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(71) Applicant: SURGICAL DYNAMICS, INC. [US/US]; 111 Glover Avenue, Norwalk, CT 06856 (US).

(72) Inventors: WINSLOW, Charles, J.; 27 Hilton Court, Walnut Creek, CA 94520 (US). MITCHELL, Steven, T.; 776 Duke Circle, Pleasant Hill, CA 94523 (US).

(74) Agent: GERSHON, Neil, D.; United States Surgical Corporation, 150 Glover Avenue, Norwalk, CT 06856 (US).

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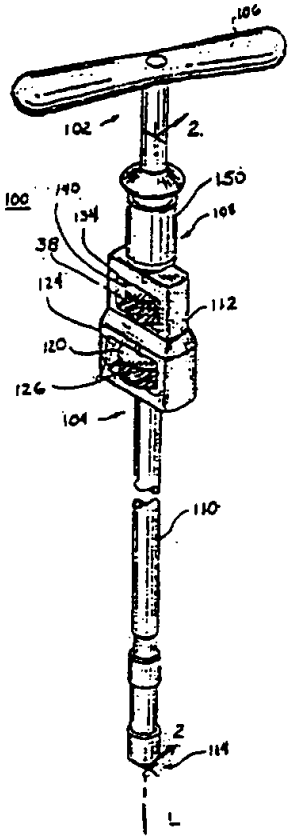
(57) Abstract

Apparatus for, and methods of, inserting implants (200) are disclosed wherein the apparatus includes a handle portion (112) and a body portion attached to the handle portion (112). The body portion includes an outer tubular member (110), an inner tubular member (118) and an inner shaft (132). The outer tubular member (11) is fixed to the handle portion (112) for rotation therewith and with implant engaging structure (116) on its distal end. The inner tubular member (118) is disposed within the outer tubular member (110) and can move longitudinally and rotationally therein. Second implant engaging structure (130) is positioned at the distal end of the inner tubular member (118). The inner shaft (132) rotates relative the inner and outer tubular members and has a third implant engaging structure (144). At least one of the engaging structures attaches to a removable cap (206) of the implant.



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APPARATUS AND METHOD FOR IMPLANT INSERTION

BACKGROUND

This application is a continuation-in-part of U.S. application Serial No. 08/354,364, filed on December 12, 1994, which is a continuation-in-part of U.S. application Serial No. 08/306,879, filed on September 15, 1994. The contents of these applications are incorporated herein by reference.

1. Technical Field

This disclosure relates generally to apparatus and methods for implant insertion. More particularly, to apparatus and methods for insertion of implants to facilitate fusion of adjacent bony structure.

2. Background of the Related Art

A large number of orthopedic procedures involve the insertion of either natural or prosthetic implants into bone or associated tissues. These procedures include, for example, ligament repair, joint repair or replacement, non-union fractures, facial reconstruction, spinal stabilization and spinal fusion. In a typical procedure, an insert, dowel or screw is inserted into a prepared bore formed in the bone or tissues to facilitate repair and healing. See, for example, U.S. Patent Nos.: 5,470,334 to Ross et al.; 5,454,811 to Huebner; 5,480,403 to Lee et al.; 5,40,805 to Warren; 5,358,511 to Gattuma et al.; and 4,877,020 to Vich.

Some implants are particularly configured with cavities and bores to facilitate bony ingrowth and enhance anchoring of the implant at the insertion site. See, for example, U.S. Patent Nos.: 4,328,593 to Sutter et al.; 4,936,851 to Fox et al.; and 4,878,915 to Brantigan. Implants in the form of fusion cages having internal cavities to receive bone growth stimulation materials such as bone chips and fragments are disclosed, for example, in U.S. Patent Nos.: 4,501,269 to Bagby; 4,961,740 to Ray et al.;

5,015,247 to Michaelson; and 5,489,307 to Kuslich et al. These types of implants are particularly well suited for intervertebral spinal fusion procedures necessitated by injury, disease or some degenerative disorder of the spinal disc. Subsequently, there may be progressive degeneration leading to mechanical instability between adjacent vertebrae necessitating direct fusion of the vertebrae while maintaining a pre-defined intervertebral space. This fusion may be accomplished by the insertion of one or more of the specialized implants as discussed above and also discussed in commonly assigned U.S. Patent No. 5,026,373, incorporated herein by reference.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar spine. Fusions in the cervical area of the spine are primarily done using an anterior approach. Typically, an implant such as a plug, dowel, prosthesis or cage is inserted into a preformed cavity inside the interbody, interdiscal space. Since it is desirable in these procedures to promote a "bone to bone" bridge, connective tissue and at least a portion of the discal tissue is removed. Preferably, relatively deep cuts are made in the adjacent bones in order to penetrate into the softer, more vascularized cancellous region to facilitate bone growth across the implant.

When installing these specialized implants, an insertion tool is used to position the implant in the desired intervertebral location. See, for example, U.S. Patent Nos.: 3,848,601 to Ma et al.; 4,501,269 to Bagby; 4,877,020 to Vich; and 4,878,915 to Brantigan. Once in position, the insertion tool is removed and, where the implant structure permits, bone chips or other bone growth inducing substances are packed into the implant in vivo. Subsequently, an end cap or other sealing structure is positioned to close the implant. See, for example, commonly assigned U.S. Patent No. 4,961,740 to Ray et al. incorporated herein by reference.

Typical insertion tools use either a single implant engagement structure or, at most, two implant engagement structures to facilitate positioning of the implant. For example, in U.S. Patent No. 4,501,269 to Bagby, prongs are used to engage the implant. In U.S. Patent Nos. 4,878,915 to Brantigan and 5,015,247 to Michaelson, a threaded rod and slot are used to engage the implant. In U.S. Patent Nos.: 4,961,740 to Ray et al.;

5,489,308 and 5,489,307, both to Kuslich et al.; and 4,936,838 to Bagby, a single central shaft is used. In all of these insertion tools, no structure is provided to permit the insertion tool to attach to an outer peripheral portion of the implant, either in vitro or in vivo. Further, these tools do not provide structure which separately engages both the implant and the implant closure, e.g. an end cap.

Accordingly, a need exists for an insertion tool which is capable of either inserting an implant preloaded with bone chips, etc. Such in vitro packing facilitates the surgical procedure because it is often time consuming and relatively difficult, especially for example in cervical applications, to pack the cage in vivo. It would also be advantageous if such insertion tool could be additionally used to insert/position an empty implant for subsequent in vivo packing and closure.

SUMMARY

Apparatus for and methods of inserting implants are disclosed wherein the apparatus includes a handle portion and a body portion attached to the handle portion and defining a longitudinal axis. The body portion includes an outer tubular member fixed relative to the handle portion for rotation therewith about the longitudinal axis. The outer tubular member has first implant engaging structure adjacent a distal end. An inner tubular member is disposed at least partially within the outer tubular member and is mounted for longitudinal motion relative to the outer tubular member. Second implant engaging structure is positioned adjacent a distal end of the inner tubular member. The body portion further includes an inner shaft, coaxially mounted at least partially within the inner tubular member for independent rotation relative to the inner and outer tubular members, the inner shaft having third implant engaging structure adjacent a distal end.

In a method for inserting an implant having a hollow portion with a closed distal end and a removable cap, the first, second and third implant engaging structures are attached to the implant with at least one of the engaging structures attached to the removable cap and another of the engaging structure attached to the hollow portion. The implant is

preferably preloaded with bone chips and/or bone growth inducing substances prior to attachment. Thereafter, the preloaded implant is inserted into the desired surgical location.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the subject implant insertion apparatus are described below with reference to the drawings wherein:

FIG. 1 is a perspective view of an implant insertion apparatus constructed in accordance with a preferred embodiment of the subject disclosure:

FIG. 2 is a side view in cross-section of the implant insertion apparatus taken along line 2-2 of FIG. 1;

FIG. 2A is an enlarged side view in cross-section of the connection between the handle portion and the body portion of the implant insertion apparatus of FIG. 1;

FIG. 2B is an enlarged perspective view of the distal ends of the outer and inner tubular members of the implant insertion apparatus of FIG. 1;

FIG. 2C is an enlarged perspective view of an interchangeable distal end of the outer tubular member of the implant insertion apparatus of FIG. 1;

FIG. 3 is an enlarged perspective view of one type of implant configured for interbody fusion;

FIG. 4 is an enlarged proximal end view of the implant of FIG. 3 illustrating the structure of the removable end cap;

FIG. 5 is an enlarged end view in cross-section of the implant taken along line 5-5 of FIG. 3.

FIG. 6 is an enlarged perspective view of the implant of FIG. 3 with parts separated and loading of bone chips in process;

FIG. 6A is a side view in partial cross-section showing an end cap mounted to the inner tubular member and the inner shaft;

FIG. 7 is a perspective view of a preloaded implant with removable end cap in place;

FIG. 8A is an enlarged side view in partial cross-section illustrating the distal end of the implant insertion apparatus of FIG. 1 and the implant of FIG. 7;

FIG. 8B is an enlarged side view of the housing and rotation wheels of the body portion illustrating the relative position of the inner tubular member as shown in FIG. 8A;

FIG. 9A is an enlarged side view in partial cross-section illustrating the distal end of the implant insertion apparatus of FIG. 1 with the second and third implant engagement structure attached to the removable cap of the implant of FIG. 7;

FIG. 9B is an enlarged side view of the housing and rotation wheels of the body portion illustrating the relative position of the inner tubular member and the inner shaft as shown in FIG. 9A;

FIG. 10A is an enlarged side view in partial cross-section illustrating the distal end of the implant insertion apparatus of FIG. 1 with the first, second and third implant engagement structure attached to the implant of FIG. 7;

FIG. 10B is an enlarged side view of the housing and rotation wheels of the body portion illustrating the relative position of the inner shaft, the inner tubular member and the outer tubular member as shown in FIG. 10A;

FIG. 11 is a side view illustrating the insertion of the implant of FIG. 7 using the insertion apparatus of FIG. 1; and

FIG. 12 is an enlarged top view in partial cross-section of a pair of implants in place in the intervertebral space of a lumbar spinal section.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The preferred embodiments of the apparatus and methods disclosed herein are discussed in terms of orthopedic spinal fusion procedures and apparatus. It is also envisioned, however, that the disclosure is applicable to a wide variety of procedures including, but not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and spinal stabilization. In addition, it is believed that the present apparatus finds application in both open and minimally invasive procedures

including endoscopic and arthroscopic procedures wherein access to the surgical site is achieved through a cannula or small incision.

In the description which follows, the term "proximal", as is traditional, will refer to the portion of the structure which is closer to the operator, while the term "distal" will refer to the portion which is further from the operator.

Referring now in detail to the drawings in which like reference numerals identify similar or identical elements, a preferred embodiment of the implant insertion apparatus is illustrated in FIGS. 1 and 2 and is designated generally by reference numeral 100. Implant insertion apparatus 100 includes a removable handle portion 102 and a body portion 104. Handle portion 102 has a T-handle 106 positioned at a proximal end and releasable engagement structure 108 at a distal end thereof.

Body portion 104 defines a longitudinal axis "L" and includes an outer tubular member 110 fixed to a housing 112 for longitudinal rotation therewith. First implant engaging structure 114 is positioned adjacent a distal end of outer tubular member 110. Outer tubular member 110 preferably includes a removable distal end portion 158 described below. In the embodiment shown, the implant engaging structure is a pair of distally extending tabs 116 projecting from the distal end of outer tubular member 110.

Body portion 104 further includes an inner tubular member 118 disposed at least partially within outer tubular member 110. Inner tubular member 118 is mounted for limited longitudinal motion relative to outer tubular member 110 and is independently rotatable relative to outer tubular member 110 by wheel 120. In the illustrated embodiment, set screw 122 anchors wheel 120 to the inner tubular member 118. A first cavity 124 is defined in housing 112 and is dimensioned to limit the relative longitudinal motion of inner tubular member 118 by confining wheel 120 between walls 112a, 112b. As shown in FIG. 1, the periphery of wheel 120 may be provided with knurling 126 to enhance its frictional characteristics.

Inner tubular member 118 is normally biased to a distalmost longitudinal position relative to outer tubular member 110 as shown in FIG. 2. Coil spring 127, mounted in housing 112, abuts a proximal end of inner tubular member 118 and biases

inner tubular member distally. Second implant engaging structure 128 is formed adjacent a distal end of the inner tubular member 118. In the illustrated embodiment, the second implant engaging structure 128 is a hollow polygonal structure having a plurality of flat sides 130 extending from the distal end of inner tubular member 118.

Body portion 104 also includes an inner shaft 132, coaxially mounted at least partially within the inner tubular member 118. Inner shaft 132 is longitudinally rotatable relative to inner tubular member 118 and outer tubular member 110 by wheel 134. As shown, set screw 136 connects wheel 134 to a distal end of inner shaft 132. In a preferred embodiment, the outer periphery of wheel 134 is provided with a friction enhancing surface such as knurling 138.

A second cavity 140 is defined in housing 112 proximal to first cavity 124 and serves to confine wheel 134, and thus inner shaft 132, to limited longitudinal motion relative to outer and inner tubular members 110 and 118, respectively between walls 112c, 112d. Wheels 120 and 134 preferably extend radially beyond at least one outer peripheral surface of house 112 to facilitate actuation by the fingers of a user.

Inner shaft 132 has third implant engaging structure 142 positioned adjacent a distal end (See Figs 2 and 6A). In the illustrated embodiment, this structure is threads 144 formed on a distal end of inner shaft 132.

Referring now to FIGS. 2 and 2A, releasable engagement structure 108 of the illustrated embodiment of implant insertion apparatus 100 includes a distal sleeve 146 having an inner surface configured to engage hexagonal projection 148 formed on a proximal end of housing 112.

Proximal sleeve 150 is operatively associated with distal sleeve 146 and includes an internal spring loaded ball system 152 configured to releasably engage an annular channel 154 which extends proximally from hexagonal projection 148. Proximal sleeve 150 is mounted on a distal end of handle portion 102 for relative longitudinal motion between a locked position (FIG. 2) and an unlocked position (FIG. 2A). In the locked position, ball system 152 is forced radially inward into annular channel 154. Spring 156 normally biases proximal sleeve 150 into this locked position. As shown in FIG. 2A, in

the unlocked position, proximal sleeve 150 is retracted to release ball system 152 from annular channel 154. This enables the removal of handle portion 102 from the body portion 104 so the handle portion can be attached to and used with other instrumentation necessary for performing the surgical procedure.

Referring to FIGS. 2B and 2C in view of FIG. 1, a versatile feature of the illustrated embodiment is shown. In this preferred embodiment, a distal end portion 158 of outer tubular member 110, which contains first implant engagement structure 114, is interchangeably attached via a friction fit. This allows the user to position another distal end portion 160, such as that shown in Fig. 2C, mounting either a different size (e.g. diameter) implant or configuration of implant engagement structure on the same implant insertion apparatus. Thus, the insertion apparatus can be readily adapted to insert different implants.

An implant designed for use in spinal fusion procedures is shown in FIGS. 3-5 and designated generally by the reference number 200. This implant is commonly referred to as a "fusion cage" and, in this embodiment, is specifically configured for a posterior access spinal fusion procedure. Subsequent discussion regarding an exemplary use of the implant insertion tool 100 will be focused on this posterior spinal fusion procedure inserting fusion cage 200. It is contemplated, however, that the disclosed implant insertion tool has broad application in a wide variety of implant insertion procedures beyond either anterior or posterior spinal fusion.

Fusion cage 200 includes a body portion 202 with a closed distal end 204 and a proximal end 206. The distal end 204 is rounded or bull nosed to facilitate insertion of the fusion cage 200 relative to one or more bone structures. The proximal end 206 defines an opening 208 (FIG. 6) which communicates with an internal cavity 210 (FIG. 5) defined by fusion cage 200. In the illustrated embodiment, opening 208 is threaded to receive an end cap 212. This end cap 212 is used to close off the proximal end 206 and to retain bone growth inducing substances, such as bone chips 214 (FIG. 6), packed therein.

Referring to FIG. 4, end cap 212 defines a threaded bore 216 which is configured to receive third implant engaging structure 142 of inner shaft 132 as will be

discussed in further detail below. End cap 212 also defines a substantially square depression 218 coaxial with thread bore 216 and configured to receive second implant engaging structure 128 on inner tubular member 118.

The proximal end 206 further defines first and second peripheral indentations 220, 222 which are centered about transverse axis "T". These peripheral indentations 220, 222 are configured to receive first implant engagement structure 114, in this case tabs 116. These indentations may also be used to line up the fusion cage 200 for proper insertion and placement between the adjacent vertebral structure.

A helical thread 224 is formed on the outer peripheral surface of the fusion cage 200. A plurality of apertures 226 are defined by and extend through the fusion cage 200. In the illustrated fusion cage 200, apertures 226 are formed by broaching grooves 228 (FIG. 5) in the internal surface 230 of internal cavity 210. This technique removes material from the valleys between the turns of the thread 224, thus defining apertures 226 to advantageously provide immediate contact between the vertebral body and the bone chips located inside the cage when the cage is positioned in the body.

Referring now to FIGS. 6, 6A and 7, two methods of closing the end cap 212 in the opening 208 of proximal end 206 are illustrated. In FIG. 6, bone chips 214 are deposited into internal cavity 210 using forceps. Thereafter, end cap 212 can be manually threaded into opening 208 either by hand or with a socket wrench-type instrument. Alternatively, end cap 212 can be positioned into engagement with second and third implant engaging structure 128, 142 of implant insertion apparatus 100. This is done by positioning the flat sides 130 of second implant engaging structure 128 into square depression 218 of end cap 212. The distal end of inner shaft 132 is then threaded into bore 216 of end cap 212 by rotating wheel 134 (FIG. 1). End cap 212 is then securely engaged by the second and third implant engaging structure 128, 142. The implant insertion apparatus 100 is positioned with the engaged end cap 212 in juxtaposed axial alignment with opening 208 in proximal end 206 of fusion cage 200. Rotation of wheel 120 threads the end cap 212 into the fusion cage 200. As shown, in both methods, packing of the cage occurs outside the body. This facilitates insertion of bone chips since the chips are

individually placed with a forceps and lightly tapped, e.g., compacted, inside the cage. This is especially advantageous where access to the cage once implanted is limited and/or with smaller cages such as in cervical applications.

Mounting a packed fusion cage (FIG. 7) onto the insertion apparatus 100 and subsequent insertion into an intervertebral space will now be described with reference to FIGS. 8 through 12. In FIGS. 8A and 8B, the packed fusion cage is positioned in axial alignment with the proximal end of fusion cage 200, aligning tabs 116 with indentations 220, 222; flat sides 130 with square depression 218; and threads 144 with threaded bore 216.

Referring now to FIGS. 9A, 9B, 10A and 10B, fusion cage 200 is moved initially into engagement with inner tubular member 118 such that flat sides 130 are disposed in square depression 218 of end cap 212. Further proximal motion (indicated by the arrows in FIGS. 9A and 9B) of inner shaft 118 relative to inner shaft 132 by either pressing cage 200 against the apparatus or moving wheel 120 proximally brings threads 144 into engagement with threaded bore 216 and tabs 116 of outer tubular member 110 into simultaneous engagement with indentations 220 and 222. (FIG. 10A) Wheel 120 can be slightly rotated to ensure alignment of tabs 116 and indentations 220, 222. Then, wheel 134 is rotated to cause the threaded inner shaft to engage the fusion cage 200 by end cap 212 thus securely mounting the fusion cage 200 on the distal end of the implant insertion apparatus 100 as the cage 200 is pulled proximally via the engagement of the threads.

Thereafter, the implant insertion apparatus 100 is positioned adjacent the implant site (FIG. 11) which typically includes a pretapped bore formed in an intervertebral space between two adjacent vertebra. (Alternately, the fusion cage could be self-tapping.) The implant insertion apparatus 100 may be guided into position using a cannula or C-retractor 300 to facilitate accurate insertion of fusion cage 200. The T-handle 106 is then rotated to rotate outer tubular member 110 to engage threads 224 of the fusion cage 200 (shown in phantom) in the intervertebral space 302.

Once the fusion cage 200 is in position, wheel 134 is rotated to disengage threads 144 from threaded bore 216. This releases the implant insertion apparatus 100 from the implanted fusion cage 200. (FIG. 12)

Note that since the fusion cage 200 is grasped and inserted by the apparatus 100 from its open end, once positioned inside the body, the end cap 212 can be removed if the user desires to view or access the bone chips in the internal cavity 210.

The implant insertion apparatus 100 can also be utilized to insert an empty implant such as fusion cage 200 into the intervertebra space and subsequently seal the fusion cage after packing the fusion cage with bone growth inducing substance in vivo. In this procedure, the empty fusion cage is engaged with the first, second and third implant engagement structure 114, 128, 142 and inserted in the same manner outlined above. Once in place in the body, wheel 120 is rotated to remove end cap 212 from body portion 202 and the implant insertion apparatus with attached end cap 212 (FIG. 6A) is removed from the site.

Thereafter, the fusion cage 200 can be packed and the procedure reversed to thread the end cap 212 securely back into place on the body portion 202 using apparatus 100 as described above without affecting the relative position of the body portion 202 at the site. This would avoid the necessity for a separate cap insertion tool since apparatus 100 could serve the dual function of inserting the cage and attaching the end cap.

It will be understood that a wide variety of modifications may be made to the embodiments of the apparatus and methods disclosed herein. For example, the first, second and/or third implant engaging structures can be modified to facilitate engagement with a vast number of implants, both prosthetic and natural. Also, endoscopic, arthroscopic and percutaneous methods of use are easily accommodated. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. Apparatus for implant insertion comprising:

a handle portion; and

a body portion attached to the handle portion and defining a longitudinal axis, the body portion including an outer tubular member fixed relative to the handle portion for rotation therewith about the longitudinal axis, the outer tubular member having first implant engaging structure adjacent a distal end, an inner tubular member disposed at least partially within the outer tubular member and mounted for longitudinal motion relative to the outer tubular member, the inner tubular member being rotatable independent of the outer tubular member and having second implant engaging structure adjacent a distal end and an inner shaft, coaxially mounted at least partially within the inner tubular member for independent rotation relative to the inner and outer tubular members, the inner shaft having third implant engaging structure adjacent a distal end.

2. Apparatus as in claim 1 wherein the handle portion is releasably attached to the body portion.

3. Apparatus as in claim 1 further comprising a wheel positioned on the inner tubular member for independent rotation thereof relative to the outer tubular member.

4. Apparatus as in claim 1 further comprising a wheel positioned on the inner shaft for independent rotation thereof relative to the outer and inner tubular members.

5. Apparatus as in claim 1 wherein the first implant engaging structure comprises a pair of tabs projecting from the distal end of the outer tubular member.

6. Apparatus as in claim 1 wherein the second implant engaging structure comprises a polygonal structure extending from the distal end of the inner tubular member.

7. Apparatus as in claim 1 wherein the third implant engaging structure comprises a threaded portion formed on the distal end of the inner shaft.

8. Apparatus as in claim 1 wherein the first implant engaging structure is removably mounted to the body portion.

9. Apparatus as in claim 2 wherein the handle portion is T-shaped.

10. Apparatus for implant insertion comprising:

a handle portion; and

a body portion defining a longitudinal axis and having a proximal end configured to engage the handle portion, a distal end configured to engage an implant, and a housing fixed relative to the proximal end and positioned intermediate the proximal and distal ends, the body portion including an outer tubular member fixed to the housing and extending distally therefrom, the outer tubular member having first implant engaging structure at a distal end, an inner tubular member disposed at least partially within the outer tubular member and mounted for longitudinal motion relative to the outer tubular member, the inner tubular member including a first wheel confined at least partially within a first cavity in the housing for rotating the inner tubular member relative to the outer tubular member, the inner tubular member having second implant engaging structure adjacent a distal end and an inner shaft, coaxially mounted at least partially within the inner tubular member, the inner shaft including a second wheel confined at least partially within a second cavity in the housing for independently rotating the inner shaft relative to the inner and outer tubular members, the inner shaft having third implant engaging structure adjacent a distal end.

11. Apparatus as in claim 10 wherein the first implant engaging structure comprises a pair of tabs projecting from the distal end of the outer tubular member.

12. Apparatus as in claim 10 wherein the second implant engaging structure comprises a polygonal structure extending from the distal end of the inner tubular member.

13. Apparatus as in claim 10 wherein the third implant engaging structure comprises a threaded portion formed on the distal end of the inner shaft.

14. Apparatus as in claim 10 wherein the first implant engaging structure is removably mounted to the body portion.

15. Apparatus as in claim 10 wherein the handle portion is T-shaped.

16. Apparatus as in claim 11 wherein the tabs are on radially opposed sides of the longitudinal axis and are configured to engage an outer peripheral wall of an implant.

17. In an apparatus for insertion of a hollow implant having a closed distal end section accessible through a removable proximal end cap, the apparatus having a handle portion and a body portion with implant engaging structure adjacent a distal end thereof, the improvement comprising a body portion attached to the handle portion and defining a longitudinal axis, the body portion including an outer tubular member fixed relative to the handle portion for rotation therewith about the longitudinal axis, the outer tubular member having first implant engaging structure adjacent a distal end, an inner tubular member disposed at least partially within the outer tubular member and mounted for longitudinal motion relative to the outer tubular member, the inner tubular member being rotatable independent of the outer tubular member and having second implant engaging structure adjacent a distal end and an inner shaft, coaxially mounted at least partially within

the inner tubular member for independent rotation relative to the inner and outer tubular members, the inner shaft having third implant engaging structure adjacent a distal end.

18. Apparatus as in claim 17 wherein the handle portion is releasably attached to the body portion.

19. Apparatus as in claim 17 further comprising a wheel positioned on the inner tubular member for independent rotation thereof relative to the outer tubular member.

20. Apparatus as in claim 17 further comprising a wheel positioned on the inner shaft for independent rotation thereof relative to the outer and inner tubular members.

21. Apparatus as in claim 17 wherein the first implant engaging structure comprises a pair of tabs projecting from the distal end of the outer tubular member.

22. Apparatus as in claim 21 wherein the pair of tabs are positioned on the distal end of the outer tubular member to engage the closed distal end section of the prosthetic implant.

23. Apparatus as in claim 17 wherein the second implant engaging structure comprises a polygonal structure extending from the distal end of the inner tubular member.

24. Apparatus as in claim 23 wherein the polygonal structure is positioned on the distal end of the inner tubular member to engage the proximal end cap of the prosthetic implant.

25. Apparatus as in claim 17 wherein the third implant engaging structure comprises a threaded portion formed on the distal end of the inner shaft.

26. Apparatus as in claim 25 wherein the threaded portion formed on the distal end of the inner shaft is configured to threadably engage the proximal end cap of the prosthetic implant.

27. A method of inserting an implant comprising the steps of:

providing an apparatus including a handle portion and a body portion attached to the handle portion and defining a longitudinal axis, the body portion including an outer tubular member fixed relative to the handle portion for rotation therewith about the longitudinal axis, the outer tubular member having first implant engaging structure adjacent a distal end, an inner tubular member disposed at least partially within the outer tubular member and mounted for longitudinal motion relative to the outer tubular member and having second implant engaging structure adjacent a distal end and an inner shaft, coaxially mounted at least partially within the inner tubular member for independent rotation relative to the inner and outer tubular members, the inner shaft having third implant engaging structure adjacent a distal end;

providing an implant having a hollow portion with a closed distal end and a removable proximal end cap;

attaching the first, second and third implant engaging structures to the implant; and

inserting the implant into a desired surgical location.

28. A method as in claim 27 wherein the implant includes a threaded portion formed on an outer peripheral surface of the hollow closed distal end and the inserting step including rotating the implant into a desired surgical location.

29. A method as in claim 28 wherein the first implant engaging structure includes a pair of tabs positioned on a distal end of the outer tubular member and the attaching step includes engaging the tabs with the hollow closed distal end of the implant.

30. A method as in claim 28 wherein the attaching step includes engaging the second and third implant engaging structure to the proximal end cap of the implant.

31. A method as in claim 27 further comprising the step of loading the implant with bone growth stimulation media.

32. A method as in claim 31 wherein the step of loading the implant is carried out before the implant is inserted.

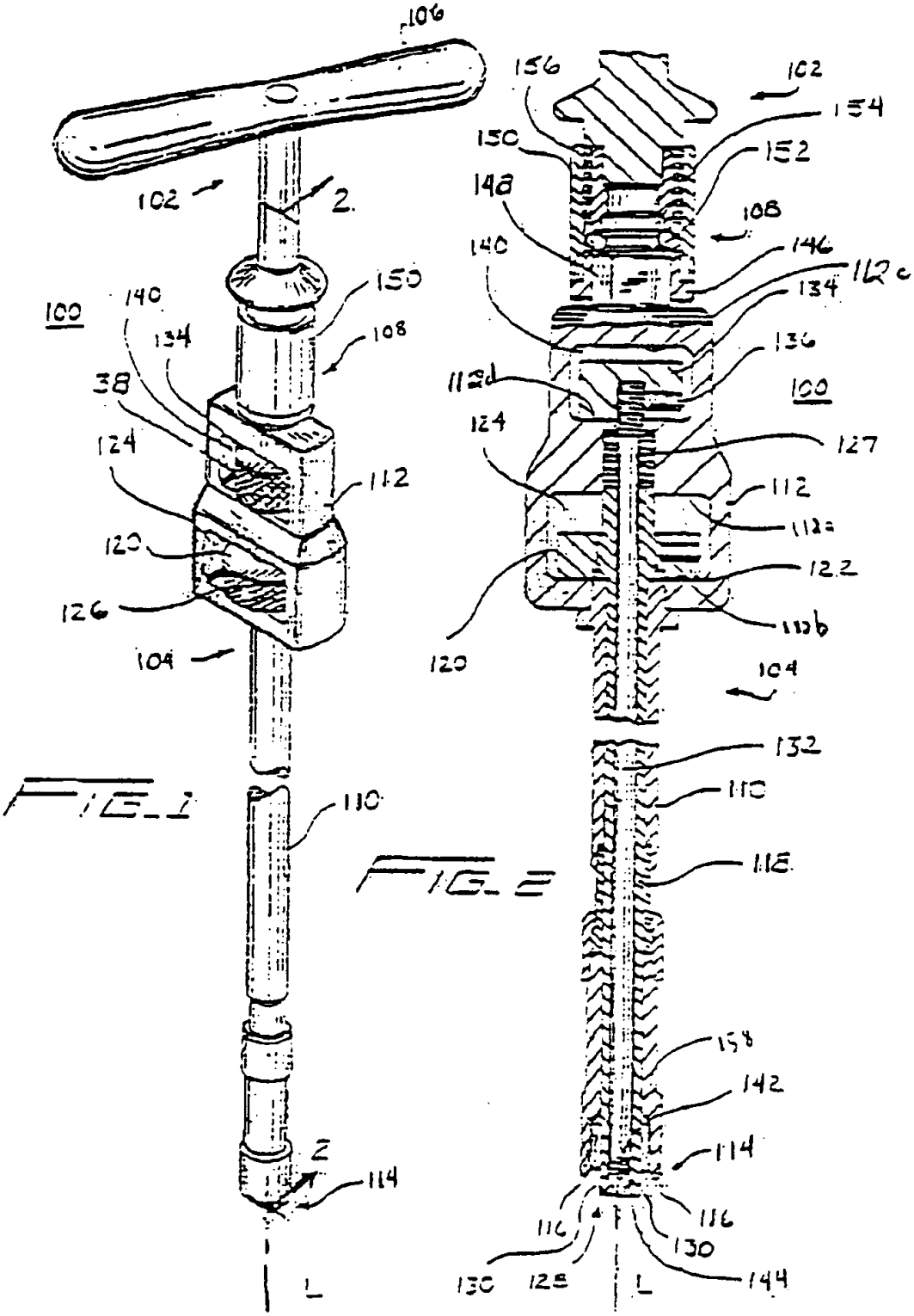
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FIG. 1
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148
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140
146
112c
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136
100
112d
124
127
112
112a
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112b
120
104
132
110
116
130
144
FIG. 2

FIG. 2A

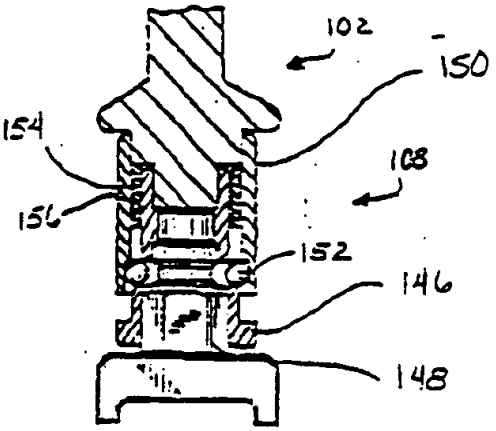


FIG. 2B

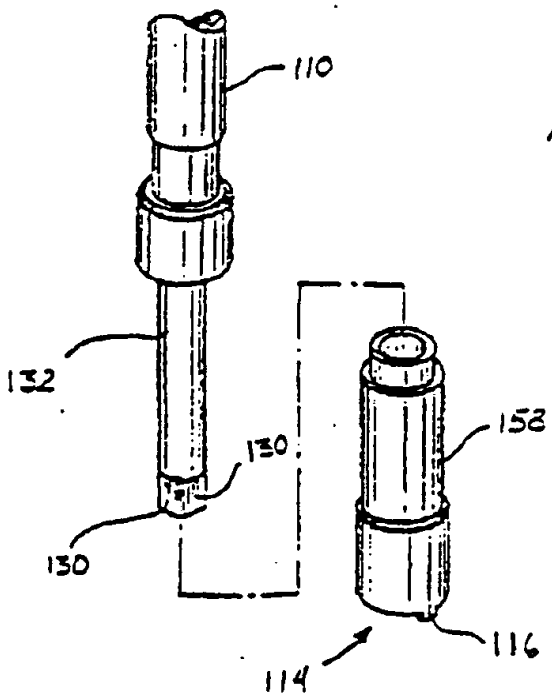
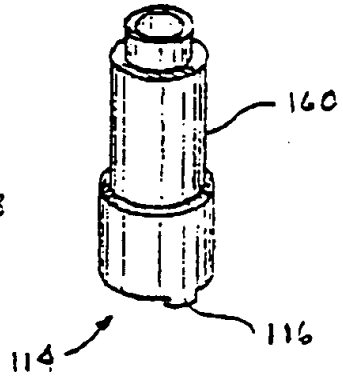


FIG. 2C



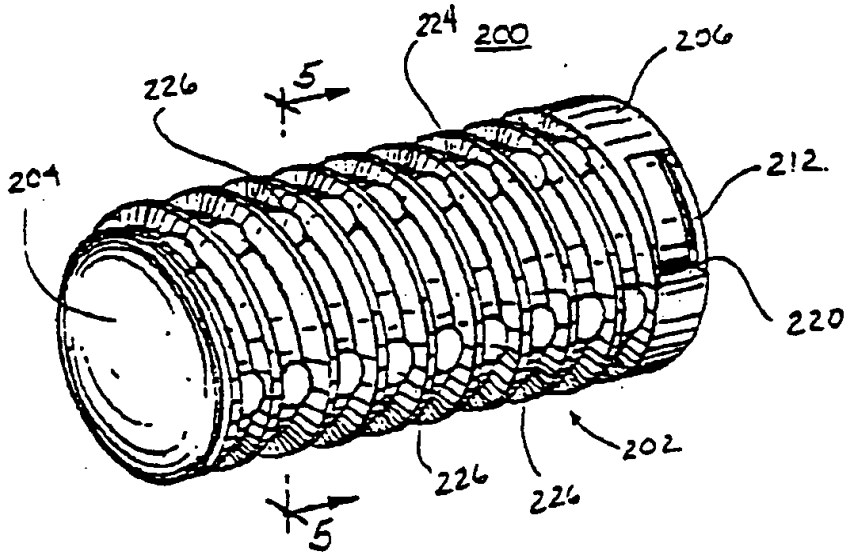

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FIG. 3

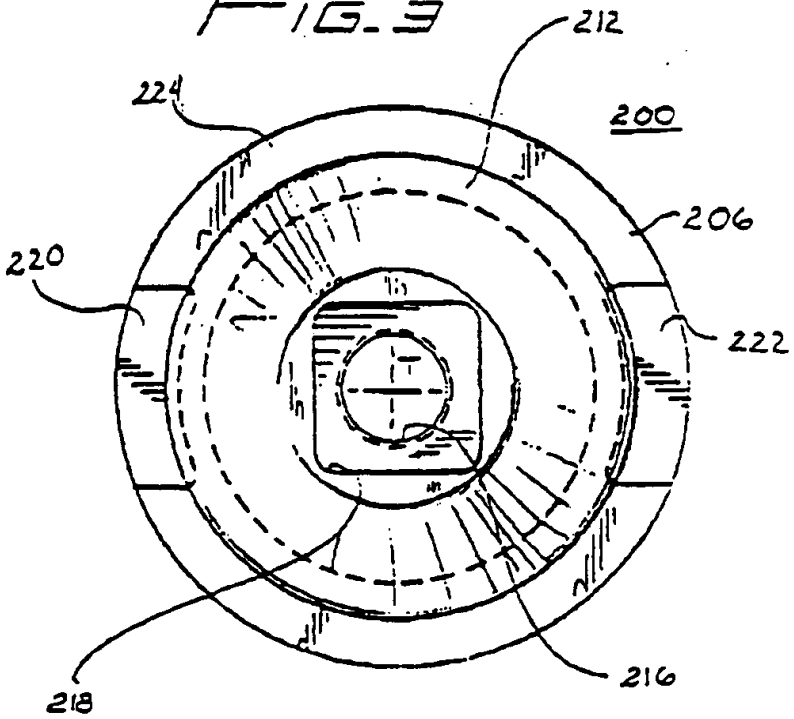
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FIG. 4

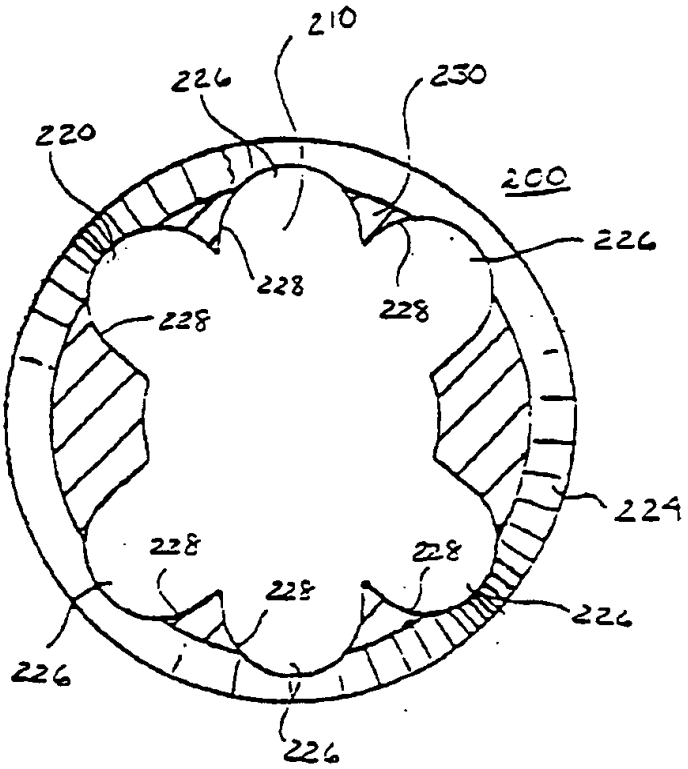

FIG. 5

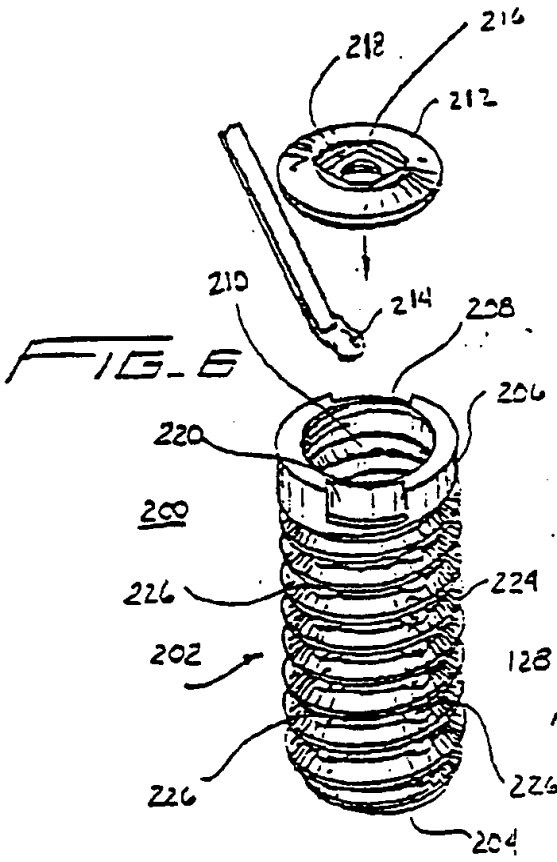

FIG_6

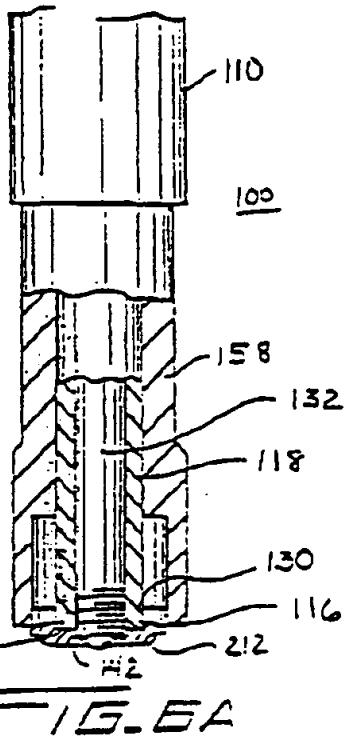

FIG_6A

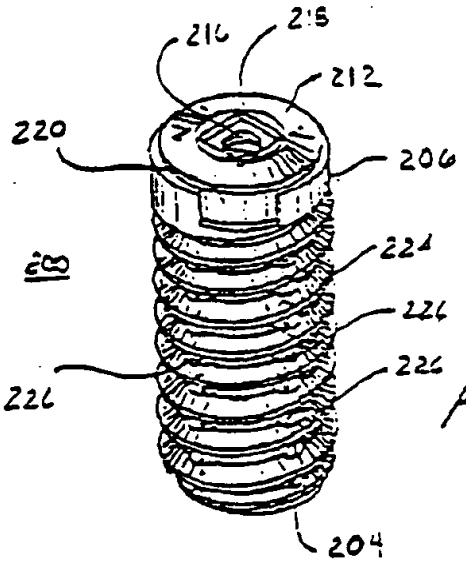

FIG_7

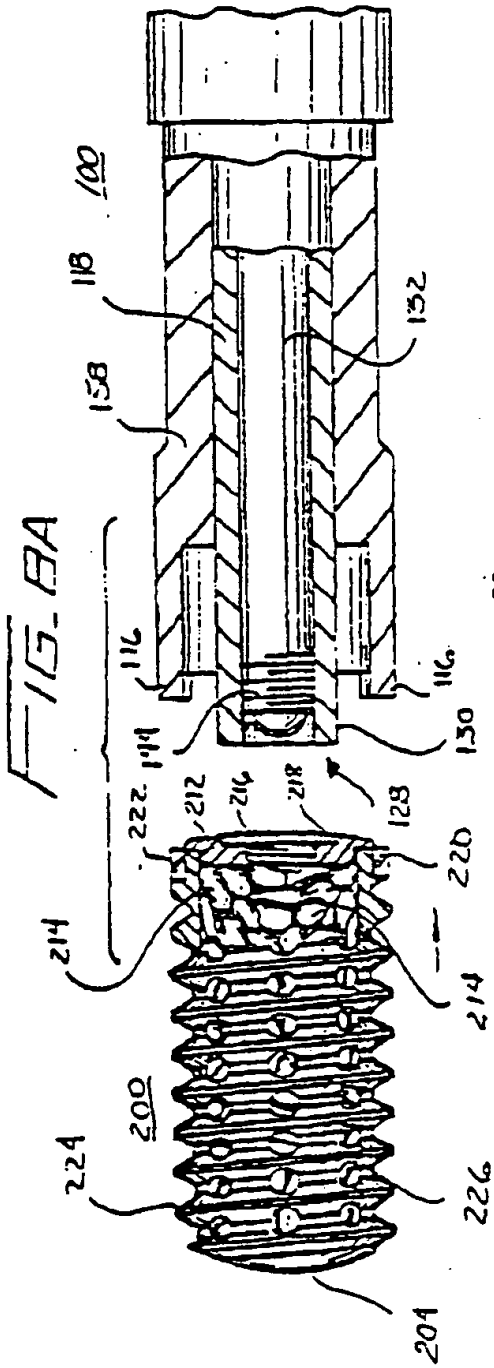
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FIG. 8A

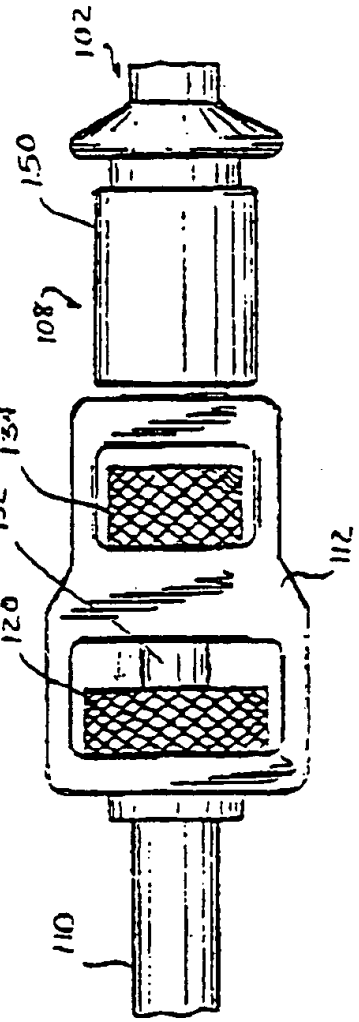
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FIG. 8B

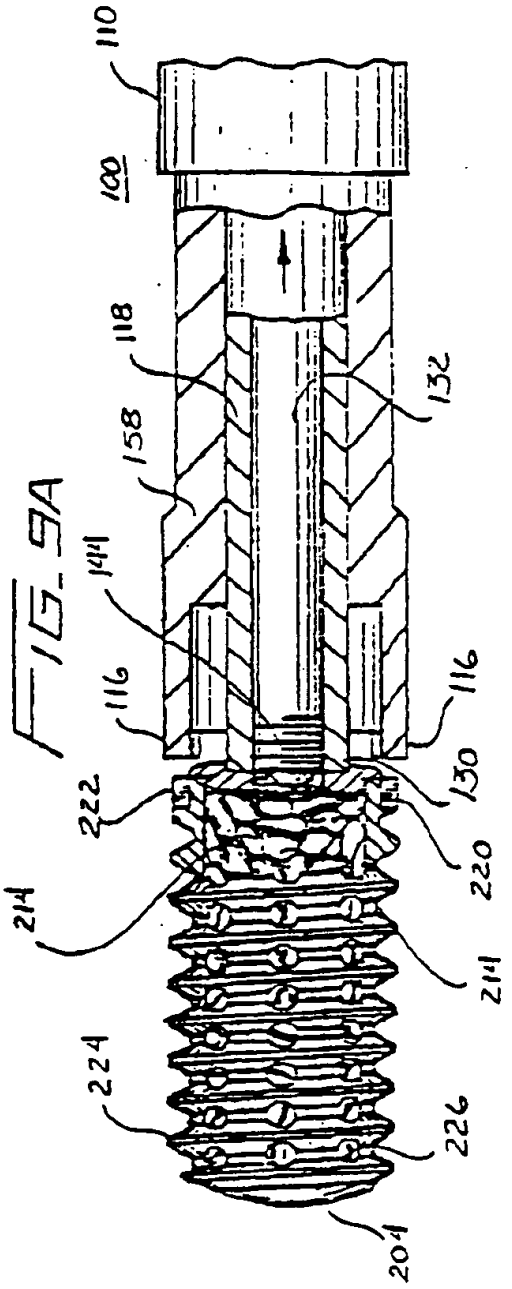
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FIG_9A

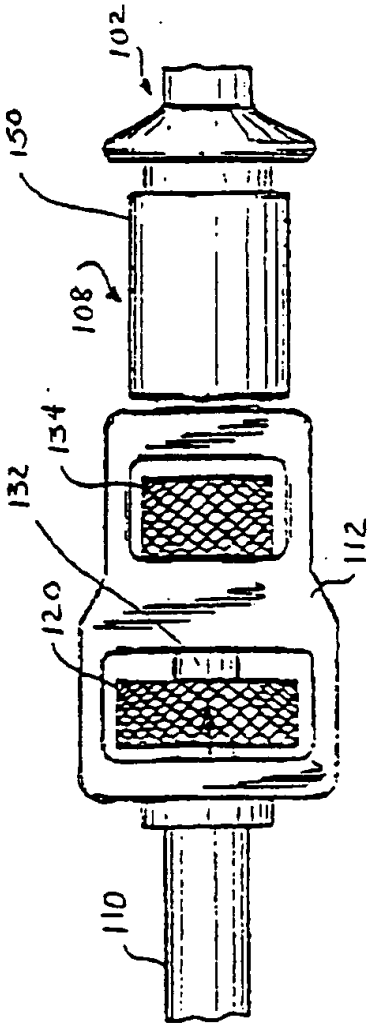
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FIG_9B

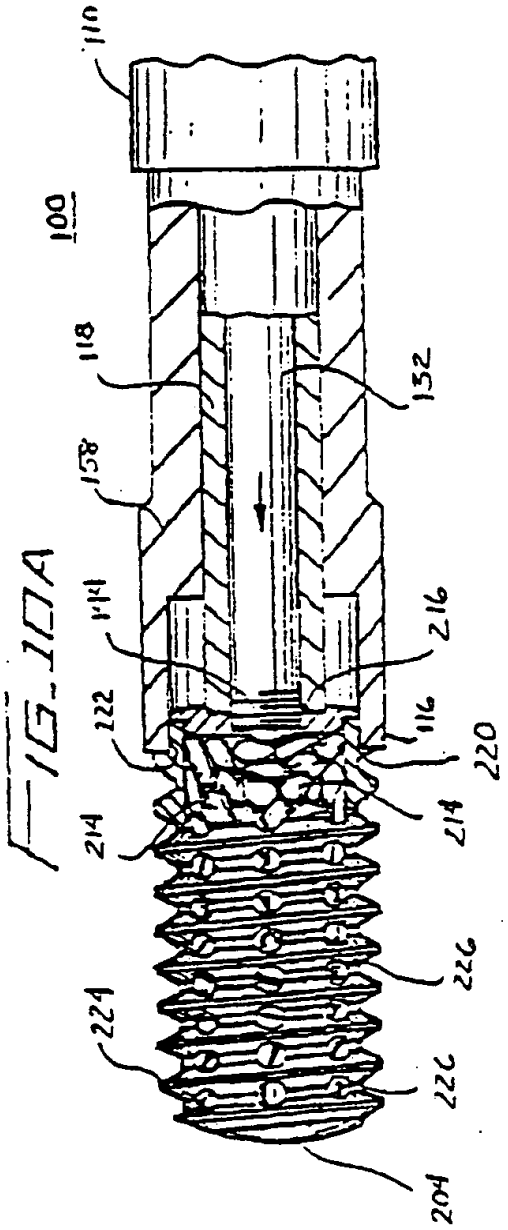
FIG_10A
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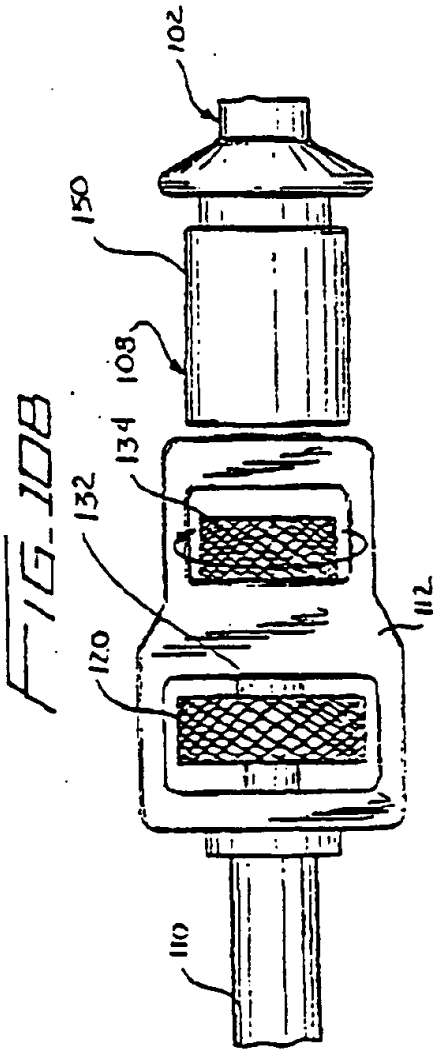
FIG_10B
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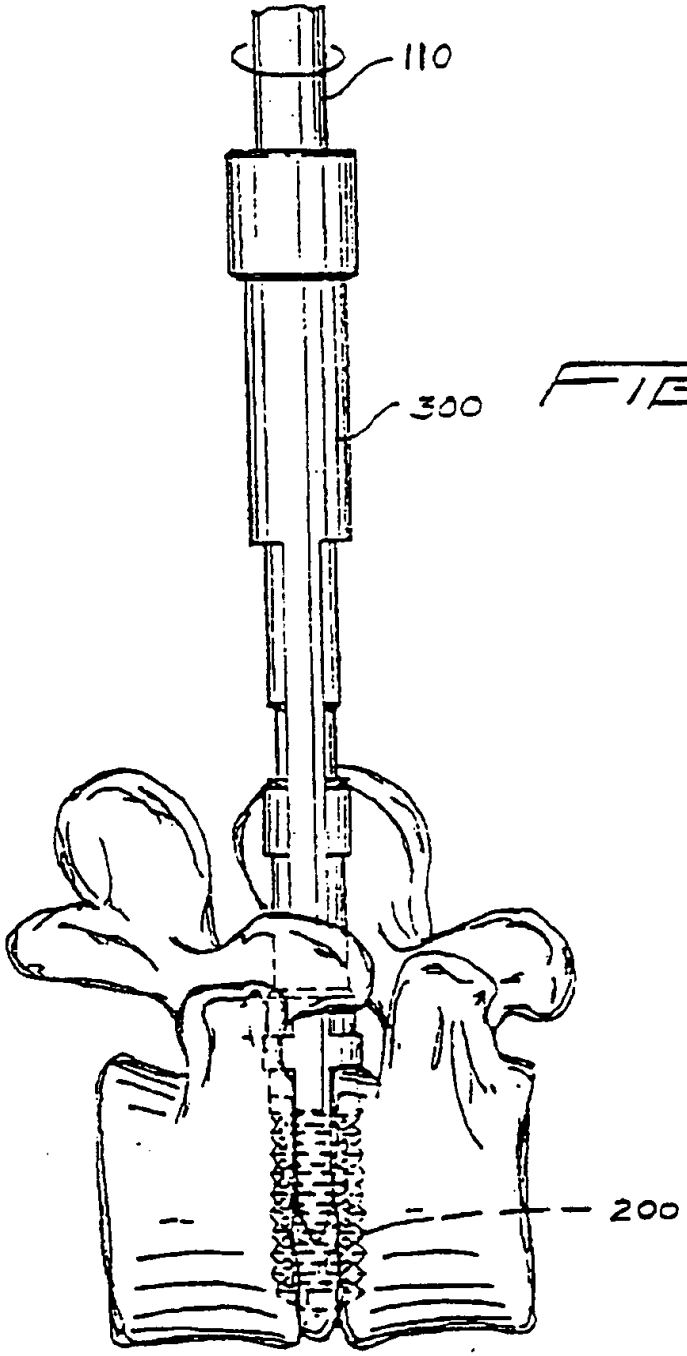
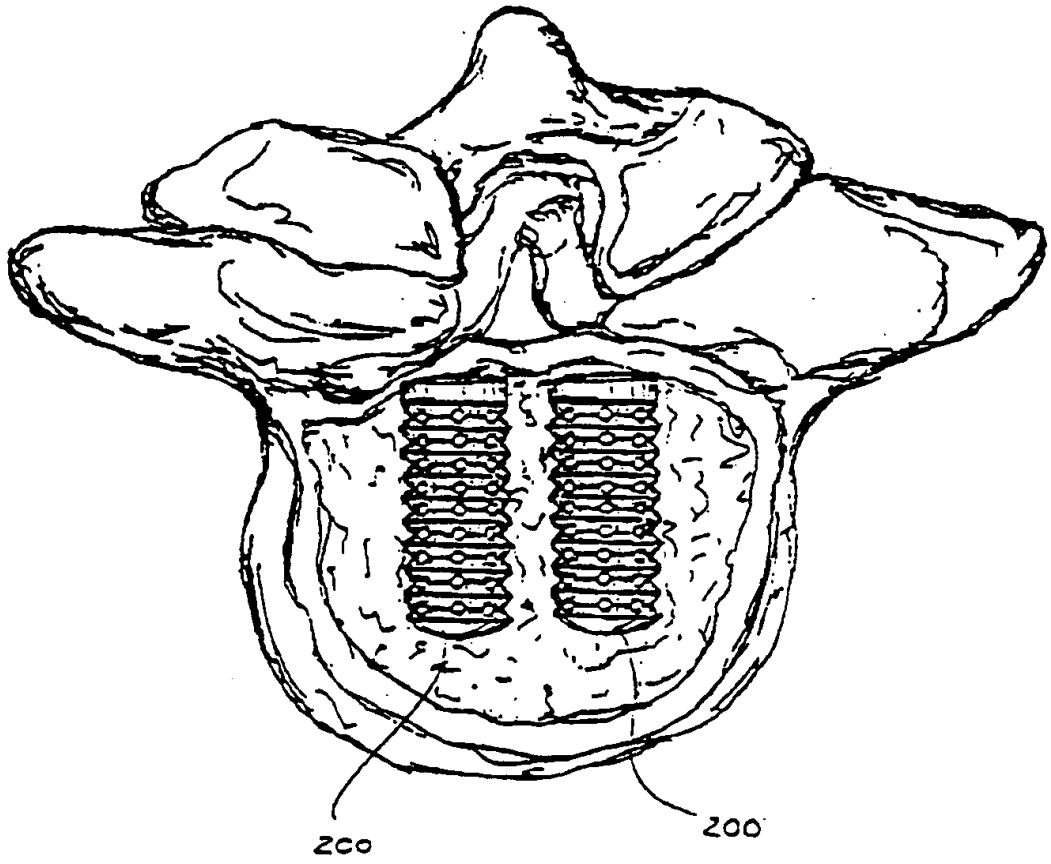


FIG_11

FIG. 12



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/03869

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/56
US CL :606/104

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. : 606/60, 61, 72, 73, 86, 91, 99, 104; 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,489,307 (KUSLICH et al) 06 February 1996, Fig. 56.	1, 3, 4, 7, 9, 10, 13, 15, 17, 19, 20, 25, 26 --- 2, 8, 14, 18
A	US, A, 5,354,292 (BRAEUER et al) 11 October 1994, Fig. 1A.	1

☐ 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
26 APRIL 1997

Date of mailing of the international search report
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(71) Déposant *(pour tous les Etats désignés sauf US)*: SCIENT'X S.A.R.L. [FR/FR]; 6, avenue de Ségur, F-75007 Paris (FR).

(72) Inventeurs; et
(75) Inventeurs/Déposants *(US seulement)*: BENEZECH, Jacques [FR/FR]; Avenue Charles-Flahaut, F-34000 Montpellier (FR). ALBY, Albert [FR/FR]; 3, rue Verdi, F-75016 Paris (FR).

(74) Mandataire: DE PASTORS, Alice; 13, avenue du Général-Leclerc, F-78150 Le Chesnay (FR).

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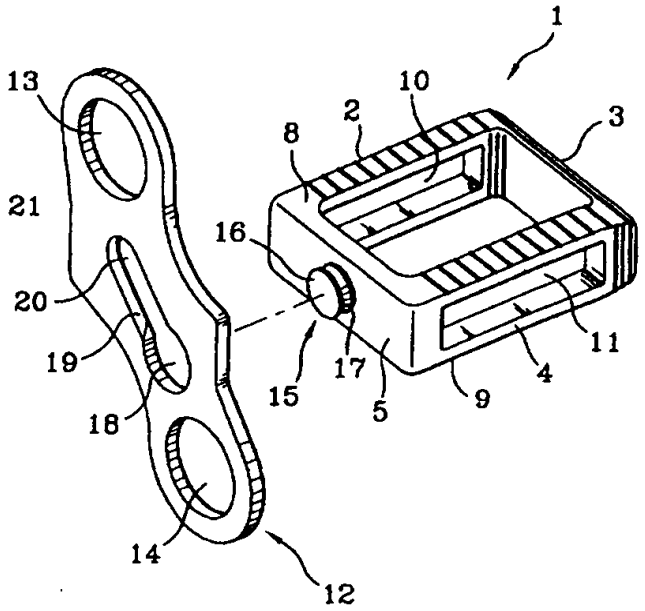
(54) Title: INTERSOMATIC SETTING AND FUSION SYSTEM

(54) Titre: SYSTEME DE CONTENTION ET DE FUSION INTERSOMATIQUE

(57) Abstract

Intersomatic vertebra setting and fusion system including one or more open inner housings for receiving the spongy bone and to be inserted between two vertebrae during a dissectomy, characterised in that said housing (1) has an outer plate element (12), on its rear surface (5), extending on either side of the housing (1) in a plane substantially perpendicular to the insertion plane of the housing (1), and provided at each of the ends thereof with means (13, 14) for anchoring the plate to at least two adjacent vertebrae to be secured to each other by means of the cage (1). The system can be separated into two parts: the housing and the plate.



(57) Abrégé

Système de contention et de fusion intersomatique des vertèbres comportant au moins une cage interne ouverte recevant de l'os spongieux et destiné à être interposé entre deux vertèbres lors de dissectomie, caractérisée en ce que ladite cage (1) comporte sur sa face antérieure (5) un élément externe formant une plaque (12) s'étendant dans un plan sensiblement perpendiculaire au plan d'introduction de la cage (1), de part et d'autre de celle-ci, et disposant à chacune de ses extrémités de moyens d'ancrage (13, 14) sur au moins deux vertèbres adjacentes à solidariser entre elles par l'intermédiaire de la cage (1). Le système peut se désolidariser en deux parties: cage et plaque.

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SYSTEME DE CONTENTION ET DE FUSION INTERSOMATIQUE

La présente invention concerne un système de contention et de fusion intersomatique des vertèbres comportant au moins une cage interne ouverte recevant de l'os spongieux et destinée à être interposée entre deux vertèbres lors de dissectomie et à pouvoir procéder à la mise en place d'un greffon osseux ou d'un matériau favorisant la fusion intersomatique qui favorisera la fusion des deux vertèbres concernées.

De telles cagés sont connues par exemple, par les demandes de brevet FR2703580, EP493698, EP599419, FR2124815, EP307241, EP615428.

Ces cages sont de forme globalement parallélipipédiques ou ovoïdes. Elles sont rigides, métalliques ou en matériau biocompatible et destinées à recevoir de l'os spongieux grâce à des faces supérieure et inférieure ouvertes.

Si les cages du type précité donnent généralement de bons résultats, il n'en reste pas moins vrai que dans certains cas il est nécessaire d'assurer le positionnement et la « non-mobilité » de la cage afin de se mettre à l'abri, d'une façon sûre, d'une migration possible ou d'éviter tout risque de déplacement secondaire de la cage.

L'invention vise à atteindre ces objectifs et concerne à cet effet un système de contention et de fusion intersomatique des vertèbres comportant au moins une cage interne ouverte recevant de l'os spongieux ou un substitut osseux et destinée à être interposée entre deux vertèbres lors de dissectomie, caractérisé en ce que ladite cage comporte sur sa face antérieure un élément externe formant une bride (plaque) s'étendant dans un plan sensiblement perpendiculaire au plan d'introduction de la cage, de part et

d'autre de celle-ci, et disposant à chacune de ses extrémités de moyens d'ancrage sur au moins deux vertèbres adjacentes à solidariser entre elles.

La dite cage est rigide, en métal ou matériau plastique biocompatible, de forme globalement parallélépipédique et adaptée à l'espace intervertébral et prévue pour recevoir de l'os spongieux ou matériau substitut osseux grâce à ses faces supérieure et inférieure ouvertes et/ou par une ouverture frontale.

Le système de l'invention est réalisé selon les besoins sous une forme cage-plaque monobloc ou sous forme d'une cage interne et d'une plaque externe, comportant des moyens d'assemblage de la plaque à la cage.

La présente invention concerne également les caractéristiques qui ressortiront au cours de la description qui va suivre et qui devront être considérées isolément ou selon toutes leurs combinaisons techniques possibles.

Cette description donnée à titre d'exemple non limitatif fera mieux comprendre comment l'invention peut être réalisée, en référence aux dessins annexés, sur lesquels:

- la figure 1 est une vue en perspective éclatée d'un système de contention selon un premier exemple de réalisation de l'invention;

- la figure 2 est une vue en perspective éclatée d'un système de contention selon un second exemple de réalisation de l'invention;

- la figure 3 est une vue d'un système de contention monobloc.

A titre d'exemple non limitatif, la cage 1 représentée sur la figure 1 est constituée globalement par un parallélépipède rigide dont les parois latérales 2, 3, 4, 5 sont destinées à emprisonner de l'os spongieux ou substitut osseux et dont les faces supérieure 8 et inférieure 9 sont ouvertes vers deux vertèbres successives.

Les faces antérieure 5 et postérieure 3 ont des hauteurs déterminées afin d'assurer la conservation d'un espace intervertébral approprié.

Toujours selon le présent exemple, les parois latérales 2 et 4 de la cage 1 sont pourvues de larges lumières 10 et 11 de forme semblable à celles des parois latérales correspondantes 2 et 4 dans lesquelles elles sont percées.

La cage 1 est ainsi pourvue d'ouvertures sur quatre de ses faces. La cage 1 comporte par ailleurs sur sa face antérieure 5 un élément externe formant une bride 12 (désignée par la suite par plaque) s'étendant dans un plan sensiblement perpendiculaire au plan d'introduction de la cage 1, de part et d'autre de celle-ci, et disposant à chacune de ses extrémités de moyens d'ancrage 13 et 14 sur au moins deux vertèbres adjacentes à solidariser entre elles par l'intermédiaire de la cage 1.

Bien entendu, la bride externe ou plaque 12 pourrait être obtenue de manière monobloc avec la cage interne 1, par exemple par moulage de l'ensemble cage-plaque.

Néanmoins, il a été préféré selon le présent exemple de réalisation, de présenter une plaque 12 et une cage interne 1 réalisées distinctement et solidarisées entre elles ultérieurement par l'intermédiaire de moyens d'assemblage.

Toujours selon l'exemple de la figure 1, ces moyens d'assemblage de la plaque 12 sur la cage 1 sont constitués par un pion 15 cylindrique réalisé sur une face antérieure verticale 5 de la dite cage et une gorge périphérique 17 aménagée sous la tête circulaire 16 du dit pion 15, la dite tête 16 étant susceptible d'être introduite dans une partie correspondante d'une zone élargie 18 d'une lumière oblongue 19 en forme de boutonnière percée dans la plaque 12, et la dite gorge 17 étant de dimension telle à pouvoir coulisser entre les bords latéraux d'une zone rétrécie 20 de ladite

boutonnière jusqu'à ce que la tête 16 du pion 15 coopère en verrouillage axial avec la face externe 21 de la plaque 12.

On peut prévoir qu'un tel engagement du pion dans la boutonnière puisse se faire à force dans la zone rétrécie.

Bien entendu, la cage qui vient d'être décrite ci-dessus pourra avoir des dimensions différentes tant en hauteur qu'en largeur et en profondeur.

Elle pourra également avoir comme dans l'exemple qui va suivre, une forme anatomique préférée.

On peut également supposer que la pose de l'os spongieux ou autre substitut osseux sera faite préalablement ou après positionnement de la cage 1 entre les vertèbres.

L'exemple de réalisation représenté sur la figure 2 diffère essentiellement du précédent en ce que les moyens d'assemblage de la plaque 12A sur la cage 1A sont constitués par une glissière en queue d'aronde dont la partie formant mortaise 30 est réalisée sur une face interne 31 de la plaque 12A dans un sens de coulissement vertical et la partie tenon correspondante 32 sur la face frontale externe 5A de la cage 1A, ou inversement.

On notera que selon le présent exemple de réalisation, la cage 1A ne comporte plus d'ouvertures latérales comme dans l'exemple précédent.

En fait, la face frontale externe 5A de la cage 1A et la face correspondante 31 de la plaque 12A avec laquelle elle coopère comportent chacune des lumières oblongues identiques 33, 34 destinées à être mises en coïncidence lors de l'assemblage de la plaque 12A sur la cage 1A, de manière à permettre l'introduction de l'os spongieux, frontalement après mise en place de la cage 1A.

On remarquera également la forme et le profil particulier de la cage 1A selon l'exemple de la figure 2 permettant une adaptation parfaite à l'espace intervertébral.

L'exemple de réalisation représenté sur la figure 3 diffère de l'exemple de la figure 2 en ce qu'il est réalisé de manière monobloc.

La face antérieure 5A de la cage-plaque comporte une lumière oblongue 33 de manière à permettre d'introduire frontalement de l'os spongieux dans la partie cage après mise en place de la dite cage-plaque.

D'une manière commune aux exemples de réalisation des figures 1, 2 et 3 qui viennent d'être citées, les moyens d'ancrage de la plaque 12, 12A sur les vertèbres, après fixation de la cage 1, 1A, s'effectuent par l'intermédiaire de vis pédiculaires (non représentées) traversant des trous correspondants 13, 14 pratiqués aux extrémités de ladite bride 12, 12A.

Il est à noter, selon une autre caractéristique de l'invention, que les trous de fixation 13, 14 de la plaque 12, 12A sont disposés de part et d'autre d'un axe vertical médian X, X' de l'ensemble, sur une diagonale Y, Y'.

Selon un mode de réalisation non représenté, le système de contention peut mettre en oeuvre deux ou plus cages internes 1, 1A solidarisées entre elles et par rapport à trois ou plus vertèbres successives par l'intermédiaire d'une plaque 12, 12A comportant deux moyens d'assemblage 15, 18 ou 30, 32 avec lesdites cages 1, 1A et deux trous de fixation d'extrémité 13, 14 et un trou intermédiaire coopérant avec trois ou plus vis pédiculaires d'ancrage sur les vertèbres.

Les plaques sont représentées avec une vis de fixation par vertèbre mais elles peuvent en comporter davantage, 2 par exemple.

Il est bien entendu que le système de contention peut également être constitué de deux ou plusieurs ensembles cage-plaque tels que définis dans les exemples des figures 1, 2 ou

3 reliés entre eux par les dites plaques se chevauchant on non, deux par deux.

Les systèmes de contention de l'invention sont réalisés en alliage de titane ou matériau équivalent ou bien en matière plastique bio-compatible.

REVENDICATIONS

1 - Système de contention et de fusion intersomatique des vertèbres comportant au moins une cage interne ouverte recevant de l'os spongieux ou substitut osseux et destinée à être interposée entre deux vertèbres lors de dissectomie, caractérisé en ce que ladite cage (1, 1A) comporte sur sa face antérieure (5, 5A) un élément externe formant une plaque (12, 12A) s'étendant dans un plan sensiblement perpendiculaire au plan d'introduction de la cage (1, 1A), de part et d'autre de celle-ci, et disposant à chacune de ses extrémités de moyens d'ancrage (13, 14) sur au moins deux vertèbres adjacentes à solidariser entre elles par l'intermédiaire de la cage (1, 1A).

2 - Système selon la revendication 1, caractérisé en ce que la plaque externe (12, 12A) est obtenue de manière monobloc avec la cage interne (1, 1A).

3 - Système selon la revendication 2 caractérisé en ce que la face frontale externe (5A) de la cage-plaque comporte une lumière oblongue (33) pour permettre l'introduction de l'os spongieux frontalement après la mise en place de la cage-plaque.

4 - Système selon la revendication 1, caractérisé en ce que la plaque externe (12) et la cage interne (1) sont réalisées distinctement et solidarisées entre elles ultérieurement par l'intermédiaire de moyens d'assemblage.

5 - Système selon la revendication 4, caractérisé en ce que les moyens d'assemblage de la plaque (12) sur la cage (1) sont constitués par un pion (15) cylindrique réalisé sur une face antérieure verticale (5) de la dite cage et une gorge périphérique (17), aménagée sous une tête circulaire (16) dudit pion (15), la dite tête (16) étant susceptible d'être introduite dans une partie correspondante d'une zone élargie (18) d'une lumière oblongue (19) en forme de

boutonnière percée dans la plaque (12), et la dite gorge (17) étant de dimension telle à pouvoir coulisser entre les bords latéraux d'une zone rétrécie (20) de ladite boutonnière jusqu'à ce que la tête (16) du pion (15) coopère en verrouillage axial avec la face externe (21) de la plaque (12)

6 - Système selon la revendication 5, caractérisé en ce que la cage interne (1) comporte, outre des faces supérieure (8) et inférieure (9) ouvertes, des parois latérales (2, 4) pourvues de lumières d'introduction (10, 11) de l'os spongieux.

7 - Système selon la revendication 4, caractérisé en ce que les moyens d'assemblage de la plaque (12A) sur la cage (1A) sont constitués par une glissière en queue d'aronde dont la partie formant mortaise (30) est réalisée sur une face interne (31) de la plaque (12A) dans un sens de coulissement vertical et la partie tenon correspondante (32) sur la face frontale externe (5A) de la cage (1A), ou inversement.

8 - Système selon la revendication 7, caractérisé en ce que la face frontale externe (5A) de la cage (1A) et la face correspondante (31) de la plaque (12A) avec laquelle elle coopère comportent chacune des lumières oblongues identiques (33, 34) destinées à être mises en coïncidence lors de l'assemblage de la plaque (12A) sur la cage (1A), de manière à permettre l'introduction de l'os spongieux, frontalement après mise en place de la cage (1A).

9 - Système selon l'une des revendications précédentes, caractérisé en ce que les moyens d'ancrage de la plaque (12, 12A) sur les vertèbres, après fixation de la cage (1, 1A), s'effectuent par l'intermédiaire de vis pédiculaires traversant des trous correspondants (13, 14) pratiqués aux extrémités de ladite plaque (12, 12A).

10 - Système selon la revendication 9, caractérisé en ce que les trous de fixation (13, 14) de la plaque (12, 12A)

sont disposés de part et d'autre d'un axe vertical médian (X, X') de l'ensemble, sur une diagonale (Y, Y').

11 - Système selon l'une des revendications précédentes, caractérisé en ce qu'il met en oeuvre deux ou plus cages internes (1, 1A) solidarisées entre elles et par rapport à trois ou plus vertèbres successives par l'intermédiaire d'une plaque (12, 12A) comportant deux moyens d'assemblage (15, 18 ou 30, 32) avec lesdites cages (1, 1A) et deux trous de fixation d'extrémité (13, 14) et un trou intermédiaire coopérant avec trois ou plus vis pédiculaires d'ancrage sur les vertèbres.

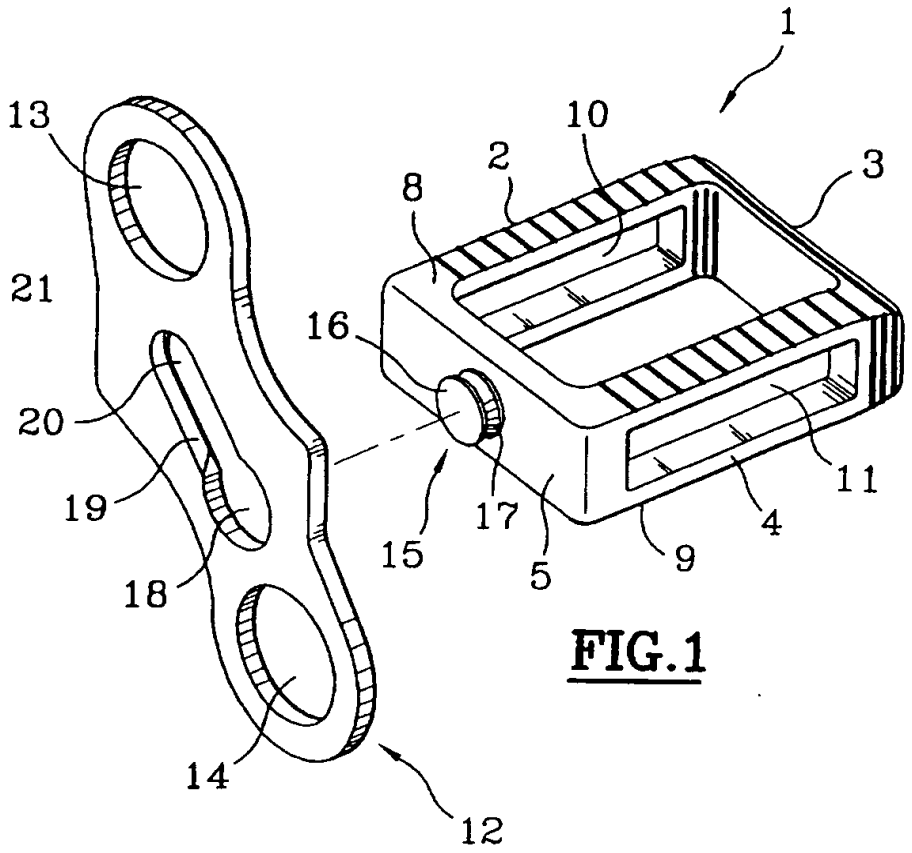
1
13
10
2
3
8
21
16
20
19
18
15
17
5
9
4
11
14
12

FIG.1

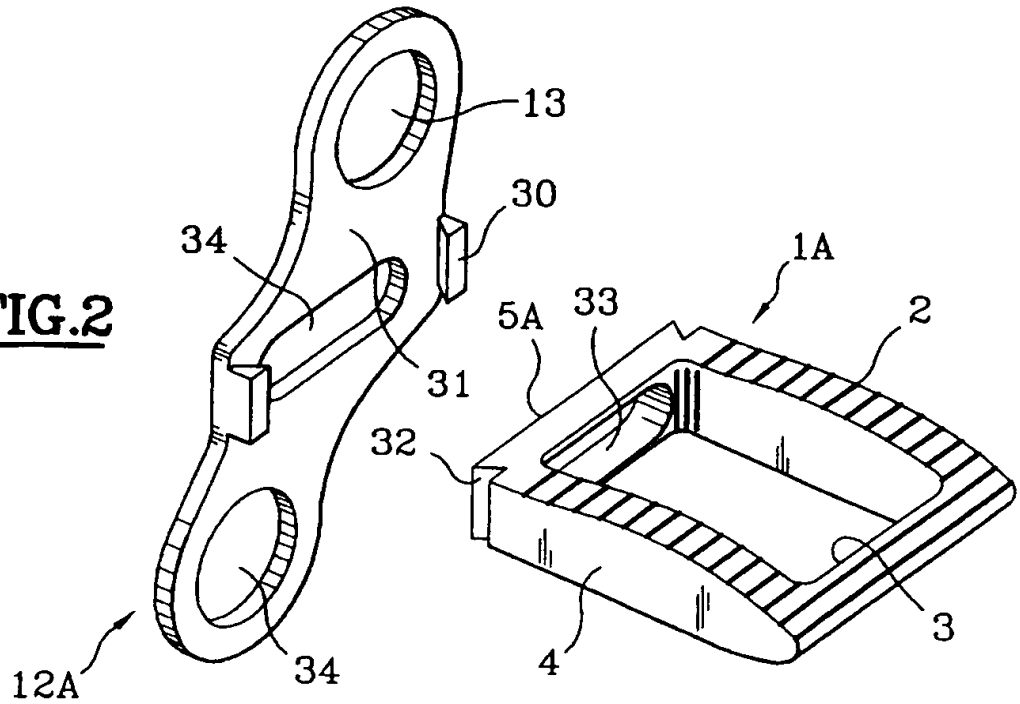
13
30
34
1A
5A
33
2
31
32
3
4
12A
34

FIG.2

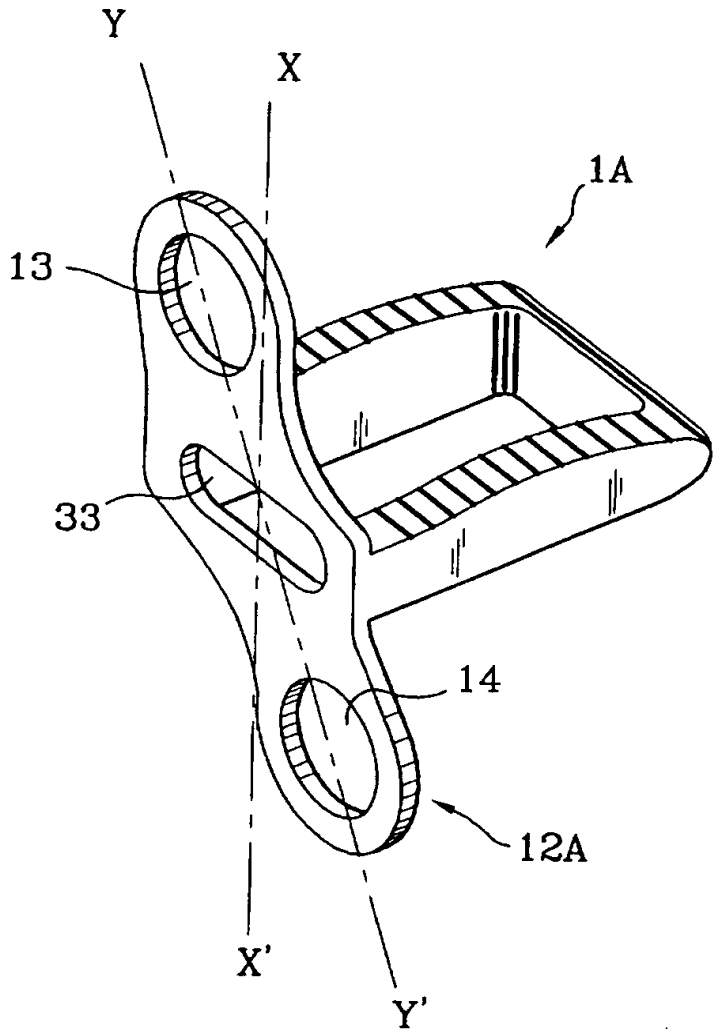

FIG.3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/FR 97/00591

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/44

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 95 08306 A (SYNTHESES AG) 30 March 1995 see claims 1,13; figures 3,8	1
Y A	EP 0 179 695 A (KEHR) 30 April 1986 see abstract; figures 1-4	1 2,9
A	EP 0 298 233 A (GEBRÜDER SULZER AG) 11 January 1989 see abstract; figures	1,2,9
A	US 4 599 086 A (DOTY) 8 July 1986 see column 4, line 47 - line 58; figures 1,7,9	1,4,9,11
A	DE 43 02 397 A (ASAHI KOGAKU KOGYO K.K.) 29 July 1993 see figures 1,13	1,2,4,9

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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

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

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

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

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

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
21 July 1997	06. 08. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Kanal, P

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/FR 97/00591

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 88 07 485 U (MECRON MEDIZINISCHE PRODUKTE GMBH) 10 August 1989 see figure 2 -----	1,2,9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/FR 97/00591

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9508306 A	30-03-95	BE 1007549 A	01-08-95
		CA 2151481 A	30-03-95
		EP 0670702 A	13-09-95
		JP 8503876 T	30-04-96
EP 179695 A	30-04-86	FR 2570594 A	28-03-86
EP 298233 A	11-01-89	CH 672588 A	15-12-89
		DE 3867154 A	06-02-92
		US 4955908 A	11-09-90
US 4599086 A	08-07-86	NONE	
DE 4302397 A	29-07-93	JP 5269160 A	19-10-93
		US 5534031 A	09-07-96
DE 8807485 U	10-08-89	CA 1325078 A	14-12-93
		DE 58905879 D	18-11-93
		EP 0346269 A	13-12-89
		JP 2111358 A	24-04-90
		US 5002576 A	26-03-91

RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale No
PCT/FR 97/00591

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 6 A61F2/44

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 6 A61F

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si cela est réalisable, termes de recherche utilisés)

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
Y	WO 95 08306 A (SYNTHESES AG) 30 Mars 1995 voir revendications 1,13; figures 3,8	1
Y A	EP 0 179 695 A (KEHR) 30 Avril 1986 voir abrégé; figures 1-4	1 2,9
A	EP 0 298 233 A (GEBRÜDER SULZER AG) 11 Janvier 1989 voir abrégé; figures	1,2,9
A	US 4 599 086 A (DOTY) 8 Juillet 1986 voir colonne 4, ligne 47 - ligne 58; figures 1,7,9	1,4,9,11
A	DE 43 02 397 A (ASAHI KOGAKU KOGYO K.K.) 29 Juillet 1993 voir figures 1,13	1,2,4,9

-/--

[X] Voir la suite du cadre C pour la fin de la liste des documents

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21 Juillet 1997	06. 08. 97

Nom et adresse postale de l'administration chargée de la recherche internationale	Fonctionnaire autorisé
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Formulaire PCT/ISA/210 (deuxième feuille) (juillet 1992)

RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale No
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C.(suite) DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas echéant, l'indication des passages pertinents	no. des revendications visées
A	DE 88 07 485 U (MECRON MEDIZINISCHE PRODUKTE GMBH) 10 Août 1989 voir figure 2 -----	1,2,9

1

RAPPORT DE RECHERCHE INTERNATIONALE

Renseignements relatifs aux membres de familles de brevets

Demande Internationale No
PCT/FR 97/00591

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
WO 9508306 A	30-03-95	BE 1007549 A	01-08-95
		CA 2151481 A	30-03-95
		EP 0670702 A	13-09-95
		JP 8503876 T	30-04-96
EP 179695 A	30-04-86	FR 2570594 A	28-03-86
EP 298233 A	11-01-89	CH 672588 A	15-12-89
		DE 3867154 A	06-02-92
		US 4955908 A	11-09-90
US 4599086 A	08-07-86	AUCUN	
DE 4302397 A	29-07-93	JP 5269160 A	19-10-93
		US 5534031 A	09-07-96
DE 8807485 U	10-08-89	CA 1325078 A	14-12-93
		DE 58905879 D	18-11-93
		EP 0346269 A	13-12-89
		JP 2111358 A	24-04-90
		US 5002576 A	26-03-91

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INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT)

(51) Internationale Patentklassifikation 6 : A61F 2/44, A61L 27/00 — A1

(11) Internationale Veröffentlichungsnummer: **WO 98/09586**

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(22) Internationales Anmeldedatum: 4. September 1996 (04.09.96)

(71) Anmelder *(für alle Bestimmungsstaaten ausser CA US)*: SYNTHES AG CHUR [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).

(71) Anmelder *(nur für CA)*: SYNTHES (U.S.A) [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).

(72) Erfinder; und

(75) Erfinder/Anmelder *(nur für US)*: WEBB, John [GB/GB]; Spinal Unit, Queen's Medical Centre, Nottingham (GB). KNOTHE, Inga, Maren [DE/CH]; Klösterlirain 2, CH-2542 Pieterlen (CH). HAEFELI, Thomas [CH/CH]; Bahnhofstrasse 35, CH-2540 Grenchen (CH). BENOIT, Alfred [CH/CH]; Nelkenweg 7, CH-2543 Lengnau (CH).

(74) Anwalt: LUSUARDI, Werther; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).

(81) Bestimmungsstaaten: CA, JP, US, europäisches Patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Veröffentlicht
Mit internationalem Recherchenbericht.

(54) Title: INTERVERTEBRAL IMPLANT

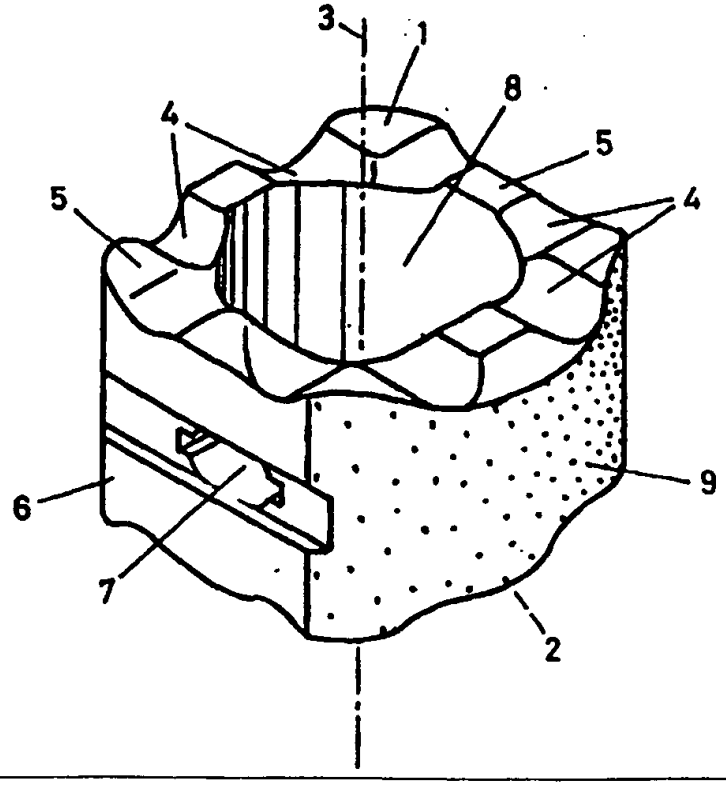
(54) Bezeichnung: ZWISCHENWIRBEL-IMPLANTAT

(57) Abstract

A hollow cylindrical intervertebral implant with a longitudinal axis (3), a covering surface (1) and a base surface (2), made essentially of a ceramic material presenting a maximum porosity of 30 vol. % and which pores are filled with air. The inventive implant is distinguished by the fact that it compensates the distance (corresponding to intervertebral disk height) - after successful primary fusion - between both vertebral bodies during the absorption process - upon adequate fusion - and is resorbed by said bodies after a certain amount of time.

(57) Zusammenfassung

Das hohlzylinderförmige Zwischenwirbel-Implantat mit der Längsachse (3), der Deckfläche (1) und der Grundfläche (2) besteht im wesentlichen aus einem keramischen Werkstoff, der eine Porosität von höchstens 30 Vol.-% aufweist und dessen Poren mit Luft gefüllt sind. Das erfindungsgemässe Implantat zeichnet sich dadurch aus, dass es - nach erfolgter Primärfusion - die Distanz (entsprechend der Bandscheibenhöhe) zwischen den beiden Wirbelkörpern während des Resorptionsprozesses - bei gleichzeitig adäquater Fusion - ausgleicht und nach einer bestimmten Zeit vom Körper resorbiert wird.



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Codes zur Identifizierung von PCT-Vertragsstaaten auf den Kopfbögen der Schriften, die internationale Anmeldungen gemäss dem PCT veröffentlichen.

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Zwischenwirbel-Implantat

Die Erfindung betrifft ein Zwischenwirbel-Implantat gemäss dem Oberbegriff des Patentanspruchs 1.

Solche Zwischenwirbel-Implantate werden bei der Fusion von Wirbelkörpern - nach der Entfernung der dazwischenliegenden Bandscheibe - eingesetzt, insbesondere im Bereich der lumbalen Wirbelsäule. Pro Zwischenwirbelraum werden ein bis zwei Implantate verwendet.

Aus der EP-B 346.269 FUHRMANN ET AL. ist bereits ein Zwischenwirbelimplantat bekannt, bei dem die nach aussen weisenden Stirn- und Seiten-Oberflächen des Implantats aus Hydroxyl-Apatit oder keramischem HIP-Material beschichtet sind. Nachteilig bei diesem bekannten Implantat ist der Umstand, dass der Grundkörper des Implantats aus üblichen nicht-keramischen und damit auch nicht-resorbierbaren Materialien besteht.

Aus der US-A-5 306 303 LYNCH ist bereits ein Zwischenwirbel-Implantat bekannt, welches vollständig aus einem porösen keramischen Material besteht. Nachteilig bei diesem bekannten Implantat ist jedoch einerseits die geringe Druckstabilität, die

sich aus der relativ hohen Porosität ergibt und anderseits, dass sich das Implantat nicht mit Knochenspänen füllen lässt, um eine schnellere Knochen-Einbettung zu erzielen.

Aus der EP 505 634 OKA et al. ist schliesslich ein weiteres Zwischenwirbelimplantat bekannt, welches aus einem porösen Keramik-Grundkörper mit in den Poren eingelagertem Hydrogel besteht. Auch bei diesem bekannten Implantat ist, wegen seiner mit Hydrogel gefüllten Poren, die Druckstabilität ungenügend.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt die Aufgabe zugrunde, ein Zwischenwirbel-Implantat zu schaffen, welches den verschiedenen Krafteinwirkungen an der Wirbelsäule standhalten kann und eine genügend grosse Auflage an den Endplatten aufweist, um ein Einsinken derselben zu verhindern. Es soll zudem eine möglichst rasche Fusion der beiden Wirbelkörper und eine rasche Inkorporation des Implantats ermöglichen unter Berücksichtigung der Höhe, welche die Bandscheibe vor deren Entfernung einnahm. In einem nächsten Schritt soll sich das Implantat vollständig (oder annähernd vollständig) durch körpereigenen Knochen ersetzen können.

Zur Lösung dieses Problems ist das eingangs genannte Implantat durch die Merkmale des kennzeichnenden Teils des unabhängigen Anspruchs 1 weitergebildet.

Damit ist der Vorteil erzielbar, dass das erfindungsgemässe Implantat - nach der erfolgten Primärfusion - die Distanz (entsprechend der Bandscheibenhöhe) zwischen den beiden Wirbelkörpern während des Resorptionsprozesses - bei gleichzeitig adäquater Fusion - ausgleicht und dass das Implantat nach einer bestimmten Zeit, wegen der auftretenden Resorption, im Körper nicht mehr nachweisbar ist.

Ein weiterer wesentlicher Vorteil ergibt sich auch aus der Röntgentransparenz des Implantats, welche störende Effekte bei der Beurteilung der umliegenden knöchernen Strukturen vermeidet..

Das Zwischenwirbelimplantat kann entweder als prismatischer oder zylindrischer Körper ausgebildet sein. Gemäss einer bevorzugten Weiterbildung der Erfindung beträgt die Porosität des keramischen Werkstoffs höchstens 9 Vol.-%, vorzugsweise höchstens 5 Vol.-%. Dank der verringerten Porosität des Implantats ergibt sich eine hohe Druckfestigkeit, was vor allem im lumbalen Bereich der Wirbelsäule eine Grundvoraussetzung bildet. Eine möglichst grosse druckstabile Kontaktfläche von Endplatte zu Implantat ist hier wichtig. Deshalb sollte die Wandstärke des ringförmigen Zwischenwirbel-Implantats mindestens 4 mm, vorzugsweise mindestens 6 mm betragen, um einem Einsinken des Implantats in die Endplatten vorzubeugen.

Bei einer weiteren bevorzugten Ausführungsform der Erfindung beträgt die Dichte des keramischen Werstoffs mehr als 2,8, vorzugsweise mehr als 3,1, was die Druckfestigkeit des Implantats weiter verbessert.

Vorzugsweise ist das Implantat als hohler Kreiszylinder ausgebildet, um das Einbringen von körpereigenen Knochenspänen oder ähnlichen biokompatiblen Materialien zu ermöglichen und somit einer raschen Fusion des Implantats Vorschub zu leisten.

Gemäss einer weiteren bevorzugten Ausführungsform der Erfindung ist die Deckfläche und/oder die Grundfläche des Implantats nicht planar ausgebildet, sondern weist quer zur Zylinderachse des Implantats verlaufenden Rillen und/oder Erhöhungen auf. Diese dreidimensionale Strukturierung der Deck- und Grundfläche ermöglich direkt nach dem Einführung des Implantats in den Zwischenwirbelraum eine Primärverankerung, womit die Lagestabilität des Implantats , bzw. die Rotationsstabilität der benachbarten Wirbelkörper erhöht wird. Die dreidimensionale Strukturierung ist vorzugsweise in Form von "Wellen" (Erhöhungen, bzw. Versteifungen mit ausgeprägten Radien) in Längs- und Querrichtung ausgebildet.

Je nach Anwendungsbereich des Implantats ist die Deckfläche und/oder die Grundflächen parallel oder keilförmig zueinander zulaufend angeordnet, um in jedem Bereich der Wirbelsäule die Kurvenbildung adäquat nachformen zu können (Lordose, Kyphose).

Das Implantat besitzt vorzugsweise eine nach aussen gewölbte konvexe Deckfläche und/oder Grundfläche, welche der konkaven Formgebung der natürlichen Wirbelkörper-Endplatten angeglichen ist, um eine bessere Kontaktzone zwischen Implantat und Endplatten zu erreichen.

Vorzugsweise weist der Mantel des Zwischenwirbel-Implantats eine oder mehrere Perforationen auf, welche primär der Aufnahme eines Instrumentes zur Manipulation des Implantats dienen. Die Perforationen können sowohl an der anterioren Seite des Implantats, als auch in der lateralen Zone des Implantats angebracht werden. Im weiteren dienen die Perforationen in der Mantelfläche zur Förderung der primären knöchernen Durchbauung des Implantats.

Die Lagestabilität des Implantats kann noch dadurch verbessert werden, dass der Mantel des Zwischenwirbel-Implantat mit einer feinen dreidimensionalen Strukturierung versehen wird, welche das Anwachsen des Knochens in einer frühen Phase fördert. Diese Feinstrukturierung ist vorzugsweise 0,5 - 1,0 mm tief bei einer Rillenbreite von 0,5 - 1,0 mm. Die Anordnung der Strukturierung kann über die gesamte Mantelfläche erfolgen.

Für das erfindungsgemässe Implantat eignen sich die üblichen in der Medizin bereits erprobten keramischen Materialien mit der erfindungsgemäss definierten Porosität, wobei insbesondere polykristalline Keramiken bevorzugt werden, bei welchen der Fremdphasenanteil kleiner als 3 vorzugsweise kleiner als 2

Gew.-% ist. Die Druckfestigkeit des keramischen Werkstoffs beträgt zweckmässigerweise 400 - 600 MPa, vorzugsweise 450 - 550 MPa.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellungen eines Ausführungsbeispiels noch näher erläutert.

Die einzige Figur zeigt:

Eine perspektivische Darstellung des erfindungsgemässen Implantats.

Das in der einzigen Figur dargestellte Zwischenwirbel-Implantat besteht im wesentlichen aus einem Hohlzylinder mit Innenraum 8, Längsachse 3, Deckfläche 1 und Grundfläche 2. Das Zwischenwirbel-Implantat besteht im wesentlichen aus einem polykristallinen, keramischen Werkstoff. Der keramische Werkstoff weist eine Porosität von 5 Vol.-% auf, wobei die Poren mit Luft gefüllt sind. Die Porenweite ist kleiner als 100 µm, vorzugsweise kleiner als 50 µm.
Der Fremdphasenanteil des keramischen Materials beträgt 1,5 Gew.-%. Die Druckfestigkeit des keramischen Werkstoffs beträgt 500 MPa.

Die Deck- und Grundflächen 1,2 sind für den Knochenkontakt zu den Deckplatten zweier Wirbelkörper bestimmt und entsprechend ausgebildet. Die Wandstärke des Zwischenwirbel-Implantats beträgt 7 mm und die Dichte des keramischen Werkstoffs beträgt 3,2. Die Deckfläche 1 und die Grundfläche 2 sind nicht planar ausgebildet, sondern sind mit einer Anzahl quer (d.h. radial) zur Längsachse 3 verlaufender Rillen 4 und Erhöhungen 5 versehen.
Die Deckfläche 1 und die Grundfläche 2 sind zueinander keilförmig zulaufend angeordnet und sind leicht nach aussen konvex gewölbt.

Im Mantel 6 des Zwischenwirbel-Implantats ist anterior eine Perforation 7 vorgesehen, welche der Aufnahme eines Manipulations-Instrumentes dient. Der Mantel ist ferner mit einer dreidimensionalen Strukturierung 9 versehen, welche eine Tiefe von 0,75 mm aufweist.

Nachstehend wird nun die klinische Anwendung des erfindungsgemässen Zwischenwirbelimplantats im Detail beschrieben.

Das in der einzigen Figur gezeigte Implantat wird mit Knochenspänen (bone graft oder Knochenersatzmaterial), eventuell unter Komprimierung derselben, gefüllt, mit einem geeigneten in die Perforation 7 eingeführten Instrument gefasst und unter

Zuhilfenahme eines Distraktionsinstrumentes in den ausgeräumten Zwischenwirbelraum eingeführt.

Patentansprüche

1. Zwischenwirbel-Implantat prismatischer oder zylindrischer Gestalt mit der Längsachse (3), dessen Deckfläche (1) und Grundfläche (2) für den Knochenkontakt zu den Deckplatten zweier Wirbelkörper bestimmt sind, wobei das Zwischenwirbel-Implantat im wesentlichen aus einem keramischen Werkstoff besteht,
dadurch gekennzeichnet, dass
A) der keramische Werkstoff eine Porosität von höchstens 30 Vol.-% aufweist und
B) die Poren des keramischen Werkstoffs mit Luft gefüllt sind.

2. Implantat nach Anspruch 1, dadurch gekennzeichnet, dass die Porosität des keramischen Werstoffs höchstens 9 Vol.-%, vorzugsweise höchstens 5 Vol.-% beträgt.

3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Wandstärke des Zwischenwirbel-Implantats mindestens 4 mm, vorzugsweise mindestens 6 mm beträgt.

4. Implantat nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die Dichte des keramischen Werstoffs grösser als 2,8, vorzugsweise grösser als 3,1 ist.

5. Implantat nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass das Zwischenwirbel-Implantat als hohler Kreiszylinder mit der Längsachse (3) ausgebildet ist.

6. Implantat nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass die Deckfläche (1) und/oder die Grundfläche (2) nicht planar ausgebildet ist und vorzugsweise mit quer zur Längsachse (3) verlaufenden Rillen (4) und/oder Erhöhungen (5) versehen ist.

7. Implantat nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass die Deckfläche (1) und die Grundfläche (2) parallel zueinander angeordnet sind.

8. Implantat nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass die Deckfläche (1) und die Grundfläche (2) keilförmig zueinander zulaufend angeordnet sind.

9. Implantat nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, dass die Deckfläche (1) und/oder die Grundfläche (2) nach aussen konvex gewölbt ist.

10. Implantat nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, dass der Mantel (6) des Zwischenwirbel-Implantats mit einer oder mehreren Perforationen (7) versehen ist.

11. Implantat nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, dass der Mantel (6) des Zwischenwirbel-Implantat mit einer dreidimensionalen Strukturierung (9) versehen ist, vorzugsweise mit einer Tiefe der Strukturierung von 0,5 - 1,0 mm.

12. Implantat nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, dass das keramische Material polykristallin ist.

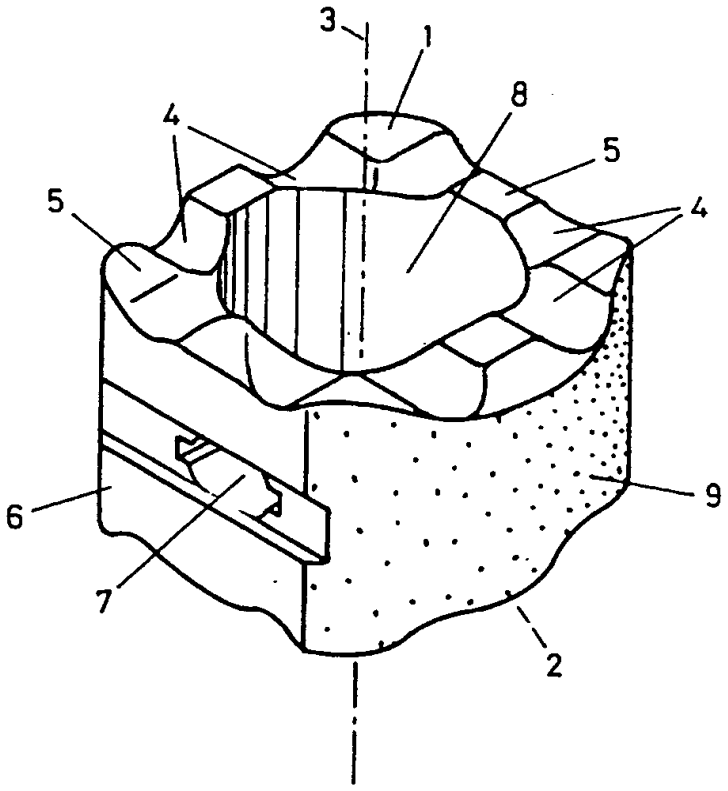
13. Implantat nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, dass das keramische Material einen Fremdphasenanteil von kleiner als 3 vorzugsweise kleiner als 2 Gew.-% aufweist.

14. Implantat nach einem der Ansprüche 1 bis 13, dadurch gekennzeichnet, dass die Druckfestigkeit des keramischen Werkstoffs 400 - 600 MPa, vorzugsweise 450 - 550 MPa beträgt.

15. Implantat nach einem der Ansprüche 1 bis 14, dadurch gekennzeichnet, dass die Porenweite kleiner als 100 µm, vorzugsweise kleiner als 50 µm ist.

16. Implantat nach einem der Ansprüche 1 bis 15, dadurch gekennzeichnet, dass der keramische Werkstoff röntgentransparent ist.

1/1



INTERNATIONAL SEARCH REPORT

In ational Application No
PCT/CH 96/00303

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/44 A61L27/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 493 698 A (HÄRLE) 8 July 1992 see the whole document ---	1,8,10, 15
A	WO 88 03417 A (MATERIAL CONSULTANTS OY) 19 May 1988 see page 24, line 9 see page 32, line 11 - line 20 see abstract; figures 6,7 ---	1,7,16
A	US 4 683 161 A (RICE) 28 July 1987 see column 1, line 47 - line 54 see column 9, line 54 - line 56 --- -/--	1

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Date of the actual completion of the international search	Date of mailing of the international search report
12 May 1997	20.05.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Klein, C

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH 96/00303

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	FR 2 703 580 A (ROBERT) 14 October 1994 see abstract; figure 1	6,8,16
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INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH 96/00303

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
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IPK 6 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	EP 0 493 698 A (HÄRLE) 8.Juli 1992 siehe das ganze Dokument ---	1,8,10, 15
A	WO 88 03417 A (MATERIAL CONSULTANTS OY) 19.Mai 1988 siehe Seite 24, Zeile 9 siehe Seite 32, Zeile 11 - Zeile 20 siehe Zusammenfassung; Abbildungen 6,7 ---	1,7,16
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[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

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12.Mai 1997	20.05.97

Name und Postanschrift der Internationale Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Klein, C

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INTERNATIONALER RECHERCHENBERICHT

In ternationales Aktenzeichen
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C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	EP 0 505 634 A (KYOCERA CORPORATION) 30.September 1992 in der Anmeldung erwähnt siehe Seite 5, Zeile 25; Abbildungen 2-4 siehe Zusammenfassung; Anspruch 6	1,7
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Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

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(71) Applicant: SURGICAL DYNAMICS, INC. [US/US]; 111 Glover Avenue, Norwalk, CT 06856 (US).

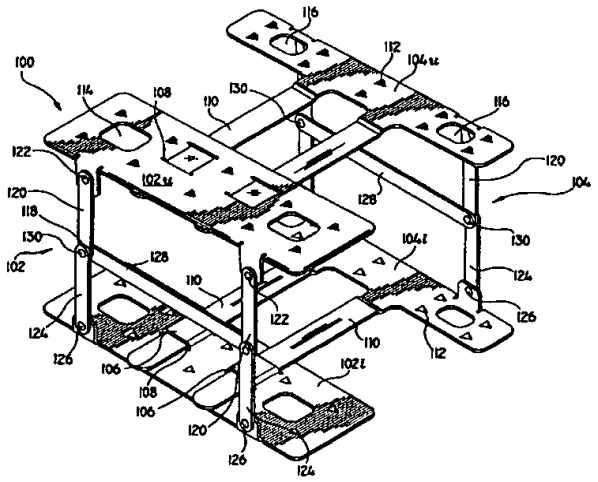
(72) Inventors: LARSEN, Scott, W.; 18 Sugar Hill Road, Newtown, CT 06470 (US). SHIKHMAN, Oleg; 80 Camp Field Drive, Fairfield, CT 06432 (US).

(74) Agent: GERSHON, Neil, D.; United States Surgical Corporation, 150 Glover Avenue, Norwalk, CT 06856 (US).

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

Published
With international search report.

(54) Title: SPINAL FUSION IMPLANT AND METHOD OF INSERTION THEREOF



(57) Abstract

A spinal fusion implant includes lower and upper plate members (1021, 1041, 102u, 104u) dimensioned for at least partial insertion within the intervertebral space defined between adjacent vertebrae. The lower and upper plate members (1021, 1041, 102u, 104u) have contacting surfaces (112) for engaging respective vertebral end faces of the adjacent vertebrae. A linkage mechanism (118) including at least one link member operatively connects the lower and upper plate members (1021, 1041, 102u, 104u). The linkage mechanism (118) is actually to cause relative movement of the lower and upper plate members (1021, 1041, 102u, 104u), wherein upon actuation, the contacting surfaces of the lower and upper plate members engage the vertebral end faces with the lower and upper plate members (1021, 1041, 102u, 104u) supporting the adjacent vertebrae in spaced relation during healing.

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SPINAL FUSION IMPLANT AND METHOD OF INSERTION THEREOF

BACKGROUND

1. Technical Field

The present disclosure relates generally to a surgical apparatus for fusing adjacent bone structures, and, more particularly, to an apparatus and method for fusing adjacent vertebrae.

2. Background of the Related Art

The fusion of adjacent bone structures is commonly performed to provide for long-term replacement to compensate for degenerative or deteriorated disorders in bone. For example, an intervertebral disc which is a ligamentous cushion disposed between adjacent vertebrae, may undergo deterioration as a result of injury, disease, tumor or other disorders. The disc shrinks or flattens leading to mechanical instability and painful disc translocations.

Conventional procedures for disc surgery include partial or total excision of the injured disc portion, e.g., discectomy, and replacement of the excised disc with biologically acceptable plugs or bone wedges. The plugs are driven between adjacent vertebrae to maintain normal intervertebral spacing and to achieve, over a period of time, bony fusion with the plug and opposed vertebrae. For example, U.S. Patent No. 4,887,020 to Vich discloses a cylindrical bone plug having a thread on its exterior, which is screwed into a correspondingly dimensioned cylindrical bore drilled in the intervertebral space.

Other devices and methods for intervertebral fusion are disclosed in U.S. Patent Nos. 4,863,477 to Monson; 4,874,389 to Downey; 4,932,969 to Fray et al;

5,306,307 to Senter et al; 5,306,308 to Gross et al.; and 5,401,269 to Buttner-Janz et al. The Monson '477 device discloses a synthetic intervertebral disc prosthesis molded in the same shape and general dimensions as a natural disc. The prosthesis includes two halves joined together to form a body having a fluid-tight cavity in its interior. The upper and lower surfaces of the disc each have a plurality of small suction cup-like projections molded thereon for frictionally engaging the adjacent vertebrae. The prosthesis is inserted within the intervertebral space and a volume of fluid is injected into the interior cavity of the prosthesis to create the necessary amount of resiliency which restores proper vertebral spacing.

More recently, emphasis has been placed on fusing bone structures (i.e., adjoining vertebrae) with prosthetic cage implants. One fusion cage implant is disclosed in commonly assigned U.S. Patent No. 5,026,373 to Ray et al.. The Ray '373 fusion cage includes a cylindrical cage body having a thread formed as part of its external surface and apertures extending through its wall which communicate with an internal cavity of the cage body. The fusion cage is inserted within a tapped bore or channel formed in the intervertebral space. The adjacent vertebral bone structures communicate through the apertures with bone growth inducing substances within the internal cavity to unite and eventually form a solid fusion of the adjacent vertebrae.

SUMMARY

Accordingly, the present disclosure is directed to further improvements in the fusion of adjacent bone structures, e.g., adjacent vertebrae. In a preferred embodiment, an implant for insertion within an intervertebral space between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation is disclosed. The implant includes lower and upper plate members dimensioned for at least partial insertion within the

intervertebral space and having contacting surfaces for engaging respective vertebral end faces of the adjacent vertebrae. A linkage mechanism including at least one link member operatively connects the lower and upper plate members. The linkage mechanism is actuable to cause relative movement of the lower and upper plate members, wherein upon actuation, the contacting surfaces of the lower and upper plate members engage the vertebral end faces with the lower and upper plate members supporting the adjacent vertebrae in spaced relation during healing. The linkage mechanism is preferably adapted to cause lateral displacing movement of at least one plate member upon actuation thereof such that contacting surfaces of the lower and upper plate members are in general parallel relation when in the deployed position. Preferably, the contacting surfaces of the lower and upper plate members have discontinuities to engage the vertebral end plates. The discontinuities may be in the form of projections dimensioned for penetrating the vertebral end plates. The lower and upper plate members may further include at least one opening extending therethrough to permit bone ingrowth.

In another preferred embodiment, an implant for insertion within the intervertebral space includes first and second plate members having engaging surfaces with discontinuities to engage vertebral end faces of the vertebrae, and at least one resilient member disposed between the first and second plate members to bias the first and second plate members to a generally open spaced arrangement. The one resilient member is configured and dimensioned to exert forces on the plate members sufficient to support the adjacent vertebrae in spaced relation during healing while permitting relative movement thereof to accommodate variations in loads realized during normal flexural movement of the vertebral column. Preferably, the one resilient member is a coil spring member. A plurality of coiled spring members may be incorporated as well.

In another preferred embodiment, an implant for insertion within the intervertebral space includes at least first and second supporting members dimensioned for insertion within the intervertebral space and having contacting surfaces for contacting vertebral end faces of the adjacent vertebrae. The first member has an inner arcuate articulating surface cooperating with a correspondingly dimensioned outer arcuate articulating surface of the second member to permit articulating movement of the first member so as to accommodate movement of the vertebral column during healing. Articulating surfaces of the first and second plate members each define a constant radius of curvature with the radius of curvature of each of the first and second plate members being substantially equal.

The contacting surfaces of the first and second plate members each include a plurality of apertures to permit bone ingrowth. A resilient member may be disposed between the first and second support members to facilitate the absorption of compressive forces.

In yet another preferred embodiment, the implant includes at least first and second support members having engaging surfaces for engaging vertebral end plates of the vertebrae, and a camming arrangement having at least one camming member operatively engageable with the first and second support members. The camming member is moveable to move the first and second support members between a non-deployed position and a deployed position. The camming member includes a camming block having a camming surface which is engageable with a corresponding camming surface of at least one of the support members whereby, upon movement of the camming member, the camming surfaces interact to move the first and second support members between the non-deployed and the deployed positions. An actuating screw transverses a bore defined in the camming block and threadably engages a threaded bore associated with one of the first and second

support members. The actuating screw is rotatable to cause corresponding movement of the camming block.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the disclosure are described hereinbelow with reference to the drawings wherein:

FIG. 1 is a perspective view of a preferred embodiment of the implant for facilitating spinal fusion constructed in accordance with the principles of the present disclosure;

FIG. 2 is a perspective view with parts separated of the implant of FIG. 1;

FIG. 3 is a perspective view of the implant in a collapsed position;

FIG. 4 is a view illustrating the implant in the collapsed position and inserted within an intervertebral space defined between adjacent vertebrae;

FIG. 5 is an isolated view further depicting the implant positioned within the intervertebral space;

FIG. 6 is a view similar to the view of FIG. 5 illustrating the implant in its extended position supporting the adjacent vertebrae in spaced relation;

FIG. 7 is a perspective view of an alternate embodiment of the implant of FIG. 1;

FIG. 8 is a perspective view with parts separated of the implant of FIG. 7 illustrating the first and second support members, support springs disposed between the support members and a flexible cover surrounding the support spring;

FIG. 9 is a sectional view illustrating the implant positioned within the intervertebral space;

FIG. 10 is an isolated view illustrating a preferred arrangement for mounting the flexible cover about the support members;

FIG. 11 is a view similar to the view of FIG. 9 illustrating the implant slightly compressed during normal flexural movement of the vertebral column;

FIG. 12 is a perspective view of another alternate embodiment of the spinal implant;

FIGS. 13-14 are perspective view of the respective upper and lower support members of the implant of FIG. 12 illustrating the ball and socket arrangement for permitting relative articulating movement of the support members;

FIG. 15 is a side plan view of the spinal implant of FIG. 12 in the assembled condition;

FIG. 16 is a sectional view illustrating the implant positioned within the intervertebral space;

FIG. 17 is a view similar to the view of FIG. 16 illustrating articulating movement of the upper support member via the ball and socket arrangement;

FIG. 18 is a side plan view of an alternate embodiment of the spinal implant of FIG. 12 incorporating a resilient layer disposed between the upper and lower support member;

FIG. 19 is a sectional view illustrating the implant of FIG. 18 positioned within the intervertebral space;

FIG. 20 is a view similar to the view of FIG. 19 illustrating articulating movement of the upper support member relative to the lower support member;

FIG. 21 is a perspective view of another alternate embodiment of the spinal implant;

FIG. 22 is a perspective view with parts separated of the implant of FIG. 21 illustrating the upper and lower support members, and the camming mechanism disposed between the support members for selectively moving the first and second support members between a retracted position and an extended position;

FIG. 23 is a sectional view illustrating the implant in the retracted position positioned within the intervertebral space;

FIG. 24 is a view similar to the view of FIG. 23 illustrating the implant in the extended position;

FIG. 25 is a side plan view of another alternate embodiment of the spinal implant;

FIG. 26 is a cross-sectional view taken along the lines 26-26 of FIG. 25; and

FIGS. 27-28 are views similar to the view of FIG. 26 illustrating adjusting motion of the implant during flexural movement of the vertebral column.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

The apparatus of the present disclosure is intended for fusing adjacent bone structures and has particular application in the spinal fusion of adjacent vertebrae subsequent to a discectomy procedure. The apparatus may be implanted using any conventional surgical approach, e.g., anterior and/or posterior approaches, or may be implanted utilizing minimally invasive or endoscopic surgical techniques currently being utilized to carry out discectomy and spinal implant procedures.

Referring now to FIGS. 1-3, there is illustrated the apparatus constructed in accordance with the principles of the present disclosure. Apparatus 100 includes two separable support components 102, 104 which are adapted for adjusting sliding movement

relative to each other to selectively vary the overall width of the implant. Support component 102 has upper and lower support plates 102u,102l while support component 104 has upper and lower plates 104u, 104l. As shown, plates 102u, 102l of component 102 each have a greater width than plates 104u, 104l of component 104.

Upper and lower plate portions 102u, 102l of support component 102 each include two raised portions 106 extending generally transversely therefrom which define longitudinal slots 108. Upper and lower plates 104u, 104l each have two transverse tongue portions 110 extending therefrom which are correspondingly dimensioned to be received within transverse slots 108 to mount support component 104 to support component 102. Tongue portions 110 are strategically dimensioned to slide within slots 108 thereby permitting selective adjusting movement of the component 104 relative to component 102. In this manner, the overall width of implant 100 may be varied to accommodate vertebral columns of various sizes or to increase or minimize the supporting capacity of the implant during healing. In particular, support components 102, 104 may be selectively moved toward each other via the tongue and slot arrangement to decrease the overall width of the implant 100 thereby permitting more lateral movement of the vertebral column during healing. On the other hand, support components 102, 104 may be moved away from each other to increase the overall width of the implant thereby providing a more stabilizing effect to the vertebral column.

Referring still to FIGS. 1-3, upper plate portions 102u, 104u and lower plate portions 102l, 104l each possess associated outer contacting surfaces which engage the vertebral end faces. The contacting surfaces define discontinuities to assist in engaging the vertebral end faces upon insertion within the intervertebral space. Preferably, the discontinuities are in the form of triangular-shaped projections 112 extending from the contacting surfaces, which define pointed edges to penetrate the vertebral end faces to

thereby resist tendency of the implant to move or become dislodged once positioned within the adjacent bone structures. Other discontinuities are envisioned as well such as knurling, bristle-coatings, etc... Upper plate portions 102u, 104u and lower plate portions 102l, 104l also include apertures 114, 116. Apertures 114, 116 permit bone ingrowth through their respective plates to facilitate fusion of the implant with the vertebral bodies.

As best depicted in FIG. 1, linkage mechanism, identified generally by reference numeral 118, respectively operatively connects upper and lower plate portions 102u, 102l and upper and lower plate portions 104u, 104l. Each linkage mechanism 118 is preferably identical and includes transverse connecting links 120 connected to opposed ends of upper plate portions 102u, 104u through pins 122 and transverse connecting links 124 connected to opposed ends of lower plate portions 102l, 104l through pins 126. Connecting links 120, 124 are interconnected by longitudinal links 128 through pins 130. Each linkage mechanism 118 is moveable between the extended position shown in FIG. 1 where upper and lower plate portions are at their most displaced position and a collapsed position shown in FIG. 3.

Referring now to FIGS. 4-5, the implant 100 is shown positioned within the intervertebral space "i" defined between adjacent vertebrae "V_1, V_2". Implant 100 is typically inserted within the intervertebral space "i" subsequent to a discectomy procedure. Discectomy involves removal of a least a portion of the degenerated disc material with the use of the cutting instruments (not shown) e.g., scalpels, rongeurs, etc...

Prior to insertion, the width of implant 100 is adjusted by selectively adjusting the relative positioning of support components 102, 104 through the tongue and slot arrangement in the manner discussed above. Implant 100, in its collapsed condition, is thereafter positioned within the intervertebral space "i" with the use of a grasping instrument (not shown). As mentioned, conventional anterior or posterior approaches, as

well as laparosopic approaches, may be utilized. In the collapsed condition, implant 100 presents a reduced profile which facilitates its insertion. Once implant 100 is inserted and appropriately positioned, the linkage mechanisms 118 are actuated to displace upper plate portions 102u, 104u from lower plate portions 102l, 104l to move the implant to at least a partially extended position shown in FIG. 6. In this position, upper and lower plate portions 102u, 104u, 102l, 104l contact the vertebral end plates of the adjacent vertebrae in supporting engaged relation with triangular projections 112 of the plate portions penetrating the end plates to securely fix the implant member within the intervertebral space. In the deployed or extended position of FIG. 6, implant 100 forms a strut between adjacent vertebrae "V_1 V_2" supporting the vertebrae in desired spaced relation. Linkage mechanisms 118 sufficiently support components 102,104 in the extended position. It is envisioned that linkage mechanisms 118 may be locked in the deployed position by conventional arrangements such as with locking screws, etc... As shown, upper plate portions 102u, 104u are in general parallel relation with lower plate portions 102l, 104l. Over a period of time, the adjacent vertebral tissue communicates through apertures 114, 118 defined in the support components 102, 104 to form a solid fusion.

It is envisioned that the interior cavity of implant 100 defined between the upper and lower plate portions may be packed with bone growth inducing substances as known in the art prior to insertion to facilitate the fusion process.

Referring now to FIGS. 7-8, there is illustrated an alternate embodiment of the spinal implant of the present disclosure. Implant 200 is intended to be used in a similar manner to that described in connection with implant 100 of FIG. 1, i.e., within the intervertebral space defined between adjacent vertebrae subsequent to a discectomy procedure. Implant 200 includes first and second plate members 202, 204 supported in spaced relation by a plurality of coiled support springs 206 which are disposed between the

plate members 202, 204. Springs 206 are received in correspondingly dimensioned impressions 208 defined in the inner surfaces of first and second plate members 202, 204 and extend in a generally transverse direction relative to each plate 202, 204 as shown. Support springs 206 permit deflecting movement, e.g., compressive movement of first and second plate members 202, 204 to permit flexural compressive movement of the vertebral column. Springs 206 are correspondingly dimensioned to provide sufficient force to withstand extreme compressive forces exerted by the spinal column.

As best depicted in FIGS. 8-9, first plate 202 includes a plurality (e.g., four) of transversely extending rigid tubular portions 210. Second plate 204 includes a plurality (e.g., four) of transversely extending rigid rod portions 212 extending from the inner surface thereof. Rod portions 212 are correspondingly dimensioned to be received within inner bores 214 defined by the tubular portions 210 to facilitate mounting of the first and second plate members 202, 204. In particular, the tubular portion 210 and rod portion 212 arrangement functions in preventing lateral movement of the first plate member 202 relative to the second plate member 204. The arrangement also serves in limiting the amount of compressive movement of plate members 202, 204 by engagement of the remote ends 210e of the tubular portions 210 with the inner surface of plate member 204. It is to be noted that tubular portions 210 are appropriately dimensioned to permit reciprocating movement of the rod portions 212 therein during compressive movement of the vertebral column.

Referring to FIGS. 9-10, in conjunction with FIG. 8, a flexible cover 216 may be positioned about the periphery of implant 100 to enclose the coiled spring members 206. Cover 216 is preferably fabricated from a suitable biocompatible material. Cover 216 functions in preventing bone ingrowth from contacting the coiled support springs 206. Bone ingrowth within support spring 206 may potentially degrade the functioning of

springs 206. Cover 216 is preferably mounted to upper and lower plate members 202, 204 through a tongue and groove arrangement shown in detail in FIG. 10. Preferably, the outer ends of flexible cover 216 define a tongue 218 which is accommodated within corresponding recesses 220 formed in first and second plate members 202, 204.

FIGS. 9 and 11 depict implant 100 positioned within the intervertebral space "i" defined between adjacent vertebrae "V_1 V_2". FIG. 9 illustrates implant 100 in a fully extended position corresponding to a minimal load exerted on the vertebral column. FIG. 11 illustrates implant 100 in a compressed condition when the vertebral column is subjected to a large compressive load with support springs 206 absorbing the load. In addition, in the inserted position of implant 200, pyramid-shaped projections 222 extending from the contacting surface 202, 204 penetrate the vertebral end plates of the "V_1, V_2" to facilitate mounting of the implant 200 within the intervertebral space "i", and to prevent the implant 200 from becoming dislodged prior to achieving full fusion with the adjacent vertebrae "V_1, V_2".

Referring now to FIGS. 12-17 there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Spinal implant 300 includes first and second support members 302, 304 which supportingly engage adjacent vertebrae "V_1, V_2" upon insertion within an intervertebral space "i". Support member 302 includes a pair of parallel plates 306, 308 interconnected to each other through transverse side plate portions 312 and transverse intermediate plate portion 314. Similarly, second support member 304 includes a pair of parallel plate portions 316, 318 interconnected by side plate portions 320 and intermediate plate portion 322. First support member 302 and second support member 304 are preferably each integrally formed to form a single unit and may be fabricated from a ceramic material, a biocompatible metallic material or a biocompatible polymeric material. The respective upper and lower plate portions 306, 318 of first and

second support members 302, 304 have tissue contacting surfaces which define discontinuous surfaces to permit bone ingrowth during fusion. In a preferred embodiment, the discontinuous surfaces include a plurality of apertures 324 which permit bone ingrowth and a plurality of projections 326 which are disposed on a peripheral area of the respective plate portions. Projections 326 define penetrating tip portions which engage the vertebral end plate upon application within the intervertebral space.

Referring now to FIGS. 13-15, first and second support members 302, 304 are supported in general spaced relation by a ball and socket arrangement. In particular, first support member 302 has an integrally formed spherical portion 328 extending from lower plate 308. Second support member 304 has a projecting portion 330 extending from upper plate 316 and defining a generally spherical recess or socket 332 correspondingly dimensioned to accommodate spherical portion 328 of first support member 302. Spherical portion 328 is capable of articulating movement within socket 332 thereby permitting the vertebral column to flex through a generally "normal" range of motion. Preferably, spherical portion 328 and socket 332 define generally equivalent radii of curvatures.

FIGS. 16 and 17 depict spinal implant 300 disposed within the intervertebral space "i" defined between adjacent vertebrae "V_1, V_2". As shown in FIG. 16, implant 300 supportingly contacts the upper and lower vertebrae "V_1, V_2" through the engagement of first support member 302 and second support member 304 with the vertebral end faces. Projections 326 extending from the upper and lower plate portions 316, 318 of first and second support members 302, 304 penetrate the vertebral end faces to assist in retaining the implant 300 within the intervertebral space "i" during healing.

FIG. 17 illustrates the articulating movement of the first support member 302 relative to the second support member 304 during movement of the spine. As shown, spherical portion 328 slides within socket 332 to permit such articulating movement.

FIGS. 18-20 depict an alternate embodiment of the spinal implant 300 of FIGS. 12-17. This embodiment is similar in most respects to the implant 300, but, further incorporates a resilient layer 350 disposed between first and second support members 302, 304. Resilient layer 350 is preferably a sponge like material and serves to provide a cushion between first and second support members 302, 304 and the adjacent vertebrae "V_1, V_2" to accommodate compressive forces realized by the vertebral column during movement as depicted in FIG. 20.

Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebrae "V_1, V_2" upon insertion within the intervertebral space "i". Implant 400 further includes a camming arrangement for moving upper and lower support members 402, 404 between an open and a closed position. The preferred camming arrangement includes a camming block 412 which is adapted for traversing movement within the interior of implant 400. Camming block 412 defines an inclined camming surface 414 which engages a correspondingly dimensioned inner surface 416 of support member 402. The camming arrangement further includes a threaded element, e.g., screw 418, which traverses a bore 420 within camming block 412 and threadably engages an internal threaded bore 422 of lower support member 404.

Support members 402, 404 are interconnected through a pin and slot arrangement. More particularly, support member 402 has a pair of transversely extending slots 424 formed in side plates 426. Support member 404 has a pair of correspondingly positioned apertures 428 formed in side plates 430. A pin 432 traverses each slot and

opening arrangement to connect upper support member 402 and lower support member 404.

FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402.

Referring now to FIGS. 25-28, another alternate embodiment of the present disclosure is illustrated. Implant 500 includes upper and lower support members 502, 504 and at a resilient layer 506 disposed between the support members 502, 504. Each support member 502, 504 includes first and second plate members 508, 510. First and second plate members 508, 510 are interconnected by peripheral interconnecting members 512, 514 and intermediate interconnecting member 516. An internal cavity 518 is defined between the plate members 508, 510. Support members 502, 504 are each preferably integrally formed to form a single component as shown.

First plate member 508 has a plurality of apertures 520 extending therethrough in communication with internal cavity 518 to promote bone ingrowth to facilitate the fusion process. A plurality of triangular-shaped projections 522 or teeth extend from the first plate member 508 and are dimensioned to penetrate the vertebral end faces to facilitate retention of the implant 500 within the intervertebral space. First plate member 510 of support member 504 is preferably inclined relative to axis "a" of the implant. This inclined configuration provides.

Resilient layer 506 disposed between plate members 508, 510 is preferably formed of a resilient material such as synthetic rubber or other elastomeric material. Resilient layer 506 provides sufficient forces to maintain the adjacent vertebrae in spaced relation while permitting relative flexural compressive movement of the vertebral column as depicted in FIGS. 27-28. Alternately, instead of resilient layer 506, compression springs, covered by a flexible film so as not to interfere with surrounding tissue, could be positioned between the upper and lower support member. Parallel pins to provide shear strength can be positioned adjacent the springs spanning the space between the upper and lower supports.

While the above description contains many specifics, these specifics should not be construed as limitations on the scope of the disclosure, but merely as exemplifications of preferred embodiments thereof. Those skilled in the art will envision many other possible variations that are within the scope and spirit of the disclosure as defined by the claims appended hereto.

WHAT IS CLAIMED IS:

1. An implant for insertion within an intervertebral space between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation, which comprises:

lower and upper plate members dimensioned for at least partial insertion within the intervertebral space defined between adjacent vertebrae, the lower and upper plate members having contacting surfaces for engaging respective vertebral end faces of the adjacent vertebrae; and

a linkage mechanism including at least one link member operatively connecting the lower and upper plate members, the linkage mechanism actuable to cause relative movement of the lower and upper plate members, wherein upon actuation, the contacting surfaces of the lower and upper plate members engage the vertebral end faces with the lower and upper plate members supporting the adjacent vertebrae in spaced relation during healing.

2. The prosthetic implant according to claim 1 wherein the linkage mechanism is adapted to cause lateral displacing movement of at least one plate member upon actuation thereof such that the contacting surfaces of the lower and upper plate members are in general parallel relation when in the deployed position.

3. The prosthetic implant according to claim 2 wherein the contacting surfaces of the lower and upper plate members have discontinuities to engage the vertebral end plates.

4. The prosthetic implant according to claim 3 wherein the discontinuities are projections dimensioned for penetrating the vertebral end plates.

5. The prosthetic implant according to claim 3 wherein the lower and upper plate members each include at least one opening extending therethrough to permit bone ingrowth.

6. The prosthetic implant according to claim 1 wherein each of the lower and upper plate members include first and second plate portions, the first and second plate portions being relatively moveable such that the width of each plate member is selectively adjustable.

7. The prosthetic implant according to claim 6 including two linkage mechanisms, a first of the linkage mechanisms interconnecting the first plate portions of the lower and upper support members, a second of the linkage mechanisms interconnecting the second plate portions of the first and second support members.

8. The prosthetic implant according to claim 7 wherein the first and second plate portions are connected through a tongue and slot arrangement, the tongue and slot arrangement adjustable to permit relative movement of the first and second plate portions.

9. An implant for insertion within an intervertebral space between adjacent vertebrae for supporting the vertebrae in spaced relation during healing, which comprises an implant member including first and second support components, the support

components being operatively connected and moveable relative to each other to selectively adjust the effective width of the implant member, each support component including upper and lower plate portions with contacting surfaces for engaging respective vertebral end faces of the adjacent vertebrae.

10. An implant for insertion within an intervertebral space defined between adjacent vertebrae, comprising first and second plate members dimensioned for insertion within the intervertebral space, the first and second plate members having engaging surfaces with discontinuities to engage vertebral end faces of the vertebrae, and at least one resilient member disposed between the first and second plate members to bias the first and second plate members to a generally open spaced arrangement, the one resilient member configured and dimensioned to exert forces on the plate members sufficient to support the adjacent vertebrae in spaced relation during healing while permitting relative movement thereof to accommodate variations in loads realized during normal flexural movement of the vertebral column.

11. The implant according to claim 10 wherein the resilient member is a coil spring member.

12. The implant according to claim 11 including a plurality of coiled spring members disposed between the plate members.

13. The implant according to claim 12 including a flexible cover surrounding the spring members to prevent bone ingrowth within the spring members.

14. The implant according to claim 10 wherein the resilient member includes a resilient layer.

15. An implant for insertion within an intervertebral space defined between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation during healing which comprises at least first and second supporting members dimensioned for insertion within the intervertebral space and having contacting surfaces for contacting vertebral end faces of the adjacent vertebrae, the first member having an inner arcuate articulating surface cooperating with a correspondingly dimensioned outer arcuate articulating surface of the second member to permit articulating movement of the first member to accommodate movement of the vertebral column during healing.

16. The implant according to claim 15 wherein the contacting surfaces of the first and second plate members each include a plurality of apertures to permit bone ingrowth.

17. The implant according to claim 15 wherein the articulating surfaces of the first and second plate members each define a constant radius of curvature, the radius of curvature of each of the first and second plate members being substantially equal.

18. The implant according to claim 15 further including a resilient member disposed between the first and second support members.

19. The implant according to claim 18 wherein the resilient member includes a layer of sponge-like material.

20. An implant for insertion within an intervertebral space defined between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation during healing, which comprises at least first and second support members dimensioned for insertion within the intervertebral space defined between adjacent vertebrae and having engaging surfaces for engaging vertebral end plates of the vertebrae, and a camming arrangement having at least one camming member operatively engageable with the first and second support members, the camming member moveable to move the first and second support members between a non-deployed position and a deployed position.

21. The implant according to claim 20 wherein the camming member includes a camming block having a camming surface, the camming surface engageable with a corresponding camming surface of at least one of the support members whereby upon movement of the camming member the camming surfaces interact to move the first and second support members between the non-deployed and the deployed positions.

22. The implant according to claim 21 including an actuating screw transversing a bore defined in the camming block and threadably engaging a threaded bore associated with one of the first and second support members, the actuating screw rotatable to cause corresponding movement of the camming block.

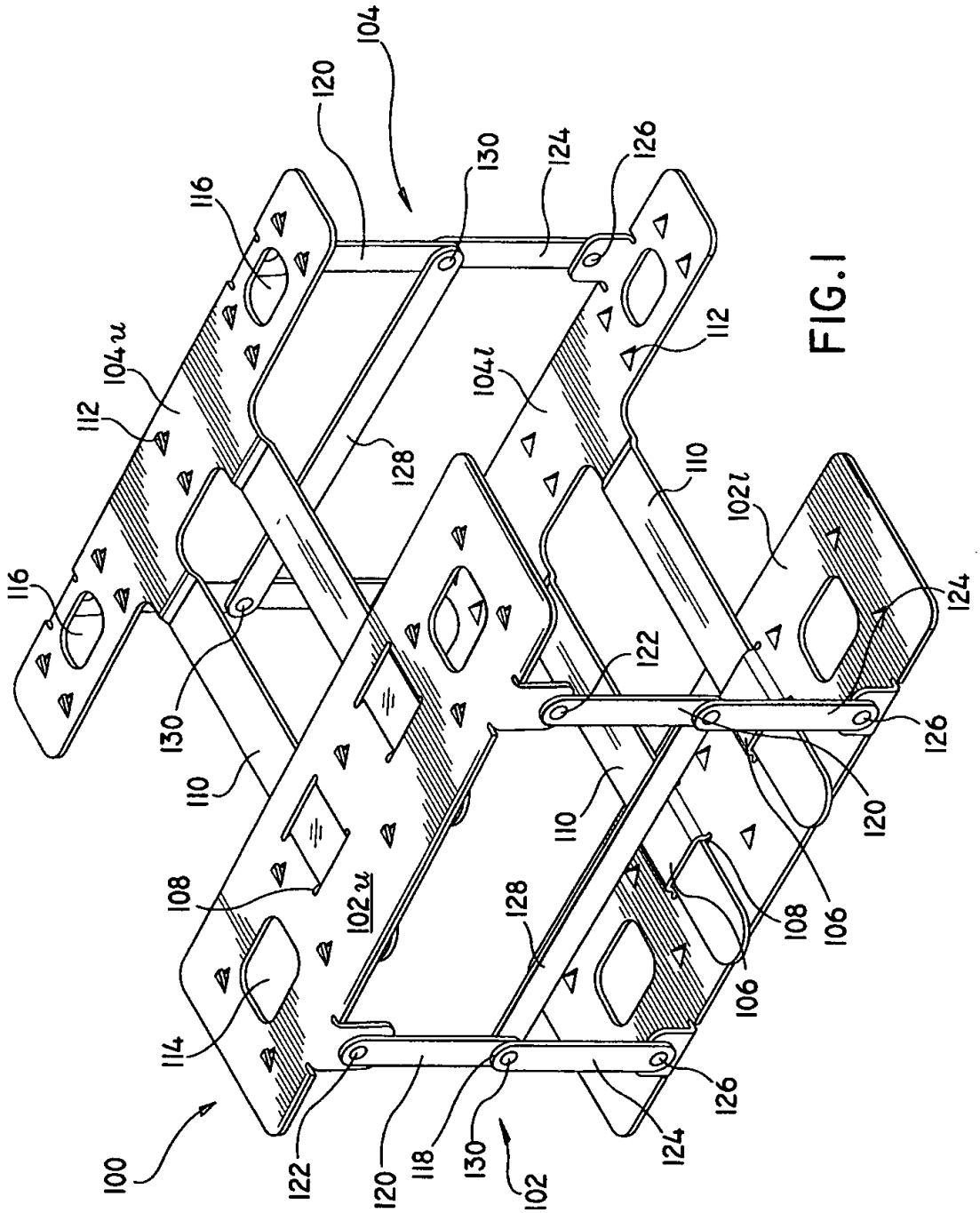
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FIG. 1

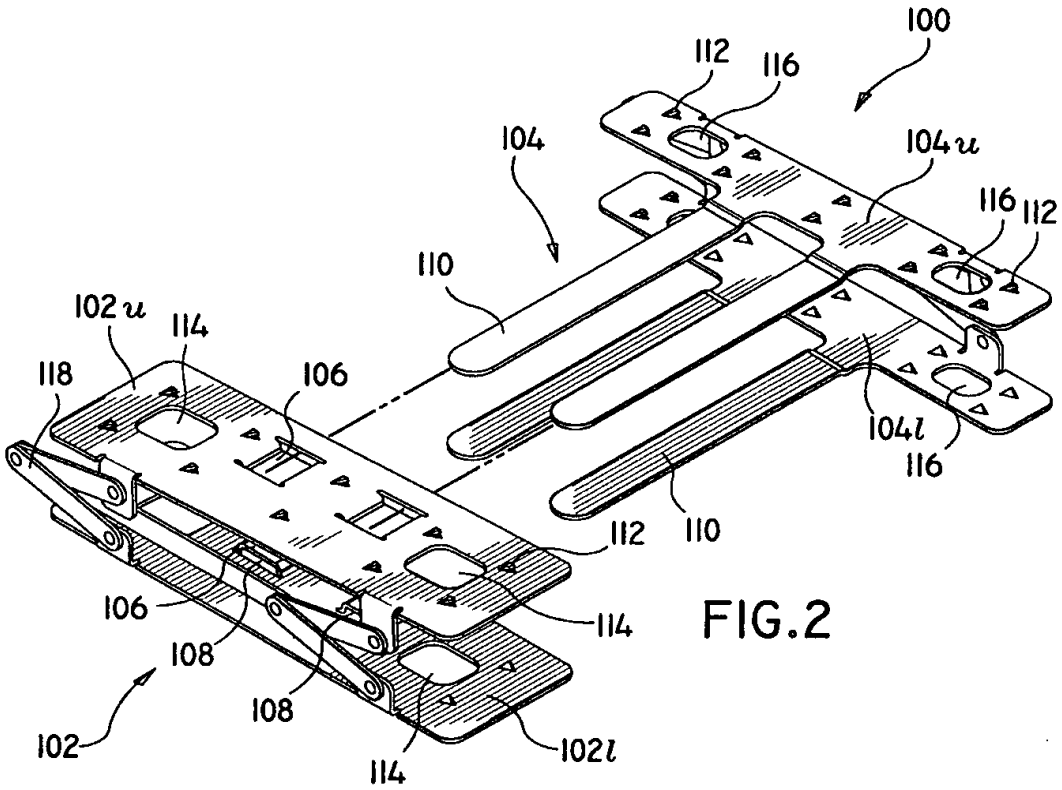
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FIG.2

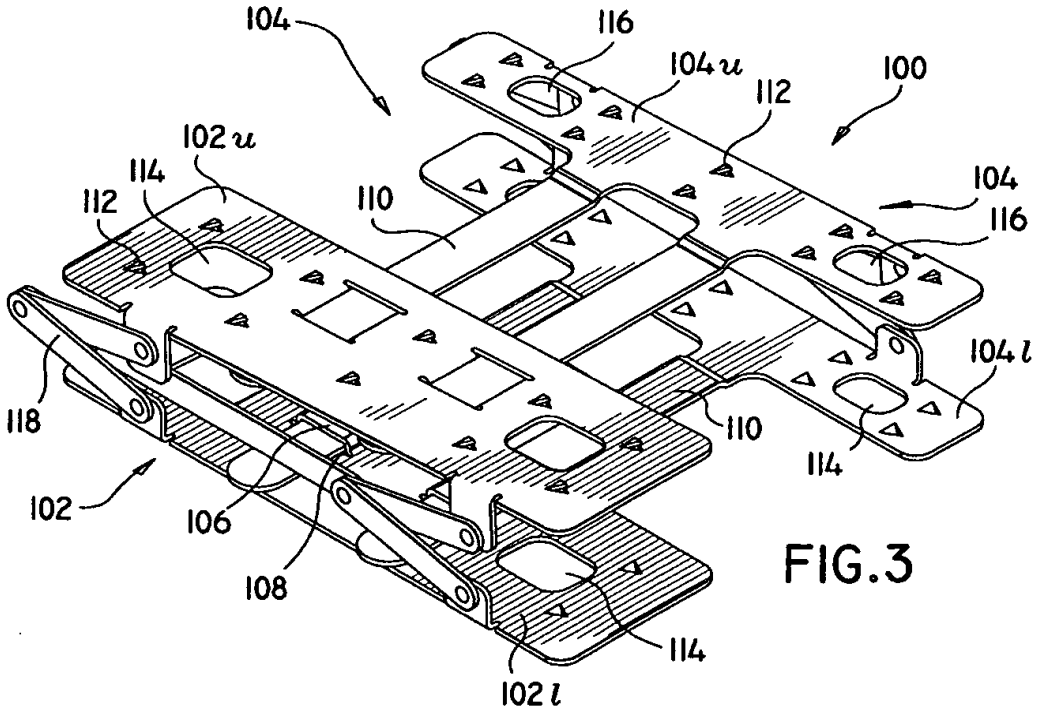
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FIG.3

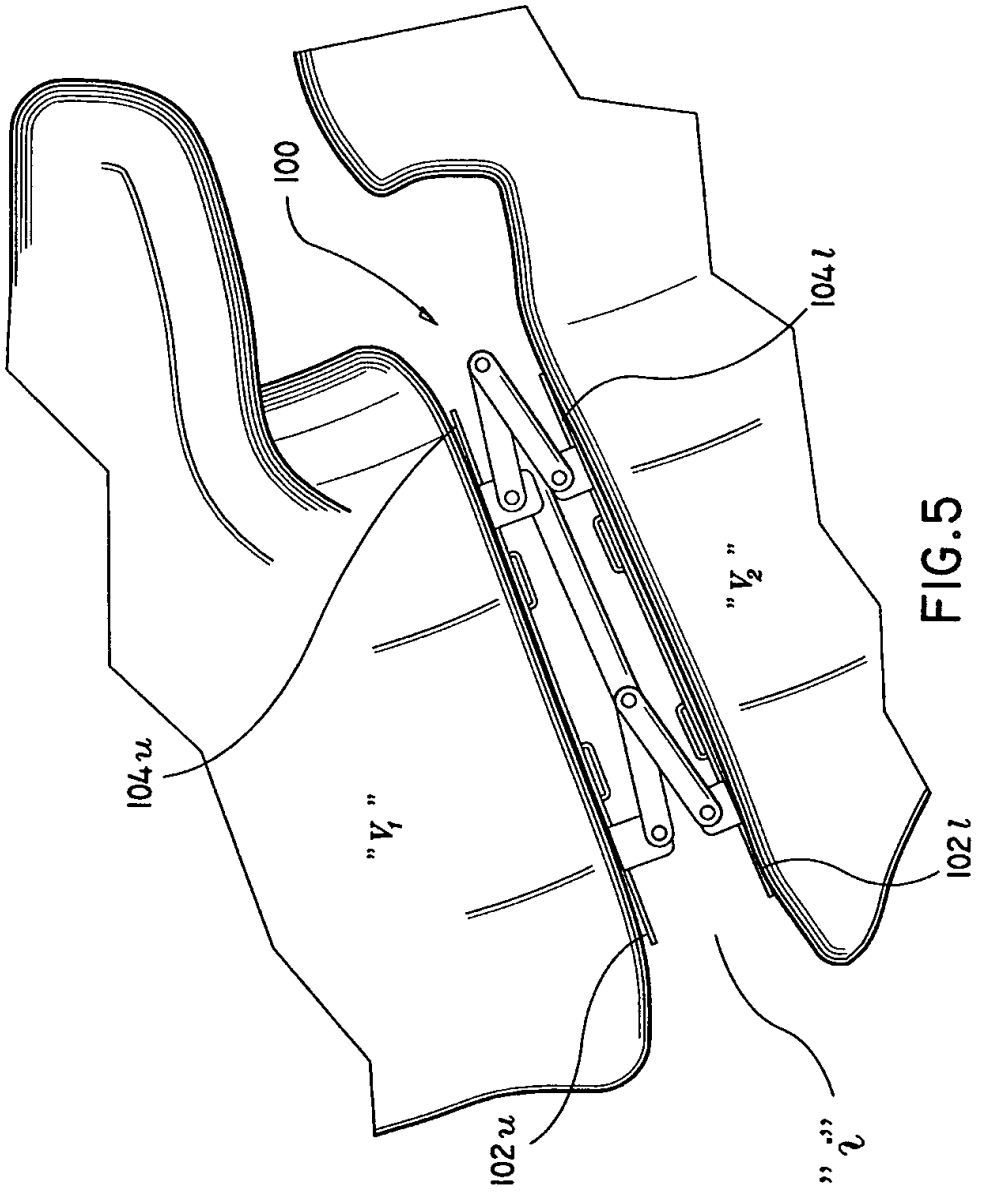
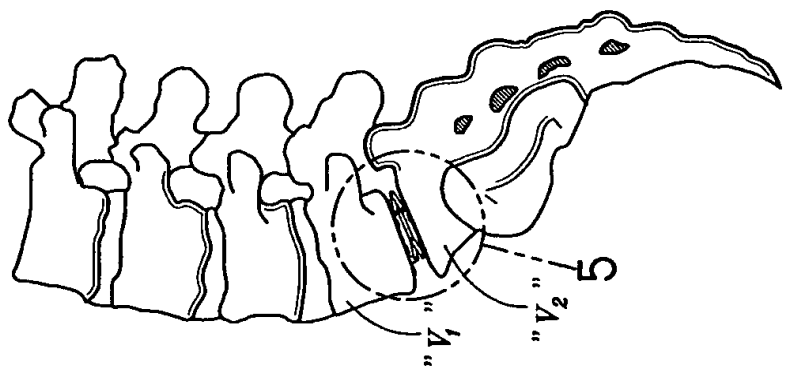


FIG.5

FIG.4



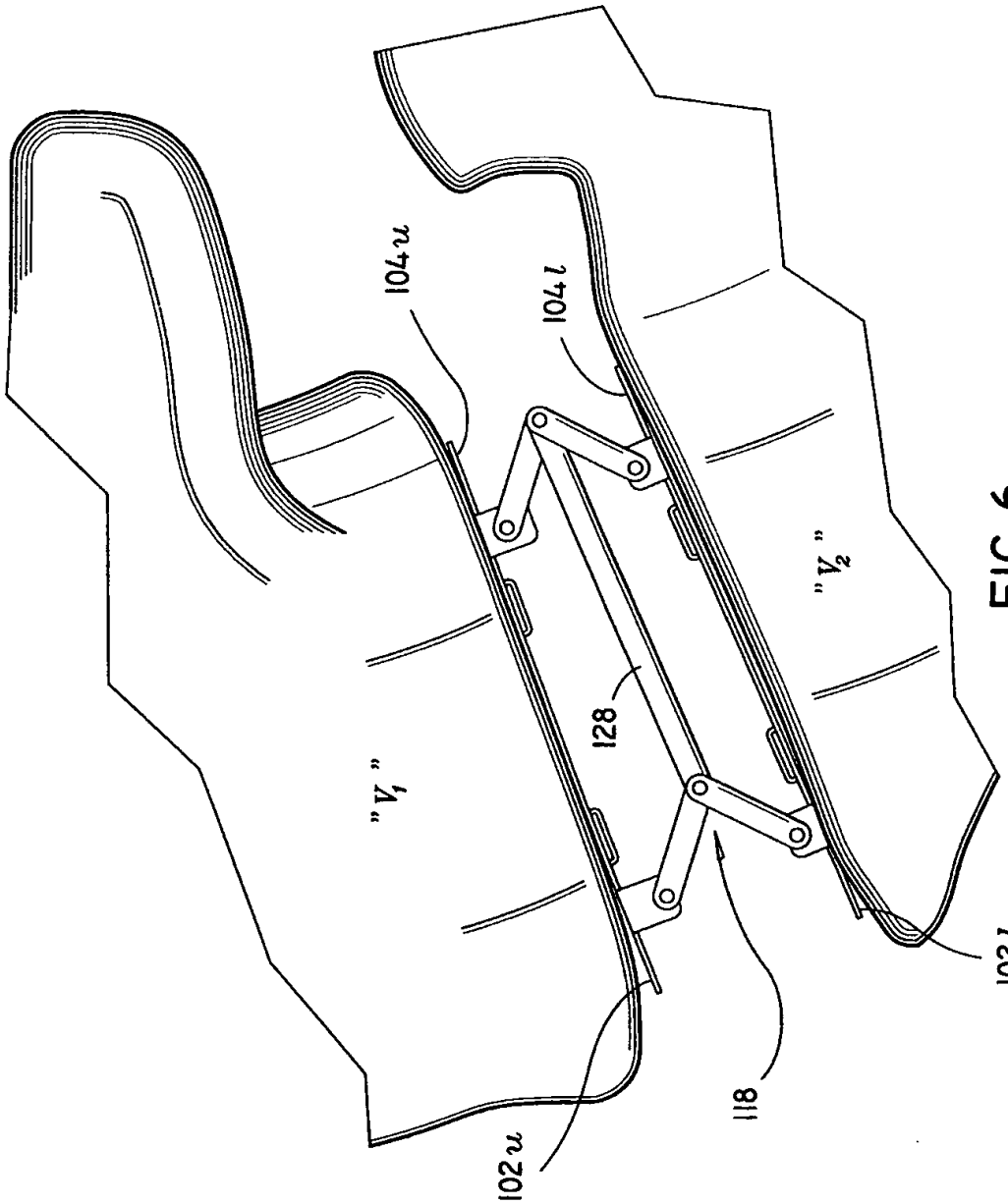


FIG.6

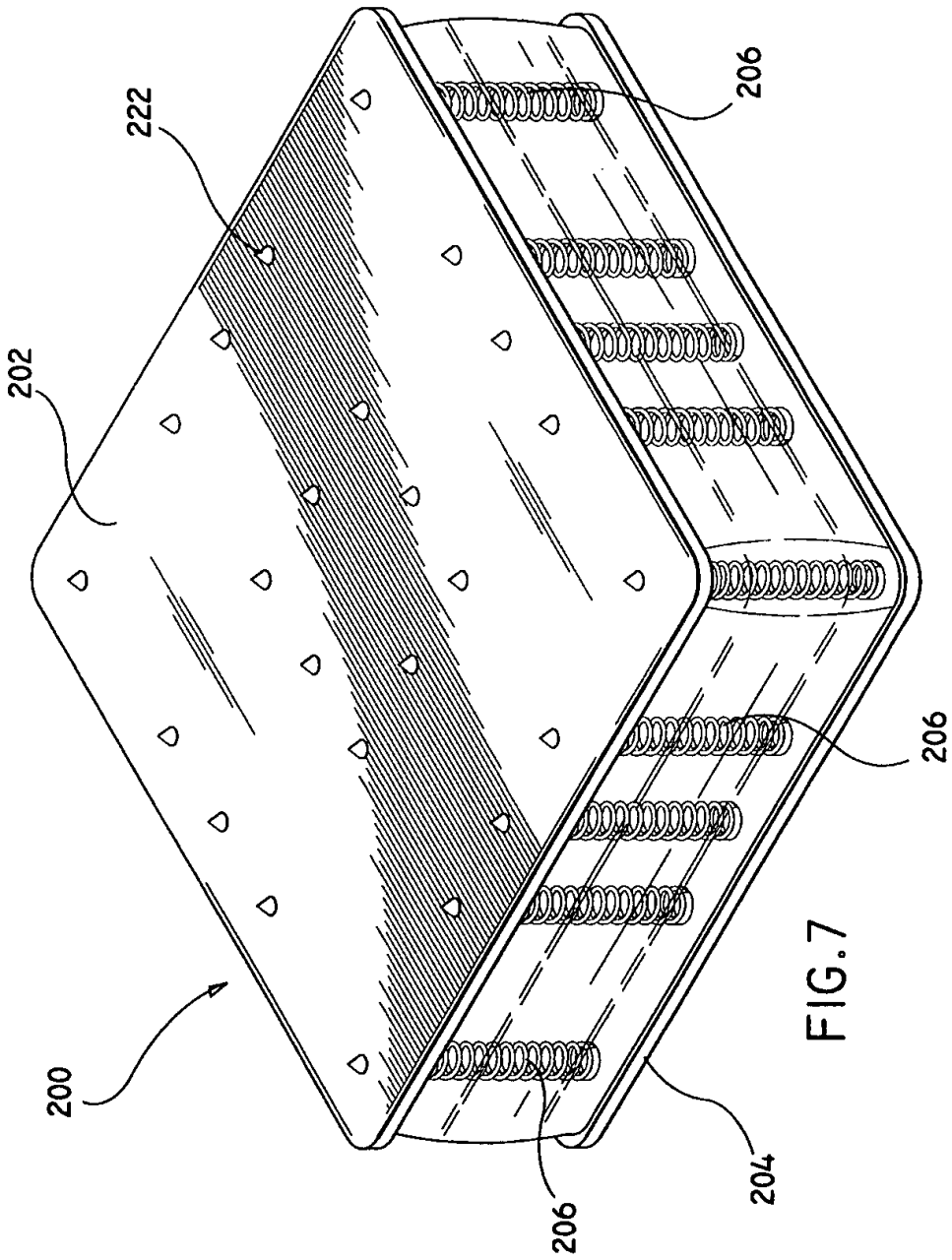


FIG.7

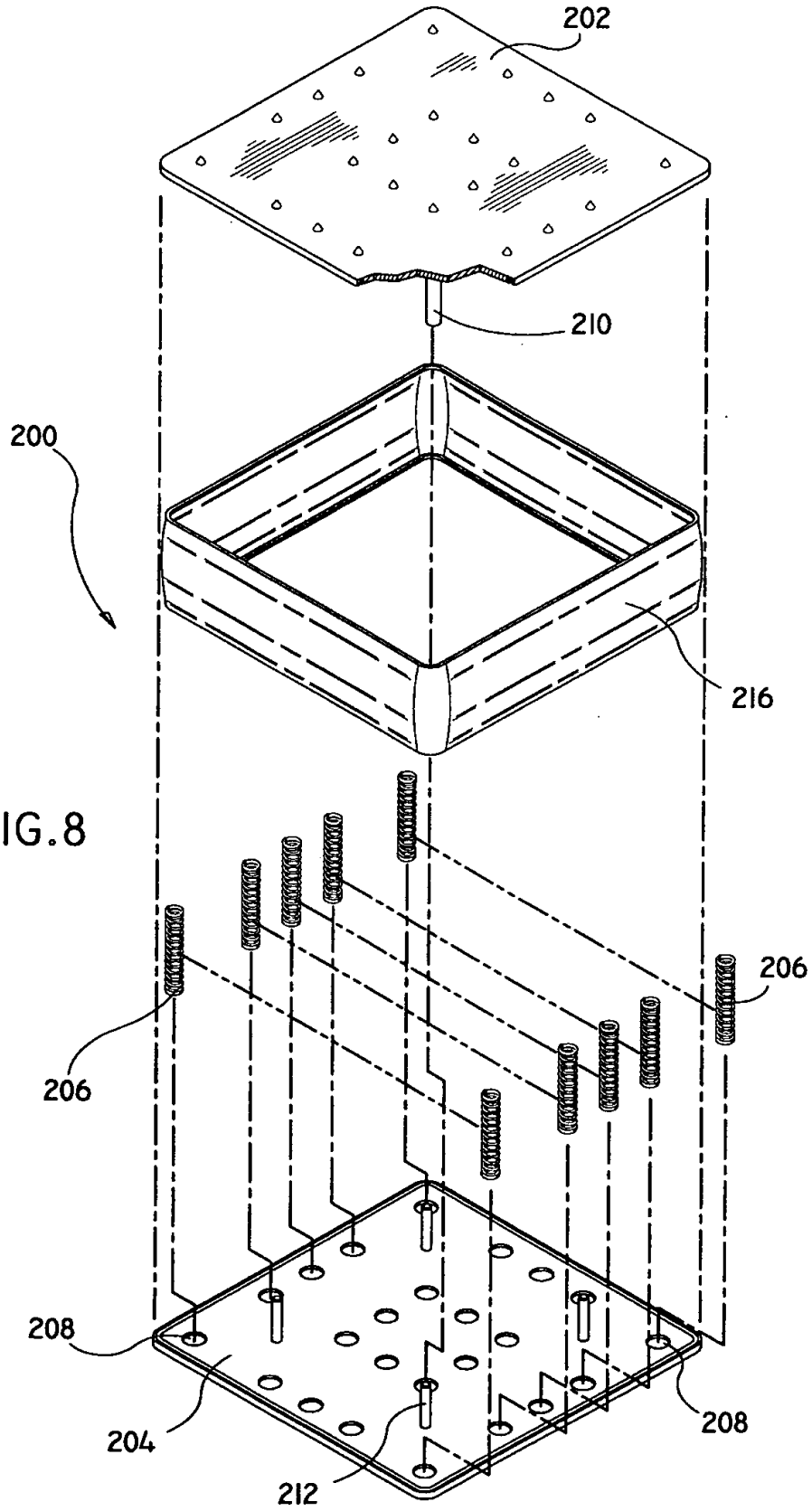


FIG.8

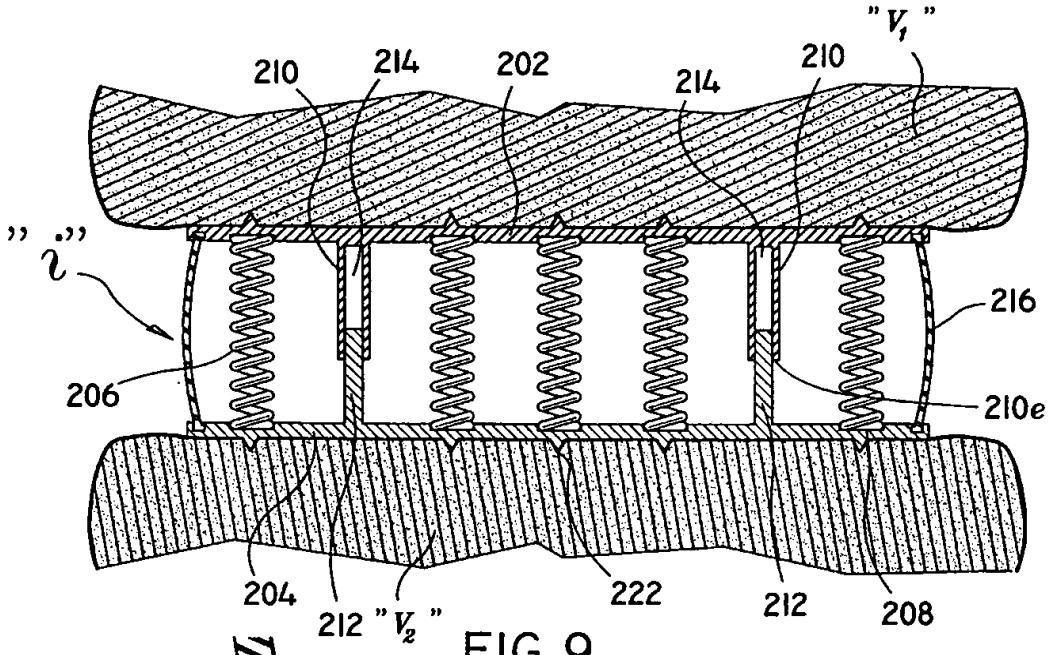


FIG.9

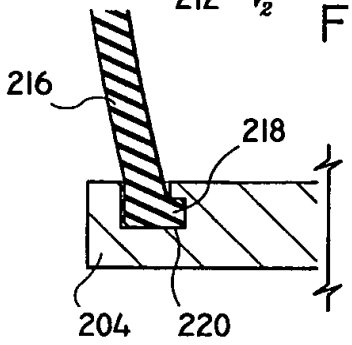


FIG.10

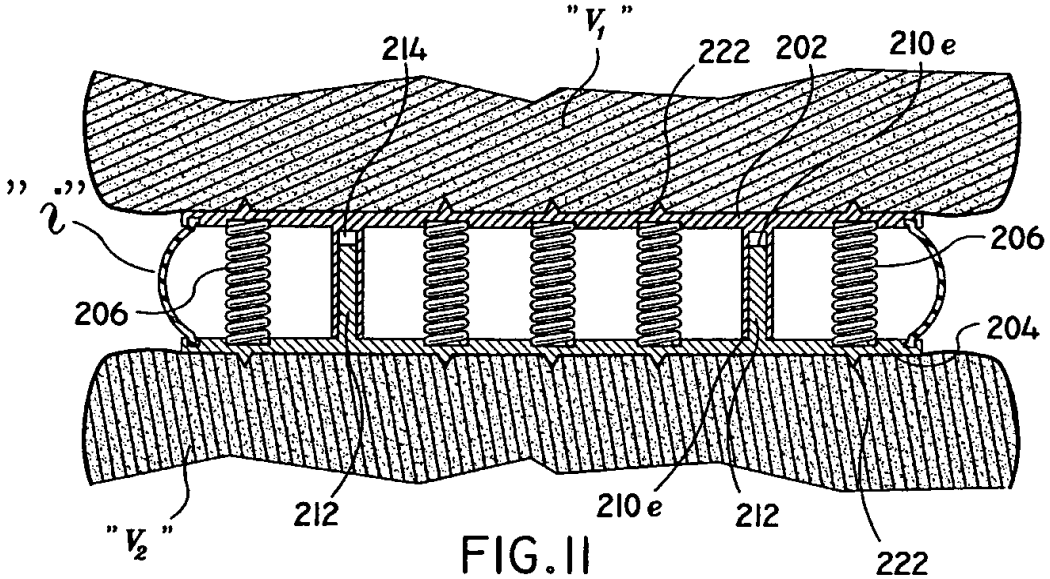


FIG.11

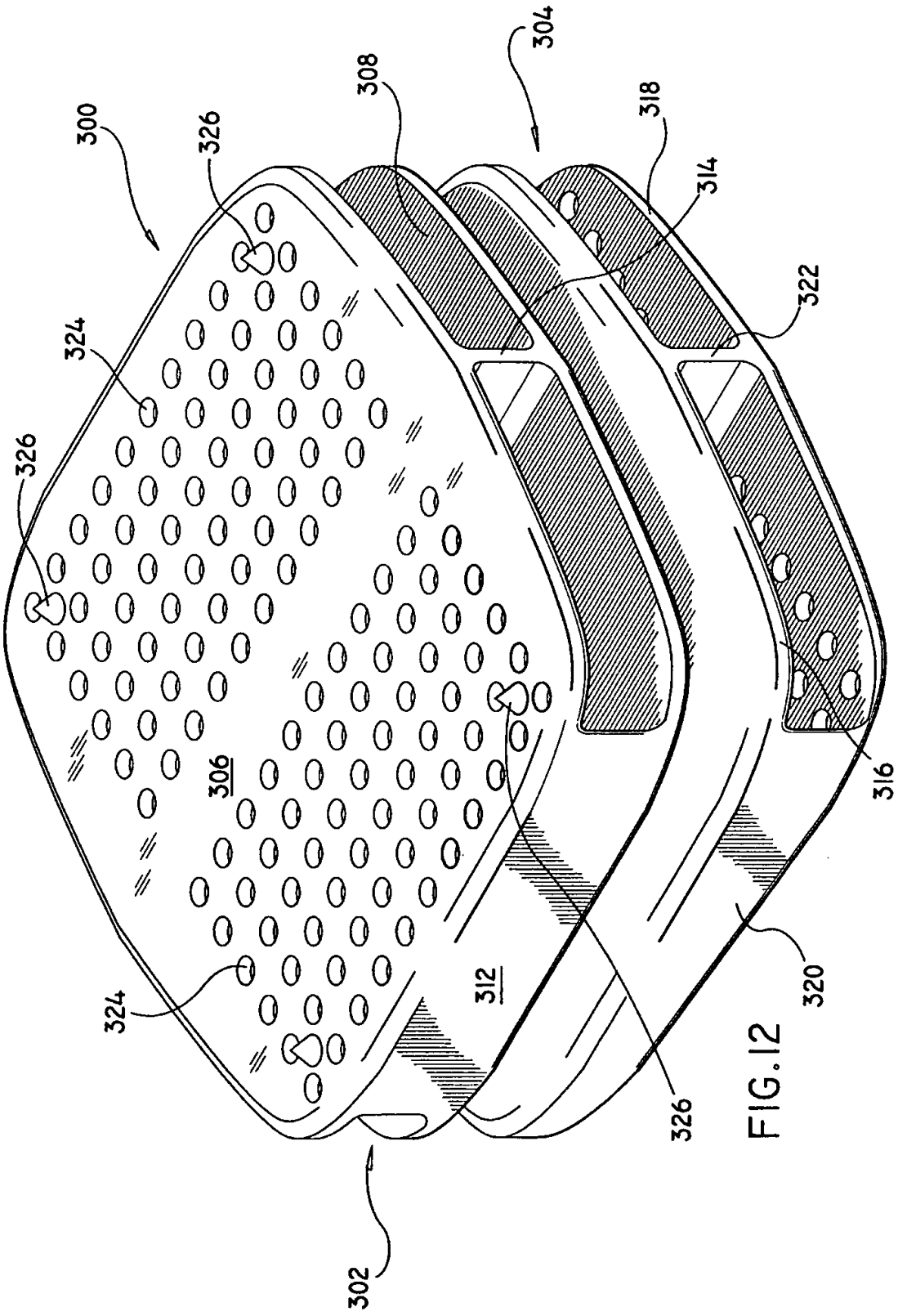


FIG. 12

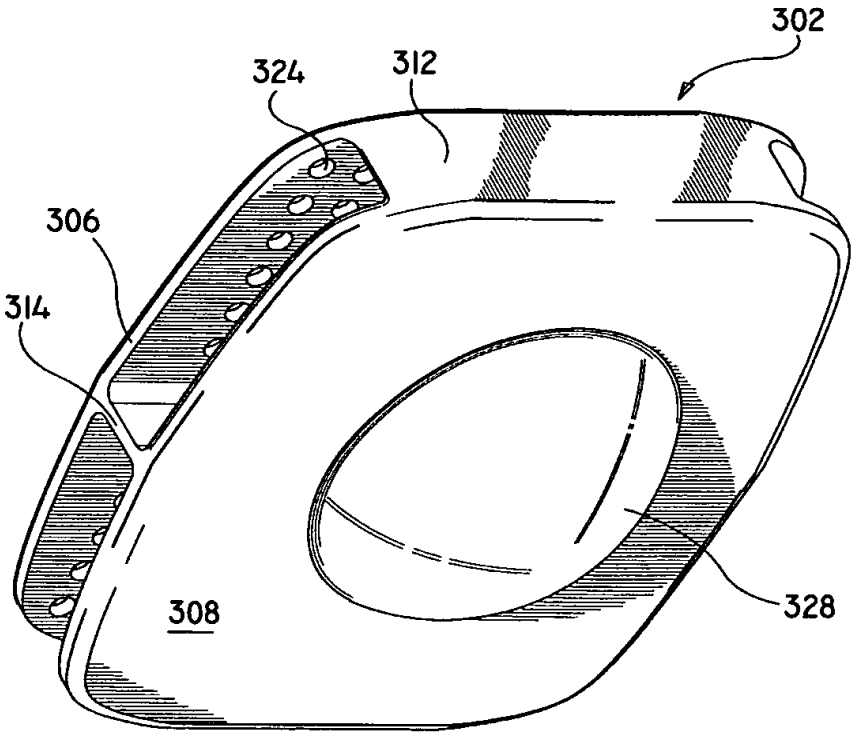


FIG. 13

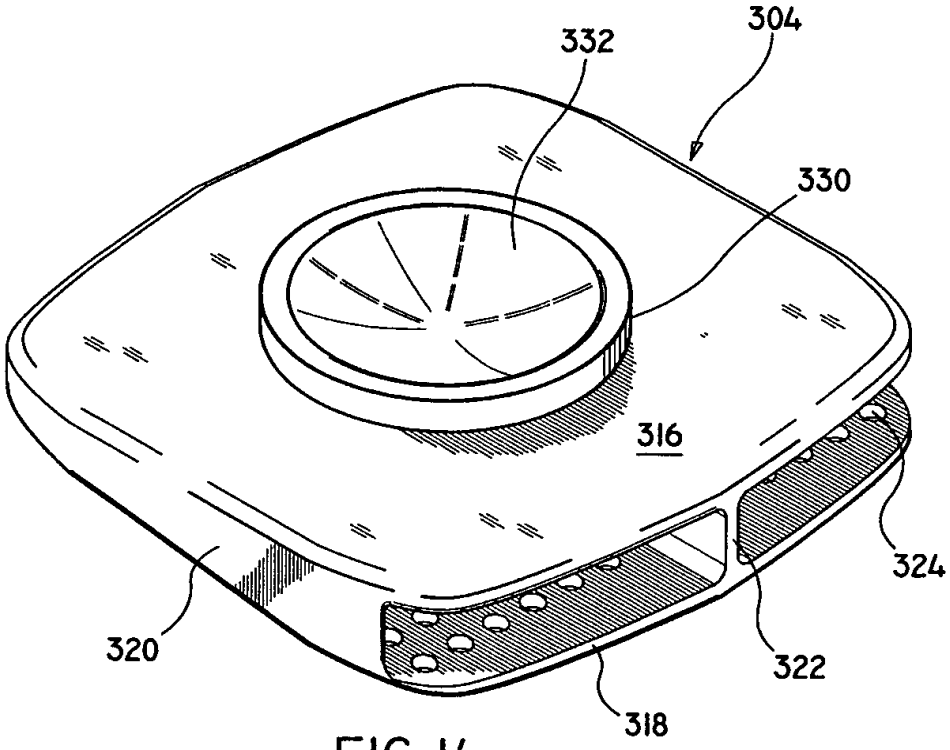


FIG. 14

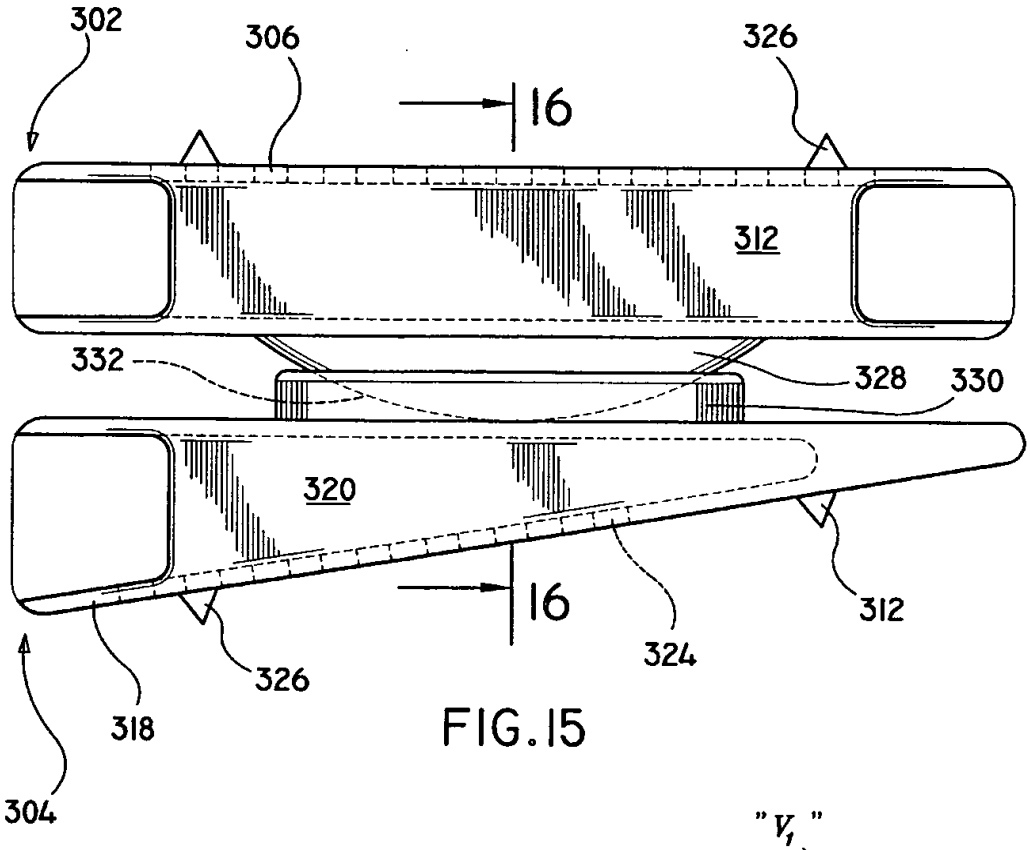

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FIG.15

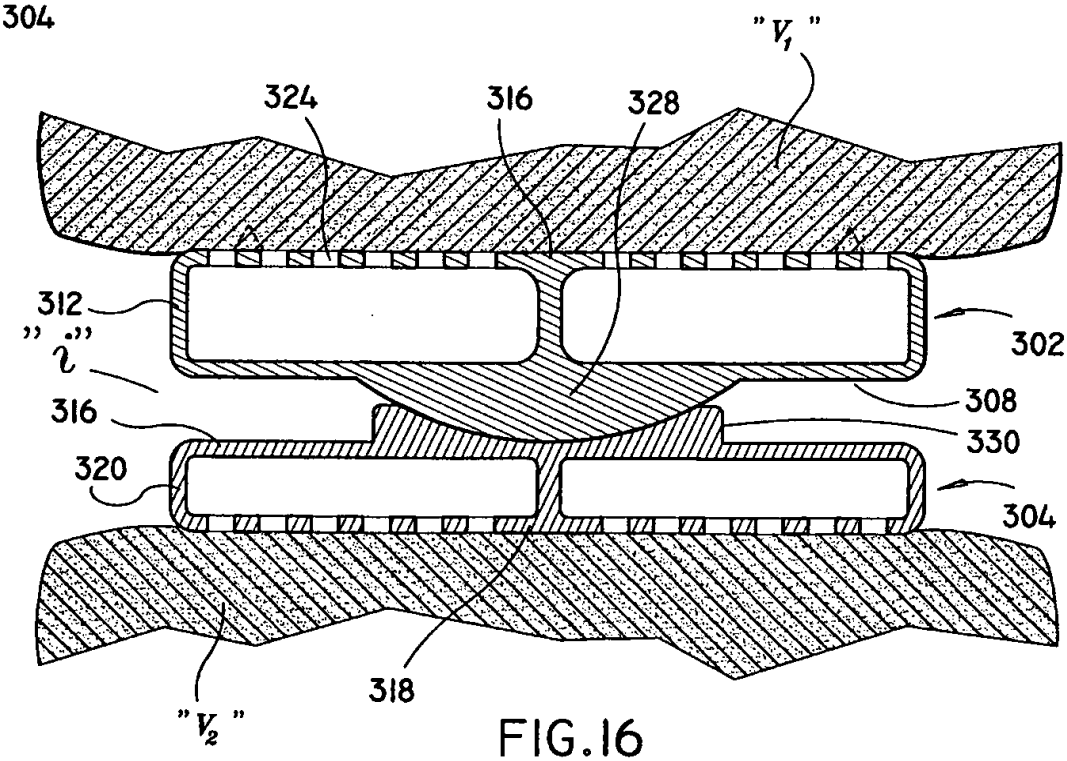
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FIG.16

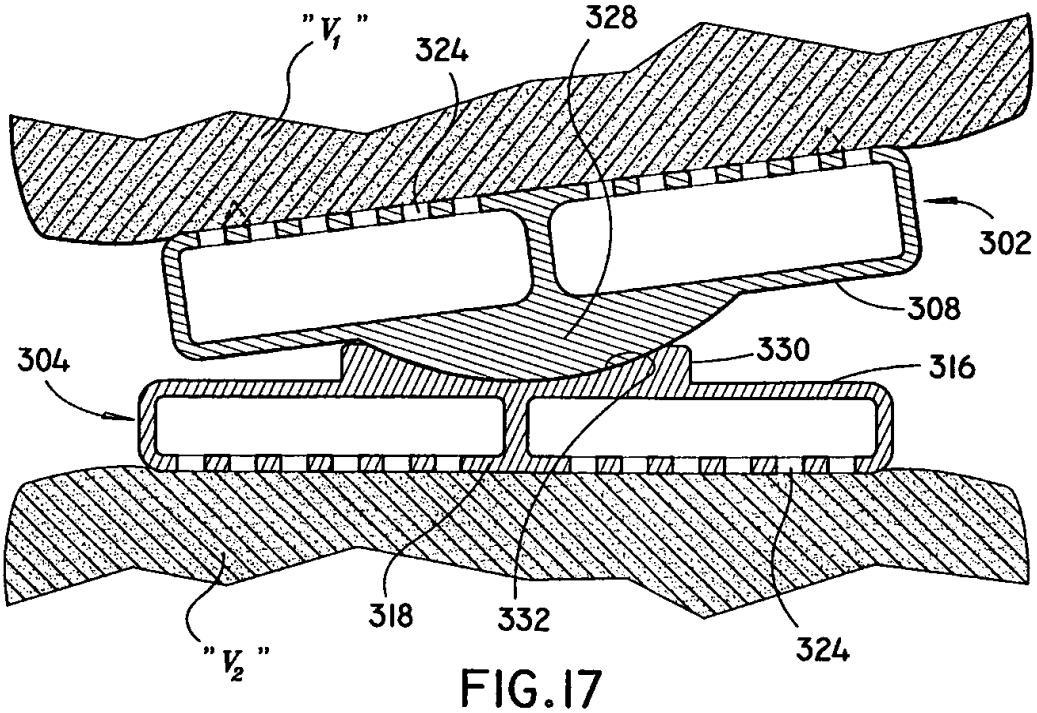
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FIG.17

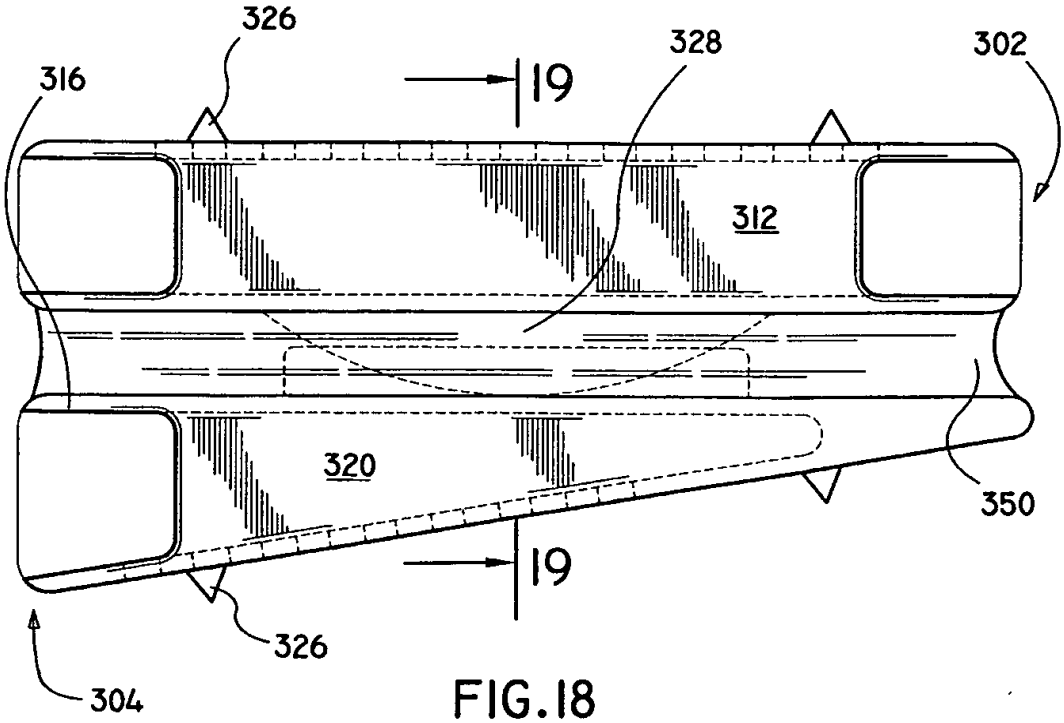
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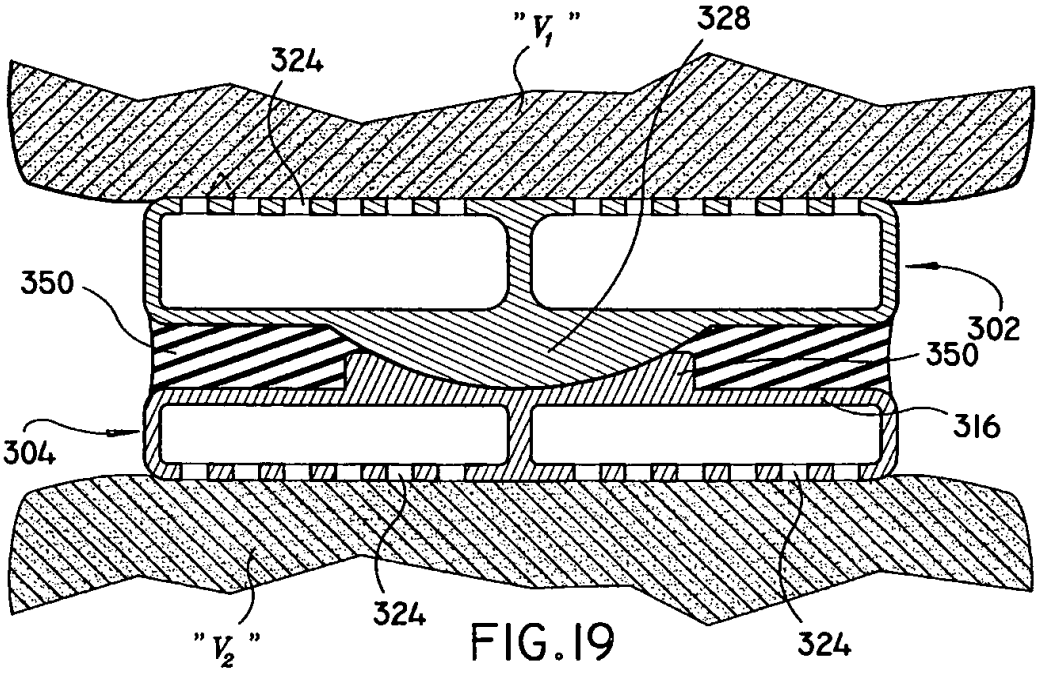
FIG.18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"V_2"
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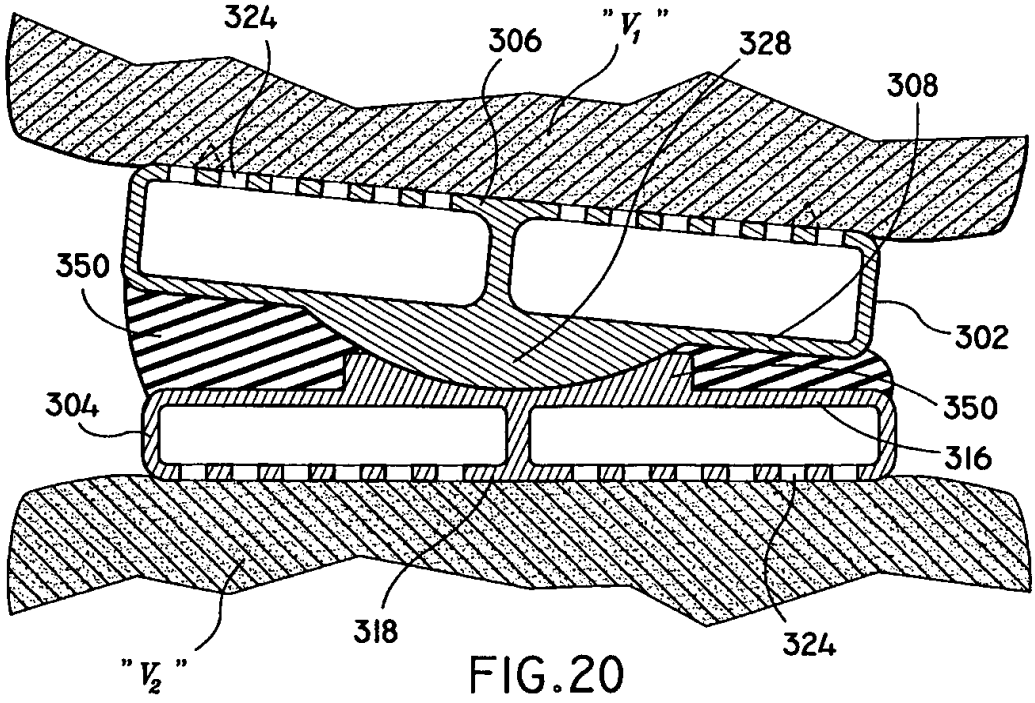
FIG.19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"V_2"
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FIG.20

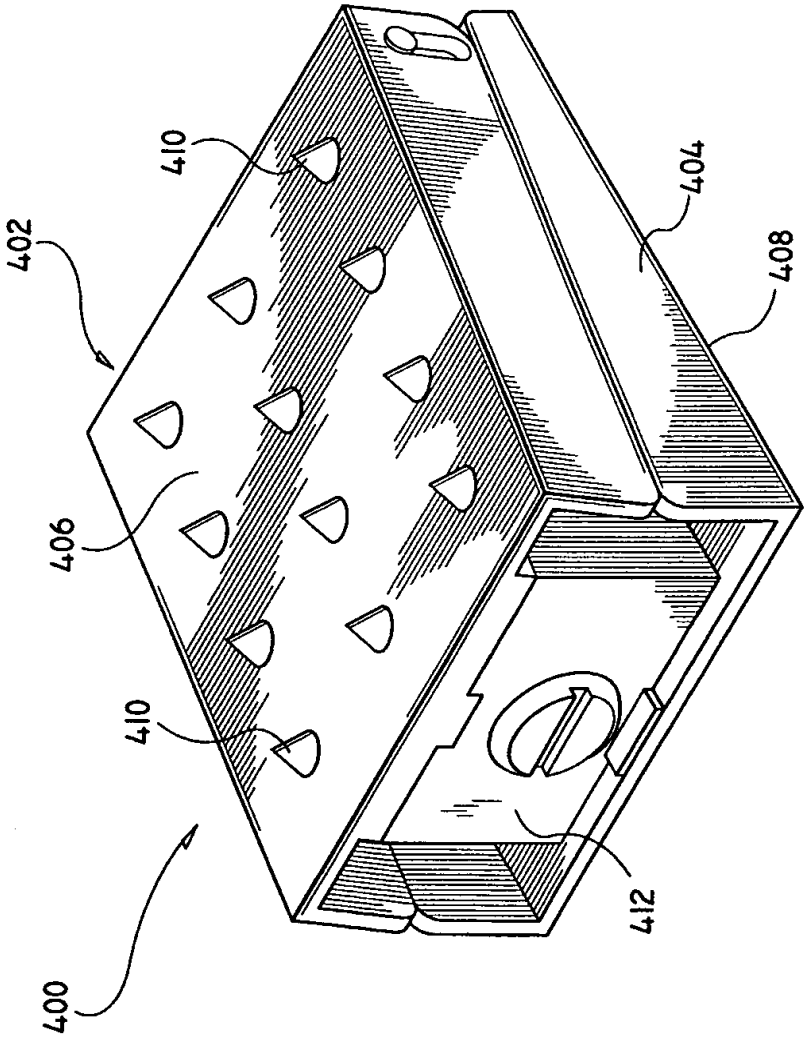
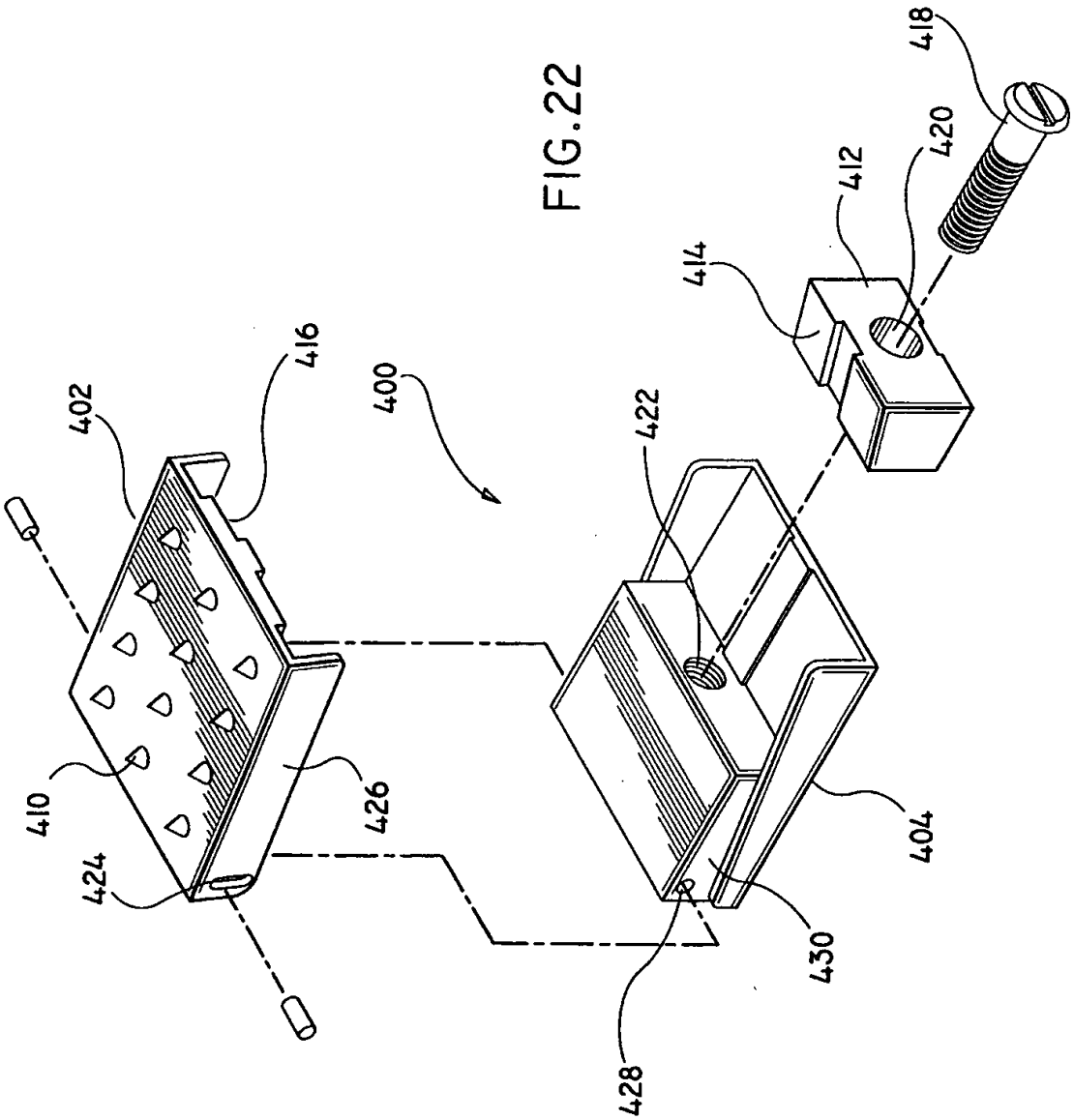
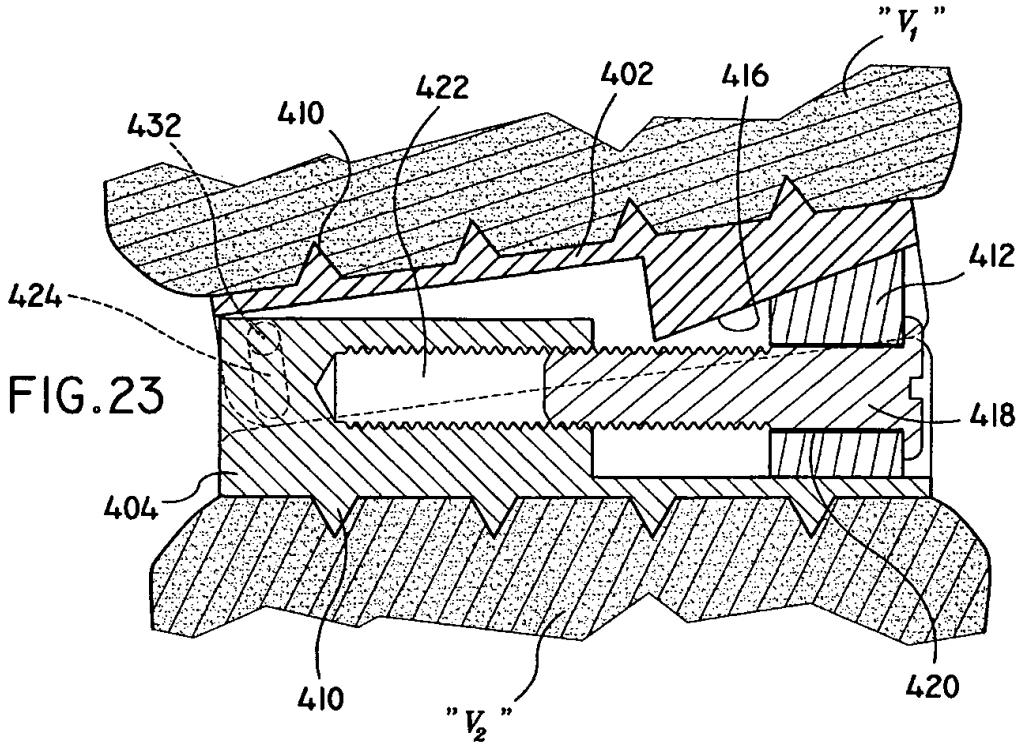


FIG. 21

FIG.22

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"V2"
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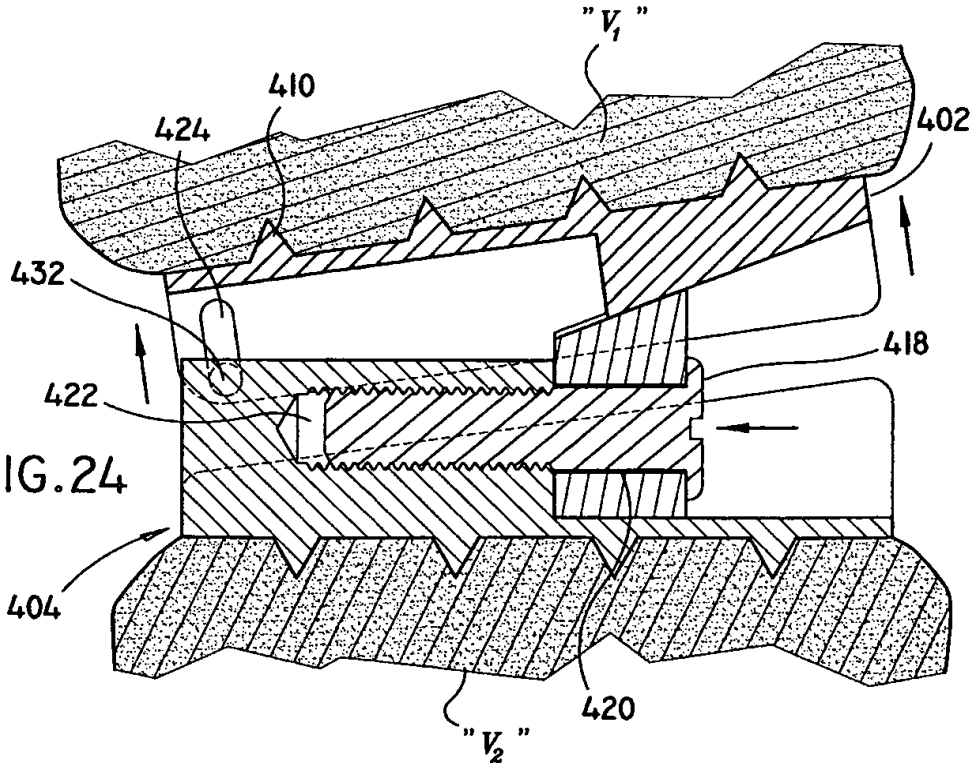
FIG.23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"V2"

FIG.24

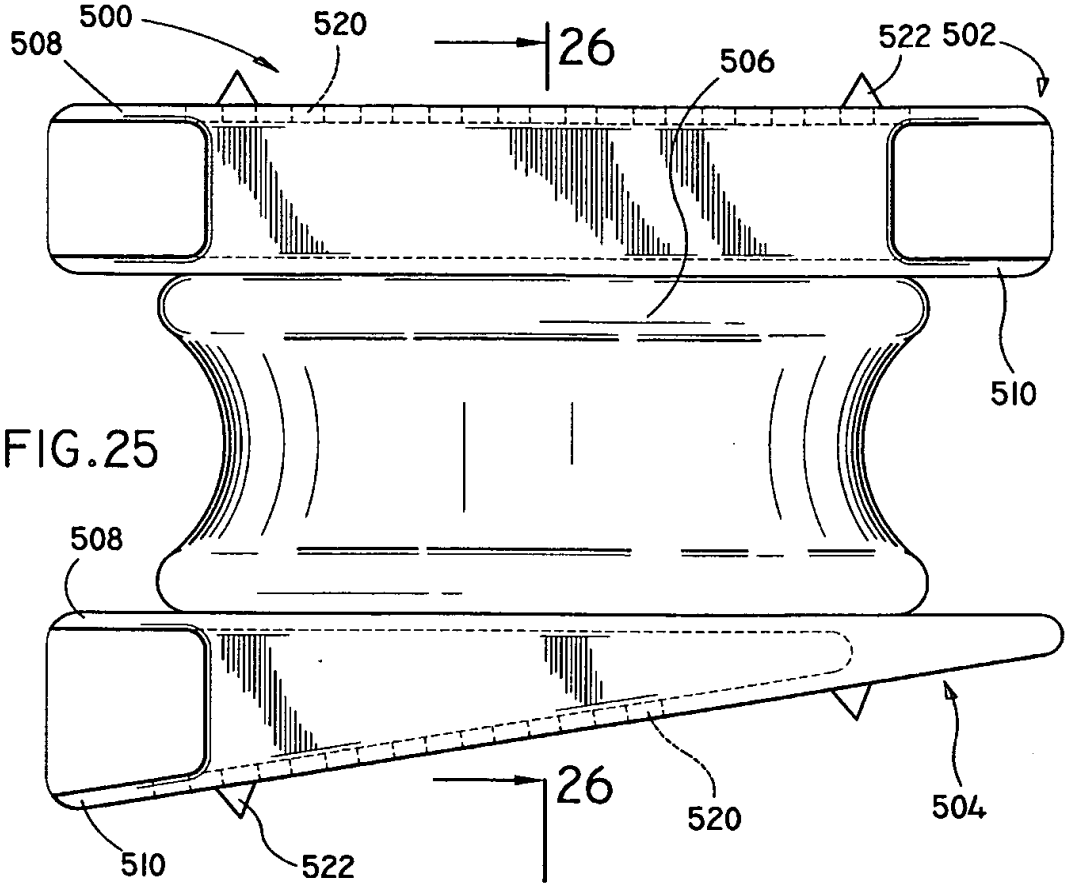
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FIG.25

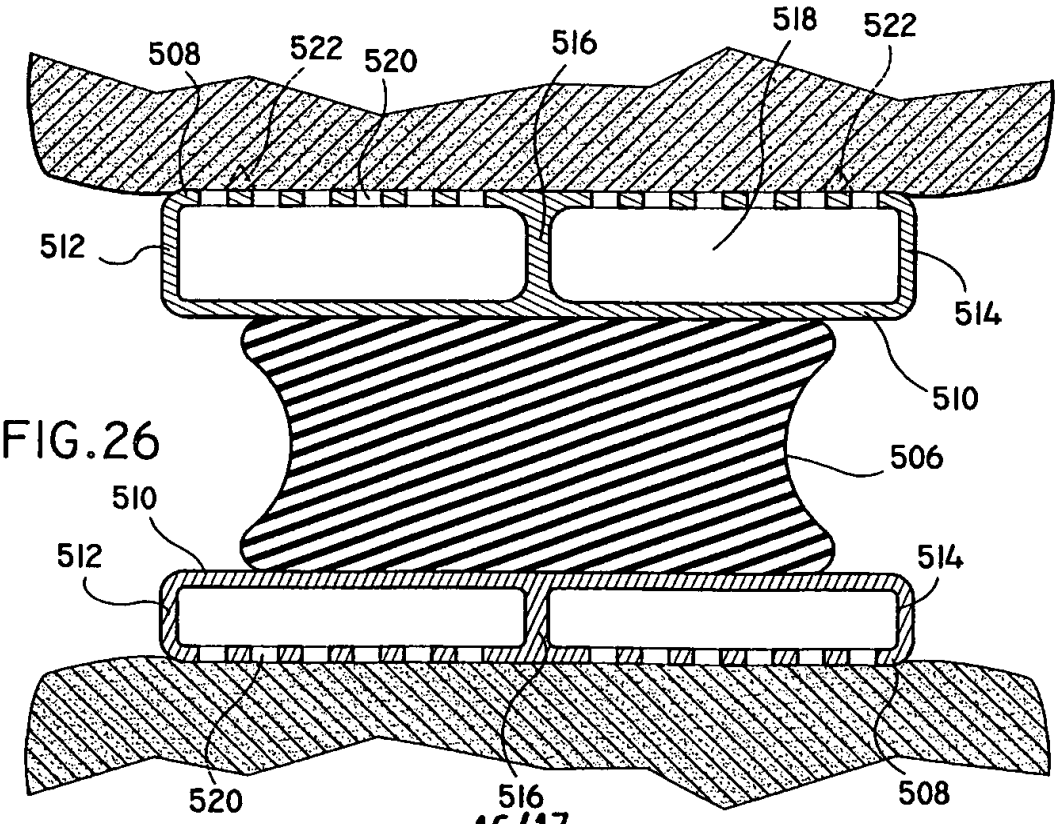
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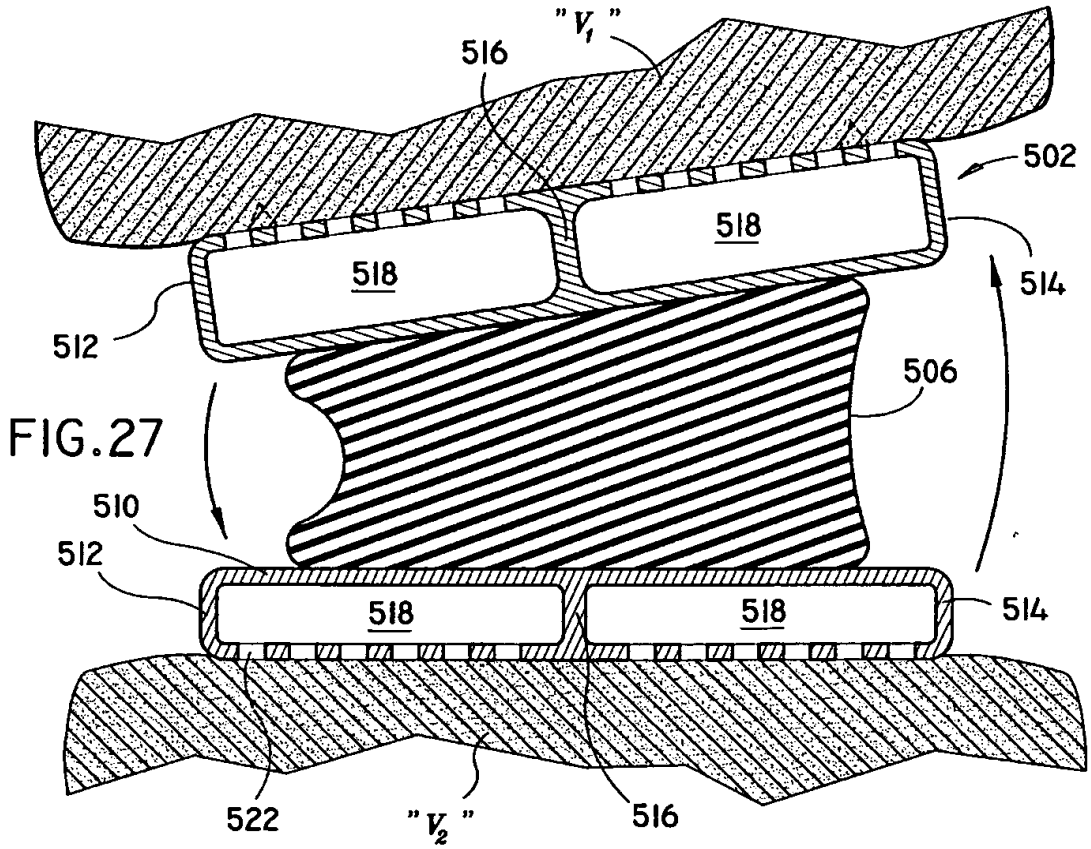
FIG.26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"V_2"
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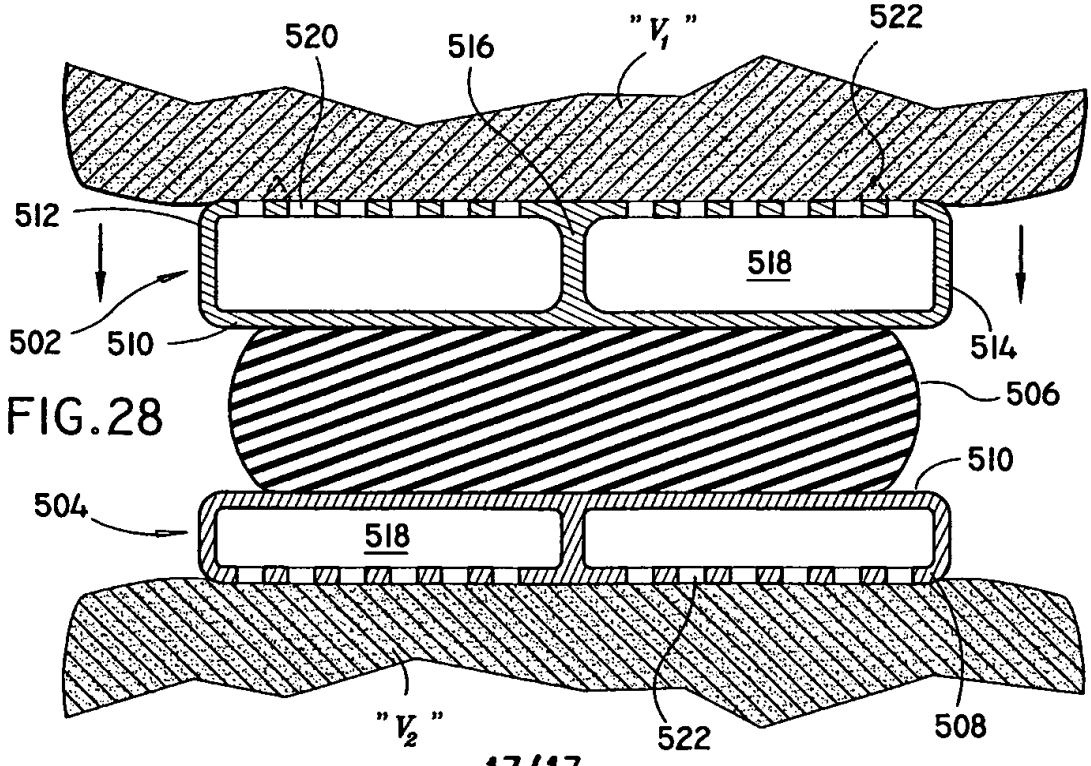
FIG.27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"V_2"
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FIG.28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/17383

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/44
US CL :606/61; 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. : 623/17; 606/61

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,360,430 A (LIN) 01 November 1994, Figs.1 and 3.	9-11
X,P	US 5,665,122 A (KAMBIN) 09 September 1997, Fig. 9.	9, 20, 21
X	EP 94/256681 A (BAUMGARTNER) 27 October 1993, Fig. 1A.	10, 14
X --- Y	WO 94/04100 A (MAZDA) 03 March 1994, Fig. 3.	15, 17-19 --- 16
X,P ----- Y,P	US 5,609,635 A (MICHELSON) 11 March 1997, Figs. 1, 8, 30, and 31.	20-22 --- 16

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

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"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
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Date of the actual completion of the international search 12 DECEMBER 1997	Date of mailing of the international search report 13 JAN 1998
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/17383

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,071,437 A (STEFFEE) 10 December 1991, Fig. 2.	10
X	US 5,002,576 A (FUHRMANN et al.) 26 March 1991, Fig. 1.	10
A	US 5,258,031 A (SALIB et al.) 02 November 1993, Fig. 3.	15
X	EP 0 610 837 A (NAVARRO et al) 17 August 1994, Ffig.2.	10
A	US 5,507,816 A (BULLIVANT) 16 April 1996, Fig.1A.	15

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

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(51) International Patent Classification 6 : A61F 2/44, A61B 17/02, 17/16

A2

(11) International Publication Number: WO 98/17208

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08/822,530	24 March 1997 (24.03.97)	US

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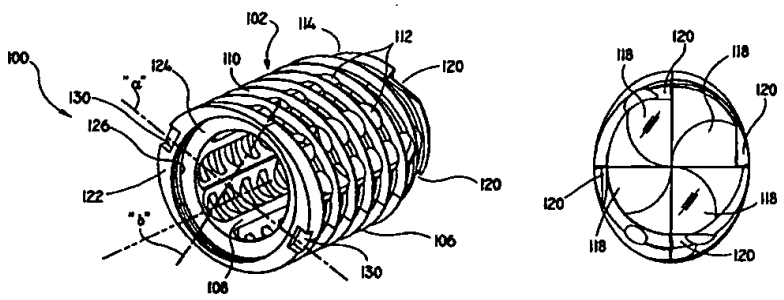
(71) Applicant: SURGICAL DYNAMICS, INC. [US/US]; 111 Glover Avenue, Norwalk, CT 06856 (US).

(72) Inventor: WINSLOW, Charles, J.; 25 Hilton Court, Walnut Creek, CA 94595 (US).

(74) Agents: ANDRES, John, C. et al.; United States Surgical Corporation, 150 Glover Avenue, Norwalk, CT 06856 (US).

(54) Title: APPARATUS FOR FUSING ADJACENT BONE STRUCTURES



(57) Abstract

An apparatus for facilitating the fusion of adjacent bone structures (V1, V2) includes an implant member (100) configured for insertion within a space defined between adjacent bone structures (V1, V2). The implant member (100) includes an entry end portion (114) and a trailing end portion (122) and defines a longitudinal axis. The implant member (100) includes at least a longitudinal portion (102) having a generally elliptical cross-sectional dimension with a major cross-sectional dimension (a) greater than a minor cross-sectional dimension (b). A system (200) for drilling a bore in adjacent vertebrae (V1, V2) to facilitate the insertion of a fusion implant (100) includes a surgical retractor (202) having a sleeve member (210) with proximal (212) and distal (214) end portions and defining a longitudinal opening and a drill instrument (204) positionable within the longitudinal opening of the surgical retractor (202). The retractor (202) is configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae (V1, V2) to distract the adjacent vertebrae (V1, V2) to a desired predetermined distracted position. At least one anchoring member may be associated with the surgical retractor (202) to facilitate mounting thereof to the vertebrae (V1, V2). The drill instrument (204) includes an elongate member (220) having a longitudinal passageway and defining at least one distal cutting surface and a drill member (224) disposed within the elongate member (220) and having a distal drill head. The drill member (224) is rotatably movable within the elongate member (220) and is also longitudinally fixed to the elongate member (220) such that advancement of the drill member (224) within the retractor (202) causes corresponding advancement of the elongate member (220) such that the distal cutting surface of the elongate member (220) and the distal drill head of the drill member (224) cooperate to cut a non-circular, e.g., an eliptical-shaped, bore in the adjacent vertebrae (V1, V2). Preferably, the elongate member (220) of the drill instrument (204) includes first and second diametrically opposed distal cutting surfaces. The cutting surfaces may be arcuately-shaped.

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APPARATUS FOR FUSING ADJACENT BONE STRUCTURES

BACKGROUND

1. Technical Field

The present disclosure generally relates to a surgical apparatus for fusing adjacent bone structures, and, more particularly, to an apparatus, instrumentation and associated method for fusing adjacent vertebrae.

2. Background of the Related Art

The fusion of adjacent bone structures is commonly performed to provide for long-term replacement to compensate for degenerative or deteriorated disorders in bone. For example, an intervertebral disc, which is a ligamentous cushion disposed between adjacent vertebrae, may undergo deterioration as a result of injury, disease, tumor or other disorders. The disk shrinks or flattens leading to mechanical instability and painful disc translocations.

Conventional procedures for disc surgery include partial or total excision of the injured disc portion, e.g., discectomy, and replacement of the excised disc with biologically acceptable plugs or bone wedges. The plugs are driven between adjacent vertebrae to maintain normal intervertebral spacing and to achieve, over a period of time, bony fusion with the plug and opposed vertebrae. For example, U.S. Patent No. 4,887,020 to Vich discloses a threaded cylindrical bone plug which is screwed into a correspondingly dimensioned cylindrical bore drilled in the intervertebral space. Other bone grafting plugs are disclosed in U.S. Patent No. 4,950,296.

More recently, emphasis has been placed on fusing bone structures (i.e., adjoining vertebrae) with prosthetic cage implants. One fusion cage implant is disclosed in commonly assigned U.S. Patent No. 5,026,373 to Ray et al., the contents of which are incorporated herein by reference. The Ray '373 fusion cage

includes a cage having a thread formed as part of its external surface and apertures extending through its wall which communicate with an internal cavity of the cage body. The fusion cage is inserted within a tapped bore or channel formed in the intervertebral space thereby stabilizing the vertebrae and maintaining a pre-defined intervertebral space. Preferably, a pair of fusion cages are implanted within the intervertebral space. The adjacent vertebral bone structures communicate through the apertures and with bone growth inducing substances which are within the internal cavity to unite and eventually form a solid fusion of the adjacent vertebrae. FIGS. 1-2 illustrate the insertion of a pair of the Ray '373 fusion cages positioned within an intervertebral space.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar spine. Fusions in the cervical area of the spine are also performed using an anterior or a posterior approach. Typically, an implant such as a plug, dowel, prosthesis or cage is inserted into a preformed cavity inside the interbody, interdiscal space. Since it is desirable in these procedures to promote a "bone to bone" bridge, connective tissue and at least a portion of the distal tissue is removed. Preferably, relatively deep cuts are made in the adjacent bones in order to penetrate into the softer, more vascularized cancellous region to facilitate bone growth across the implant.

One of the more critical tasks performed in the insertion of a surgical fusion implant, particularly, in intervertebral spinal fusion, is the formation of the implant receiving cavity or bore within the adjacent vertebrae. More particularly, the drilled bore should be centered with respect to and preferably parallel to the vertebral end plates to ensure removal of equal portions of bone from the adjacent vertebrae throughout the length of the cut and subsequent appropriate seating of the implant relative to the vertebral bodies.

Surgical instruments for spinal fusion implant insertion are known. For example, U.S. Patent No. 5,484,437 to Michelson discloses a method and apparatus incorporating an outer and an inner sleeve arrangement. The outer sleeve has teeth at one end which are driven directly into the posterior surface of the adjacent vertebrae. The inner sleeve is positioned within the outer sleeve and serves to guide instruments such as a drill used to form the implant receiving bore. U.S. Patent Nos.: 5,487,307 to Kuslich et al.; 5,015,247 to Michelson; and 4,878,915 to Brantigan disclose similar arrangements. Other arrangements include the use of guide rods which are placed in pilot holes formed in the vertebral bodies. The guide rods guide a bore forming hollow drill into the intervertebral space.

Although some of the current instrumentation and methods associated therewith for enhancing the placement of spinal fusion implants have been generally effective for their intended purposes, there exists certain limitations with the design of this instrumentation which detract from their usefulness. For example, the arrangement disclosed in the Michelson '437 patent and similar arrangements do not provide for automatic alignment of the outer sleeve to ensure that the bore formed by a drill introduced into the outer sleeve is in optimal alignment for a tapping procedure (if required) and reception of the spinal implant. Rather, such orientation is dependent directly upon the skill of the surgeon. Moreover, the outer sleeve, which is only mounted only at its extreme distal end to the posterior surface of the adjacent vertebrae, is subject to disorientation or dislodgment during insertion and/or removal of the drill and/or tapping instrument. Similarly, the use of guide rods increases the number of steps required to implant the fusion cage and is also subject to possible misalignment.

U.S. Patent Application Serial No. 08/615,379, filed March 14, 1996, the contents of which are incorporated herein by reference, discloses a method and associated instrumentation to facilitate the introduction of a fusion implant. The instrumentation disclosed in the '379 application ensures optimal alignment of the drilled bore for reception of the fusion implant and, if appropriate, for bore tapping procedures. The instrumentation includes a surgical retractor and a drill. The retractor is configured for distracting adjacent vertebral bodies to facilitate the insertion and application of an implant, for providing a cannula for insertion of auxiliary instruments, e.g., the drill, and for ensuring proper alignment of the instrumentation and accurate insertion of the implant. The instrumentation and method disclosed in the '379 application is well suited for implanting an implant having a general circular cross-sectional portion such as the aforedescribed Ray '373 fusion cage.

SUMMARY

Although the Ray '373 fusion cage implant has proven to be effective in stabilizing the vertebrae and promoting vertebral fusion subsequent, for example, discectomy, the present disclosure is directed to further improvements in interbody fusion.

Accordingly, an apparatus for facilitating the fusion of adjacent bone structures is disclosed. The apparatus includes an implant member configured for insertion within a space defined between adjacent bone structures and having an entry end portion and a trailing end portion. The implant member includes at least a longitudinal portion having a generally elliptical cross-sectional dimension transverse to a longitudinal axis of the implant member. The elliptical configuration enhances the supporting characteristics of the implant member by increasing surface area contact of the implant member with the bone structures.

The implant member preferably includes an exterior surface portion having discontinuities to permit bone ingrowth. The external surface portion may also include a threaded portion to facilitate insertion between adjacent bone structures. A hollow interior cavity is defined within the implant member to accommodate bone growth inducing substances to facilitate the fusion process. A plurality of apertures extend through the external surface portion in communication with the interior cavity wall portion, to thereby permit bone ingrowth to facilitate fusion of the adjacent bone structure.

The entry end portion of the implant member defines a generally circular cross-sectional dimension transverse to the longitudinal axis to facilitate positioning between the adjacent bone structures. The entry end portion includes closed entry end surface.

At least one flute may be formed on the exterior surface portion to capture bone material removed during insertion of the implant within the bone structures. The one flute is disposed adjacent the entry end portion and is formed in the threaded portion. Preferably, the one flute extends to the closed entry end surface.

An apparatus for facilitating fusion of adjacent vertebrae is also disclosed. The apparatus includes an implant member configured and dimensioned for insertion within an intervertebral space defined between adjacent vertebrae. The implant member includes at least a longitudinal section having a transverse cross-sectional dimension defining a generally elliptical configuration. The implant member includes an internal cavity for accommodating bone growth inducing substances and a plurality of apertures extending through an external wall portion thereof in communication with the internal cavity. An external threaded portion is formed on the implant member for facilitating insertion within the intervertebral space.

A system and associated method to facilitate insertion of the fusion implants is also disclosed. In a preferred embodiment, a system for drilling a bore in adjacent vertebrae to facilitate the insertion of a fusion implant includes a surgical retractor including a sleeve member with proximal and distal end portions and defining a longitudinal opening and a drill instrument positionable within the longitudinal opening of the surgical retractor. The distal end portion of the retractor is configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae to distract the adjacent vertebrae to a desired predetermined distracted position.

Preferably, the drill instrument includes an elongate member having a longitudinal passageway and defining at least one distal cutting surface and a drill member disposed within the elongate member and having a distal drill head. The drill member is rotatably movable within the elongate member and is also longitudinally fixed to the elongate member such that advancement of the drill member within the retractor causes corresponding advancement of the elongate member such that the distal cutting surface of the elongate member and the distal drill head of the drill member cooperate to cut a bore, e.g., an elliptical-shaped bore, in the adjacent vertebrae. Preferably, the elongate member of the drill instrument includes first and second diametrically opposed distal cutting surfaces. The cutting surfaces may be arcuately-shaped.

Preferably, the distal end portion of the retractor includes two spaced apart retractor arms having first and second support surfaces which respectively engage and distract upper and lower vertebrae. At least one anchoring member may be associated with the surgical retractor to facilitate mounting of the retractor to the vertebrae.

The system may further include alignment means for aligning and maintaining the elongate member of the drill instrument at a predetermined angular orientation within the sleeve member of the surgical retractor. The preferred alignment means is adapted to angularly orient the first and second distal cutting surfaces in general alignment within respective retractor arms of the surgical retractor. The alignment means may include at least one groove defined in the sleeve member of the surgical retractor, the one groove dimensioned to accommodate a corresponding spline of the elongate member.

The present disclosure is also directed to a system for drilling a bore in adjacent vertebrae to facilitate the insertion of a fusion implant comprising a surgical retractor including a sleeve member having proximal and distal end portions and defining a longitudinal opening, with the distal end portion configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae to distract the adjacent vertebrae and the sleeve member including an internal threaded portion. A drill instrument is positionable within the longitudinal opening of the surgical retractor, and includes a drill member having a distal cutting head and an external threaded portion engageable with the internal threaded portion of the retractor whereby rotation of the drill instrument causes distal translation of the drill instrument relative to the surgical retractor.

A method for performing a surgical procedure with the system is also disclosed. The method includes the steps of providing a surgical retractor including an elongate member defining a longitudinal opening and having two spaced apart retractor arms with first and second supporting surfaces at its distal end, inserting the retractor arms of the retractor within the intervertebral space whereby the first and second supporting surfaces of each retractor arm respectively engage and distract the adjacent opposed vertebras, mounting the surgical retractor to the adjacent vertebrae by securing an anchor member associated with the

surgical retractor to the adjacent vertebrae and performing the surgical procedure adjacent the distracted vertebrae by, e.g., introducing surgical instrumentation within the opening of the surgical retractor.

A method for fusing adjacent vertebral bodies with the system is also disclosed. The method includes the steps of accessing the intervertebral disc space, providing a retractor including a retractor sleeve having opposed retractor arms extending in a general longitudinal direction, positioning the retractor arms within the intervertebral disc space whereby first and second supporting surfaces of each arm contact opposed vertebra bodies, introducing a drill instrument into the retractor sleeve and advancing the drill instrument within the sleeve to the disc space wherein the drill instrument includes an elongate member having a longitudinal passageway and defining at least one distal cutting surface and a drill member rotatably mounted within the elongate member and having a distal cutting head, actuating the drill instrument such that the distal cutting head of the drill member and the distal cutting surface of the elongate member are advanced into the adjacent vertebrae to cooperate and cut a bore in the adjacent vertebra, removing the drill instrument from the sleeve, and introducing a fusion implant into the bore. Preferably an elliptical bore is formed and a fusion implant having an elliptical cross-sectional dimension is inserted into the bore.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiment(s) of the present disclosure are described herein with reference to the drawings wherein:

FIG. 1 is a view illustrating a portion of the vertebral column of a patient;

FIG. 2 is a view taken along line 2-2 of FIG. 1 illustrating a pair of prior art fusion implants positioned within the intervertebral space for fusion of adjacent vertebrae;

FIGS. 3-4 are front and rear perspective views of the fusion implant in accordance with the principles of the present disclosure;

FIG. 5 is a perspective view of the fusion implant of FIGS. 3-4 illustrating the implant body and detachable end cap;

FIG. 6 is a side plan view of the implant body;

FIG. 7A is an axial view taken along line 7A-7A of FIG. 6 illustrating the entry end portion of the implant body;

FIG. 7B is an axial view taken along lines 7B-7B of FIG. 6 illustrating the trailing end portion of the fusion implant;

FIG. 8 is a side cross-sectional view of the implant body and mounted end cap taken along line 8-8 of FIG. 7B;

FIG. 9 is a top cross-sectional view of the implant body and mounted end cap taken along line 9-9 of FIG. 7B;

FIG. 10A is a cross-sectional view taken along line 10A-10A of FIG. 9 illustrating a section through the major diameter of the thread;

FIG. 10B is a cross-sectional view taken along line 10B-10B of FIG. 9 illustrating a section through the minor diameter of the thread;

FIG. 11 is a cross-sectional view taken along line 11-11 of FIG. 9 illustrating the circular configuration of the entry end portion of the implant body;

FIG. 12 is a perspective view of an instrumentation kit utilized for inserting the fusion implant within the intervertebral space, including a surgical retractor, a surgical drill, an implant insertion instrument and a T-shaped handle;

FIG. 13 is a view illustrating the lateral insertion of the surgical retractor within the intervertebral space;

FIG. 14 is a view taken along line 14-14 of FIG. 13 further illustrating positioning of the retractor within the intervertebral space and engagement of the retractor with the vertebral end faces of the adjacent vertebrae;

FIG. 15 is a view similar to the view of FIG. 14 illustrating insertion of a drilling instrument into the retractor to drill a bore within the adjacent vertebrae;

FIG. 16 is a side plan view illustrating the insertion instrument with the fusion implant mounted to the insertion instrument;

FIG. 16A is a cross-sectional view of the distal end of the insertion instrument and the fusion implant illustrating mounting of the end cap to the implant body;

FIG. 17 is a view similar to the view of FIG. 15 illustrating insertion of the insertion instrument and mounted implant through the retractor;

FIGS. 18-20 are enlarged views illustrating positioning of the fusion implant within the preformed bore;

FIG. 21 is a view illustrating the fusion implant mounted within the intervertebral space;

FIG. 22 is a sectional view further illustrating the fusion implant mounted within the intervertebral space;

FIG. 23 is a view illustrating a different sized fusion implant mounted within the vertebral space;

FIG. 24 is a perspective view of an alternate system for inserting the implant of FIGS. 3-11 including a surgical retractor utilized in distracting adjacent bony structures and a surgical drilling instrument utilized in drilling a bore within the adjacent bony structure in accordance with the principles of the present disclosure;

FIG. 24A is a perspective view of an insertion instrument and detached T-handle utilized in inserting an implant within the adjacent bony structures;

FIG. 25 is a perspective view with parts separated of the surgical retractor of FIG. 24;

FIG. 26 is a side view in cross-section of the surgical retractor of FIG. 25;

FIG. 26A is an isolated view of the anchoring member being retained within the retractor;

FIG. 27 is an axial view of the surgical retractor;

FIG. 28 is a side plan view of the drilling instrument;

FIG. 29 is an isolated view in cross-section illustrating the mounting of the drill shaft and drill bit and the mounting of the extension sleeve and the drill shaft;

FIG. 30 is an axial view of the drilling instrument;

FIG. 31 is a view of a portion of the vertebral column;

FIG. 32 is a sectional view of the vertebral column taking along the lines 31-31 of FIG. 31 illustrating insertion of the surgical retractor within the intervertebral space;

FIG. 33 is a cross-sectional view further illustrating the surgical retractor inserted within the intervertebral space;

FIG. 34 is a view similar to the view of FIG. 33 illustrating mounting of the anchoring screws into the vertebral column;

FIG. 35 is a view similar to the view of FIG. 34 illustrating insertion of the drilling instrument into the surgical retractor;

FIG. 36 is a view similar to the view of FIG. 35 illustrating advancement of the drilling instrument to drill a bore within adjacent vertebrae;

FIG. 36A is a cross-sectional view taken along the lines 36A-36A of FIG. 36;

FIG. 37 is a view similar to the view of FIG. 36 illustrating insertion of the insertion instrument and mounted fusion implant into the surgical retractor to insert the implant;

FIG. 38 is a sectional view illustrating the fusion implant mounted within the intervertebral space; and

FIG. 39 is a view further illustrating the fusion implant mounted within the intervertebral space.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The preferred embodiment of the apparatus and method disclosed herein are discussed in terms of orthopedic spinal fusion procedures and instrumentation. It is envisioned, however, that the disclosure is applicable to a wide variety of procedures including, but, not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and spinal stabilization. In addition, it is believed that the present method and instrumentation finds application in both open and minimally invasive procedures including endoscopic and arthroscopic procedures wherein access to the surgical site is achieved through a cannula or small incision.

The following discussion includes a description of the fusion implant utilized in performing a spinal fusion followed by a description of the preferred method for spinal fusion in accordance with the present disclosure.

In the discussion which follows, the term "proximal", as is traditional, will refer to the portion of the structure which is closer to the operator, while the term "distal" will refer to the portion which is further from the operator.

Fusion Implant

Referring now to the drawings in which like reference numerals identify similar or identical elements throughout the several views, FIGS. 3-5 illustrate in perspective the fusion implant of the present disclosure. Fusion implant 100 is contemplated to be a self-tapping implant, i.e., the implant is intended to be inserted within a preformed bore in adjacent bone structures, e.g., adjacent vertebrae, without necessitating tapping of an internal thread within the bone structures prior to insertion and is preferably configured for lumbar vertebrae. Fusion implant 100 includes elongated implant body 102 and end cap 104 which is mountable to the implant body 102. Implant body 102 is preferably fabricated from a suitable biocompatible rigid material such as titanium and/or alloys of titanium, stainless steel, ceramic materials or rigid polymeric materials. Implant body 102 is preferably sufficient in strength to at least partially replace the supporting function of an intervertebral disc, i.e., to maintain adjacent vertebrae in desired spaced relation, during healing and fusion, and is strategically dimensioned to span the intervertebral space such that only one implant (as opposed to two as is conventional) is required for insertion. The implant 100 is preferably provided in various lengths such as about 24 mm, 26 mm and 28 mm for example.

As best depicted in FIGS. 5-7B, implant body 102 is generally elliptical in configuration defining a major axis "a" greater than a minor axis "b" (FIG. 5). This configuration provides a greater surface area of the implant so as to facilitate contacting engagement and support of the implant with the adjacent vertebrae. In particular, as discussed in greater detail hereinbelow, in the inserted position of the fusion implant 100, the major axis "a" is in general parallel relation with the vertebral end faces of the adjacent vertebrae, thus, positioning the major arc or outer surface of implant body 102 in contact with the vertebral end faces. The oval or elliptical configuration and dimensions enable one implant to be

utilized instead of two implants of the prior art. The elliptical configuration of implant body 102 also minimizes any tendency of the inserted implant 100 from backing out of the preformed bore. Implant body 102 includes an outer wall 106 which enclose an inner cavity 108 defined within the interior of the implant body 102. Inner cavity 108 accommodates bone growth inducing substances which facilitate the fusion process.

In a preferred embodiment, the diameter of the implant 102 along its major axis preferably ranges from about 16 mm to about 20 mm, and preferably is about 19 mm. The diameter along the minor axis preferably ranges from about 14 mm to about 17 mm, and preferably is about 16 mm. Other dimensions are also contemplated.

With reference to FIGS. 8-10B, in conjunction with FIG. 5, outer wall 106 has an external threaded configuration formed as part of its exterior surface. External threaded configuration including a continuous helical thread 110 which assists in advancing implant body 102 into a preformed channel provided in the adjacent vertebrae. Thread 110 as shown preferably has an angled face on the posterior side and a sharp end toward the anterior side to prevent expulsion to the anterior side. Thread 110 is preferably a self-tapping cutting thread, i.e., the threads are capable of deburring bone material during advancement into the performed channel. Alternatively, a thread can be tapped in the bone prior to insertion of the implant.

A plurality of apertures 112 extend through outer wall 106 of implant body 102. Apertures 112 are preferably formed by broaching grooves in the internal surface of the internal cavity 108. The effect of such broaching is to remove material from the valleys between the threads 110, thus defining the apertures 112. The advantages of such an arrangement are disclosed in U.S. Patent No. 4,961,740, the contents of which are incorporated herein by reference,

and include immediate bone to bone contact between the vertebral bodies or bone structures and the bone inducing substances packed within the internal cavity 108 of the implant body 102. Apertures 112 are preferably substantially the same in dimension although it is envisioned that the dimensions of the apertures may vary to provide for more or less bone to bone contact as desired.

As best depicted in FIGS. 10A-10B, apertures 112 are clustered about a transverse axis or minor axis "b", both at the upper and lower end of the axis. Consequently, apertures 112 come into contact with the upper and lower vertebral bone structures to encourage bone growth through implant body 102 from the vertebral bone structures. The lateral sections of implant body 102 formed along the major axis "a" do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process.

With reference now to FIGS. 6-7A and 11, the entry or leading end potion (distal) 114 of implant body 102 is preferably rounded, i.e., generally circular in cross-section as best depicted in FIG. 11 and defines a closed rounded entry end surface 116. This facilitates insertion. End surface 116 includes a plurality of flutes or relief grooves 118 formed in its surface. (four are shown). Flutes 118 assist in insertion of fusion implant 100 within the intervertebral space by capturing bone material deburred during the self-tapping process. In a preferred embodiment, flutes 118 meet at a central point of the longitudinal axis on the entry end of surface 116 and extend proximally to at least the first turn of the thread on implant body 102. The flute portions formed on thread 110 are defined by the sections 120 which are removed from the thread. (See also FIG. 5.) This arrangement permits adequate relief for purposes of self tapping of implant 100 in the intervertebral space. It is also envisioned that the flutes may run deeper and extend from the leading end 114 completely to the end cap 104, or, to a position intermediate the end cap 104 and the leading end 114.

With reference now to FIG. 5 and FIG. 7B, the trailing end portion 122 of implant body 102 has a generally annular recess 124 which receives end cap 104. An internal thread 126 is disposed adjacent annular recess 124 and cooperates with external thread 128 on the periphery of end cap 104 to mount the end cap to implant body 102. Trailing end portion 122 also includes a pair of diametrically opposed notches 130. Notches 130 are dimensioned to be engaged by corresponding structure of an insertion apparatus utilized in inserting the implant within the vertebral column. End cap 104 includes a central threaded aperture 132 which threadably engages corresponding structure of the insertion apparatus to assist in the mounting of the cap 104 on implant body 102.

Instrumentation Kit

Referring now to FIG. 12, there is illustrated one preferred instrumentation kit for inserting spinal implant 100 within the intervertebral space. The instrumentation kit 200 includes surgical retractor 202, drill instrument 204 and insertion instrument 206. A T-shaped handle 208 is also provided in kit 200, and is utilized to actuate drill instrument 204 and insertion instrument 206.

Surgical retractor 202 is disclosed in commonly assigned U.S. patent Application Serial No. 08/615,379, filed March 14, 1996, the contents of which are incorporated herein by reference. Retractor 202 is configured for distracting adjacent vertebral bodies to facilitate the insertion and application of an implant, for providing a cannula for insertion of the instruments, and for ensuring proper alignment of the instrumentation and accurate insertion of the implant. Retractor 202 includes sleeve 210 with an enlarged head 212 at the proximal end of the sleeve 210. Sleeve 210 includes first and second diametrically opposed retractor arms 214 having first and second parallel vertebrae supporting surfaces 216, 218.

Drill instrument 204 is also disclosed in the '379 application. Drill instrument 204 includes drill shaft 220, extension shaft 222 and drill bit 224 mounted at the distal end of the drill shaft. T-handle 208 is mountable to a proximal mounting section of the drill instrument 204. Extension shaft 222 has first and second collars 226, 228 which cooperate to control the depth of penetration of drill shaft 220 into the adjacent vertebrae.

Insertion instrument 206 is disclosed in commonly assigned U.S. patent Application Serial No. 08/616,120, filed March 14, 1996, the contents of which are also incorporated herein by reference. Insertion instrument 206 includes implant engaging structure 230 at its distal end which is correspondingly configured to mount and release implant 100 as will be discussed herein below. A pair of control wheels 232, 234 serve to control actuation of insertion instrument 206 thereby controlling mounting and releasing of the implant within the intervertebral space.

Insertion of Fusion Implant With Instrumentation Kit

The insertion of the fusion implant 100 with the instrumentation kit 200 into an intervertebral space defined between adjacent lumbar vertebrae will now be described. The subsequent description will be particularly discussed in conjunction with an open antero-lateral approach for spinal fusion implant insertion. However, it is to be appreciated that other approaches, e.g., posterior, direct anterior, etc... could be utilized. Laparoscopic approaches are also envisioned.

With respect now to FIG. 13, the intervertebral space "i" is accessed utilizing appropriate retractors to expose the anterior vertebral surface. Thereafter, retractor 202 is inserted within the intervertebral space "i" from an antero-lateral or oblique approach with relation to the vertebral columns 216, 218 as depicted in

FIG. 13. Such approach provides advantages with regard to avoiding interference by the great vessels "g" (FIG. 13) and limiting penetration of the anterior longitudinal ligament "l". The retractor may be inserted by placing an impactor cap at the proximal end and impacting the retractor into the intervertebral space.

FIG. 14 depicts retractor 202 positioned within the intervertebral space "i" with the retractor arms 214 arranged such that the first and second supporting surfaces 216,218 of each retractor arm 214 respectively engage the opposed vertebral bodies "V_1, V_2". Upon insertion of retractor arms 214, the vertebral bodies "V_1, V_2" are distracted whereby the retractor arms become firmly lodged within the intervertebral space "i".

Referring now to FIG. 15, the drilling instrument 204 is now utilized to prepare the disc space and vertebral end plates for insertion of the fusion implant. The cutting depth of drilling instrument 204 is adjusted as desired (i.e., to correspond to the length of the fusion implant) by adjusting collars 226, 228. With the T-handle 208 mounted to drilling instrument 204, the instrument is introduced into retractor 202 and advanced to contact the anterior surface of the vertebral bodies "V_1 V_2". Drilling instrument 204 is advanced into the intervertebral space "i" by rotating T-handle 208 to shear the soft tissue and cut the bone of the adjacent vertebrae "V_1 V_2" thereby forming a bore which extends into the adjacent vertebrae "V_1, V_2".

Subsequent to the drilling process, fusion implant 100 is packed with bone growth inducing substances "b" as in conventional in the art and end cap is threaded into recess 124 of implant body 102 either by hand, with a socket wrench-type instrument or with insertion instrument 206 as depicted in FIG. 16A. In particular, as shown in FIG. 16A, end cap 104 may be threaded onto mounting screw 232 of insertion instrument 206 and then threaded into recess 124 of implant body 102 via rotation of wheel 232. The fusion implant 100 is then mounted on

insertion instrument 206 by positioning distal tabs 234 of insertion instrument 206 within correspondingly dimensional recesses 128 of end cap 104 (FIG. 5). FIG. 16 illustrates fusion implant 100 mounted to insertion instrument 206. Further details of the mounting of implant 100 to insertion instrument 206 may be ascertained by reference to the '120 application.

Referring now to FIG. 17, insertion instrument 206 and mounted implant 100 is introduced within retractor 204 and advanced to a position adjacent the vertebral bodies "V_1, V_2". Thereafter, insertion instrument 206 is rotated via T-shaped handle 202 which is mounted to the instrument 206 to thereby cause corresponding rotation of fusion implant 100. As fusion implant 100 rotates, the thread 110 of the implant body 102 bites into the vertebral bodies "V_1, V_2". Continued rotation of insertion tool 206 causes implant to move through the position shown in FIG. 18 to the position shown in FIG. 19 to be self-tapped within the preformed bore. Implant 100 is released from its mounting to insertion tool 206 and the instrument 206 and retractor 204 are removed from the disc area.

FIGS. 20-22 depict fusion implant 100 inserted within the intervertebral space "i". As shown, fusion implant 100 forms a strut across the intervertebral space "i" to maintain the adjacent vertebrae "V_1, V_2" in appropriate spaced relation during the fusion process. The implant is thus preferably inserted at an angle of between about 15 degrees and about 45 degrees, and more preferably at about 30 degrees to the longitudinal axis of the spine and to the right of the great vessels as view anteriorly. As also shown, in the inserted position of implant 100, the major axis "a" is in general parallel relation to the vertebral end plates thus presenting the greater arc or surface area of implant body 102 to contact and support the adjacent vertebrae. Over a period of time, the adjacent vertebral tissue communicates through apertures 112 with the bone growth inducing substances "b" within the interior cavity 108 of implant to form a solid

fusion. Thus only one implant is required as opposed to two implants of the prior art as shown in Fig. 2. Implantation of the implants M1, M2 of Fig. 2 require greater manipulation due to the presence of the great vessels "g" and require increased penetration of the anterior longitudinal ligament "l".

FIG. 23 by way of example illustrates a different sized fusion implant 100' positioned within the intervertebral space. This cage fills a larger portion of the disc space.

Alternate Instrumentation Kit

FIG. 24 illustrates, in perspective, an alternate surgical system or kit particularly contemplated for facilitating the insertion of the fusion implant of FIGS. 3-11 within the intervertebral space defined between adjacent vertebrae. System 500 generally includes two surgical instruments, namely retractor 1000 and drilling instrument 2000 which is positionable within the retractor 1000.

With reference now to FIGS. 25-27, in conjunction with FIG. 24, retractor 1000 includes elongated retractor sleeve 1020 defining a longitudinal axis "a" and having longitudinal opening or passageway 1040 extending therethrough. Retractor sleeve 1020 includes first and second diametrically opposed rails 1060 extending longitudinally along the outer surface of the retractor sleeve 1020. Each rail 1060 has a longitudinal opening 1080. An anchoring member 1100 is disposed within opening 1080 of each rail 1060. Anchoring member 1100 is intended to positively fix retractor 1000 to the bony structures, e..g, adjacent vertebrae. In the preferred embodiment, anchoring member 1100 is in the form of an elongated screw as shown and includes a distal screw thread 1120 which is advantageously configured to penetrate and become mounted within bony tissue. The proximal end of anchoring member 1100 includes structure, e.g., a Phillips head 1140, to be engaged by a driving member, e.g., a Phillips head screw driver or the like, to

rotate and advance the anchoring member 1100 in a conventional manner. As depicted in FIG. 26, each anchoring member 1100 is biased proximally by coil spring 1160 whereby distal screw thread 1120 is disposed within opening 1060 of rail 1060 in the unadvanced position of the anchoring member 1100. Anchoring member 1100 is retained within each rail 1060 by lip 1180 extending within opening 1080 of each rail 1060 and engaging the proximal edge of the anchoring member (FIG. 26A), thereby preventing the anchoring member 1100 from exiting the proximal end of retractor sleeve 1020.

Anchoring member 1100 thus constitutes "anchoring means" to positively mount surgical retractor 1000 to the adjacent vertebrae. Other forms of anchoring means are envisioned as well such as, but, not limited to, fasteners, staples, clips etc... which may be driven from the proximal location of retractor sleeve 1020. Additional forms of "anchoring means" may include suture ties, bands, clamps, etc. ...

With reference again to FIGS. 25-27, retractor 1000 includes first and second diametrically opposed retractor arms 1200 extending from the distal end of retractor sleeve 1020. Each retractor arm 1200 has first and second supporting surfaces 1200a, 1200b (FIG. 26) extending in general parallel relation to each other and preferably to the longitudinal axis of retractor sleeve 1020. The height "h" of each arm (i.e., the distance between supporting surfaces 1200a, 1200b) corresponds to the height of the space between adjacent bony structures to be distracted. For example, in spinal implant application, the height "h" of each arm can range from about 0.28 inches to about 0.35 inches. Each arm 1200 further includes tapered end portions 1220 defining a general V-shaped configuration. End portions 1220 facilitate insertion of retractor arms 1200 within the surgical site, e.g., within the intervertebral space.

The proximal end of retractor sleeve 1020 defines an inner threaded bore 1240. Threaded bore 1240 assists in causing translation of the surgical drilling instrument 2000 through retractor sleeve 1020 as will be discussed. Retractor 1000 further includes first and second inner longitudinal recesses 1260 which each extend from the proximal end of retractor sleeve 1020 to an intermediate point of retractor arms 1200. First and second longitudinal recesses 1260 function in maintaining proper alignment of the surgical drilling instrument 2000 inserted within retractor 1000 as will be appreciated from the description provided hereinbelow.

Referring now to FIGS. 28-30, in conjunction with FIG. 24, the surgical drilling instrument 2000 of the system 100 will be discussed. Drilling instrument 2000 is advantageously configured to form an elliptical-shaped bore in the adjacent vertebrae to accommodate the elliptical implant. Clearly, the drill can be configured to form other shaped bores. Drilling instrument 2000 includes drill shaft 2020, drill bit 2040 connected to and extending distally from the drill shaft 2020 and extension sleeve 2060 mounted to the distal end of the drill shaft 2020. In a preferred arrangement, depicted in detail in FIG. 29, drill shaft 2020 includes an internal threaded recess 2080 which threadably engages external threaded portion 2100 of drill bit 2040 to connect the components. With this arrangement, rotational movement of the drill shaft 2020 causes corresponding rotational movement of the drill bit 2040. Drill bit 2040 defines distal cutting edges 2040a which form a generally circular bore in the bone structures.

Extension sleeve 2060 is mounted to drill shaft 2020 to permit relative rotational movement of the two components. In a preferred arrangement, drill shaft 2020 includes a circumferential mounting recess 2120 which receives correspondingly dimensioned circumferential mounting lip 2140 of extension sleeve 2060 in sliding manner to permit rotational movement of the drill shaft 2020 and,

thus, rotational movement of the drill bit 2040 within the extension sleeve 2060. Extension sleeve 2060 further defines first and second axial splines 2160 disposed on the outer surface of the extension sleeve 2060 in diametrical arrangement. Axial splines 2160 are received within longitudinal recesses 1260 (FIG. 25) within the interior of the sleeve 2060 to rotationally fix the extension sleeve 2060 within retractor 1000.

Extension sleeve 2060 further defines diametrically opposed cutting arms 2180 at its distal end. Cutting arms 2180 define distal cutting surfaces 2180a which are advantageously dimensioned to cut or shear bony tissue upon advancement of the drill instrument 2000 into the tissue. Cutting surfaces 2180a are preferably arcuate in cross-section as best depicted in FIG. 30. As will be better appreciated hereinbelow, cutting surfaces 2180a in combination with drill bit 2020 form a general elliptical bore in the bony tissue. In particular, drill bit 2020 forms through a drilling action a circular hole while cutting surfaces 2180a cut by a chiseling, shearing action diametrically opposed arcuate sections adjacent the circular bore thereby defining an elliptical configuration of the formed bore in the tissue section.

Referring still to FIGS. 28-30, drill shaft 2020 further includes stationary collar 2200 and first and second movable collars 2220, 2240 adjacent the stationary collar 2200. Moveable collars 2220, 2240 are threadably mounted on threaded portion 2260 and are each moveable on the threaded portion 2260 between a proximalmost position adjacent stationery collar 2200 and a distalmost portion remote from the collar 2200. First collar 2220 serves as a positioning collar, i.e., by adjusting the positioning of first collar 2220 on threaded portion 2260, the depth of penetration of drill shaft 2020 into the bony structures may be adjusted. Second collar 2240 serves as a locking collar to selectively lock the first collar 2220 at a predetermined location on threaded portion 2260.

Drill shaft 2020 further includes an intermediate external threaded portion 2280 disposed at about the midpoint of the drill shaft 2020 to assist in translation of the drill shaft 2020 within the retractor 1000. More particularly, threaded portion 2280 cooperatively threadably engages internal threaded bore 1240 disposed within retractor sleeve 1020. Accordingly, rotation of the drill shaft 2020 causes the drill shaft 2020 to translate longitudinally within the retractor 1000. The proximal end of drill shaft 2020 includes mounting structure 2300, e.g., a hexagonal-shaped head, which cooperates with corresponding structure of a T-shaped handle (to be discussed) to assist in operating the drilling instrument.

FIG. 24A illustrates one type of insertion instrument 4000 utilized to insert the implant 100 within the intervertebral space and a T-shaped handle 5000 utilized to actuate the insertion instrument 4000 and the drilling instrument 2000. Insertion instrument 4000 is disclosed in commonly assigned U.S. patent Application Serial No. 08/616,120, filed March 14, 1996, the contents of which are incorporated herein by reference. Insertion instrument 4000 includes implant engaging structure 4020 at its distal end which is correspondingly configured to mount and release implant 100 as will be discussed hereinbelow. A pair of control wheels 4040, 4060 serve to control actuation of insertion instrument 4000 thereby controlling mounting and releasing of the implant within the intervertebral space. T-shaped handle 5000 is mountable to the proximal end of drilling instrument 2000 and to the proximal end of the insertion instrument 4000. Handle 5000 includes hex-head recess 5020. Further details of this instrument 4000 and handle 5000 may be ascertained by reference to the '120 application.

Use of the System For Insertion of the Fusion Implant

The use of the system 500 for the insertion of the fusion implant 100 into an intervertebral space defined between adjacent lumbar vertebrae will now be described. The subsequent description will be particularly discussed in conjunction with an open antero-lateral approach for spinal fusion implant insertion. However, it is to be appreciated that other approaches, e.g., posterior, direct anterior, etc... could be utilized. Laparoscopic approaches are also envisioned.

With respect now to FIGS. 31-32, the desired intervertebral space "i" between adjacent vertebrae "v_1, v_2" is accessed utilizing appropriate retractors to expose the anterior vertebral surface. Thereafter, retractor 1000 is inserted within the intervertebral space "i" from an antero-lateral or oblique approach with relation to the vertebral columns "v_1, v_2" as depicted in FIG. 32. Such approach provides advantages with regard to avoiding interference by the great vessels "g", limiting penetration of the anterior longitudinal ligament "l" and minimizing resection of the psoas muscle. The retractor 1000 may be inserted by impacting the proximal end of the retractor to drive the retractor into the intervertebral space.

FIG. 33 depicts retractor 1000 positioned within the intervertebral space "i" with the retractor arms 1200 arranged such that the first and second supporting surfaces 1200a, 1200b of each retractor arm 1200 respectively engage the opposed vertebral bodies "v_1, v_2". Upon insertion of retractor arms 1200, the vertebral bodies "v_1, v_2" are distracted whereby the retractor arms 1200 become firmly lodged within the intervertebral space "i". As noted above, upon insertion of the retractor arms 1200, the vertebrae "v_1,v_2" are distracted to a desired operative position. As depicted in FIG. 34, anchoring members 1100 are then advanced within their respective openings 1080 of rails 1060 and mounted within the vertebra "v_1, v_2" with the use of mounting tool 6000, e.g., an elongated driver

or the like, whereby the distal screw thread 1120 of each anchoring member engages the vertebral tissue. As a result, retractor 1000 is positively fixed to the vertebral column.

Referring now to FIG. 35, the drilling instrument 2000 is now utilized to prepare the disc space and vertebral end plates for insertion of the fusion implant. The cutting depth of drilling instrument 2000 is adjusted as desired (i.e., to correspond to the length of the fusion implant) by adjusting collars 2220, 2240 of the drilling instrument 2000. In particular, collar 2220 is moved to the desired position on threaded portion 2260 on the drill shaft 2020 and locking collar 2240 is moved adjacent the collar 2220 to lock the collar 2220 at the position. With the T-handle 5000 mounted to drilling instrument 2000, by corresponding reception of hex-head mounting structure 2300 within hex-head bore 5020 of handle 5000, the instrument is introduced into retractor sleeve 1020. Preferably, drill instrument 2000 is inserted within retractor sleeve 1020 whereby axial splines 2160 on the exterior surface of extension sleeve 2060 are received within internal recesses 1260 extending the length of the retractor sleeve 1020 and retractor arms 1200. T-shaped handle 5000 is thereafter rotated which causes drill shaft 2020 and drill bit 2040 to rotate. With reference to FIGS. 36 and 36A, as drill shaft 2020 rotates, it also advances within retractor sleeve 1020 due to the threaded engagement of threaded portion 2280 on the drill shaft 2020 with internal threaded portion 1240 of retractor sleeve 1020 thereby advancing the drill bit 2040 into the adjacent vertebrae "v_1, v_2" to form a circular bore in the end plates of the adjacent vertebrae. In addition, as drill shaft 2020 advances it also drives extension sleeve 2060 distally within the adjacent vertebrae. Due to the interengagement of axial splines 2160 and longitudinal recesses 1260, extension sleeve 2060 advances without rotating whereby cutting surfaces 2180a at the distal end of extension sleeve 2060 cuts through a shearing action into the adjacent

vertebrae "v_1, v_2". Thus, the cutting surfaces 2180a of the cutting arms 2180 are retained at the desired angular orientation adjacent retractor arms 1200. The arcuate orientation of the cutting surfaces 2180a of extension sleeve 2060 in combination with drill bit 2040 form a general elliptical opening in the adjacent vertebrae "v_1, v_2". It is to be noted that drilling instrument is advanced within retractor sleeve 1020 until positioning collar 2220 engages the proximal end of the retractor sleeve as shown in FIG. 36 - the length of travel of drilling instrument being predetermined by adjusting collars 2220, 2240 as discussed above.

Subsequent to the drilling process, fusion implant 100 is packed with bone growth inducing substances as is conventional in the art and end cap 104 is threaded into a threaded recess of implant body 102. The fusion implant 100 is then mounted on insertion instrument 4000 by cooperative engagement of the engaging structure 4020 of the insertion instrument with the implant 100 as discussed above.

Referring now to FIG. 37, insertion instrument 4000 and mounted implant 100 is introduced within retractor 1000 and advanced to a position adjacent the vertebral bodies "v_1, v_2". Thereafter, insertion instrument 4000 is rotated via T-shaped handle 5000 which is mounted to the instrument 4000 to thereby cause corresponding rotation of fusion implant 3000. As fusion implant 3000 rotates, the thread 3080 of the implant body 3020 bites into the vertebral bodes "v_1, v_2". Continued rotation of insertion tool 4000 causes implant 3000 to be self-tapped within the preformed bore. Implant 3000 is released from its mounting to insertion tool 4000 and the instrument 4000 and retractor 1000 are removed from the disc area.

FIGS. 38-39 depict fusion implant 100 inserted within the intervertebral space "i". As shown, fusion implant 100 forms a strut across the intervertebral space "i" to maintain the adjacent vertebrae "v_1, v_2" in appropriate

spaced relation during the fusion process. The implant is thus preferably inserted at an angle of between about 15 degrees and about 45 degrees, and more preferably at about 30 degrees to the longitudinal axis of the spine and to the right of the great vessels as view anteriorly. As also shown, in the inserted position of implant 100, the major axis "a" is in general parallel relation to the vertebral end plates thus presenting the great arc or surface area of implant body 102 to contact and support the adjacent vertebrae. Over a period of time, the adjacent vertebral tissue communicates through apertures 112 with the bone growth inducing substances within the interior cavity of implant 100 to form a solid fusion. Thus only one implant is required.

While the above description contains many specifics, these specifics should not be construed as limitations on the scope of the disclosure, but merely as exemplifications of preferred embodiments thereof. For example, the fusion implant 100, 100' could also be used for thoracic and cervical vertebrae. Those skilled in the art will envision many other possible variations that are within the scope and spirit of the disclosure as defined by the claims appended hereto.

WHAT IS CLAIMED IS:

1. An apparatus for facilitating the fusion of adjacent bone structures comprising an implant member configured for insertion within a space defined between adjacent bone structures, the implant member including an entry end portion and a trailing end portion and defining a longitudinal axis, the implant member including at least a longitudinal portion having a generally elliptical cross-sectional dimension transverse to the longitudinal axis.

2. The apparatus according to claim 1 wherein the external surface portion includes a threaded portion to facilitate insertion within the space defined between adjacent bone structures.

3. The apparatus according to claim 2 wherein the implant member includes a hollow interior cavity dimensioned to accommodate bone growth inducing substances.

4. The apparatus according to claim 3 wherein the implant member includes a plurality of apertures extending through an external surface portion in communication with the interior cavity, to thereby permit bone ingrowth to facilitate fusion of the adjacent bone structure.

5. The apparatus according to claim 2 wherein the entry end portion of the implant member defines a generally circular cross-sectional dimension transverse to the longitudinal axis to facilitate positioning between the adjacent bone structures.

6. The apparatus according to claim 5 wherein the entry end portion includes a closed entry end surface.

7. The apparatus according to claim 3 wherein the implant member includes an exterior surface portion having at least one flute formed therein.

8. The apparatus according to claim 7 wherein the one flute is disposed adjacent the entry end portion and is formed in the threaded portion.

9. The apparatus according to claim 8 wherein the entry end portion includes a closed entry end surface.

10. The apparatus according to claim 9 wherein the one flute extends to the closed entry end surface.

11. The apparatus according to claim 1 further including an end cap mountable to the trailing end portion of the implant member to enclose the interior cavity.

12. The apparatus according to claim 1 wherein the implant member is configured for insertion within the intervertebral space defined between adjacent vertebrae.

13. An apparatus for facilitating fusion of adjacent vertebrae comprising an elongated implant member configured and dimensioned for insertion within an intervertebral space defined between adjacent vertebrae, the implant member including at least a longitudinal section having a transverse cross-sectional dimension defining a generally elliptical configuration, the implant member including an internal cavity for accommodating bone growth inducing substances and having a plurality of apertures extending through an external wall portion thereof in communication with the internal cavity.

14. The apparatus according to claim 13 wherein the implant member includes an external threaded portion for facilitating insertion within the intervertebral space.

15. The apparatus according to claim 14 wherein the implant member includes at least one flute, the one flute being formed in the threaded portion.

16. The apparatus according to claim 14 wherein the implant member includes an entry section having a closed entry end surface.

17. The apparatus according to claim 16 including at least one flute formed in the entry end surface.

18. The apparatus according to claim 14 wherein the implant member includes an entry end section, the entry end section having a transverse cross-sectional dimension defining a generally circular configuration.

19. The apparatus according to claim 14 further including an end cap mountable to the implant member to enclose the internal bore.

20. The apparatus according to claim 18, wherein the implant includes a trailing end portion and an intermediate portion between the trailing end portion and the entry end portion, the entire intermediate portion and [trailing end portion] having a transverse cross-sectional dimension defining a generally elliptical configuration.

21. A method for fusion of adjacent vertebrae, comprising the steps of:

accessing the intervertebral space defined between adjacent vertebrae;

positioning a fusion apparatus into the intervertebral space, the fusion apparatus including an implant body having at least a longitudinal section defining a general elliptical transverse cross-section with a major axis greater than a minor axis; and

permitting bone ingrowth into contacting surfaces of the implant body to facilitate fusion of the adjacent vertebrae.

22. The method according to claim 21 wherein the step of positioning includes arranging the implant member within the intervertebral space whereby the major axis of the implant member is in general parallel relation with the vertebral end faces to the adjacent vertebrae.

23. The method according to claim 22 including the step of introducing bone growth inducing substances within an internal cavity defined within the implant body whereby the adjacent vertebrae communicates with the bone growth inducing substances to form a solid fusion.

24. The method according to claim 23 wherein the implant body includes an exterior wall portion having apertures extending therethrough wherein the step of permitting bone ingrowth includes permitting bony tissue of the adjacent vertebrae to grow through the apertures to communicate with the bone growth inducing substances.

25. The method according to claim 24 wherein the implant body includes an external threaded portion, wherein the step of positioning includes screwing the implant body into a preformed receiving bore formed into the adjacent vertebrae.

26. The method according to claim 25 wherein the external threaded portion of the implant body includes a cutting thread wherein the step of screwing the implant body includes advancing the implant body within the preformed receiving bore whereby the cutting thread deburrs bone tissue to self-tap the implant body within the preformed receiving bore.

27. The method according to claim 21, wherein the implant is inserted laterally with respect to the longitudinal axis of the spine.

28. A method for fusion of adjacent vertebrae comprising the steps of:

accessing the intervertebral space of the lumbar spine defined between adjacent vertebrae;

positioning a fusion apparatus into the intervertebral space of the lumbar spine and at an angle of between about 15° and about 45° with respect to the longitudinal axis of the spine and to the right of the great vessels when viewed anteriorly.

29. A system for drilling a bore in adjacent vertebrae to facilitate the insertion of a fusion implant, which comprises:

a surgical retractor including a sleeve member having proximal and distal end portions and defining a longitudinal opening, the distal end portion configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae to distract the adjacent vertebrae; and

a drill instrument positionable within the longitudinal opening of the surgical retractor, the drill instrument including:

an elongate member defining at least one distal cutting surface; and

a drill member disposed within the elongate member and having a distal cutting head, the drill member being rotatably movable within the elongate member and being longitudinally fixed to the elongate member such that advancement of the drill member within the adjacent vertebrae causes corresponding advancement of the elongate member such that the distal cutting surface and the distal cutting head cooperate to cut a bore in the adjacent vertebrae.

30. The system according to claim 29 wherein the distal end portion of the sleeve member of the surgical retractor includes two spaced apart retractor arms having first and second supporting surfaces.

31. The system according to claim 30 wherein the elongate member of the drill instrument includes first and second diametrically opposed distal cutting surfaces.

32. The system according to claim 29 including alignment means for aligning and maintaining the elongate member of the drill instrument at a predetermined angular orientation within the sleeve member of the surgical retractor.

33. The system according to claim 32 wherein the alignment means includes at least one groove defined in the sleeve member of the surgical retractor, the at least one groove dimensioned to accommodate a corresponding spline of the elongate member.

34. The system according to claim 29 wherein the sleeve member of the surgical retractor includes an internal threaded portion, the internal threaded portion threadably engageable with an external threaded portion of the drill instrument whereby rotation of the drill instrument causes distal translation of the drill instrument relative to the surgical retractor.

35. The system according to claim 29 including at least one anchoring member associated with the elongate member and moveable relative to the elongated member to facilitate mounting to vertebrae.

36. A system for drilling a bore in adjacent vertebrae to facilitate the insertion of a fusion implant, which comprises:

a surgical retractor including a sleeve member having proximal and distal end portions and defining a longitudinal opening, the distal end portion configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae to distract the adjacent vertebrae, the sleeve member including an internal threaded portion;

a drill instrument positionable within the longitudinal opening of the surgical retractor, the drill instrument including a drill member having a distal cutting head and an external threaded portion engageable with the internal threaded portion of the retractor whereby rotation of the drill instrument causes distal translation of the drill instrument relative to the surgical retractor.

37. The system according to claim 36 wherein the distal end portion of the sleeve member of the surgical retractor includes two spaced apart retractor arms having first and second supporting surfaces.

38. A method for performing a surgical procedure, comprising the steps of:

providing a surgical retractor including an elongate member having proximal and distal end portions and defining a longitudinal opening, the distal end portion including two spaced apart retractor arms having first and second supporting surfaces;

inserting the retractor arms within the intervertebral space whereby the first and second supporting surfaces of each retractor arm respectively engage and distract the adjacent opposed vertebrae;

mounting the surgical retractor to the adjacent vertebrae by securing anchor members associated with the surgical retractor to the adjacent vertebrae; and

performing the surgical procedure adjacent the distracted vertebrae.

39. The method according to claim 38 wherein the step of performing includes introducing surgical instrumentation within the opening of the surgical retractor to perform the surgical procedure.

40. A method for fusing adjacent vertebral bodies, comprising the steps of:

a) accessing the intervertebral disc space;

b) providing a retractor including a retractor sleeve having proximal and distal end portions, the distal end portion having opposed retractor arms extending in a general longitudinal direction;

c) positioning the retractor arms within the intervertebral disc space whereby first and second supporting surfaces of each arm contact opposed vertebra bodies;

d) introducing a drill instrument into the retractor sleeve and advancing the drill instrument within the sleeve to the disc space, the drill instrument including an elongate member defining at least one distal cutting surface and a drill member rotatably mounted within the elongate member and having a distal cutting head;

e) actuating the drill instrument such that the distal cutting head of the drill member and the distal cutting surface of the elongate member are advanced into the adjacent vertebrae to cooperate and cut a bore in the vertebra bodies;

f) removing the drill instrument from the sleeve; and

g) introducing a fusion implant into the bore.

41. The method according to claim 40 wherein the bore formed in the vertebral bodies defines a general elliptical cross-sectional dimension and wherein the step of introducing includes inserting a fusion implant having a general elliptical cross-sectional dimension into the bore.

42. The method according to claim 41 wherein in a final inserted position of the fusion implant, a major axis of the implant is in the transverse direction generally parallel to the vertebral end plates.

43. A surgical retractor instrument comprising an elongated member having proximal and distal end portions and defining a longitudinal passage for reception of a surgical instrument, the distal end portion having first and second retractor arms extending in a general longitudinal direction, each retractor arm having first and second supporting surfaces for engaging opposed tissue portions, each retractor arm defining a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon insertion thereof, and at least one anchoring member associated with the elongated member and moveable relative to the elongated member to facilitate mounting to the tissue portion.

44. The surgical retractor according to claim 43 wherein the at least one anchoring member includes a distal screw thread wherein rotation of the one anchoring member advances the screw thread into the tissue portion.

45. The surgical retractor according to claim 43 including an outer rail extending longitudinally along an outer surface of the elongated member, the rail defining a longitudinal opening for at least partial reception of the at least one anchoring member.

46. The surgical retractor according to claim 43 including first and second anchoring members associated with the elongated member.

47. The surgical retractor according to claim 46 including first and second diametrically opposed outer rails extending longitudinally along an outer surface of the elongated member, the first and second rails each defining a longitudinal opening for reception of respective first and second anchoring members.

48. The surgical retractor according to claim 43 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation.

49. The surgical retractor according to claim 48 wherein each retractor arm has a tapered end portion for facilitating insertion within an intervertebral space.

50. The surgical retractor according to claim 48 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation to a longitudinal axis of the elongated body.

51. A surgical drill instrument for drilling a bore in bony tissue comprising an elongate member defining a longitudinal axis and having a longitudinal passageway and a drill member positioned within the longitudinal passageway of the elongate member and mounted for rotational movement therein, the elongate member defining at least one distal cutting surface dimensioned to cut bony tissue, the drill member including a distal cutting head, the drill member operatively connected to the elongate member such that rotation and advancement of the drill member causes corresponding advancement of the elongate member such that the one distal cutting head surface of the elongate member and the distal cutting head of the drill head cooperate to form a substantially elliptical bore in the bony tissue upon advancement therein.

52. The surgical retractor according to claim 51 wherein the elongate member includes first and second diametrically opposed distal cutting surfaces.

53. The surgical retractor according to claim 52 wherein the distal cutting surfaces are arcuately shaped.

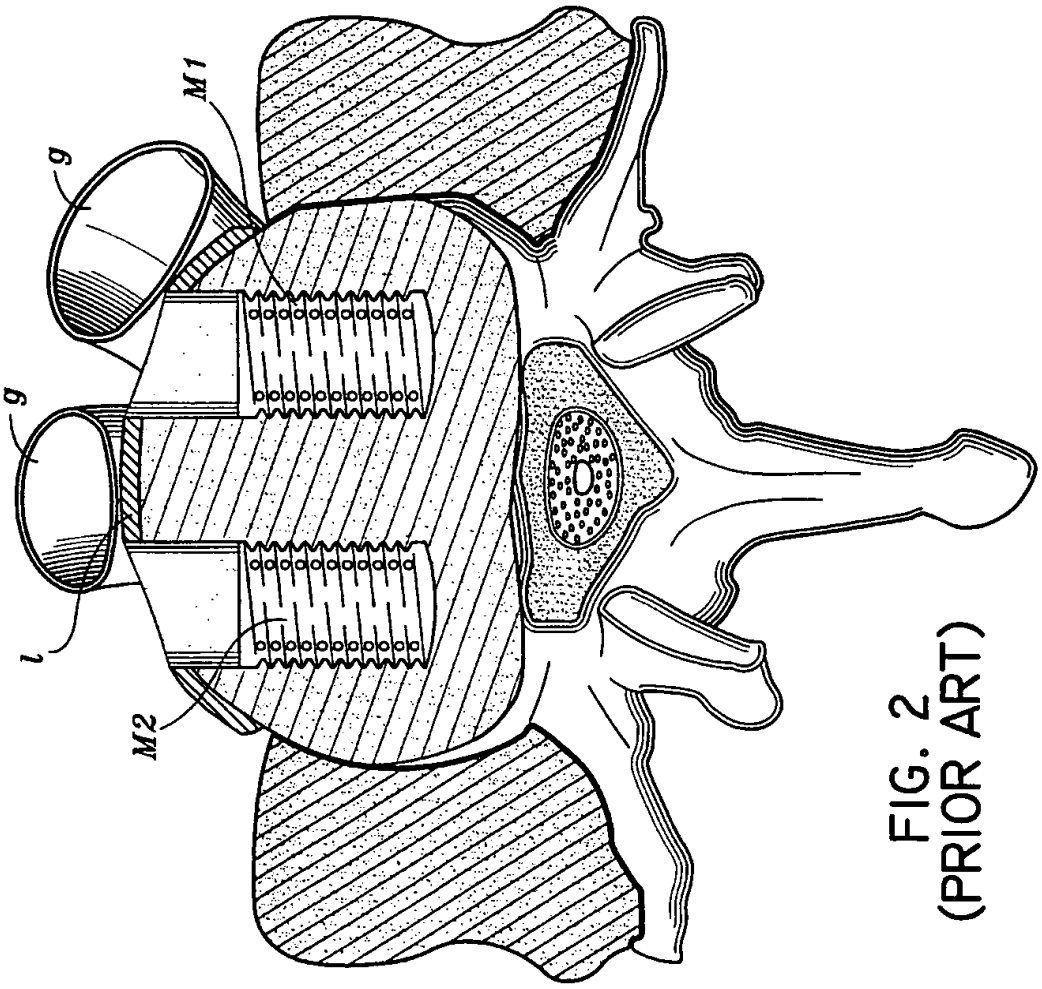


FIG. 2
(PRIOR ART)

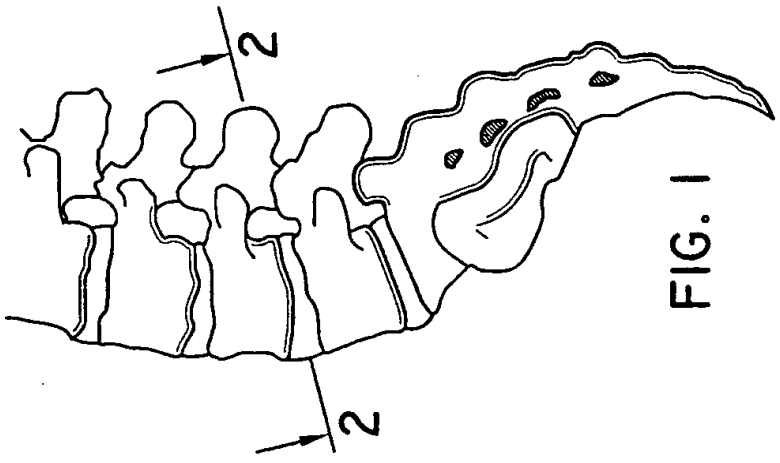
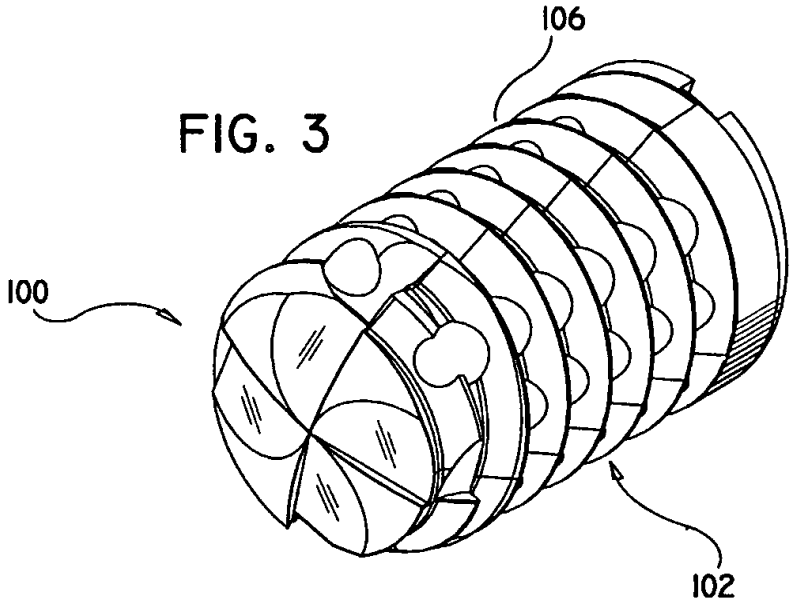


FIG. 1

FIG. 3



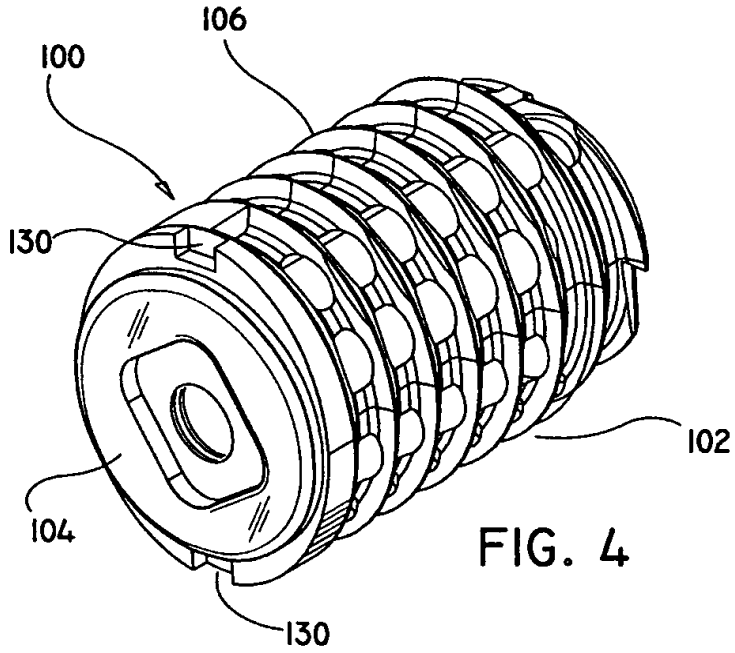


FIG. 4

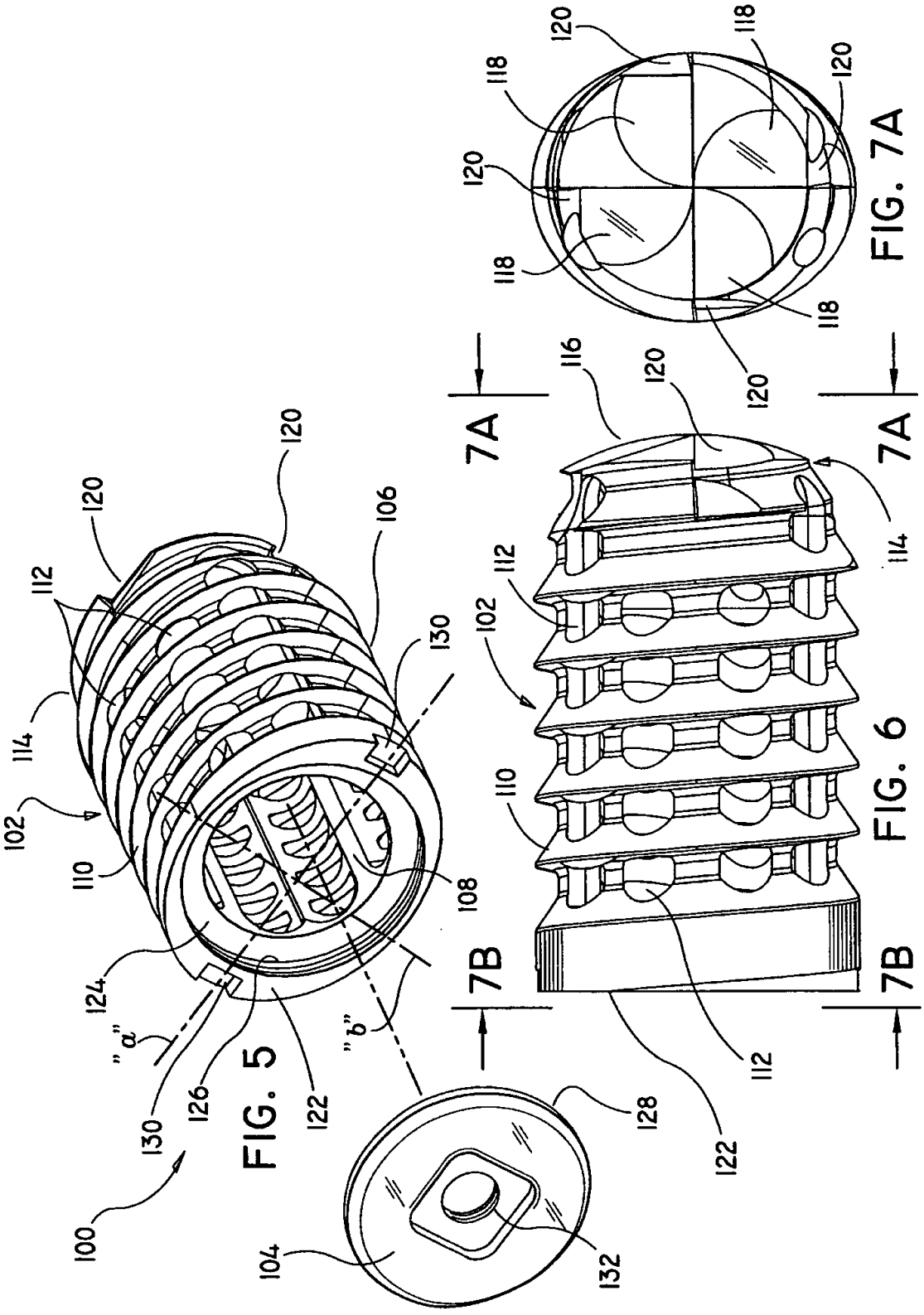


FIG. 5

FIG. 6

FIG. 7A

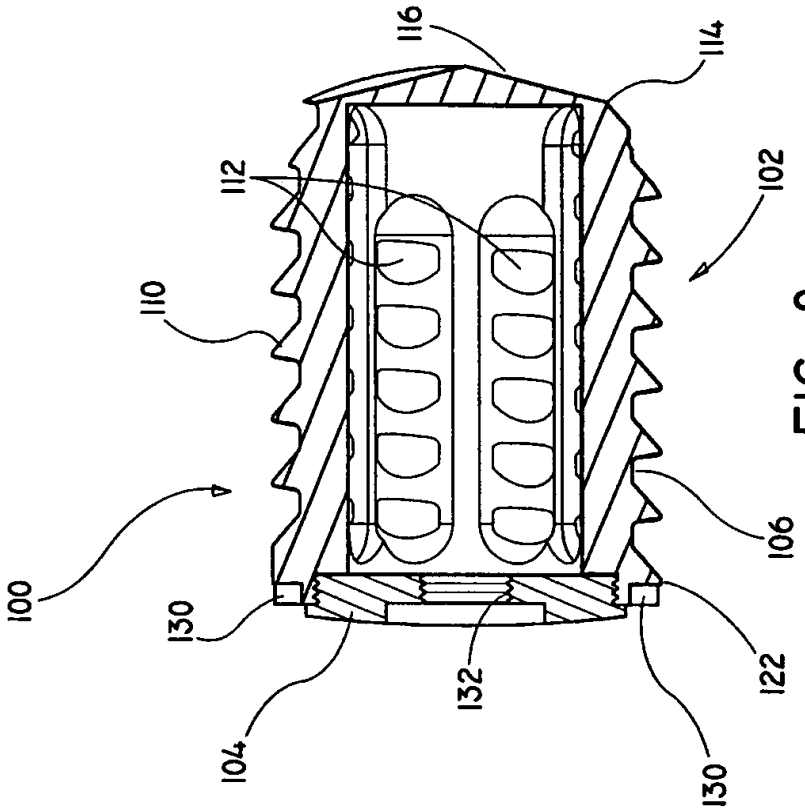


FIG. 8

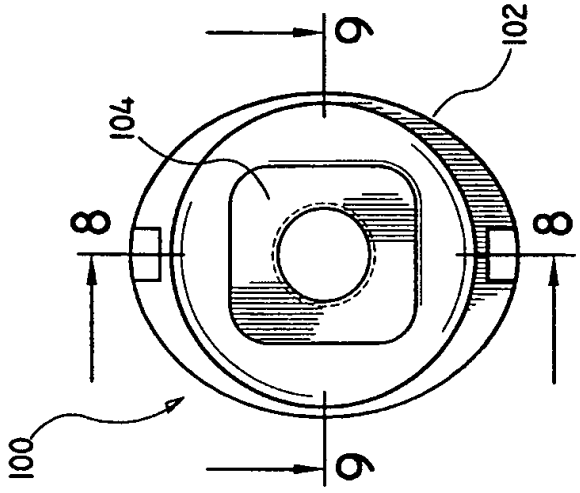


FIG. 7B

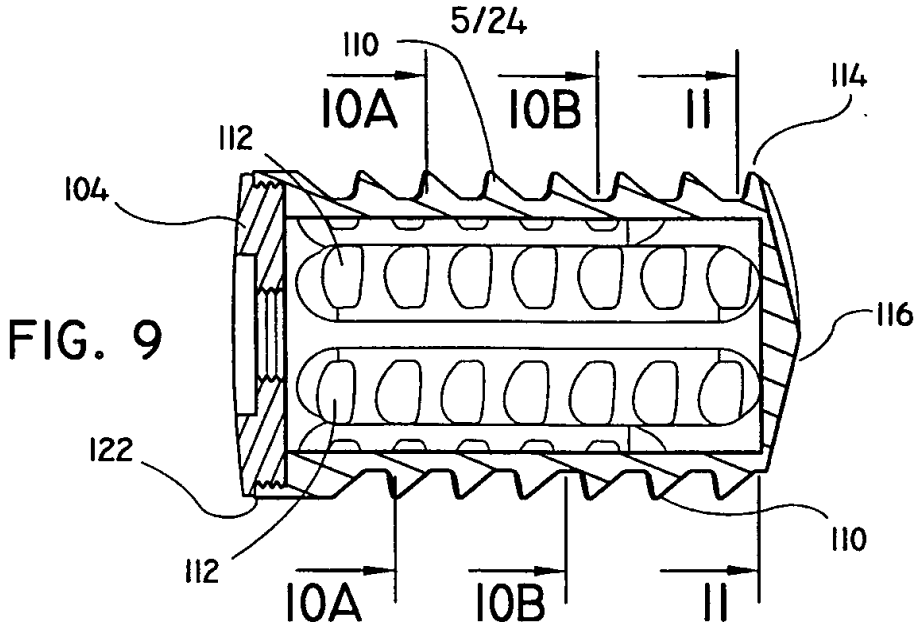


FIG. 9

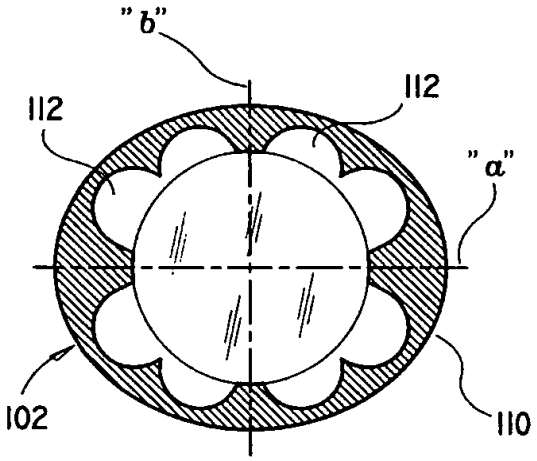


FIG. 10A

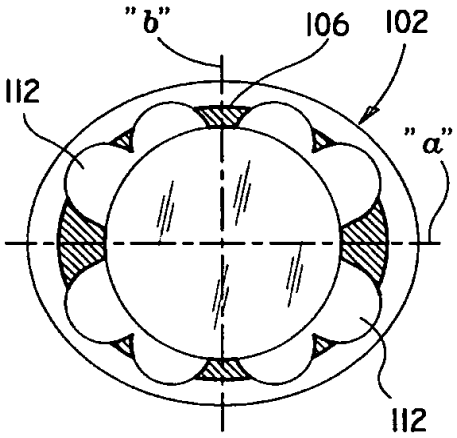


FIG. 10B

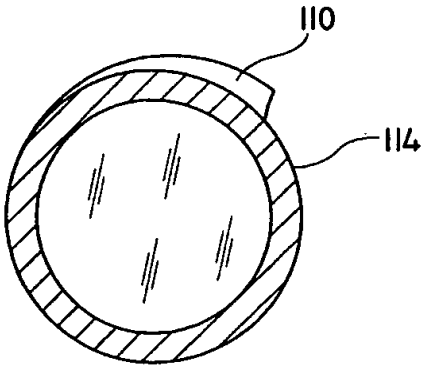


FIG. 11

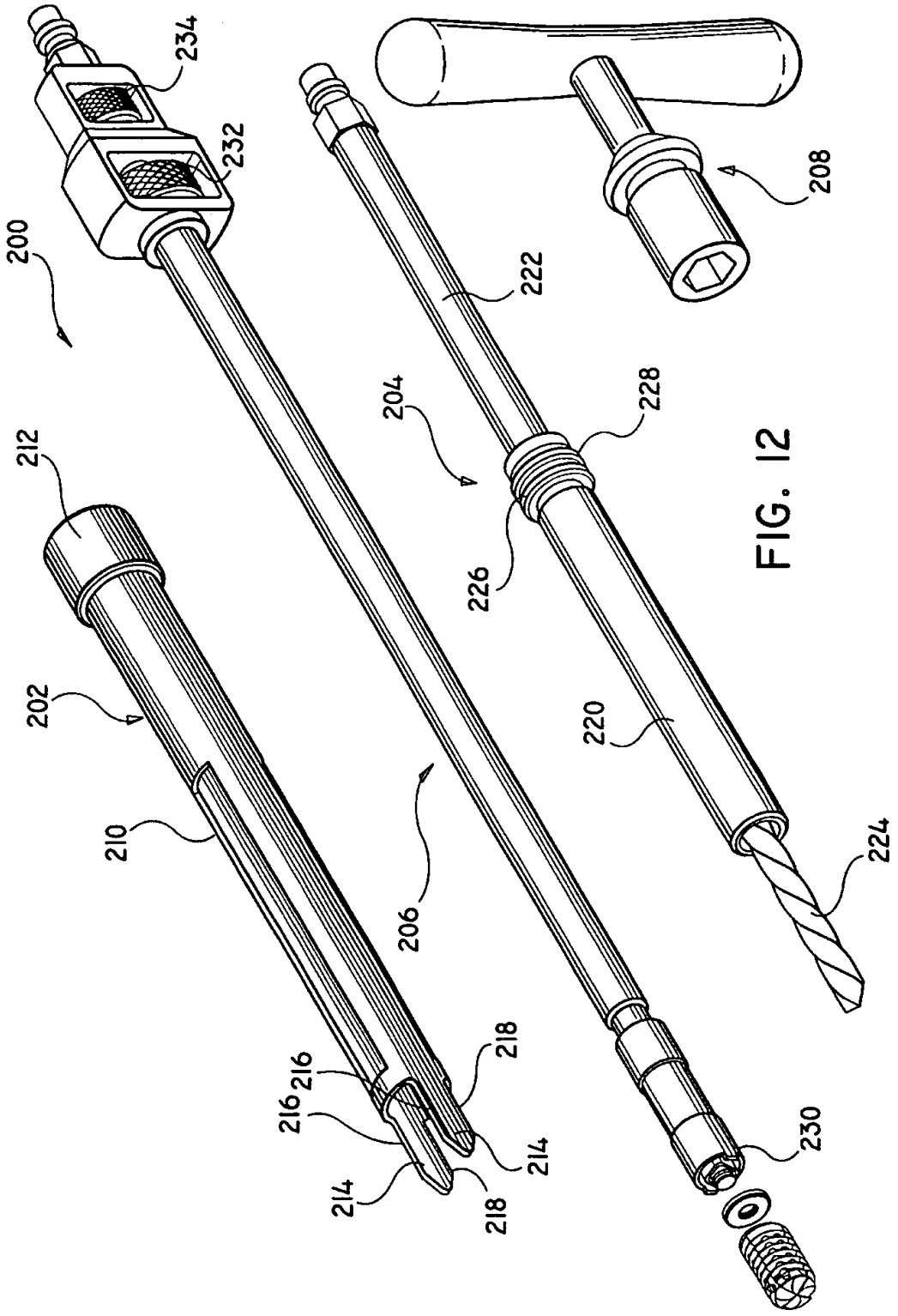

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FIG. 12

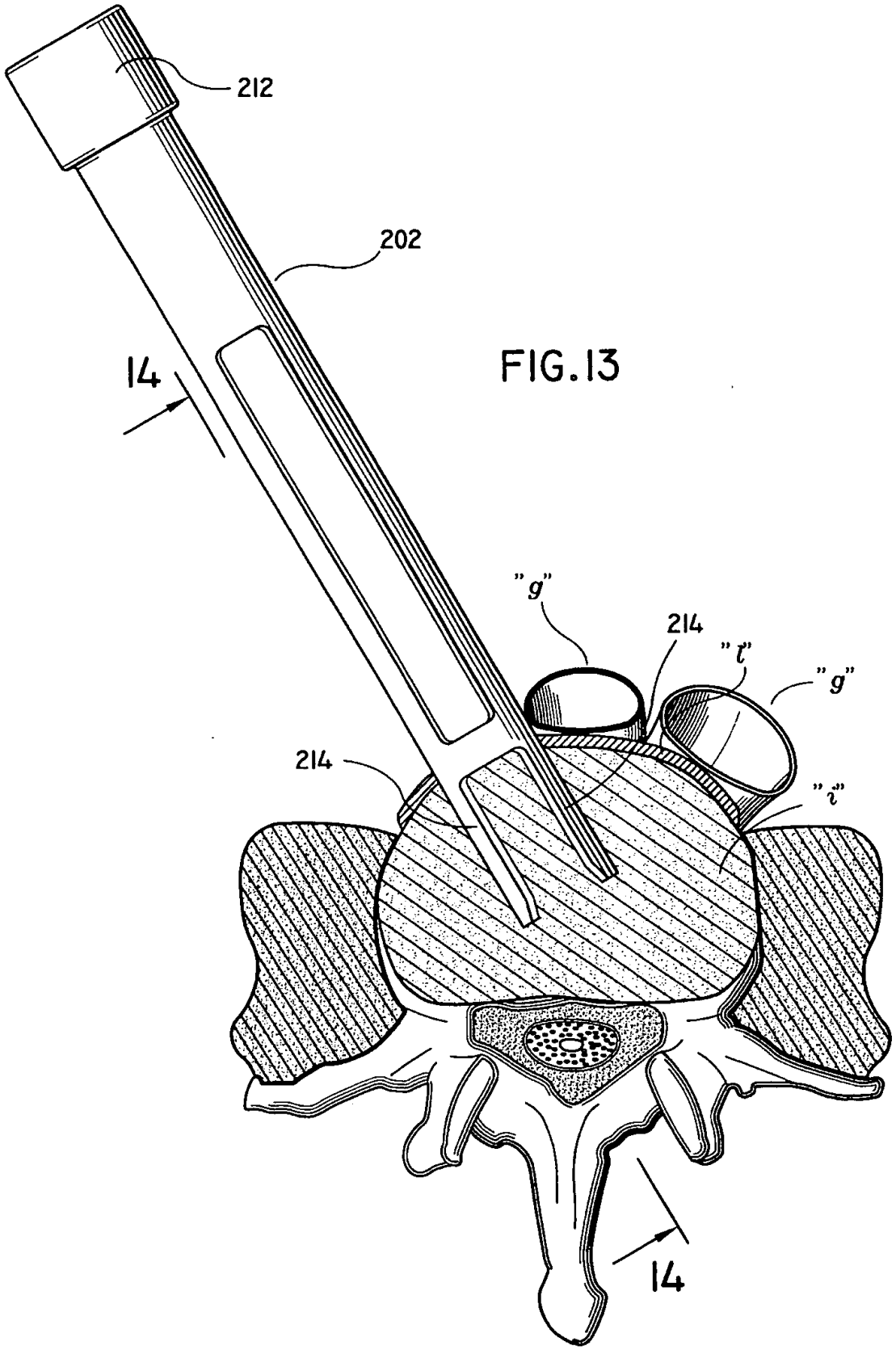


FIG. 13

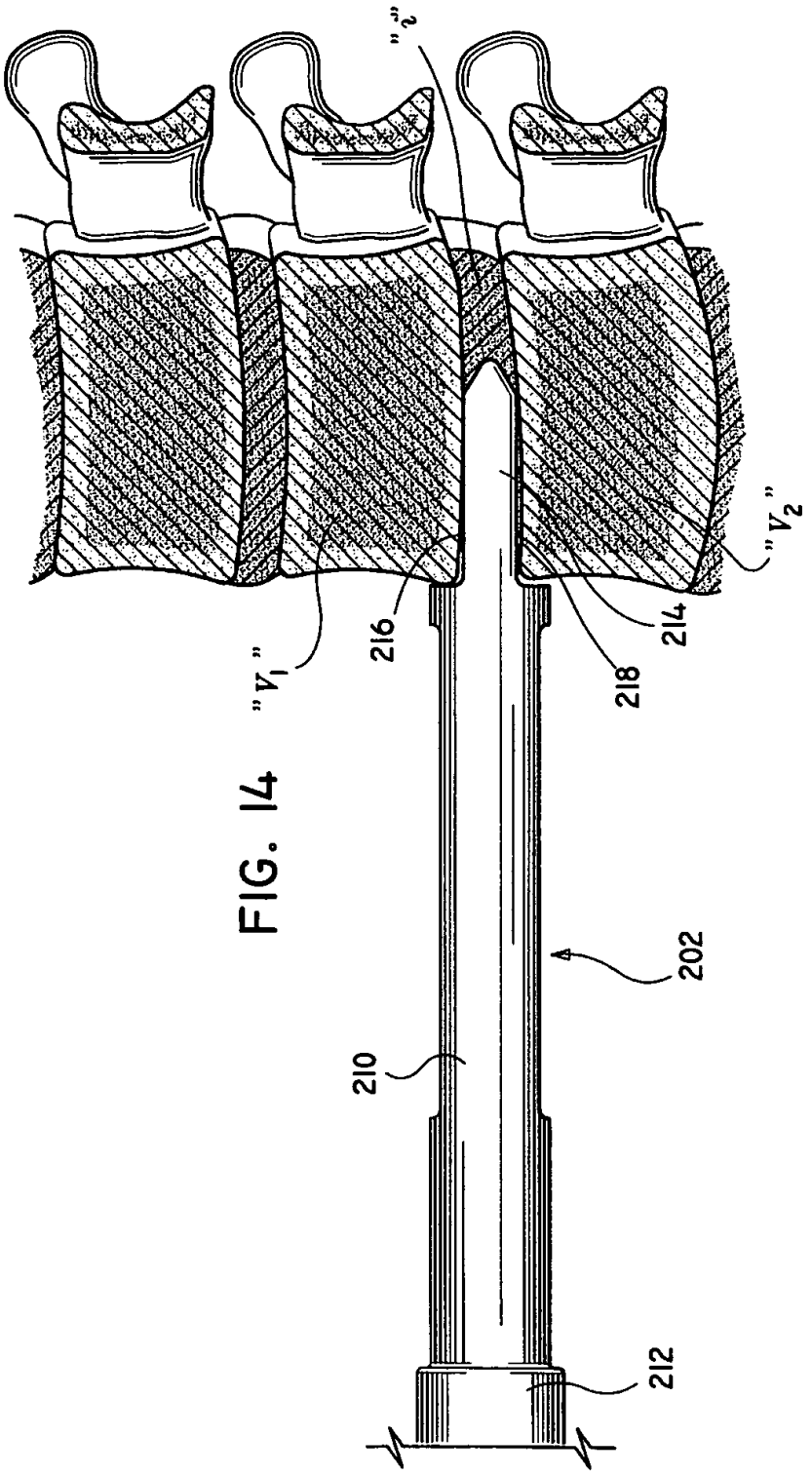


FIG. 14

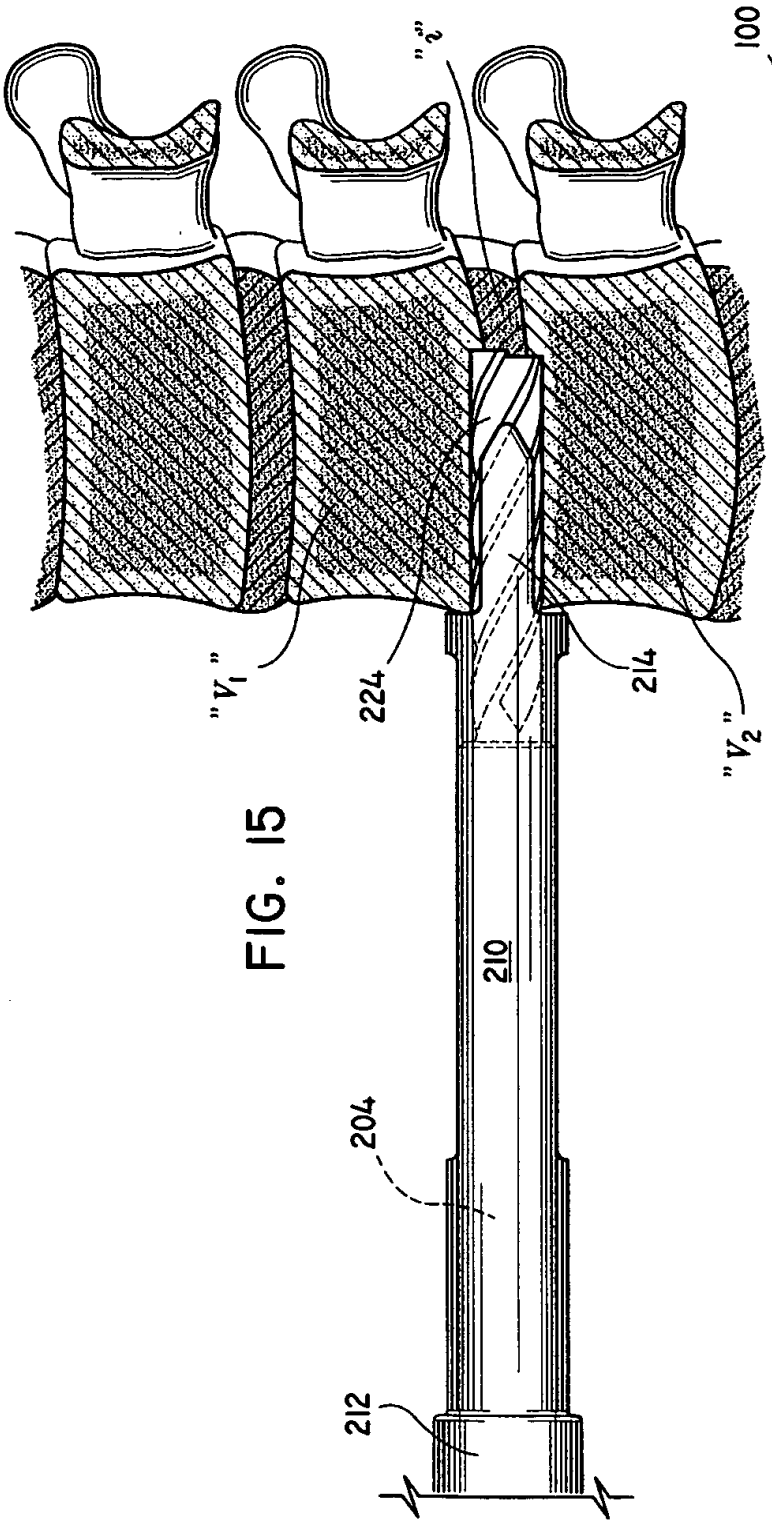


FIG. 15

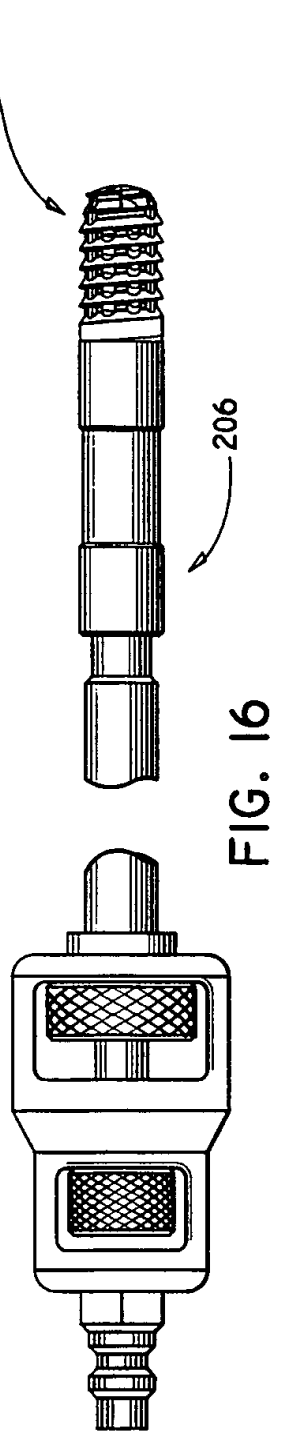


FIG. 16

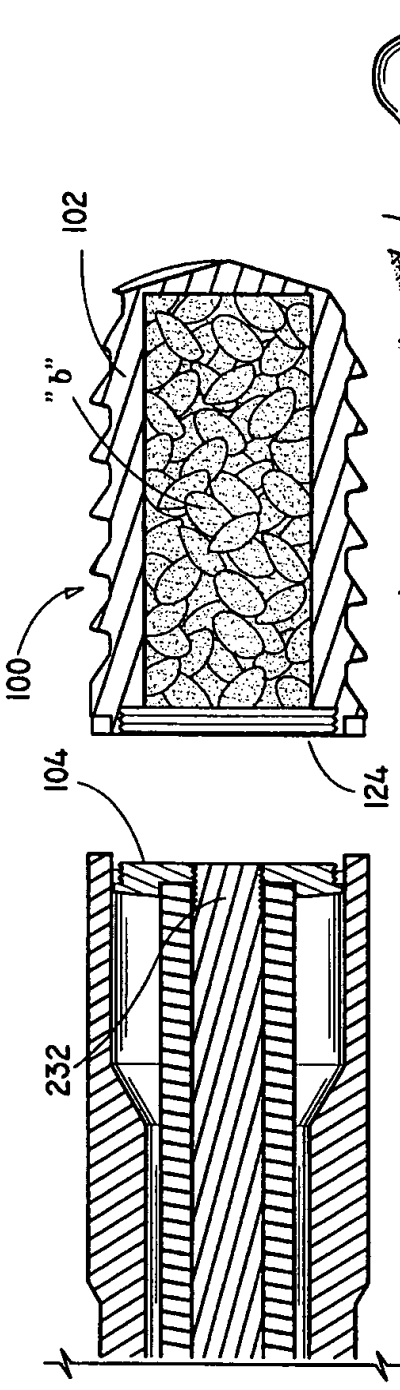


FIG. 16A

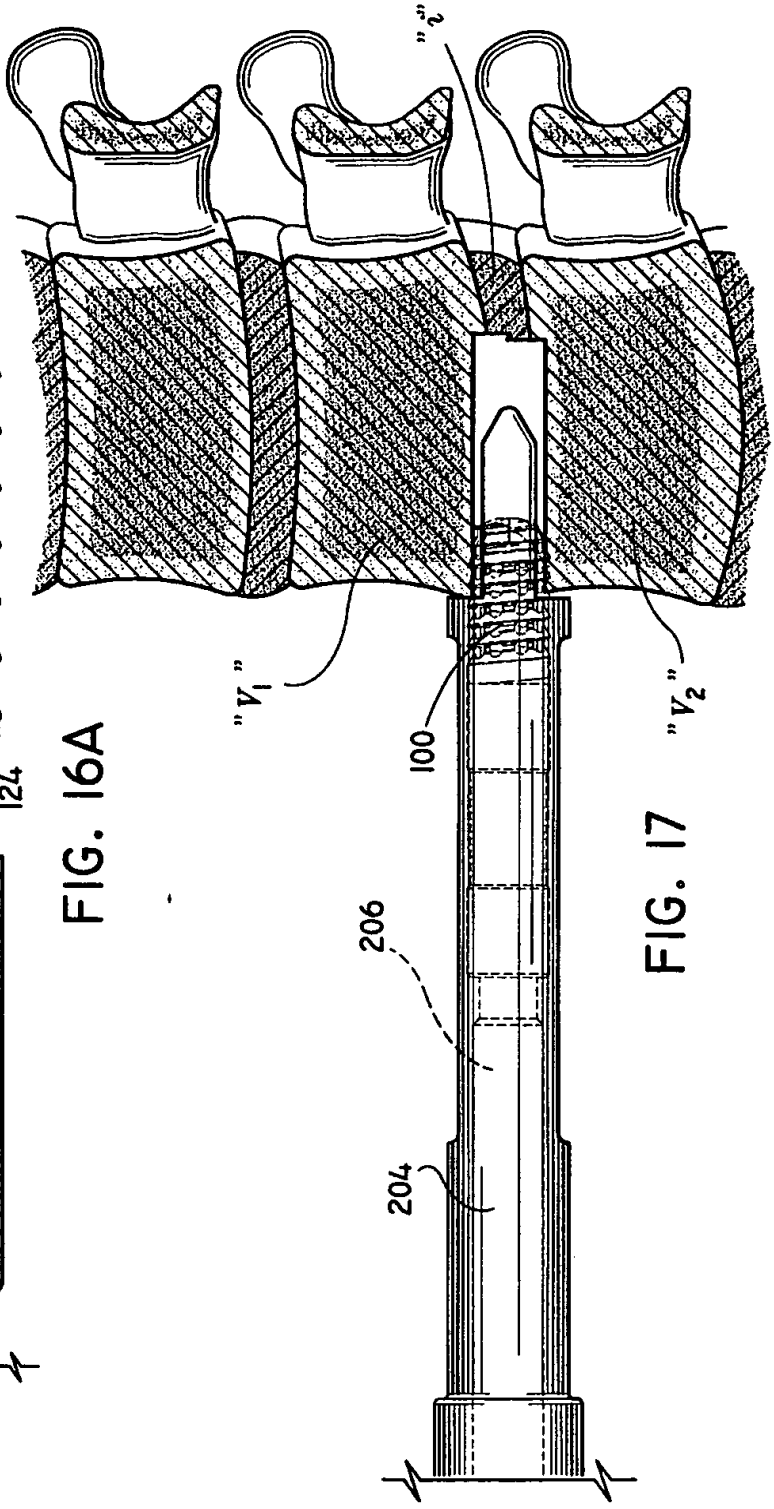


FIG. 17

FIG. 18

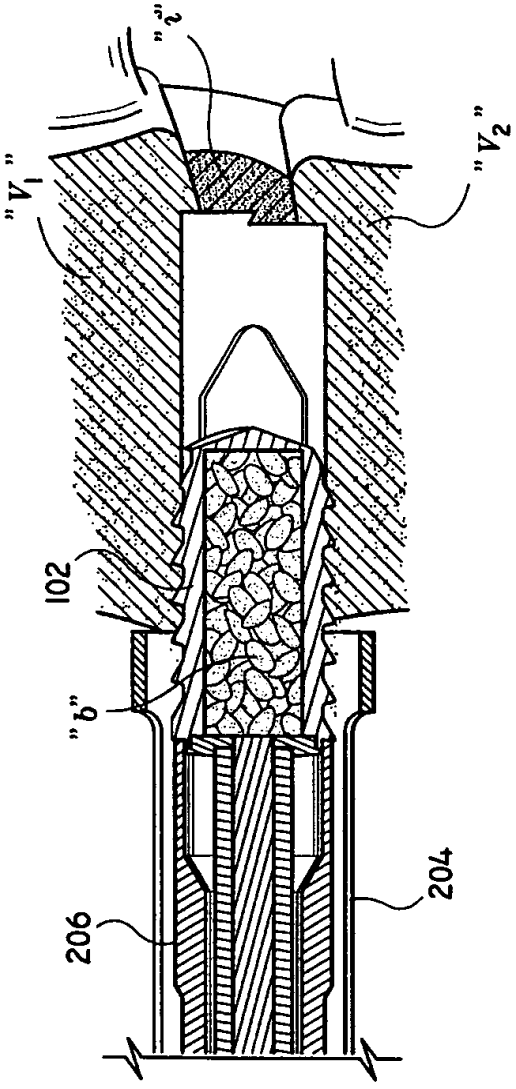
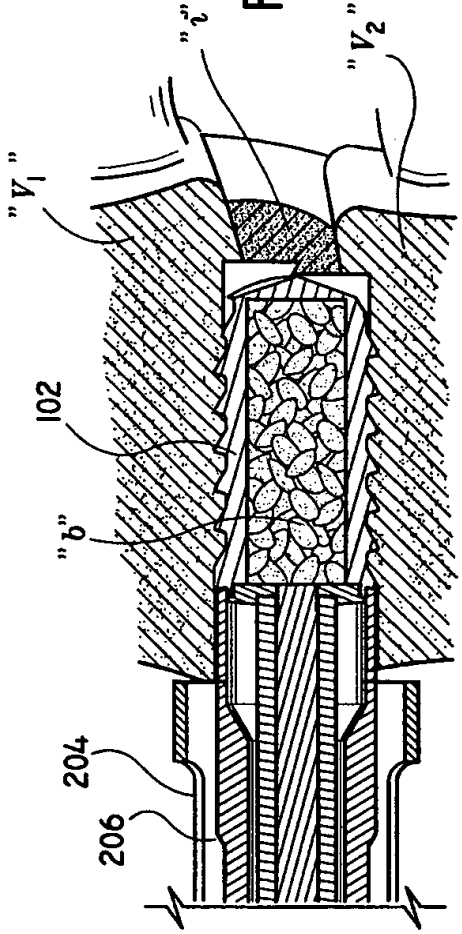


FIG. 19



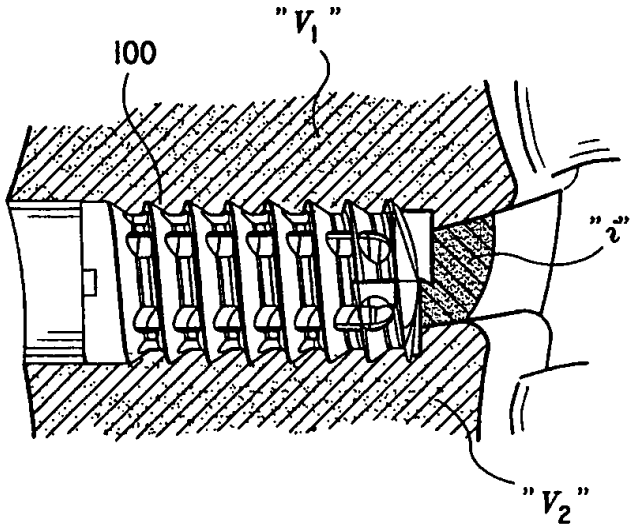


FIG. 20

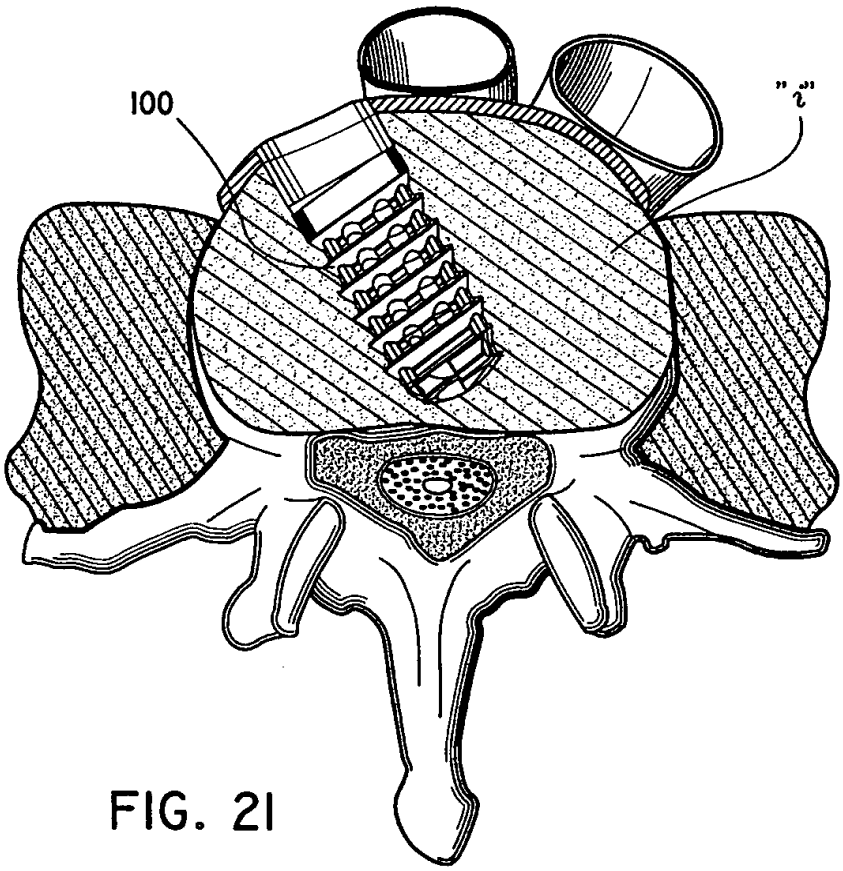


FIG. 21

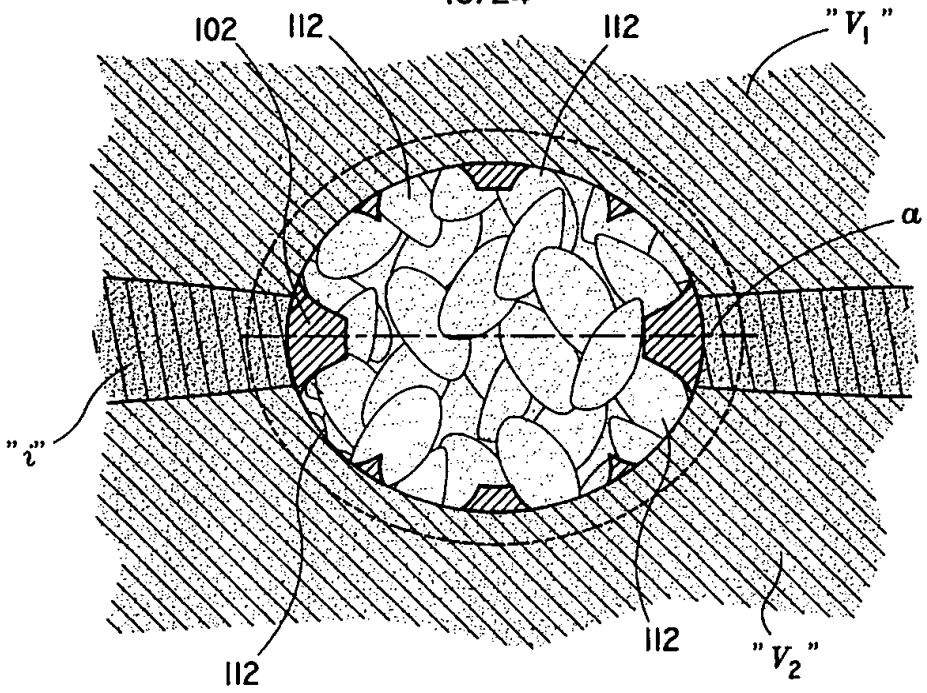


FIG. 22

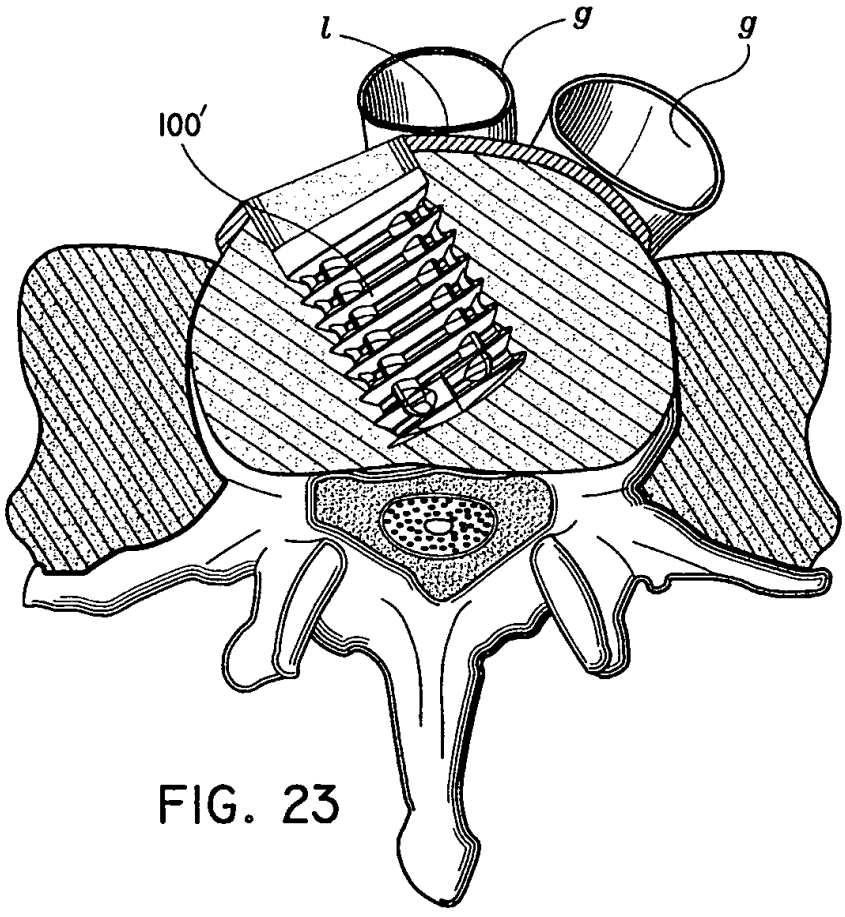


FIG. 23

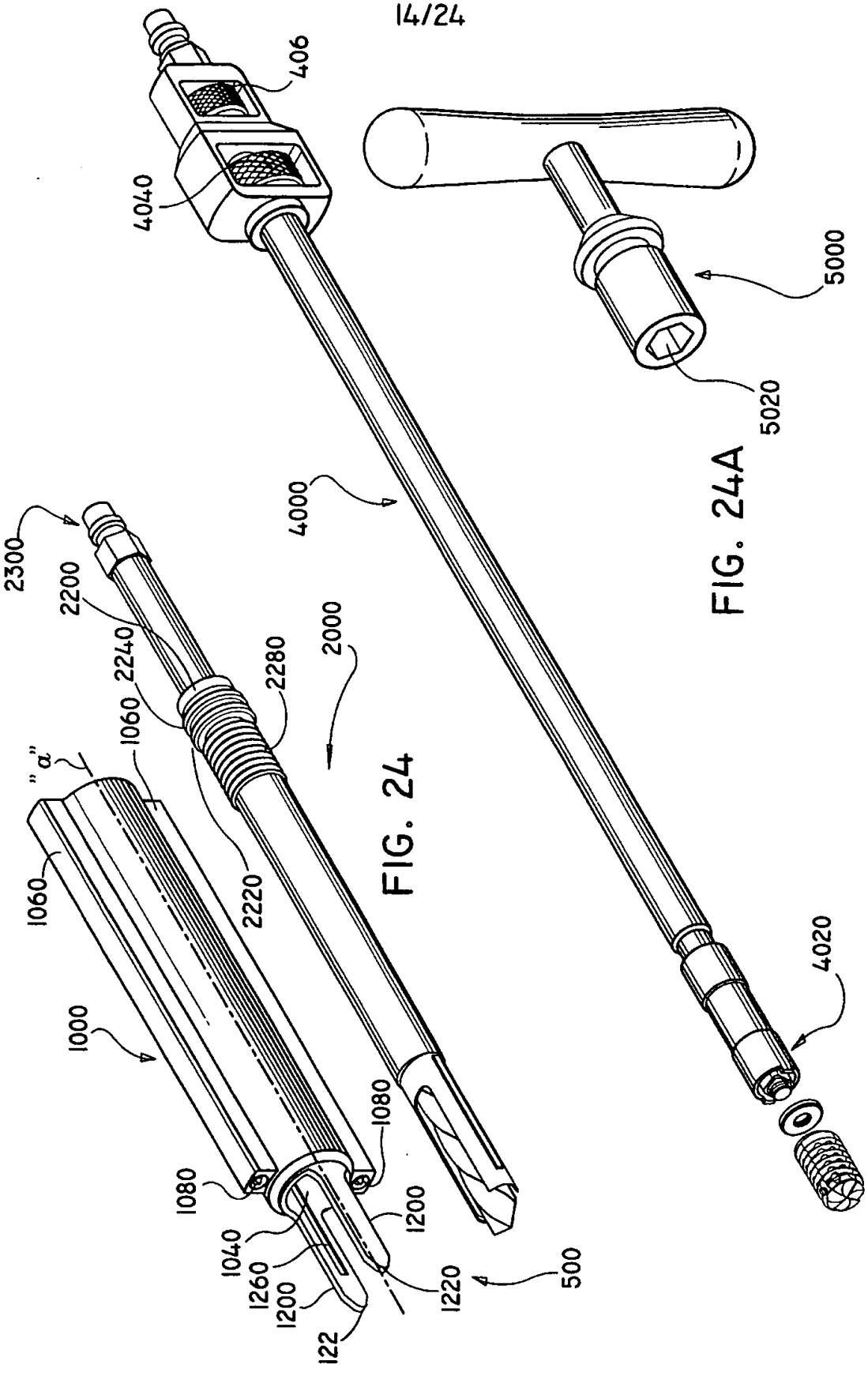
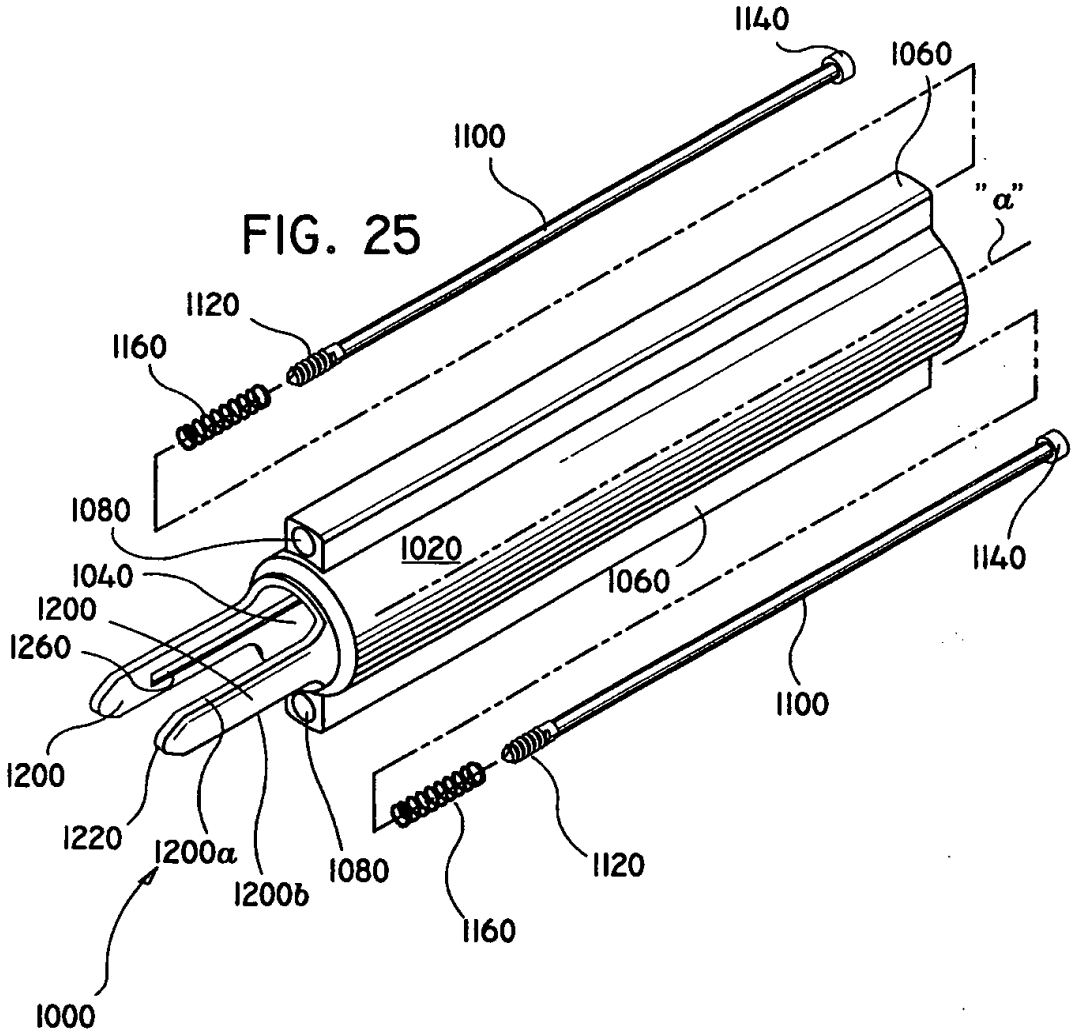


FIG. 24A

FIG. 24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1060
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"α"
1120
1160
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1200
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1200a
1200b
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1100
1120
1160
1000

FIG. 25

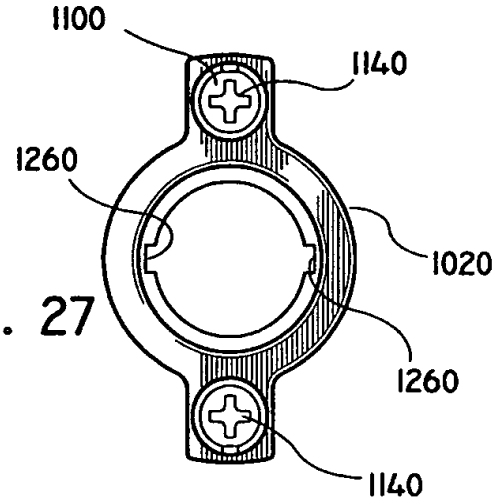
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FIG. 27

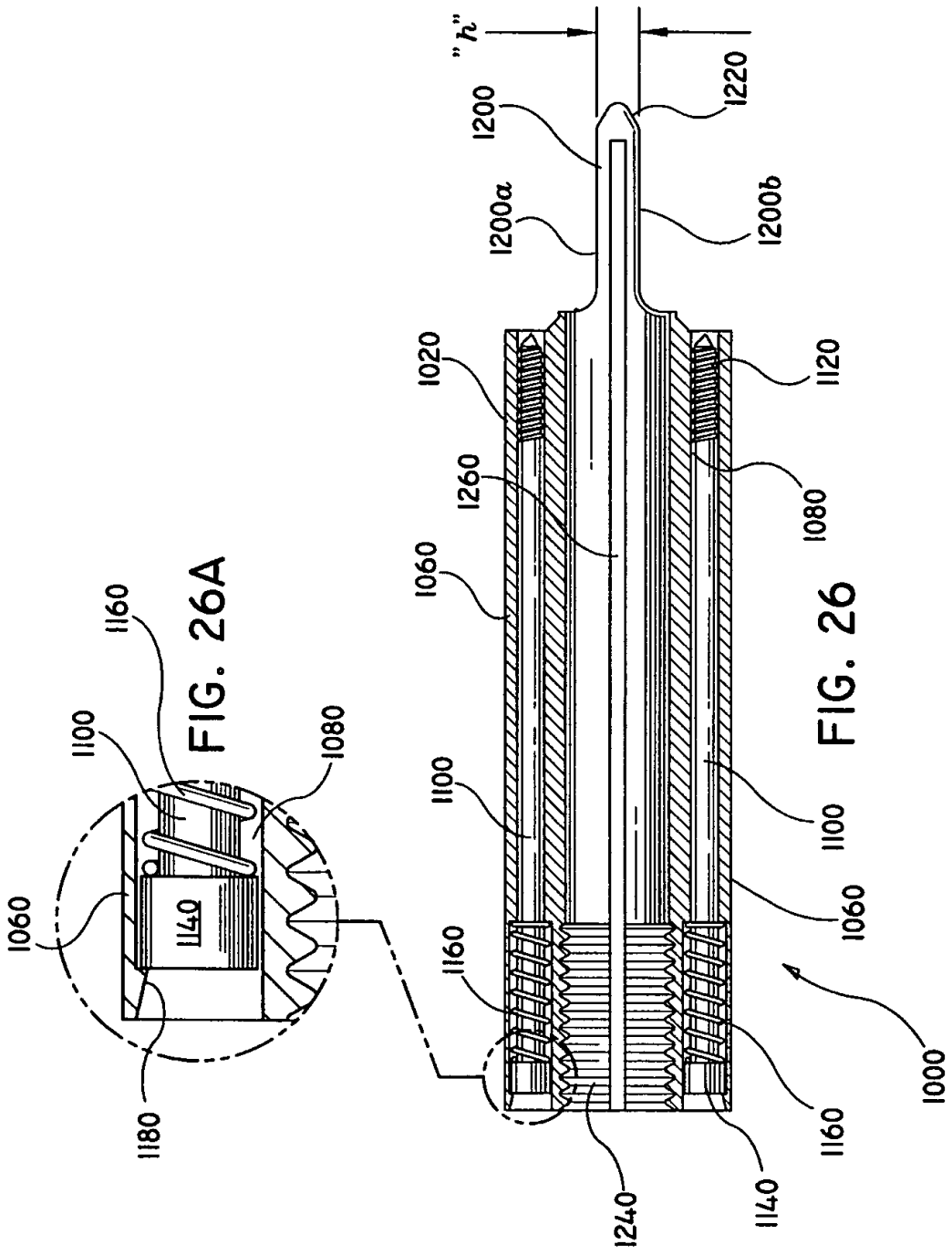

FIG. 26A

FIG. 26

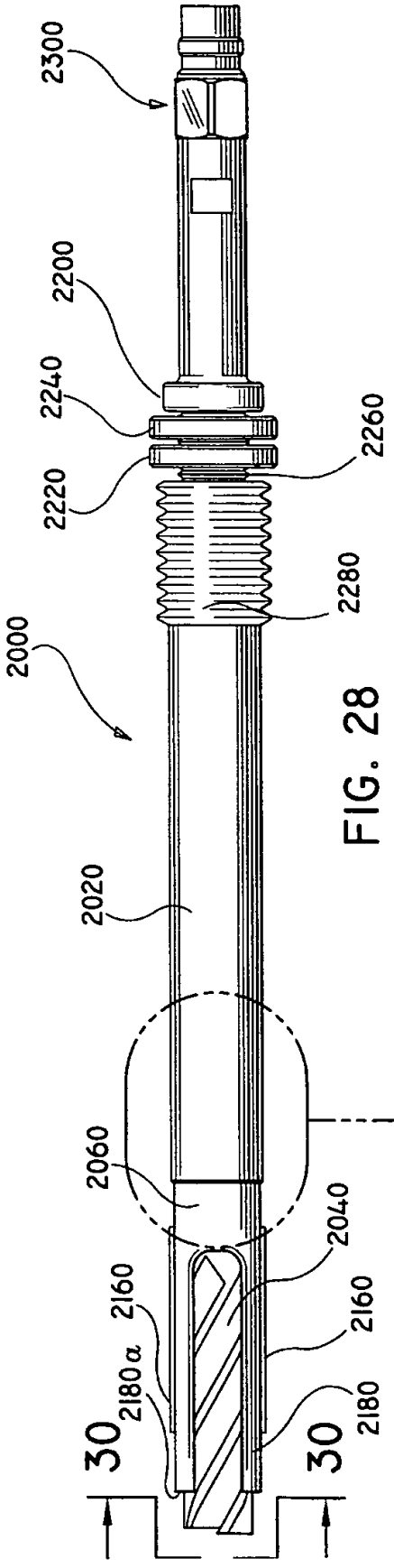

FIG. 28

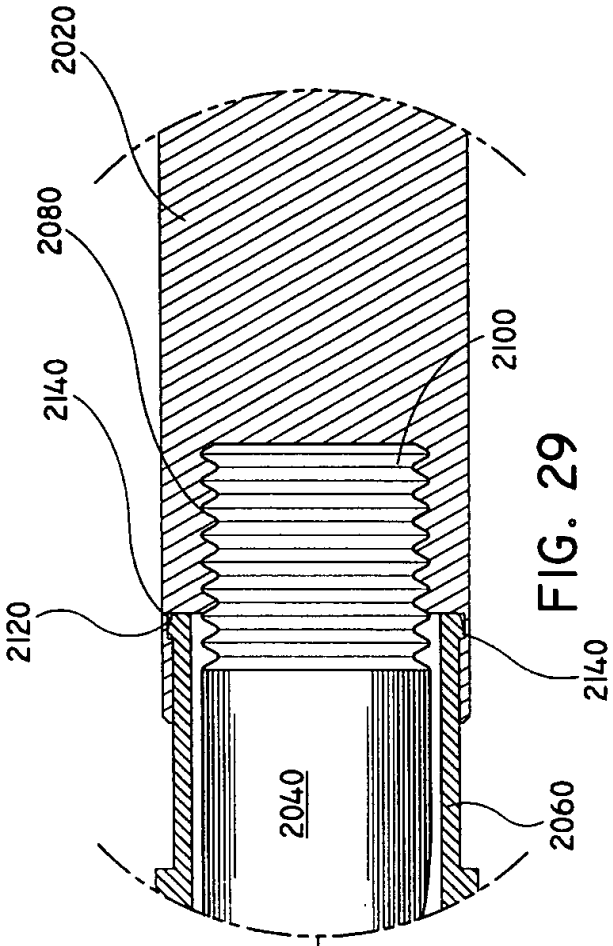

FIG. 29

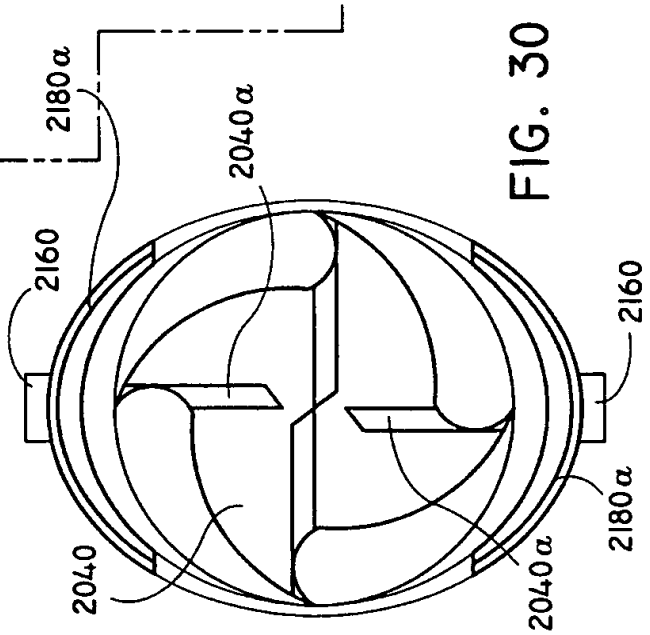

FIG. 30

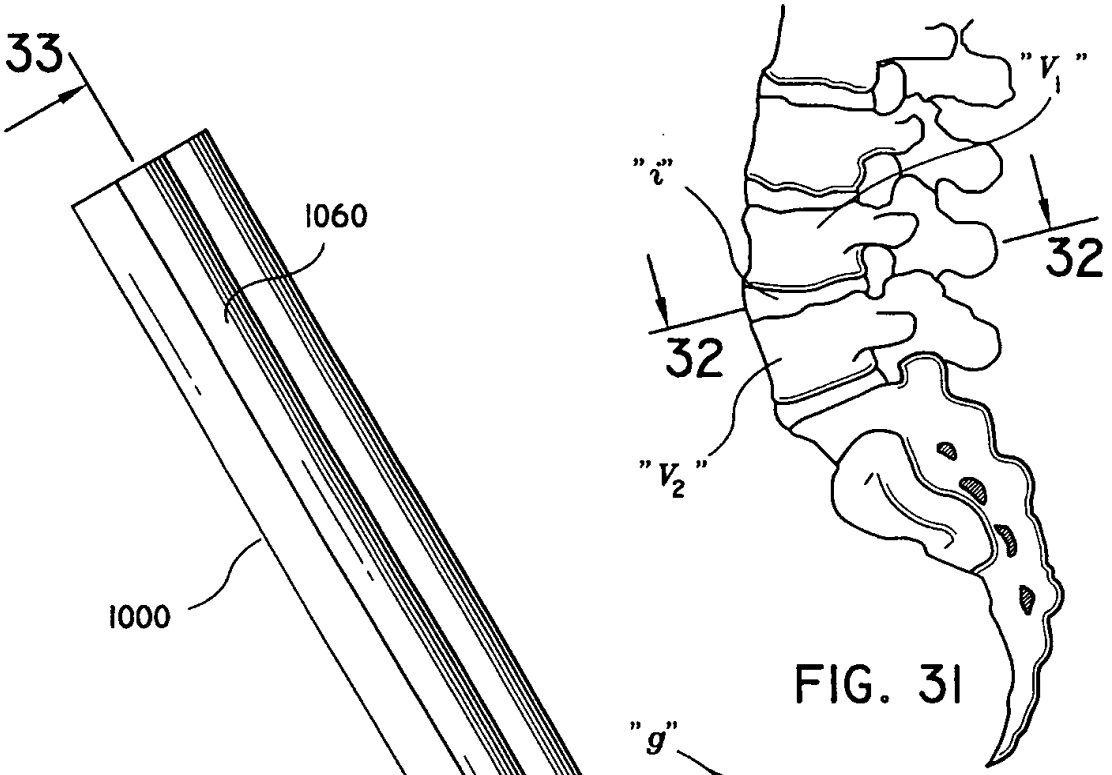

FIG. 31

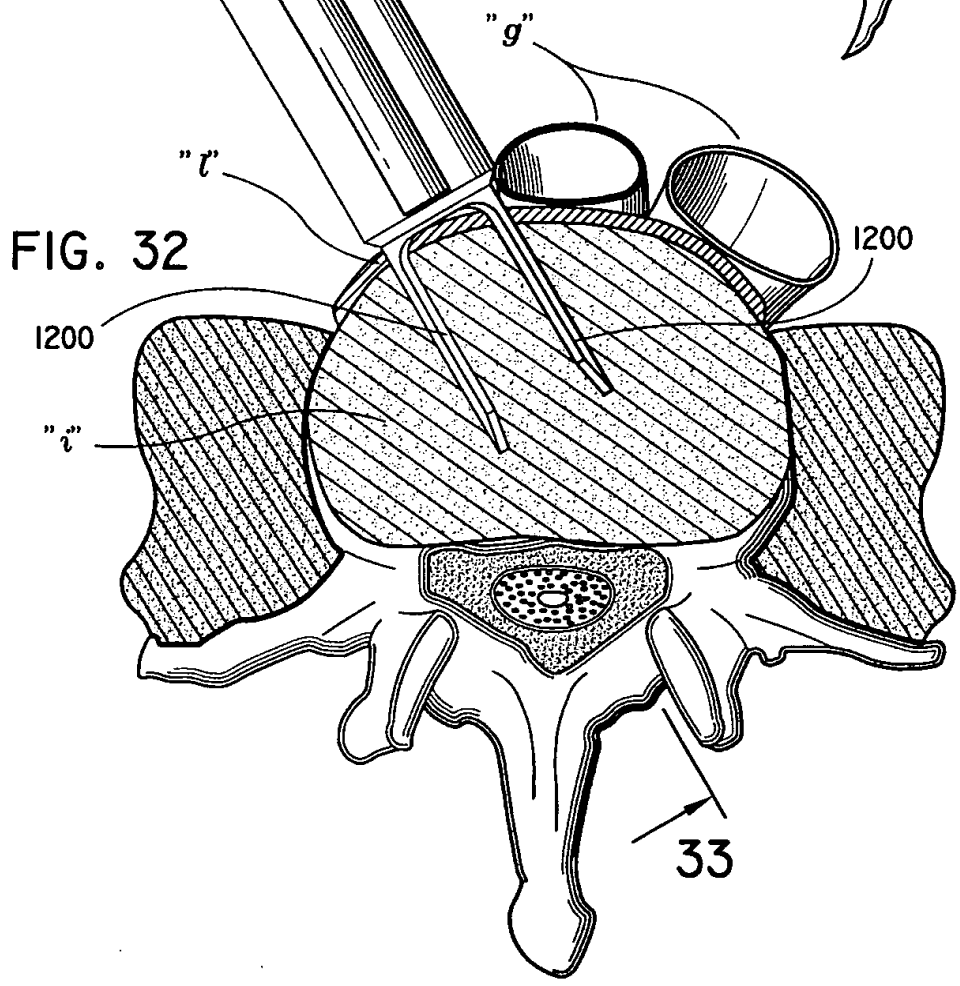

FIG. 32

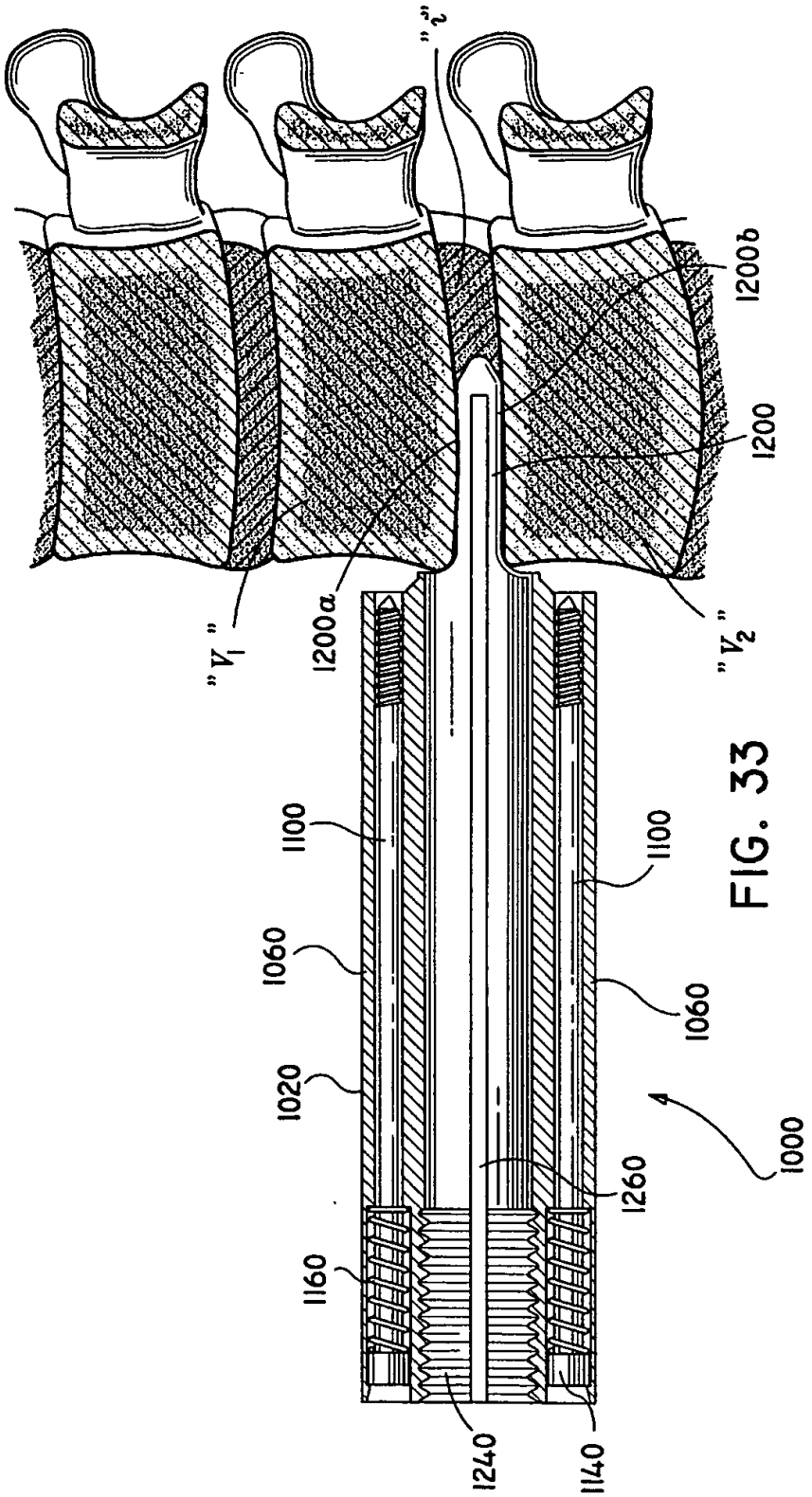
"V2"
1200b
1200
"V1"
1200a
"V2"
1100
1100
1060
1060
1020
1000
1260
1160
1240
1140

FIG. 33

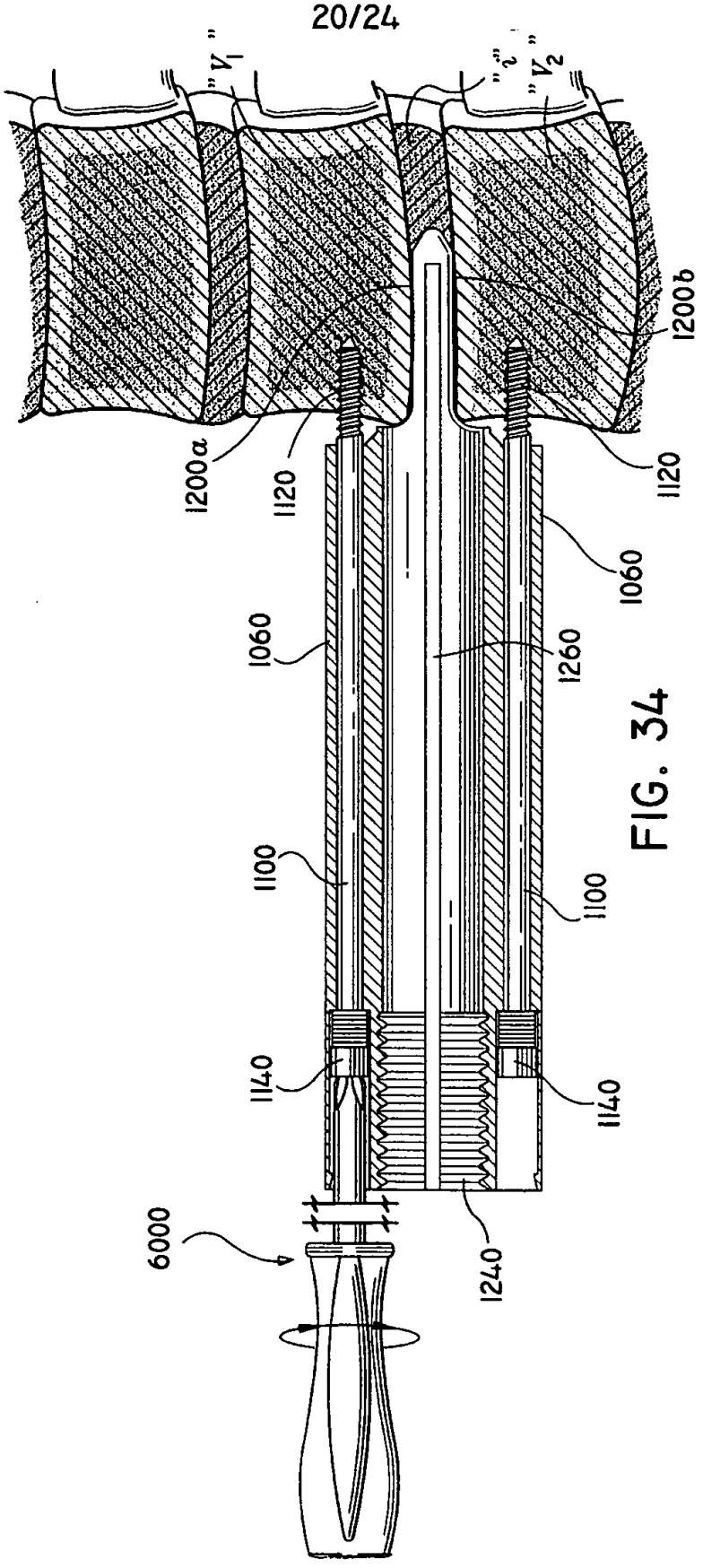
"V1"
"V2"
1200b
1200a
1120
1120
1060
1060
1260
1100
1100
1140
1140
6000
1240

FIG. 34

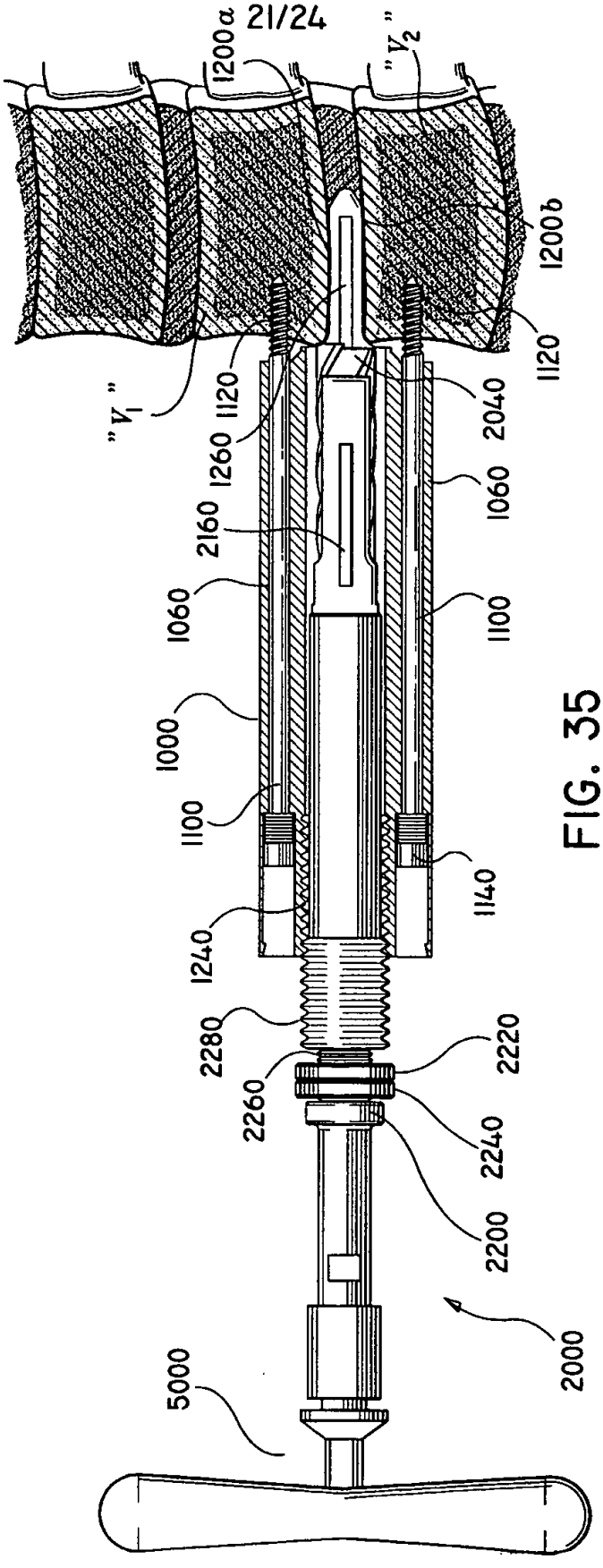
1200a
"V2"
1200b
"V1"
1120
1120
2040
1260
1060
2160
1060
1100
1000
1100
1140
1240
2280
2220
2260
2240
2200
2000
5000

FIG. 35

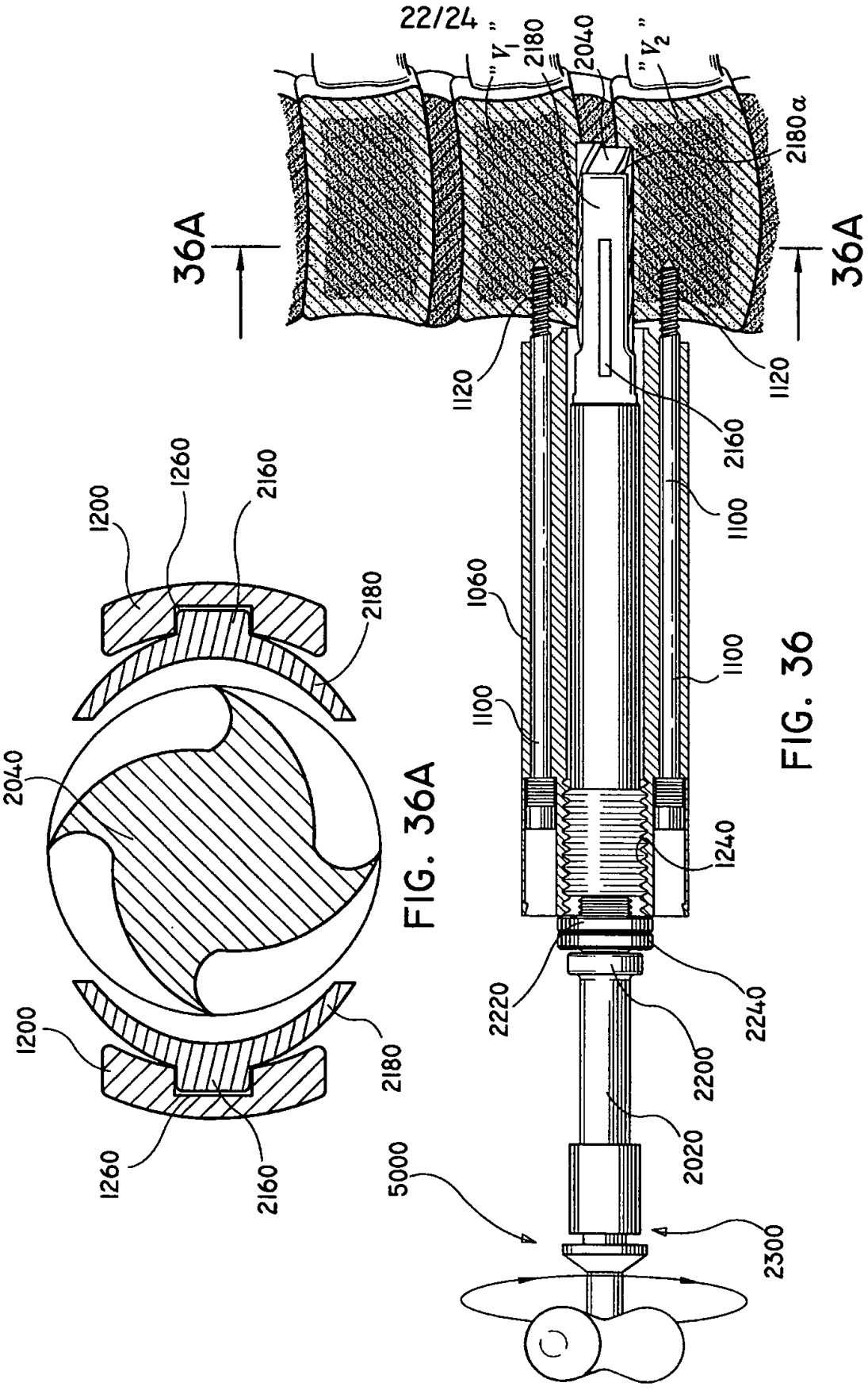

FIG. 36A

FIG. 36

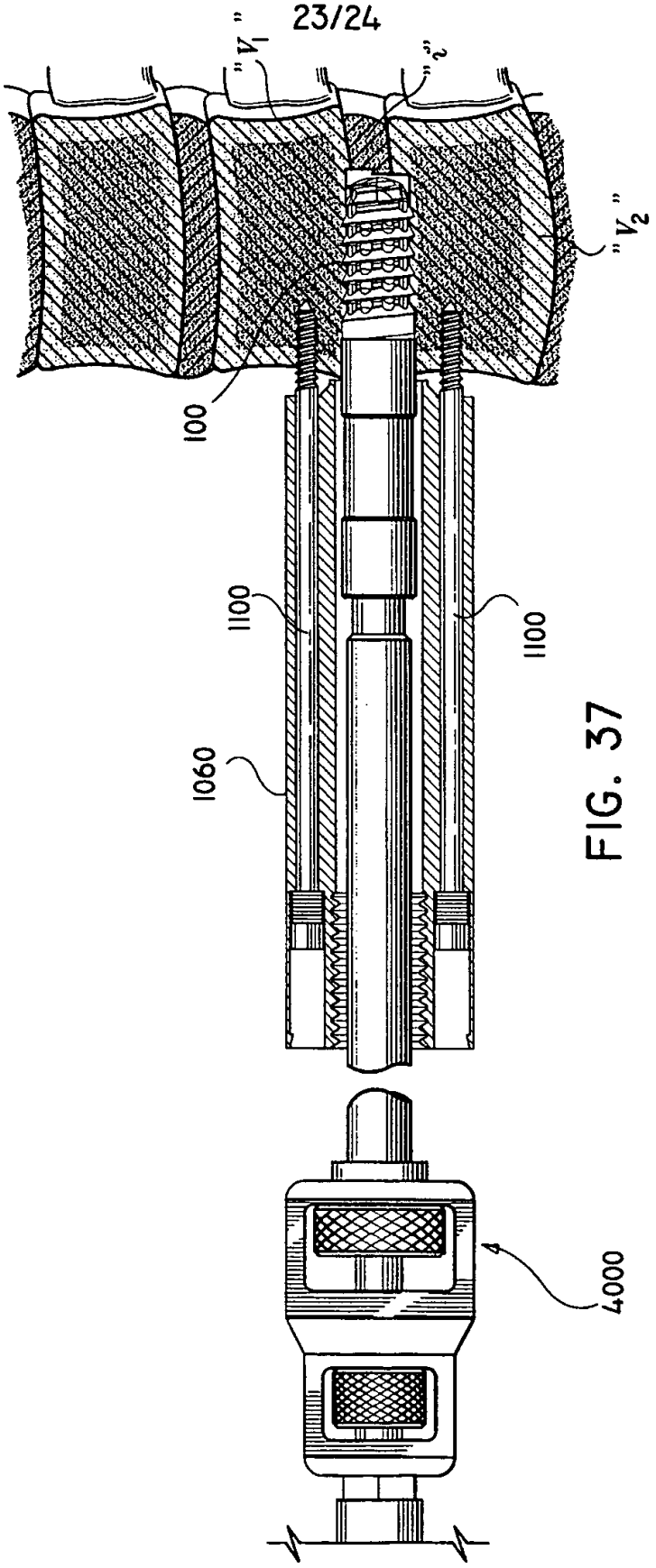

FIG. 37

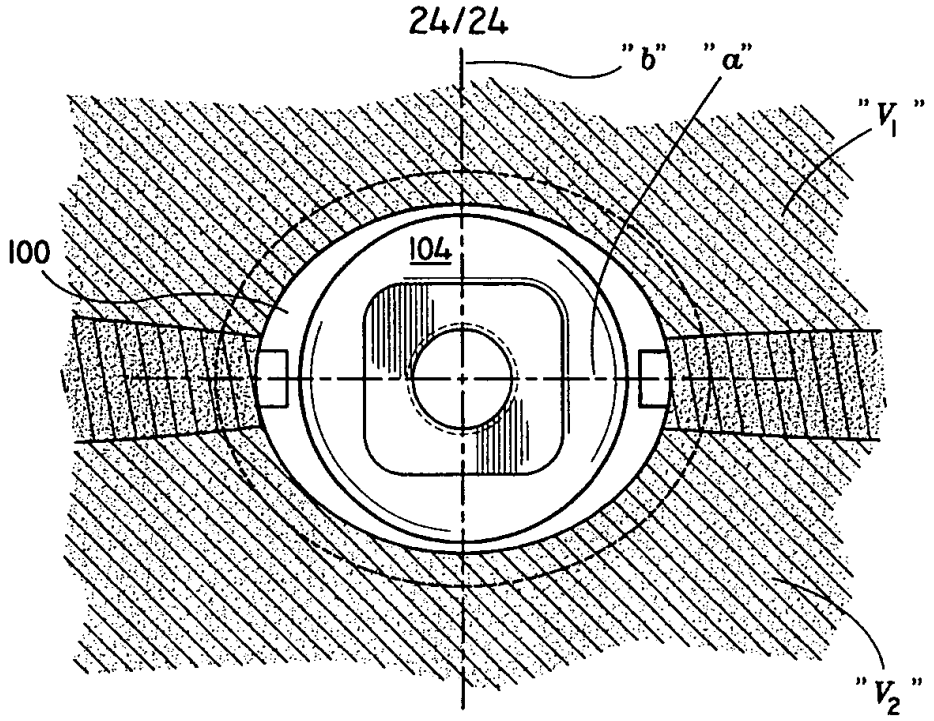

FIG. 38

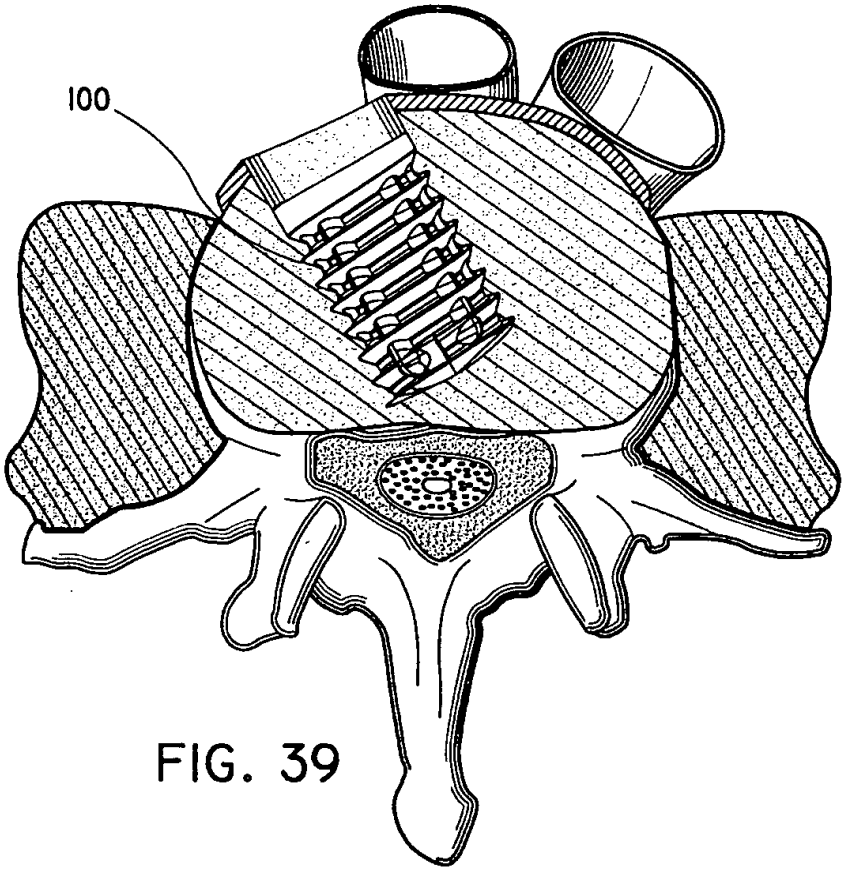

FIG. 39