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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.	ER 453203 757 US

2013 U.S. PTO  
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**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

**ADDRESS TO:** Commissioner for Patents  
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**ACCOMPANYING APPLICATION PARTS**

9.  **Assignment Papers** (cover sheet & document(s))  
Name of Assignee \_\_\_\_\_
10.  **37 CFR 3.73(b) Statement**  **Power of Attorney**  
*(when there is an assignee)*
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:

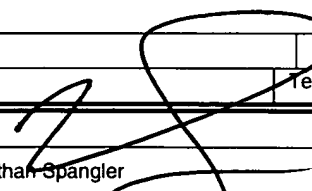
Continuation     Divisional     Continuation-in-part (CIP)    of prior application No.: \_\_\_\_\_

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
Country	Zip Code
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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20427  
032905

Effective on 12/08/2004.  
Pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).  
**FEE TRANSMITTAL**  
**For FY 2005**

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

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)

**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		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
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.

**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)**

Non-English Specification, \$130 fee (no small entity discount)      **Fees Paid (\$)** \_\_\_\_\_

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

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, 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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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**

5                   **SYSTEMS AND METHODS FOR SPINAL FUSION**

By Inventors:

10                   MATTHEW CURRAN, a citizen of the United States  
                          Residing in San Diego, California

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                          Residing in Medford, Oregon

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Filed:

March 29, 2005

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# 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.

5 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-  
10 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  
15 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  
20 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  
5 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.

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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  
15 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.

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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:

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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;

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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;

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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;

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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;

5 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;

10 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;

15 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;

20 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  
5 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.  
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  
15 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  
20 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.

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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.

10 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.

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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.

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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 kyphosis 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.

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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.

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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.

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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.

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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.

20 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  
5 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

10 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  
15 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  
20 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.

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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.

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

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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.

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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.

5           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  
10       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.

15       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.

20       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.

5 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 10 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.

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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 20 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.

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

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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.

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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.

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

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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.

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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.

20

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.

5

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.

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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.

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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.

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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.

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## **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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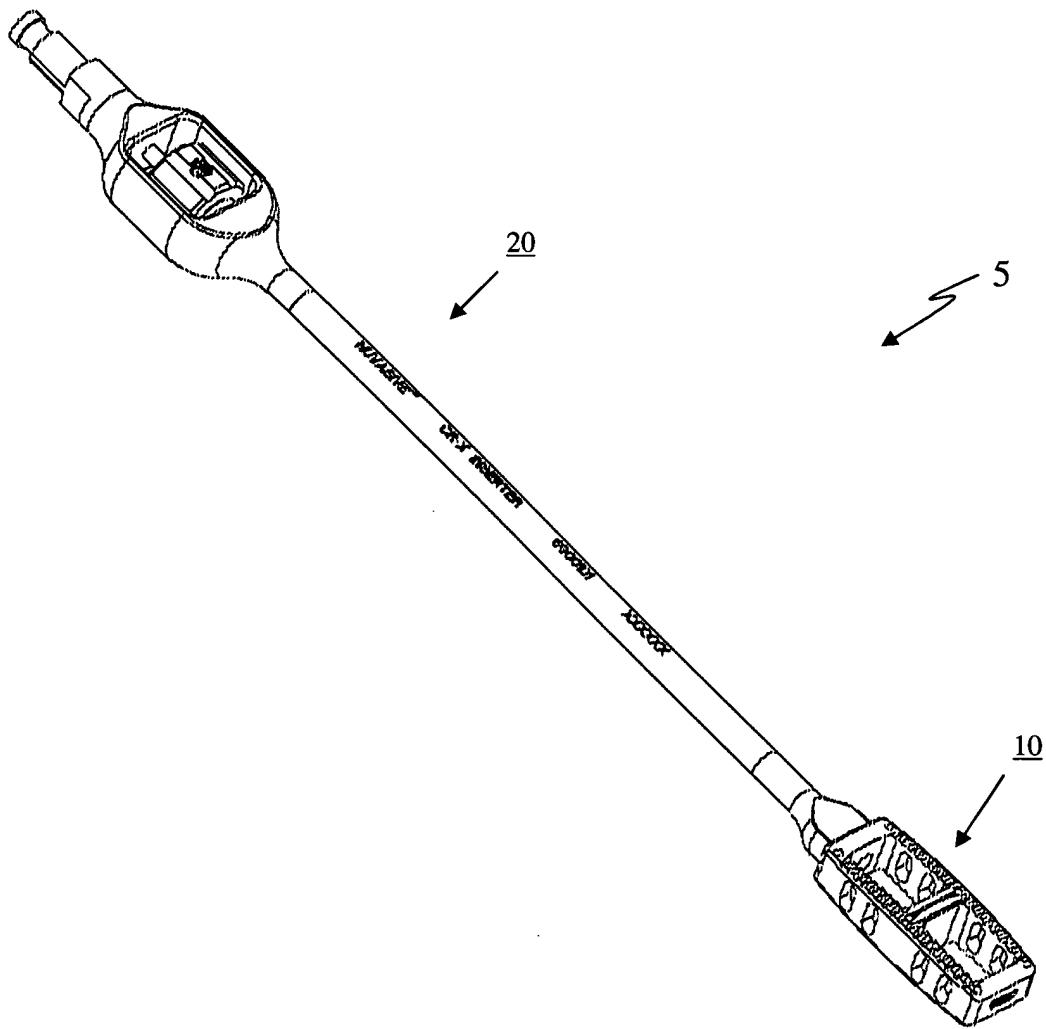
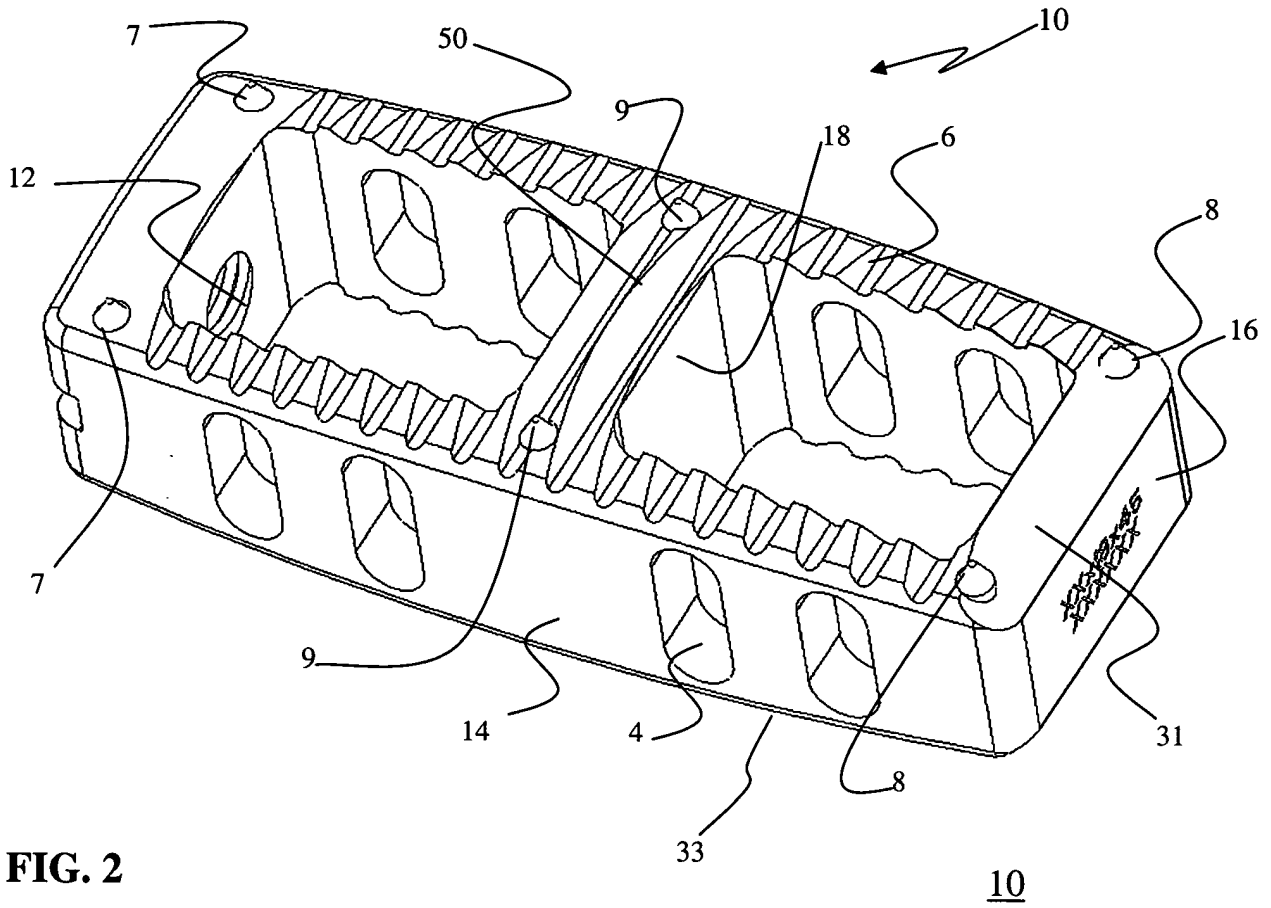


FIG. 1

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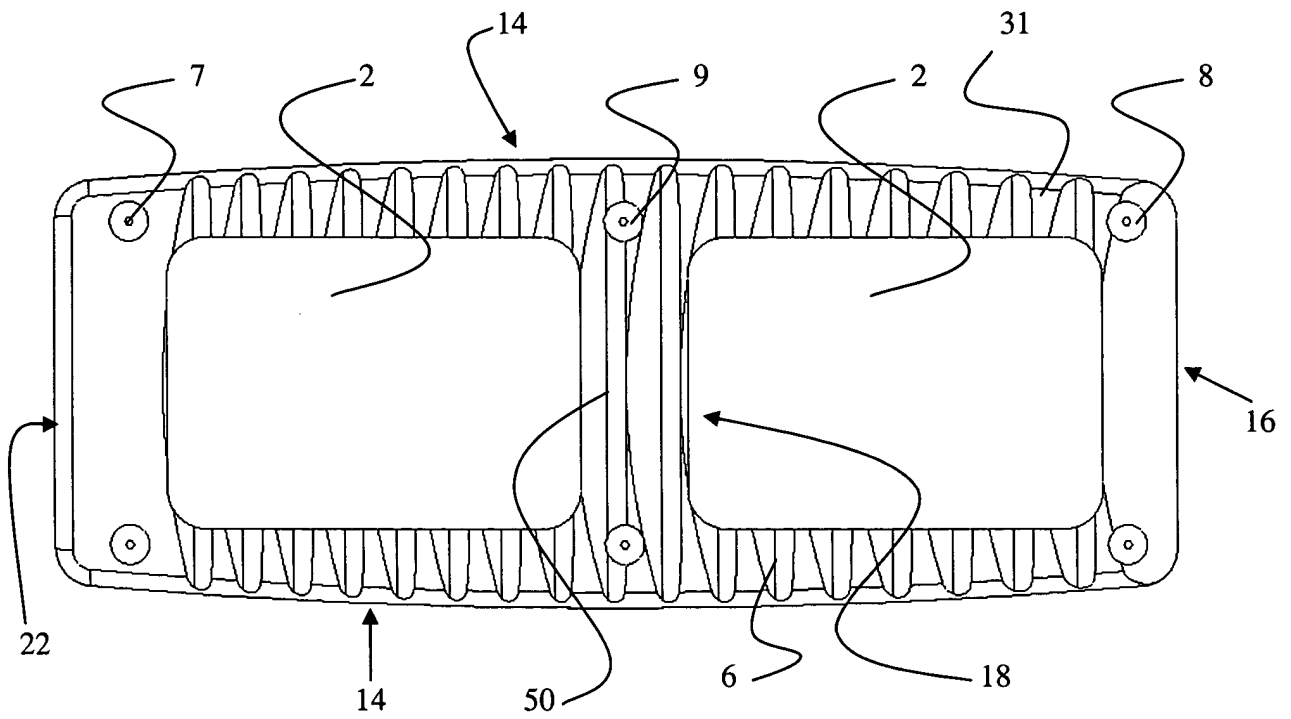


FIG. 3

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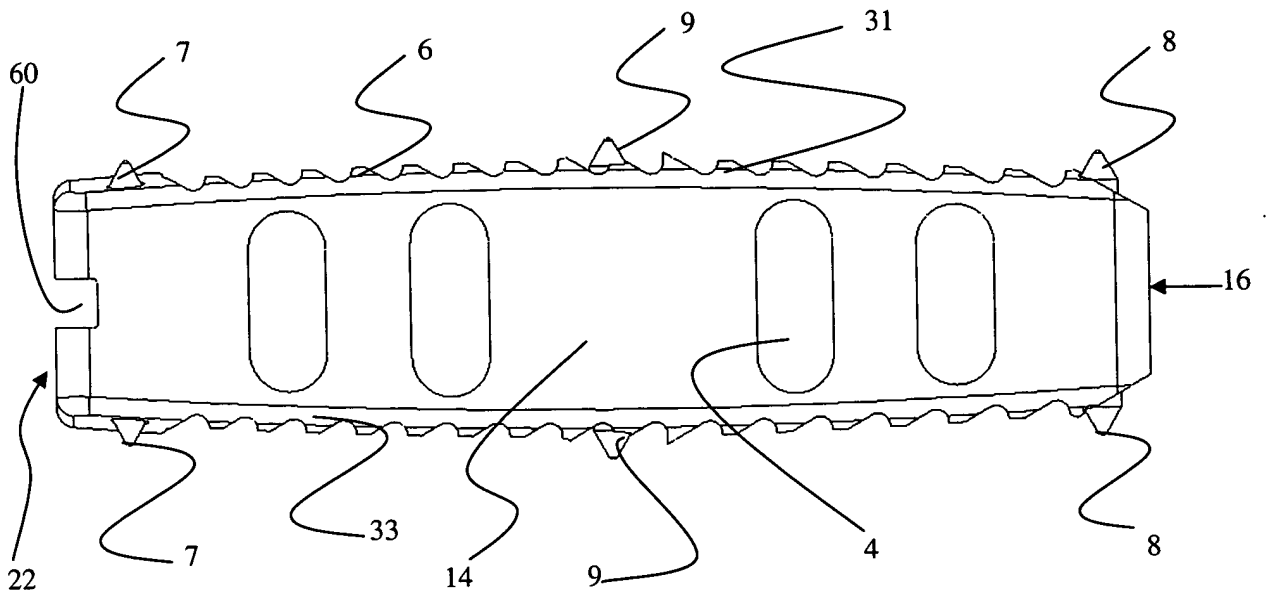


FIG. 4

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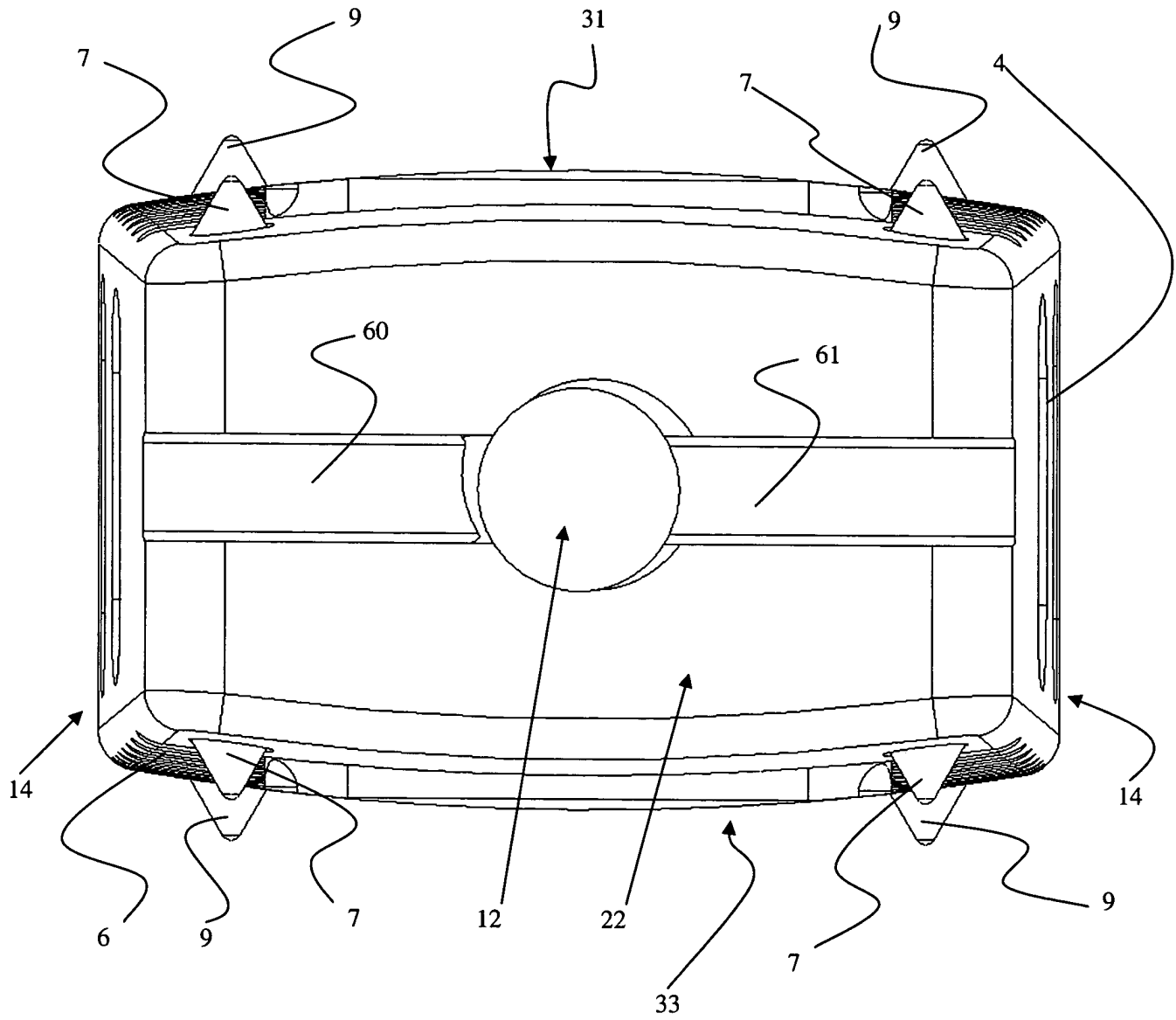


FIG. 5

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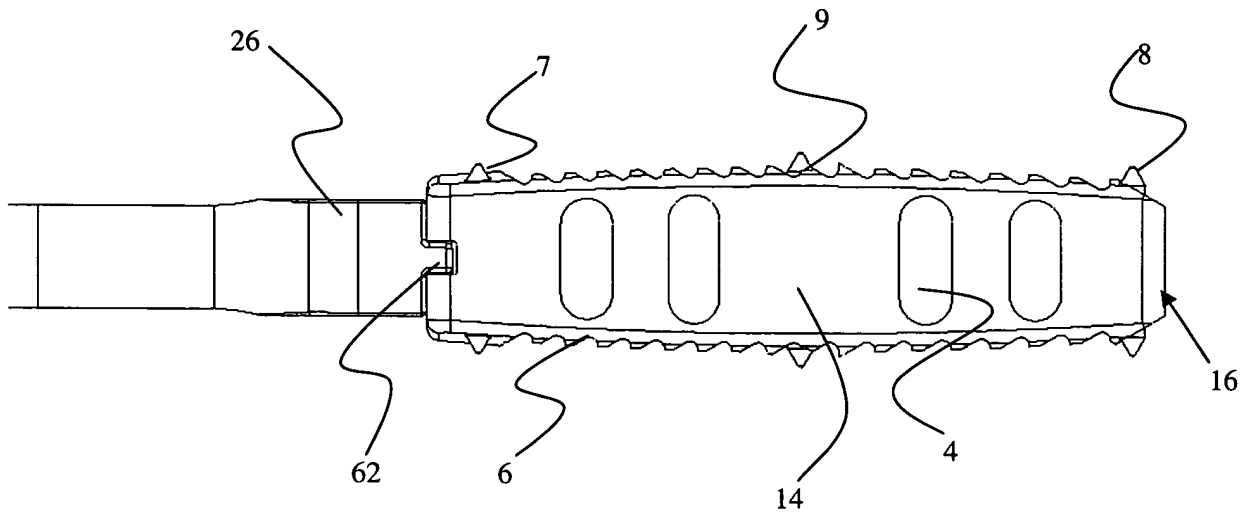
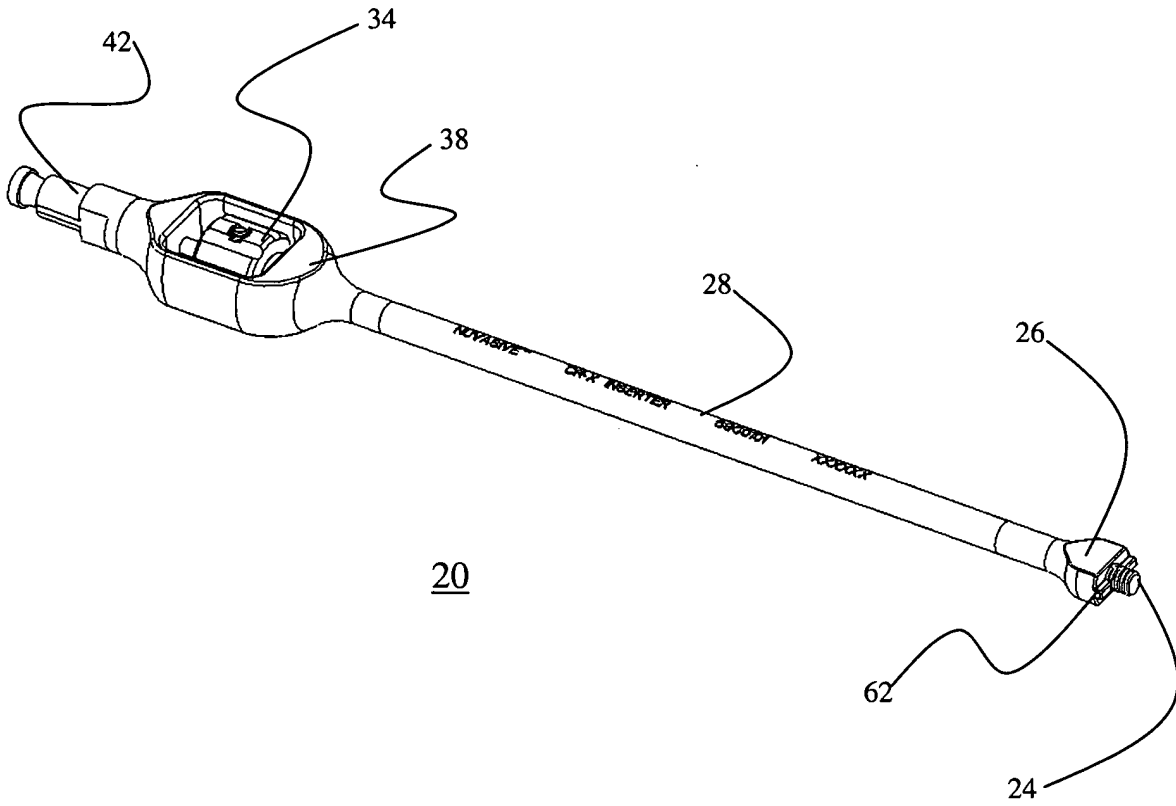
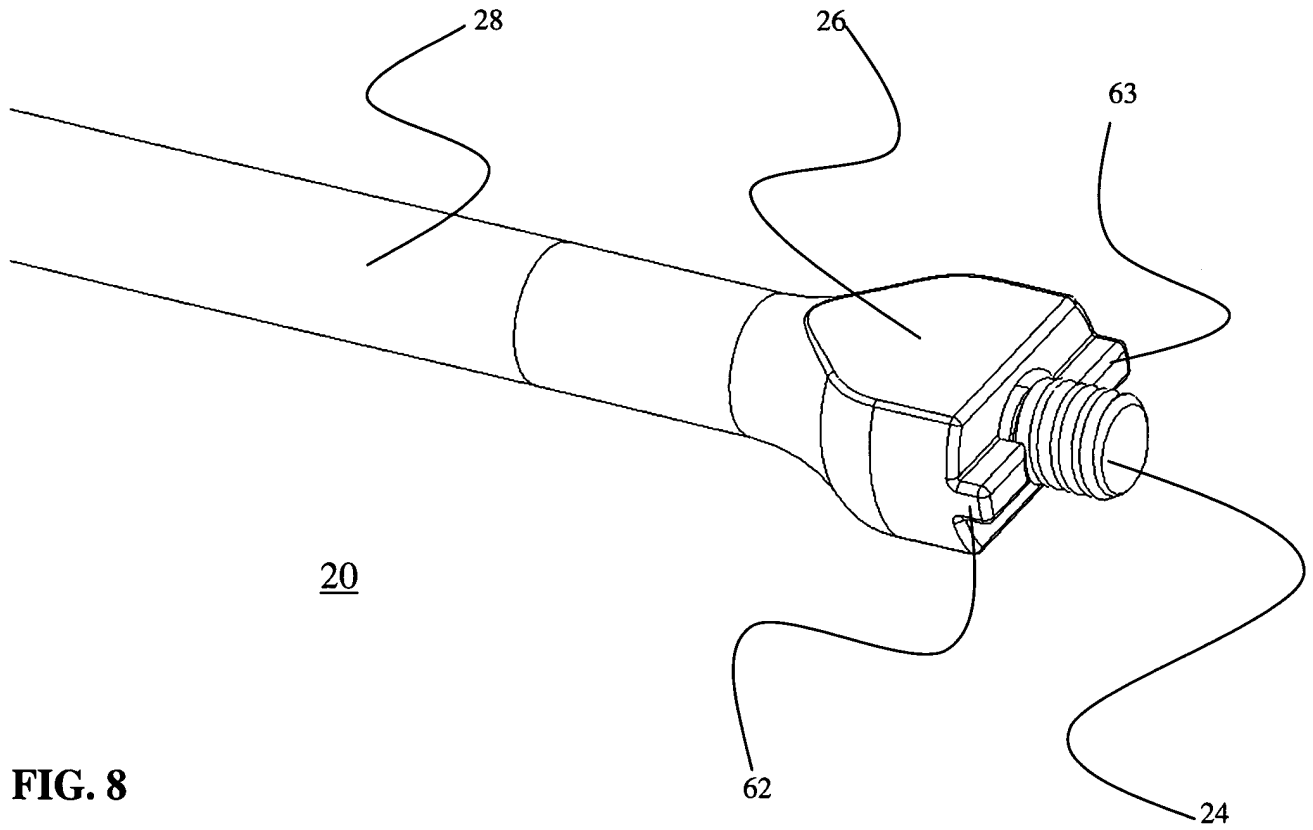


FIG. 6



**FIG. 7**



**FIG. 8**

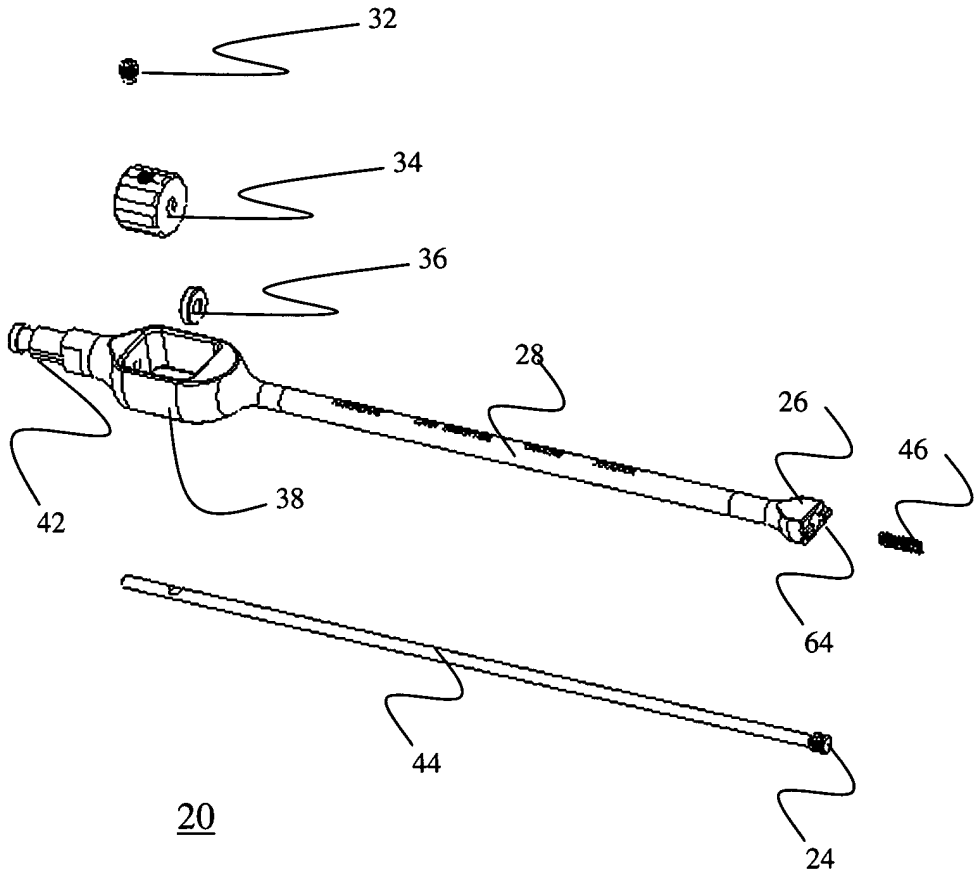


FIG. 9

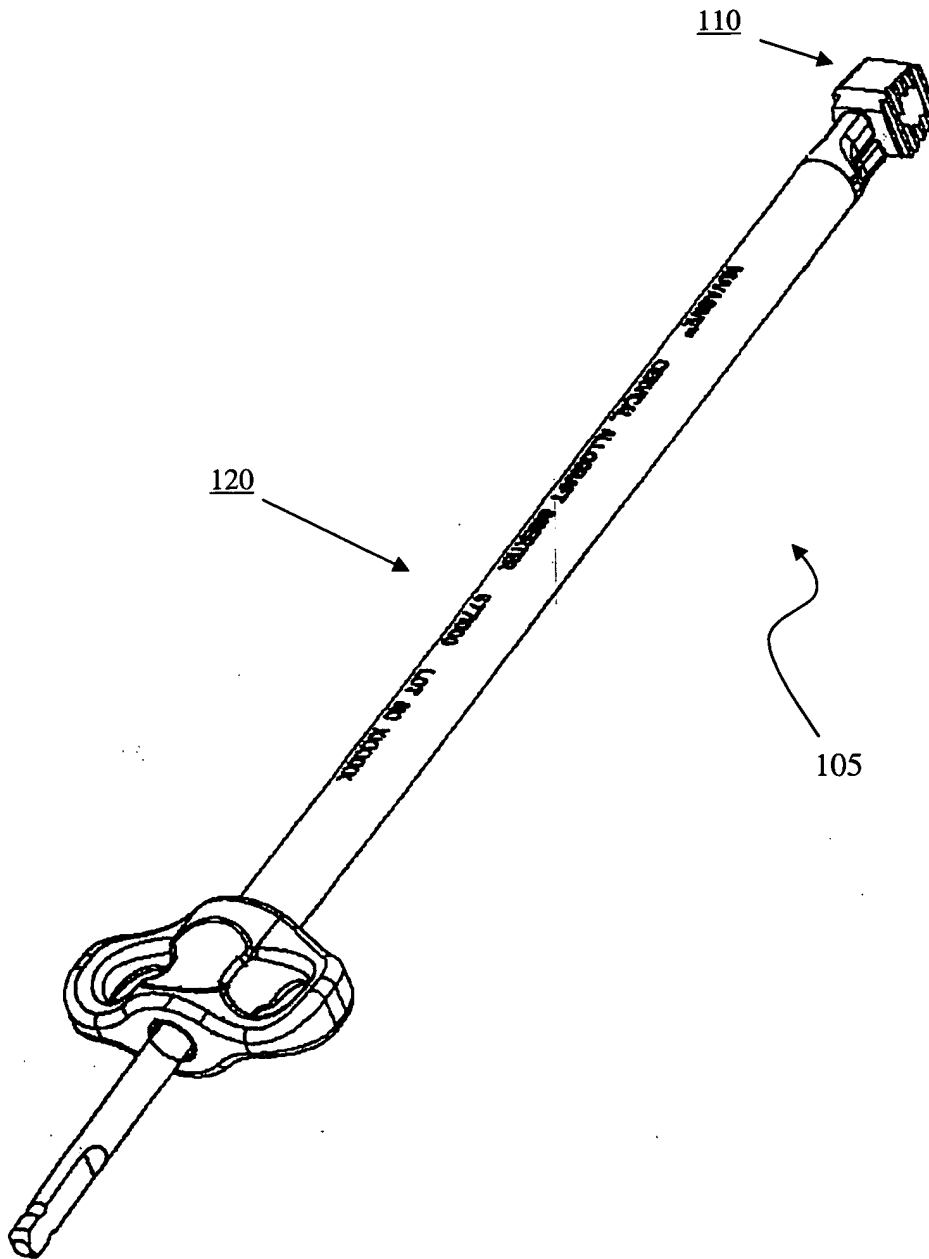


FIG. 10

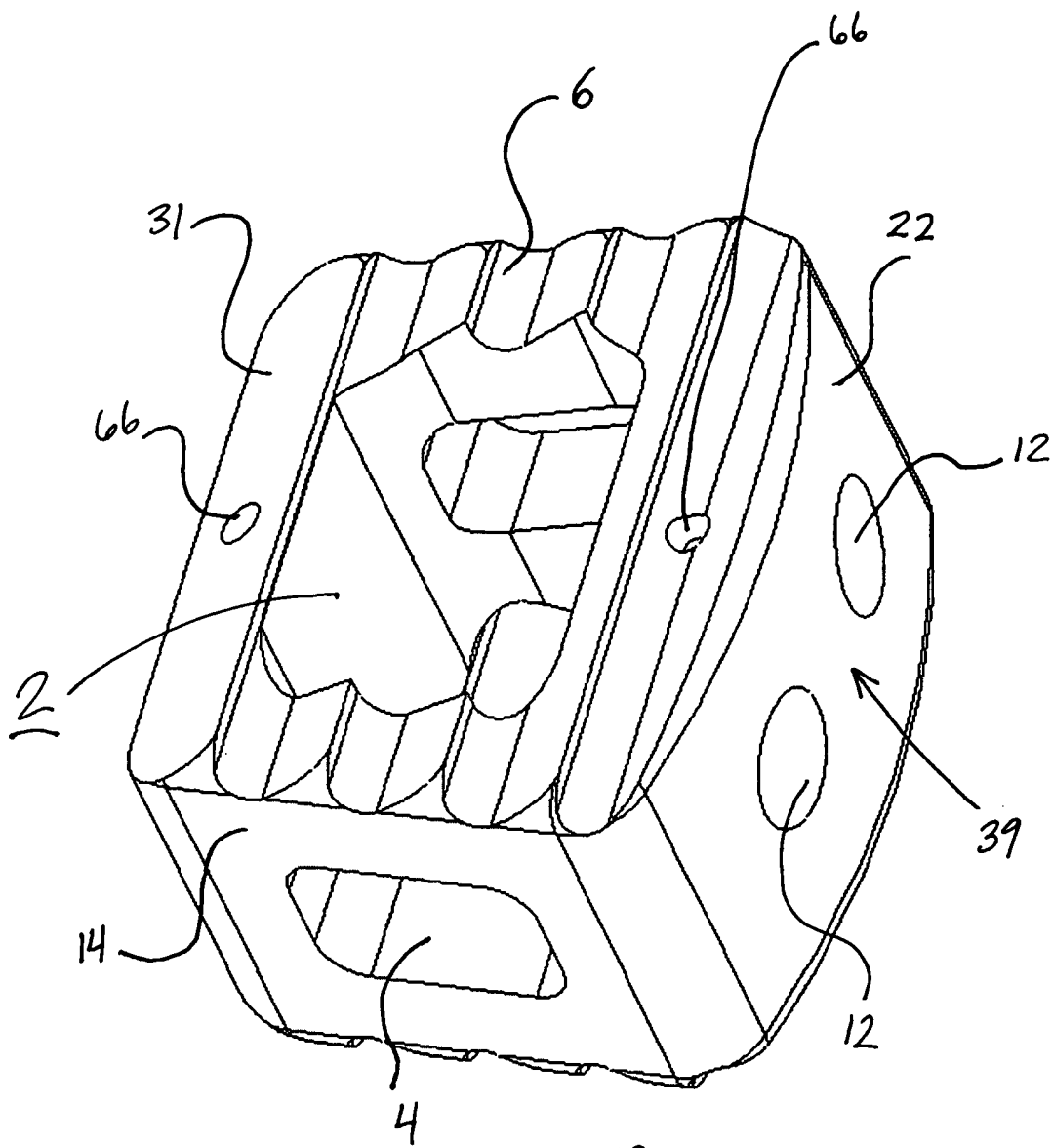


Fig. 11

110



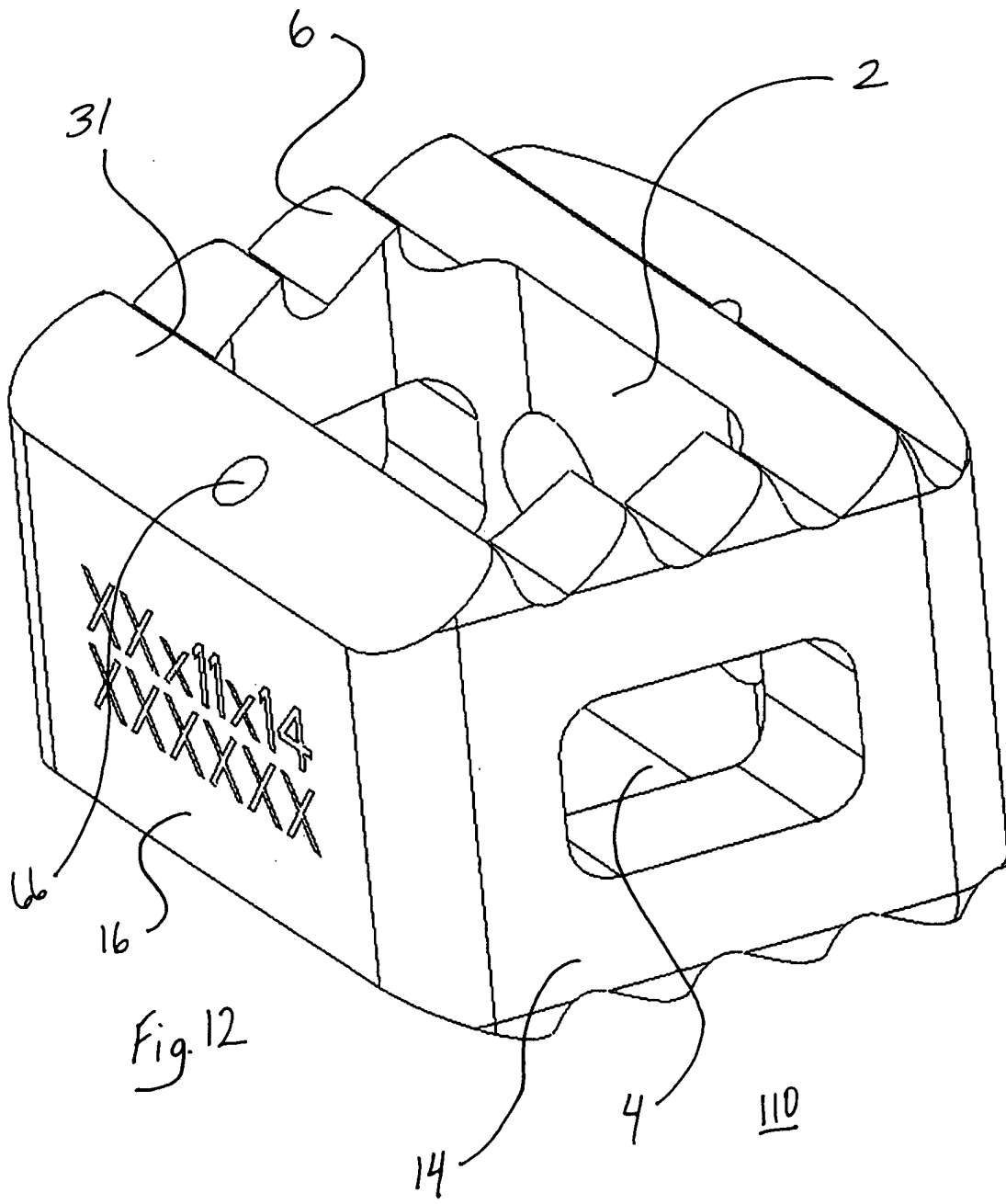


Fig. 12

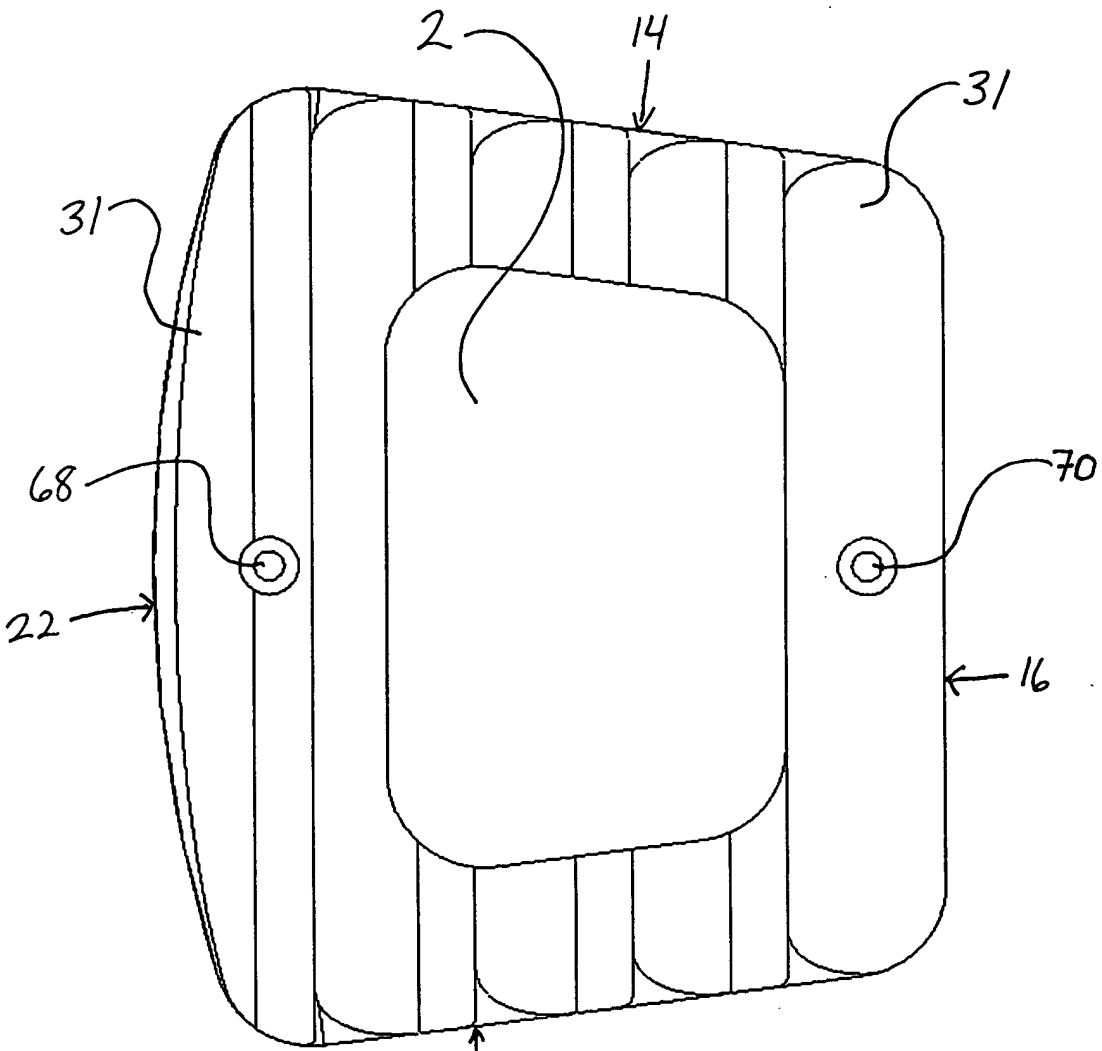
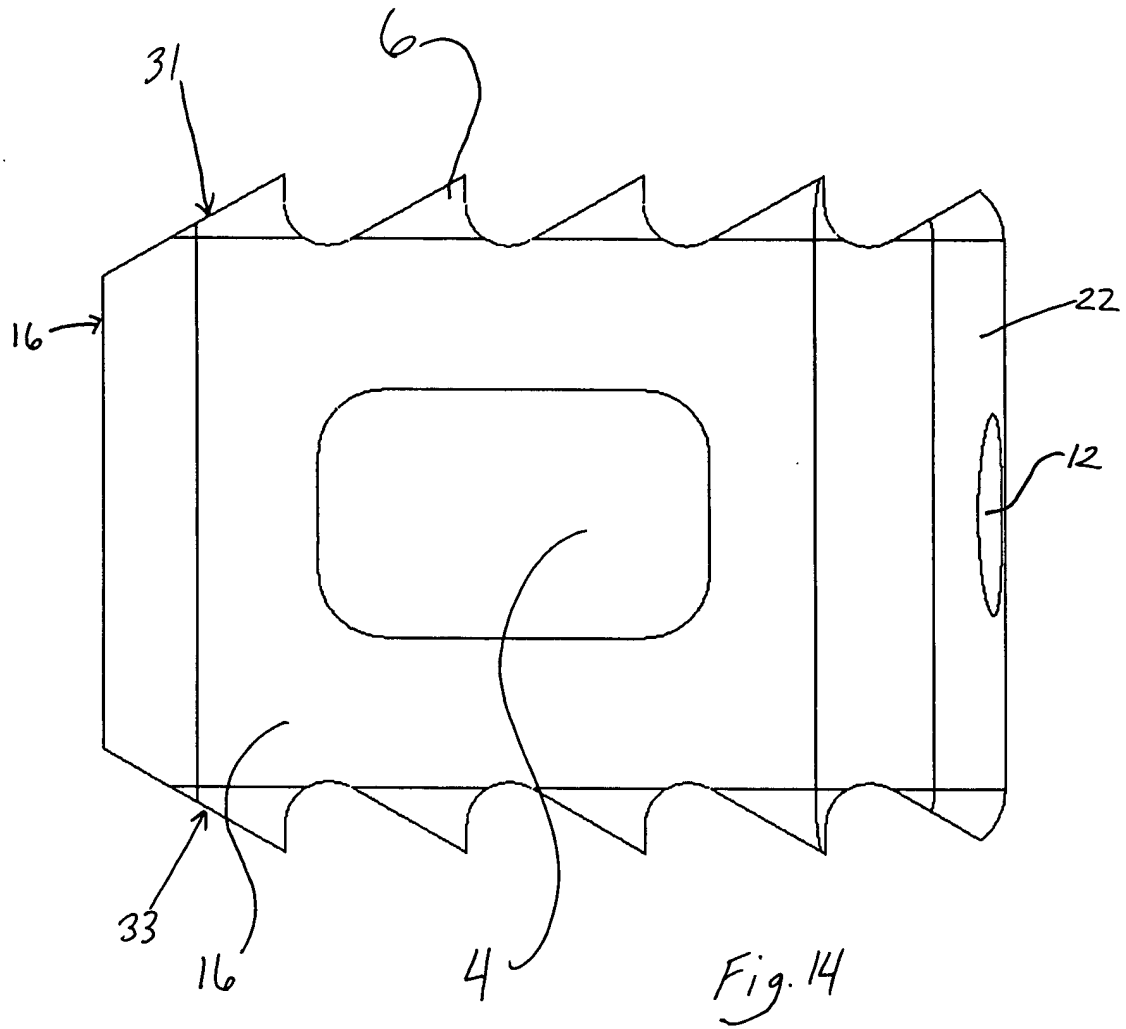


Fig. 13



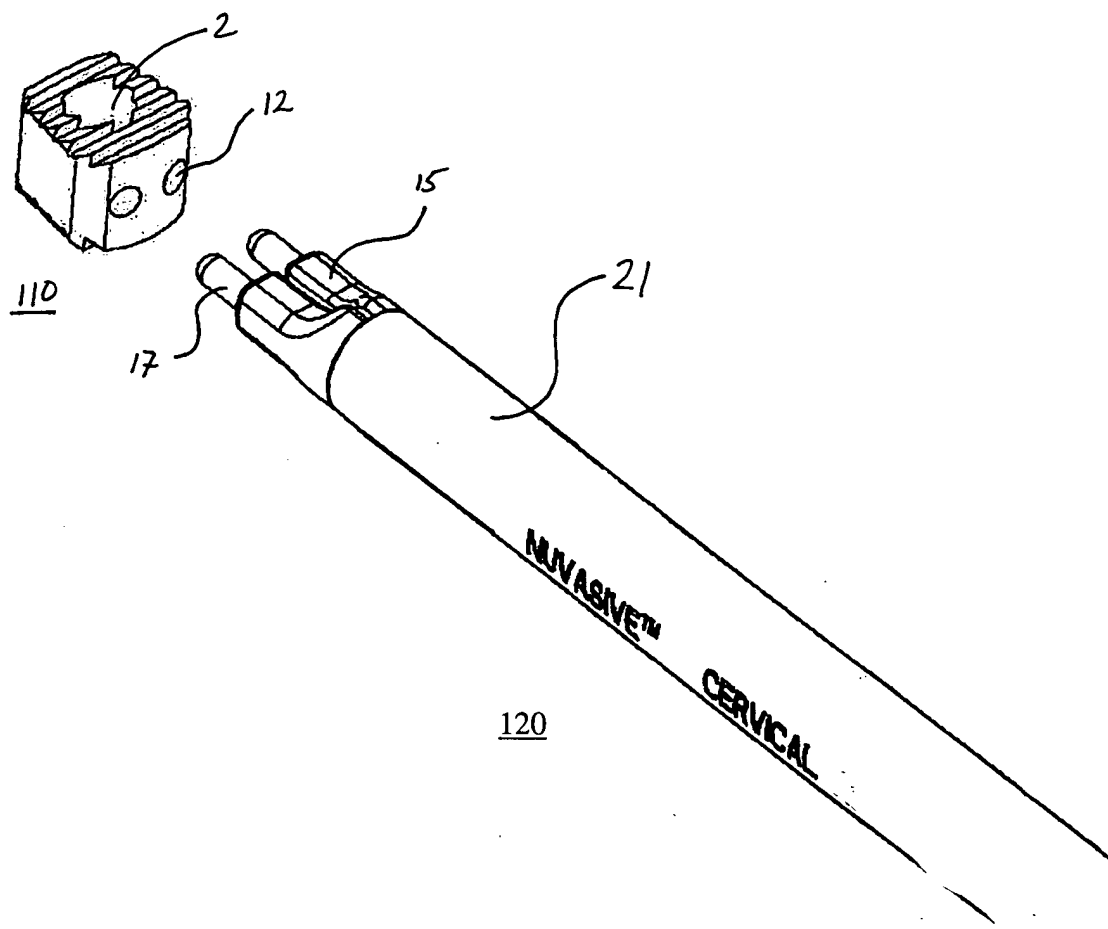


FIG. 15

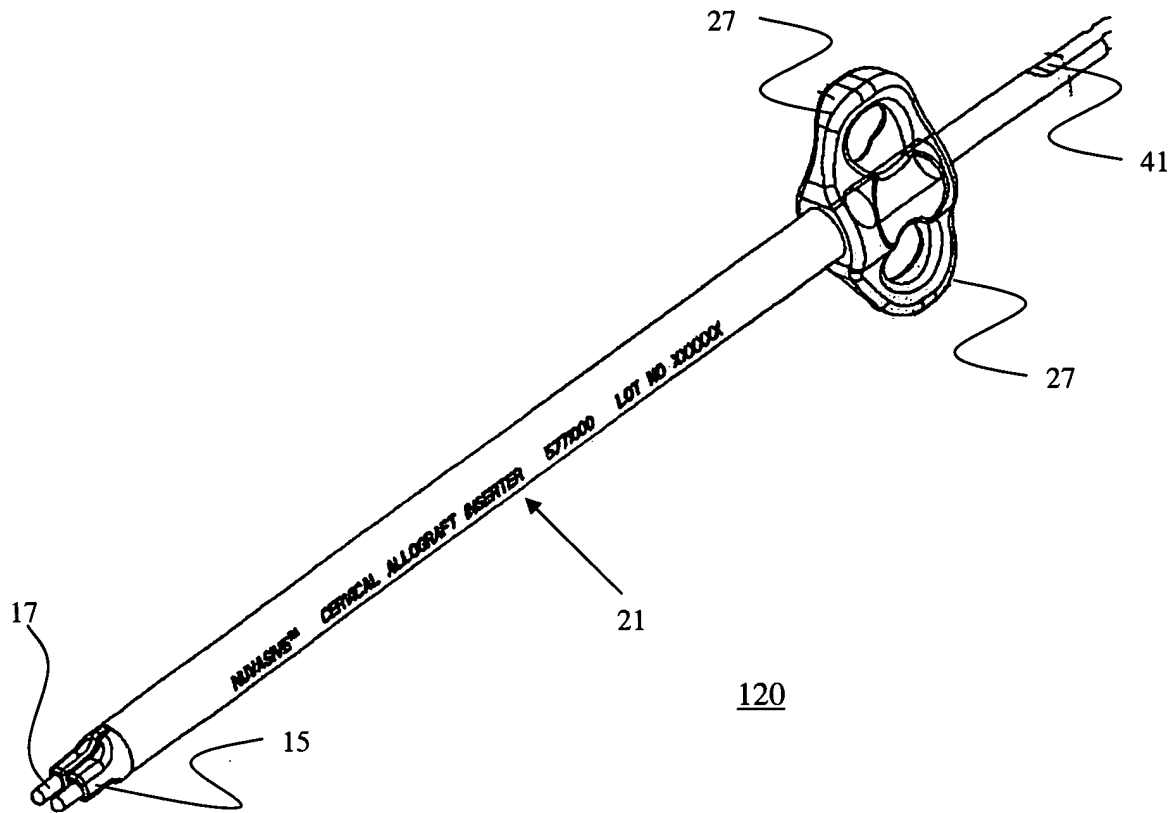


FIG. 16

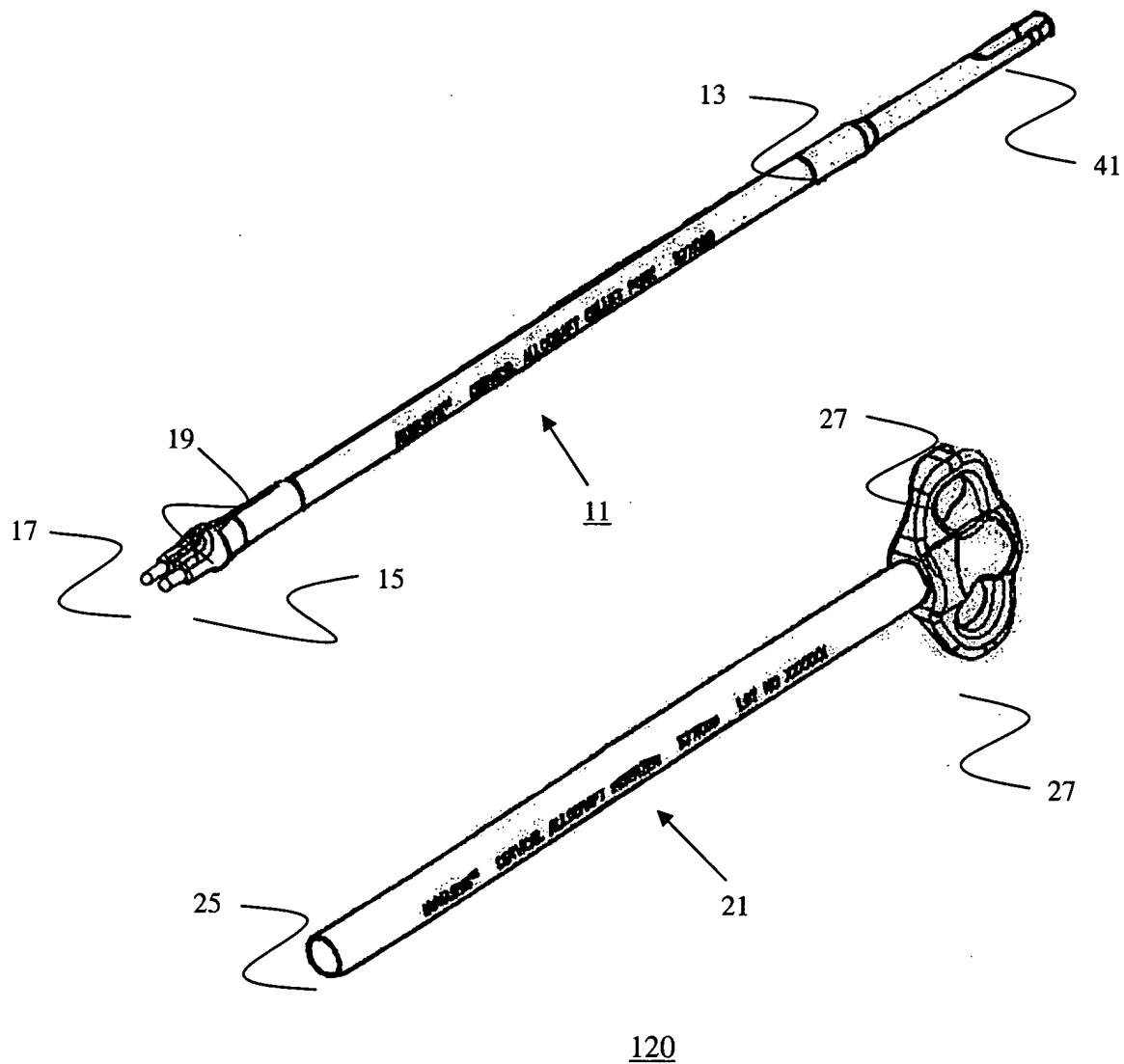


FIG. 17

FIG. 18

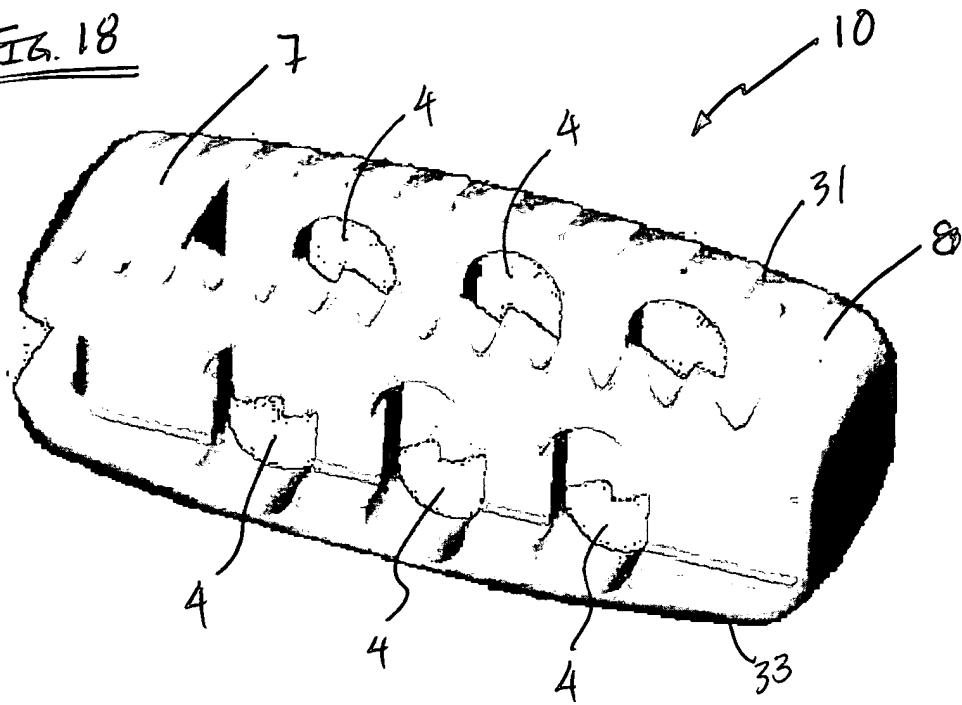


FIG. 19

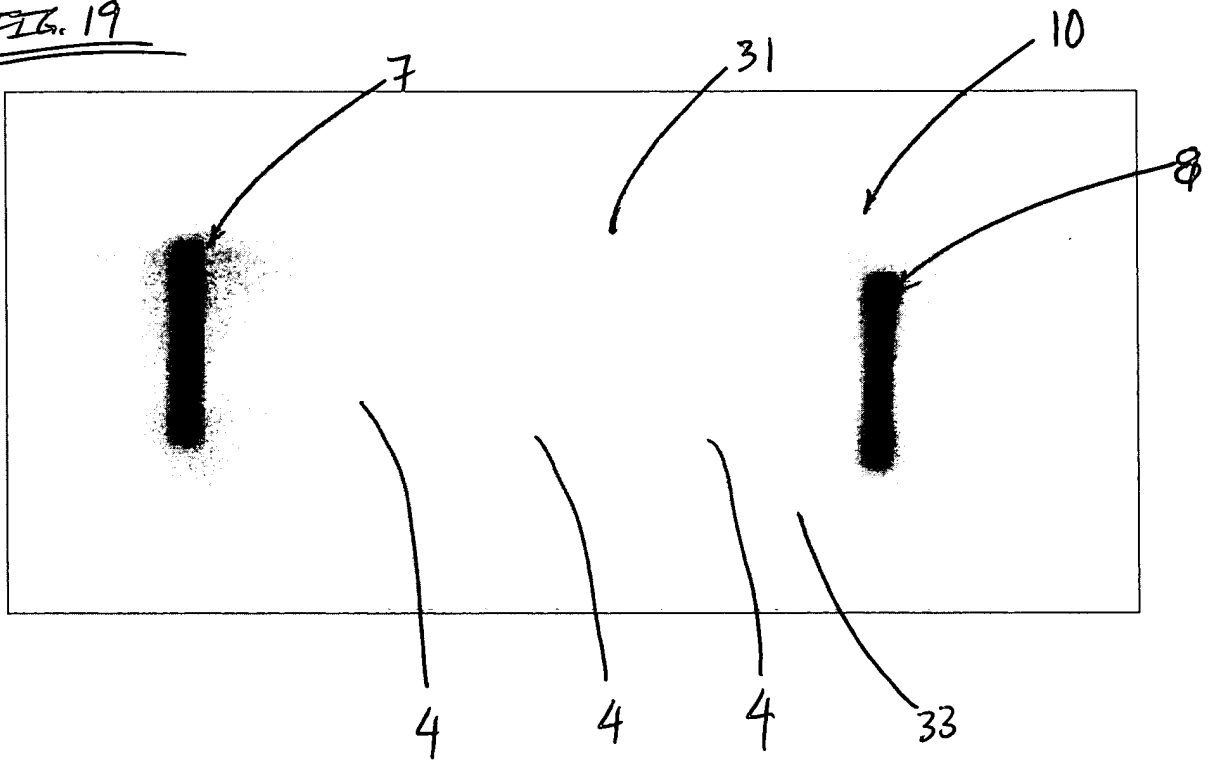


FIG. 20

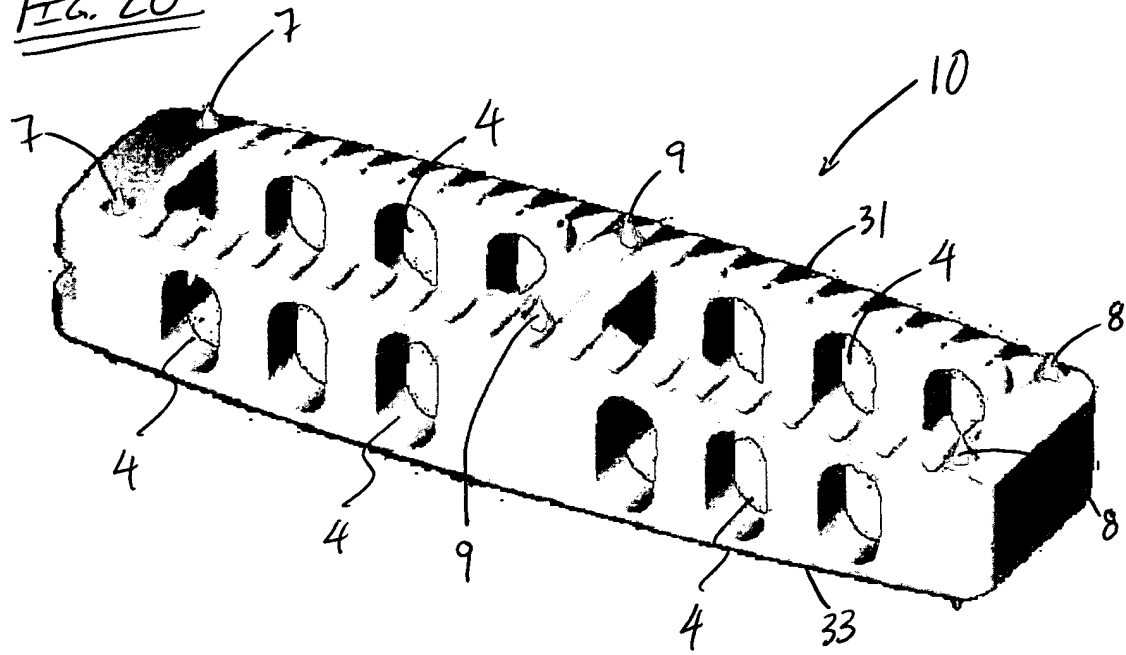


FIG. 21

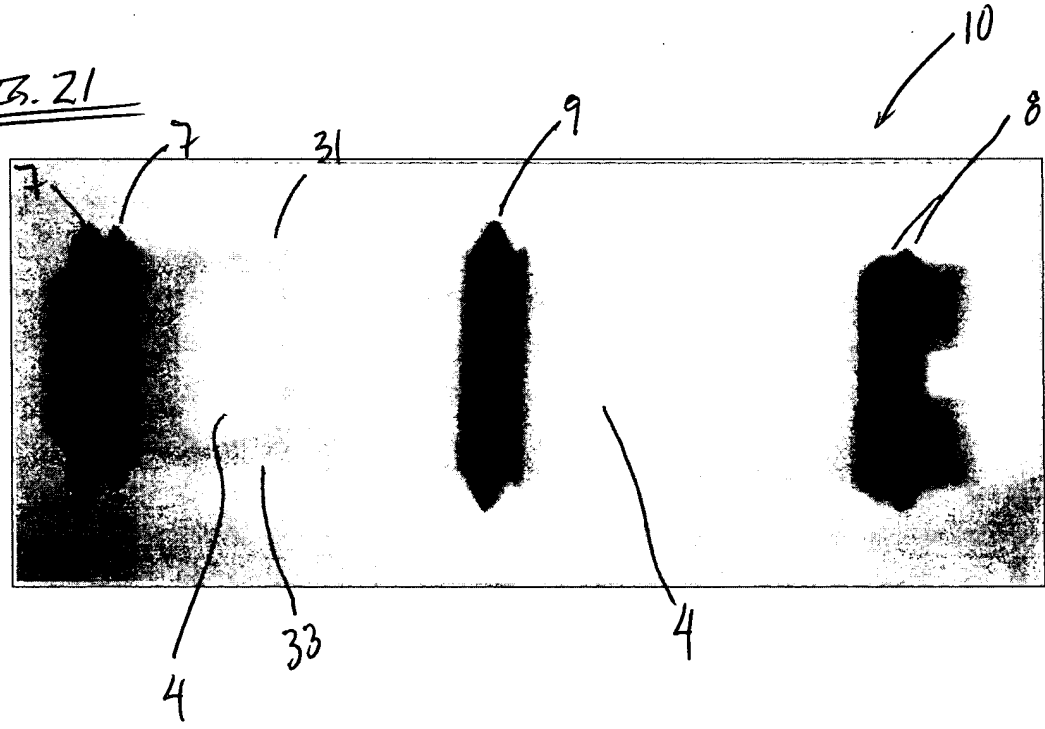




FIG. 22

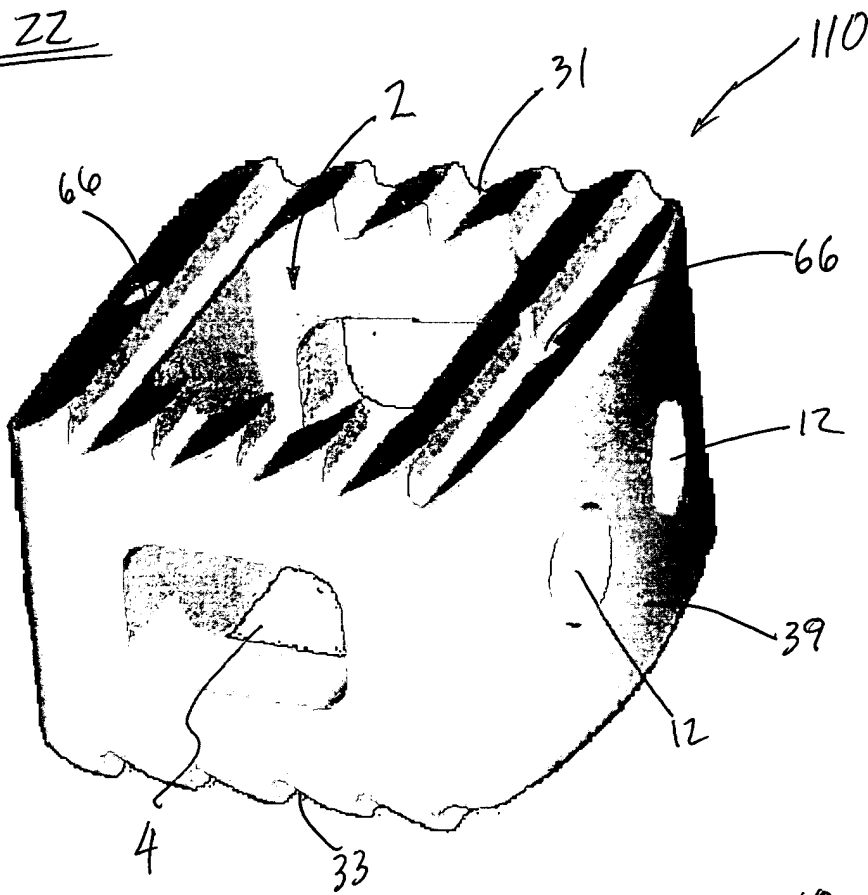
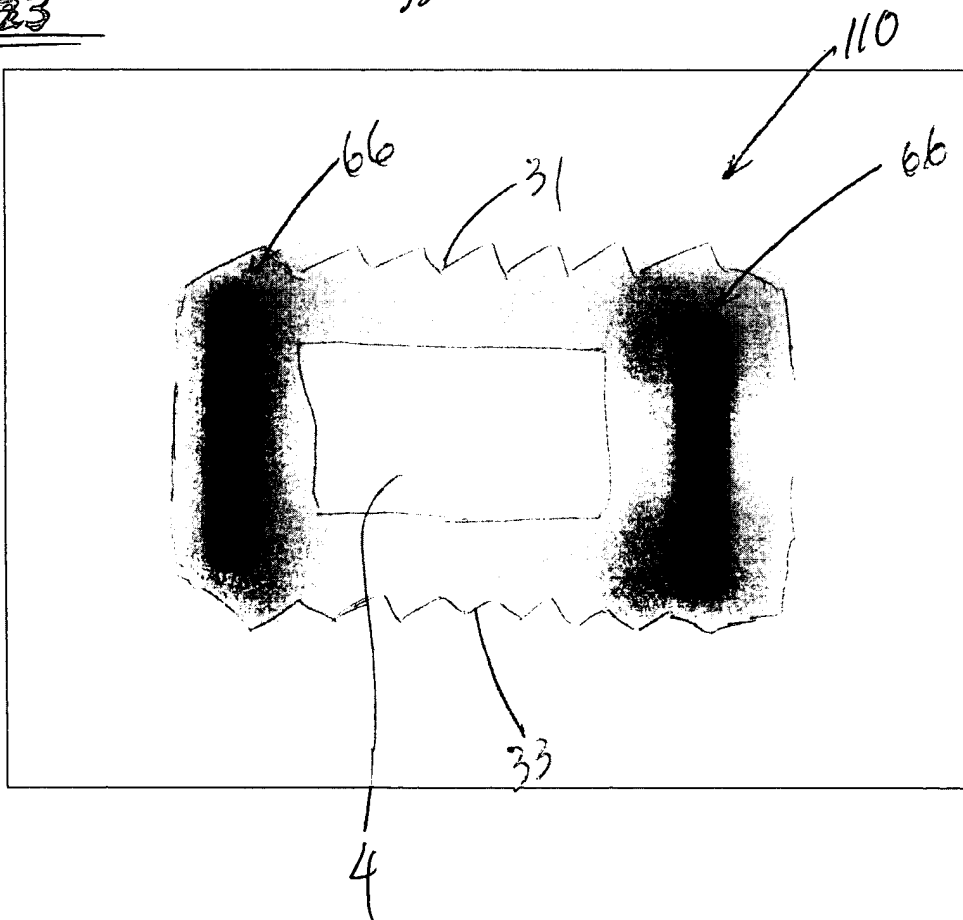


FIG. 23



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<b>DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)</b>  <input checked="" type="checkbox"/> Declaration Submitted With Initial Filing <b>OR</b> <input type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)	Attorney Docket Number	104US1
	First Named Inventor	Matthew Curran
	<i>COMPLETE IF KNOWN</i>	
	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
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

[Page 1 of 2]

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

**DECLARATION — Utility or Design Patent Application**

Direct all correspondence to:	<input checked="" type="checkbox"/> The address associated with Customer Number:	<input type="checkbox"/> OR	<input type="checkbox"/> Correspondence address below
	30,328		
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.			
<b>NAME OF SOLE OR FIRST INVENTOR:</b>		<input type="checkbox"/> 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
<b>NAME OF SECOND INVENTOR:</b>		<input type="checkbox"/> 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
MEOFORD	OREGON		US
Mailing Address			
City	State	Zip	Country
<input type="checkbox"/> 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

**SMALL ENTITY**  **TYPE** OR

**OTHER THAN SMALL ENTITY**

	(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 <input type="checkbox"/>		

RATE	FEE
BASIC FEE	150.00
X\$ 25=	150
X100=	
+180=	
TOTAL	300

RATE	FEE
BASIC FEE	300.00
X\$50=	
X200=	
+360=	
TOTAL	

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

## CLAIMS AS AMENDED - PART II

**SMALL ENTITY** OR

**OTHER THAN SMALL ENTITY**

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR
	Total	*	Minus **
	Independent	*	Minus ***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR
	Total	*	Minus **
	Independent	*	Minus ***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR
	Total	*	Minus **
	Independent	*	Minus ***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
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

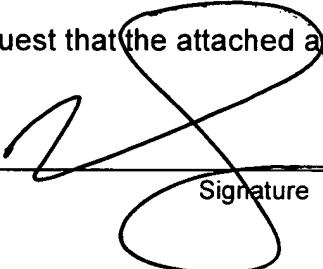
PTO-1556  
(5/87)

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<b>NONPUBLICATION REQUEST UNDER 35 U.S.C. 122(b)(2)(B)(i)</b>	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	<u>MARCH 29, 2005</u> Date
<u>JONATHAN SPANGLER</u> Typed or printed name	<u>40,182</u> Registration Number, if applicable
<u>(658) 243-0029</u> 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)).**

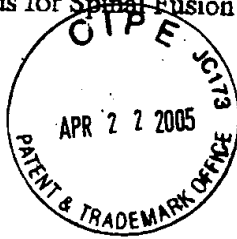
This collection of information is required by 37 CFR 1.213(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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



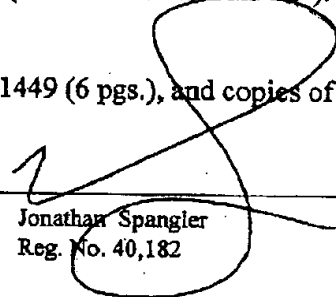
Serial No.: 11/093,409  
Due Date: N/A  
Group Art Unit: Unknown

**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"):

- A return postcard and this transmittal document.
- 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

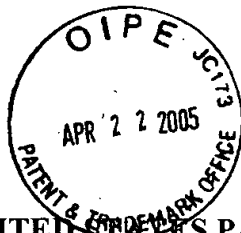
CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450,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

**INFORMATION DISCLOSURE STATEMENT**

Serial No :11/093,409

Filing Date: March 29, 2005

Title: System and Methods for Spinal Fusion

Page 2

Dkt: 104US1

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

Respectfully submitted,

MATTHEW CURRAN ET AL.

By their Representatives,

**CUSTOMER NUMBER: 30328**

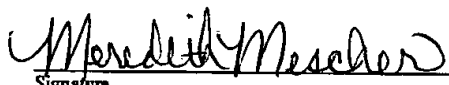
858-909-1807

Date 4-19-05

By   
Jonathan Spangler  
Reg. No. 40,182

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

MEREDITH MESCHER  
Name

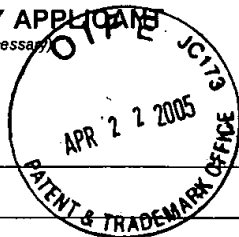
  
Signature

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Complete if Known

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

Sheet 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 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. † Applicant's unique citation designation number (optional) ‡ Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	11/093,409
<b>Filing Date</b>	March 29, 2005
<b>First Named Inventor</b>	Matthew Curran
<b>Group Art Unit</b>	Unknown
<b>Examiner Name</b>	Unknown
<b>Attorney Docket No: 104US1</b>	

Sheet 2 of 6

	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 Disclosure Statement Form (PTO-1449)

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

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

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

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Attorney Docket No: 104US1

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Sheet 6 of 6	Attorney Docket No: 104US1	

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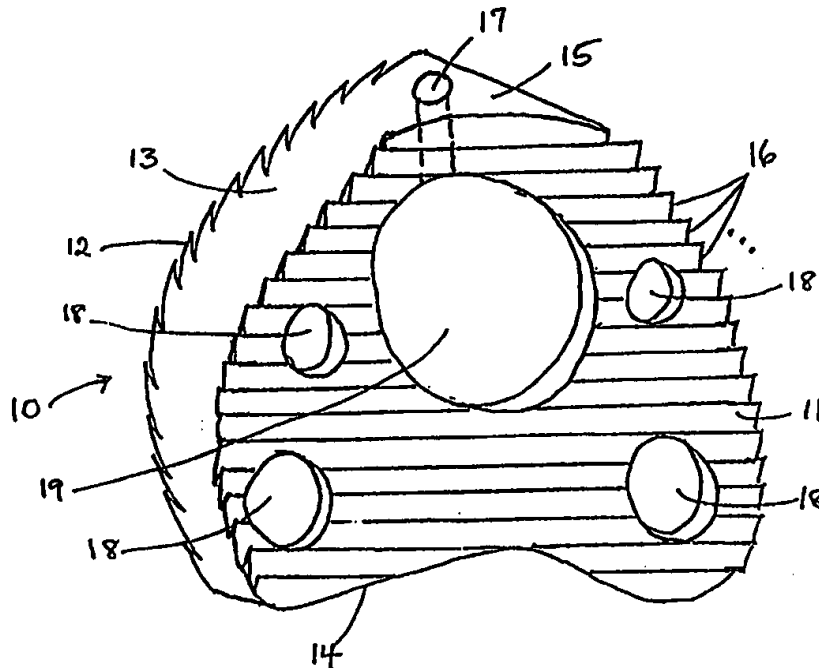




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>6</sup> : <b>A61F 2/44</b></p>	<p><b>A1</b></p>	<p>(11) International Publication Number: <b>WO 99/08627</b> (43) International Publication Date: 25 February 1999 (25.02.99)</p>
<p>(21) International Application Number: PCT/US98/16650 (22) International Filing Date: 11 August 1998 (11.08.98)</p> <p>(30) Priority Data: 60/055,291 13 August 1997 (13.08.97) US 60/074,076 9 February 1998 (09.02.98) US 60/074,197 10 February 1998 (10.02.98) US 60/081,803 15 April 1998 (15.04.98) US 09/131,716 10 August 1998 (10.08.98) US</p> <p>(71) Applicant: CAMBRIDGE SCIENTIFIC, INC. [US/US]; 195 Common Street, Belmont, MA 02178 (US).</p> <p>(72) Inventors: GRESSER, Joseph, D.; 40 Salisbury Road, Brookline, MA 02146 (US). TRANTOLO, Debra, J.; 28 Radford Road, Princeton, MA 01541 (US). LANGER, Robert, S.; 77 Lombard Street, Newton, MA 02159 (US). LEWANDROWSKI, Kai-Uwe; Apartment 6, 423 Washington Street, Brookline, MA 02446 (US). KLIBANOV, Alexander, M.; 61 West Boulevard Road, Newton, MA 02159 (US). WISE, Donald, L.; 195 Common Street, Belmont, MA 02178 (US).</p>	<p>(74) Agents: HEINE, Holliday, C. et al.; Weingarten, Schurgin, Gagnebin &amp; Hayes LLP, Ten Post Office Square, Boston, MA 02109 (US).</p> <p>(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p><b>Published</b> <i>With international search report.</i></p>	

(54) Title: RESORBABLE INTERBODY SPINAL FUSION DEVICES



(57) Abstract

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

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TITLE OF THE INVENTION  
Resorbable Interbody Spinal Fusion Devices

5                   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  
10                   entire disclosures of which are incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR  
DEVELOPMENT

15                   Not applicable

BACKGROUND OF THE INVENTION

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

20                   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  
25                   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  
30                   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  
35                   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

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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.

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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( $\epsilon$ -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-

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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

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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.

5 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:

10 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;

15 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;

20 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;

30 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;

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

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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.

5

#### 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



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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 posteriorly, is 6-8 mm thick, enlarging to about 7-9 mm at the anterior edge; thus the device has a taper of

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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.

5           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  
10           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  
15           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  
20           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( $\epsilon$ -caprolactone); polyanhydride; poly(ortho ester);  
25           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(glycolic acid); poly(lactide-co-glycolide); and combinations thereof. Selection of a particular polymer is based primarily on the known properties of the polymer, such  
30           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  
35           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

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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).

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5 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  
10 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.

15 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  
20 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.

25 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.  
30 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  
35 a PLGA is the polymer which is undergoing hydrolysis. Thus,

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

5 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  
10 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,  $K_a$ )  
15 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.

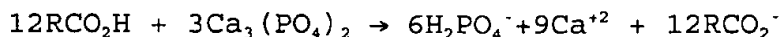
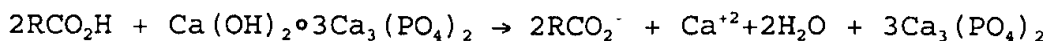
20 Hydroxyapatite (HA) and calcium carbonate (CC) were each investigated as buffering fillers. Results demonstrate that the inclusion of CC or HA in a, e.g., PLGA fixture can effectively moderate the rate of pH decline as the fixture degrades. Further, the rapid decline in pH can be offset without considering 100% neutralization of the lactic and  
25 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.

30 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  
35 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

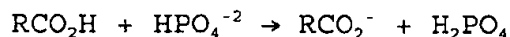
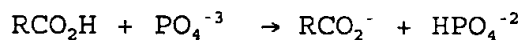
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of a buffered hydrolytic degradation and induction of bony ingrowth as resorption of the implant progresses. A resorbable buffered bone fixture with such properties could provide structural support to stabilize and support a spinal repair over the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

According to the invention a preferred buffering compound is hydroxyapatite. The formula  $\text{Ca}_{10}(\text{OH})_2(\text{PO}_4)_6$  may be written as  $\text{Ca}(\text{OH})_2 \cdot 3\text{Ca}_3(\text{PO}_4)_2$ . When written in this manner it is seen that the following neutralization reactions may be written:



The dissociation constant of water (the conjugate acid of the hydroxyl ion) is  $K_w = 10^{-14}$ . The basic phosphate ion,  $\text{PO}_4^{-3}$ , can neutralize two protons forming the following acids, for which dissociation constants are given:



$$K_2 \text{ of } \text{H}_2\text{PO}_4^{-1} = 6.2 \times 10^{-8}$$

$$K_3 \text{ of } \text{HPO}_4^{-2} = 4.2 \times 10^{-13}$$

Buffers included in the polymer in solid form preferably have a relatively small particle size, for example, between less than 1.0 and 250  $\mu\text{m}$ . 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

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size ranges of <45, 45-90, 90-125, 125-180, 180-250  $\mu\text{m}$  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  $\mu\text{m}$ . 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  $\alpha$ -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

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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.

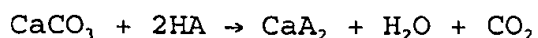
Necessarily, the conjugate acid of the buffering compound has an acid dissociation constant that is smaller than the acid dissociation constant of the acidic products generated upon hydrolysis of the bioerodible polymer. Alternatively, the buffering compound preferably has a hydrolysis constant that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

$$\text{RMW} = 14.03x + 58.04$$

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),  $\text{RMW} = 69.96$ . 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



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.



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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.

5 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  
10 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  
15 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  
20 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%.

25 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  
30 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  
35 final shape may be accomplished at this point by any desirable machining process, such as lathing.

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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( $\epsilon$ -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

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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.

5           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  
10           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  
15           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,  
20           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  
25           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  
30           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  
35           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

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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

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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 (Instron 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<sup>2</sup>, 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

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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

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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  $\gamma$ -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

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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.



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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.

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## CLAIMS

What is claimed is:

- 5 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.
- 10 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.
- 15 4. The resorbable interbody spinal fusion device of claim 3, wherein said grafting material is an autologous grafting material.
- 20 5. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a tapered wedge or cone.
- 25 6. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a threaded screw.
- 30 7. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a threaded rod of cruciform configuration.
- 35 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

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

5 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.

10 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( $\epsilon$ -caprolactone), polyanhydride, polyester, copoly(ether-ester), polyamide, polylactone, poly(propylene fumarate), and  
15 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  
20 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.  
25

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.  
30

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.  
35

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

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

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

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

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

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

25 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.

30 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  
35 therein.

-27-

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

providing a mold for said resorbable interbody spinal fusion device;

5 orienting reinforcing fibers under tension in said mold;

introducing a resorbable material into said mold;

molding said resorbable material under pressure; and

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

10

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

15

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

20

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

25

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

30

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

35

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

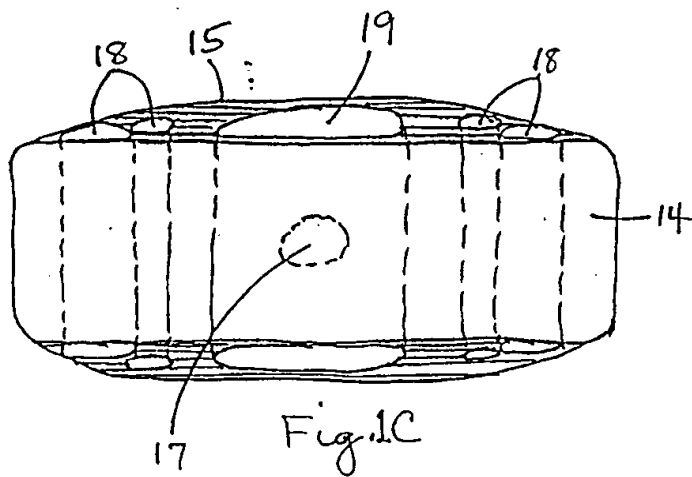
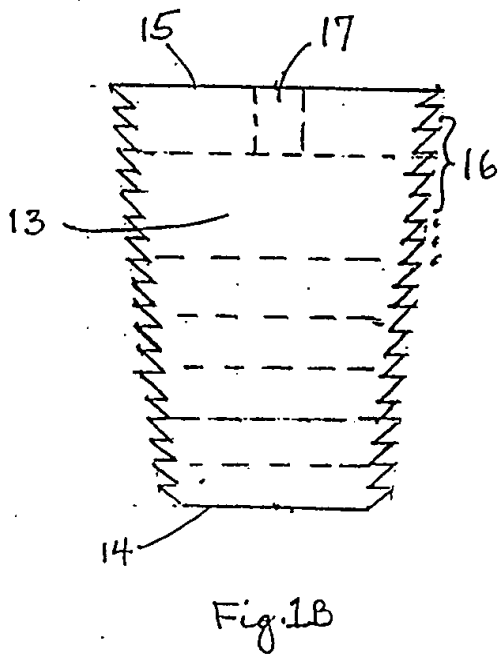
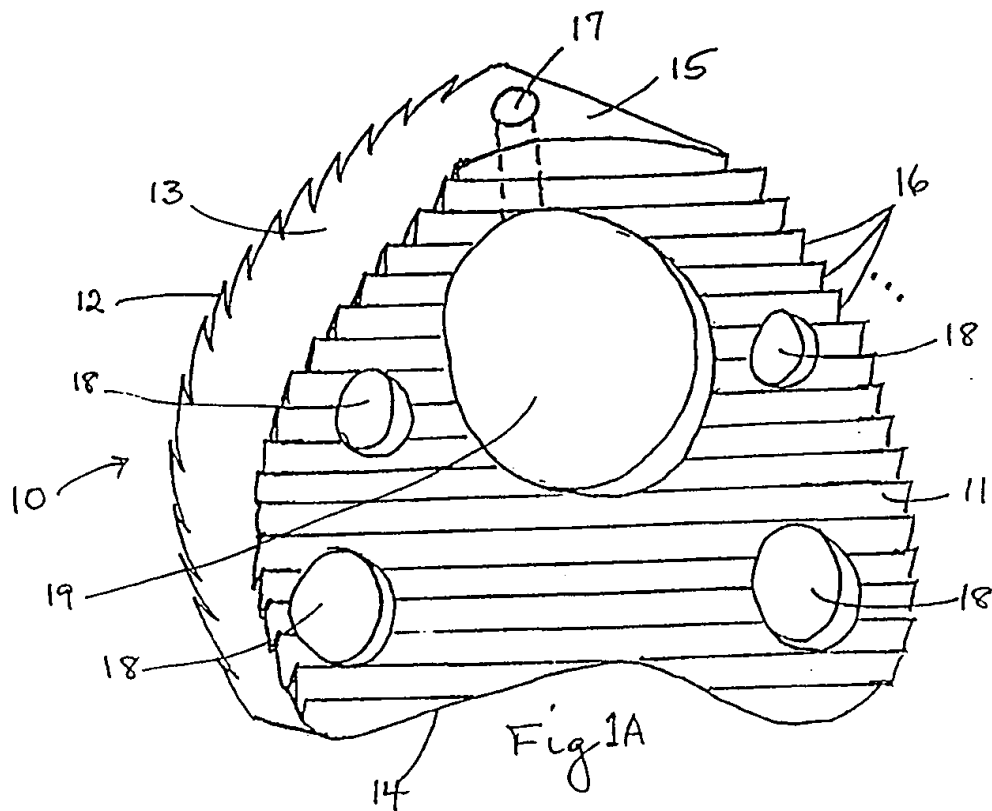
-28-

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

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

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

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



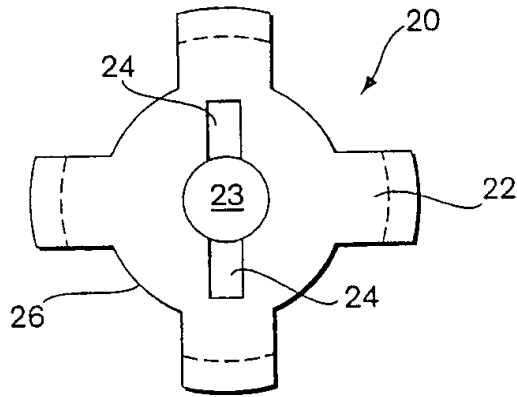


Fig. 2A

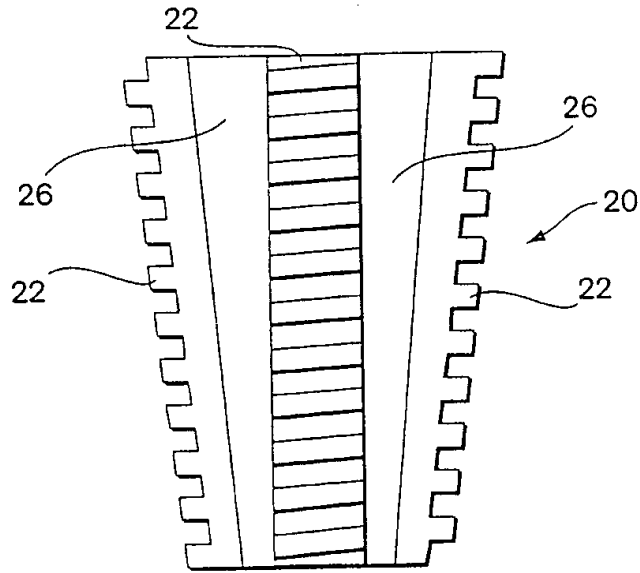


Fig. 2B

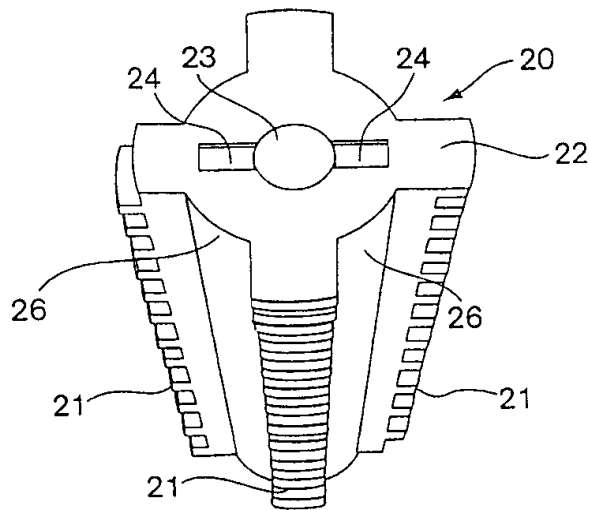


Fig. 2C



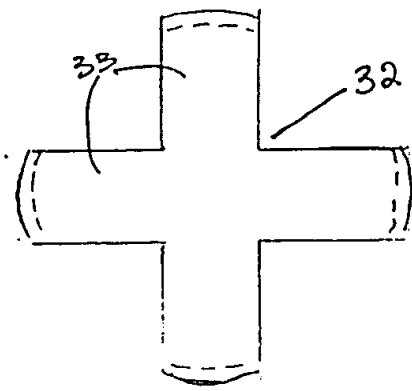


Fig. 3A

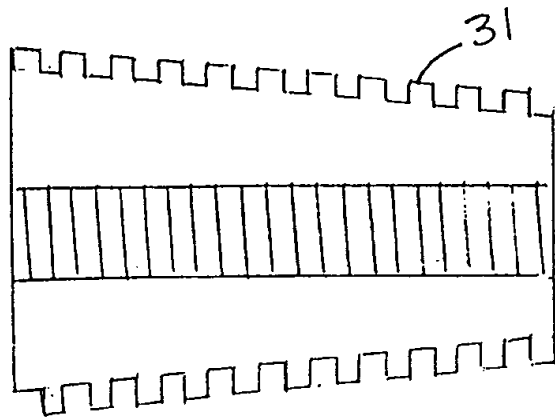


Fig. 3B

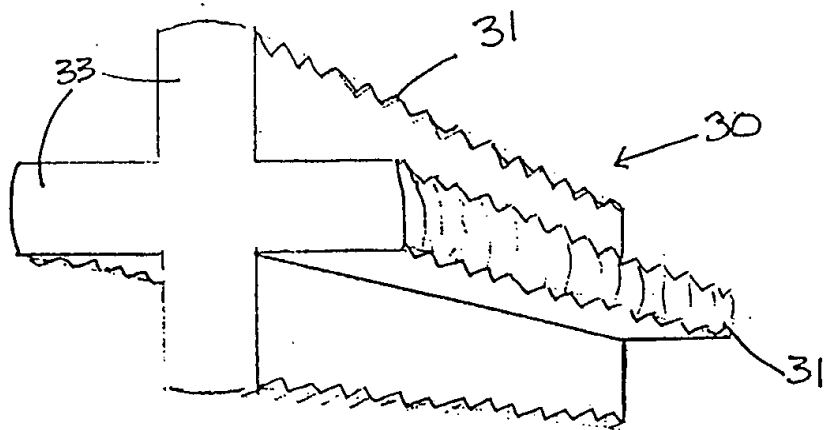
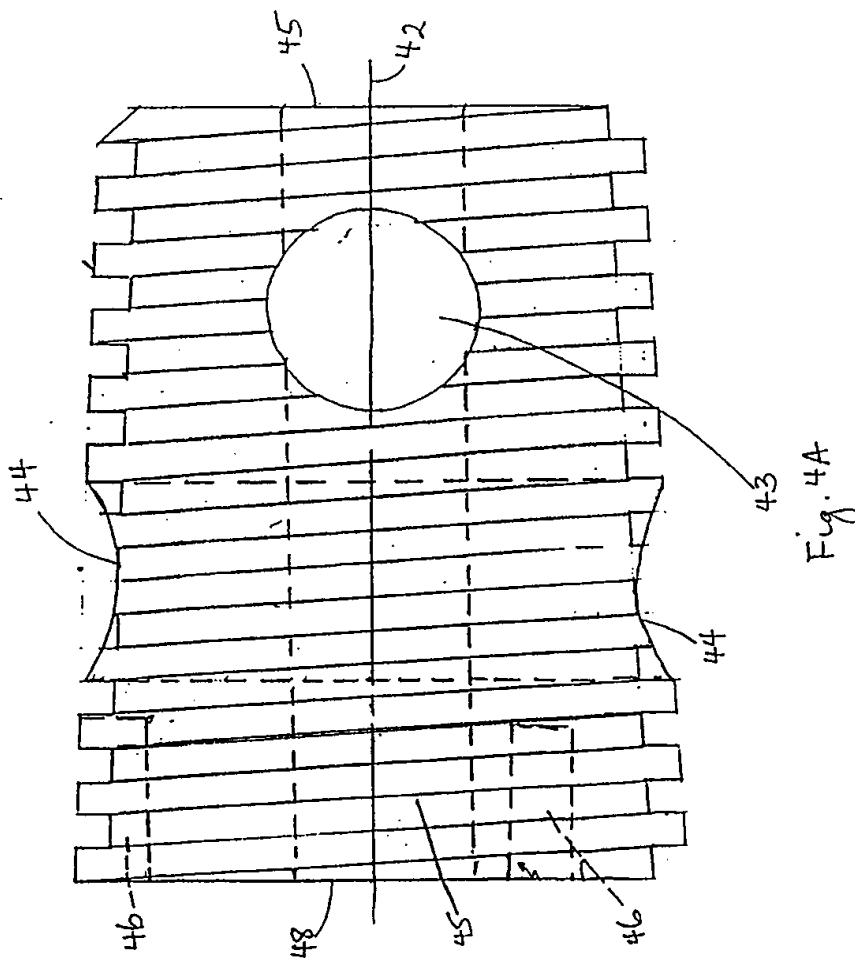
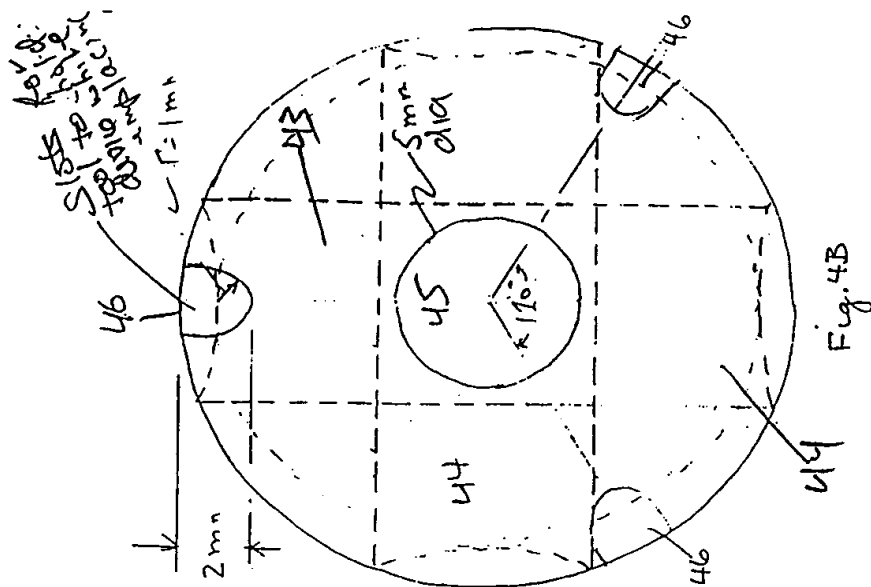
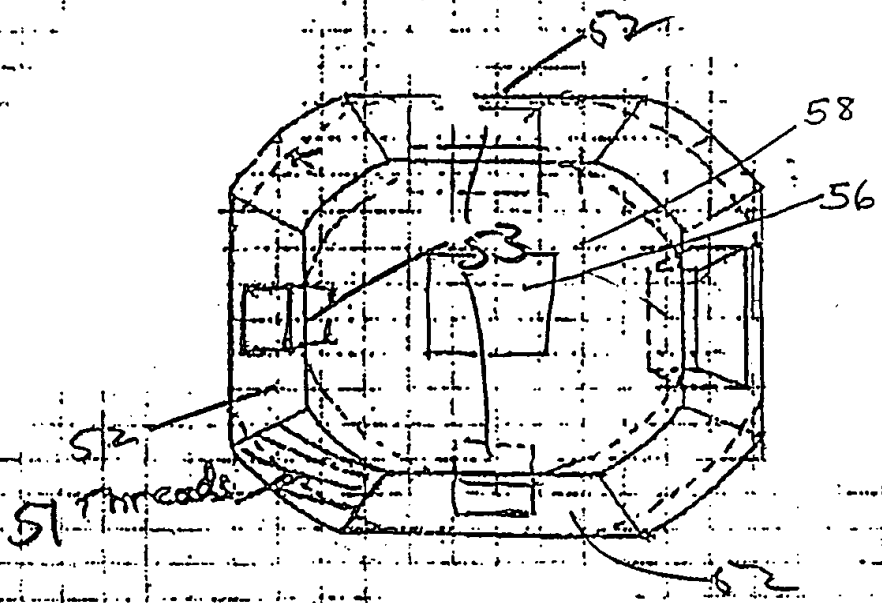
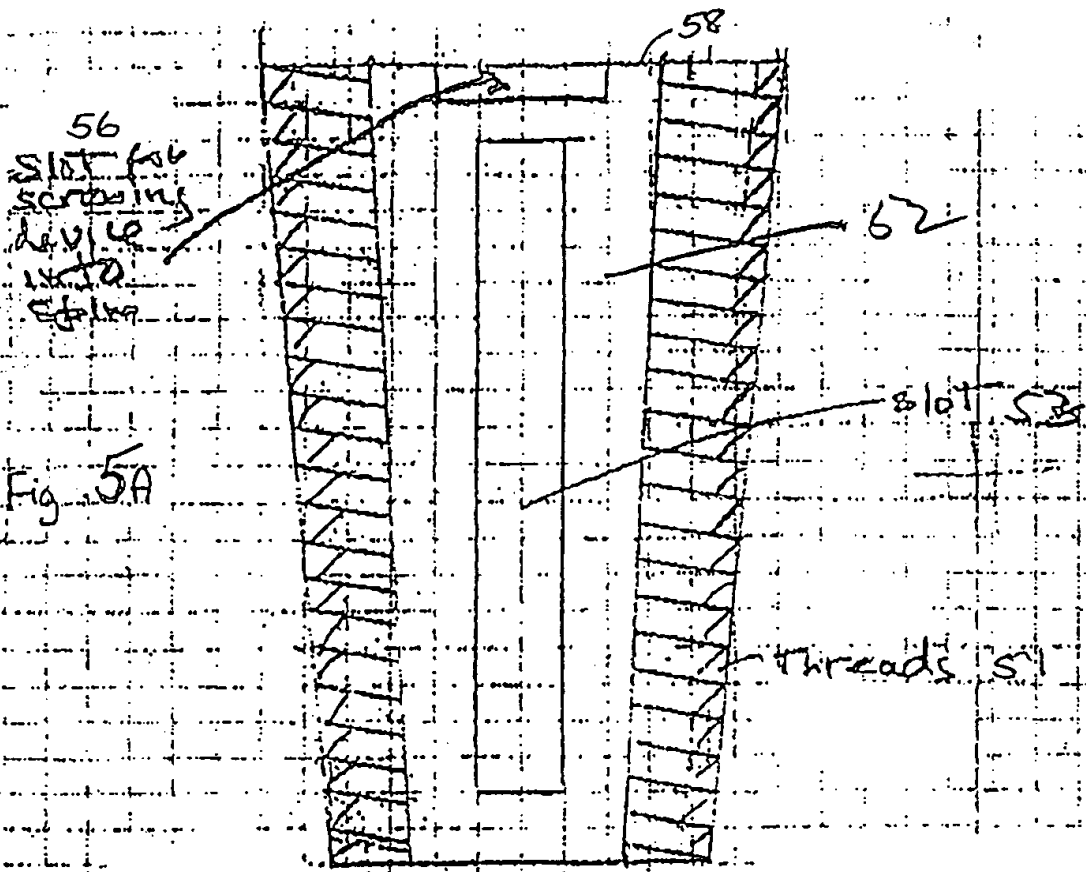


Fig. 3C





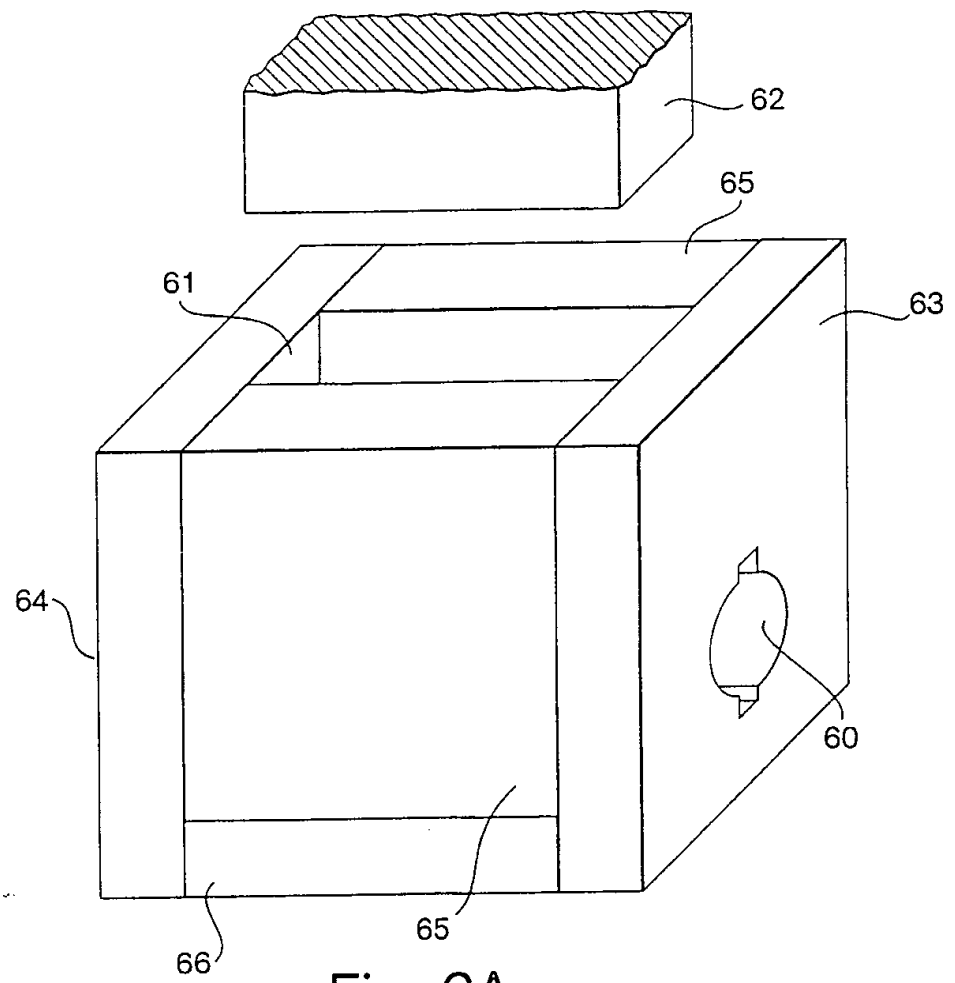


Fig. 6A

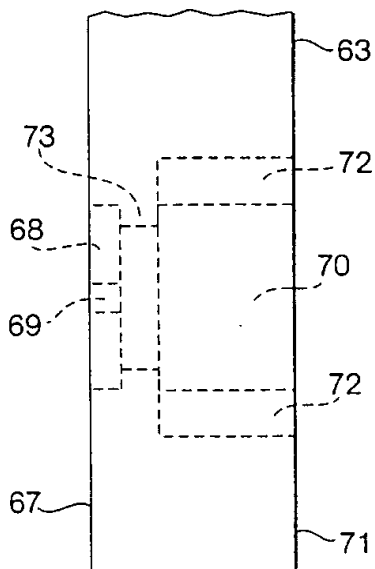


Fig. 6B

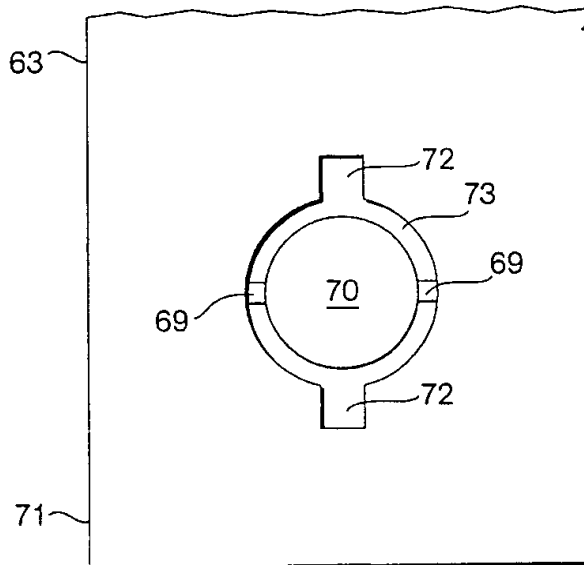


Fig. 6C

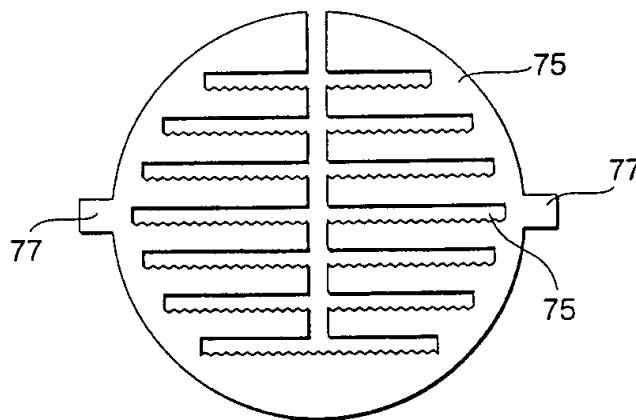


Fig. 6D

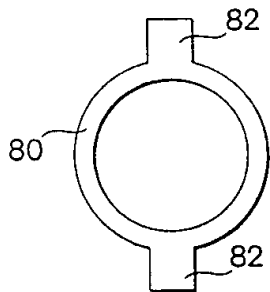


Fig. 6E

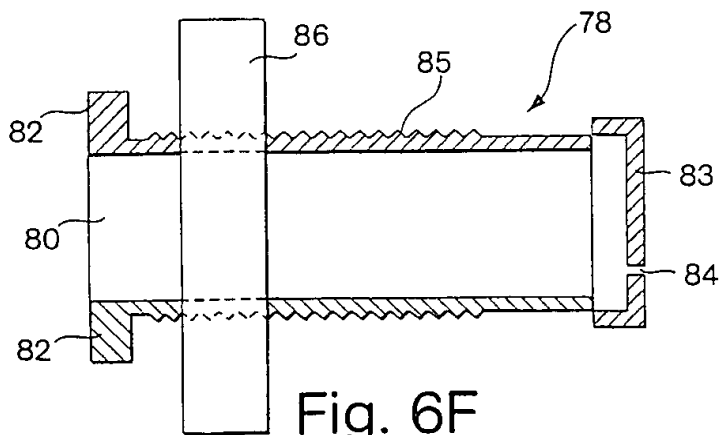


Fig. 6F

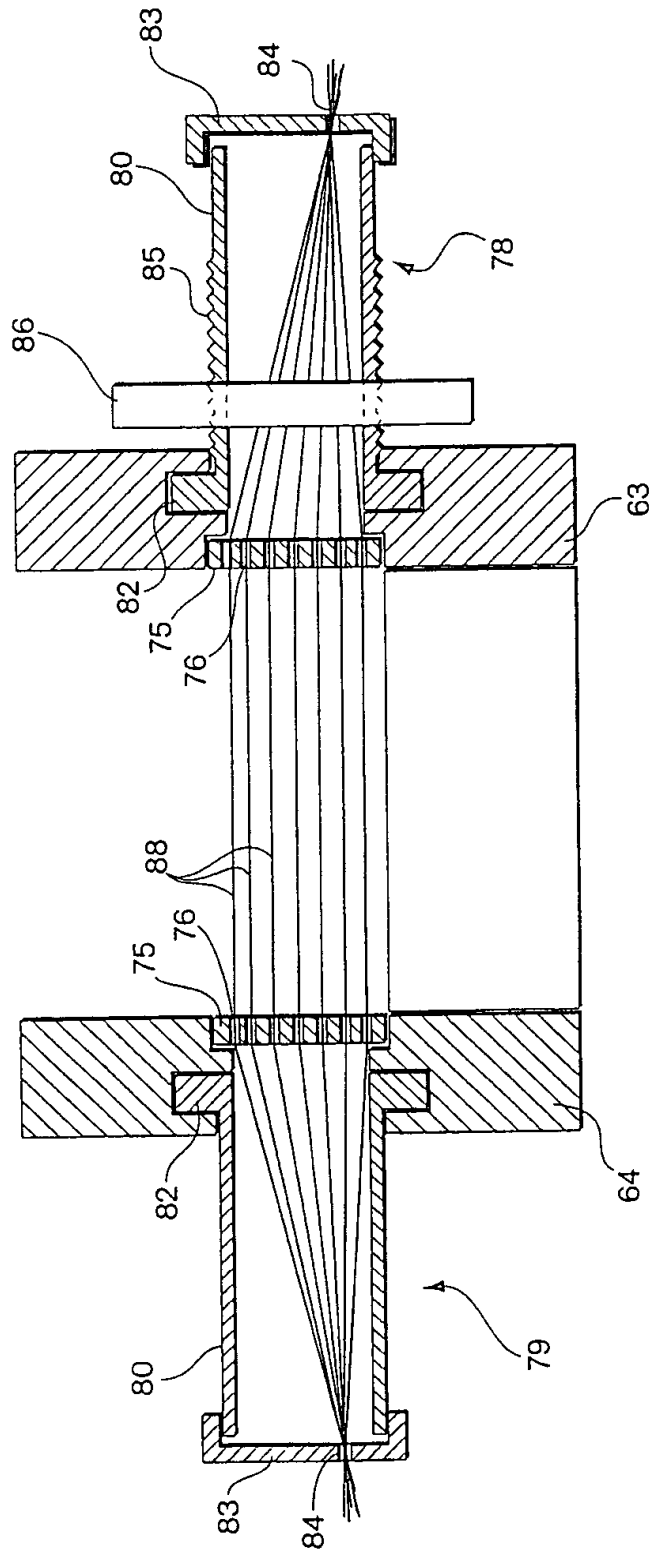


Fig. 6G

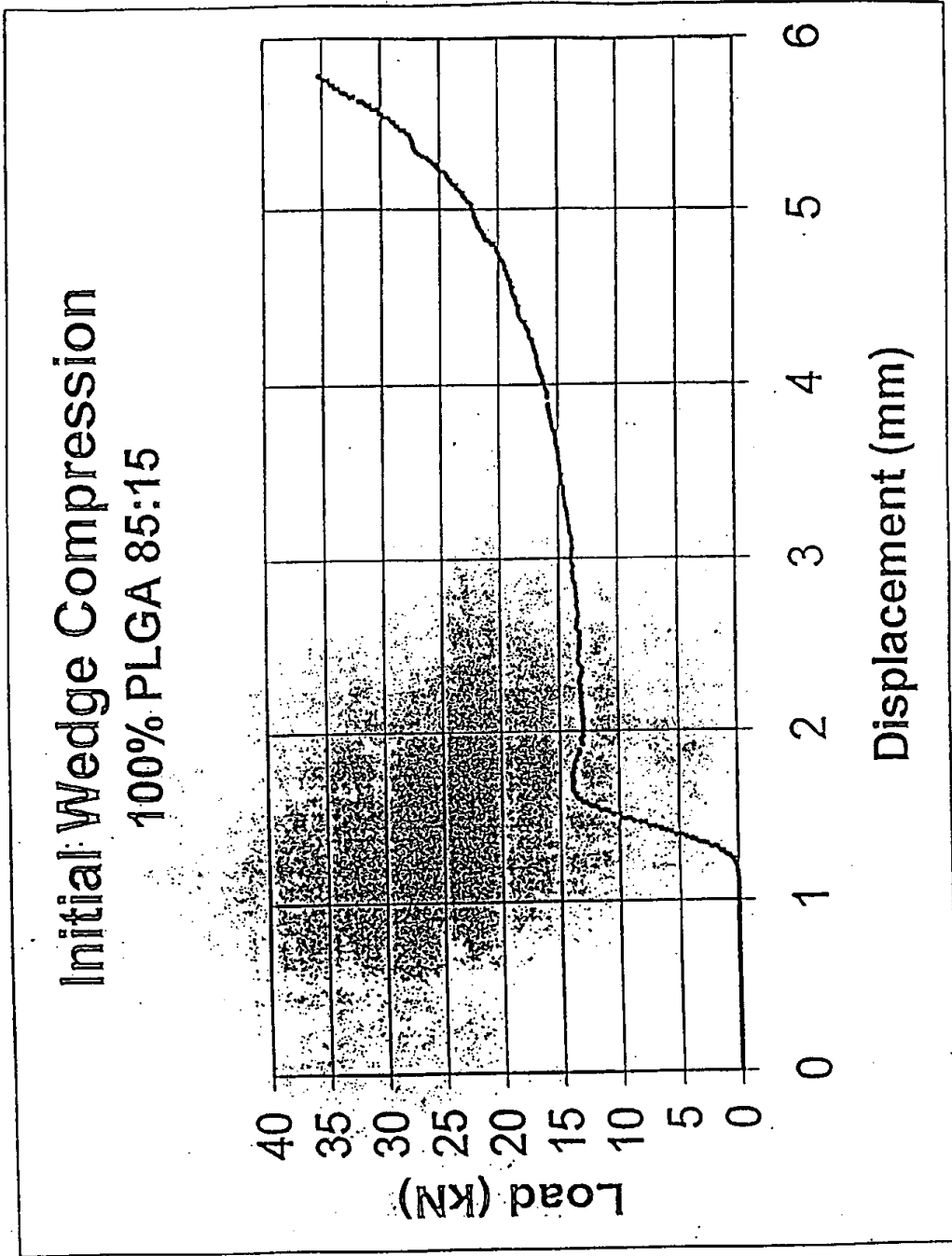


Fig. 7

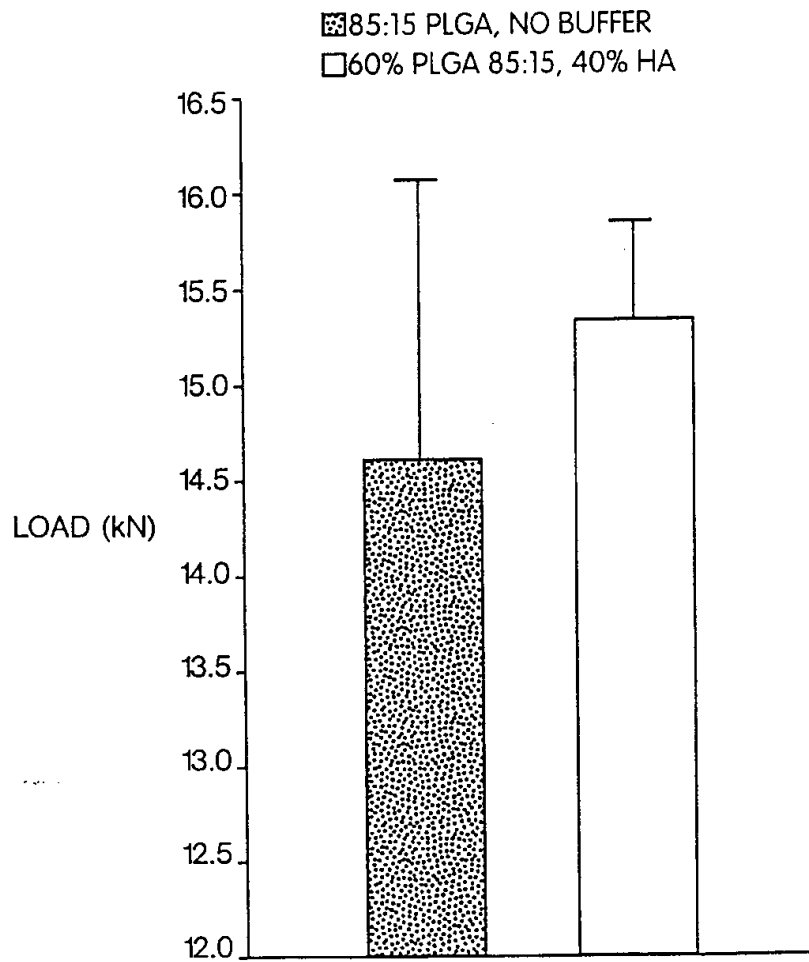


Fig. 8



INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/16650

A. CLASSIFICATION OF SUBJECT MATTER

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

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606,65, 77; 623/17

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

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Date of the actual completion of the international search

14 SEPTEMBER 1998

Date of mailing of the international search report

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International application No.  
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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

**B. FIELDS SEARCHED**

Electronic data bases consulted (Name of data base and where practicable terms used):

APS

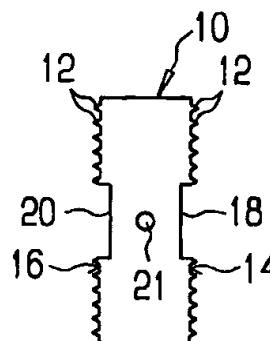
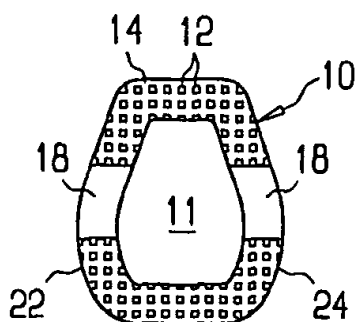
Search Terms: (resorbable or bioresorbable or absorbable or bioabsorbable or degradable or biodegradable) and buffer? and (glycoli? or lacti? or polyglycol? or poly lacti?); and propylene fumarate. search terms: 264/257/ccls and (resorbable or bioresorbable or absorbable or bioabsorbable or degradable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



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61F 2/44</b>	<b>A2</b>	(11) International Publication Number: <b>WO 99/38461</b> (43) International Publication Date: 5 August 1999 (05.08.99)
<p>(21) International Application Number: PCT/EP99/00433</p> <p>(22) International Filing Date: 22 January 1999 (22.01.99)</p> <p>(30) Priority Data: 60/073,271 30 January 1998 (30.01.98) US 60/095,425 5 August 1998 (05.08.98) US</p> <p>(71) Applicant (for all designated States except CA): SYNTHES AG CHUR [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).</p> <p>(71) Applicant (for CA only): SYNTHES (U.S.A.) [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).</p> <p>(72) Inventors: PAUL, David, C.; 1513 Valley Road, Drexel Hill, PA 19026 (US). EMCH, Hansjuerg, W.; 1527 Spruce Street, Philadelphia, PA 19102 (US). SCHENK, Beat; 59 Cobblestone Drive, Paoli, PA 19301 (US). CARVER, Jeffrey, L.; 1011 Welsh Ayres Way, Downingtown, PA 19335 (US). BAKER, Kelly, J.; 1878 Shadyside Road, Coatesville, PA 19320 (US).</p> <p>(74) Agent: LUSUARDI, Werther, Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).</p>		<p>(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p><b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i></p>

(54) Title: ALLOGENIC INTERVERTEBRAL IMPLANT



## (57) Abstract

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

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## ALLOGENIC INTERVERTEBRAL IMPLANT

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

In the drawings:

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

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

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

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

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

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

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

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

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

FIG. 10 shows an alternative tooth configuration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



## CLAIMS

1. Intervertebral implant (10) comprising an annular plug of allogenic bone conforming in size and shape with end plates of vertebrae, wherein top and bottom surfaces (14,16) of the implant (10) include a three-dimensional structure (12) positioned thereon for interlocking with adjacent vertebrae.
2. Intervertebral implant (10) according to claim 1, wherein said three-dimensional structure (12) includes a plurality of teeth.
3. Intervertebral implant (10) according to claim 1 or 2, wherein said three-dimensional structure (12) has a minimum height of 0,5 mm relative to the top and bottom surfaces (14,16).
4. Intervertebral implant (10) according to one of the claims 1 to 3, wherein said three-dimensional structure (12) has a maximum height of 1,5 mm relative to the top and bottom surfaces (14,16).
5. Intervertebral implant (10) according to one of the claims 1 to 4, wherein said allogenic bone has been obtained from a human long bone, preferably from a femur, humerus, radius, ulna or fibula.
6. Intervertebral implant (10) according to claim 5, wherein said allogenic bone is a cross section transverse to the longitudinal axis of said long bone, preferably with a height of 5 to 8 mm.

7. Intervertebral implant (10) according to one of the claims 1 to 6, wherein said allogenic bone is treated with an antiseptic solution.
8. Intervertebral implant (10) according to one of the claims 1 to 7, wherein said allogenic bone has been process frozen or freeze dried.
9. Intervertebral implant (10) according to one of the claims 1 to 8, wherein the allogenic bone comprises glutaraldehyde.
10. Intervertebral implant (10) according to one of the claims 1 to 9, wherein the interior space delineated by the annular plug is filled with spongiosa, bone graft substitutes or artificial bone material.
11. Intervertebral implant (10) according to one of the claims 1 to 10, wherein the top and bottom (14,16) surfaces each have a channel (18,20) for receiving a surgical instrument.
12. Intervertebral implant (10) according to claim 11, wherein the channels (18,20) run in an anterior-posterior direction.
13. Intervertebral implant (10) according to claim 11, wherein the channels (18,20) run in an antero-lateral direction.
14. Intervertebral implant (10) according to claim 11, wherein the channels (18,20) run in a lateral direction.

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

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

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

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

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

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

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

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

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

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

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

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

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

FIG. 1

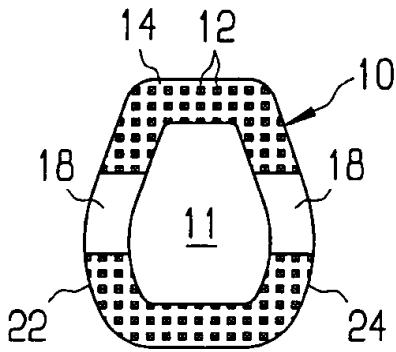


FIG. 2

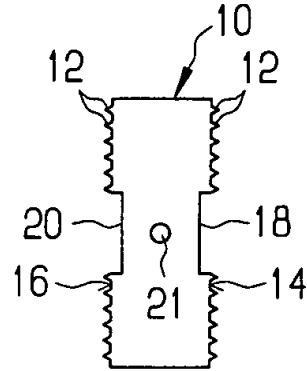


FIG. 3

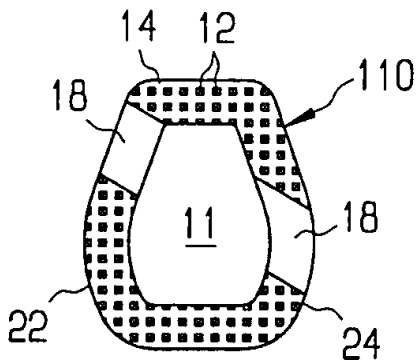


FIG. 4

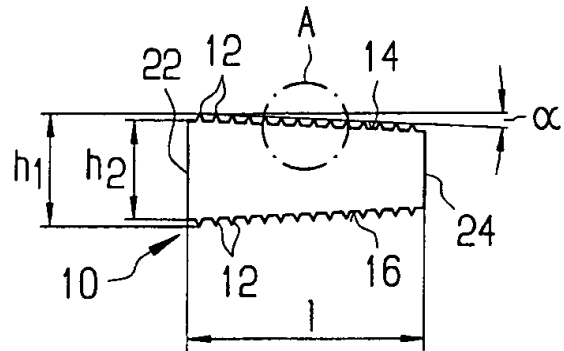


FIG. 5

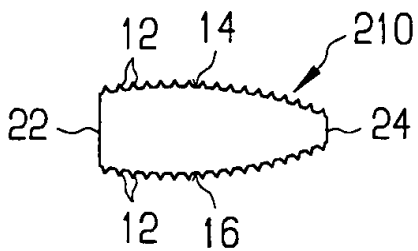


FIG. 6

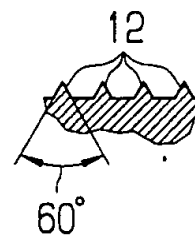


FIG. 7

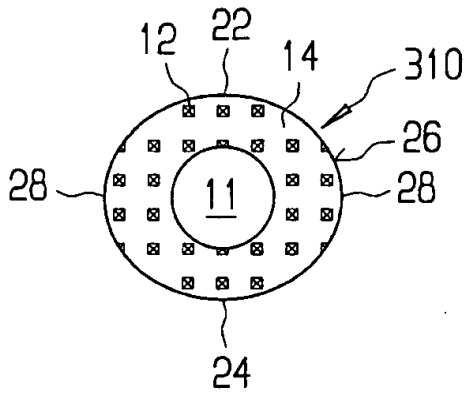


FIG. 8

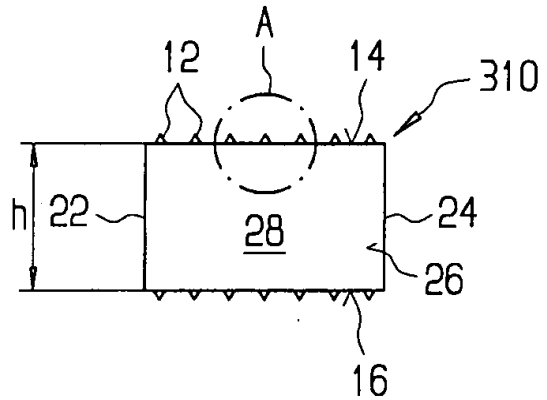


FIG. 9

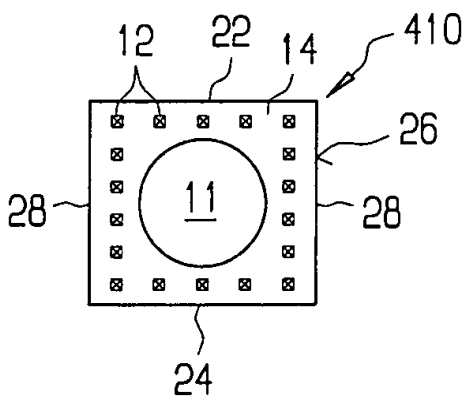
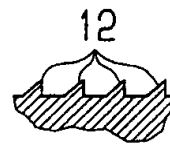


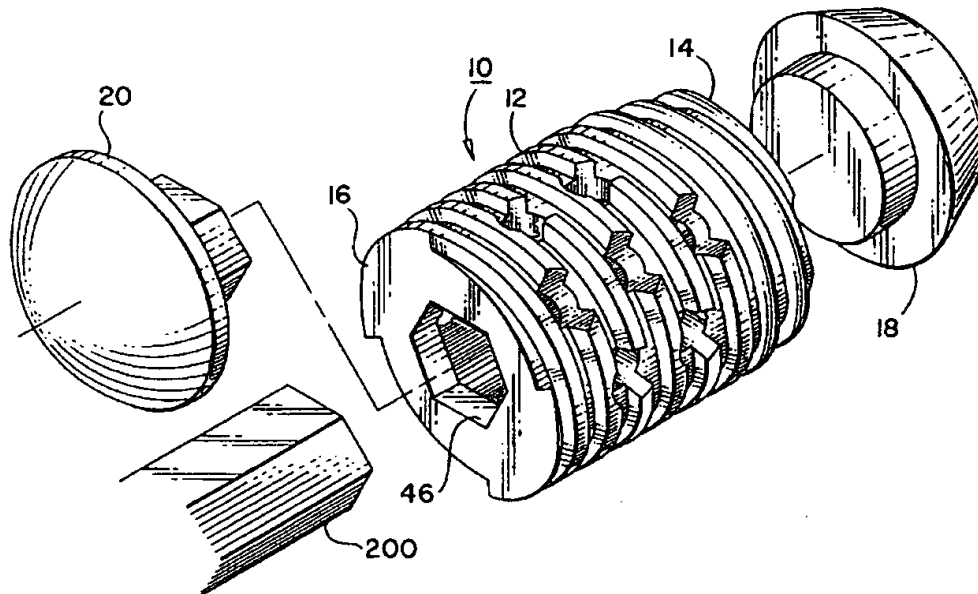
FIG. 10





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

(72) Kuslich, Stephen D., US  
(72) Corin, James D., US  
(72) Bagby, George W., US  
(73) Spine-Tech, Inc., US  
(51) Int. Cl.<sup>6</sup> A61B 17/70  
(30) 1989/07/06 (376,657) US  
(30) 1989/09/08 (405,564) US  
(54) **IMPLANT RACHIDIEN**  
(54) **SPINAL IMPLANT**



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

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

## SPINAL IMPLANT

ABSTRACT OF THE DISCLOSURE

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



## SPINAL IMPLANT

BACKGROUND OF THE INVENTION1. Field of the Invention

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

2. Description of the Prior Art

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

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

stabilizing contiguous vertebrae in the lumbar region of the spine.

Surgical techniques are known for use in spinal stabilization. Surgical techniques seek to rigidly join 5 vertebrae which are separated by a degenerated disk. Ideally, the surgery effectively replaces the vertebra-disk-vertebra combination with a single rigid vertebra. Various surgical techniques have developed which attempt to approach or approximate this ideal.

10 One technique known in the art is to partially remove a degenerated disk and to insert a bone graft into the void formed by the removed disk. Other techniques involve the use of an implant which, acting alone or in combination with bone fragments, replace the use of bone 15 grafts. An example of such implant is shown in U.S. Pat. No. 4,501,269 to Bagby dated February 26, 1985. In Bagby, a large, cylindrical basket is driven into a hole formed between bones which are to be joined. The basket is hollow and is filled with bone fragments which are produced during 20 a boring step. Bone-to-bone fusion is achieved through and about the basket. In Bagby, the hole for the Bagby is slightly smaller than the diameter of the basket. This structure results in the spreading of the opposing bone segments upon insertion of the basket. This results in 25 taughtness, which provides initial stabilization. Eventual

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

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

### III.

#### SUMMARY OF THE INVENTION

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

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

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

5 Other aspects of this invention are as follows:

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

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

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

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

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

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

opening extending generally radially to said axis; and

5           said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between  
10           said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae.

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

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

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

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

30           said body having means defining a chamber disposed within said body;

35           said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis, said opening comprising a hole having a

hole axis extending generally perpendicular to a  
 plane defined by said opening at an exterior  
 surface of said shell, said hole formed through  
 said shell with said hole disposed with said  
 5 hole axis offset from said longitudinal axis;  
 and

said body having a transverse dimension  
 generally transverse to said longitudinal axis  
 and dimensioned so as to be greater than said  
 10 bore for said body to urge said opposing  
 vertebrae apart and to stretch said annulus upon  
 insertion of said body into said bore between  
 said vertebrae with a portion of said body  
 opposing a first of said opposing vertebrae and  
 15 with an opposite side of said body opposing a  
 second of said opposing vertebrae.

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

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

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

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

35 said body having means defining a chamber  
 disposed within said body and said body is  
 provided with a rib disposed within said

cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib including at least a rigid extension extending between and connecting diametrically opposed sides of said body;

said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae;

said rib is disposed between said leading and trailing ends, said implant further including a first flange at said leading end and a second flange at said trailing end, said first and second flanges extending radially into said chamber.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective exploded of view of an implant according to a preferred embodiment of the present invention;

Fig. 2 is a side elevation view of a body portion of the implant of Fig. 1;

Fig. 2A is a side elevation view of an alternative embodiment of a body portion of an implant according to the present invention;

Fig. 3 is an end view taken in elevation of the trailing end of the body portion of Fig. 2 taken along line 3-3 of Fig. 2;

5 Fig. 3A is the same view as Fig. 3 showing an alternative embodiment;

Fig. 4 is a view taken along lines 4-4 of Fig. 2;

Fig. 4a is the same view as Fig. 4 showing an alternative embodiment;

10 Fig. 5 is a view taken along line 5-5 of Fig. 2;

Fig. 6 is a view taken along lines 6-6 of Fig. 3;



Fig. 7 is an enlarged view, taken in section, of the threads of the body of Fig. 2 adjacent the trailing end;

Fig. 7A is a view, taken in section, of the threads of the body portion of Fig. 2 adjacent a leading end of the body;

Fig. 8 is a side sectional view of a leading end cap of the implant of Fig. 1;

Fig. 9 is an inside end elevation view of the end cap of Fig. 8 taken along line 9-9 of Fig. 8;

Fig. 10 is a side sectional view of a trailing end cap of the implant of Fig. 1;

Fig. 11 is an end elevation view of the end cap of Fig. 10 taken along line 11-11 of Fig. 10;

Fig. 12 is a top plan view showing insertion of a single implant of Fig. 1 into an intervertebral space;

Fig. 12A is a view taken along lines 12A-12A of Fig. 12;

Fig. 13 is a top plan view showing an alternative embodiment of the present invention in place in a vertebra;

Fig. 13A is a view taken along lines 13A-13A of Fig. 13;

Fig. 14 is a perspective view of an alternative embodiment of the present invention showing an implant body leading end, side and top;

Fig. 15 is a perspective view of the body of Fig. 14 showing a trailing end, side and top;

Fig. 16 is a top plan view of the embodiment of Figs. 14 and 15;

5 Fig. 17 is a side sectional view taken along lines 17-17 of Fig. 16;

Fig. 18 is a side elevation view of a trailing end cap for use with the embodiment of Figs. 14 and 15;

10 Fig. 19 is an end view taken in elevation of the end cap of Fig. 18;

Fig. 20 is an elevation view a trailing end of the embodiment of Figs. 14 and 15;

Fig. 21 is an elevation view of a leading end of the body of the embodiment of Figs. 14 and 15;

15 Fig. 22 is a side elevation view of the body portion of Figs. 14 and 15;

Fig. 23 is a top plan view of an assembled implant including body portion and end cap shown in place in a vertebra body;

20 Fig. 24 is an anterior elevation view showing a bore drilling sequence prior to insertion of the implant as shown in Fig. 23;

Fig. 25 is a view taken along lines 25-25 of Fig. 23;

25

## V.

DESCRIPTION OF THE PREFERRED EMBODIMENT5       A.   General.

Reference is now directed to Figs. 1 and 12. Fig. 1 is an exploded perspective view of an implant according to a preferred embodiment of the present invention. The implant is shown generally at 10. Fig. 12 shows the implant 10 inserted within a bore 102 formed in a human vertebra body 100.

For ease of description, the implant 10 (as well as alternative embodiments of the invention) will be described for use in a human spine. Further, dimensions, when given, will be preferred dimensions for use in a specific spinal location of a particular class of humans -- notably, the L-5 vertebra of a typical adult male. It will be appreciated that the present invention is intended for use in a wide variety of vertebra sizes and a wide variety of animal species. The dimensions of the implant 10 (as well as the dimensions of the alternative embodiments) will vary necessarily with the size of the vertebra in which the implant 10 is to be used. However, making variations to the dimensions and sizes in order to accommodate differing sizes of vertebrae will be well within the skill of the art.

30

B. First Preferred Embodiment.

With reference now directed to Figs. 1-12, a first preferred embodiment of the present invention will now be described. Identical elements are numbered identically throughout.

The implant 10 includes a body 12 (shown separately in Figs. 2, 3-6) having a leading end 14 and a trailing end 16 which are spaced apart along a longitudinal axis X-X of the body 12. The implant also includes a leading end cap 18 and a trailing end cap 20 (shown separately in Figs. 8-9 and Figs. 10-11, respectively).

Body 12 is integrally constructed from a rigid, biocompatible material. While any rigid, biocompatible material (such as a ceramic) could be used, body 12 is preferably formed from titanium and/or its alloys. Titanium and/or its alloys is preferred since it is noncorrosive and fatigue resistant. Also, titanium is widely used in prosthetic devices and the material has a proven record of satisfactory performance.

With best reference to Figs. 2-7 and 7A, the body 12 includes a hollow cylindrical shell 22 of predetermined diameter  $D_1$  (see Fig. 3). For reasons that will be later described  $D_1$  is selected to be about .5 inches.

The shell 22 surrounds and defines an interior chamber 24. Chamber 24 has a diameter  $D_2$  of preferably about .384 inches.

Threads 26 and 28 are formed on the exterior surface of shell 22 spirally wound around shell 22 and integral therewith. While double threading is shown, single threading or multiple threading in excess of double  
5 threading could be applied. Threads 26, 28 are disposed and selected for the threads 26, 28 to engage the bone material of opposing vertebrae and draw the body 12 in the direction of axis X-X upon rotation of the body 12 about axis X-X.

10 In a preferred embodiment, body 12 is self-tapping. Mainly, the threading 26, 28 (see Fig. 2) adjacent leading end 14 is tapered as shown by angle  $A_1$  (which is preferably about  $15^\circ$ , see Fig. 2). Away from the tapered end 14, and adjacent the trailing end 16, the  
15 threads 26, 28 present flat, annular surfaces 30 which are in alignment and parallel to shell 22. Accordingly, the thread profile presents a generally bullet-shaped profile which is cylindrical along the majority of the body 12 and tapers inwardly toward axis X-X at the leading end 14.

20 The tapered portion of body 12 preferably has a length  $L_1$  of about .198 inches. The overall length of body 12,  $L_2$ , is preferably about .740 inches. (See Fig. 2).

To assist in the self-tapping, the threads 26, 28 experience a change in profile from the leading end 14 to  
25 the trailing end 16. At the leading end 14, the threads are sharp, as shown in Fig. 7A. When the taper portion of

body 12 is passed, the threads 26, 28 assume a profile which is generally rectangular as shown in Fig. 7. For ease of discussion, the sharp portions of threads 26, 28 are numbered 26a, 28a in the drawings.

5           The changing thread profiles are selected to assist in advancing the implant 10 into an intervertebral space and to hold the implant 10 securely in place when fully advanced. The sharp portion of threads 26, 28 (thread portions 26a, 28a shown in Fig. 7A) cut bone better  
10 and assist in advancing the implant 10. The generally rectangular thread profile (Fig. 7) has greater cross-sectional area and better opposes bone surfaces to hold the implant 10 in place.

          Preferred dimensions of the threading 26, 28 are  
15 shown in Figs. 7 and 7A with a pitch,  $P$ , (distance between opposing threads) equaling about .10 inch for both the rectangular and sharp threading of Figs. 7 and 7A. The bevel  $B_1$ , of the sharp threading (Fig. 7A) is preferably about  $57^\circ$ . The bevel,  $B_2$ , of the rectangular thread  
20 portion (Fig. 7) is preferably about  $5^\circ$ . The height,  $H$ , of the rectangular thread is about .10 inches. This, together with the diameter  $D_1$  (see Fig. 3) of the shell 22 results in overall diameter of the body 12 being about .6 inches. It will be appreciated that these dimensions as well as  
25 remaining dimensions given throughout this application are preferred dimensions and may be varied while retaining the

structure and function of the present invention. The scope of the claims of the present invention is not intended to be limited by dimensions which are set forth only to illustrate a preferred embodiment.

5           The body 12 has a plurality of holes 32 formed radially through the shell 22 and threads 26, 28. The holes 32 provide communication between interior chamber 24 and an exterior of the body 12.

10           The holes 32 are identical and each is preferably about .125 inches in diameter. Shown best in Fig. 4, each of the holes 32 includes a countersunk portion 34 at the radially outer surface of threads 26, 28. Preferably, the countersunk portion 34 has a diameter of about .155 inches.

15           The countersunk portion 34 creates cutting a beveled edge 33 on the rectangular threads 26, 28 in the location of the holes 32. This cutting edge 33 is best shown in Fig. 6. The cutting edges 33 chip away bone as the body 12 is rotated. The bone chips will migrate through the holes 32 into chamber 24. As will be  
20 described, it is anticipated that this chipping action will enhance the bone-to-bone fusion sought with the present invention.

25           In the region of the self-tapping sharp threads 26a, 28a (Fig. 7A), the threads 26a, 28a are shown self-tapping in Fig. 5 to present self-tapping cutting edges 36

set at a  $90^\circ$  cutting angle  $A_3$ . The cutting edges 36 are shown spaced apart by an angle  $A_4$  of about  $120^\circ$ .

In the preferred embodiment as shown, holes 32 extend through the threads 26 and 28. An alternative embodiment would have the threads 26 and 28 spaced apart a distance greater than that shown in the present drawings, with the holes 32 extending through the shell 22 and not passing through threads 26 and 28. Such a design presents enhanced structural integrity since the more massive threads 26 and 28 are not being broken. However, such an alternative design forgoes the anticipated benefits which may be attributed to the chipping action of the cutting edges 33 of the threads adjacent holes 32.

The number of holes 32 in the body 12 as shown is twenty. This number may vary. The number is selected to be as many and as large as possible (to enhance bone fusion), while not compromising the strength of the body 12.

As previously indicated, the body 12 extends from a leading end 14 to a trailing end 16. Leading end 14 has a circular axial opening 40 formed therethrough in communication with chamber 24. Disposed inwardly from leading end 14 is an annular groove 42 (see Fig. 6) provided to facilitate attachment of leading end cap 18 as will be described.



Trailing end 16 has an inwardly projecting flange 44. Opposing surfaces of flange 44 define a centrally located hexagon-shaped axial opening 46.

When the implant 10 is in place in an intervertebral space, circular axial opening 40 and hexagon axial opening 46 are covered by caps 18 and 20. Shown best in Figs. 8 and 9, the leading end cap 18 includes a cylindrical hub portion 50 and an annular flange 52 extending from hub portion 50. Also extending from hub portion 50 on the side opposite flange 52 is a tapered cap portion 54 which extends from a large diameter 55 and tapers inwardly to a smaller diameter terminal end 56. An angle of taper  $A_2$  (Fig. 8) is preferably about  $15^\circ$  to correspond with the angle of taper  $A_1$  (Fig. 2) of body 12. The large diameter 55 is preferably selected to equal the diameter of body 12 at leading end 14. Flange 52 is selected to be snap received into annular groove 42. So received, cap 18 is permanently attached to the leading end 14 covering axial opening 40.

Trailing end cover 20 (Figs. 10 and 11) includes an arcuate cap 58 sized to cover end 16 with a flat surface portion 59 of cap 20 abutting trailing end 16. Six flexible retaining clips 60 are provided centrally extending from surface 59. Clips 60 are sized to be snap received within hexagon-shaped opening 46. Accordingly, the cooperation of surface 59 and the barbed portion 61 of

clips 60 capture flange 44 to thereby hold trailing end cap 20 securely against trailing end 16. For reasons that will be described, each of caps 18 and 20 are preferably formed from high-density polyethylene.

5

C. Method of Use.

Referring to Figs. 12 and 12A, the method of use of the implant 10 will now be described. In use of the implant 10, a surgeon forms a bore 102 through the intervertebral space in a disk 114 separating two opposing vertebral bodies 100 and 100a. The bore 102 is sized to be as large as possible to remove disk material 114 and to at least partially cut into opposing surfaces of the bone of vertebral bodies 100, 100a. It will be appreciated that it is well within the skill of the art to form bores such as bore 102.

Fig. 12 and 12A show a bore 102 formed through a posterior approach through a spine. In a posterior approach, a surgeon approaches the vertebra through the back of the patient. Preferably, the axis of the bore 102 is formed an angle with the anterior-posterior axis, A-P, of the vertebra body 100, 100a. As shown in the preferred surgical approach, the angle  $A_6$  between the A-P axis and the bore axis is about  $10^\circ$ .

It is recognized that there are limits on the maximum size of a bore 102 that can directly drilled in a vertebra body via a posterior approach. Limitations on the

diameter of the bore 102 include location of important nerves and blood vessels which can be damaged by excessively large bore drilling operations. The maximum size bore that can be cut will depend on the particular  
5 location of the spine, the species of the animal, age and sex. A common safe maximum for an adult male spine in the L-5 area would be a bore diameter of about .5 inches.

For reasons that will be described, it is preferred that the bore diameter will be smaller than the  
10 diameter,  $D_1$ , of body shell 22. Specifically, it is anticipated that a bore diameter of about 3 millimeters less than diameter  $D_1$  will be preferred. With such structure, the body 12 spreads apart opposing vertebrae upon insertion. By virtue of the spreading effect, the  
15 disk annulus becomes taught, thereby providing for the initial stabilization between the opposing vertebrae.

(Those skilled in the art will recognize the annulus as being the fibrous outer circumferential portion of the disk). In the drawings, the implant is shown spreading  
20 apart the vertebrae and stretching the annulus. Eventual fusion of the opposing vertebrae results from bone growth through body 12, as will be described.

The implant 10 is partially assembled with leading end cap 18 snapped onto leading end 14. With trailing end  
25 cap 20 removed, the implant 10 is partially placed within bore 102 with the tapered leading end 14 received within

bore 102. An advancing tool (the tip of which is shown in Fig. 1) is provided having a hexagon-shaped tip 200 complementarily sized to be received within opening 46. The tip 200 is inserted by the surgeon into opening 46.

5 The surgeon then turns the tool and, hence, the body 12, in a clockwise direction (from the perspective of the surgeon). The turning action of the body 12 causes the sharp threads 26a, 28a (Fig. 7A) to cut into the bone of the opposing vertebrae bodies 100, 100a to advance the body

10 12 into bore 102 to the fully inserted position shown in Fig. 12. The rectangular threads 26, 28 (Fig. 7) retain the body 12 in the desired axial position relative to bore 102. Leading end cap 18 covering axial opening 40 prevents disk material from migrating through axial opening 40 into

15 chamber 24 during insertion of implant 10 as well as during the patient's recovery phase.

With the implant body 12 fully inserted as shown in Fig. 12, the trailing end cap 18 has not yet been installed. Accordingly, axial opening 46 exposes chamber

20 24 to the surgeon once the tool tip 200 is removed. With opening 46 still exposing chamber 24, a surgeon can impact a graft medium 202 (preferably bone chips) into chamber 24 (see Fig. 12A). Any impacted bone chips will supplement bone chips that may migrate through holes 32 as a result of

25 the cutting action of cutting edges 33 against the vertebra bone surfaces.

With the graft medium fully applied to chamber 24, the surgeon snaps cap 20 into hole 46 to cover the trailing end 16. Figs. 12 and 12A show such a fully assembled and inserted implant 10. The surgeon can then close the  
5 patient through any suitable technique. With the completed implant 10 installed in the manner indicated, the bone graft 202 within chamber 24 and openings 32 fuses together with the bone of the opposing vertebrae 100, 100a to thereby join the vertebrae 100, 100a together.

10 As previously indicated, end caps 18, 20 are preferably formed from high density polyethylene. Such material is nonabrasive and inert, and has a slippery touch. This latter feature is particularly valuable for trailing end cap 20, which may oppose the epidural tissue.  
15 To avoid damage or irritation of the dura, the slippery, inert, nonabrasive polyurethane trailing end cap 20 is provided. Trailing end cap 20 is intended to cover axial opening 46 and retain the bone chips within chamber 24 while providing a nonabrasive and nonirritating surface  
20 opposing the epidura. Also, like leading end cap 18, trailing end cap 20 prevents disk material from entering chamber 24.

In a preferred embodiment, the end caps 18, 20 formed of polyethylene which is radiolucent. Radiolucent  
25 material permits X-rays to pass. Accordingly, with radiolucent end caps 18, 20, an attending physician can

study the growth of bone within chamber 24 without the need for exploratory surgery.

It will be appreciated that radiolucent end cap 18, 20, while desirable in a preferred embodiment, are not  
5 necessary to the practice of the full scope of the present invention. For example, the leading end 14 could taper completely as an integral portion of the solid body 12 as shown in Fig. 2A. In such an embodiment, the body 12' assumes a more complete hollow bullet-shaped profile where  
10 the leading edge 14' includes a sharp point 15' to better assist the insertion and advancement of the body 12' into the intervertebral space.

In Figs. 12 and 12A, the implant 10 is shown installed on the left side (from the patient's perspective)  
15 of the anterior-posterior axis, A-P. For a posterior approach as shown in Fig. 12, it is anticipated that two prostheses 10 will be used, with a second implant disposed on the right side of the anterior-posterior axis, A-P, and installed in a manner identical to that of implant 10 on  
20 the left side. However, for ease of illustration, the right side implant is not shown installed. When installed, such prostheses would be positioned with the right and left prostheses being symmetrically disposed about axis A-P.

25 D. Alternative Design

Figs. 3A and 4A show an alternative. The implant 10''' of the embodiment of Figs. 3A and 4A is identical to

that discussed above except as to the placement of holes 32'''. For ease of understanding the comparison between implant 10''' and implant 10, the reader will note that Figs. 3A and 4A are the same view of implant 10''' as Figs. 3 and 4 are of implant 10.

Unlike implant 10, implant 10''' does not have holes 32''' circumferentially spaced about body 12'''. Instead, as best shown in Fig. 4A, holes 32''' are placed on diametrically opposed sides of body 12'''.

Upon insertion of the implant 10''', the surgeon positions the implant 10''' with holes 32''' opposing the bone material of the vertebra bodies 100, 100a. As a result, no disc material 114 may enter into chamber 24'''. This prevents possible interference of disc material with the bone fusion process.

To assist a surgeon, indicia markings 15''' are placed on flange 44'''. The markings 15''' are aligned with the axis of holes 32'''. The surgeon turns body 12''' into position until markings 15''' are aligned pointing to bodies 100, 100a. So positioned, the surgeon knows the holes 32''' are opposing bone and not disc material.

E. Alternative Method and Apparatus for Anterior Approach.

The foregoing description and illustration describe the insertion of an implant 10 through a posterior approach. Figs. 13 and 13A show an alternative embodiment

of the invention for use in an anterior approach where a bore 102' is formed from the front of the spine and axially aligned with the anterior-posterior axis, A-P. Since the bore 102' is formed from an anterior approach, the size  
5 restrictions of a posteriorly formed bore (namely, locations of nerves and blood vessels) are largely avoided. As a result, a large diameter bore 102' can be formed. A comparison of Figs. 12A and 13A show the relative increase of bore diameter. This increase results in an enhanced  
10 surface area of exposed vertebra bone and an increased amount of graft material in an implant.

The implant 10'' shown in Figs. 13 and 13A may be identical in proportional dimensions to that of implant 10, only enlarged to be received within the larger bore 102'.  
15 However, the implant 10'' shown in Figs. 13 and 13A differs from that shown in Figs. 12 and 12A. Namely, the implant 10'' shown in Figs. 13 and 13A does not include a tapered leading end. Instead, the entire implant body 12" is cylindrical-shaped to illustrate that, while a tapered  
20 leading end is preferred, it is not necessary to practice the teachings of the present invention.

25 F. Further Alternative Embodiments.

Figs. 15-25 illustrate yet a further embodiment of an implant for use in spinal stabilization. As shown in those figures, the implant 120 (shown assembled in Figs. 23 and 25) includes a body portion 122 (shown in perspective



in Figs. 14 and 15) which is generally oval-shaped in cross section and formed from rigid, biocompatible material (preferably titanium). The body 122 includes generally flat side walls 124, 126 joined by upper and lower semi-cylindrical arcuate ribs 128. Arcuate ribs 128 are spaced apart to define a plurality of upper and lower semi-circular arcuate openings 130 which provide communication between a hollow interior 132 of body 122 and an exterior. The ribs 128 define upper and lower walls of the implant 120 with the walls having openings 130 therethrough.

Body 122 extends from a leading or anterior end 133, and a trailing or posterior end 134. Anterior end 133 has a centrally positioned cover plate 136 which partially covers end 132 but leaves upper and lower semi-circular axial openings 138 exposing interior 132 through end 133.

Shown best in Fig. 16, body 122 is tapered at the leading end 133, with the side walls 124, 126 tapering inwardly at an angle  $A_7$ , of preferably  $10^\circ$  each. Also, the upper and lower planar of the ribs 128 are tapered inwardly as best shown in Fig. 22 at a preferred taper angles,  $A_8$ , of about  $3^\circ$ . The edges defined by the juncture of walls 124, 126, ribs 128 and end 133 are rounded to facilitate insertion of implant 120 as will be described.

The posterior end 134 (shown in Fig. 14) has an axial opening 142 which communicates with the body interior 132. A pair of opposing retaining ribs 146 are shown

partially extending from the side walls 124, 126 into opening 142. A posterior end cap 147 is provided with an arcuate, smooth cap 149 sized to cover end 134 and opening 142. End cap 147 has retaining clips 148 selected to snap  
5 behind ribs 146 to thereby attach cap 147 against end 144.

10 G. Method of Use of Alternative Embodiment.

implant 120 is intended for use in a posterior approach with two prostheses 120 being inserted on opposite sides of the anterior-posterior axis of a vertebra. For  
15 ease of illustration, only one prosthetic device is shown inserted in Figs. 23-25.

Fig. 24 shows a method for drilling the bore 154 to receive the oval-shaped implant 120. As shown in Fig. 24, three circular bores 150, 151, 152 are drilled in  
20 vertical alignment in opposing vertebra bodies 100', 100a' and separating disk 114'. The three bores 150, 151, 152 cooperate to form a generally oval-shaped bore 154.

Bore 154 is sized to be slightly smaller than the dimensions of body 122. The surgeon inserts the tapered  
25 leading end 133 into bore 154. With any suitable hammering mechanism, the surgeon then impacts on the uncapped posterior end 134 to drive the implant 120 into the bore 154 as shown in Figs. 23 and 25. The tapers A, and A<sub>2</sub>

(Figs. 16 and 22) and the rounded corners on leading end 133 assist in the insertion.

With the implant fully inserted, the surgeon fills the chamber 132 with graft medium 155 (again, preferably 5 bone chips), the surgeon then installs the polyethylene posterior cap 147 to cover posterior end 134 and provide a non-abrasive surface opposing the epidura.

The implant 120 of Figs. 14-25 greatly enhances the depth of insertion into opposing vertebrae 100', 100a' 10 through a posterior approach. Namely, an oval bore 154 can be formed having a height,  $H_2$  (see Fig. 24) equal to about three times the diameter of bores 102 described in previous embodiments. This added depth directly into the bone 15 material of the vertebra body 100', 100a' increases the surface area available for grafting to thereby enhance the probability of a successful graft. Also, the increased depth into each of the vertebra bodies provides increased surface to prevent relative rotation of the opposing vertebrae 100', 100a' about the axis of the spine.

20 The side walls 124, 126 of the implant do not have openings and, therefore prevent disk material from penetrating into the chamber and thereby interfering with the bone fusion. The implant 120 is sized for the upper and lower openings 133 to be located completely above and 25 below, respectively, the disk layer 114'. Also, plate 136 on end 133 is sized to be about the thickness of layer 114'

(or slightly greater) to prevent disk material from entering the interior 132 of implant 120. Openings 138 are positioned to oppose only bone of vertebra 100', 100a'.

From the foregoing detailed description of the present invention, it has been shown how the invention has been attained in a preferred embodiment, including alternative embodiments. However, modifications and equivalents of these concepts are intended to be included within the scope of this invention.

10

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:
  - a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;
  - said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;
  - said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;
  - said body having means defining a chamber disposed within said body and said body is provided with a rib disposed within said cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib dividing said chamber into a leading end chamber and a trailing end chamber, and said rib including at least a rigid extension extending between and connecting diametrically opposed sides of said body;
  - said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis; and
  - said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae.

2. An implant according to Claim 1 wherein said implant includes means spaced away from said trailing end for receiving an advancing tool for advancing said implant into said bore.
  
3. An implant according to Claim 1 wherein said rib has a rib opening formed therein, said rib opening sized to receive a distal end of an insertion tool for insertion of said distal end into said rib opening and for turning said implant upon turning of said tool.
  
4. An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:
  - a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;
  - said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;
  - said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;
  - said body having means defining a chamber disposed within said body;
  - said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis, said opening comprising a hole having a hole axis extending generally perpendicular to a plane defined by said opening at an exterior surface of said shell, said hole formed through said shell with said hole disposed with said hole axis offset from said longitudinal axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae.

5. An implant according to Claim 4 wherein  
said body has a plurality of walls defining a plurality of holes each having a hole axis extending generally parallel to said walls and perpendicular to a plane defined by said holes at an exterior surface of said body, said holes formed through said body in communication with said chamber, said holes disposed with said hole axes not intersecting said longitudinal axis;  
said holes have cutting edges positioned to oppose said vertebrae to chip bone from said vertebrae into said holes.
  
6. An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:  
a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;  
said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;  
said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;  
said body having means defining a chamber disposed within said body and said body is provided with a rib

disposed within said cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib including at least a rigid extension extending between and connecting diametrically opposed sides of said body;

said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae;

said rib is disposed between said leading and trailing ends, said implant further including a first flange at said leading end and a second flange at said trailing end, said first and second flanges extending radially into said chamber.



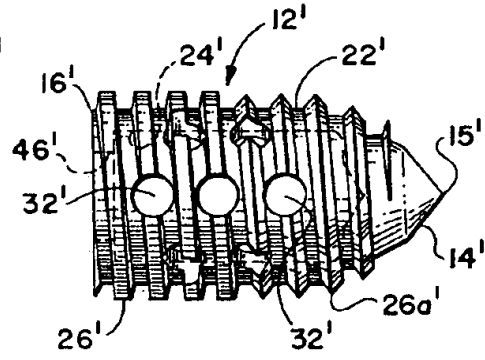
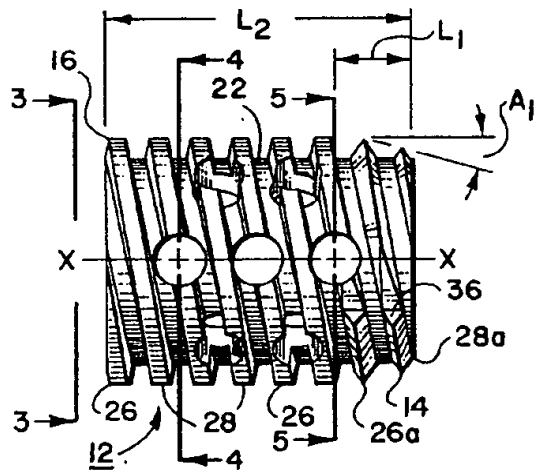
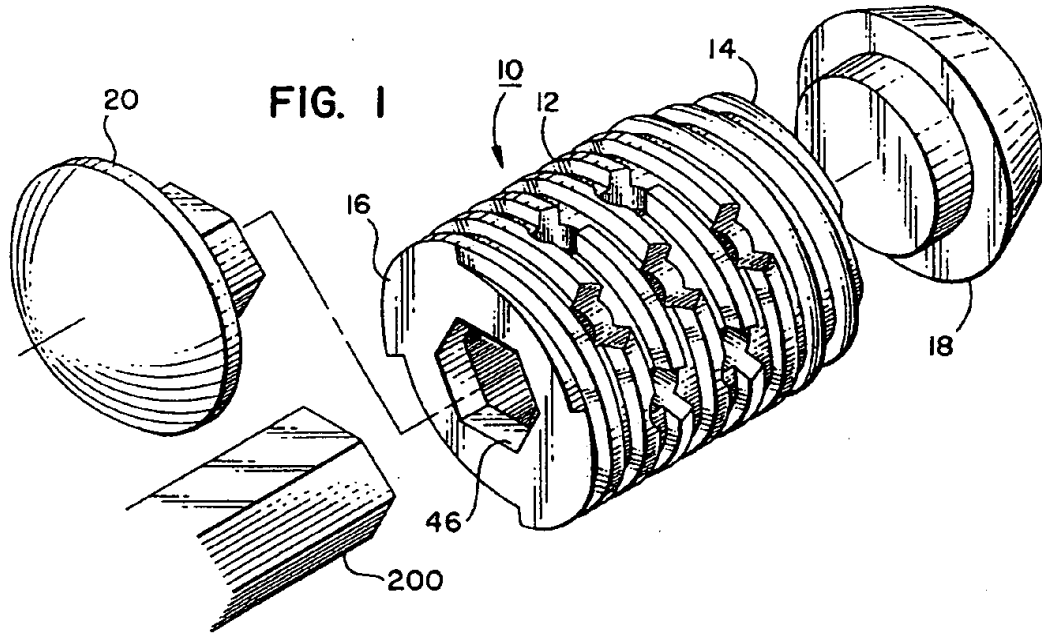


FIG. 2A

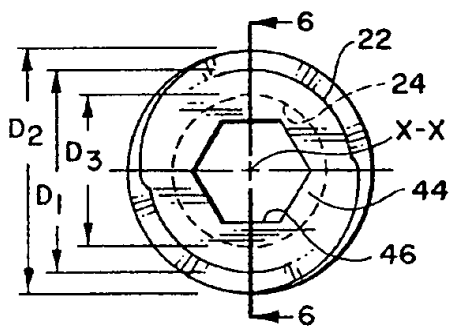


FIG. 3

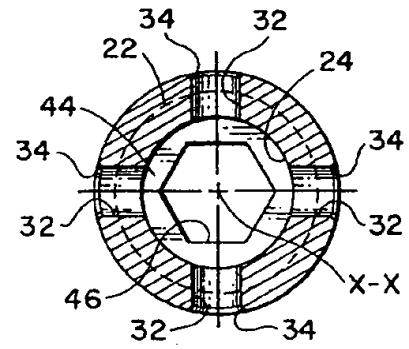


FIG. 4

*Sim. M. Bureau*

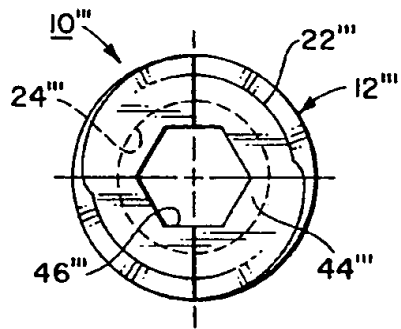


FIG. 3A

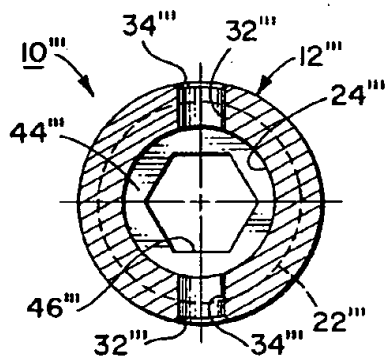


FIG. 4A

*Signed: M. Bunnay*

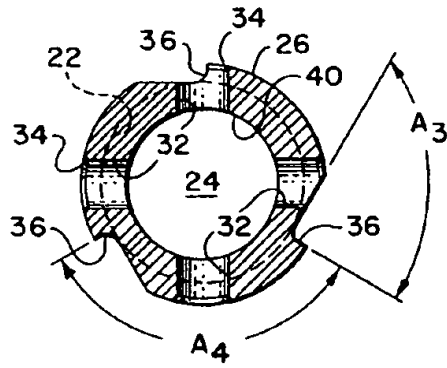


FIG. 5

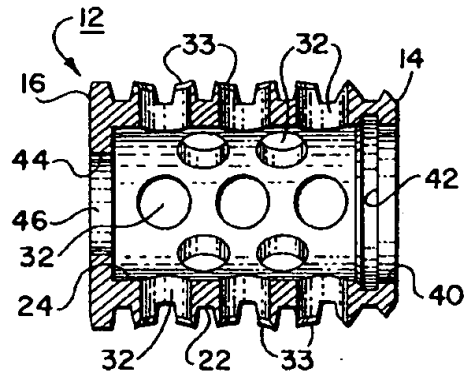


FIG. 6

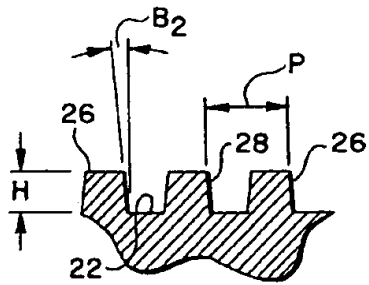


FIG. 7

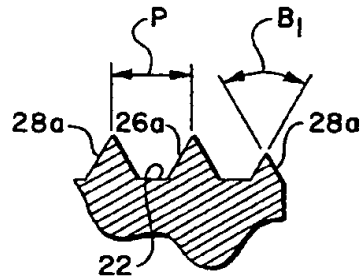


FIG. 7A

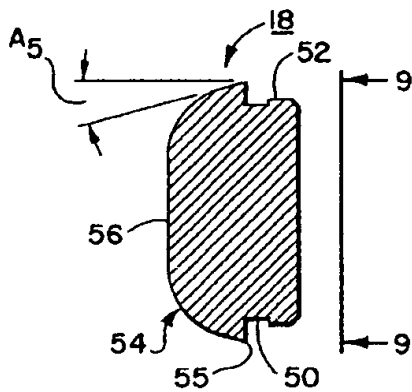


FIG. 8

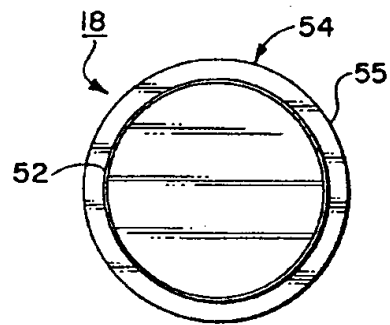


FIG. 9

*Sim. M. Bureau*

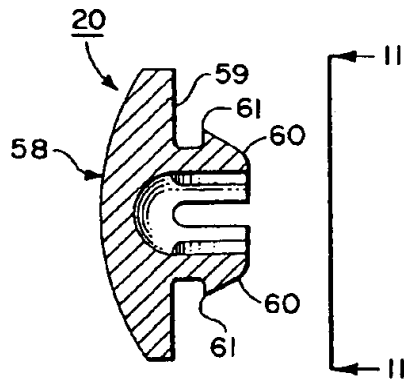


FIG. 10

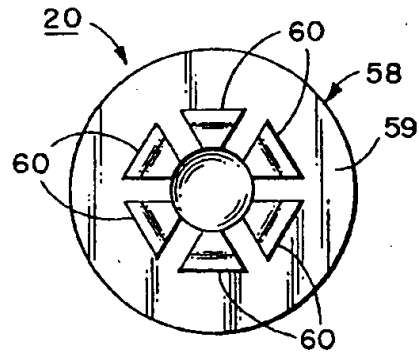


FIG. 11

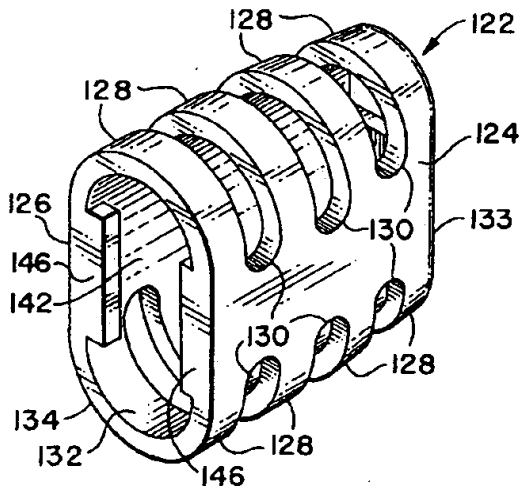


FIG. 14

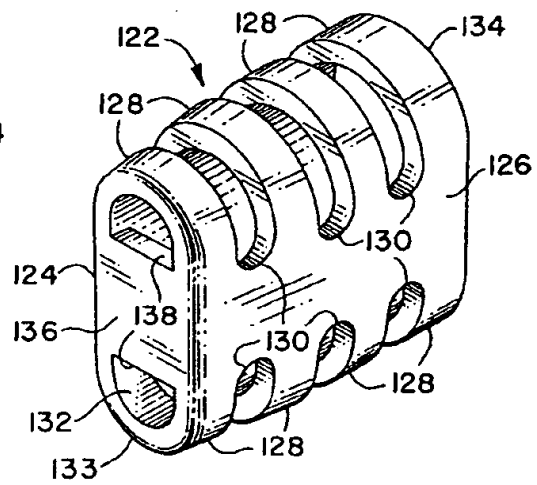


FIG. 15

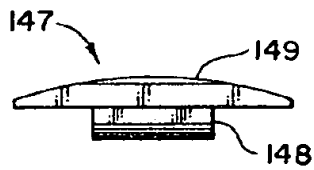


FIG. 18

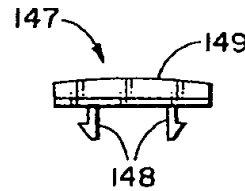


FIG. 19

*Sim. J. G. Bennett*

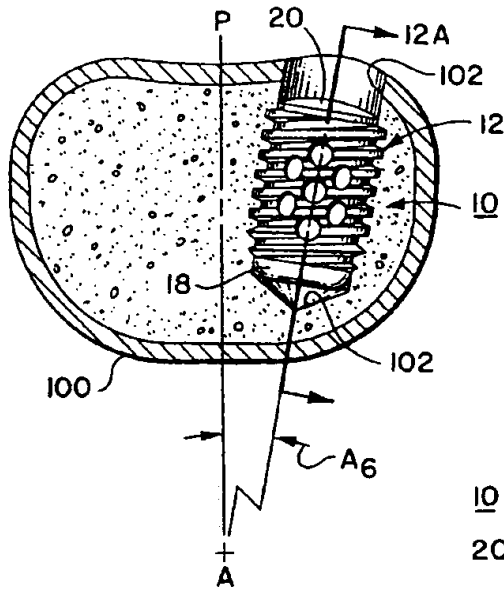


FIG. 12

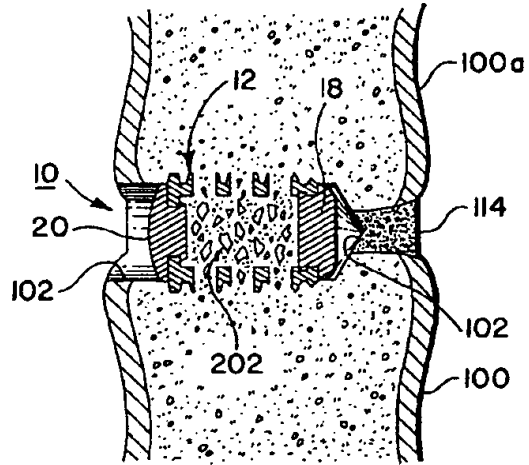


FIG. 12A

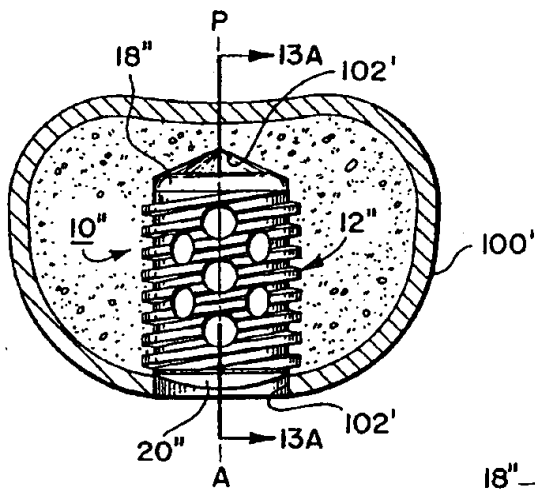


FIG. 13

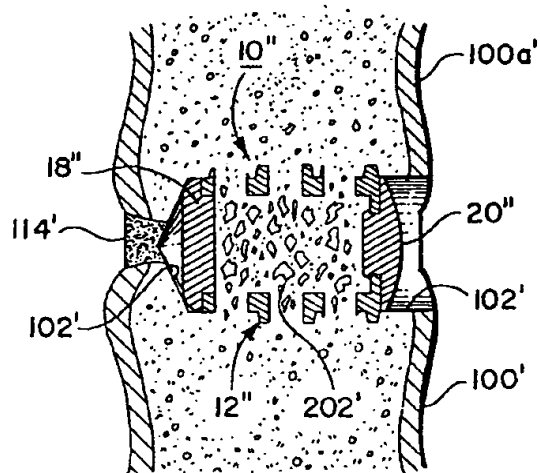


FIG. 13A

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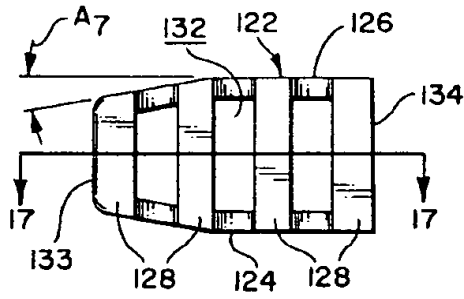


FIG. 16

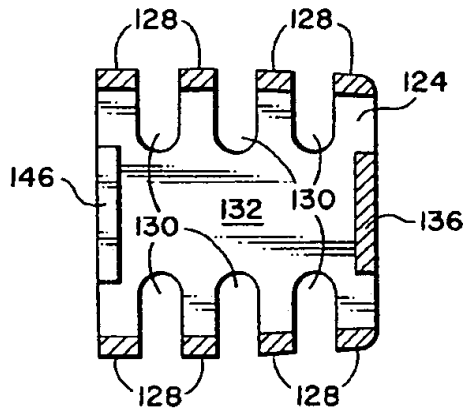


FIG. 17

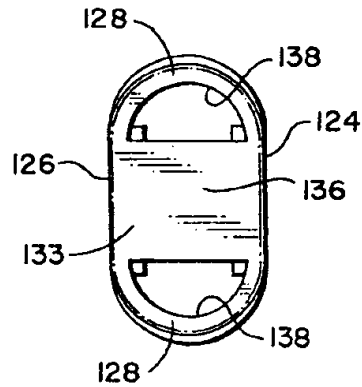


FIG. 21

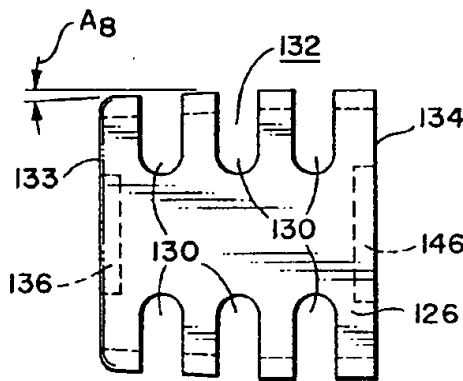


FIG. 22

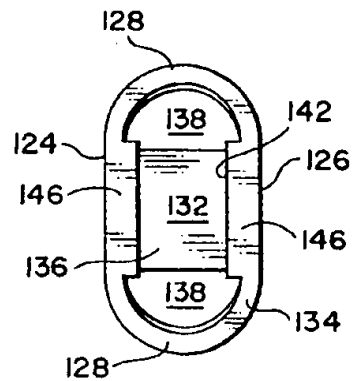


FIG. 20

*Sim. M. Bunnell*

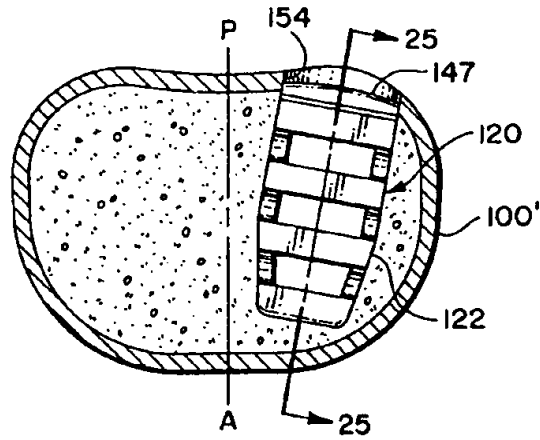


FIG. 23

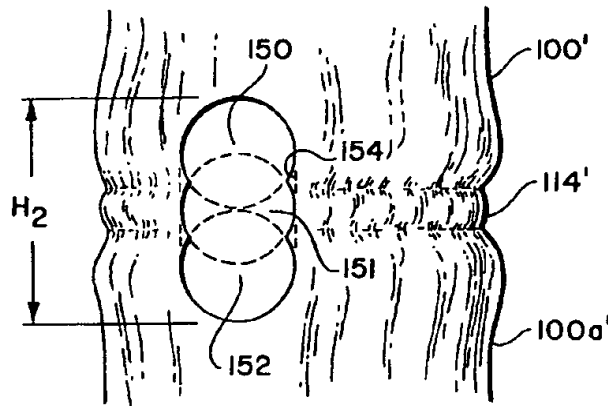


FIG. 24

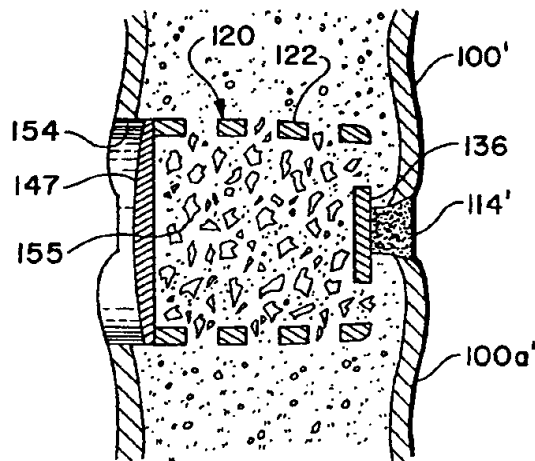


FIG. 25

*Sim. M. Suresh*