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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	104US1
First Inventor	Matthew Curran
Title	Systems and Methods For Spinal Fusi
Express Mail Label No.	ER453203757US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☑ **Fee Transmittal Form** (e.g., PTO/SB/17)
   (Submit an original and a duplicate for fee processing)
2. ☑ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☑ **Specification** [*Total Pages*_____]
   Both the claims and abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. ☑ **Drawing(s)** (*35 U.S.C. 113*) [*Total Sheets* _____]
5. **Oath or Declaration** [*Total Sheets* _____]
   a. ☑ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Box 18 completed)
   i. ☐ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
   (if applicable, items a. – c. are required)
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

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ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee_____
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☑ **Return Receipt Postcard** (MPEP 503)
    (Should be specifically itemized)
15. ☐ **Certified Copy of Priority Document(s)**
    (if foreign priority is claimed)
16. ☑ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. ☐ Other:_____

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

Prior application information: *Examiner* _____ *Art Unit:* _____

19. CORRESPONDENCE ADDRESS

☑ The address associated with Customer Number: 30,328 *OR* ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Fax	

Signature		Date	March 29, 2005
Name (Print/Type)	Jonathan Spangler	Registration No. (Attorney/Agent)	40,182

This collection of information is required by 37 CFR 1.53(b). 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. 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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PTO/SB/17 (12-04v2)
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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2005

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($)

Complete if Known	
Application Number	N/A
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Examiner Name	N/A
Art Unit	N/A
Attorney Docket No.	104US1

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 50-2040 Deposit Account Name: NuVasive

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☑ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☑ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☑ Credit any overpayments

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 20 or HP =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 3 or HP =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), 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).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____	/ 50 = _____ (round **up** to a whole number)	x _____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	_____
Other (e.g., late filing surcharge): _____	_____

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 40,182	Telephone (858)243-0029
Name (Print/Type)	Jonathan Spangler		Date March 29, 2005

ER453203757US

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service (Express Mail No ER453203757US) under 37 CFR 1.10 on March 29, 2005 and is directed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Jonathan D. Spangler

NON-PROVISIONAL APPLICATION

FOR UNITED STATES LETTERS PATENT

SYSTEMS AND METHODS FOR SPINAL FUSION

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Filed:

March 29, 2005

SYSTEMS AND METHODS FOR SPINAL FUSION

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of the filing date under 35 USC 119(e) of United States Provisional Application entitled "Systems and Methods for Spinal Fusion," serial No. 60/557,536 filed March 29, 2004, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to spinal surgery and, more particularly, to a system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites.

II. Discussion of the Prior Art

Currently there are nearly 500,000 spine lumbar and cervical fusion procedures performed each year in the United States. Such procedures are commonly performed to correct problems, such as chronic back or neck pain, which result from degenerated intervertebral discs or trauma. Generally, spinal fusion procedures involve removing some or all of the diseased or damaged disc, and inserting one or more intervertebral implants into the resulting disc space. Introducing the intervertebral implant serves to restore the height between adjacent vertebrae

("disc height"), which reduces if not eliminates neural impingement commonly associated with a damaged or diseased disc.

Autologous bone grafts are widely used intervertebral implant for lumbar fusion. Autologous bone grafts are obtained by harvesting a section of bone from the iliac crest of the patient and thereafter implanting the article of autologous bone graft to effect fusion. While generally effective, the use of autologous bone grafts suffers certain drawbacks. A primary drawback is the morbidity associated with harvesting the autologous graft from the patient's iliac crest. Another related drawback is the added surgical time required to perform the bone-harvesting.

Allograft bone grafts have been employed with increased regularity in an effort to overcome the drawbacks of autologous bone grafts. Allograft bone grafts are harvested from cadaveric specimens, machined, and sterilized for implantation. While allograft bone grafts eliminate the morbidity associated with iliac crest bone harvesting, as well as decrease the overall surgical time, they still suffer certain drawbacks. A primary drawback is supply constraint, in that the tissue banks that process and produce allograft bone implants find it difficult to forecast allograft given the inherent challenges in forecasting the receipt of cadavers. Another related drawback is that it is difficult to manufacture the allograft with consistent shape and strength characteristics given the variation from cadaver to cadaver.

The present invention is directed at overcoming, or at least improving upon, the disadvantages of the prior art.

SUMMARY OF THE INVENTION

The present invention overcomes the drawbacks of the prior art by providing a spinal fusion system and related methods involving the use of a spinal fusion implant of non-bone construction. The non-bone construction of the spinal fusion implant of the present invention overcomes the drawbacks of the prior art in that it is not supply limited (as with allograft) and does not require harvesting bone from the patient (as with autograft). The spinal fusion implant of the present invention may be comprised of any suitable non-bone composition, including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone (PEKK)), ceramic, metal or any combination of these materials.

The spinal fusion implant of the present invention may be provided in any number of suitable shapes and sizes depending upon the particular surgical procedure or need. The spinal fusion implant of the present invention may be dimensioned for use in the cervical and/or lumbar spine without departing from the scope of the present invention. For lumbar fusion, the spinal fusion implant of the present invention may be dimensioned, by way of example only, having a width ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 25 and 45 mm. For cervical fusion, the spinal fusion implant of the present invention may be dimensioned, by way of example only, having a width about 11 mm, a height ranging between 5 and 12 mm, and a length about 14 mm.

The spinal fusion implant of the present invention may be provided with any number of additional features for promoting fusion, such as apertures extending between the upper and lower vertebral bodies which allow a boney bridge to form through the spinal fusion implant of the present invention. Such fusion-promoting apertures may be dimensioned to receive any number of suitable osteoinductive agents, including but not limited to bone morphogenic protein (BMP) and bio-resorbable polymers, including but not limited to any of a variety of poly (D,L-lactide-co-glycolide) based polymers. The spinal fusion implant of the present invention is preferably equipped with one or more lateral openings which aid it provides in visualization at the time of implantation and at subsequent clinical evaluations.

The spinal fusion implant of the present invention may be provided with any number of suitable anti-migration features to prevent spinal fusion implant from migrating or moving from the disc space after implantation. Suitable anti-migration features may include, but are not necessarily limited to, angled teeth formed along the upper and/or lower surfaces of the spinal fusion implant and/or spike elements disposed partially within and partially outside the upper and/or lower surfaces of the spinal fusion implant. Such anti-migration features provide the additional benefit of increasing the overall surface area between the spinal fusion implant of the present invention and the adjacent vertebrae, which promotes overall bone fusion rates.

The spinal fusion implant of the present invention may be provided with any number of features for enhancing the visualization of the implant during and/or after implantation into a spinal target site. According to one aspect of the present invention, such visualization enhancement features may take the form of the spike elements used for anti-migration, which

may be manufactured from any of a variety of suitable materials, including but not limited to a metal, ceramic, and/or polymer material, preferably having radiopaque characteristics. The spike elements may also take any of a variety of suitable shapes, including but not limited to a generally elongated element disposed within the implant such that the ends thereof extend generally perpendicularly from the upper and/or lower surfaces of the implant. The spike elements may each comprise a unitary element extending through upper and lower surfaces or, alternatively, each spike element may comprise a shorter element which only extends through a single surface (that is, does not extend through the entire height of the implant). In any event, when the spike elements are provided having radiodense characteristics and the implant is manufactured from a radiolucent material (such as, by way of example only, PEEK and/or PEKK), the spike elements will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant during implantation and/or the placement of the implant after implantation.

The spinal implant of the present invention may be introduced into a spinal target site through the use of any of a variety of suitable instruments having the capability to releasably engage the spinal implant. In a preferred embodiment, the insertion instrument permits quick, direct, accurate placement of the spinal implant of the present invention into the intervertebral space. According to one embodiment, the insertion instrument includes a threaded engagement element dimensioned to threadably engage into a receiving aperture formed in the spinal fusion implant of the present invention. According to another embodiment, the insertion instrument includes an elongate fork member and a generally tubular lock member.

BRIEF DESCRIPTION OF THE DRAWINGS

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

Figure 1 is a perspective view of a spinal fusion system of the present invention, including a lumbar fusion implant releasably coupled to an insertion instrument according to one embodiment of the present invention;

Figure 2 is a perspective view of the lumbar fusion implant of FIG. 1, illustrating (among other things) fusion apertures extending between top and bottom surfaces, a plurality of visualization apertures extending through the side walls, and a variety of anti-migration features according to one embodiment of the present invention;

Figure 3 is a top view of the lumbar fusion implant of FIG. 1, illustrating (among other things) the fusion apertures and the anti-migration features according to one embodiment of the present invention;

Figure 4 is a side view of the lumbar fusion implant of FIG. 1, illustrating (among other things) the visualization apertures, the anti-migration feature, and a receiving aperture for releasably engaging the insertion instrument of FIG. 1 according to one embodiment of the present invention;

Figure 5 is an end view of the lumbar fusion implant of FIG. 1, illustrating (among other things) the receiving aperture formed in the proximal end, the anti-migration features, and the visualization apertures according to one embodiment of the present invention;

Figure 6 is an enlarged side view of the lumbar fusion implant of FIG. 1 releasably coupled to the distal end of the insertion instrument of FIG. 1 according to one embodiment of the present invention;

Figure 7 is a perspective view of the insertion instrument of FIG. 1 in a fully assembled form according to one embodiment of the present invention;

Figure 8 is an enlarged perspective view of the distal region of the insertion instrument of FIG. 1 according to one embodiment of the present invention;

Figure 9 is a perspective exploded view of the insertion instrument of FIG. 1, illustrating the component parts of the insertion instrument according to one embodiment of the present invention;

Figure 10 is a perspective view of a spinal fusion system of the present invention, including a cervical fusion implant releasably coupled to a cervical insertion instrument according to one embodiment of the present invention;

Figure 11 is a perspective view of the proximal side of the cervical fusion implant of FIG. 10, illustrating (among other things) fusion apertures extending between top and bottom surfaces, a plurality of visualization apertures extending through the lateral walls, a plurality of receiving apertures, and a variety of anti-migration features according to one embodiment of the present invention;

Figure 12 is a perspective view of the distal side cervical fusion implant of FIG. 10, illustrating (among other things) the visualization apertures and anti-migration features;

Figure 13 is a top view of the cervical fusion implant of FIG. 10, illustrating (among other things) the fusion apertures and anti-migration features according to one embodiment of the present invention;

Figure 14 is a side view of the cervical fusion implant of FIG. 10, illustrating (among other things) the visualization apertures, the anti-migration features, and one of two receiving apertures provided in the proximal end for releasably engaging the cervical insertion instrument of FIG. 10 according to one embodiment of the present invention;

Figure 15 is a perspective view of the cervical fusion implant of the present invention just prior to attachment to the cervical insertion device according to one embodiment of the present invention;

Figure 16 is a perspective view of the insertion instrument of FIG. 10 in a fully assembled form according to one embodiment of the present invention;

Figure 17 is a perspective exploded view of the insertion instrument of FIG. 10, illustrating the component parts of the insertion instrument according to one embodiment of the present invention;

Figures 18 and 19 are perspective and side views, respectively, illustrating the "enhanced visualization" feature of the present invention as employed within a lumbar fusion implant according to one embodiment of the present invention;

Figures 20 and 21 are perspective and side views, respectively, illustrating the "enhanced visualization" feature of the present invention as employed within a lumbar fusion implant according to one embodiment of the present invention; and

Figures 22 and 23 are perspective and side views, respectively, illustrating the "enhanced visualization" feature of the present invention as employed within a cervical fusion implant according to one embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous

implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The system to facilitate bone fusion and related methods disclosed herein boasts a variety of inventive features and components that warrant patent protection, both individually and in combination.

FIG. 1 illustrates, by way of example only, a spinal fusion system 5 for performing spinal fusion between adjacent lumbar vertebrae, including an exemplary spinal fusion implant 10 and an exemplary insertion instrument 20 provided in accordance with the present invention. The spinal fusion implant 10 may be comprised of any suitable non-bone composition having suitable radiolucent characteristics, including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone (PEKK)) or any combination of PEEK and PEKK. The spinal fusion implant 10 of the present invention may be dimensioned, by way of example only, having a width ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 25 and 45 mm.

As will be described in detail below, the insertion instrument 20 is configured to releasably maintain the exemplary spinal fusion implant 10 in the proper orientation during insertion into a lumbar disc space and thereafter released to deposit the implant 10. The exemplary spinal fusion implant 10, having been deposited in the disc space, facilitates spinal fusion over time by maintaining a restored disc height as natural bone growth occurs through

and/or past the implant 10, resulting in the formation of a boney bridge extending between the adjacent vertebral bodies. The implant 10 is particularly suited for introduction into the disc space via a lateral (trans-psoas) approach to the spine, but may be introduced in any of a variety of approaches, such as posterior, anterior, antero-lateral, and postero-lateral, without departing from the scope of the present invention (depending upon the sizing of the implant 10).

The spinal fusion implant 10 of the present invention may be provided with any number of additional features for promoting fusion, such as apertures 2 extending between the upper and lower vertebral bodies which allow a boney bridge to form through the spinal fusion implant 10. According to a still further aspect of the present invention, this fusion may be facilitated or augmented by introducing or positioning various osteoinductive materials within the apertures 2 and/or adjacent to the spinal fusion implant 10. Such osteoinductive materials may be introduced before, during, or after the insertion of the exemplary spinal fusion implant 10, and may include (but are not necessarily limited to) autologous bone harvested from the patient receiving the spinal fusion implant 10, bone allograft, bone xenograft, any number of non-bone implants (e.g. ceramic, metallic, polymer), bone morphogenic protein, and bio-resorbable compositions, including but not limited to any of a variety of poly (D,L-lactide-co-glycolide) based polymers.

The spinal fusion implant 10 of the present invention is preferably equipped with one or more visualization apertures 4 situated along the lateral sides, which aid in visualization at the time of implantation and at subsequent clinical evaluations. More specifically, based on the generally radiolucent nature of the implant 10, the visualization apertures 4 provide the ability to visualize the interior of the implant 10 during X-ray and/or other suitable imaging techniques

which are undertaken from the side (or "lateral") perspective of the implant 10. If fusion has taken place, the visualization apertures 4 will provide a method for the surgeon to make follow up assessments as to the degree of fusion without any visual interference from the spinal fusion implant 10. Further, the visualization apertures 4 will provide an avenue for cellular migration to the exterior of the spinal fusion implant 10. Thus the spinal fusion implant 10 will serve as additional scaffolding for bone fusion on the exterior of the spinal fusion implant 10.

FIGS. 2-5 depict various embodiments of the exemplary spinal fusion implant 10. Some common attributes are shared among the various embodiments. More specifically, each spinal fusion implant 10 has a top surface 31, a bottom surface 33, lateral sides 14, a proximal side 22, and a distal side 16. In one embodiment, the top and bottom surfaces 31, 33 are generally parallel. It can be appreciated by one skilled in the art that although the surfaces 31, 33 are generally parallel to one another, they may be provided in any number of suitable shapes, including but not limited to concave and/or convex. When provided as convex shapes, the top and bottom surfaces 31, 33 may better match the natural contours of the vertebral end plates. Although not shown, it will be appreciated that the top and bottom surfaces 31, 33 may be angled relative to one another to better match the natural lordosis of the lumbar and cervical spine or the natural kyphosis of the thoracic spine.

The exemplary spinal fusion implant 10 also preferably includes anti-migration features designed to increase the friction between the spinal fusion implant 10 and the adjacent contacting surfaces of the vertebral bodies so as to prohibit migration of the spinal fusion implant 10 after implantation. Such anti-migration features may include ridges 6 provided along the top surface

31 and/or bottom surface 33. Additional anti-migration features may also include a pair of spike elements 7 disposed within the proximal region of the implant 10, a pair of spike elements 8 disposed within the distal region of the implant 10, and a pair of spike elements 9 disposed within the central region of the implant 10. Spike elements 7, 8, 9 may extend from the top surface 31 and/or bottom surface 33 within the respective proximal, distal and central regions of the implant 10. The spike elements 7, 8, 9 may be manufactured from any of a variety of suitable materials, including but not limited to a metal, ceramic, and/or polymer material, preferably having radiopaque characteristics. The spike elements 7, 8, 9 may also take any of a variety of suitable shapes, including but not limited to a generally elongated element disposed within the implant 10 such that the ends thereof extend generally perpendicularly from the upper and/or lower surfaces 31, 33 of the implant 10. As best appreciated in FIG. 4, the spike elements 7, 8, 9 may each comprise a unitary element extending through upper and lower surfaces 31, 33. Alternatively, each spike element 7, 8, 9 may comprise a shorter element which only extends through a single surface 31, 33 (that is, does not extend through the entire height of the implant 10). In any event, when the spike elements 7, 8, 9 are provided having radiodense characteristics and the implant 10 is manufactured from a radiolucent material (such as, by way of example only, PEEK and/or PEKK), the spike elements 7, 8, 9 will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant 10 during implantation and/or the placement of the implant 10 after implantation.

The spinal fusion implant 10 has two large fusion apertures 2, separated by a medial support 50, extending in a vertical fashion through the top surface 31 and bottom surface 33. The fusion apertures 2 function primarily as an avenue for bony fusion between adjacent

vertebrae. The fusion apertures 2 may be provided in any of a variety of suitable shapes, including but not limited to the generally rectangular shape best viewed in FIG. 3, or a generally circular, oblong and/or triangular shape or any combination thereof. The spinal fusion implant 10 may have a plurality of visualization apertures 4 which allow a clinician to make visual observations of the degree of bony fusion un-obscured by the lateral side 14 to facilitate further diagnosis and treatment. The visualization apertures 4 may be provided in any of a variety of suitable shapes, including but not limited to the generally oblong shape best viewed in FIG. 4, or a generally circular, rectangular and/or triangular shape or any combination thereof.

The spinal fusion implant 10 may be provided with any number of suitable features for engaging the insertion instrument 20 without departing from the scope of the present invention. As best viewed in FIGS. 4-6, one engagement mechanism involves providing a threaded receiving aperture 12 in the proximal sidewall 22 of the spinal fusion implant 10 of the present invention. The threaded receiving aperture 12 is dimensioned to threadably receive a threaded connector 24 on the insertion instrument 20 (as will be described in greater detail below). The receiving aperture 12 extends inwardly from the proximal side 22 in a generally perpendicular fashion relative to the proximal side 22. Although shown as having a generally circular cross-section, it will be appreciated that the receiving aperture 12 may be provided having any number of suitable shapes or cross-sections, including but not limited to rectangular or triangular. In addition to the receiving aperture 12, the spinal fusion implant 10 is preferably equipped with a pair of grooved purchase regions 60, 61 extending generally horizontally from either side of the receiving aperture 12. The grooved purchase regions 60, 61 are dimensioned to receive corresponding distal head ridges 62, 63 on the insertion instrument 20 (as will be described in

greater detail below), which collectively provide an enhanced engagement between the implant 10 and instrument 20.

FIGS. 6-9 detail the exemplary insertion instrument 20 according to one embodiment of the invention. The exemplary insertion instrument 20 includes an elongate tubular element 28 and an inserter shaft 44. The elongate tubular element 28 is constructed with a distal head 26 at its distal end, distal head ridges 62, 63 on the distal end of the distal head 26, a thumbwheel housing 38 at its proximal end and a handle 42 at its proximal end. The elongate tubular element 28 is generally cylindrical and of a length sufficient to allow the device to span from the surgical target site to a location sufficiently outside the patient's body so the handle 42 and thumbwheel housing 38 can be easily accessed by a clinician or a complimentary controlling device.

The elongate tubular element 28 is dimensioned to receive a spring 46 and the proximal end of the inserter shaft 44 into the inner bore 64 of the elongate tubular element 28. The inserter shaft 44 is dimensioned such that the threaded connector 24 at the distal end of the inserter shaft 44 just protrudes past the distal head ridges 62, 63 to allow engagement with the receiving aperture 12 of the spinal fusion implant 10. It should be appreciated by one skilled in the art that such a construction allows the inserter shaft 44 to be able to rotate freely within the elongate tubular element 28 while stabilized by a spring 46 to reduce any slidable play in the insertion instrument 20.

The handle 42 is generally disposed at the proximal end of the insertion instrument 20. The handle 42 is fixed to the thumbwheel housing 38 allowing easy handling by the clinician.

Because the handle 42 is fixed the clinician has easy access to the thumbwheel 34 and can stably turn the thumbwheel 34 relative to the thumbwheel housing 38. Additionally, the relative orientation of the thumbwheel housing 38 to the handle 42 orients the clinician with respect to the distal head 26 and distal head ridge 62. By way of example, the thumbwheel housing 38 holds a thumbwheel 34, a set screw 32, and a spacer 36. The inserter shaft 44 is attached to the thumbwheel 34 and is freely rotatable with low friction due to the spacer 36. One skilled in the art can appreciate myriad methods of assembling a housing similar to the above described.

FIG. 6 details the distal head ridge of the exemplary insertion instrument 20 coupled to the spinal fusion implant 10 through the purchase regions 60, 61. The distal head ridges 62, 63 are dimensioned to fit slidably into the purchase regions 60, 61 with low friction to allow accurate engagement of the threaded connector 24 to the receiving aperture 12 of the spinal fusion implant 10. In the presented embodiment, the outer dimension of the threaded connector 24 is smaller than the largest outer dimension of the distal head 26 and elongate tubular element 28. Alternatively, other methods of creating a gripping surface are contemplated including but not limited to knurling or facets.

In order to use the system to perform a spinal fusion procedure, the clinician must first designate the appropriate implant size. After the spinal fusion implant 10 is chosen, the distal head ridges 62, 63 of the inserter shaft 44 are inserted into the purchase regions 60, 61 of the spinal fusion implant 10. At that time the spinal fusion implant 10 and insertion instrument 20 are slidably engaged with one another. Before the clinician can manipulate the combined spinal fusion implant 10 and insertion instrument 20, they must be releasably secured together. In order

to secure the spinal fusion implant 10 onto the threaded connector 24 of the inserter instrument 20, the clinician employs the thumbwheel 34 to rotate the inserter shaft 44 and threaded connector 24. The rotation of the threaded connector 24 will releasably engage the receiving aperture of the spinal fusion implant 10 and stabilize the insertion instrument 20 relative to the spinal fusion implant 10.

A clinician can utilize the secured system in either an open or minimally invasive spinal fusion procedure. In either type of procedure, a working channel is created in a patient that reaches the targeted spinal level. After the creation of that channel, the intervertebral space may be prepared via any number of well known preparation tools, including but not limited to kerrisons, rongeurs, pituitaries, and rasps. After preparation, the insertion instrument 20 is used to place a spinal fusion implant 10 into the prepared intervertebral space. Once the implant 10 is inserted into the prepared space, the implant 10 is released from the insertion instrument 20 by rotating the thumbwheel 34 to disengage the threaded connector 24 from the receiving aperture 12. That motion removes the compressive force on the purchase regions 60, 61 between the distal head 26 and the distal head ridges 62, 63 of the spinal fusion implant 10 and allows the insertion instrument to be slidably removed from the implant 10. After the threaded connector 24 is disengaged from the implant 10, the insertion instrument 20 is removed from the working channel and the channel is closed. As previously mentioned, additional materials may be included in the procedure before, during or after the insertion of the spinal fusion implant 10 to aid the natural fusion of the targeted spinal level.

FIG. 10 illustrates a spinal fusion system 105 for performing spinal fusion between adjacent cervical vertebrae, including an exemplary spinal fusion implant 110 and an exemplary cervical insertion instrument 120 provided in accordance with the present invention. The spinal fusion implant 110 may comprise of any suitable non-bone composition having suitable radiolucent characteristics, including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone (PEKK)) or any combination of PEEK and PEKK. The spinal fusion implant 110 may be provided in any number of suitable sizes, such as, by way of example only, a width ranging between 11 to 14 mm, a height ranging between 5 and 12 mm, and a length ranging from 14 and 16 mm.

As will be described in detail below, the cervical insertion instrument 120 is configured to releasably maintain the exemplary cervical fusion implant 110 in the proper orientation for insertion. The cervical fusion implant 110 may be simultaneously introduced into a disc space while locked within the cervical insertion instrument 120 and thereafter released. The exemplary cervical fusion implant 110, having been deposited in the disc space, effects spinal fusion over time as the natural bone healing process integrates and binds the implant with the adjacent vertebral bodies. This fusion may be facilitated or augmented by introducing or positioning various materials in a space created within or adjacent to the cervical fusion implant 110. Those materials may be introduced before, during, or after the insertion of the exemplary cervical fusion implant 110. The additional material may include bone autograft harvested from the patient receiving the spinal fusion implant 10, one or more additional bone allograft, bio-resorbables or xenograft implants, any number of non-bone implants, and any number of fusion promoting compounds such as bone morphogenic protein.

FIGS. 11-14 depict various embodiments of the exemplary cervical fusion implant 110. Some common attributes are shared among the various embodiments. More specifically, each cervical fusion implant 110 has a top surface 31, a bottom surface 33, lateral sides 14, a proximal side 22, and a distal side 16. In one embodiment, the top and bottom surfaces 31, 33 are generally parallel. It can be appreciated by one skilled in the art that although the surfaces are generally parallel, that the top 31 and bottom 33 surfaces may be angled with respect to one another to match the natural curve of the spine (i.e. lordosis or kyphosis). By way of example, implants for the cervical or lumbar regions of the spine will have anterior height greater than the posterior height to match the natural lordosis in those regions. Inversely, the implants designed for implantation into the thoracic region will be manufactured with a posterior height greater than the anterior height to match the natural kyophosis in that region. Additionally, the angled surface can aid in overall fit within the vertebral disc space.

The cervical fusion implant 110 preferably includes two receiving apertures 12 which are centrally aligned on the proximal side 22. The receiving apertures 12 extend inwardly from the proximal side 22 in a generally perpendicular fashion relative to the proximal side 22. Although shown as having a generally circular cross-section, it will be appreciated that the receiving aperture 12 may be provided having any number of suitable shapes or cross-sections, including but not limited to rectangular or triangular.

The exemplary cervical fusion implant 110 also preferably includes anti-migration features such as anti-migration teeth 6 along the top surface 31 and bottom surface 33.

Additional anti-migration features may include a plurality of proximal anti-migration spikes 68 and/or distal anti-migration spikes 70 integrated vertically through the cervical fusion implant 110. The anti-migration features increase the friction between the cervical fusion implant 110 and the adjacent contacting surfaces of the vertebral bodies. That friction prohibits migration of the cervical fusion implant 110 during the propagation of natural bony fusion. It should be appreciated by one skilled in the art that such anti-migration teeth 6 can be oriented in a any manner other than generally vertically (as shown) without departing from the scope of the present invention. Moreover, as described above, the spikes 68, 70 may be constructed from any of a variety of radiopaque materials, including but not limited to a metal, ceramic, and/or polymer material. When the spike elements 68, 70 are provided having such radiodense characteristics, and the implant 110 is manufactured from a radiolucent material (such as, by way of example only, PEEK and/or PEKK), the spike elements 68, 70 will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant 110 during implantation and/or the placement of the implant 110 after implantation.

The cervical fusion implant 110 has one large fusion aperture 2, extending in a vertical fashion through the top surface 31 and bottom surface 33 which will function primarily as the avenue for bony fusion between adjacent vertebrae. The cervical fusion implant 110 may have a plurality of visualization apertures 4 which can also serve as an avenue of bony fusion on the lateral sides 14 via cell migration or additional adjuvants. The visualization apertures 4 serve an additional function of allowing a clinician to make visual observations of the degree of bony fusion un-obscured by the lateral side 14 to facilitate further diagnosis and treatment.

FIG. 15 illustrates, by way of example, the orientation of the cervical fusion implant 110 prior to attachment to the cervical insertion instrument 120 by a clinician. One skilled in the art would appreciate that although the current embodiment shows a slidable engagement, various other methods of engagement are contemplated, such as, threadable or hooking features.

FIGS. 16-17 detail the tubular lock member 21 of the exemplary cervical inserter instrument 110. The tubular lock member 21 includes a central bore 25 dimensioned to receive the proximal end of the elongate fork member 11 therein. The internal dimension of the central bore 25 is smaller than the largest freestanding outer dimension of the taper feature 19. As a result, the portion of the elongate fork member 11 that may be received by the central bore 25 of the tubular lock member 21 is limited by interference between the distal end of the tubular lock member 21 and the taper feature 19 of the elongate fork member 11. In the present embodiment, the outer dimension of the threaded feature 13 of the elongate fork member 11 is smaller than the largest outer dimension of the taper feature 19 on the elongate fork member 11. A thread feature 23 (not shown) at the proximal end of the tubular lock member 21 is situated inside the central bore 25. The thread feature 23 matches the thread feature 13 on the elongate fork member 11 so that they can be threadably attached to one another. To ease the rotation of the tubular lock member 21 by hand, two semi-circular wings 27 may be provided protruding laterally outward from either side of the tubular lock member 21. Alternatively, other methods of creating a gripping surface are contemplated including but not limited to knurling or facets.

A clinician can utilize the secured system in either an open or minimally invasive spinal fusion procedure. In either type of procedure, a working channel is created in a patient that

reaches the targeted spinal level. After the creation of that channel, the intervertebral space would be prepared (via known instruments as described above). After preparation, the insertion instrument 120 is used to place a cervical fusion implant 110 into the prepared intervertebral space. Once the cervical fusion implant 110 is inserted into the prepared space, the implant 110 is released from the cervical insertion instrument 120 by retracting the tubular lock member 21 from the elongate fork member 11 by rotating the tubular lock member 21 with respect to the elongate fork member 11 in the opposite direction from that used to initially secure the implant 110. That motion removes the compressive force on the purchase region 39 between the apertures 12 of the cervical fusion implant 110 and allows the engagement features 17 to be slidably removed from the apertures 12. After the engagement features 17 are disengaged from the cervical fusion implant 110, the cervical inserter instrument 120 is removed from the working channel and the channel is closed. As previously mentioned, additional materials may be included in the procedure before, during or after the insertion of the cervical fusion implant 110 to aid the natural fusion of the targeted spinal level.

In order to use the system to perform a spinal fusion procedure, the clinician must first designate the appropriate implant size. After the cervical fusion implant 110 is chosen, the engagement features 17 of the elongate fork member 11 are inserted into the apertures 12 on the implant 110. At that time the cervical fusion implant 110 and elongate fork member 11 are slidably engaged with one another. Before the clinician can manipulate the combined cervical fusion implant 110 and elongated fork member 11, they must be releasably secured together. In order to secure the cervical fusion implant 110 onto the elongate fork member 11, the clinician would next employ the tubular lock member 21. The clinician would insert the proximal end of

the elongate fork member 11 into the central bore 25 of the tubular lock member 21 at its distal end. The tubular lock member 21 would then be advanced over the elongate fork member 11 until the thread feature 13 of that member and the thread feature 23 of the tubular lock member 21 become engaged.

Once engaged, advancement of the tubular lock member requires rotation of the tubular lock member 21 with respect to the elongate fork member 11. Preferably, after only a small amount of engagement of the thread features the distal end of the tubular lock member 21 would contact the taper feature 19 of the elongate fork member 11. The tubular lock member 21 would be advanced creating greater interference as the distal end approaches the distal end of the taper feature 19 which has the larger outer dimension. The increasing interference would laterally displace the clamping arms 15 of the elongate fork member 11 towards each other. Since the engagement features 17 of the elongate fork member 11 were initially inserted into the apertures 12 of the exemplary cervical fusion implant 110, the displacement of the clamping arms 15 would create a compressive force on the purchase region 39 separating the apertures 12 of the exemplary cervical fusion implant 110. That compressive force allows a clinician to manipulate the system without the exemplary cervical fusion implant 110 becoming disengaged from the cervical inserter instrument 120.

The enhanced visualization features of the implants 10, 110 are explained in greater detail with reference to FIGS. 18-23. FIG. 18 illustrates an implant 10 dimensioned particularly for use in a posterior approach (PLIF) having (by way of example only) a width ranging between 9 and 11 mm, a height ranging between 8 and 14 mm, and a length ranging between 25 and 30 mm.

FIG. 19 illustrates the implant 10 of FIG. 18 from a side perspective via as taken via X-ray or fluoroscopy techniques, clearly showing the location of the spike elements 7 and 8 (there is no central spike element 9 as with FIG. 1) relative to the implant 10 and visualization apertures 4. FIG. 20 illustrates an implant 10 dimensioned particularly for use in a lateral approach (XLIF™ by NuVasive) having (by way of example only) a width of approximately 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 40 and 45 mm. FIG. 21 illustrates the implant 10 of FIG. 20 from a side perspective via as taken via X-ray or fluoroscopy techniques, clearly showing the location of the spike elements 7, 8, 9 relative to the implant 10 and visualization apertures 4. FIG. 22 illustrates an implant 110 dimensioned particularly for use in the cervical spine having (by way of example only) a width of approximately 11 mm, a height ranging between 5 and 12 mm, and a length of approximately 14 mm. FIG. 23 illustrates the implant 110 of FIG. 22 from a side perspective via as taken via X-ray or fluoroscopy techniques, clearly showing the location of the spike elements 66 relative to the implant 110 and visualization apertures 4. In this fashion, a surgeon may easily track the progress of the implant 10, 110 during implantation and/or after implantation by visualizing the spike elements 7,8,9 and 66, respectively, under X-ray and/or fluoroscopy according to the present invention.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the description herein of specific embodiments is not intended to limit the invention to the particular forms disclosed, but on the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

For example, while described herein primarily with reference to the lumbar and cervical spinal surgery, it is to be readily appreciated that the spinal fusion implants of the present invention may be suitable for accomplishing fusion in the thoracic spine without departing from the scope of the present invention. Moreover, it is to be readily appreciated that the insertion tools described herein may be employed with implants of any number of suitable constructions, including but not limited to metal, ceramic, plastic or composite.

Claims

What is claimed is:

1. A spinal fusion system comprising;

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

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

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

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

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

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

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

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

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

8. The spinal fusion system of Claim 7, wherein the securing mechanism includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member such that turning the rotation device causes the generally elongated shaft

member to turn, and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture, releasably securing the implant to the insertion instrument.

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

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

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

12. The spinal fusion system of Claim 11, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate

fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.

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

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

(a) releasably securing a spinal fusion implant to an insertion instrument, the spinal fusion implant including a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having at least one receiving aperture for engaging an insertion instrument, and two lateral sides, and the insertion instrument including a generally elongated tubular member

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

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

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

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

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

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

18. The spinal fusion method of Claim 14, wherein the implant further includes anti-migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement, the anti-migration features including at least one of

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

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

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

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

22. The spinal fusion method of Claim 21, wherein the proximal end of the implant further includes at least one purchase region adjacent to the receiving aperture and

wherein the distal opening of the generally elongated tubular member is situated in a distal head, the distal head including at least one distal head ridge, adjacent to the distal opening, for engaging the purchase region on the implant and enhancing the engagement between the implant and the insertion instrument.

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

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

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

26. The spinal fusion method of Claim 25, including a securing mechanism for releasably securing the engagement features in the receiving apertures of the implant, the securing mechanism including, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near

the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device.

ABSTRACT

A system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites.

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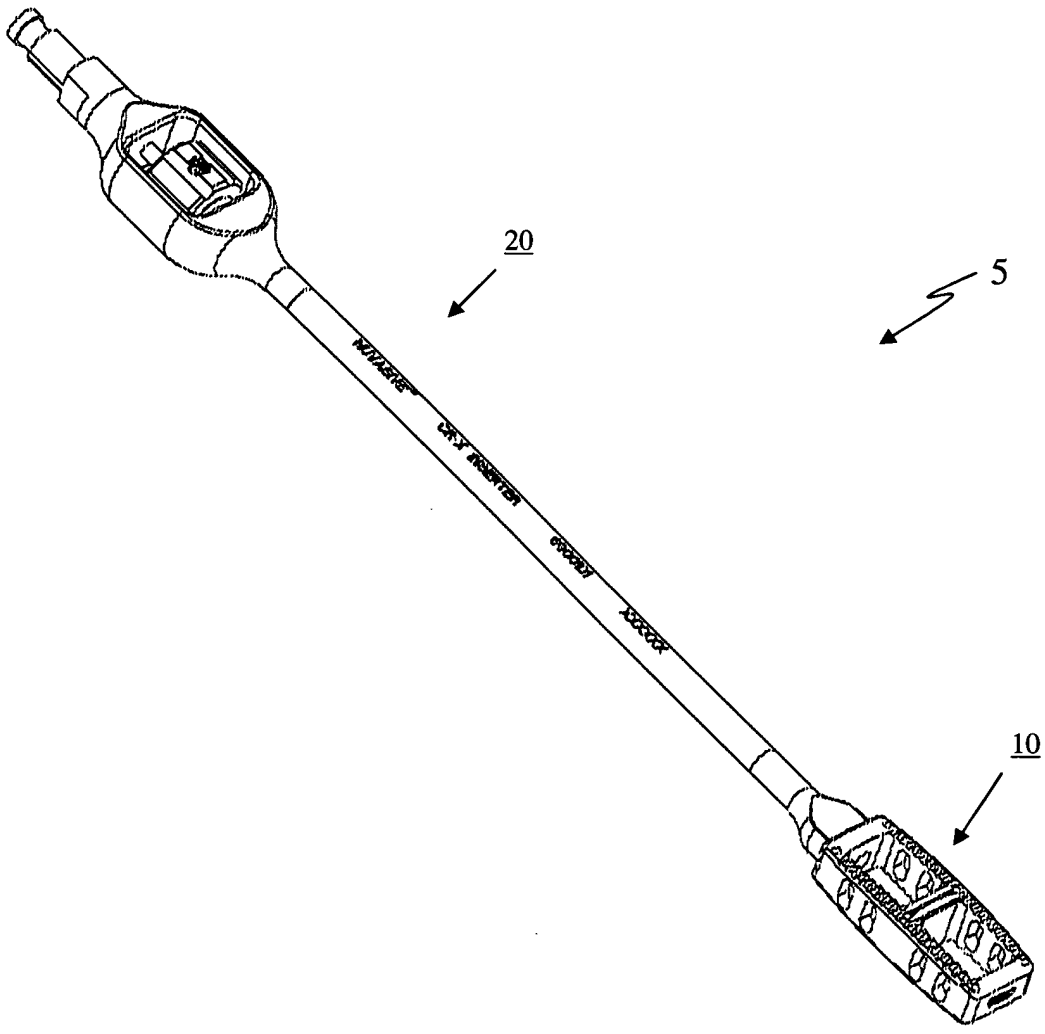

FIG. 1

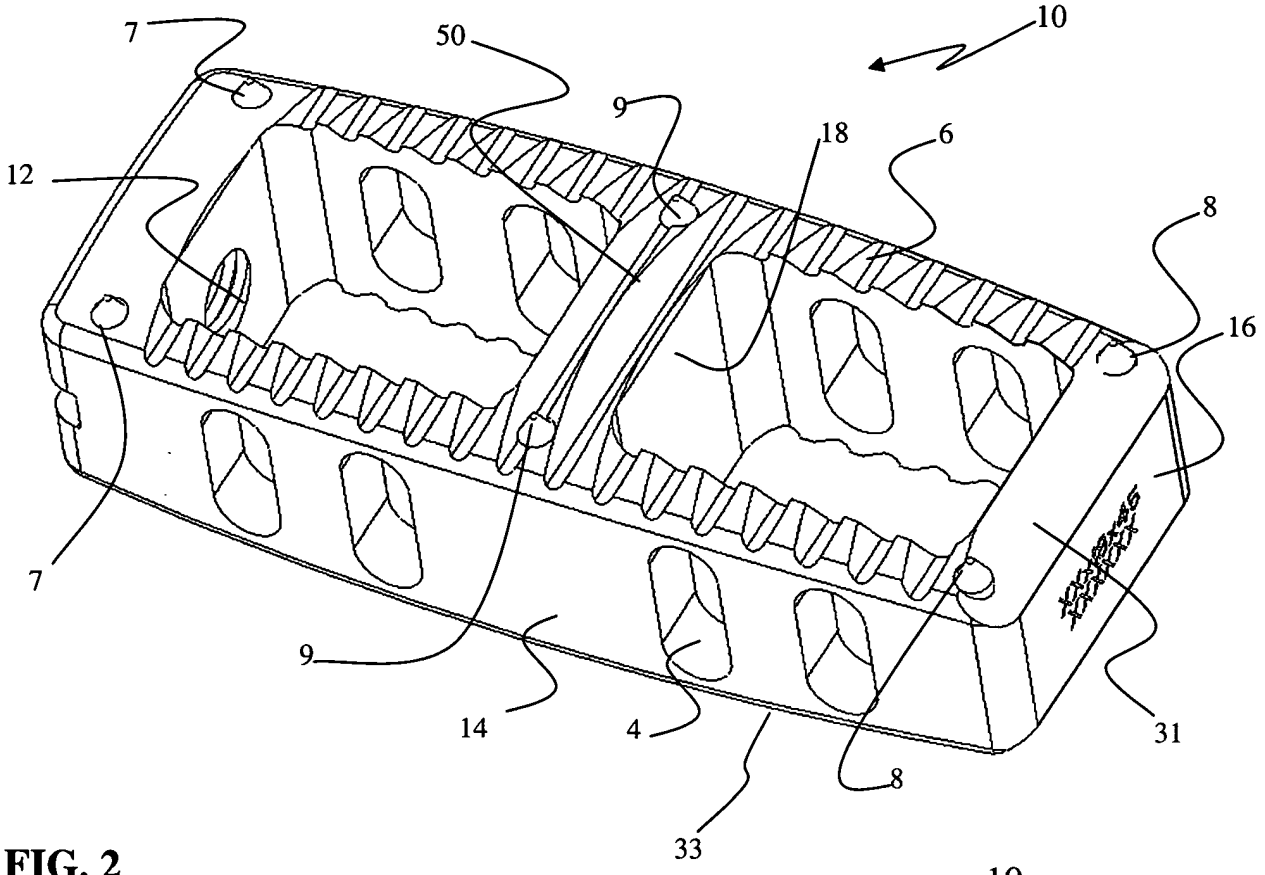

FIG. 2

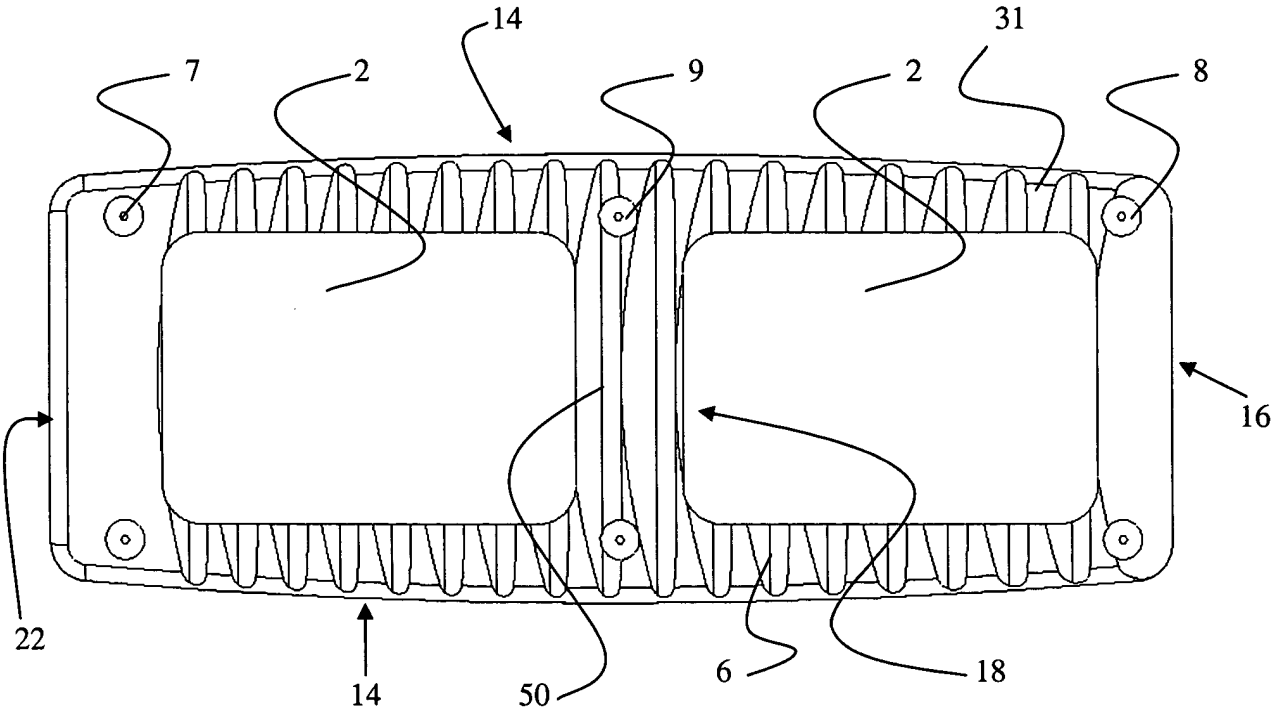

FIG. 3 10

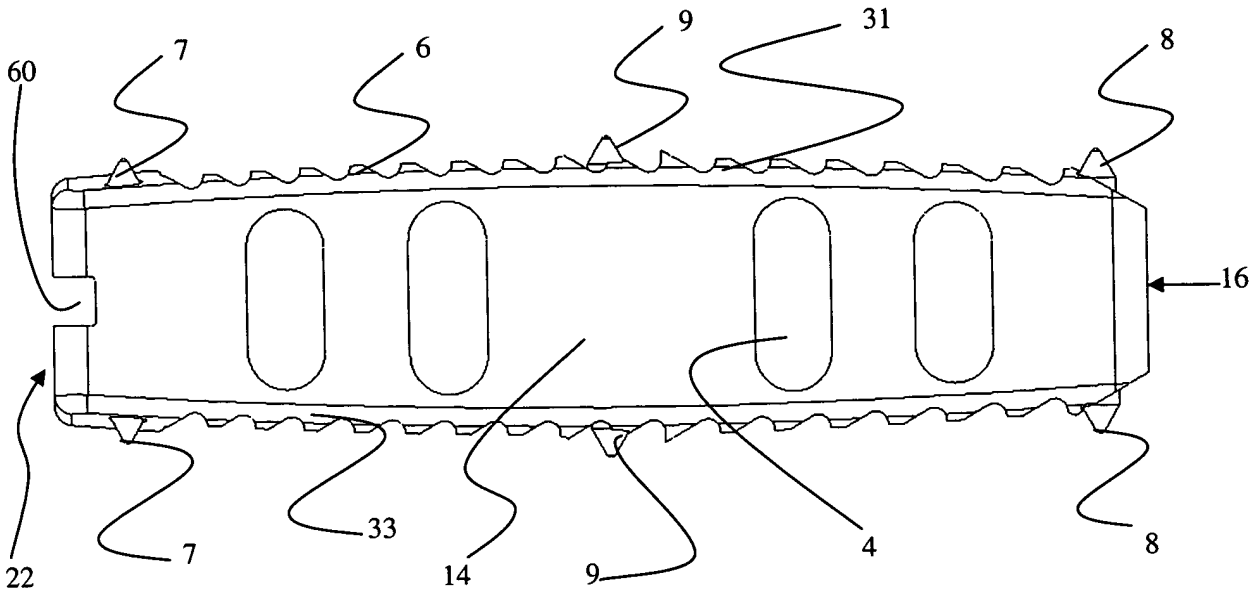

FIG. 4 10

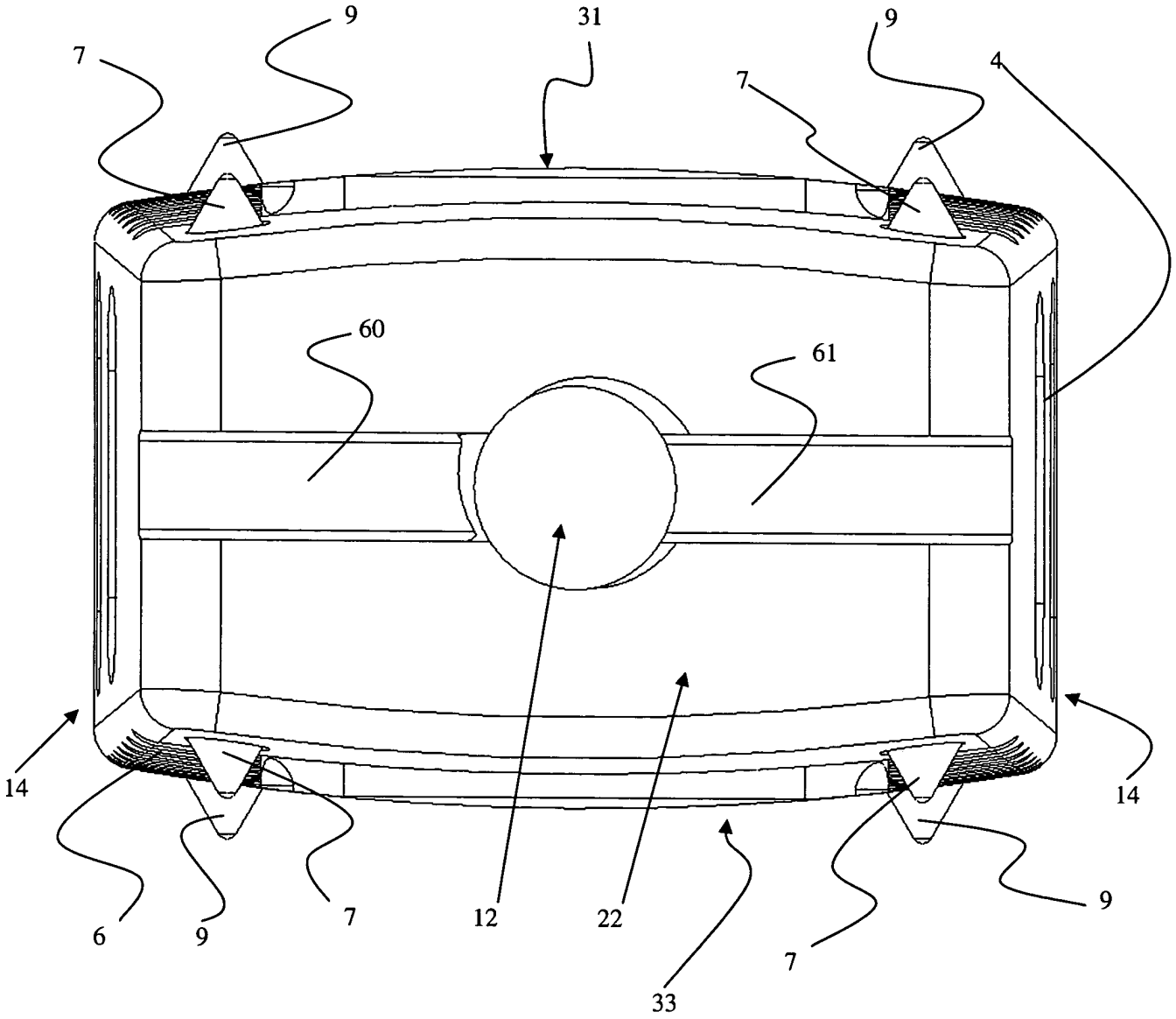

FIG. 5

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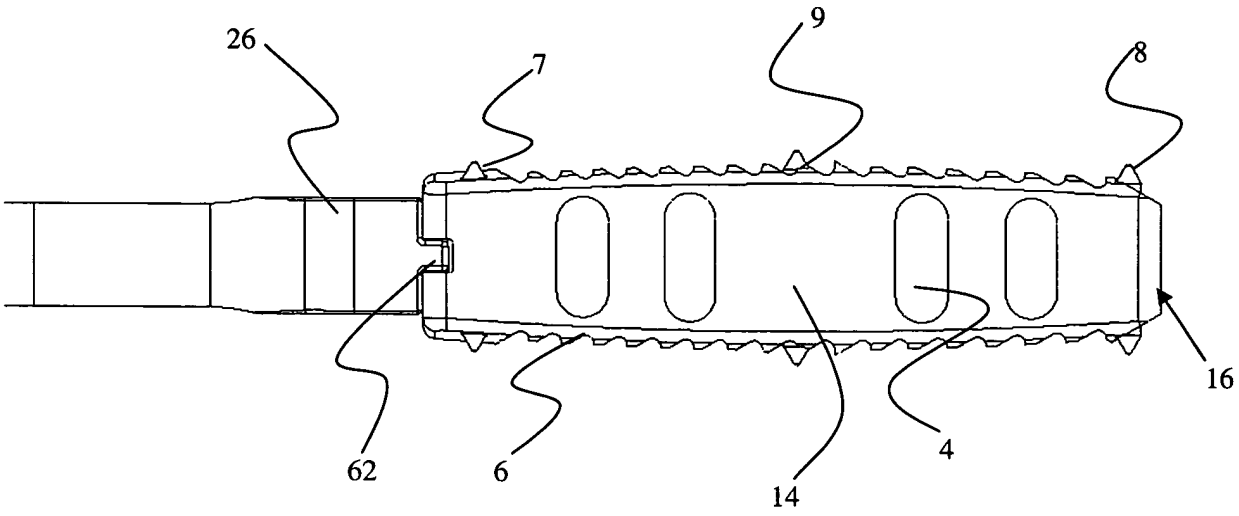


FIG. 6

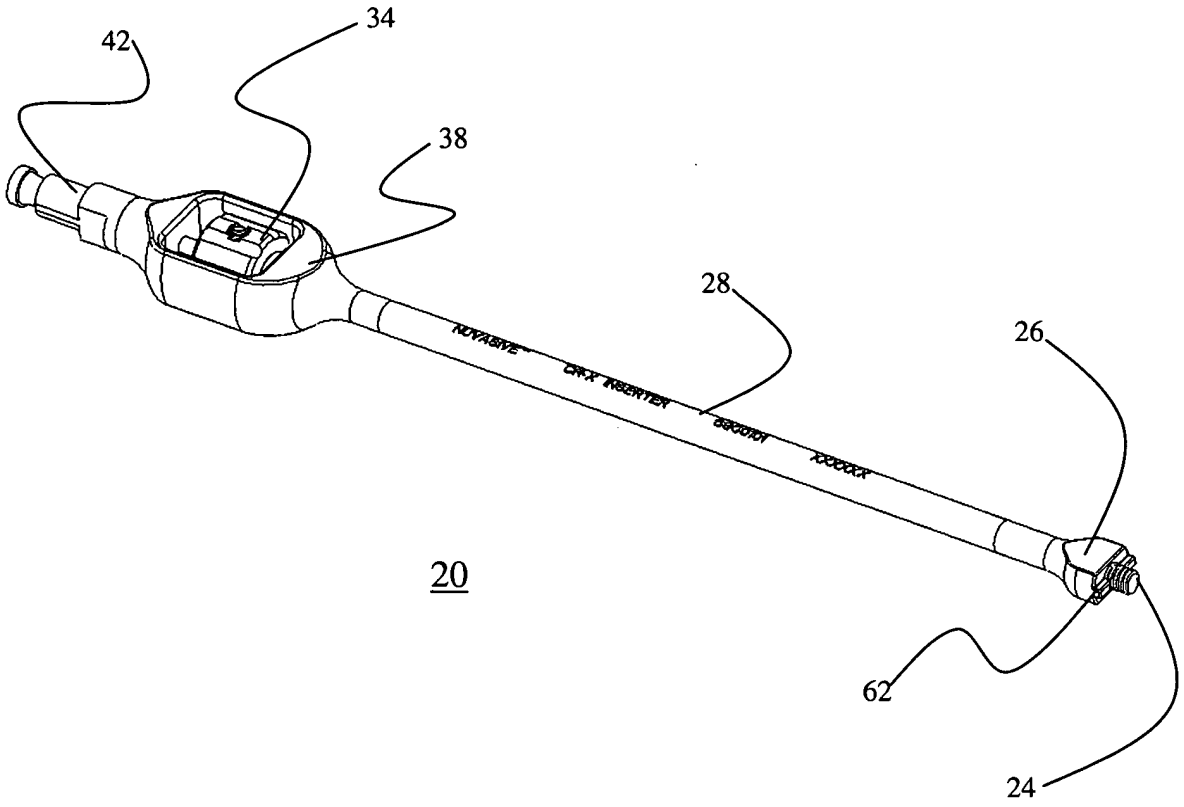


FIG. 7

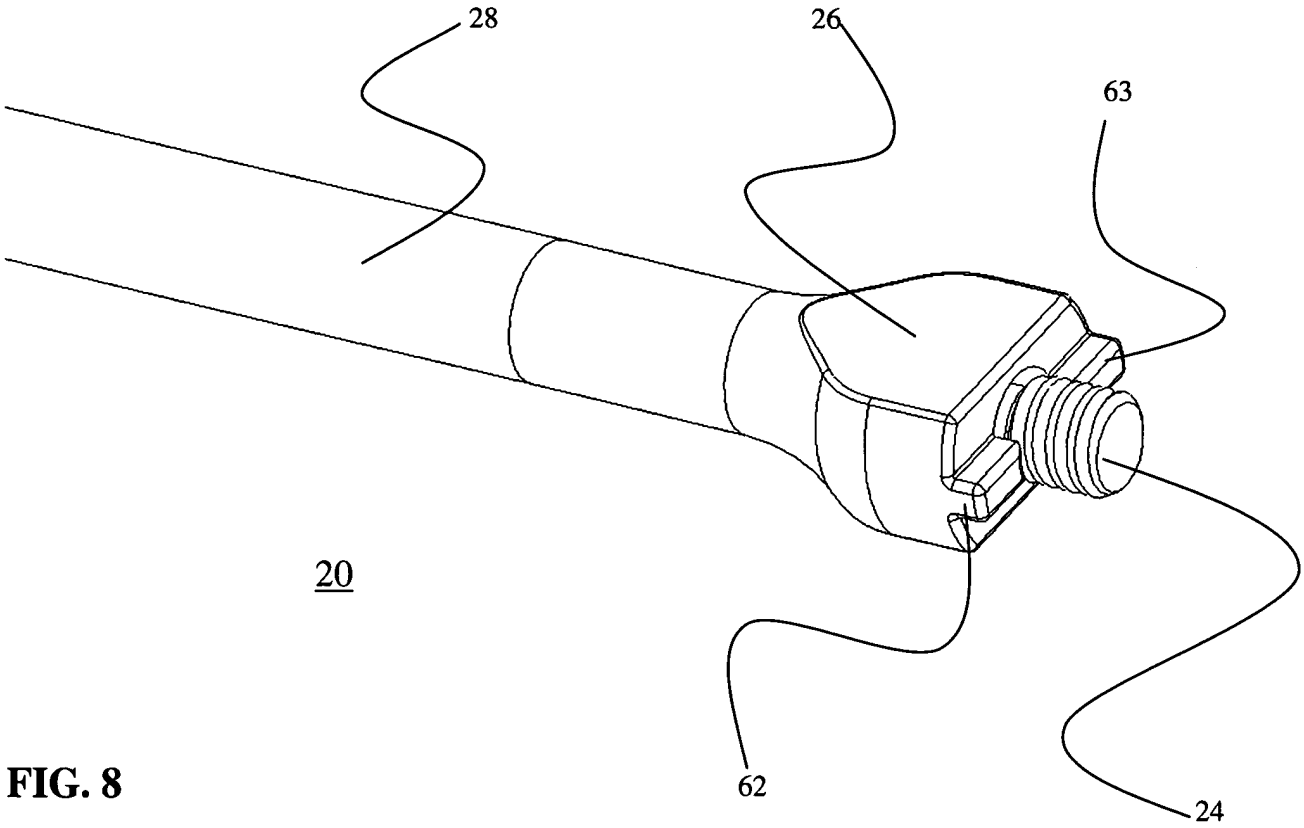


FIG. 8

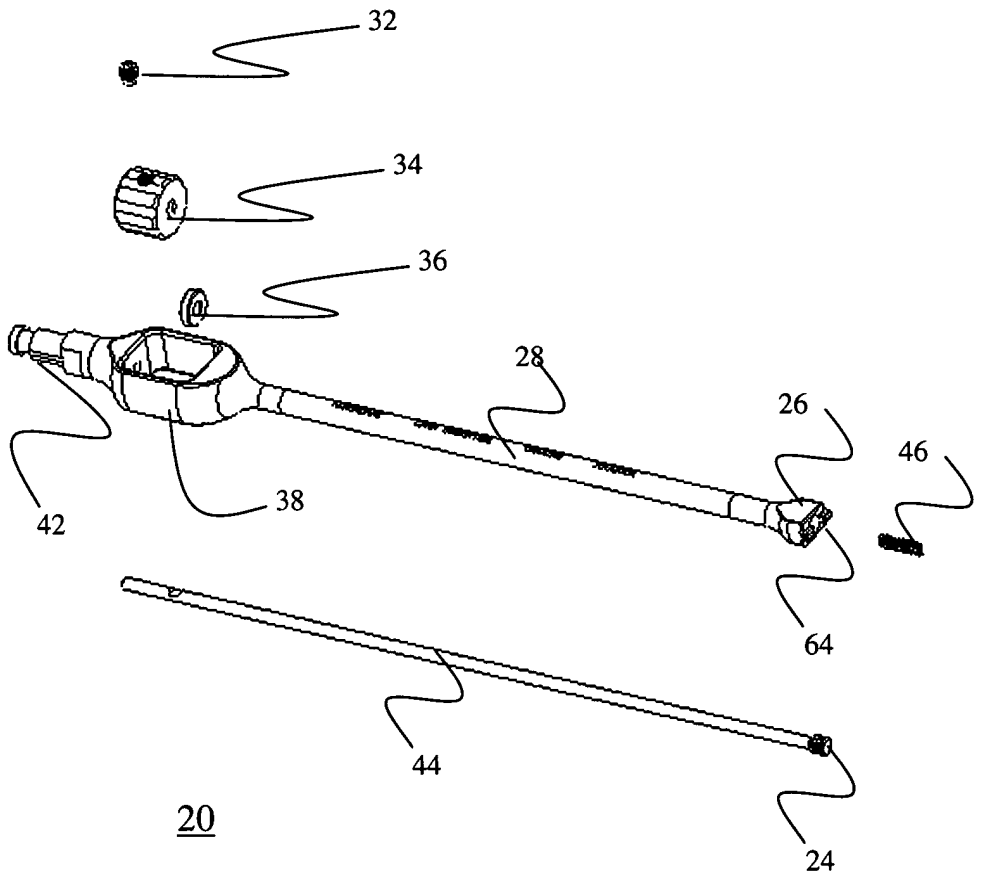


FIG. 9

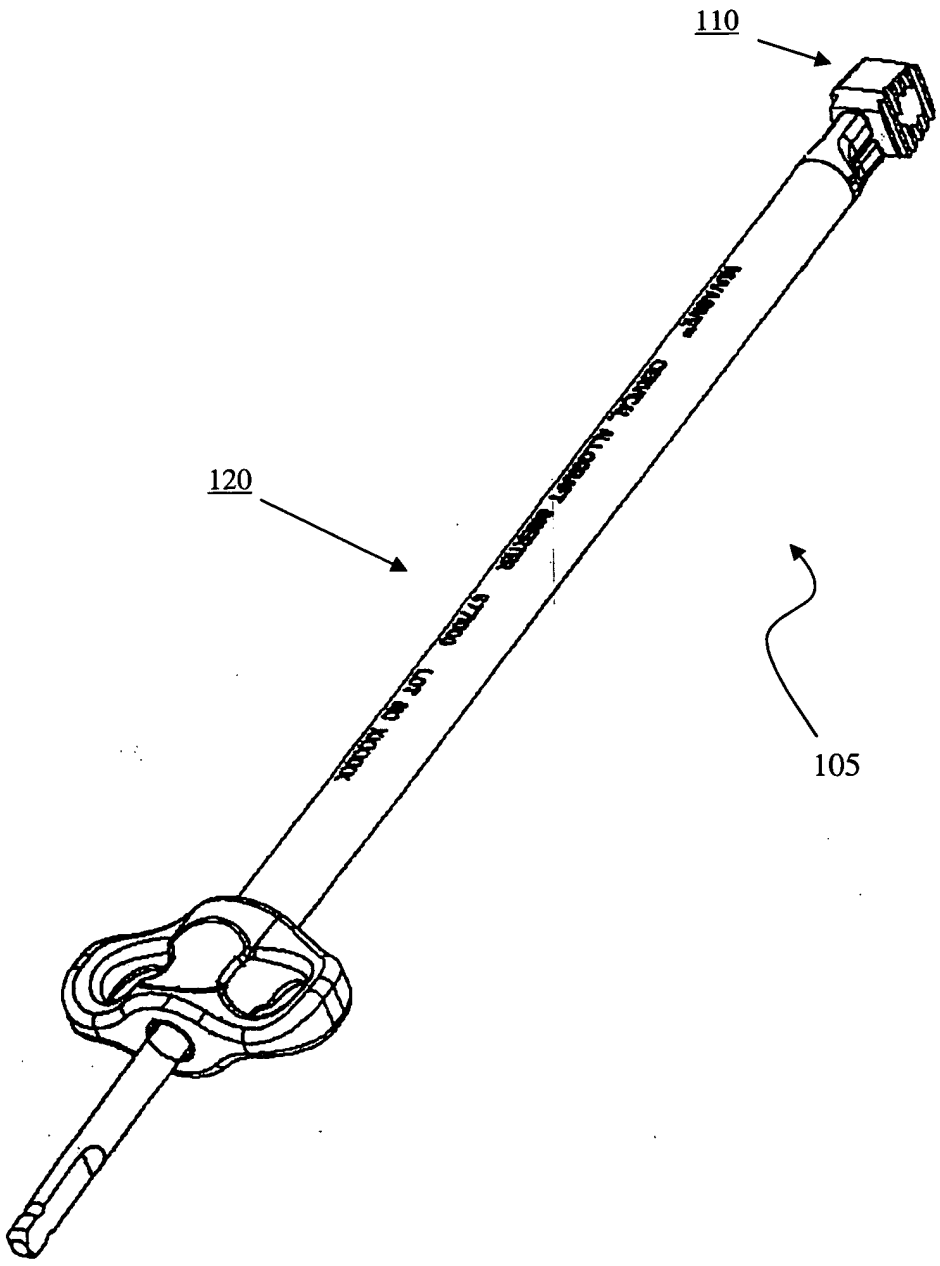


FIG. 10

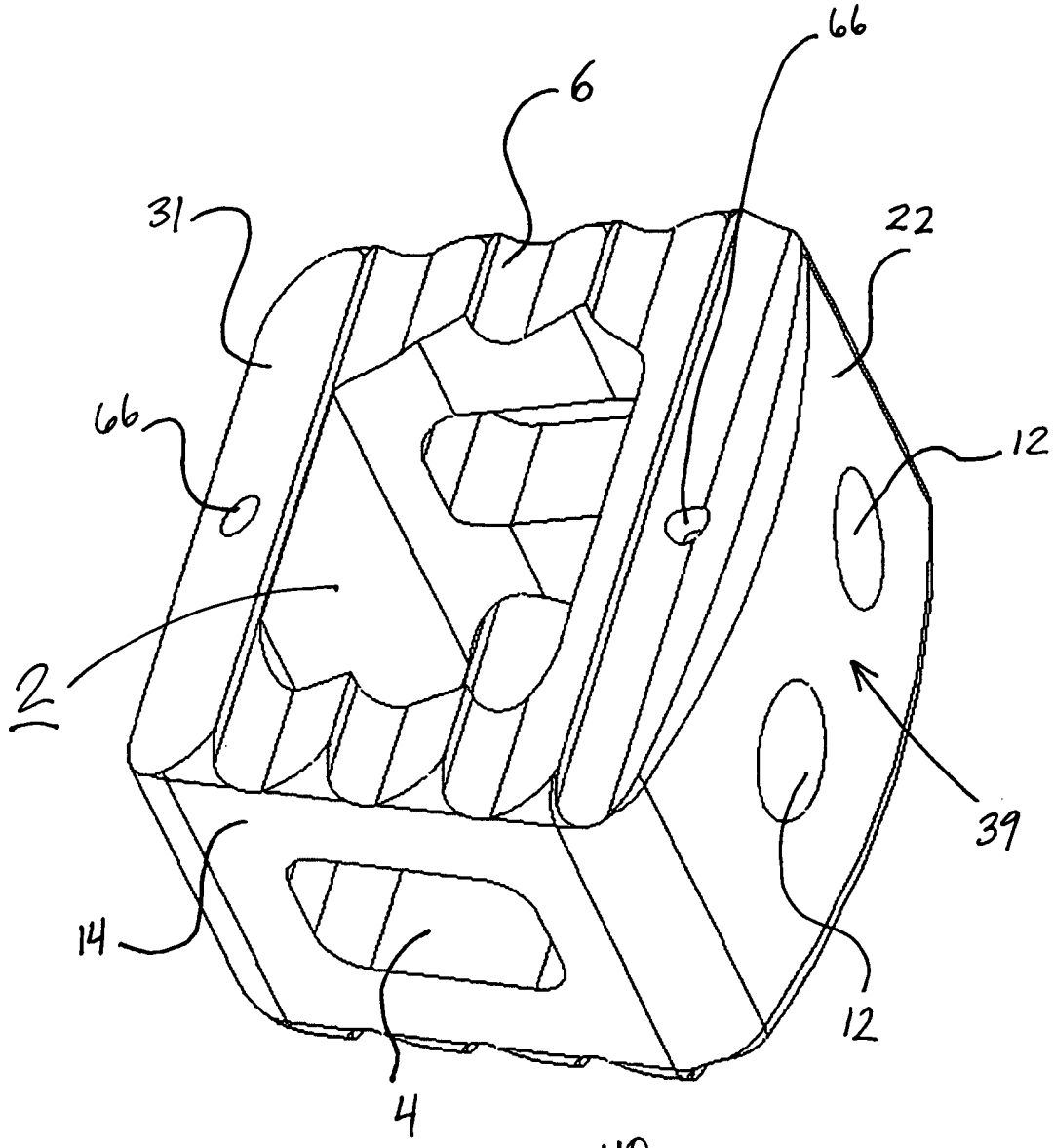


Fig. 11

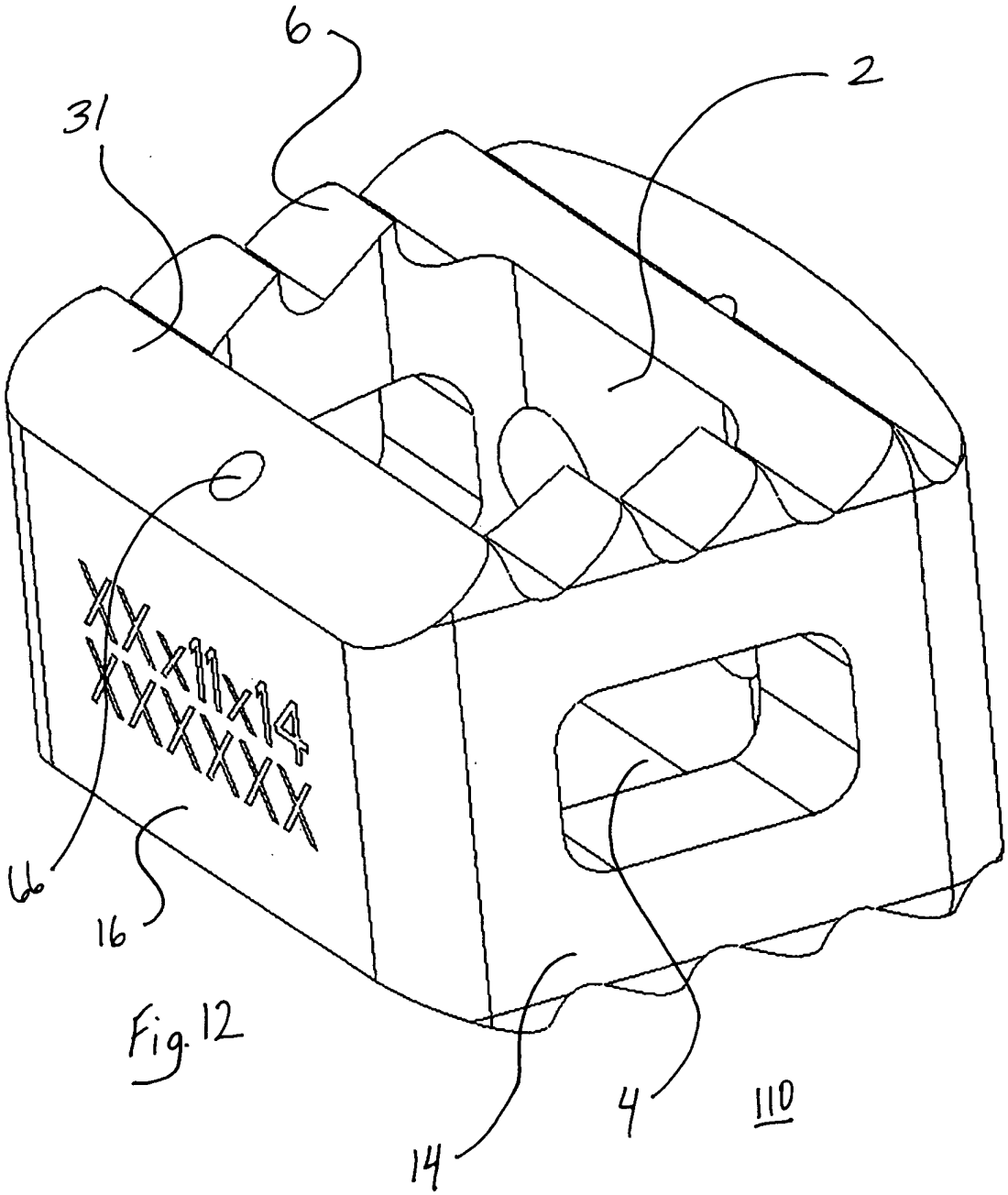


Fig. 12

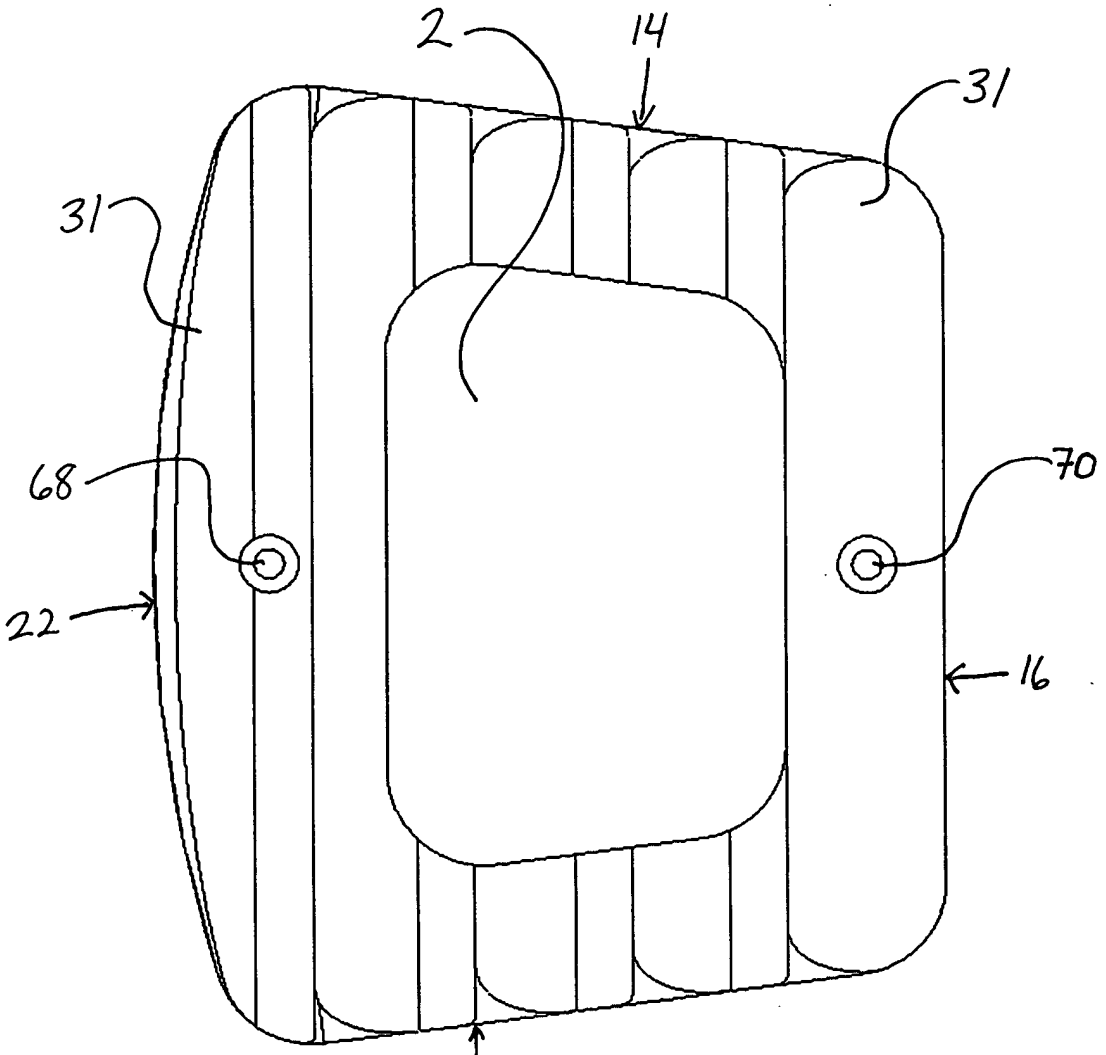


Fig. 13

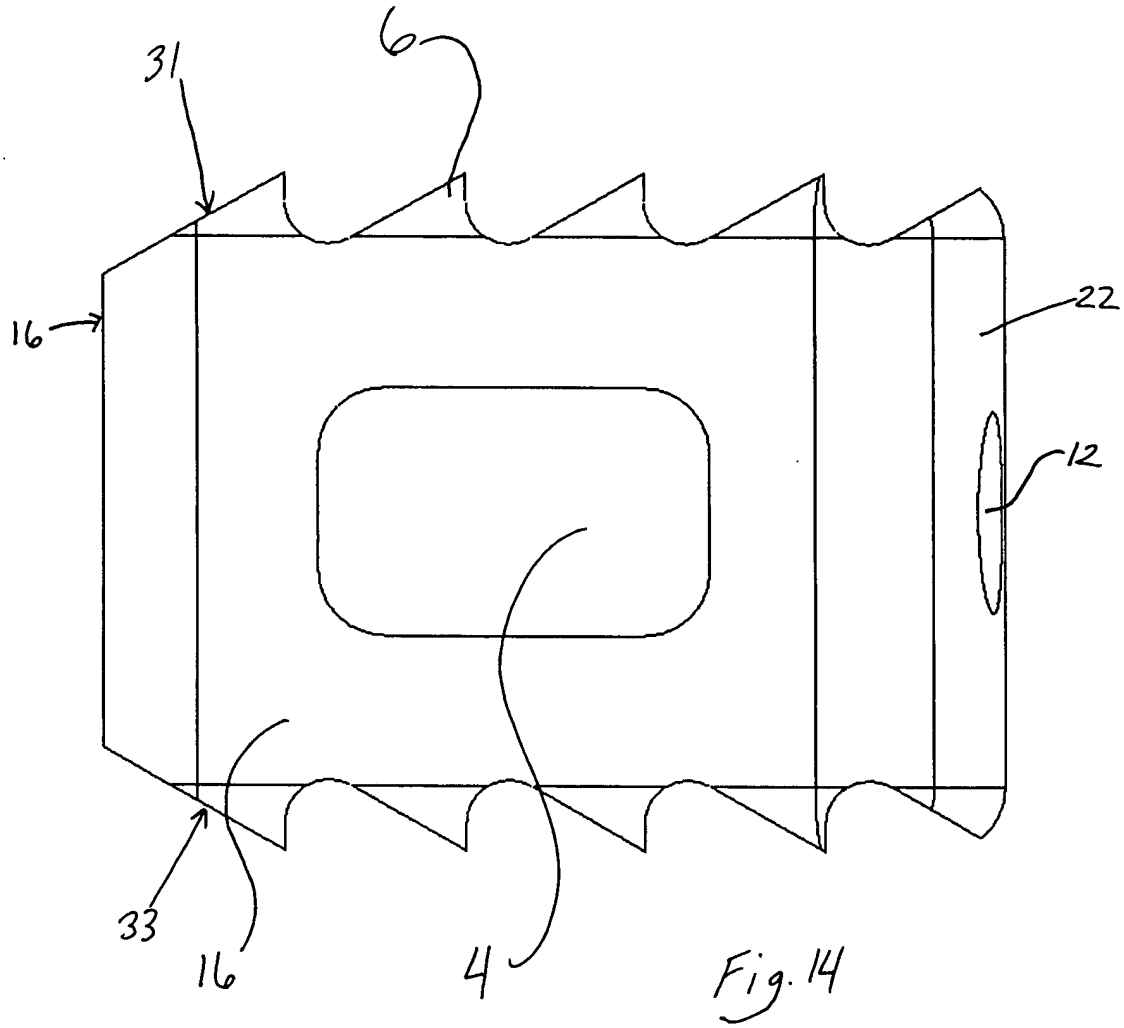


Fig. 14

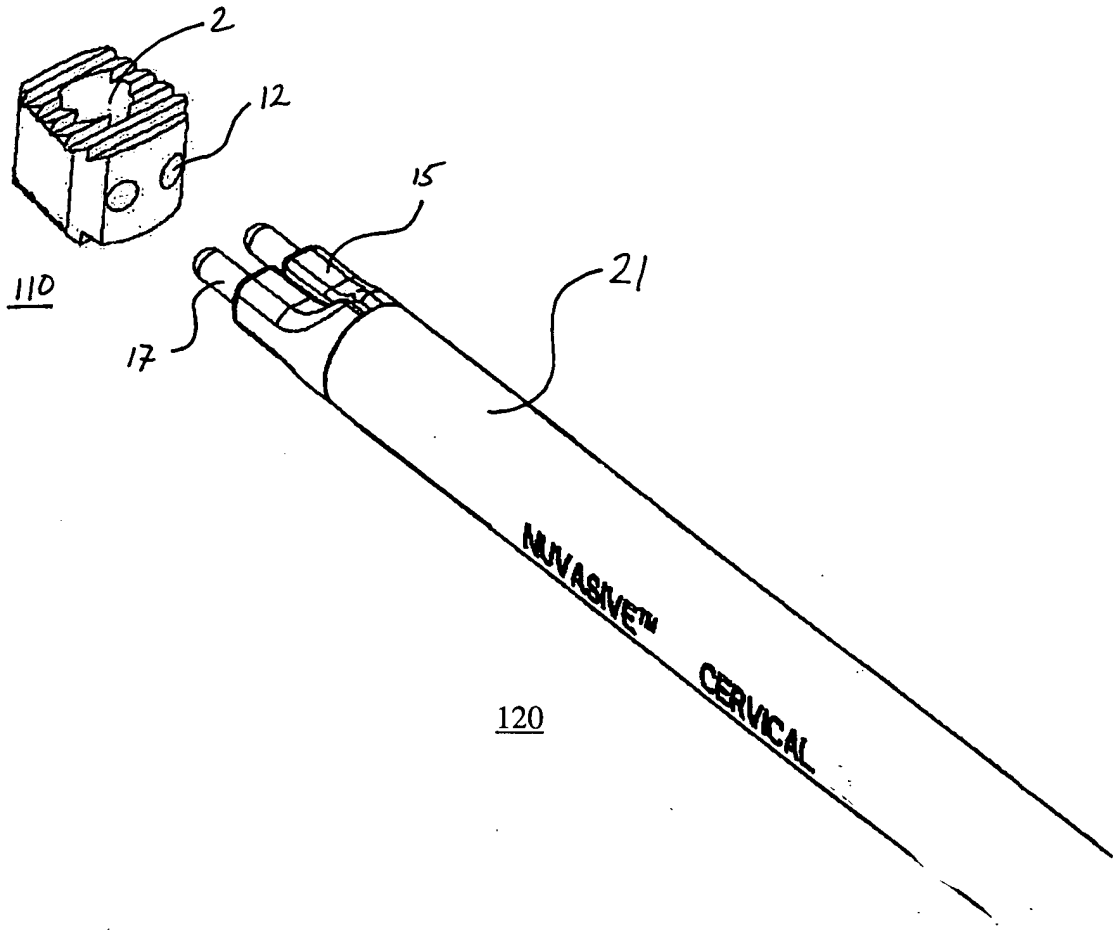


FIG. 15

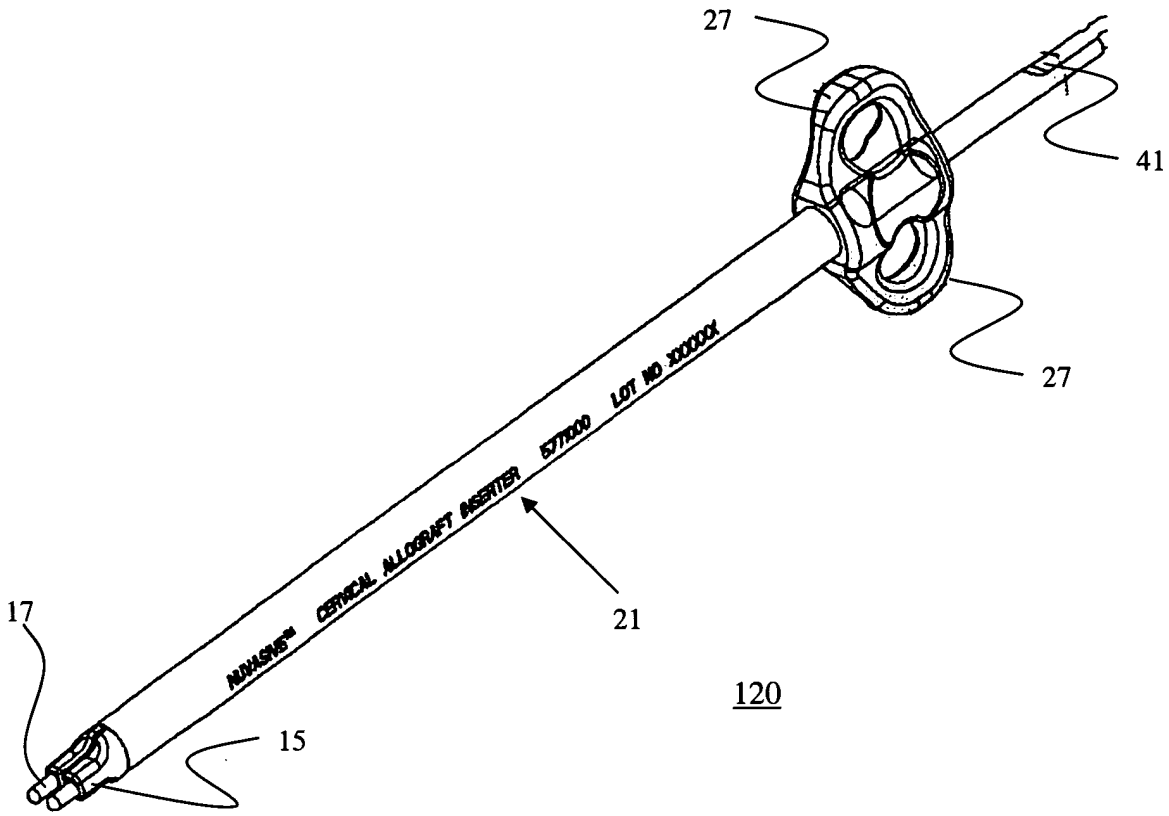


FIG. 16

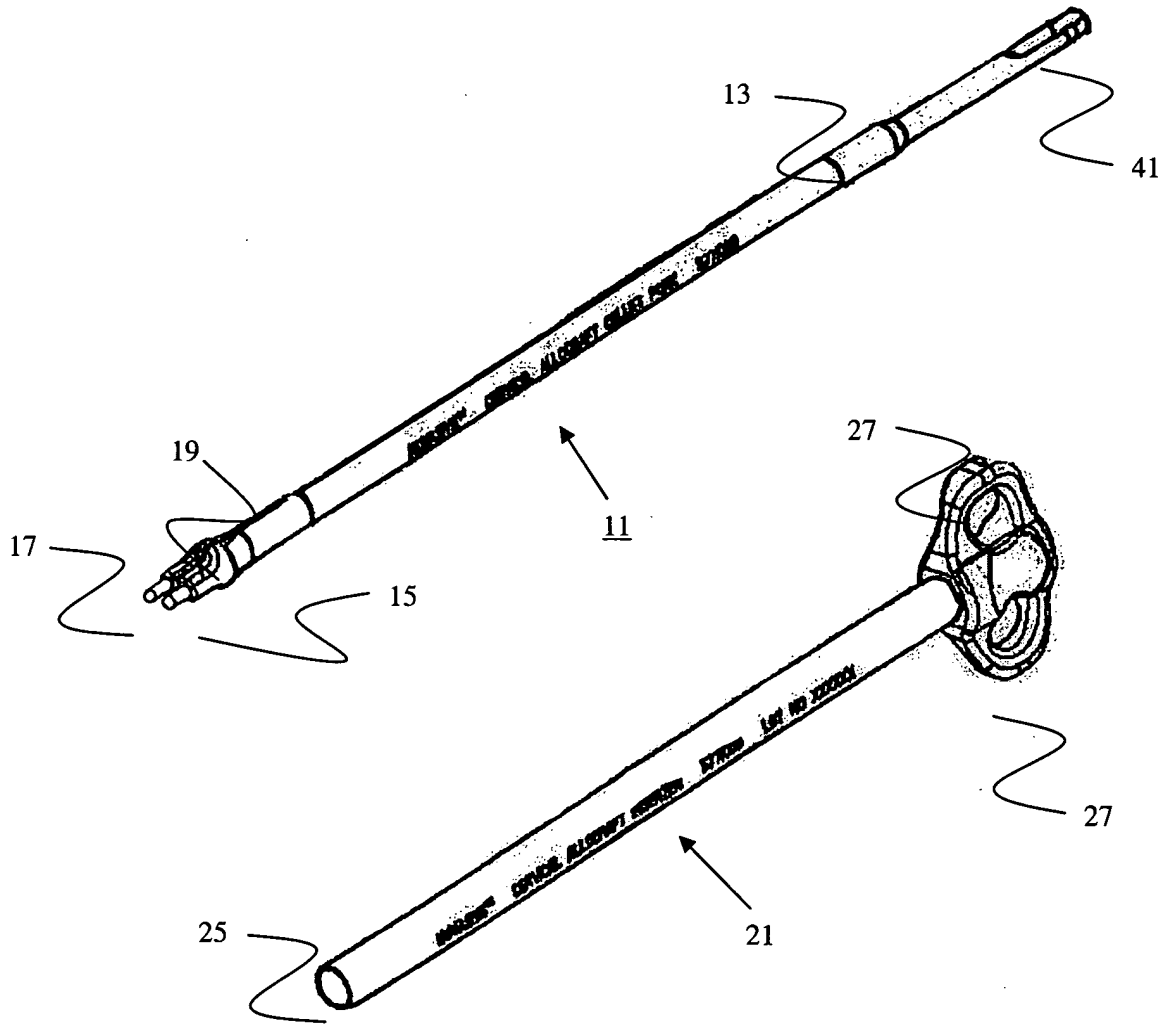


FIG. 17

FIG. 18

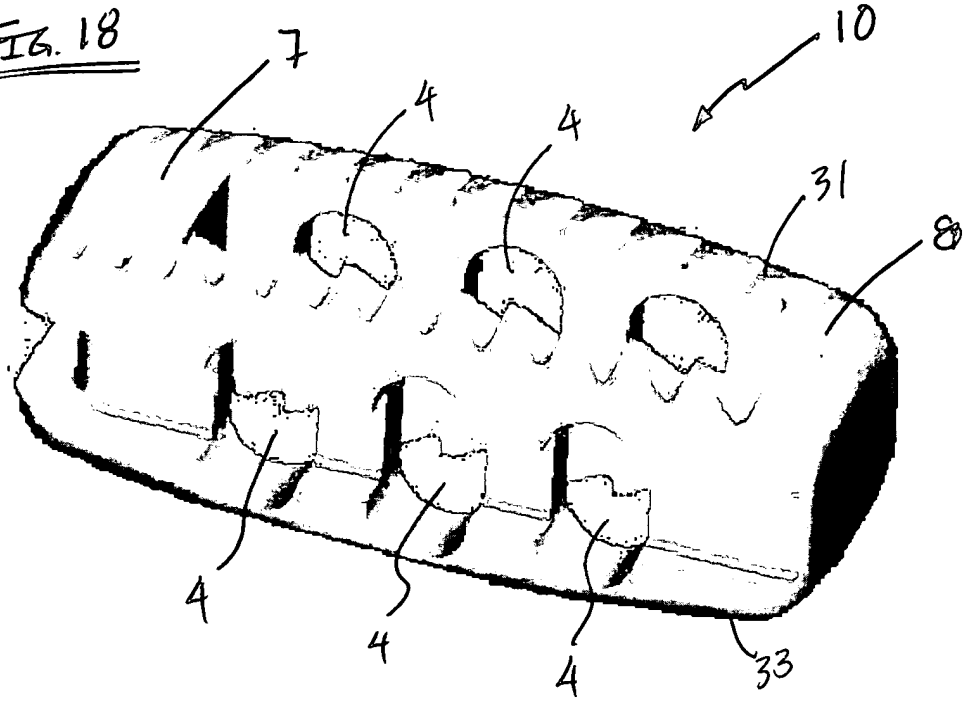


FIG. 19

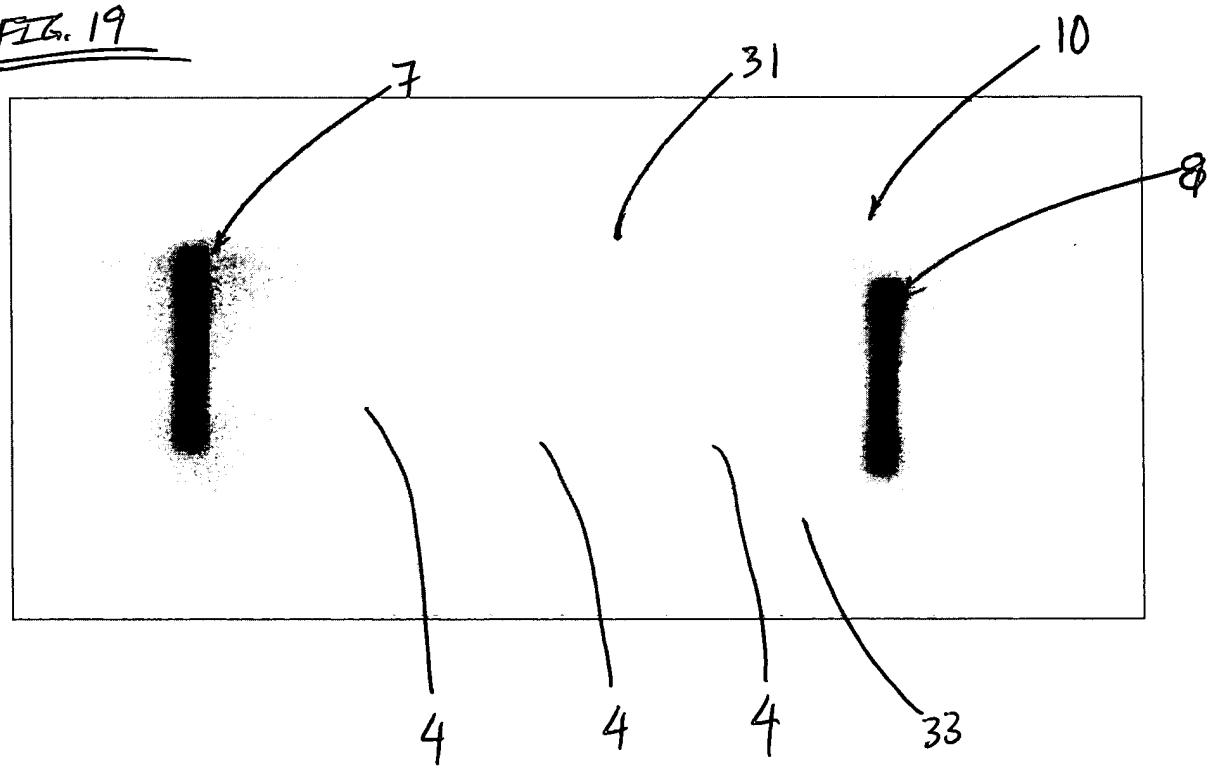


FIG. 20

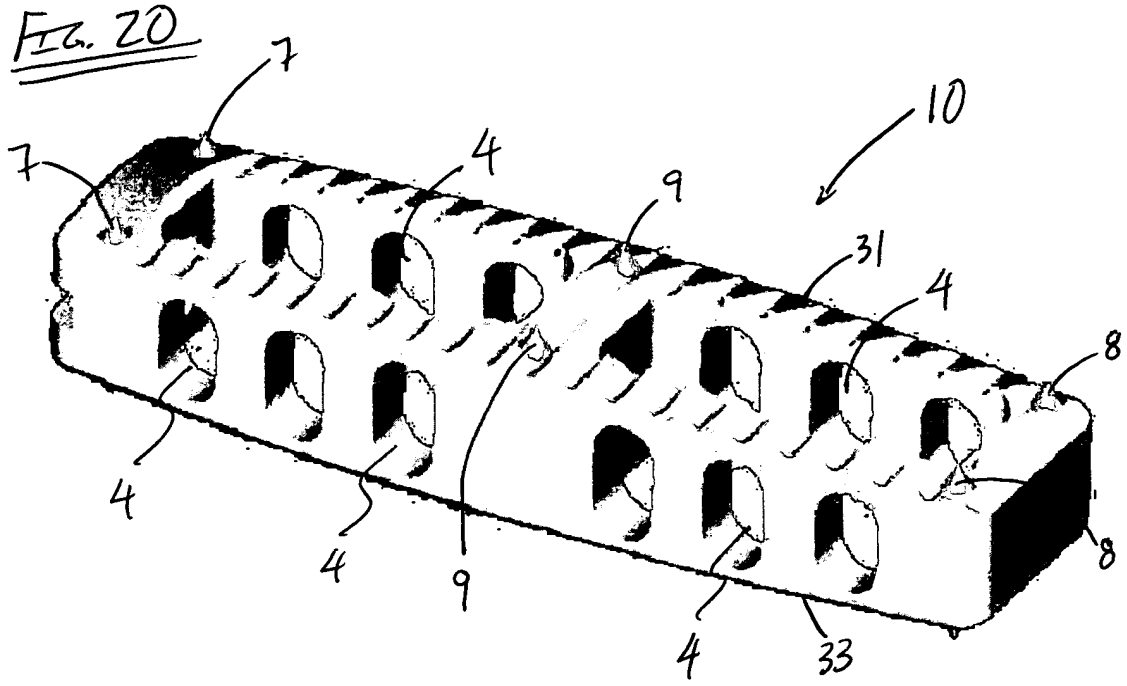


FIG. 21

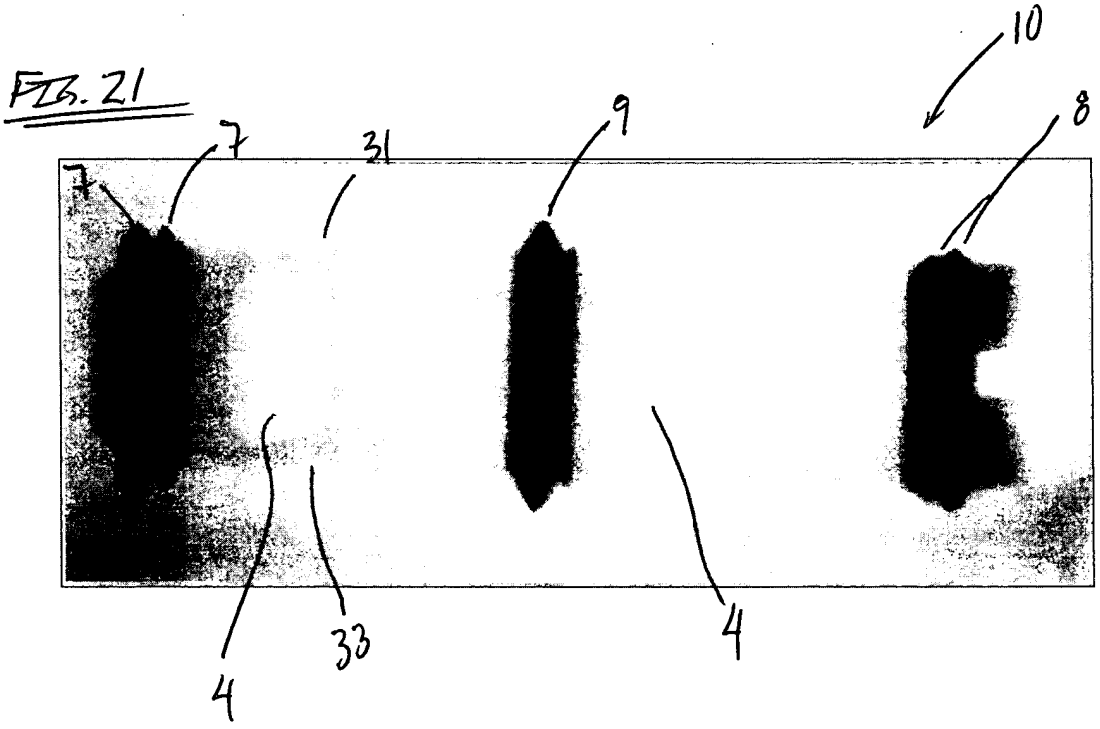


FIG. 22

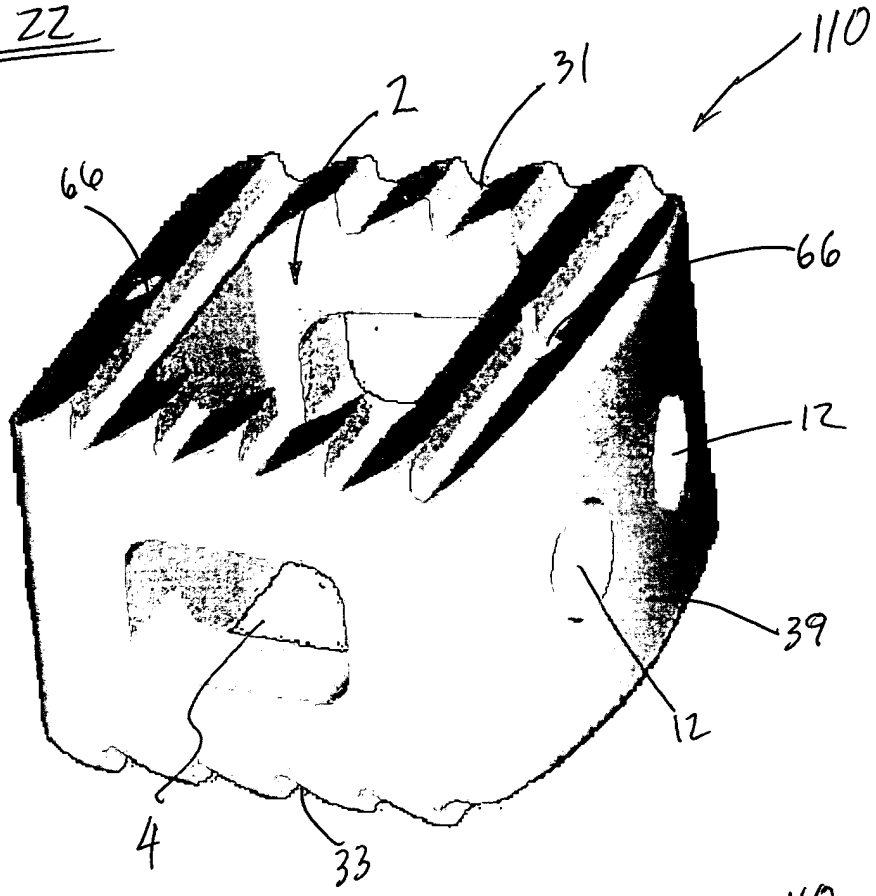
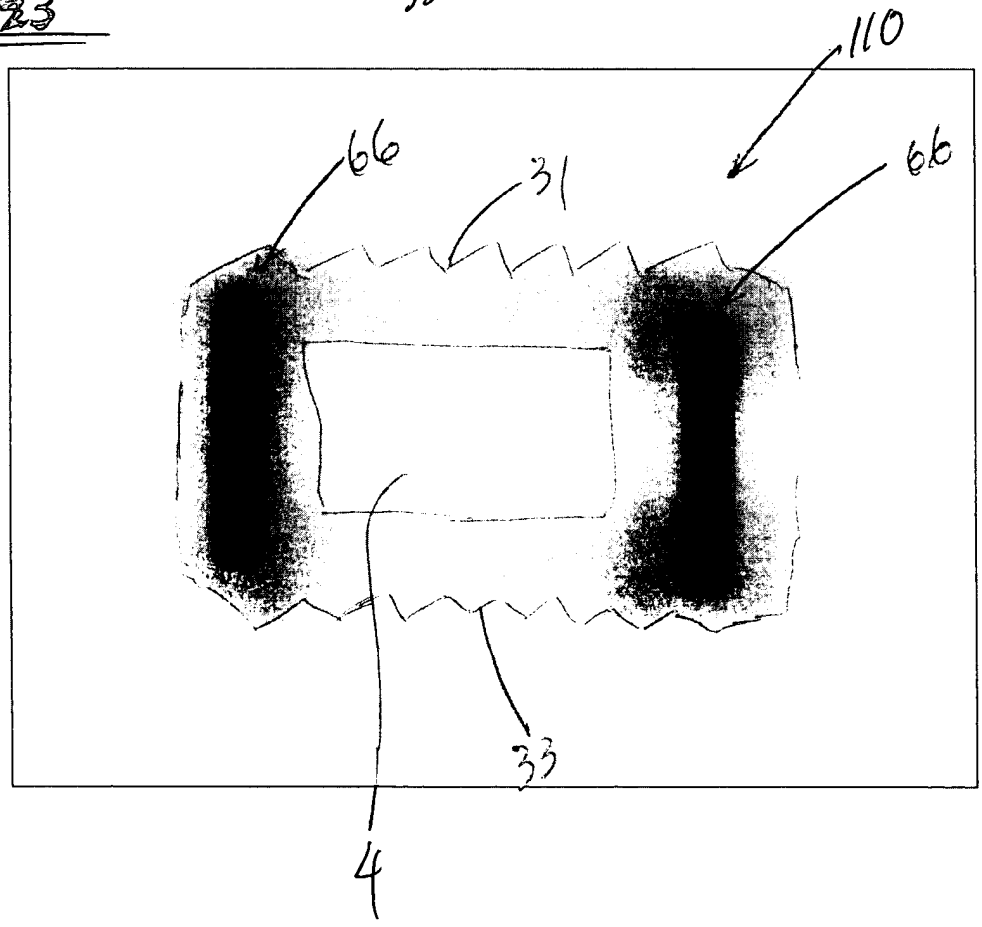


FIG. 23



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PTO/SB/01 (09-04)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

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

Attorney Docket Number	104US1
First Named Inventor	Matthew Curran
COMPLETE IF KNOWN	
Application Number	N/A
Filing Date	N/A
Art Unit	N/A
Examiner Name	N/A

I hereby declare that:

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

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

Systems and Methods for Spinal Fusion

(Title of the Invention)

the specification of which

☑ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) ☐ as United States Application Number or PCT International Application Number ☐ and was amended on (MM/DD/YYYY) ☐ (if applicable).

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

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

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

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

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

PTO/SB/01 (09-04)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION — Utility or Design Patent Application

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

Name

Address

City	State	ZIP

Country	Telephone	Fax

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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

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

Inventor's Signature	Date
	March 29, 2005

Residence: City	State	Country	Citizenship
Carlsbad	CA	USA	USA

Mailing Address
3218 Rancho Quartillo

City	State	Zip	Country
Carlsbad	CA	92009	USA

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

Given Name (first and middle [if any])	Family Name or Surname
MARK	PETERSON

Inventor's Signature	Date

Residence: City	State	Country	Citizenship
MEDFORD	OREGON		US

Mailing Address

City	State	Zip	Country

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

PATENT APPLICATION FEE DETERMINATION RECORD
Effective December 8, 2004

11093409

CLAIMS AS FILED - PART I

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

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

SMALL ENTITY TYPE ☑			OR	OTHER THAN SMALL ENTITY	
RATE	FEE			RATE	FEE
BASIC FEE	150.00		OR	BASIC FEE	300.00
X$ 25=	150		OR	X$50=	
X100=			OR	X200=	
+180=			OR	+360=	
TOTAL	300		OR	TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A

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

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

AMENDMENT B

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

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

1,141

AMENDMENT C

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

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

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

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

04/01/2005 JBALINAN 00000022 502040 11093409

01 FC:2011 150.00 DA
02 FC:2111 250.00 DA
03 FC:2311 100.00 DA
04 FC:2202 150.00 DA

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002 — 489-267/69033

PTO/SB/35 (09-04)
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NONPUBLICATION REQUEST UNDER 35 U.S.C. 122(b)(2)(B)(i)	First Named Inventor	MATTHEW CURRAN
	Title	SYSTEMS AND METHODS FOR SPINAL FUSION
	Attorney Docket Number	104 US1

I hereby certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing.

I hereby request that the attached application not be published under 35 U.S.C. 122(b).

Signature — MARCH 29, 2005 (Date)

JONATHAN SPANGLER (Typed or printed name) — 40,182 (Registration Number, if applicable)

(658) 243-0029 (Telephone Number)

This request must be signed in compliance with 37 CFR 1.33(b) and submitted with the application **upon filing.**

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. 122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. 122(b)(2)(B)(iii)).**

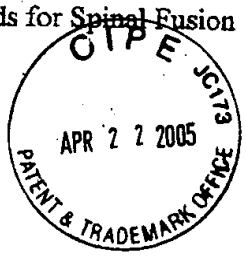
IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Matthew Curran et al.

Title: System and Methods for Spinal Fusion

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



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

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

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

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

Customer Number: 30328

By _____
Jonathan Spangler
Reg. No. 40,182

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

MEREDITH MESCHER
Name

Meredith Mescher
Signature

(GENERAL)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

INFORMATION DISCLOSURE STATEMENT

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

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

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

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

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

Respectfully submitted,

MATTHEW CURRAN ET AL.

By their Representatives,

CUSTOMER NUMBER: 30328
858-909-1807

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

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MEREDITH MESCHER
Name

Meredith Mescher
Signature

PTO/SB/08A(08-03)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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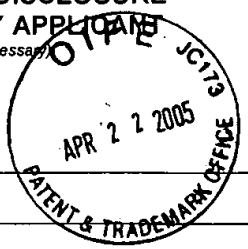

Complete if Known	
Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 1 of 6

Attorney Docket No: 104US1

US PATENT DOCUMENTS				
Examiner Initial *	**USP Document Number**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**Pages,Columns,Lines,Where Relevant Passages or Relevant Figures Appear**
	US-2002/0058950 A1	05/16/2002	Winterbottom, et al.	
	US-2003/0105528	06/05/2003	Shimp, et al.	
	US-3,486,505	12/30/1969	Morrison, Gordon M.	
	US-3,518,993	07/07/1970	Blake, Lawrence W.	
	US-3,604,487	09/14/1971	Gilbert, Richard S.	
	US-3,745,995	07/17/1973	Kraus	
	US-3,848,601	11/19/1974	Ma, et al.	
	US-4,026,304	05/31/1971	Levy	
	US-4,026,305	05/31/1977	Brownlee, et al.	
	US-4,646,738	03/03/1987	Trott, Arthur F.	
	US-4,657,550	04/14/1987	Daher	
	US-4,743,256	05/10/1988	Brantigan	
	US-4,781,591	11/01/1988	Allen	
	US-4,834,757	05/30/1989	Brantigan	
	US-4,877,020	10/31/1989	Vich	
	US-4,878,915	11/07/1989	Brantigan,	
	US-4,932,975	06/12/1990	Main, et al.	
	US-4,961,740	10/09/1990	Ray, et al.	
	US-4,962,766	10/16/1990	Herzon, G. D.	
	US-5,026,373	06/25/1991	Ray, et al.	
	US-5,055,104	10/08/1991	Ray	
	US-5,062,845	11/05/1991	Kuslich, et al.	
	US-5,092,572	03/03/1992	Litwak, et al.	
	US-5,133,717	07/28/1992	Chopin	
	US-5,133,755	07/28/1992	Brekke	
	US-5,171,278	12/15/1992	Pisharodi	
	US-5,192,327	03/09/1993	Brantigan, John W.	
	US-5,217,497	06/08/1993	Mehdian	
	US-5,269,785	12/14/1993	Bonutti	
	US-5,284,153	02/08/1994	Raymond, S. A., et al.	
	US-5,290,494	03/01/1994	Coombes, et al.	
	US-5,300,076	05/05/1994	Lerich	
	US-5,304,210	04/19/1994	Crook	
	US-5,306,307	04/26/1994	Senter, et al.	
	US-5,306,309	04/26/1994	Wagner, et al.	
	US-5,322,505	06/21/1994	Krause, Kenneth W., et al.	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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

Substitute for form 1449A/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*	*Complete if Known*	
	Application Number	11/093,409
	Filing Date	March 29, 2005
	First Named Inventor	Matthew Curran
	Group Art Unit	Unknown
	Examiner Name	Unknown
Sheet 2 of 6	Attorney Docket No: 104US1	

	US-5,334,205	08/02/1994	Cain	
	US-5,336,223	08/09/1994	Rogers	
	US-5,364,400	11/15/1994	Rego, Jr., et al.	
	US-5,395,372	03/07/1995	Holt, et al.	
	US-5,397,363	03/14/1995	Gelbard	
	US-5,405,391	04/11/1995	Henderson, et al.	
	US-5,413,602	05/09/1995	Metz-Stavenhagen.,	
	US-5,425,772	06/20/1995	Brantigan	
	US-5,431,658	07/11/1995	Moskovich	
	US-5,443,514	08/22/1995	Steffee	
	US-5,443,515	08/22/1995	Cohen, et al.	
	US-5,445,639	08/29/1995	Kuslich, et al.	
	US-5,454,811	10/03/1995	Huebner	
	US-5,458,638	10/17/1995	Kuslich, et al.	
	US-5,484,403	01/16/1996	Yoakum, et al.	
	US-5,489,308	02/06/1996	Kuslich, ,et al.	
	US-5,514,180	05/07/1996	Heggeness, M. H., et al.	
	US-5,522,879	06/04/1996	Scopelianos	
	US-5,522,899	06/04/1996	Michelson	
	US-5,524,624	06/11/1996	Tepper, et al.	
	US-5,527,312	06/18/1996	Ray	
	US-5,534,030	07/09/1996	Navarro, et al.	
	US-5,540,688	07/30/1996	Navas, Fernand	
	US-5,545,222	08/13/1996	Bonutti	
	US-5,562,736	10/08/1996	Ray, et al.	
	US-5,565,005	10/15/1996	Erickson, et al.	
	US-5,571,190	11/05/1996	Ulrich	
	US-5,571,192	11/05/1996	Schonhoffer	
	US-5,593,409	01/14/1997	Michelson, G. K.	
	US-5,609,636	03/11/1997	Kohrs, et al.	
	US-5,611,800	03/18/1997	Davis, et al.	
	US-5,611,810	03/18/1997	Arnold, et al.	
	US-5,632,747	05/27/1997	Scarborough, et al.	
	US-5,645,598	07/08/1997	Brosnahan, et al.	
	US-5,653,761	08/05/1997	Pisharodi	
	US-5,653,762	08/05/1997	Pisharodi	
	US-5,658,336	08/19/1997	Pisharodi	
	US-5,658,337	08/19/1997	Kohrs, et al.	
	US-5,662,710	09/02/1997	Bonutti	
	US-5,665,122	09/09/1997	Kambin, Parviz	
	US-5,669,909	09/23/1997	Zdeblick, et al.	
	US-5,676,703	10/14/1997	Gelbard	
	US-5,683,394	11/04/1997	Rinner	

EXAMINER **DATE CONSIDERED**

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

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

Sheet 3 of 6

Attorney Docket No: 104US1

	US-5,683,400	11/04/1997	McGuire, David A.	
	US-5,683,464	11/04/1997	Wagner, et al.	
	US-5,690,629	11/25/1997	Asher, et al.	
	US-5,700,264	12/23/1997	Zucherman, et al.	
	US-5,700,291	12/23/1997	Kuslich, et al.	
	US-5,700,292	12/23/1997	Marguiles	
	US-5,702,449	12/30/1997	McKay, W. F.	
	US-5,702,451	12/30/1997	Biedermann, et al.	
	US-5,702,453	12/30/1997	Rabbe, et al.	
	US-5,702,454	12/30/1997	Baumgartner	
	US-5,702,455	12/30/1997	Saggar, R.	
	US-5,703,451	12/30/1997	Yamamichi, et al.	
	US-5,707,373	01/13/1998	Sevrain, et al.	
	US-5,711,957	01/27/1998	Patat, et al.	
	US-5,716,415	02/10/1998	Steffee	
	US-5,720,748	02/24/1998	Kuslich, et al.	
	US-5,720,751	02/24/1998	Jackson	
	US-5,728,159	03/17/1998	Stroever, B. W., et al.	
	US-5,741,261	04/21/1998	Moskovitz, et al.	
	US-5,755,797	05/26/1998	Baumgartner	
	US-5,766,252	06/16/1998	Henry, et al.	
	US-5,772,661	06/30/1998	Michelson	
	US-5,775,331	07/07/1998	Raymond, S. A., et al.	
	US-5,779,642	04/14/1998	Nightengale, Christopher	
	US-5,782,830	07/21/1998	Farris, Robert A.	
	US-5,782,919	07/21/1998	Zdeblick, et al.	
	US-5,785,710	07/28/1998	Michelson	
	US-5,797,909	08/25/1998	Michelson	
	US-5,800,549	09/01/1998	Bao, et al.	
	US-5,800,550	09/01/1998	Sertich	
	US-5,814,084	09/29/1998	Grivas, et al.	
	US-5,851,208	12/22/1998	Trott	
	US-5,865,845	02/02/1999	Thalgott, John S.	
	US-5,865,848	02/02/1999	Baker	
	US-5,885,299	03/23/1999	Winslow, et al.	
	US-5,888,219	03/30/1999	Bonutti	
	US-5,888,224	03/30/1999	Beckers, et al.	
	US-5,893,890	04/13/1999	Pisharodi	
	US-5,904,719	05/18/1999	Errico, et al.	
	US-5,910,315	06/08/1999	Stevenson, et al.	
	US-5,954,769	09/21/1999	Rosenlicht	
	US-5,968,098	10/19/1999	Winslow	

EXAMINER **DATE CONSIDERED**

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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

Sheet 4 of 6

Attorney Docket No: 104US1

	US-5,993,474	11/30/1999	Ouchi, Teruo	
	US-6,003,426		Castro, et al.	
	US-6,004,326	12/21/1999	Castro, et al.	
	US-6,008,433	12/28/1999	Stone, K. R.	
	US-6,015,436	01/18/2000	Schunhuffer	
	US-6,033,405	03/07/2000	Winslow, et al.	
	US-6,039,761	03/21/2000	Li, et al.	
	US-6,042,582	03/28/2000	Ray	
	US-6,045,580	04/04/2000	Scarborough, et al.	
	US-6,048,342	04/11/2000	Zucherman, et al.	
	US-6,063,088	05/16/2000	Winslow	
	US-6,083,225	07/04/2000	Winslow, et al.	
	US-6,096,080	08/01/2000	Nicholson, et al.	
	US-6,102,948	08/15/2000	Brosnahan, III	
	US-6,120,506	09/19/2000	Kohrs, et al.	
	US-6,132,472	10/17/2000	Bonutti	
	US-6,159,211	12/12/2000	Boriani, Stefano , et al.	
	US-6,159,215	12/12/2000	Urbahns, et al.	
	US-6,193,756	02/27/2001	Studer, et al.	
	US-6,200,347	03/13/2001	Anderson	
	US-6,224,607	05/01/2001	Michelson, Gary K.	
	US-6,224,631	05/01/2001	Kohrs	
	US-6,241,769	06/05/2001	Nicholson, et al.	
	US-6,241,771	06/05/2001	Gresser, et al.	
	US-6,251,140	06/26/2001	Marino, et al.	
	US-6,258,125	07/10/2001	Paul, et al.	
	US-6,277,149	08/21/2001	Boyle, et al.	
	US-6,319,257	11/20/2001	Carignan, et al.	
	US-6,371,989	04/16/2002	Chauvin, et al.	
	US-6,383,221	05/07/2002	Scarborough, N. L., et al.	
	US-6,440,142	08/27/2002	Ralph, et al.	
	US-6,442,814	09/03/2002	Landry, et al.	
	US-6,454,806	09/24/2002	Cohen, et al.	
	US-6,527,773	03/04/2003	Lin, et al.	
	US-6,547,823	04/15/2003	Scarborough, N. L., et al.	
	US-6,595,998	07/22/2003	Johnson, et al.	
	US-6,626,905	09/30/2003	Schmiel, D. G., et al.	
	US-6,635,086	10/21/2003	Lin, Paul S.	
	US-6,648,895	11/18/2003	Burkus, et al.	
	US-6,755,841	06/29/2004	Fraser, R. D., et al.	

EXAMINER **DATE CONSIDERED**

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Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Group Art Unit	Unknown
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Sheet 5 of 6

Attorney Docket No: 104US1

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines, Where Relevant Passages or Relevant Figures Appear	T[2]
	CA-2015507		Kuslich, et al.		
	EP-369603	05/23/1990	Ray		
	EP-517030	05/19/1992	Siebels		
	EP-667127	08/16/1995	Sanders		
	EP-706876	04/17/1996	McMillin		
	EP-716840	06/19/1996	Pavlov, et al.		
	EP-737448	10/16/1996	Jackson, et al.		
	EP-796593	09/24/1997	Mitchell, et al.		
	EP-809974	04/15/1998	Benzel, et al.		
	EP-809975	04/15/1998	Benzel, et al.		
	EP-811356	04/15/1998	Glascott, et al.		
	EP-880938	02/12/1998	Castro, et al.		
	WO-00/45712	08/10/2000	Steiner, et al.		
	WO-00/45713	08/10/2000	Steiner, et al.		
	WO-01/41681	06/14/2001	Corwall, et al.		
	WO-01/49333	07/12/2001	Shimp, et al.		
	WO-91/06261	05/16/1991	Ray, Charles , et al.		
	WO-94/04100	03/03/1994	Mazda, et al.		
	WO-94/10928	05/26/1994	Hopf, Christoph		
	WO-95/01810	01/19/1995	Wolowacz, et al.		
	WO-96/08205	03/21/1996	Pavlov, et al.		
	WO-96/17564	03/13/1996	Rabbe, et al.		
	WO-96/41582	12/27/1996	David, et al.		
	WO-97/20513	06/12/1997	Taddia		
	WO-97/33525	09/18/1997	Winslow, Charles A.		
	WO-97/37620	10/16/1997	Benezech, et al.		
	WO-98/09586	03/12/1998	Webb, et al.		
	WO-98/14142	04/09/1998	Larsen, et al.		
	WO-98/17208	04/30/1998	Winslow, Charles		
	WO-98/25539	06/18/1998	Spath, Volker		
	WO-99/08627	02/25/1999	Gresser, et al.		
	WO-99/38461	08/05/1999	Paul, David , et al.		

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		ALLEYNE, CARGILL H., et al., "Current and future approaches to lumbar disc surgery: A literature review", Medscape Orthopedics & Sports Medicine, 1, [www.medscape.com/Medscape/OrthoSportsMed/1997/v01.n11/.../mos3057],(1997),	

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Sheet 6 of 6	Attorney Docket No: 104US1	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
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		BENINI, et al., "Undercutting decompression and posterior fusion with translaminar facet screw fixation in degenerative lumbar spinal stenosis: Technique and results", Neuro-Orthopedics, (1995),159-172	
		KAMBIN, et al., "History and current status of percutaneous arthroscopic disc surgery", Spine, 21, (1996),57S-61S	
		STEIN, et al., "Percutaneous facet joint fusion: Preliminary experience", Journal of Vascular and Interventional Radiology, 4, (1993),69-74	
		VAMVANIJ, et al., "Surgical treatment of internal disc disruption: An outcome study of four fusion techniques", Journal of Spinal Disorders, 4, (1998),375-382	

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09/131,716	10 August 1998 (10.08.98)	US

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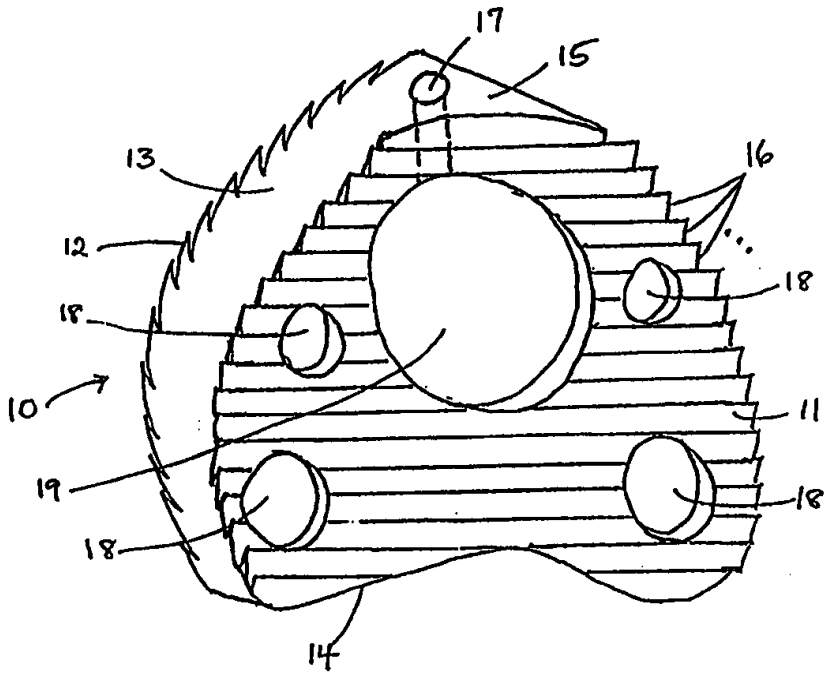

(57) Abstract

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

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TITLE OF THE INVENTION

Resorbable Interbody Spinal Fusion Devices

CROSS REFERENCE TO RELATED APPLICATIONS

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

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable

BACKGROUND OF THE INVENTION

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

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

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

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

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

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

SUMMARY OF THE INVENTION

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

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

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

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

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

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

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

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

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

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

DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION OF THE INVENTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

$$RMW = 14.03x + 58.04$$

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CLAIMS

What is claimed is:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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