through the side walls 16 and 18.

The front wall 22 is slightly convex and has a depressed portion 24 with a central threaded opening 26 for receiving the engaging end 28 of a driving member 30.

The upper surface 12 has a threaded cap 32, which has opening 33 there through, with a central allen wrench opening 34 for engagement with an allen wrench A of Figure 3. The cap 32 covers the opening into the hollow implant 10 and permits the insertion of autogenous bone material into the hollow portion of the implant 10. The cap 32 is surrounded by a series of small sized openings 36 of 1mm to 3mm passing through the upper surface and into the central hollow portion of the implant 10.

The rear wall 38 is convex so as to conform to the rear of the disc space.

The driving member 30, shown in figure 3, comprises a substantially hollow tubular member 40 having a long internal rod 42 having a turning knob 44 at one end and a threaded portion 46 at the other end for threadably engaging the threaded opening 26 of the implant 10. The engaging end 28 of the driving member 30 has a slightly convex surface to complement the slightly convex surface of the front wall 22. The engaging end 28 has an extension 48 for fitting within the depressed portion 24 on the front wall 22 of the implant 10. The engaging end 28 also has restriction members 47 and 49 to restrict the depth of penetration of the driver 30.

In use, the cap 32 is removed from the implant 10 and autogenous bone material is inserted into the hollow portion of the implant 10. The cap is then replaced. Various methods of packing the implant 10 with the autogenous bone material may be used to obtain a completely packed implant 10.

Referring to Figures 4, 4a, 5 and 5a, the method of inserting the implant is shown. The threaded end 46 of the internal rod 42 of the driving member 30 is attached to the threaded opening 26 of the implant 10 by turning of the knob 44. Once the engaging end 28 is in place, the fitting of the extended portion 48 into the depressed portion 24 prevents movement of the implant 10 in relationship to the driving member 30.

The implant is then placed at the entrance to the disc space between the two adjacent vertebrae V. The knob 44 is then tapped with hammer H sufficiently hard enough to

drive the implant 10 into the disc space. The restriction members 47 and 49 which are wider than the disc space, prevent over penetration of the implant.

The size of the implant 10 is substantially the same size as the disc space that it is replacing and thus will be larger or smaller depending on the disc space in which it is to be used. In the preferred embodiment the implant 10 is approximately 32mm wide.

Referring to Figures 4A and 5 the implant 10 is shown in place in the disc space after removal of the driving member once the implant was inserted in place.

The autogenous bone material that was packed within the hollow portion of the implant 10 serves to promote bone ingrowth between the implant and the adjacent vertebrae. Once the bone ingrowth occurs, the implant 10 will be a permanent fixture preventing dislodgement of the implant as well as preventing any movement between the adjacent vertebrae.

Referring to Figure 6 an alternative embodiment of the implant is disclosed. The implant 61 comprises a substantially rectangular member having a series of ridges 62 on the upper and lower surfaces of the implant 60. One or more grooves 64 are placed on the upper and lower surfaces as well. As indicated in Figure 6, a series of such implants 61 are used as the interbody spinal implant, each placed closely adjacent one another to approximate the size of the removed disc. A series of micro sized opening 63 perforate the implant 61, to promote bone ingrowth.

The implant of Figure 6 is inserted as follows: the disc is substantially removed by conventional means. The implants 61 are then inserted in the intervertebral space between the two vertebrae.

The size of the implant 61 of Figure 6 is approximately 26 millimeters in length and is wide enough so that four of them will substantially fill the intervertebral space, depending on which vertebras are fused.

In Figure 6a a "bullet nosed" implant 67 having a open front portion 69 to facilitate insertion of implant 67 is shown.

Referring to Figures 7 and 7a alternative embodiments of the implant 61 of Figure 6 is shown in place between two vertebrae V.

In Figure 7 the implant 70 is shown with the ridges 62 shown in the form of teeth facing the anterior. These ridges serve to prevent the implant 60 from 'walking' out of the space between the vertebrae.

In Figure 7a an embodiment of the implant 70 of Figure 6 is shown having opposed ridges 72 and 74. This serves to maintain the alignment of the vertebrae when the two vertebrae V are improperly aligned with respect to one another.

Referring to Figure 8 an adjustable implant 81 having means for adjusting the width of the implant 81 is shown. The implant 81 comprises a lower member 82 and an upper member 84 which when fitted together form an essentially rectangular implant. The upper member 84 and the lower member 82 have hollow portions that face one another and receive tapered wedges 86 and 88 that fit within the hollow portion of the upper and lower members 82 and 84. The wedges 82 and 84 are such that at their large and they are higher than the combined hollow space between the upper and lower members 84 and 82, and shallower at the other end than the hollow space between the upper and lower members.

The wedges 86 and 88 have a central threaded opening 90 and 92 in alignment with each other for receiving threaded screw 94. Deformable burrs 95 on the head 98 of the screw 94 are used for locking the screw in place. The implant has a series of holes 100 throughout the body of the implant to assist in the ingrowth process.

Referring to Figures 9 through 11 the expandable implant 81 is shown positioned between the two vertebrae V. In Figure 10 the expandable implant 81 is illustrated in its contracted position. The wedges 86 and 88 abutt the interior sloped surfaces 104 of the upper and lower members 82 and 84.

As the screw 94 is turned, as shown in Figure 11, the wedges 86 and 88 are drawn together, and the sloped portions of the wedges force the upper member 82 away from

the lower member 84. Once the screw 94 has been turned sufficiently, the screw head 98 is hit, causing the deformable burrs to be crimped so as to prevent the reverse rotation of the screw 94.

In Figure 12, another alternative embodiment of the expandable implant 81 is illustrated with spike projections 106 extending from the top and bottom members to dig into the vertebrae and assist in maintaining it in place.

In use, the disc is removed, and the implant 81 is placed between the vertebrae. The screw 94 is then turned expanding the implant. In the preferred embodiment, the width is from 8 millimeters to 18 millimeters.

Referring to Figures 13 and 14, another alternative embodiment of the invention is shown in which the implant 200 comprises a rectangular hollow member having a slightly tapered forward section 202. The cross section, shown in Figure 14, shows the rectangular configuration of the implant.

In use of the implant the interior of the implant is filled with a paste made of autogenous bone, and inserted in the place of the former disc. The strength of the material used to make the implant is such that, even though it is substantially hollow, it does have sufficient strength to withstand the forces of the vertebrae compressing the implant.

Referring to Figures 15-17, another alternative embodiment is shown in which the implant has movable projections which are movable from a first positon within the implant to a second position extending outside of the implant.

The implant 300 is of a generally rectangular configuration. The top surface 302 and the bottom surface 304 of the implant have slots 306 for permitting pivotal member 307 having spikes 308 at their ends to project through said slots 306. The spikes 308 are pinned at one end 310 within the implant 300.

Opposing wedge shaped members 312 and 314 having a central threaded opening 316 for receiving a threaded screw 318 having a head 320 and a slot 322. The wedges are

facing each other so that upon turning of the screw will draw the two wedges together, causing the wedges to cause the spikes 308 to pivot about their end 310 and cause the spikes to project out of the implant through the aligned slots 306. The depressions 329 in the pivotal member 307 engage the wedges 314 and 312 to lock the pivotal members 307 in place. A series of holes 324 for promoting bone ingrowth and fusion are provided in the implant 300.

In use, after the removal of the disc material, the implants with the spikes 308 in their withdrawn position, are inserted into the disc space. Then the screw 318 is turned until the spikes 308 are forced to enter the vertebrae material, as shown in Figure 17. The implant 300 is thus held firmly in place.

These implants have a surface configuration so as to induce bone ingrowth through the implant, and into the wall of the vertebrae in effect inducing fusion from one vertebrae V joint to the other, thereby eventually making the implant itself superfluous as the bone would do the work.

The implant itself, because of its being made of stronger material than bone, would provide structural support to the two vertebrae while awaiting bone ingrowth. Once the bone ingrowth occurred, however, the implant would be firmly and permanently fixed in place.

While the invention has been described with regards to the preferred embodiment and a number of alternative embodiments, it is recognized that other embodiments of the present invention may be devised which would not depart from the scope of the present invention.

What is claimed is:

1. An implant for fusion of two adjacent vertebrae in the spine said implant comprising a generally rectangular member, said member having a plurality of openings therein for promoting bone ingrowth with the implant and fusion of said vertebrae.

2. The implant of Claim 1 in which said rectangular member has a plurality of ratchet like members facing in the same direction on the upper and lower surfaces of said member for engagement with adjacent vertebrae.

3. The implant of Claim 2 in which said ratchet like members on the upper and lower faces face in different directions to prevent movement of the adjacent vertebrae relative to each other.

4. The implant of Claim 1 in which said implant has a tapered portion at one end.

5. The implant of Claim 1 in which the rectangular member is separable into an upper portion and a lower portion, and comprises a wedge means fitted between said upper portion and said lower portion for forcing said upper portion away from said lower portion.

6. The implant of claim 5 in which said wedge means comprises a central threaded opening with a threaded screw connecting two of said wedges, whereby turning said threaded screw draws said wedges together and forces said upper portion and lower portion of said implant away from each other.

7. The implant of claim 6 in which said implant has a plurality of openings therethrough.

8. The implant of claim 6 in which said upper and lower surface of said implant has projections for engaging the vertebrae.

9. The implant of claim 1 in which said implant has a plurality of slots in the upper and lower surfaces and a plurality of pivotal members movable between a first position within said implant and a second position outside of said implant through said slots.

10. A spinal implant comprising a hollow rectangular member, said rectangular member having a removable cap for covering said opening.

11. The implant of claim 10 in which said implant has a plurality of openings through the walls of said implant.

12. The implant of claim 10 in which said implant is substantially the same shape and dimensions as a disc.

13. The implant of claim 10 in which said implant comprises a front surface having an threaded opening therein for engagement with a threaded driving member.

14. The implant of claim 13 in which said front surface has a driver engaging portion.

15. The implant of claim 14 in which said engaging means comprises a depression on the front surface.

16. The implant of claim 10 in which said removable cap includes threads for attachment to said implant.

17. A driving member for driving a spinal implant comprising a first hollow tubular member, said hollow member having an irregular end for confirming to the external shape of a front surface of a spinal implant, and a second rod member fitted within said hollow tubular member said rod member having a threaded protion at one end and an enlarged knob portion at the other end.

18. The driver member of claim 17 in which said irregular end comprises an extended portion for fitting within a depressed portion of a spinal implant.

19. A spinal implant comprising a generally rectangular ember having a dimension of less than the width of a disc space, whereby a plurality of said implants of different widths have a width of the size of a disc space.

20. A plurality of spinal implants, the combined width of said spinal implants approximating the width of the disc space.

21. A method for replacing a disc in the spine comprising removing the disc and inserting into the resulting disc space a plurality of implants having a combined width approximating the width of the disc space.

22. The method of claim 21 in which said implants are inserted into the disc space one at a time.

23. The method of claim 21 in which said implant is made of a material that promotes bone ingrowth.

24. The method of claim 21 including the step of inserting autogenous bone material within said implant before implanting.

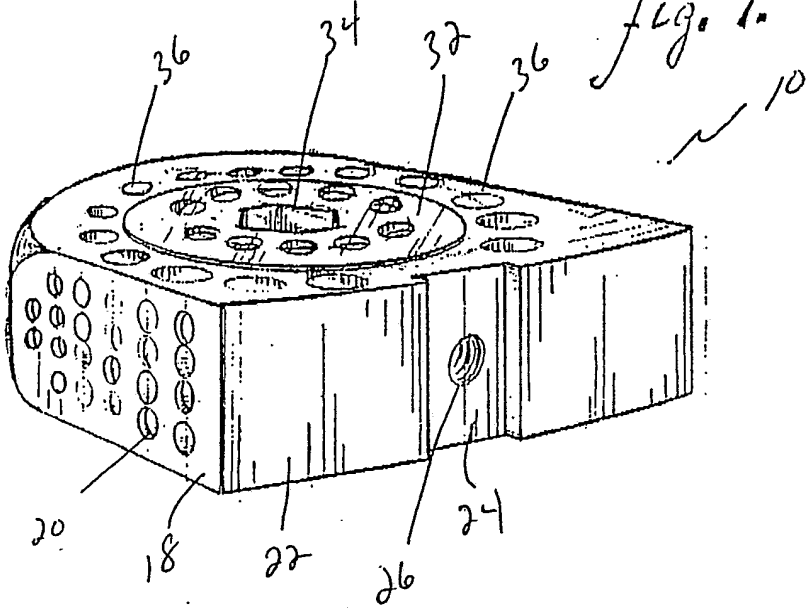


fig. 1.

fig. 1a.

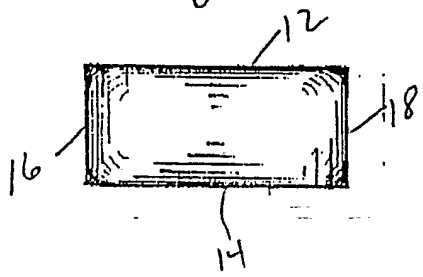
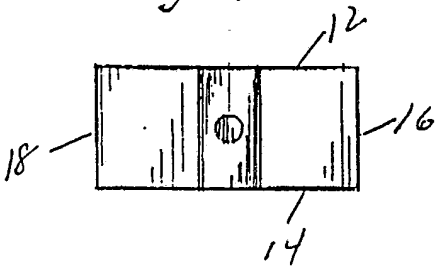


fig. 1b.



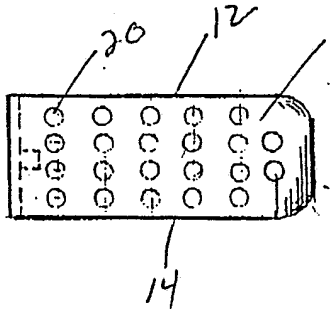


fig. 1c.

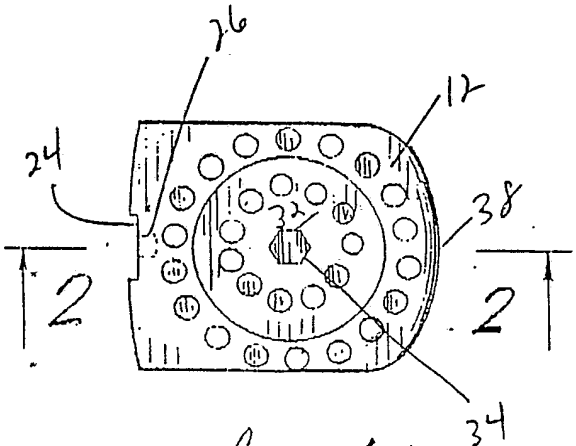


fig. 1d.

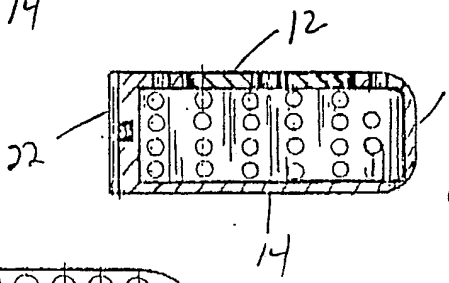


fig. 2.

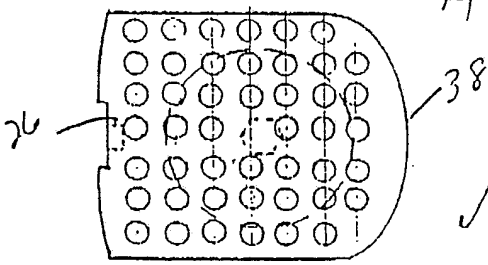


fig. 1e.

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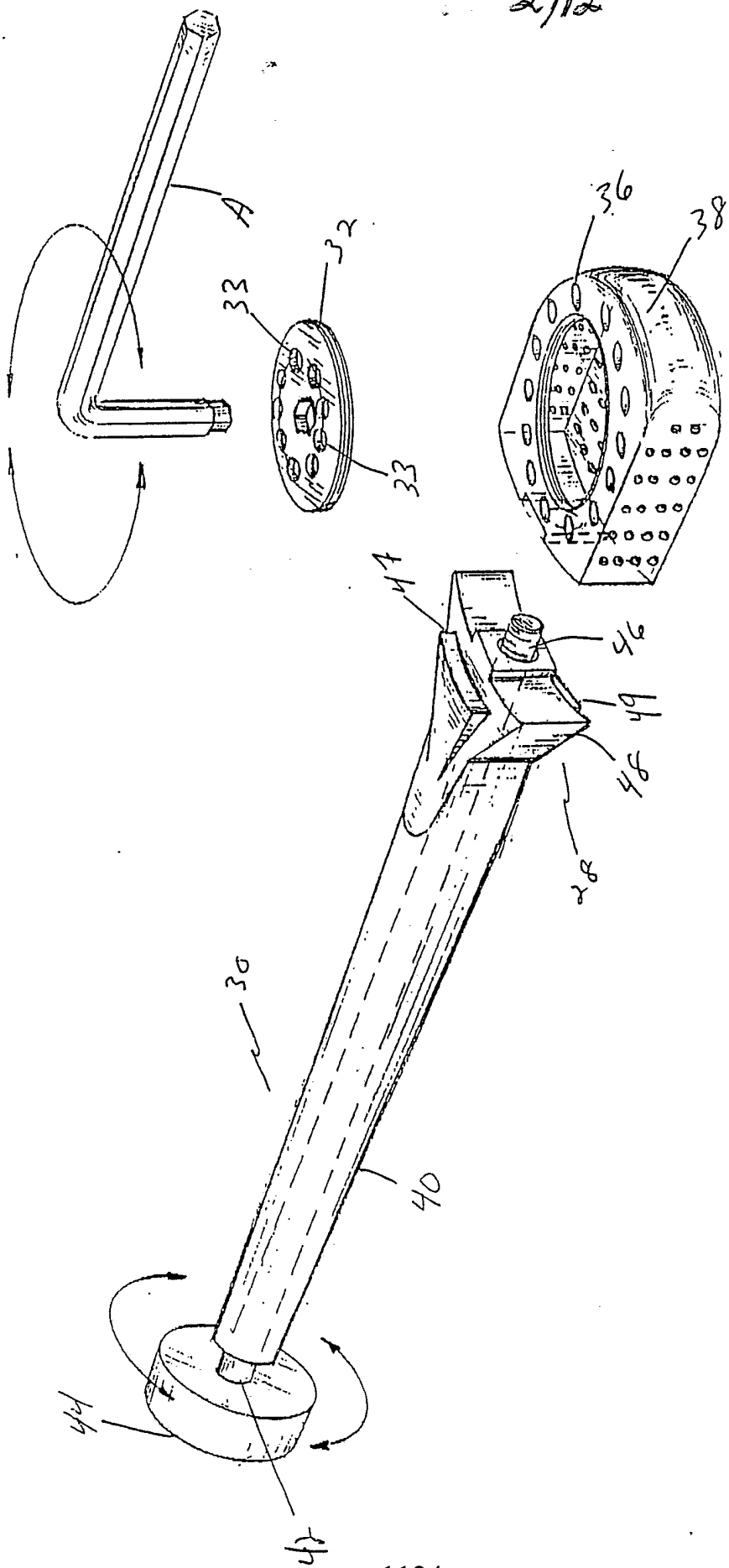

FIG. 3.

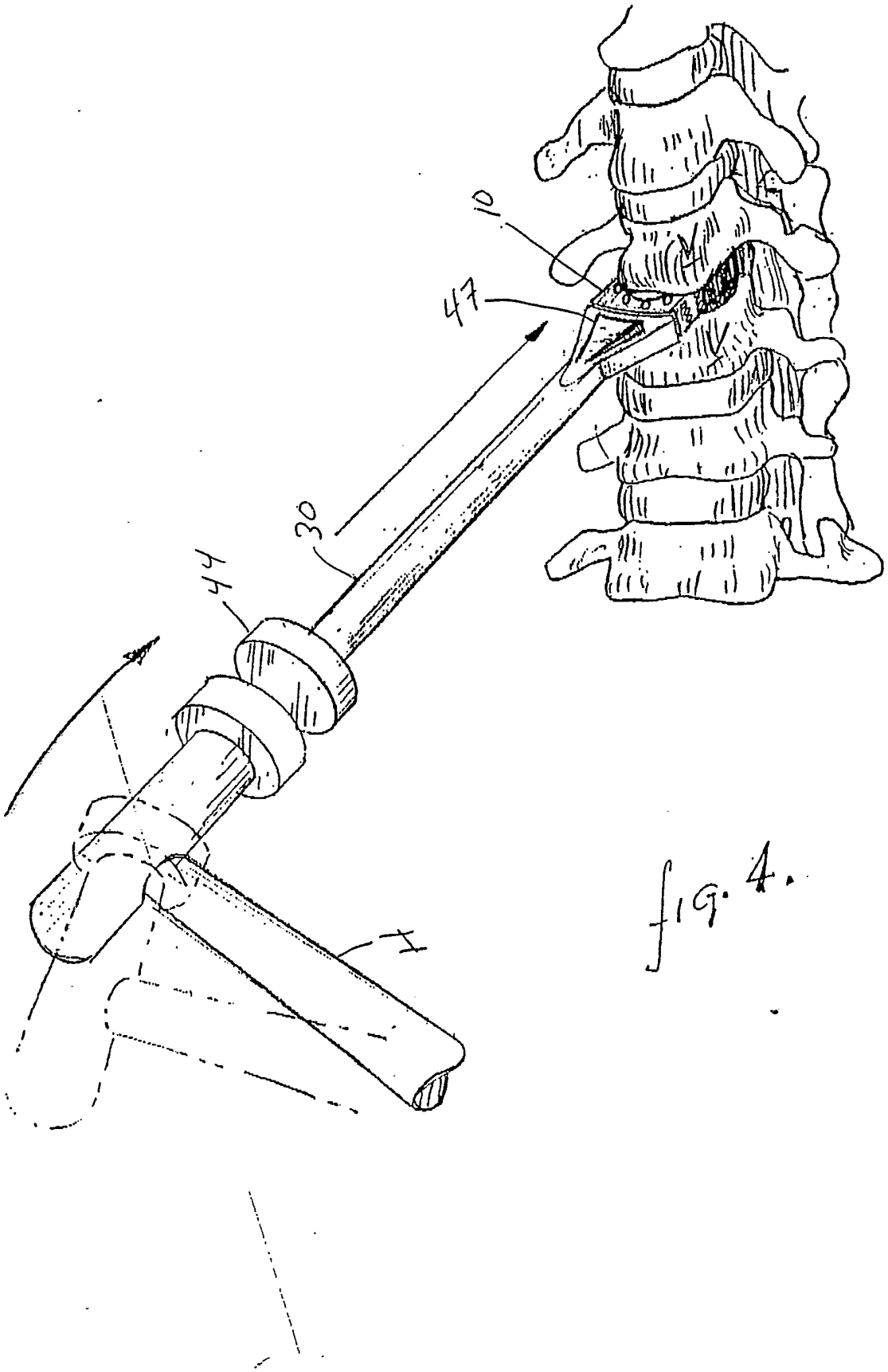

fig. 4.

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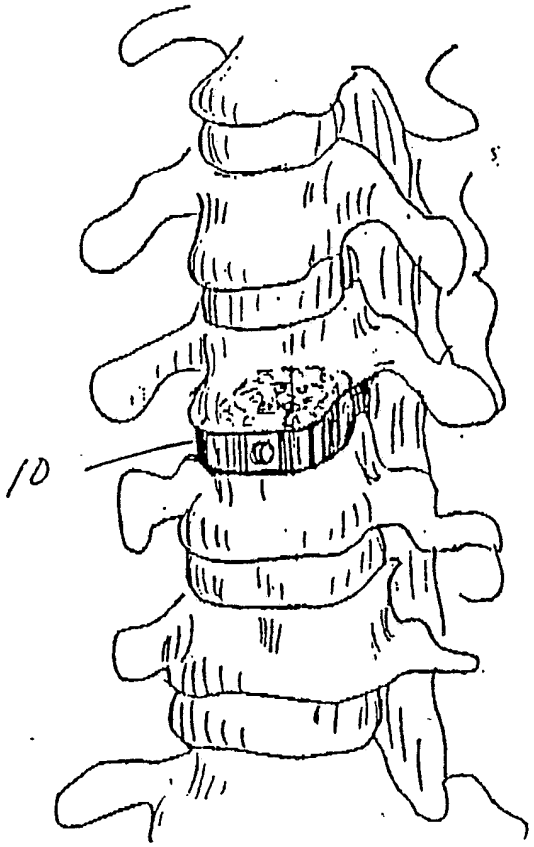
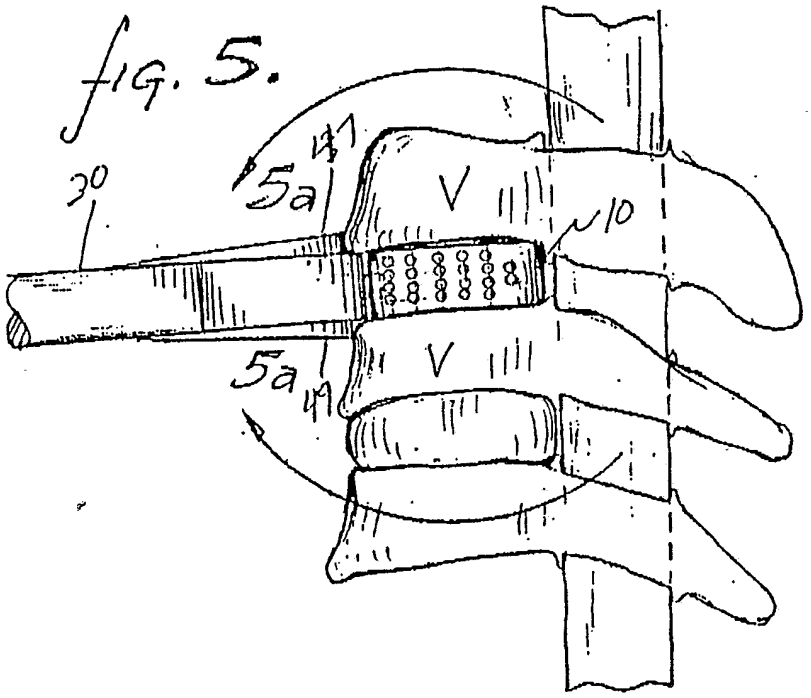


fig. 4a.

fig. 5.



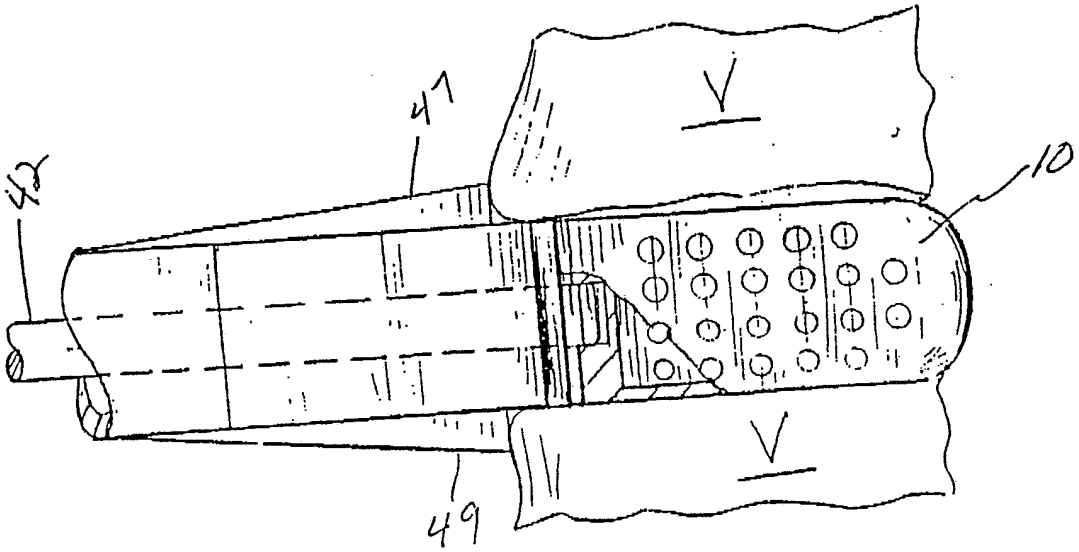


fig. 5a.

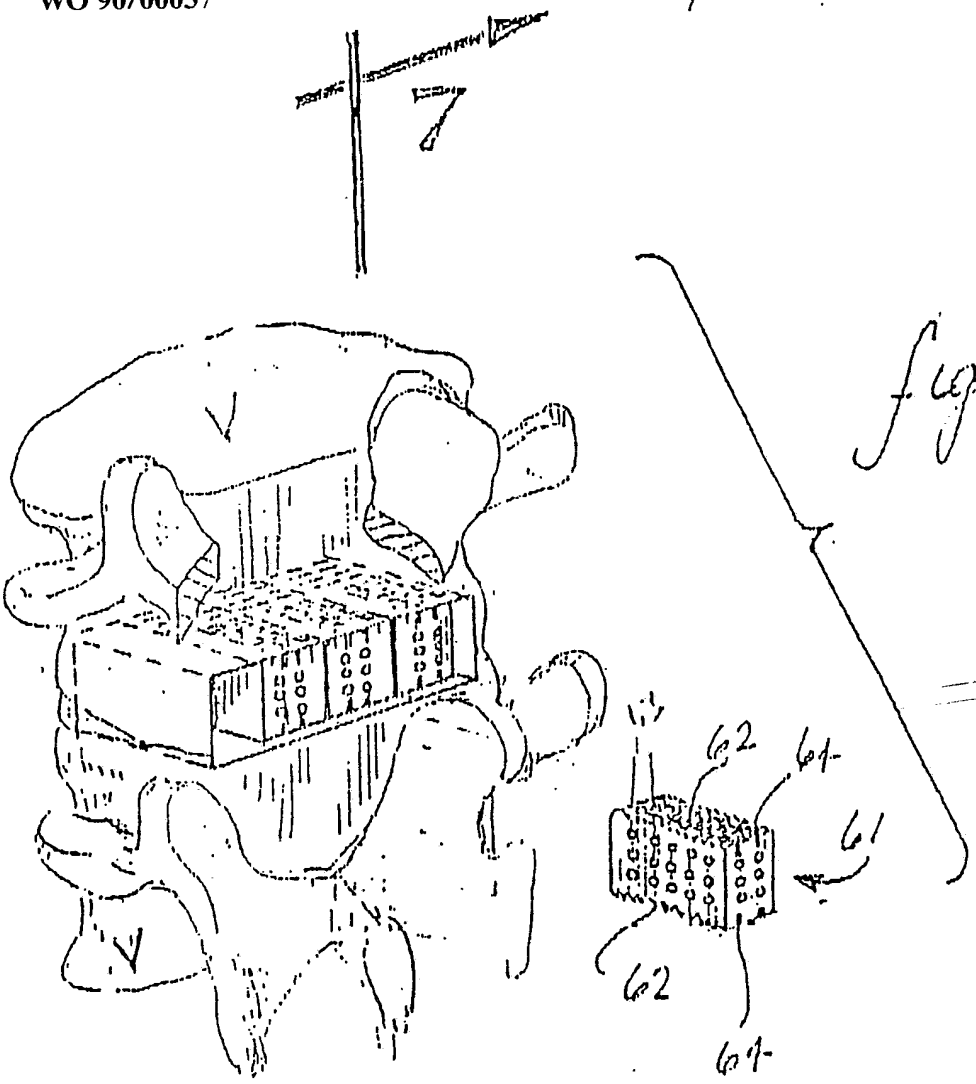


fig. 6.

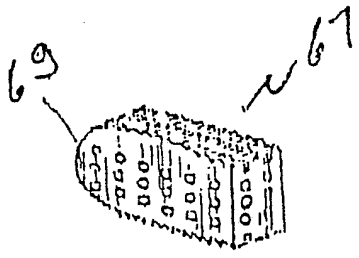


fig. 6A.

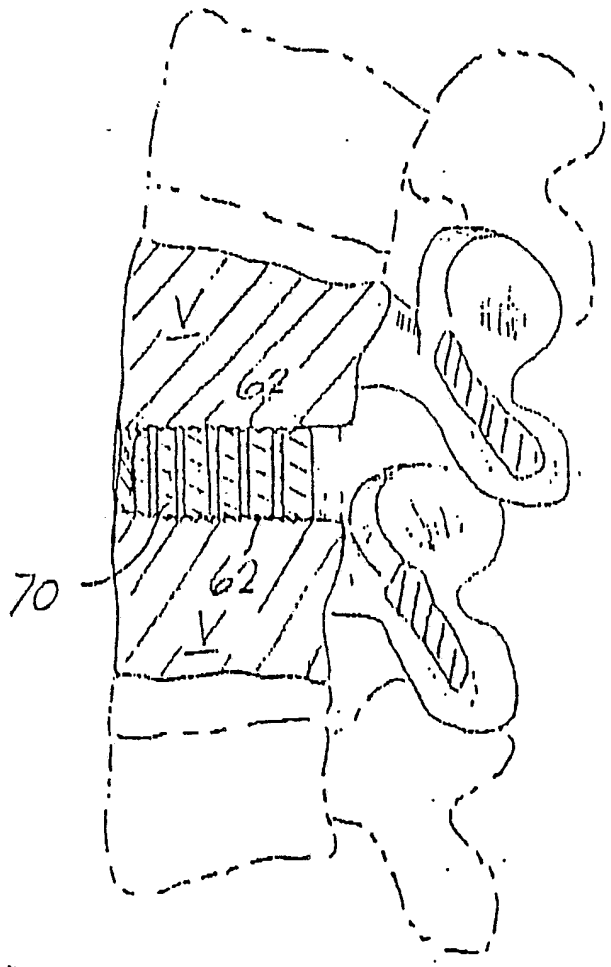


Fig. 7

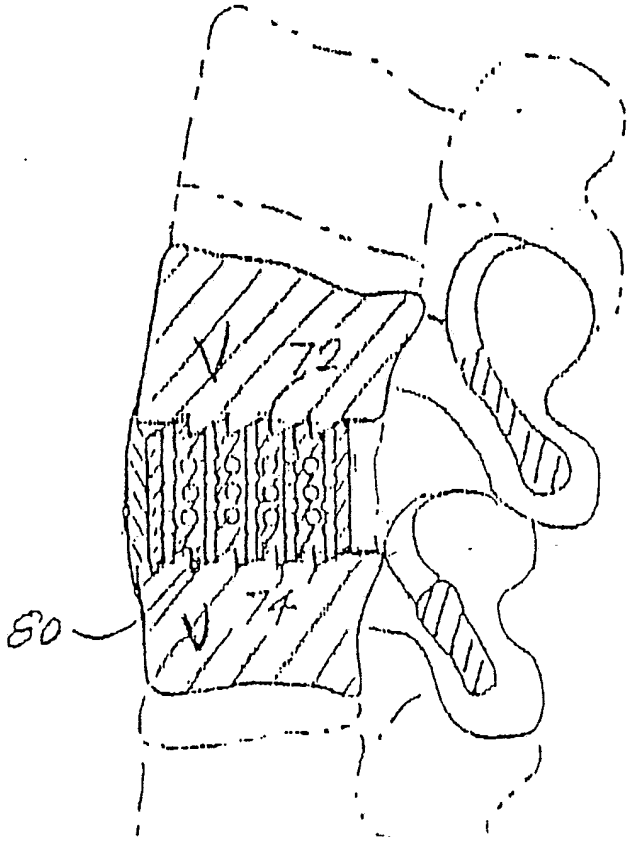


Fig. 7A.

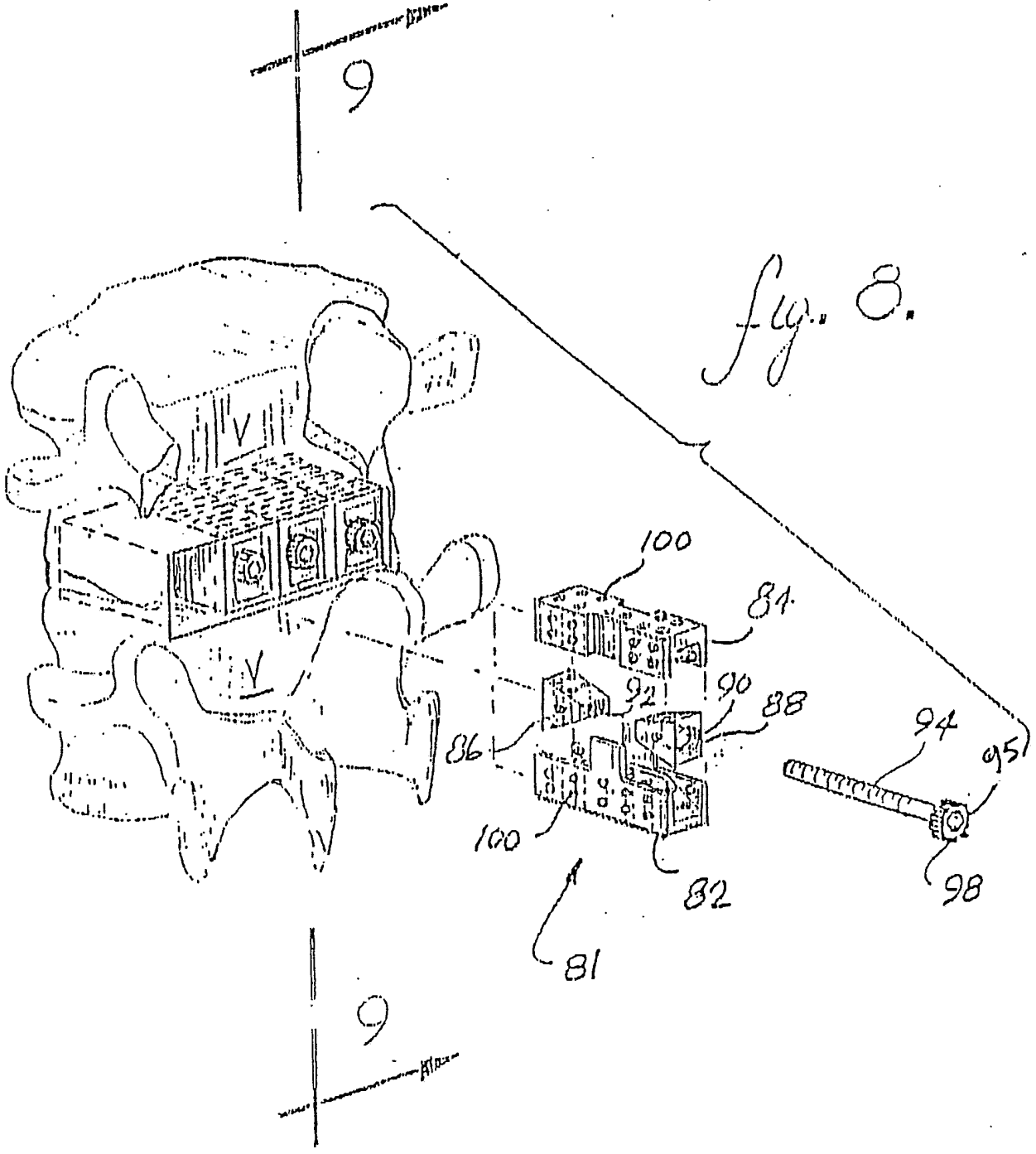


Fig. 8.

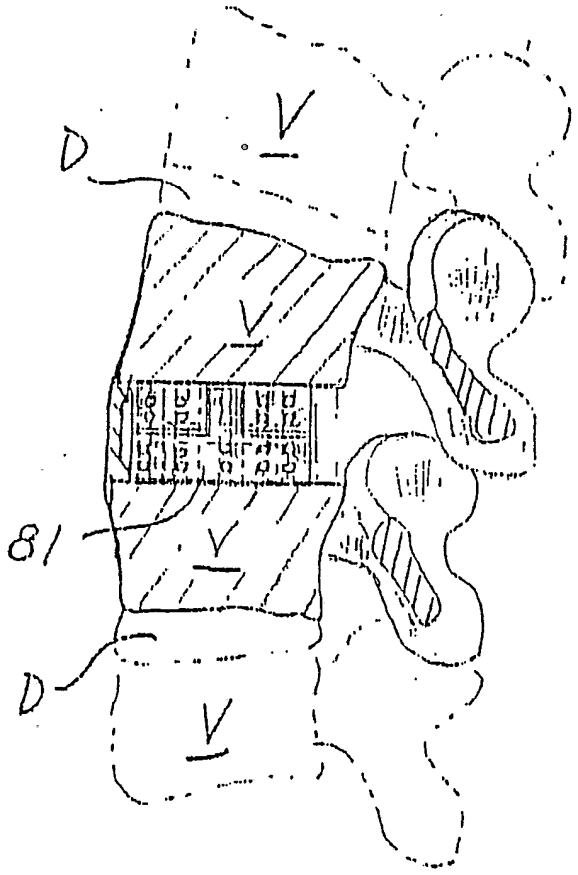


Fig. 9.

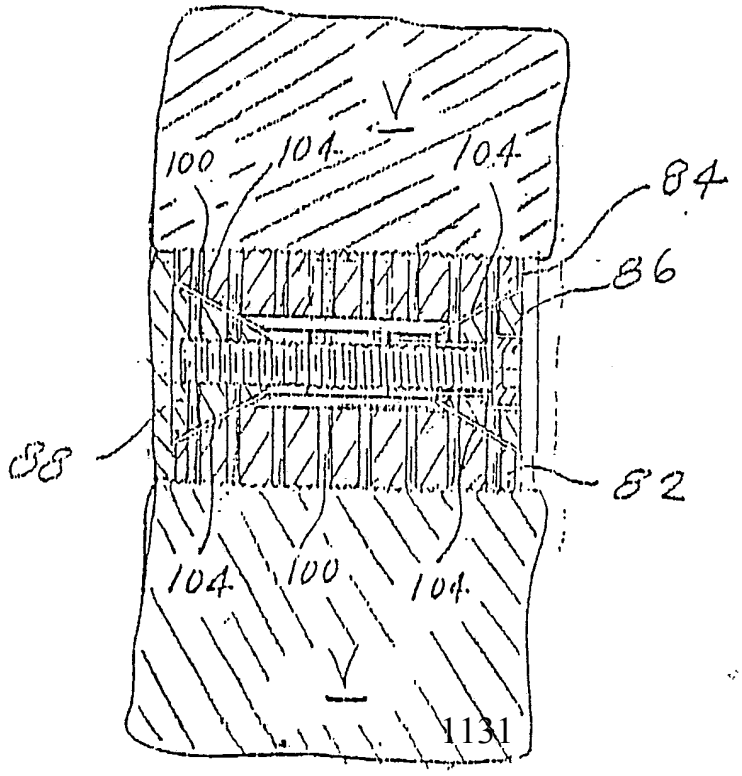


Fig. 10.

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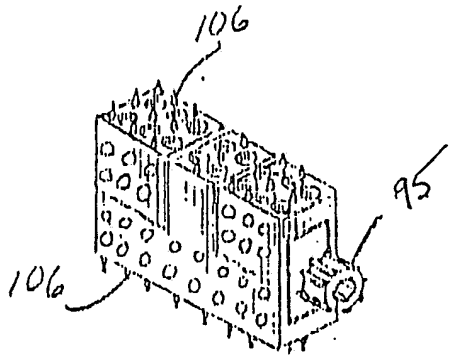


fig. 12.

fig. 13.

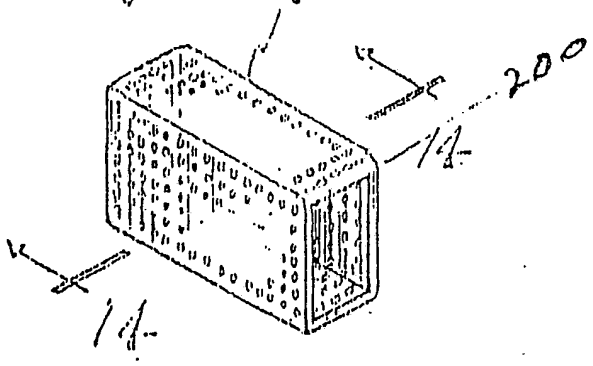
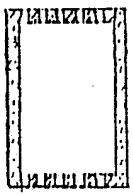


fig. 14.



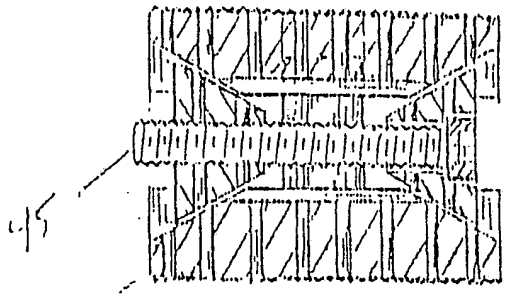


fig. 11.

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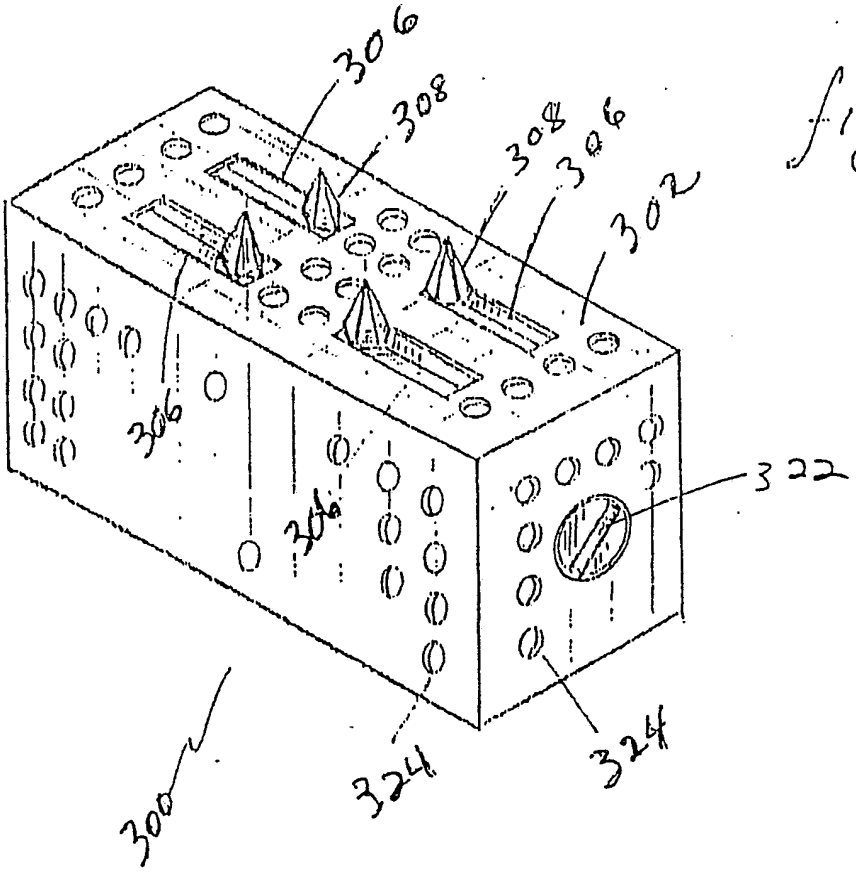

fig. 15.

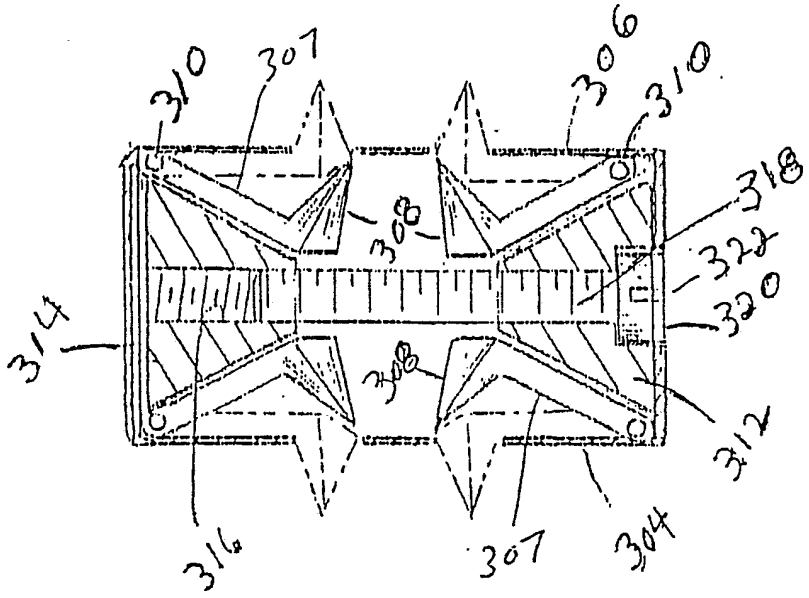

fig. 16.

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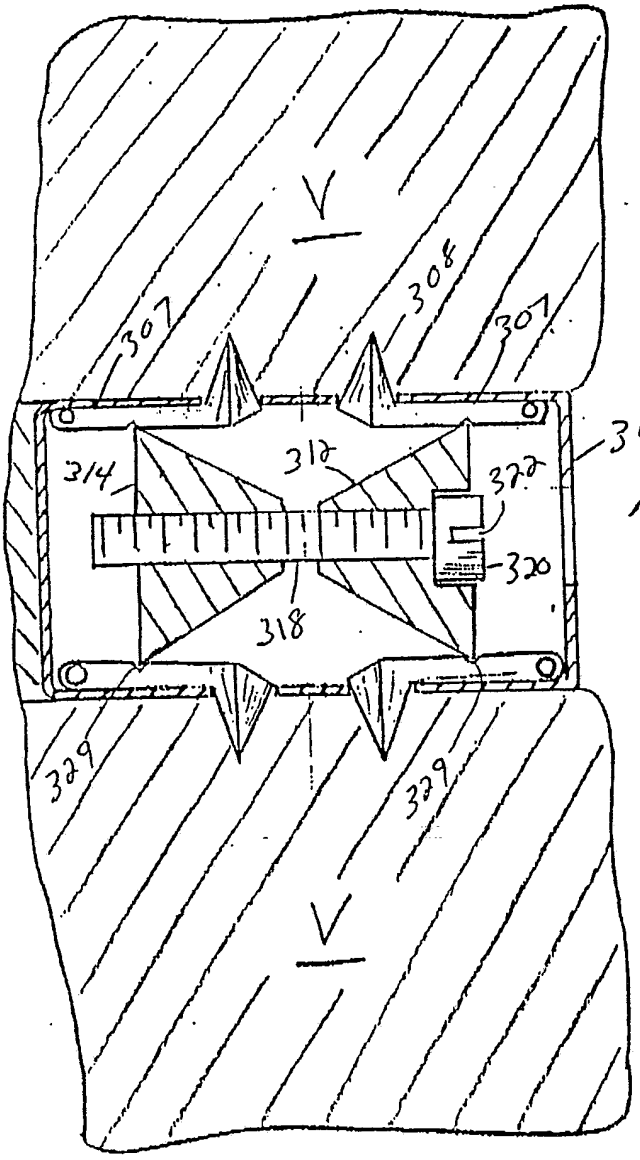

Fig. 17.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US89/02791

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4): A61F 2/44
U.S. Cl. 623/17

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	623/16, 17; 128/69, 92YM, 92YY, 92VT; 604/93, 890.1, 891.1, 892

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X, P Y, P	US, A, 4,834,757 (BRANTIGAN) 30 May 1989 See Figures; column 6, lines 51-56; column 6, line 66-column 7, line 5.	1-2, 4 3, 5-16, 24
Y	EP, A, 0,260,044 (SHEPPERD) 16 March 1988 See Figures.	5-9
Y	US, A, 4,721,103 (FREEDLAND) 26 January 1988, see Figures.	9
Y	US, A, 4,599,086 (DOTY) 08 July 1986 See Figures.	9
Y	US, A, 3,948,262 (ZAFFARONI) 06 April 1976, see column 7, line 51-column 8, line 24.	10-16
Y	US, A, 4,507,115 (KAMBARA ET AL) 26 March 1985, see Figures; column 1, lines 12-18; column 2, lines 9-11.	10-16
X Y	US, A, 4,714,469 (KENNA) 22 December 1987 See Figures.	17-18, 21-23 24

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
22 August 1989	27 SEP 1989
International Searching Authority	**Signature of Authorized Officer**
ISA/US	David J. Bender

Form PCT/ISA/210 (second sheet) (Rev.11-87)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

X	US, A, 4,349,921 (KUNTZ) 21 September 1982 See Figures 7-10; column 6, lines 39-42.	19-23

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

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

1. ☐ Claim numbers . because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers . . , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.