

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 June 2002 (27.06.2002)

PCT

(10) International Publication Number
WO 02/49539 A2

(51) International Patent Classification⁷: **A61F**

(21) International Application Number: PCT/US01/48004

(22) International Filing Date:
12 December 2001 (12.12.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/256,632 19 December 2000 (19.12.2000) US
Not furnished 21 November 2001 (21.11.2001) US

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(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, 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, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL,
TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

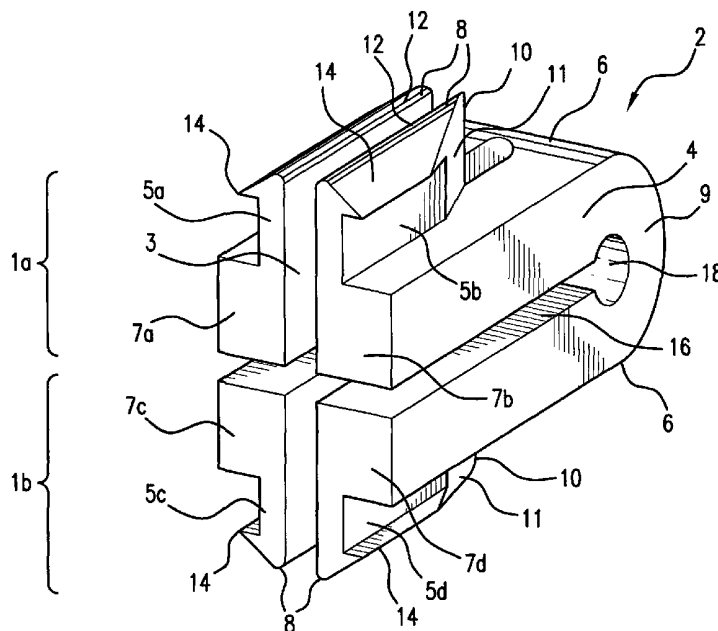
(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ,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

Published:

— without international search report and to be republished
upon receipt of that report

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

(54) Title: DYNAMIC IMPLANTED INTERVERTEBRAL SPACER



(57) Abstract: The invention is a single piece, self seating and locking dynamic intervertebral spacer. The dynamic spacer is load-supporting but also able to undergo flexure in either or both the lateral and sagittal planes.



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DYNAMIC IMPLANTED INTERVERTEBRAL SPACER

PRIORITY

5 This application is related to and claims priority from the United States Provisional Application No. 60/256,632, filed December 19, 2000.

FIELD OF THE INVENTION

10 The present invention relates to implants for repair of spinal defects and injuries. It relates in particular to implants having utility to maintain intervertebral spacing after disc removal. It further relates to intervertebral spacers which can permit at least some remaining spinal flexibility.

BACKGROUND OF THE INVENTION

15 Natural intervertebral spinal discs serve multiple purposes. The first, and perhaps most basic, is to preserve the anatomical spacing between adjacent vertebrae such that the spinal column and horizontally branching nerve bundles are allowed to function normally. A second major purpose is to allow relative flexural motion between adjacent vertebral bodies. Natural flexibility, at least of the upper spine, permits rotation about two horizontal axes and one vertical axis. Finally, the disc also serves as a shock absorber for columnar loading of the spine. However, mechanical trauma, degenerative disc disease, 20 and other pathogenesis can compromise a disc's ability to maintain the spacing, facilitate flexibility, and provide the shock absorbing function.

25 One option after the surgical removal of a damaged disc might be to allow the intervertebral space to collapse. Collapse, however, usually causes compressive damage to the spinal cord and the associated nerve bundles. Also, the intervertebral space may fill with scar tissue that can aggravate nerve damage. Thus the simple removal of a damaged disc, without providing for maintenance of the normal vertebral spacing is undesirable.

30 Discectomy therefore is usually supplemented by (1) rigid fusion of the adjacent vertebrae with new bone growth; (2) application of rigid nonfusing hardware; or (3) insertion of an artificial disc. As the patent literature shows, these approaches have

been tried in many variations but have significant disadvantages.

a. Vertebral Fusion

Well-known to those skilled in the art is interbody fusion wherein the disc is partially or wholly excised and living bone or various forms of calcium phosphate or other substrate material is placed within the space previously occupied by the disc for the purpose of restoring the normal separation, strength, and stability. Fusion is intended to provide healthy, living bone between the adjacent vertebrae.

For fusion to occur within the disc space, it is frequently necessary to prepare the adjacent vertebrae by excising portions of the cortical exterior surfaces, usually of the vertebral endplates so as to allow an interposed bone graft to come into direct contact with the cancellous (and vascularized) interior of the vertebrae.

Historically, two types of bone grafts have been available for anterior cervical fusion. One type is a round dowel plug-like configuration, such as the original Cloward dowel. The second type, a rectangular plug in a rectangular hole, is often referred to as the Smith-Robinson technique. The bone can be obtained from the patient's own iliac crest, from allograft cadaveric crest, or cut from a hard femoral cortical bone.

Both techniques can have disadvantages. For example, the dowel approach frequently flattens the intervertebral space, causing it to induce an undesirable kink in the natural lordosis. Also, the instrumentation used to implant the dowel is bulky and tends to be difficult to use. Thus many surgeons have abandoned this technique. The Smith-Robinson approach has problems because lack of preparation of the endplates leads to non-incorporation and eventual collapse. Moreover, the use of autograft bone to fill the disc space is often less than optimal since it requires an additional incision and healing and is of limited availability in its most useful form.

b. Artificial Discs

Extensive research has been devoted to developing an effective artificial disc. No such device has yet been found that is medically acceptable. Examples of various prosthetic or artificial disc attempts include Fassio, U.S. Pat. No. 2,372,622; Stubstad, U.S. Pat. No. 3,867,728; Froning, U.S. Pat. No. 3,875,595; Patil, U.S. Pat. No. 4,309,777; Kuntz, U.S. Pat. No. 4,349,921; Hirayama, et al., U.S. Pat. No. 4,946,378; Nishijima, et al., U.S. Pat. No. 5,899,941; Bryan, et al., U.S. Pat. No. 6,001,130. Substantial numbers of others exist.

c. Spacers

A number of intervertebral spacers designed for installation between adjacent vertebrae have been patented. These include: U.S. Pat. No. 6,086,613 to CAMINO, et al., relates to intervertebral spacers used in connection with spinal fusion. U.S. Pat. No. 6,039,762 to McKay describes a spacer body having an outer surface and a height approximating the height of a human disc space, said body composed of a porous, biocompatible ceramic material for permitting tissue ingrowth therethrough. U.S. Pat. No. 5,989,291 to RALPH, et al. describes an intervertebral spacer having a pair of opposing plates for seating against opposing vertebral bone surfaces, separated by at least one spring mechanism. In a first embodiment there are two Belleville washers which are oriented in opposite directions such that the narrow ends thereof are in contact with each other and the wider ends are in contact with the respective end plates. The Belleville washers work as springs. (Belleville washers are described as frustoconical in shape.)

U.S. Pat. No. 5,984,922 to McKay describes a spinal fixation device consisting of an intervertebral body wedge which is inserted between vertebral bodies by sequentially expanding the disc space using a spacer. No posterior fixation devices are needed for stabilization of the vertebrae. U.S. Pat. No. 5,888,222 to COATES, et al. describes a spinal spacer that engages adjacent vertebrae. The spacer includes a body having two ends, at least one of which "defines" an inferior vertebral engaging surface having a set of migration resistance grooves. U.S. Pat. No. 5,534,029 to Shia discloses an articulated vertebral body spacer consisting of a pair of upper and lower joint pieces to be inserted between vertebrae. This spacer allows its components to pivot in accordance with forward/backward and bending motions of vertebral bodies. U.S. Pat. No. 4,599,086 to Dogy discloses a spinal stabilization device positionable between separated but neighboring vertebrae. A wrench can be inserted into the opening until it engages a pair of pins, and then the wrench can be rotated to advance the pins into the abutting vertebral bodies.

Two spacer inventions that are designed specifically for use in connection with subsequent fusion processes are: U.S. Pat. No. 5,888,223 to BRAY, Jr., which discloses an anterior fixation device consisting of an oval shaped hollow intervertebral spacer and a retaining plate. The spacer has a side wall and superior and inferior walls. The superior and inferior walls are dome-shaped and porous to allow bone to grow

through the device to achieve fusion of two adjacent vertebral bodies; and U.S. Pat. No. 5,865,848 to Baker describing a spinal fusion implant assembly for spacing vertebrae. The device includes a translation mechanism for providing relative motion between the components.

5 An additional area of prior art includes all devices designed to be applied to one or more exterior surfaces of the spine. Such devices include all types of plates, struts, and rods which are attached by hooks, wires and screws. Other devices are simply variations on the use of rods (e.g. Harrington, Luque, Cotrel-Dubosset, Zielke), wires or cables (Dwyer), plates and screws (Steffee), or struts (Dunn, Knowles).

10 A preferable spacer would at least to some extent preserve the ability of the patient to rotate portions of the spinal column about two perpendicular horizontal axes (and linear combinations thereof) and about the vertical axis. All of the prior art approaches suffer from the drawback that they either do not attempt to preserve such flexibility or they are unable in practice to achieve a workable device. In addition they
15 suffer from other drawbacks.

 The principal drawbacks of the fusion approach are that until very recently the success rate, that is, actual achievement of fusion, has been very modest. Secondly, in cervical as opposed to lumbar application, the diminution in mobility of the spine about rotational axes is a much more significant lasting effect for the patient.

20 The principal aim of artificial discs has been to provide a prosthesis which preserves as much of the patient's prior ability to move as possible. The principal drawback of artificial discs is that they simply do not work in a medical sense.

 Spacers have the drawback that, by themselves, they do not achieve the beneficial results of fusion. On the other hand, most of them are rigid, and therefore also
25 have the same drawback as successful fusion, namely reducing the patient's flexibility.

OBJECTS OF THE INVENTION

 Accordingly, it is an object of the present invention to provide a single-piece intervertebral implant that can serve as a spacer between adjacent cervical vertebrae.
30 Another object of the invention is to provide an intervertebral implant that allows relative motion of the adjacent vertebral bodies. Another object of the present invention is to provide a low cost intervertebral implant that is small enough to allow rapid and easy

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anterior or posterior installation into either the cervical or the lumbar regions of the spine. Another object of the present invention is to provide an intervertebral implant device that is self-adhering upon installation. Another object of the present invention is to provide an intervertebral implant device that can maintain intimate, grasping adherence with the vertebral bodies, even when loaded in tension. Another object of the present invention is to provide an artificial disc prosthesis able to allow for full bending movement of the two vertebral bodies between which it is installed, allowing flexibility within both the lateral and sagittal planes. Yet another object of the present invention is to provide an intervertebral implant device that can pierce the bony cortex of the vertebral bodies during installation. And yet a further object of the present invention is to provide an intervertebral implant device that provides self-centering alignment upon installation.

Additional objects of the invention are to provide a single-piece spacer device which alone, or with a second such spacer device, can serve as a spacer between adjacent vertebra within the lumbar region of the spine as part of a vertebral fusion process. Yet another object of the present invention is to provide an intervertebral implant device that provides the correct amount of loading in order to promote bone growth and vertebral fusion. A final object of the invention is to provide a single-piece device which alone in the cervical region of the spine or in combination with a second like device in the lumbar region of the spine can be driven into an intervertebral space with a single force-applying operation for each of the one or two devices.

SUMMARY OF THE INVENTION

The present invention is an implantable intervertebral spacer designed to both preserve the space between adjacent vertebrae and to provide some continued spinal flexibility by virtue of its flexible construction. This spacer is also characterized by single piece construction and by the property of being self guiding upon initial insertion into the intervertebral space. This invention also has four spaced-apart tail pieces flexibly linked to one another, consisting of one upper set of two horizontally spaced-apart tail pieces and one lower set of two horizontally spaced-apart tail pieces, the upper and lower sets also being vertically spaced-apart from one another. Each of the two upper spaced-apart elongated tail pieces is independently flexibly linked to each of the corresponding spaced apart elongated lower tail pieces. Each of the tail pieces also comprises an elongated post

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supporting a bone gripping barb and a cutting edge having an inwardly angled facet. Upon installation between adjacent vertebral bodies, the implant is self locking by virtue of strain induced in the elongated barb-supporting posts. The device is implantable as a single unit within the intervertebral space between adjacent cervical vertebrae or it is
5 implantable in conjunction with a second spacer within the same intervertebral space. Because of the cutting edges and barbs, it is implanted by being impacted with a driver device, at which point it is firmly seated and will not pull or creep out. The device also has a wedge shaped front portion to guide it into the desired position during installation. The bone gripping induced strain manifests within each of the elongated posts supporting
10 each barb of each spaced-apart pair of barbs when the facet causes inward bending strain of the elongated posts upon installation into the vertebral bone.

The present invention is an implantable intervertebral device that can be configured also to promote bone growth and vertebral fusion. The vertical slot between the upper and lower sets of the two horizontally spaced-apart tail pieces can be loaded with
15 bone graft material and/or bone morphogenic protein so as to create a fusion column and promote intervertebral fusion. It is known that compressive loading of graft material promotes new bone growth and healing. (This principle is generally referred to as Wolff's law.) The horizontal slot between the upper and lower sets of tail pieces can be varied in height, and the radius of the internal void in the portion connecting the upper part of the
20 device to the lower part of the device can be varied, both so as to provide flexing sufficient to produce enough loading on the graft material to promote bone growth and vertebral fusion while still providing sufficient compressive strength to maintain the necessary intervertebral spacing.

The spacer of the current invention can be fabricated from metal, preferably
25 titanium or stainless steel. Or it can be fabricated from organic polymer such as thermoplastic or thermosetting plastic unfilled or filled with fibers such as glass, metal or carbon. Preferably, said implant spacer, if fabricated from organic polymer, is to be fabricated from polyether ether ketone (PEEK), most preferably filled with fibers of metal or glass or, most preferably, carbon.

30 A second embodiment of the said cervical/lumbar implant spacer employs the use of bullets situated upon elongated posts instead of barbs as a way to grip the vertebral bone. The forward cutting edge of each bullet has an angled facet that causes

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induced strain to arise within the elongated support post during installation.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an oblique view of the cervical/lumbar implant spacer;

5 **FIGURE 2A** is a lateral orthogonal view of a single cervical/lumbar spacer inserted between two vertebrae;

FIGURE 2B is a sagittal orthogonal view of a single cervical/lumbar spacer inserted between two vertebrae;

FIGURE 3A is a top view of the cervical/lumbar spacer;

10 **FIGURE 3B** is a rear view of the cervical/lumbar spacer;

FIGURE 3C is a side view of the cervical/lumbar spacer;

FIGURE 4 is an oblique view of one embodiment of the cervical/lumbar implant spacer; and

15 **FIGURE 5** is an oblique view of a second embodiment of the cervical/lumbar implant spacer.

IDENTIFICATION OF ITEMS IN THE FIGURES

FIGURE 1

20 **1a** -- upper portion

1b -- lower portion

2 -- dynamic cervical/lumbar spacer

3 -- vertical slot

4 -- body of spacer

25 **5a,5b,5c,5d** -- elongated barb support posts (**see 8**)

6 -- wedge shaped forward end of spacer

7a,7b,7c,7d -- tail pieces of spacer

8 -- bone gripping latching portion of spacer (**see 5x**)

9 -- forward portion of the spacer

30 **10** -- sharp forward cutting edge of bone gripping latch portion

11 -- medially inwardly angled facet

12 -- rounded top side

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- 14 -- elongated bone engaging barb
- 16 -- horizontal slot between tail pieces
- 18 -- stress relieving region

5 **FIGURE 2A**

- 2 -- dynamic cervical/lumbar spacer
- 7a,7c -- tail pieces of spacer
- 8 -- bone gripping latching portion of spacer
- 9 -- forward portion of the spacer
- 10 11 -- medially inwardly angled facet
- 14 -- elongated bone engaging barb
- 16 -- horizontal slot between tail pieces
- 17 -- intervertebral space
- 18 -- stress relieving region
- 15 20a -- anterior side of vertebral body
- 20b -- anterior side of vertebral body
- 22 -- motion indicating two headed arrow (vertebral)
- 24a,24b -- motion-indicating little arrows (spacer)
- 28 -- flexural fulcrum region

20

FIGURE 2B

- 2 -- dynamic cervical/lumbar spacer
- 7a,7b,7c,7d -- tail pieces of spacer
- 8 -- bone gripping latching portion of spacer
- 25 14 -- elongated bone engaging barb
- 15 -- stress relieving lateral flexure region
- 20a -- anterior side of vertebral body
- 20b -- anterior side of vertebral body
- 28 -- flexural fulcrum region
- 30 30,32 -- motion indicating arrows (vertebral)
- 34 -- motion indicating two headed arrow (vertebral)
- 35a,35b -- motion-indicating little arrows (spacer)

36a,36b -- motion-indicating little arrows (spacer)

FIGURE 3A

2 -- dynamic cervical/lumbar spacer

5 **4** -- body of spacer

5a, 5b, 5c, 5d -- elongated barb support posts

6 -- wedge shaped forward end of spacer

7b,7d -- tail pieces of spacer

8 -- bone gripping latching portion of spacer

10 **9** -- forward portion of the spacer

10 -- sharp forward cutting edge of bone gripping latch portion

11 -- medially inwardly angled facet

12 -- rounded top side

14 -- elongated bone engaging barb

15 **16** -- slot between tail pieces

18 -- stress relieving region

FIGURE 3B

2 -- dynamic cervical/lumbar spacer

20 **5a, 5b, 5c, 5d** -- elongated barb support posts

7a,7b,7c,7d -- tail pieces of spacer

8 -- bone gripping latching portion of spacer

12 -- rounded top side

14 -- elongated bone engaging barb

25 **15** -- stress relieving lateral flexure region

16 -- horizontal slot between tail pieces

FIGURE 3C

2 -- dynamic cervical/lumbar spacer

30 **6** -- wedge shaped forward end of spacer

7a,7b -- tail pieces of spacer

8 -- bone gripping latching portion of spacer

- 10 -

- 9 -- forward portion of the spacer
- 10 -- sharp forward cutting edge of bone gripping latch portion
- 11 -- medially inwardly angled facet
- 14 -- elongated bone engaging barb
- 5 15 -- stress relieving lateral flexure region

FIGURE 4

- 40 -- first embodiment of the dynamic lumbar/cervical spacer
- 42 -- wedge shaped front portion
- 10 44a,44b,44c,44d -- spaced apart elongated tail pieces
- 46 -- strain relieving circular region
- 47 -- slot separating upper and lower tail piece pairs.
- 48a,48b -- upper and lower portions of spacer 40
- 50 -- juncture slot separating the tail pieces
- 15 52a,52b,52c,52d -- elongated support posts
- 54a,54b,54c,54d -- elongated barbs
- 56 -- facets
- 58 -- sharp forward cutting edge

FIGURE 5

- 60 -- second embodiment of the dynamic lumbar/cervical spacer
- 62 -- wedge shaped front portion
- 64a,64b,64c,64d -- spaced apart elongated tail pieces
- 66 -- strain relieving circular region
- 25 67 -- slot separating upper and lower tail piece pairs.
- 68a,68b -- upper and lower portions of spacer 60
- 70 -- juncture slot separating the tail pieces
- 72a,72b,72c,72d -- elongated support posts
- 74a,74b,74c,74d -- elongated bullets
- 30 76 -- facets
- 78 -- sharp forward cutting edge

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention, known as the dynamic lumbar/cervical spacer, is an intervertebral implant device designed to perform one or a combination of three basic functions: (1) vertebral spacer; (2) spacer to be used in conjunction with vertebral fusion; and (3) artificial disc.

The said dynamic spacer is of single piece construction. It is self guiding upon initial insertion into the intervertebral space, and it is self locking upon installation between adjacent vertebral bodies. It is dynamic in the sense that it is designed to be flexible within both the sagittal and lateral planes; that is, subsequent to installation, the patient will be able to move in such a way that the vertebrae between which the spacer has been installed will be able to have some or all of the motions allowed by a natural and healthy intervertebral disc.

The dynamic spacer is provided with a pair of spaced apart cutting edges on the spacer's upper face and a similar pair of cutting edges on the spacer's lower face. The respective pairs of spaced apart cutting edges enable the spacer to cut into the adjacent vertebral bodies upon being driven into the intervertebral disc space. Each of the said cutting edges is furthermore provided with either "barbs" or "bullets" that inhibit subsequent movement or pullout of the spacer away from the vertebrae into which it has been driven. In addition, each pair of cutting edges is geometrically arranged upon an elongated post so as to provide a grasping force, through induced strain within the elongated posts so as to hold the spacer within intimate contact with each respective vertebra to which it is attached.

The dynamic vertebral spacer of the present invention is designed to be installable by being impacted or otherwise driven or forced into place with a driver device. The said spacer is also designed to be manufactured in a multiplicity of sizes and a multiplicity of proportions of length, width and height so as to accommodate a variety of intervertebral spacings and vertebral body sizes according to the needs of the patient.

The dynamic spacer is designed to also promote bone growth and intervertebral fusion. The vertical slot between the upper and lower sets of the two horizontally spaced-apart tail pieces can be configured so that it can be loaded with graft to create a fusion column and promote fusion. The horizontal slot between the upper and lower sets of tail pieces can be varied in height, and the radius of the inner void in the

portion of the implant connecting the upper portions of the spacer to the lower portions of the spacer can also be varied, so as to provide enough flexing to produce loading on the graft sufficient to promote bone growth and vertebral fusion while also providing compressive strength sufficient to maintain the required separation of the adjacent vertebrae.

Referring now to **FIGURE 1**, there is shown in oblique view one embodiment of a single dynamic cervical/lumbar spacer **2** according to the present invention. The spacer **2** consists of a single piece body **4** having a wedge shaped front end **6** and four elongated tail pieces **7a**, **7b**, **7c** and **7d** flexibly attached to one another by way of the wedge shaped front end **6** located in the forward portion **9** of the spacer. Each of the elongated tail pieces **7a**, **7b**, **7c** and **7d** has contiguous with it a bone gripping latching portion **8** consisting of an elongated post **5a**, **5b**, **5c**, **5d** upon each of which is disposed a sharp forward cutting edge **10** having a medially inwardly angled facet **11**, a rounded top side **12** and an elongated bone engaging barb **14**.

FIGURES 2A and **2B** are orthogonal views of a single dynamic spacer according to the present invention inserted between the anterior portions of two vertebral bodies **20a**, **20b**. The bone grabbing latching portions **8** of the spacer **2** are shown embedded within the adjacent vertebral bodies **20a**, **20b**. The dynamic features of the dynamic spacer **2** will become evident upon examination of the following additional **FIGURES**.

FIGURES 3A, **3B** and **3C** show three orthogonal views of the dynamic spacer **2** shown in **FIGURE 1**. **FIGURE 3A** is a side view of the spacer **2** showing the single piece body **4** with the wedge shaped front end **6** and two of the four spaced apart and elongated tail pieces **7b**, **7d** separated from one another by the slot **16** and flexibly attached to one another by way of the wedge shaped front end **6**. The slot **16** terminates in the stress relieving circular portion **18** near the front region **6** of the spacer. The bone gripping latching portions **8** are shown in **FIGURE 3A** being contiguous with the sharp forward cutting edge **10** and the medially inwardly angled facet **11** and the elongated bone engaging barb **14**. More specifically, each bone latching portion **8** consists of an elongated support post **5a**, **5b**, **5c** or **5d** upon which is disposed the elongated bone engaging barb **14** having a forward cutting edge **10** with an angled facet **11**.

Contemplation of the **FIGURES 3A**, **3B** and **3C** will reveal to those skilled

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in the mechanical arts the dynamic aspect of the present vertebral spacer invention. In particular, in **FIGURE 3B**, the respective elongated tail pieces **7a,7b,7c,7d** are able to move flexurally in relation to one another. For example, and referring to **FIGURES 2A, 2B** the spacer **2** is shown after having been inserted into the intervertebral space **17**, by being forced in or driven in by impact. During the insertion process, the four medially inwardly directed facets **11** of the bone gripping portions **8** engage the cortex bone the vertebral bodies **20a, 20b** in such as way as to force medially inwards, towards one another, the respective pairs of spaced apart elongated posts **5a, 5b** and **5c, 5d** such that induced strain in the elongated posts, as well as in the region **15** between the respective pairs of elongated tail pieces **7a,7c** and **7b,7d**, forces the elongated barbs **14** into intimate gripping contact with the vertebral bone.

During installation, flexure of the region **15** necessarily forces together the respective pairs of tail pieces **7a,7c** and **7b,7d**, but primarily induces gripping strain in the respective pairs of elongated posts **5a, 5c** and **5b, 5d**. As a result, the induced strain produces a laterally outwardly directed force that causes the elongated bone engaging barbs **14** to maintain in intimate contact with the vertebral bone. The inventor recognizes that the vertical portions of the bone gripping latching portions **8** also undergo a small degree of flexure and thereby also have an induced strain that serves to secure the spacer **2** in intimate contact with the vertebral bodies **20a, 20b**.

The dynamic aspects of the dynamic lumbar/cervical spacer are yet further evident within the context of **FIGURES 2A** and **2B**, which show the spacer **2** implanted between the two vertebrae **20a, 20b**. **FIGURE 2A** shows the spacer **2** located more or less within the sagittal plane, with said the spacer being close to the anterior side of the vertebral bodies. Note the two-headed curved arrow **22**, indicating relative motion of the two vertebral bodies, such motion being of the sort arising between vertebrae when the patient moves in such a way as corresponds to an arching of the back, i.e., bending backwards. Such increasing separation of the anterior sides of the respective vertebral bodies **20a, 20b** can be accommodated by the dynamic spacer **2** in that the elongated tail pieces **7a,7c** (and **7b,7d**, not shown) can flex apart from one another about the fulcrum **28** within the circular stress-relieving region **18** located in the forward portion **9** of the spacer. The flexure of the tail pieces **7a,7c** is indicated by the small arrows **24,26**. It is important to note that during spinal flexure of the sort causing increasing separation of the vertebral

bodies **20a**, **20b** that the bone gripping latching portions **8** remain tightly in contact with the respective vertebral bodies, according to the design function of the elongated bone engaging barbs **14**.

Correspondingly, when the patient's spine is flexed in the opposite
5 direction, as during a forward bending motion, the space between the anterior sides of the vertebral bodies **20a**, **20b** shown in **FIGURE 2A** decreases. Under such conditions, the two-headed arrow **22** would be reversed so as to indicate a coming together of the vertebral bodies. Likewise, the tail pieces, **7a**, **7c** would also be forced into closer proximity about the fulcrum **28**, and the orientation of the small motion indicating arrows
10 **24a**, **24b** would be reversed from that shown in **FIGURE 2A**. In **FIGURE 2B**, the fulcrum **28** can be seen to be a line (dotted) along the forwardmost side of the stress relieving region **18**. (NOTE: In more specific point of fact, the line denoted by the callout number **28** in **FIGURE 2B** designates a zone of tension or compression as the whole forward region **9** of the spacer flexes in respective response to the increasing or decreasing
15 separation of the upper tail pieces **7a**, **7b** from the lower tail pieces **7c**, **7d**.)

Further details of the dynamic properties of the vertebral spacer **2** according to the present invention are illustrated in **FIGURE 2B**, which is a view of the implanted spacer from the anterior side of the spine, i.e., looking toward it from the front of the patient's body. The pair of curved arrows **30**, **32** and the single two-headed arrow **34**
20 illustrate the relative motion of the two vertebral bodies **20a**, **20b** if the patient were to bend laterally (specifically toward the patient's left side). As viewed in **FIGURE 2B**, the right side of the vertebral bodies **20a**, **20b** become closer while the left side of the bodies move farther apart. The spacer **2** is able to accommodate such motion because the tail pieces **7b**, **7d** on the right side of the FIGURE can flex into closer proximity, due to
25 compression, while the tail pieces **7a**, **7c** on the left side move farther apart, due to tension. In both instances, compression or tension, the relative motions of the respective pairs of tail pieces **7a**, **7c** and **7b**, **7d** is associated with flexure about the fulcrum region **28** located within the stress relieving region **18** of the forward region **9** of the spacer.

Embodiment #1

FIGURE 4 shows in oblique view a first embodiment of the dynamic lumbar/cervical spacer **40** according to the present invention. The spacer **40** is of single-

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piece construction. It consists of a wedge shaped front portion **42** and an upper set of two spaced apart elongated tail pieces **44a, 44b** and a lower set of two spaced apart elongated tail pieces **44c, 44d**. Each of the upper pair of spaced apart tail pieces **44a, 44b** are independently flexibly linked to each of the corresponding spaced apart lower tail pieces **44c, 44d** respectively. The flexible link between the respective spaced apart upper tail pieces **44a, 44b** and the corresponding lower tail pieces **44c, 44d** is the front portion **42** containing a stress relieving circular region **46** at the forward end portion of the slot **47** separating the respective upper and lower pairs of tail pieces. The upper portion **48a** and lower portion **48b** of the spacer **40** are symmetrical with one another about the horizontal plane defined by the plane of the slot **47**. Each of the two elongated upper tail pieces **44a, 44b** is able to move in the vertical direction, independently of the other, in relation to each of the corresponding two lower tail pieces **44c, 44d**, thereby affording movement between the vertebrae (**20a, 20b** in **FIGURES 2A, 2B**) in both the lateral and the sagittal planes.

On the top of the upper portion **44a**, disposed in a bilaterally symmetric way about the vertical plane defined by the juncture slot **50** separating the left tail pieces **44a, 44c** from the right tail pieces **44b, 44d**, are two elongated posts **52a, 52c**. Each of the two elongated posts **52a, 52c** is topped by an elongated barb **54a, 54c**. Corresponding elongated barbs **54b, 54d** are disposed on the lower portion **44b** of the spacer **40**. Facets **56** are disposed at the forward end of each elongated post and barb set, providing a sharp forward cutting edge **58** at the forward end of each of the four post and barb sets. Each of the four facets **56** (only two are shown in the FIGURE) is angled in such a way that when the spacer **40** is forced between the vertebral bodies (**20a, 20b** in **FIGURES 2A, 2B**), the upper set of elongated posts **52a, 52b** and the lower sets of elongated posts **52c, 52d** are forced medially toward one another in such a way that strain is induced in the respective elongated posts so as to facilitate the ability of the elongated barbs **54a, 54b, 54c, 54d** to remain in continuing firm contact with the vertebral bone (not shown in **FIGURE 4**). As should be apparent to those skilled in the art, a portion of medially directed strain in each set of the elongated posts **52a, 52b** and **52c, 52d** is born by the respective tail pieces **44a** through **44d**.

Embodiment #2

FIGURE 5 shows in oblique view a second embodiment of the dynamic

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lumbar/cervical spacer **60** according to the present invention. The spacer **60** is of single-piece construction. It consists of a wedge shaped front portion **62** and an upper set of two spaced apart elongated tail pieces **64a, 64b** and a lower set of two spaced apart elongated tail pieces **64c, 64d**. Each of the upper pair of spaced apart tail pieces **64a, 64b** are independently flexibly linked to each of the corresponding spaced apart lower tail pieces **64c, 64d** respectively. The flexible link between the respective spaced apart upper tail pieces **64a, 64b** and the corresponding lower tail pieces **64c, 64d** is the front portion **62** containing a stress relieving circular region **66** at the forward end portion of the slot **67** separating the respective upper and lower pairs of tail pieces. The upper portion **68a** and lower portion **68b** of the spacer **60** are symmetrical with one another about the horizontal plane defined by the plane of the slot **67**. Each of the two elongated upper tail pieces **64a, 64b** is able to move in the vertical direction, independently of the other, in relation to each of the corresponding two lower tail pieces **64c, 64d**, thereby affording movement between the vertebrae (**20a, 20b** in **FIGURES 2A, 2B**) in both the lateral and the sagittal planes.

On the top of the upper portion **68a**, disposed in a bilaterally symmetric way about the vertical plane defined by the juncture slot **70** separating the left tail pieces **64a, 64c** from the right tail pieces **64b, 64d**, are two elongated posts **72a, 72c**. Each of the two elongated posts **72a, 72c** is topped by an elongated bullet **74a, 74c**. Corresponding elongated bullets **74b, 74d** are disposed on the lower portion **68b** of the spacer **60**. Facets **76** are disposed at the forward end of each elongated post and bullet set, providing a sharp forward cutting edge **78** at the forward end of each of the four post and bullet sets. Each of the four facets **76** (only two are shown in the FIGURE) is angled in such a way that when the spacer **60** is forced between the vertebral bodies (**20a, 20b** in **FIGURES 2A, 2B**), the upper set of elongated posts **72a, 72b** and the lower sets of elongated posts **72c, 72d** are forced medially toward one another in such a way that strain is induced in the respective elongated posts so as to facilitate the ability of the elongated bullets **74a, 74b, 74c, 74d** to remain in continuing firm contact with the vertebral bone (not shown in **FIGURE 5**). As should be apparent to those skilled in the art, a portion of medially directed strain in each set of the elongated posts **72a, 72b** and **72c, 72d** is born by the respective tail pieces **64a** through **64d**.

It will now be apparent to those skilled in the art that other embodiments, improvements, details and uses can be made consistent with the letter and spirit of the

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foregoing disclosure and within the scope of this patent, which is limited only by the following claims, construed in accordance with the patent law, including the doctrine of equivalents.

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CLAIMS

I claim:

1. An implantable dynamic intervertebral spacer configured to be flexible in both the sagittal and lateral planes.
2. The spacer of Claim 1 wherein the spacer is of single piece construction.
3. The spacer of Claim 2 further having a body comprising a plurality of upper tail pieces and a plurality of lower tail pieces.
4. The spacer of Claim 3 in which the plurality of upper tail pieces comprises exactly two elongated tail pieces, the plurality of lower tail pieces comprises exactly two elongated tail pieces.
5. The spacer of Claim 4 in which the tail pieces are of equal length.
6. The spacer of Claim 4 in which the two upper tail pieces are vertically spaced apart from the two lower tail pieces, the two upper tail pieces being also horizontally spaced apart from each other by a specified distance, the lower tail pieces further being horizontally spaced apart from each other by a distance equal to the spacing apart distance of the upper tail pieces.
7. The spacer of Claim 3 in which each of the plural upper tail pieces and each of the plural lower tail pieces additionally comprises a barb support post.
8. The spacer of Claim 7 in which each of the barb support posts additionally comprises attached thereto an elongated bone engaging barb.
9. The spacer of Claim 4 in which each of the exactly two upper elongated tail pieces and each of the exactly two lower elongated tail pieces additionally comprises a barb support post.
10. The spacer of Claim 9 in which each of the barb support posts additionally comprises attached thereto an elongated bone engaging barb.
11. The spacer of Claim 8 in which each of the barb support posts additionally

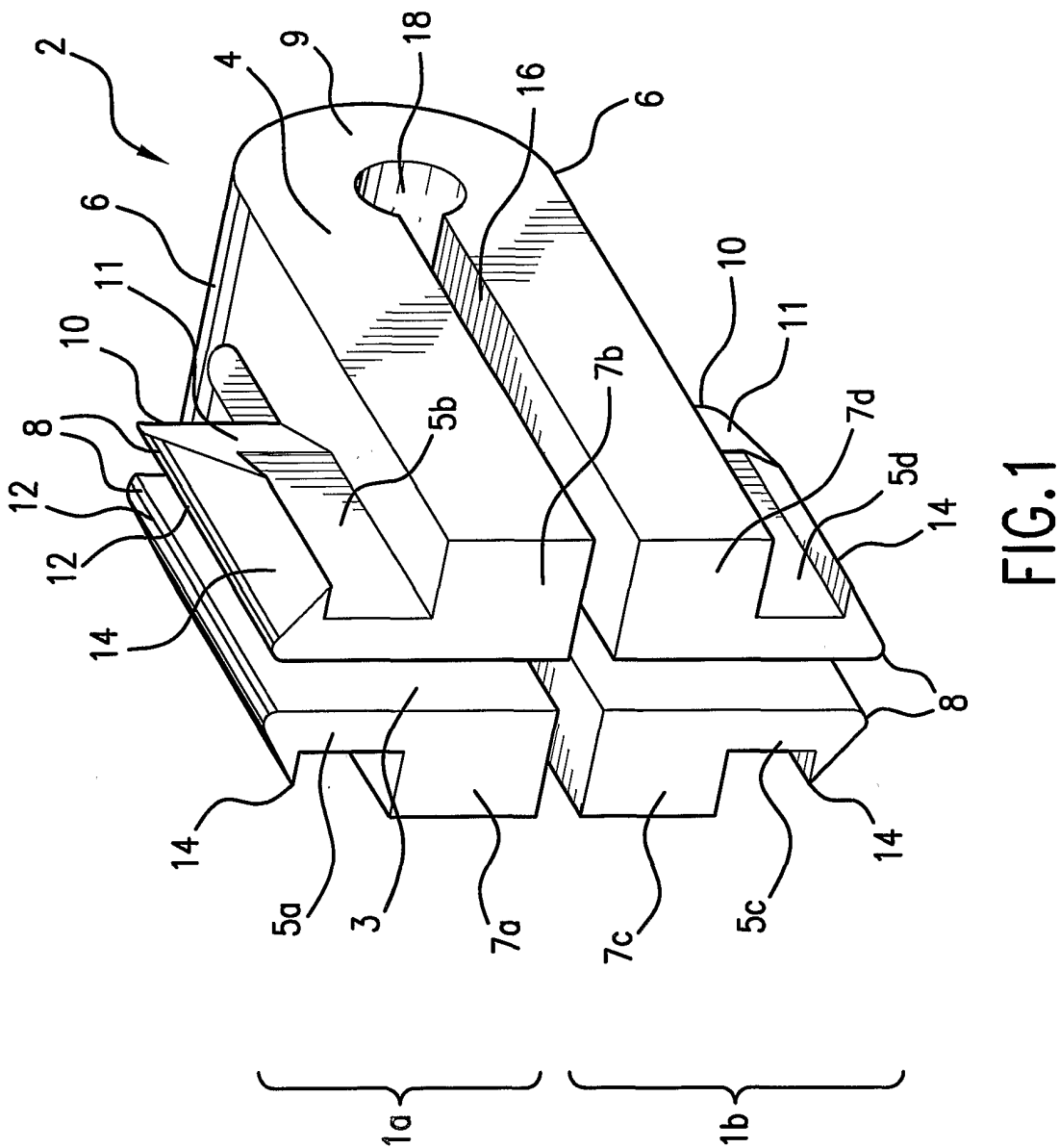
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comprising an elongated bone engaging barb further additionally comprises a medially inwardly angled facet.

12. The spacer of Claim 10 in which each of the barb support posts additionally comprising an elongated bone engaging barb further additionally comprises a medially inwardly angled facet.
13. The spacer of Claim 11 in which each of the barb support posts additionally comprising an elongated bone engaging barb further comprises a bone gripping latching portion.
14. The spacer of Claim 12 in which each of the barb support posts additionally comprising an elongated bone engaging barb further comprises a bone gripping latching portion.
15. The spacer of Claim 7 in which each of the barb support posts additionally comprises attached thereto an elongated bullet configured to engage bone.
16. The spacer of Claim 9 in which each of the barb support posts additionally comprises attached thereto an elongated bullet configured to engage bone.
17. The spacer of Claim 15 in which each of the barb support posts additionally comprising an elongated bullet configured to engage bone further additionally comprises a medially inwardly angled facet.
18. The spacer of Claim 10 in which each of the barb support posts additionally comprising an elongated bullet configured to engage bone further additionally comprises a medially inwardly angled facet.
19. The spacer of Claim 2 in which the spacer is configured to be self guiding during installation.
20. The spacer of Claim 19 in which the self guiding configuration comprises a generally wedge shaped configuration on the distal portion of the spacer.
21. The spacer of Claim 4 in which the portion of the body connecting the upper tail pieces and the lower tail pieces provides independently flexible linkage between each of the upper tail pieces and the corresponding lower tail pieces.

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22. The spacer of Claim 6 in which the two upper tail pieces and the two lower tail pieces are configured to provide a space capable of receiving bone graft and bone growth material.
23. The spacer of Claim 22 in which the two upper tail pieces and the two lower tail pieces are vertically spaced apart by a distance selected to provide sufficient flexibility to the overall configuration to promote new bone growth in bone graft and bone growth material placed in the space capable of receiving such material.
24. The spacer of Claim 3 additionally comprising a connecting portion between the upper tail pieces and the lower tail pieces, said connecting portion being configured with an open inner portion with a radius, said radius being capable of being chosen to produce a desired flexibility of the spacer as a whole.



POSTERIOR SIDE ← ANTERIOR SIDE → PATIENT'S RIGHT SIDE ← PATIENT'S LEFT SIDE →

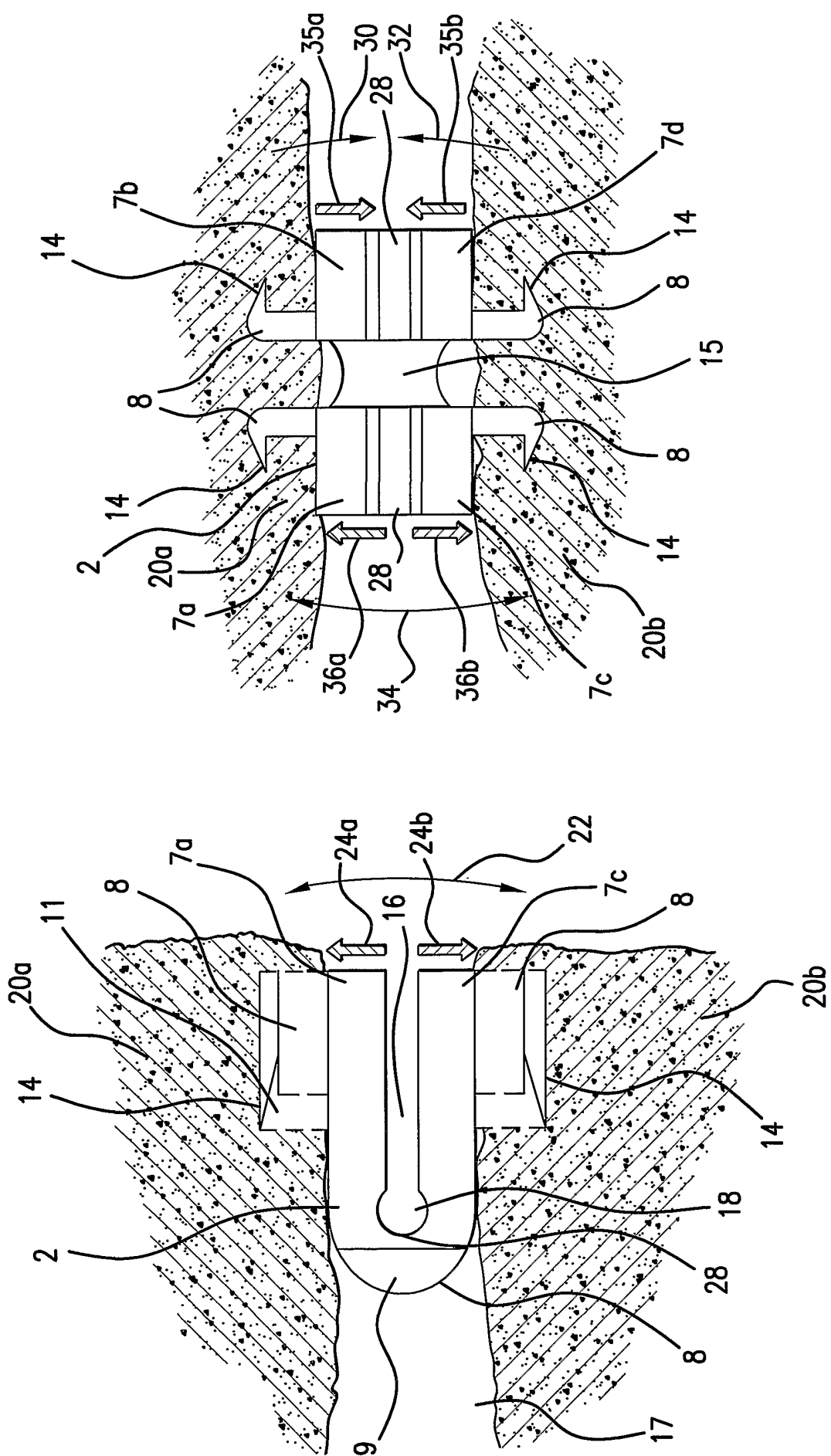


FIG. 2B

FIG. 2A

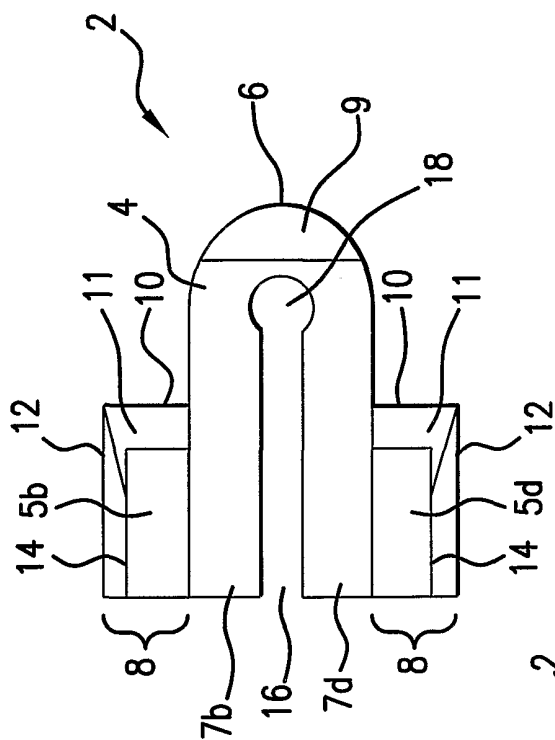


FIG. 3A

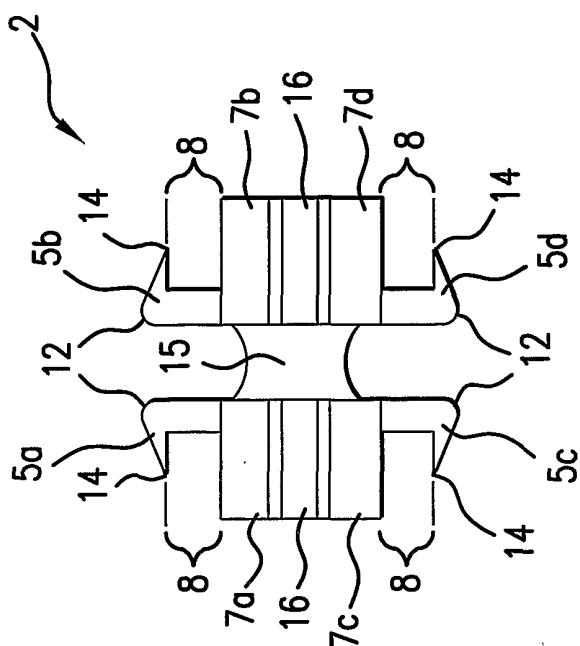


FIG. 3B

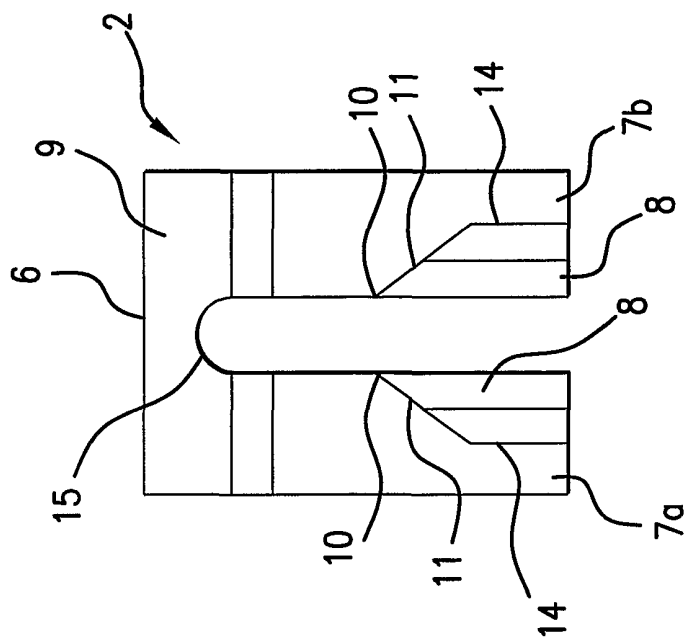


FIG. 3C

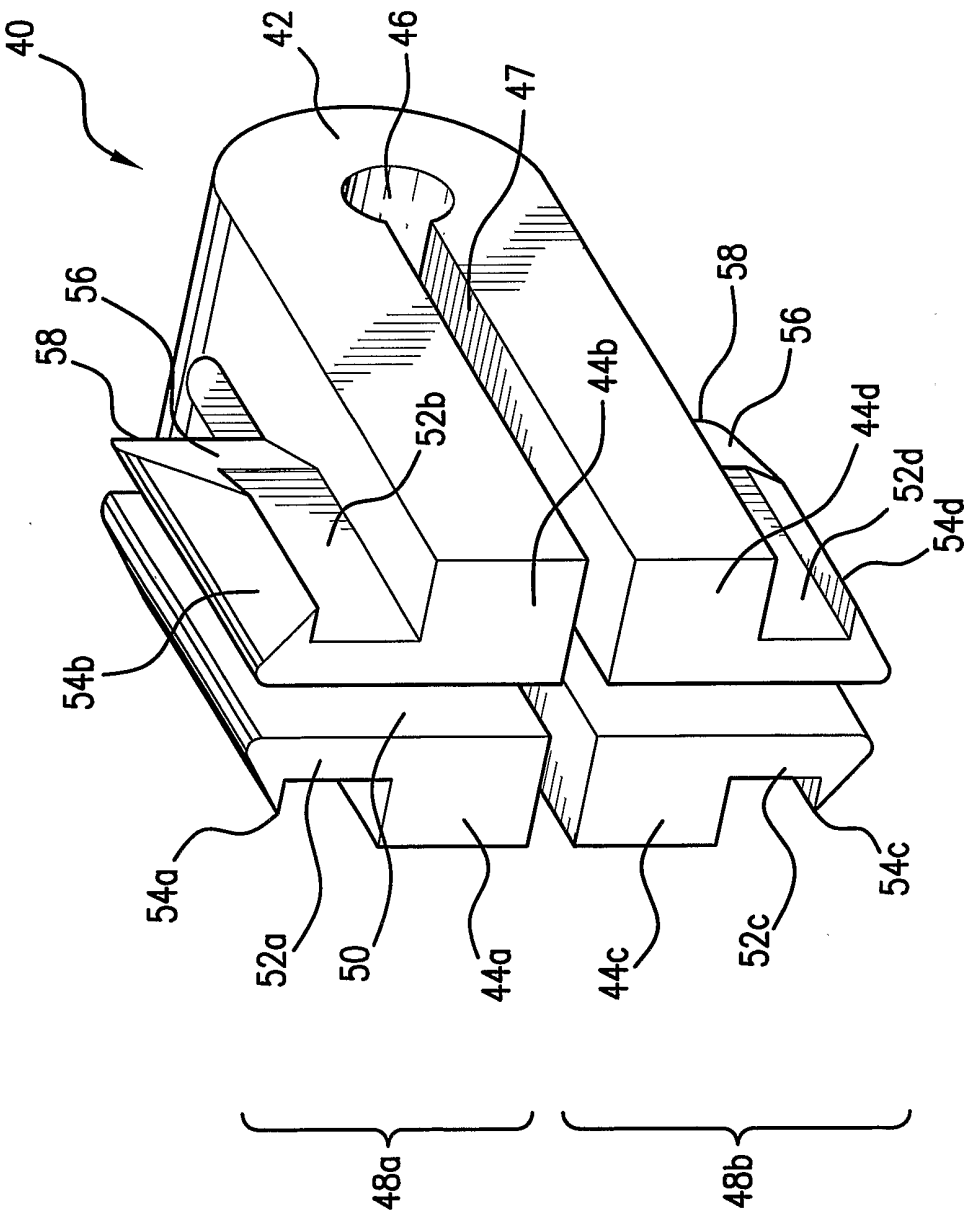


FIG. 4

