

REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978

PUBLICATION PARTICULARS AND ABSTRACT

[Section 32(3)(a) - Regulation 22(1)(g) and 31]

| | | | | | | | |
|---------------------------|---|---|-----------------|----|------------|----|------------------|
| 2-1 | 01 | Official Application No 2005/04427 | DrG Ref.: 79626 | | | | |
| 2-2 | Lodging date: 2005-05-31 | | | | | | |
| 4-3 | Acceptance date: 10-02-06 | | | | | | |
| 5-1 | International Classification: A61F | | | | | | |
| | | Not for publication. Classified by: WIPO | | | | | |
| 7-1 | Full name(s) of applicant(s): Spine Solutions Inc. | | | | | | |
| 7-2 | Full name(s) of inventor(s) MARNAY, Thierry BERTAGNOLI, Rudolf MAGEE, Frank ECKHOF, Stephan | | | | | | |
| Earliest priority claimed | | 33 | Country | 31 | Number | 32 | Date |
| | | | US | | 10/318,078 | | 13 December 2002 |
| 5-4 | Title of invention INTERVERTEBRAL IMPLANT, INSERTION TOOL AND METHOD OF INSERTING SAME | | | | | | |
| 5-7 | Abstract See next page. | | | | | | |
| Number of sheets | | | | | | | |

ADDRESS FOR SERVICE:
DR GERNTHOLTZ INC
PATENT AND TRADE MARK ATTORNEYS
PO BOX 8 CAPE TOWN 8000 SOUTH AFRICA
30 UNION ROAD MILNERTON 7441
TELEPHONE: +27 21 551 2650
TELEFAX: +27 21 551 2960

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
1 July 2004 (01.07.2004)

PCT

(10) International Publication Number
WO 2004/054480 A1

(51) International Patent Classification: A61F 2/44

(21) International Application Number:
PCT/US2003/039056

(22) International Filing Date:
10 December 2003 (10.12.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/318,078 13 December 2002 (13.12.2002) US

(71) Applicant: SPINE SOLUTIONS INC. [US/US]; 15
Maple Avenue, 2nd Floor, Paoli, PA 19301 (US).

(72) Inventors: MARNAY, Thierry; Clinique du Parc, B.
P. 20, 34171 Castelnau le Lez (FR). BERTAGNOI,
Rudolf; Kay 2a, D-94315 Straubing (DE). MAGEE,
Frank; 505 Park Avenue, New York, NY 10022 (US).
ECKHOF, Stephan; Neuhauser Strasse 47, D-78532
Tuttlingen (DE).

(74) Agent: PERRY, Marvin; Larson & Taylor, PLC, 1199
North Fairfax Street, Suite 900, Alexandria, VA 22314
(US).

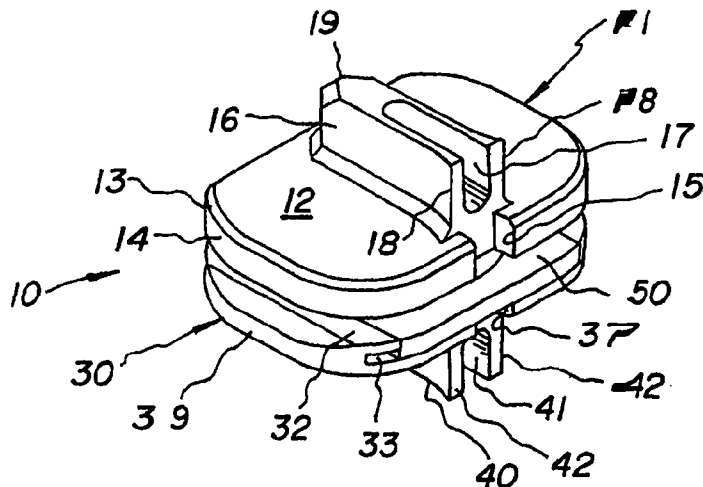
(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NI, NO, NZ, OM, PG, PI, PL, PT, RO, RU, SC,
SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA,
UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (BW, GH,
GM, KE, LS, MW, MZ, SD, SI, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE,
SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, MI, MR, NR, SN, TD, TG).

Published:
— with international search report
— before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTERVERTEBRAL IMPLANT, INSERTION TOOL AND METHOD OF INSERTING SAME



(57) Abstract: An intervertebral implant (10), alone and in combination with an insertion tool (60) for inserting same and a method for inserting same. The implant has upper and lower parts (11, 30) which have limited universal movement relative to each other. Each of the upper and lower parts (11, 30) also has a surface engaging an adjacent vertebrae. Each part has a keel (16) extending from said surface into a cutout in the adjacent vertebrae, and each keel has an opening recess (17) therein. An insertion tool has a pair of arms (61, 71) which are received in the recess of the keels through the anterior opening to securely hold and insert the implant. Projections (63, 73) and matching indentations (21, 43) in each arm and the base of its recess securely attached each arm within its keel.

WO 2004/054480 A1

**INTERVERTEBRAL IMPLANT, INSERTION
TOOL
AND METHOD OF INSERTING SAME**

FIELD OF THE INVENTION

[0001] This invention relates to intervertebral implants, and in particular, to a new and improved intervertebral implant and to an insertion tool and a method for inserting same.

BACKGROUND OF THE INVENTION

[0002] Historically, when it was necessary to completely remove a disc from between adjacent vertebrae, the normal remedy was to fuse the adjacent vertebrae together. More recently, there have been important developments in the field of disc replacement, namely disc arthroplasty which involves the insertion of an artificial intervertebral implant into the intervertebral space between adjacent vertebrae and which allows movement of the adjacent vertebrae relative to each other in flexion, extension, lateral bending, axial rotation and translation, as well as absorbing axial compression.

[0003] One such development is an artificial intervertebral implant as shown in Published Application No. WO 01/01893, published January 11, 2001. The instruments for inserting same are shown in Published Application No. WO 01/19295, published March 22, 2001.

[0004] While the intervertebral implant and instruments as shown in these publications represents a substantial improvement in the art, there exists a continuing need for improvements in the field of artificial intervertebral implants.

[0005] One such area in need of further improvements includes intervertebral implants for the intervertebral spaces between adjacent cervical vertebrae. This is because the cervical vertebrae and the dimensions of the intervertebral spaces between them are quite small. For example, the area of the cervical vertebral surfaces facing the adjacent cervical intervertebral spaces may be only about 20 percent of the intervertebral surfaces of the vertebrae in the lumbar region, thereby making this an extremely delicate area in which to insert an intervertebral implant.

BRIEF SUMMARY OF THE INVENTION

[0006] The purpose of the present invention is to provide a new and improved intervertebral implant, an insertion tool and a method for inserting same which are highly advantageous in the delicate and difficult area of the cervical spine. It is to be noted, however, that while the present invention has been developed particularly for the cervical spine, the invention is equally applicable for inserting an intervertebral implant at any location in the spine, including the lumbar spine.

[0007] Thus, although the invention has been developed and is particularly advantageous for the cervical spine, it will be described below more generally as an intervertebral implant without specifically identifying any particular portion of the spine.

[0008] It is thus an object of the present invention to provide a new and improved intervertebral implant together with an insertion tool and a method for inserting same.

[0009] It is another object of the present invention to provide an insertion tool and a method for inserting the new improved intervertebral implant.

[0010] In accordance with the present invention, there is provided an intervertebral implant having an upper part and a lower part which are operatively engaged for limited universal movement relative to each other. The upper part has a keel which is received in a cutout in the adjacent vertebrae, while the lower part has a keel which is received in a cutout in the other adjacent vertebrae. In accordance with a main feature of the present invention, these keels, in addition to providing an anchoring function within the adjacent vertebrae, include a recess open at an end thereof for receiving arms of an insertion tool. This has the advantage of allowing grasping the implant firmly but over a very limited area for inserting the implant into the intervertebral space with minimal invasion of the work area by the insertion tool.

[0011] The upper part preferably has a spherical concave portion formed in its lower surface. The lower part preferably has a plastic inlay attached thereto, which inlay has a raised spherical convex portion which engages the spherical concave portion of the upper part to provide the limited universal movement between the two.

[0012] The insertion tool usable in combination with the implant preferably has a pair of arms, each of which engages a recess within a keel, each arm having a projection which is moved toward the base of the recess to engage indentations in the base of the recesses to firmly hold the implant. The arms also include lateral support portions which engage support cutouts on the upper and lower parts to absorb lateral forces exerted on the implant so that such lateral forces do not have to be absorbed by the more delicate portions of the insertion tool arms located within the recesses of the keels.

[0013] The method of present invention comprises engaging an intervertebral implant of the type described with an insertion tool of the type described, inserting the intervertebral implant into the intervertebral space with the keels entering cutouts in the adjacent vertebrae, and then removing the insertion tool from the intervertebral implant, leaving the intervertebral implant in place within the intervertebral space.

[0014] Thus, it is an object of the present invention to provide a new and improved intervertebral implant.

[0015] It is another object of the present invention to provide an insertion tool and a method for inserting the new improved intervertebral implant.

[0016] It is another object of the present invention to provide an intervertebral implant which is particularly suitable for the cervical spine.

[0017] It is another object of the present invention to provide a new and improved intervertebral implant characterized by a recess in raised keels for receiving insertion tools for inserting the intervertebral implant.

[0018] These and other objects of the present invention will be apparent from the detailed description to follow, together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] A preferred embodiment of the invention will now be described by way of example with reference to the accompanying drawings, wherein:

[0020] Figure 1 is a perspective view of an intervertebral implant in accordance with the present invention;

[0021] Figure 2 is a front elevational view of the implant of Figure 1;

[0022] Figure 3 is a left side elevational view of the implant of Figure 1;

[0023] Figure 4 is a cross sectional view taken along line 4-4 of Figure 2;

- [0024] Figure 5 is a cross sectional view taken along line 5-5 of Figure 3;
- [0025] Figure 6 is a top plan view of the upper part of the implant of Figure 1;
- [0026] Figure 7 is a perspective view of the bottom surface of the upper part of the implant of Figure 1;
- [0027] Figure 8 is a bottom plan view of the lower part of the implant of Figure 1;
- [0028] Figure 9 is a bottom perspective view of the lower part of the implant of Figure 1;
- [0029] Figure 10 is a top perspective view of the lower part of the implant of Figure 1;
- [0030] Figure 11 is a top perspective view of the plastic inlay of the implant of Figure 1;
- [0031] Figure 12 is a top plan view of the plastic inlay of the implant of Figure 1;
- [0032] Figure 13 is a bottom perspective view of the plastic inlay of the implant of Figure 1;
- [0033] Figures 14-17 are elevational views of the implant of Figure 1 illustrating the limited universal movement of the parts thereof;
- [0034] Figure 18 is a schematic view of a pair of adjacent vertebrae prepared to receive an implant of the present invention in the intervertebral space therebetween;

[0035] Figure 19 illustrates the vertebrae of Figure 18, in a direction along line 19-19 of Figure 18 and showing the implant itself about to be inserted and showing an insertion tool prior to engaging the implant ;

[0036] Figure 20 illustrates a portion of an insertion tool for use with the implant of the present invention;

[0037] Figure 21 illustrates the vertebrae of Figure 18 with the implant in place therein and the insertion tool still holding the implant in the same position in which it held the implant during insertion; and

[0038] Figure 22 illustrates the vertebrae with the implant in place and the insertion tool removed.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0039] Referring now to the figures, like elements are represented by like numerals throughout the several views.

[0040] In this application, the words "upper" or "lower" or "uppermost" or "lowermost" or any other words describing the orientation of the intervertebral implant of the present invention are used only for convenience and are not intended to convey any limitation. More specifically, the part of the implant described in this application as the upper part can in fact be positioned as the superior or inferior part within the patient's vertebrae with the other of the two parts being the opposite part. Also, since the intervertebral implant is normally inserted from the front of the patient, the side of the vertebrae toward which the

intervertebral implant moves as it is inserted shall be referred to as the anterior side of the vertebrae and the opposite side as the posterior side and the right and left sides as lateral sides. Since the more common manner of insertion is anteriorly, the present invention will be described with respect to that orientation. However, it is to be understood that the intervertebral implant can also be inserted laterally, i.e., from the side, in which case the keels will be oriented on the implant for such lateral movement and the cutouts in the adjacent vertebrae will be open toward a lateral side to receive the keel.

[0041] Figures 1-5 illustrate in different views the assembled intervertebral implant 10 including an upper part 11, a lower part 30 and a plastic inlay 50 located therebetween but connected to the lower part 30.

[0042] The intervertebral implant of the present invention has been designed primarily for insertion in the cervical spine. This portion of the spine is characterized by the need for precision because of the relatively small dimensions of the cervical intervertebral space. For example, the implant of the present invention, when viewed in plan view (as best seen for example in Figure 6) would be approximately 12-16 millimeters in width and approximately 15-19 millimeters in length. It has been found practical to provide three sizes, 12 millimeters x 15 millimeters, 14 millimeters x 17 millimeters and 16 millimeters x 19 millimeters. The height of the implant, meaning the height from the upper surface of the upper part to the lower surface of the lower part, excluding the keels,

would normally be between 5 millimeters and 9 millimeters. These dimensions are in contrast to an intervertebral disc to be located in the lumbar area wherein the rectangular portion would have dimensions more on the order of 27 to 30 millimeters in width, 34 to 39 millimeters in length, and a height of about 10 to 14 millimeters. However, it is to be understood that the features of the present invention are equally adaptable for an intervertebral implant of a different size and design for construction in any other part of the spine including the lumbar spine.

[0043] The upper part 11 will now be described in detail with respect to Figures 1-5 which illustrate the assembled implant and Figures 6 and 7 which illustrate only the upper part 11. The upper part 11 includes an upper surface 12 which engages and supports the adjacent vertebral surface. This upper surface 12 is bounded by edges which are slightly beveled all the way around as shown at 13 with the largest portion of this bevel being along the posterior surface. Below the beveled edge 13, the upper part is bounded by a surrounding side wall 14 which has an anterior support cutout 15. Thus, in the figures the keels are shown oriented anterior to posterior with the solid portion of the keels facing posteriorly and the insertion engaging recess structure facing anteriorly.

[0044] Rising above the upper surface 12 of the upper part 11 is a keel 16 which includes a recess 17 formed therein. This recess is opened upwardly and anteriorly. Referring to Figures 4 and 6, this recess

includes an indentation 21 in the base thereof. The posterior end of the keel 16 comprises a V-shaped upper bevel 19 and a V-shaped vertical portion 20, providing a front which is "arrow" shaped, as best seen in Figure 6. The purpose of this "arrow" shape is to facilitate insertion of the keel into a cutout formed in the adjacent vertebrae. The anterior opening of the recess is flared at 18, which flare serves to anchor the anterior end of the keel 16 in its cutout in the adjacent vertebrae.

[0045] The upper part 11 includes a lower plane inner surface 24 which includes, as best seen in Figure 7, a raised rim 26 which defines a concave spherical portion 25. As best shown in Figures 4 and 5, this spherical concave portion 25 will mate with an upper convex surface of the plastic inlay 50.

[0046] The lower part 30 is described with reference to Figures 1-5 and also Figures 8-10 which show isolated views of the lower part 30.

[0047] The lower part 30 includes a lower vertebrae supporting and engaging surface 31 and an inner upper surface 32. As best seen in Figures 2, 5 and 10, this lower part includes grooves 33 and 34 formed in the interior side wall thereof beneath surface 32 and above a base surface 38. A substantially flat back wall 35 extends from base surface 38 to upper surface 32. This lower part includes a beveled edge 36 extending around the periphery of the lower surface 31 with a most pronounced bevel at the posterior thereof and a surrounding side wall 39. The purpose of the grooves 33 and 34 is to receive side flanges 53 and

54 of a plastic inlay 50, as shown in Figure 11 and as will be described in greater detail below.

[0048] Lower part 30 includes an anterior support cutout 37. A keel 40 rises upwardly (or in the usual orientation, extends downwardly) from the lower surface 31. This keel includes a recess 41 which opens downwardly and anteriorly and has a flared anterior entrance to the recess at 42, which flared entrance serves the same function as flared entrance 18 of upper part 11, i.e., to facilitate engagement of the anterior end of the keel within its cutout in the vertebrae. As best shown in Figure 4, the recess 41 opens downwardly and anteriorly and includes an indentation 43. The keel 40 includes at its posterior end a V-shaped lower bevel 45 and a V-shaped vertical portion 46 which together provide an "arrow" shape, as best seen in Figure 8 to facilitate insertion of the keel into its cutout formed in the adjacent vertebrae.

[0049] Referring momentarily to Figure 13, it will be noted that the lower surface of the plastic inlay 50 includes a raised snap-in projection 57. Referring now to Figure 10, there is illustrated a snap-in recess 44 which is adapted to receive the snap-in projection 57 such that the plastic inlay can snap into place but is thereafter prevented from being removed. This snap fit is also shown clearly in Figure 4. It will be noted, however, that while removal would not occur under normal circumstances, in fact it is possible at a subsequent time, by inserting a tool between the base of the lower part and the plastic inlay to pry the plastic inlay out and

remove it. This might be useful, for example, if it were decided to insert a new plastic inlay of a different size or if it became necessary to repair the previously inserted plastic inlay.

[0050] The upper and lower parts are made of a suitable material such as titanium, cobalt chromium molybdenum, stainless steel or ceramics. The upper surface of the upper part and the lower surface of the lower part as well as the side surfaces of the keels are coated with a porous coating of titanium. The porosity of the coating ideally permits vascularization and osteoplast formation with subsequent bony on-growth.

[0051] The plastic inlay 50 is visible in Figures 1-5. However, for convenience the numerals pointing to details thereof are not included in any of those figures, but instead are provided in Figures 11-13. It is preferably made of high density polyethylene. Figure 11 illustrates the plastic inlay 50 in its position as shown in Figure 1. It includes a flat upper surface 51 having attached thereto a convex spherical portion 52 which mates with the concave spherical portion 25 of the upper part 11. Side flanges 53 and 54 engage the grooves 33 and 34 in the lower part 30. A flat posterior wall 55 engages the posterior wall 35 of the lower part.

[0052] Referring to Figure 13, the plastic inlay 50 includes a generally flat lower surface 56 which engages the base surface 38 of the lower part and a snap-in projection 57 which is beveled on the posterior side and includes a sharp ledge on the anterior side so as to snap into

place in the recess 44 of base surface 38 to the position as best shown in Figure 4.

[0053] Figures 14-17 illustrate the limited universal movement of the upper and lower parts of the implant relative to each other when inserted in a patient's intervertebral space. Figures 14 and 15, both of which view the anterior of the implant, show maximum lateral bending to the left and right, respectively. It will be noted that in each case the raised rim 26 of the upper part 11 engages the inner surface 32 of the lower part 30. In a preferred embodiment, such lateral bending movement is possible for up to approximately 10.5° for the smaller of the three sizes and approximately 8.9° for the two larger sizes, relative to a reference position wherein the keels are aligned vertically. Figure 16, which shows a view from the right side of the patient, shows extension movement of the upper part relative to the lower part which is limited by engagement of the rim 36 with the inner surface 32 of the lower part 30. Finally, Figure 17, which is a view from the patient's left side, shows maximum flexion of the upper part 11 relative to the lower part 30. Flexion is limited by engagement of the rim 26 with the surface 51 of the inlay 50. In preferred embodiments, extension and flexion can occur up to approximately 10.5° for the smaller three sizes and approximately 8.9° for the two larger sizes, relative to a reference position wherein the keels are vertically aligned.

[0054] Figures 18-22 illustrate the method of insertion of the implant shown in Figures 1-17 and a portion of an insertion tool for use for inserting the implant.

[0055] Figure 18 is an anterior view of a pair of adjacent vertebrae V on opposite sides of a cleaned-out intervertebral space I. In preparation for inserting the intervertebral implant of the present invention, cutouts C will be formed in the vertebrae V. As shown in Figure 18 and the left hand portion of Figure 19, these cutouts start from the anterior of the vertebrae and extend for most but not all of the distance toward the posterior of the vertebrae, intersecting along its entire length with the surface of the vertebrae facing into the intervertebral space.

[0056] Figure 19 illustrates just to the right of the prepared adjacent vertebrae the intervertebral implant assembled in the form as shown in Figures 1-5. To the right thereof is an insertion tool 60 which is to be described with respect to Figures 19 and 20. This insertion tool 60 includes an upper arm 61 and a lower arm 71, which arms are arranged to move towards and away from each other as indicated by the arrows B in Figure 19. Various devices can be provided for moving these arms towards and away from each other. One such mechanism in the form of a scissors is partially shown at 80 in Figure 20. The upper and lower arms include keel engaging portions 62 and 72 which engage recesses 17 and 41, respectively. These arms include towards their outer ends projections 63 and 73 which are constructed to be received in the

indentations 21 and 43, respectively. It will be noted that these keel engaging portions 62 and 72 are relatively narrow. In fact, it is contemplated that the entire width of each keel will be approximately 2 millimeters, thus allowing less than 2 millimeters for the actual recesses. The arms 61 and 71 also include lateral support surfaces 64 and 74 which, upon engagement of the tool with the implant, will engage the front support cutouts 15 and 37.

[0057] The arms 61 and 71 will be spaced apart from each other just enough for the projections 63 and 73 to clear the bottoms of the recesses 17 and 41 until the projections 63 and 73 reach the indentations 21 and 43, at which time the arms 61 and 71 will be moved towards each other such that the projections 63 and 73 engage within the indentations 21 and 43 and the lateral support surfaces 64 and 74 are engaged within the cutouts 15 and 37. At this position, abutment surfaces 65 and 75 on the upper arm and lower arm 61 and 71, respectively, will abut each other, thus limiting further movement of the arms 61 and 71 towards each other.

[0058] With the assembled implant thus attached to the insertion tool, the insertion tool moves it into the intervertebral space with the keels 16 and 40 entering the cutouts C, while the portions of the upper and lower parts 11 and 30 posterior of the keels extend within the intervertebral space beyond the cutouts C so that upper surface 12 engages the intervertebral surface of the adjacent vertebrae V posterior of

and adjacent to the keel 16 and surface 31 of the lower part 30 engages the intervertebral surface of the adjacent lower vertebrae posterior and adjacent to the keel 40. Actually, the above described engagement of the insertion tool 60 and the implant 10 prior to insertion is the same as shown in Figure 21, just after insertion.

[0059] It will be noted that in Figure 21 there is a space above and below the arms 61 and 71 within keel recesses 17 and 41, the vertical dimension of which spaces is greater than the height of the projections 63 and 73, which would normally be about 1.2 millimeters. This is necessary so that the arms 61 and 71 can be moved upwardly and downwardly, respectively, away from the base of their respective recesses to free the projections from the indentations before the upper and lower surfaces of arms 61 and 71 engage the vertebrae at the vertical extremities of the cutouts C. Such contact is to be avoided. Once these arms have been separated accordingly, they can be moved out from the implant, anteriorly, leaving the implant in place as shown in Figure 22.

[0060] The method of the present invention will be apparent from the above described operation of the invention as shown and described with respect to Figures 18-22. In accordance with this method of the present invention, adjacent vertebrae are provided with cutouts in the manner described and an intervertebral implant of the type described is grasped with an insertion tool having arms which are received in the recesses of the keels through the anterior openings thereof. With the

implant firmly grasped by the insertion tool, the implant is inserted anteriorly with the keels leading the way into the cutouts until the proper position has been reached. At this time, naturally some force will have been exerted to distend the adjacent vertebrae from each other, but preferably just enough to allow the implant to be inserted. In fact, many professionals prefer to distend the adjacent vertebrae no more than essentially the width between the upper and lower surfaces 12 and 31 and then apply additional external force with a mallet or the like to complete insertion of the implant. After the implant has been inserted, the arms of the insertion tool are separated just enough to free the projection/indentation engagements from each other, whereupon the insertion tool is removed anteriorly, leaving the implant in place and relieving any previously applied forces applied to distend the adjacent vertebrae from each other, allowing these adjacent vertebrae to rest upon the supporting surfaces 12 and 31 of the implant.

[0061] Although the invention has been described in detail with respect to preferred embodiments thereof, it will be apparent to one skilled in the art that the invention is capable of numerous modifications and variations within the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An intervertebral implant comprising an upper part adapted to engage an adjacent vertebrae and a lower part adapted to engage an adjacent vertebrae,

the upper and lower parts being in operative contact with each other so as to allow them limited universal movement relative to each other,

each of the upper and lower parts having a raised keel on its surface engaging the adjacent vertebrae, which keel is adapted to be received within its adjacent vertebrae through a cutout formed in the anterior of that vertebrae,

and each keel having a recess therein, which has an anterior opening, for receiving an insertion tool for inserting the implant into the intervertebral space.

2. An implant according to claim 1, wherein at least one of said recesses includes an engagement structure for engaging an insertion tool to secure the tool against movement out of the recess.

3. An implant according to claim 2, wherein both of said recesses include an engagement structure.

4. An implant according to claim 2, wherein the engagement structure includes an indentation formed in the base of the recess closest to the implant and adapted to receive a projection on the insertion tool.

5. An implant according to claim 1, wherein the keels are beveled on the posterior ends thereof to facilitate entry of the keel into the cutout.

6. An implant according to claim 1, wherein the keels are flared outwardly adjacent the anterior openings to facilitate the keel engaging the anterior of the vertebrae adjacent the cutout.

7. An implant according to claim 1, the implant comprising a lower part having a plastic inlay attached thereto with an upwardly spherical convex portion and the upper part having a concave spherical portion in an operative engagement with the spherical convex portion.

8. An implant according to claim 7, the plastic inlay being snap fitted into the lower part.

9. An implant according to claim 1, wherein the upper and lower parts have anterior support cutouts adjacent the anterior keel recess openings for receiving a portion of the insertion tool.

10. In combination, an intervertebral implant and an insertion tool for inserting same,

the implant comprising an upper part adapted to engage an adjacent vertebrae and a lower part adapted to engage an adjacent vertebrae,

the upper and lower parts being in operative contact with each other so as to allow them limited universal movement relative to each other,

each of the upper and lower parts having a raised keel on its surface engaging the adjacent vertebrae, which keel is adapted to be received within its adjacent vertebrae through a cutout formed in the anterior of that vertebrae,

each keel having a recess which has an anterior opening,

and said insertion tool having a pair of arms, one engaging each recess through an anterior opening thereof, to thereby grasp the implant for insertion into the intervertebral space.

11. The invention according to claim 10, at least one recess and its respective insertion tool having a complementary engaging structure for securing the arm in the recess.

12. The invention according to claim 11, wherein the complementary engaging structure includes a raised projection on the arm and a matching indentation in the base of its recess.

13. The invention according to claim 10, wherein both recesses and their respective insertion tools include a complementary engaging structure for securing the arm in the recess.

14. The invention according to claim 10, wherein the upper and lower parts each have a front support cutout adjacent the keel recess opening for receiving a portion of the insertion tool, said arms having a first narrow portion for insertion into the recess of its respective keel and a second broader portion for engaging the front support cutouts.

15. The invention according to claim 10, wherein the insertion tools are movable in a direction into and out of their respective recesses, through the anterior opening, and in a direction perpendicular thereto to engage and release their respective implants.

16. The invention according to claim 15, said insertion tools having abutment surfaces which abut each other to limit movement of the two arms towards each other.

17. The invention according to claim 15, including a raised projection on the arm which engages a matching indentation in the base of its recess for securing that arm in its recess, and wherein the height of each arm is less than the height of the recess in which it is received by an amount greater than the height of its projection to thereby allow vertical movement of the projection out of its indentation without the arm moving upwardly out of its recess.

18. A method of inserting an intervertebral implant into an intervertebral space, comprising the steps of:

providing a cutout in the two vertebrae adjacent the intervertebral space where the implant is to be inserted, said cutouts extending vertically into the vertebrae and open anteriorly,

providing an implant having upper and lower parts adapted to engage adjacent vertebrae, which upper and lower parts are in operative engagement with each other to allow a limited universal movement relative to each other and wherein each of the upper and lower parts has a raised keel with a recess formed therein which has an anterior opening,

grasping the implant with an insertion tool that includes arms which are received in the recesses of the keels through the anterior openings thereof,

inserting the insertion tool with the implant secured thereto such that the keels and arms move into the cutouts and the implant moves into the intervertebral space between two adjacent vertebrae,

and removing the tool from the keels through the anterior openings thereof, leaving the implant in place between the adjacent vertebrae.

19. The method according to claim 18, wherein the grasping step includes having projections on the arm and pointing toward the implant engage indentations in the base of the recess.

20. The method according to claim 19, wherein the removing step includes first moving the arms away from each other to release the projection and indentation engagement and then moving the arms out of the recess.

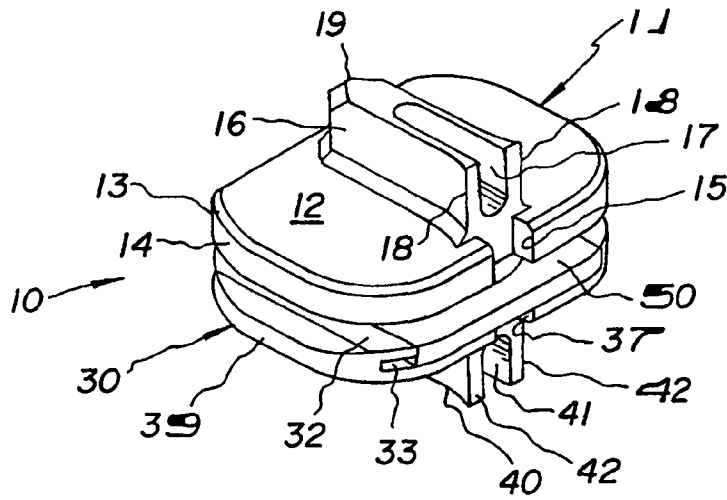


FIG. 1

FIG. 2

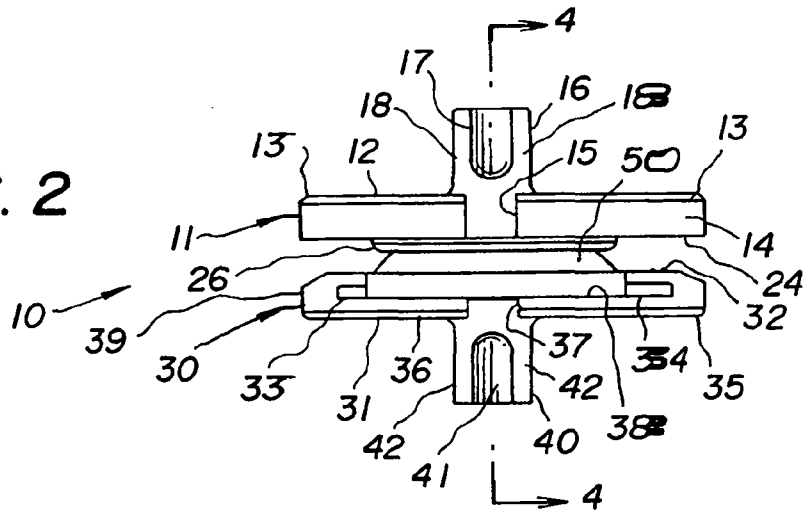
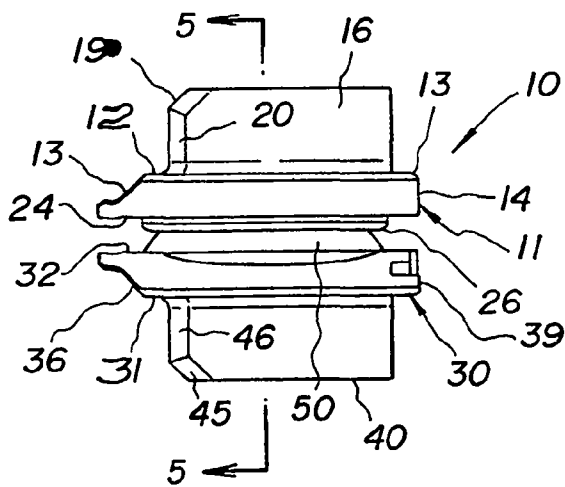


FIG. 3



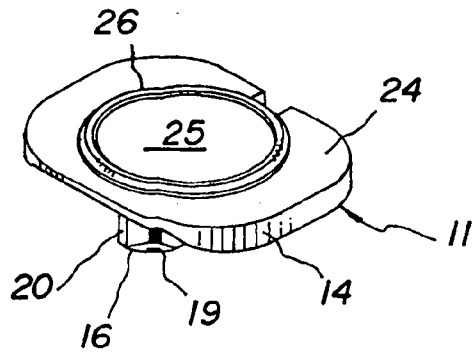


FIG. 7

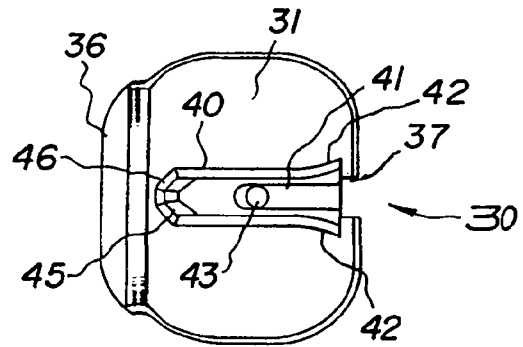


FIG. 8

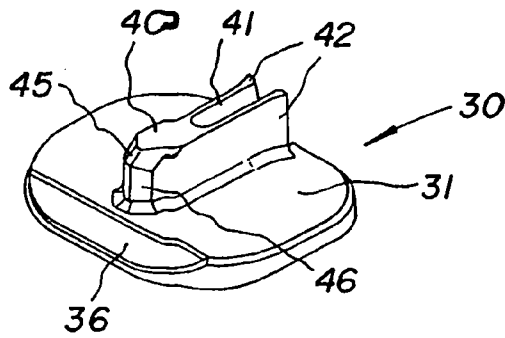


FIG. 9

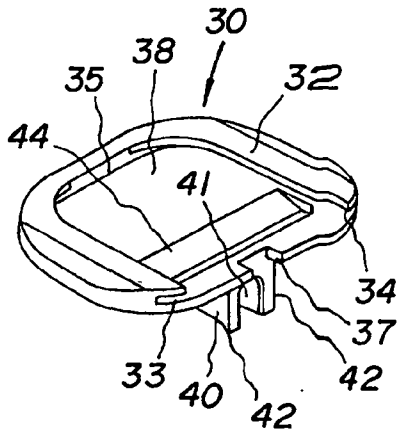


FIG. 10

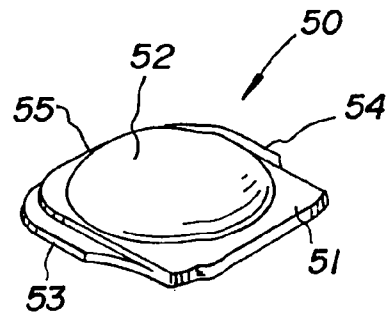


FIG. 11

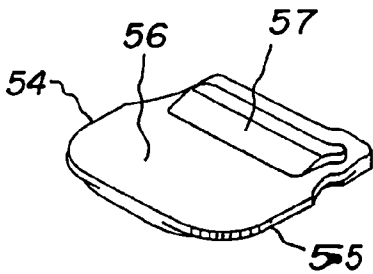


FIG. 13

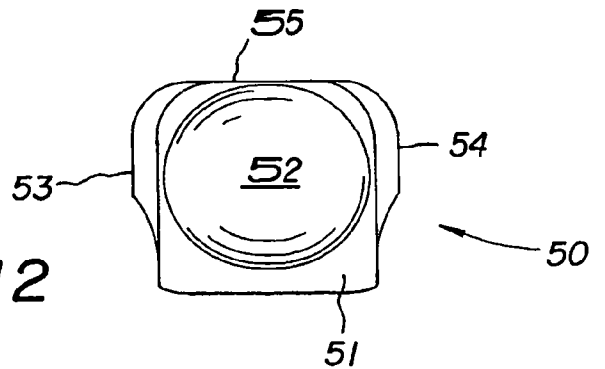


FIG. 12

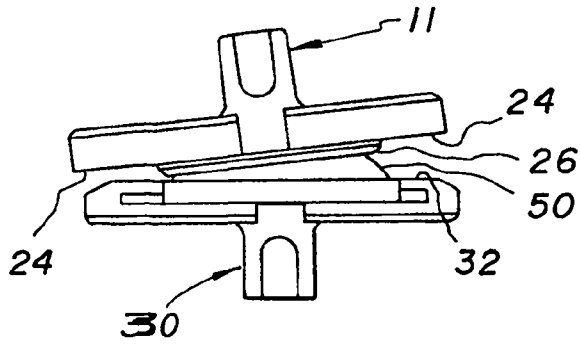


FIG. 14

FIG. 16

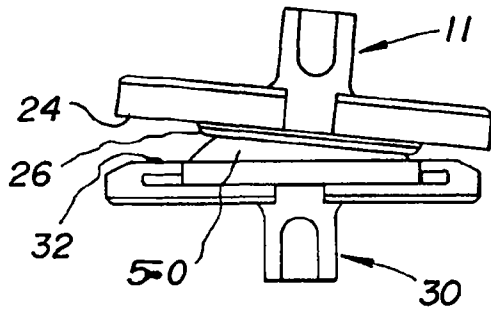
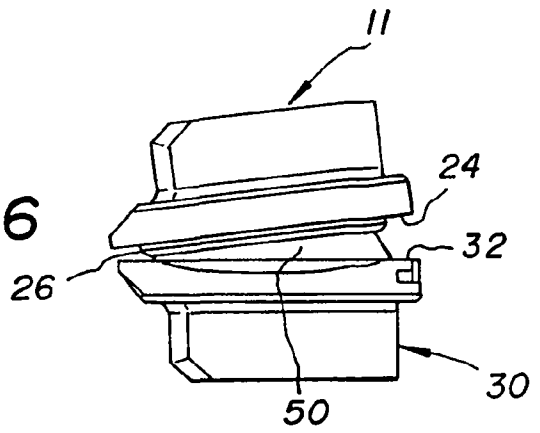


FIG. 15

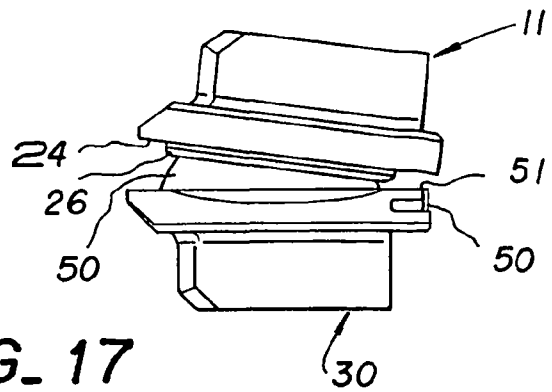
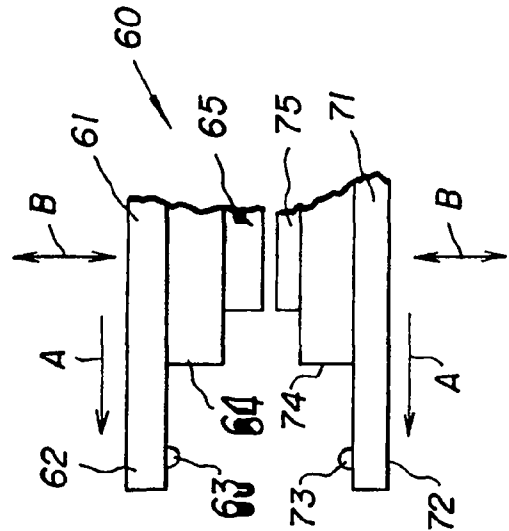
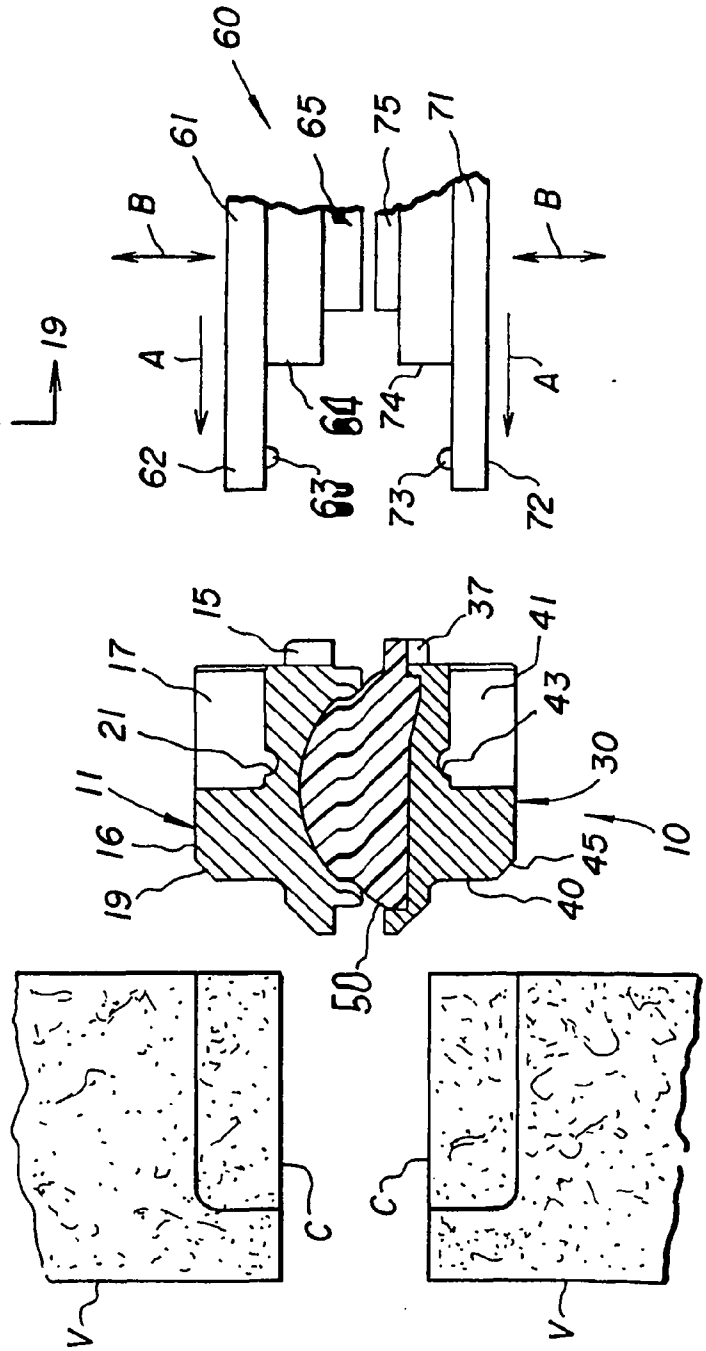
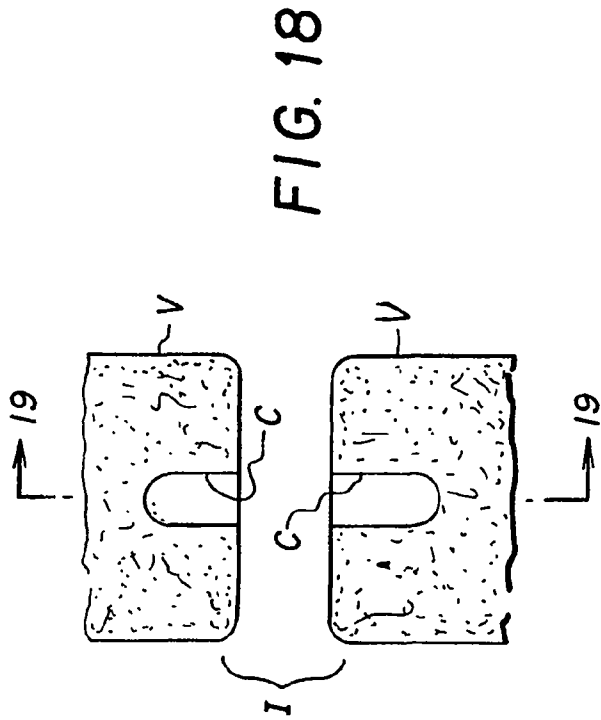


FIG. 17



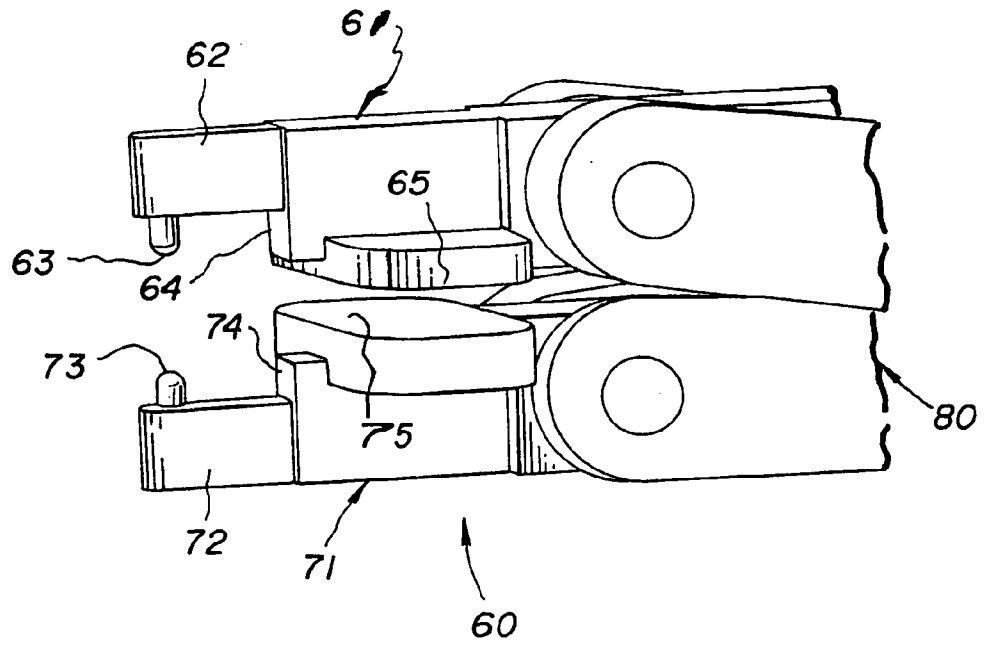


FIG. 20

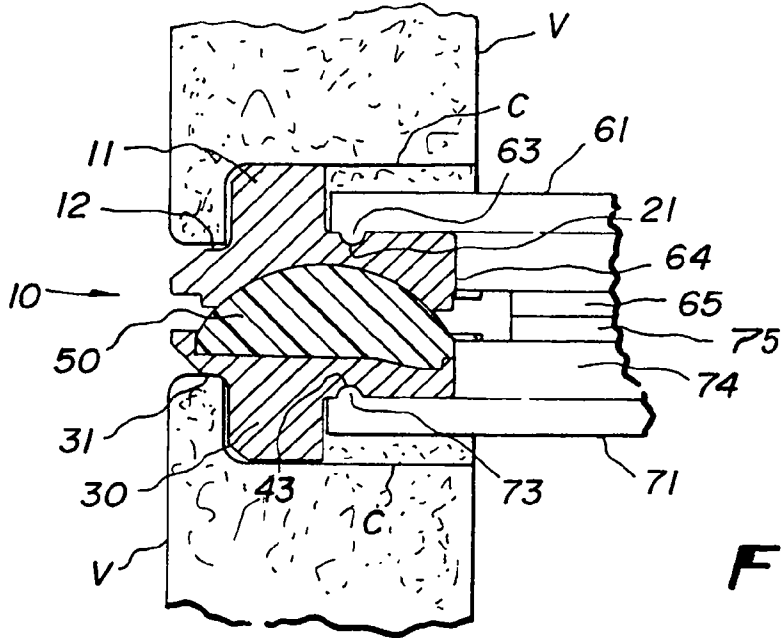


FIG. 21

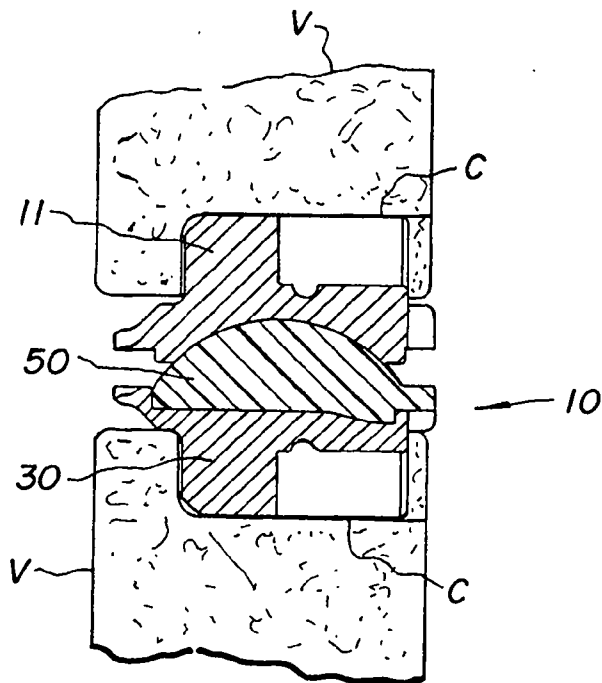


FIG. 22