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(54) **EXPANDABLE INTERBODY FUSION DEVICE**

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U.S.C. 154(b) by 1553 days.

This patent is subject to a terminal dis-
claimer.

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Related U.S. Application Data

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25, 2004.

(51) **Int. Cl.**
A61F 2/44 (2006.01)

(52) **U.S. Cl.** **623/17.15**; 623/17.16; 606/90

(58) **Field of Classification Search** ... 623/17.11–17.16;
606/53, 60, 245, 90, 99

See application file for complete search history.

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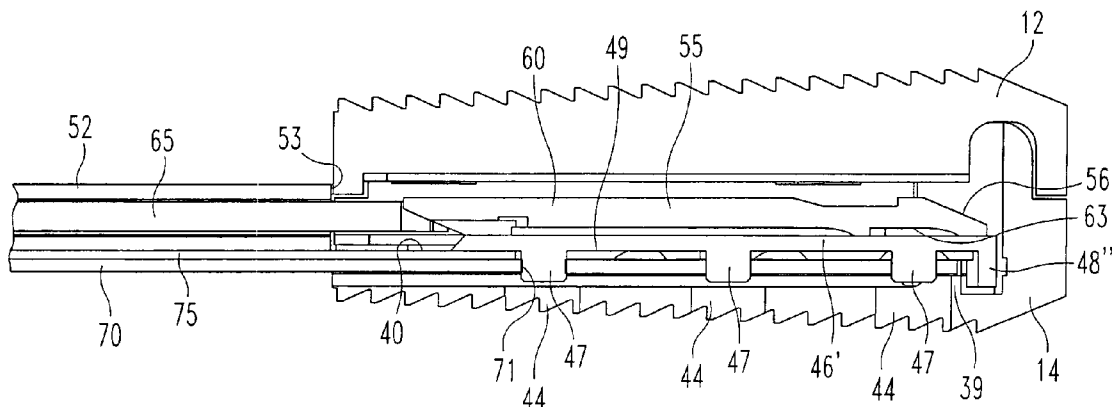
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(57) **ABSTRACT**

An expandable interbody fusion device for implantation into
the intradiscal space between two opposing vertebral bodies
of a spine comprises a superior endplate member having an
upper surface for engaging a superior vertebral body in a
spine, and an inferior endplate member having a lower sur-
face for engaging an inferior vertebral body in the spine. The
superior endplate member and the inferior endplate member
are releasably coupled and define a cavity therebetween. At
least one expansion member is configured to be introduced
into the cavity to move the superior endplate and the inferior
endplate members relatively apart upon introduction and to
thereby decouple the superior endplate member and the infer-
ior endplate member. An inserter may be releasably coupled
to the device to facilitate insertion of the device as well as to
provide a track for insertion of the expansion members.

26 Claims, 31 Drawing Sheets



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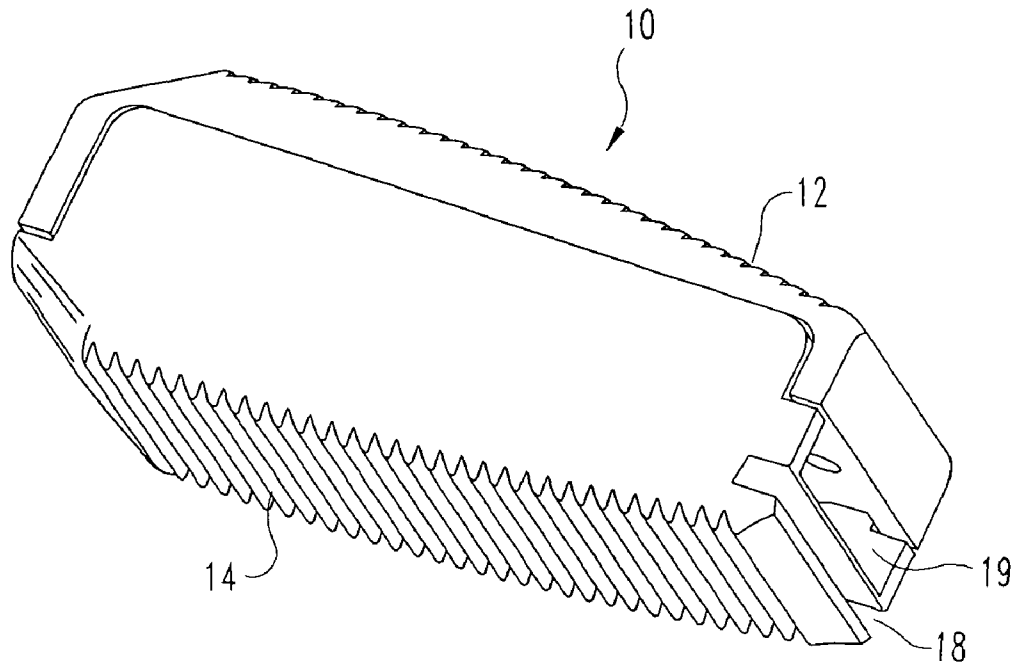


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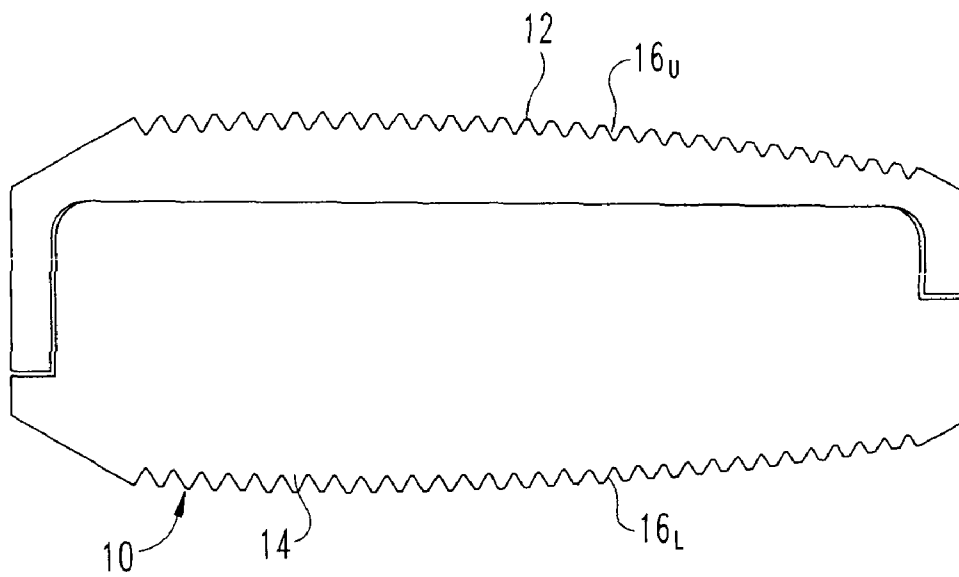


Fig. 2

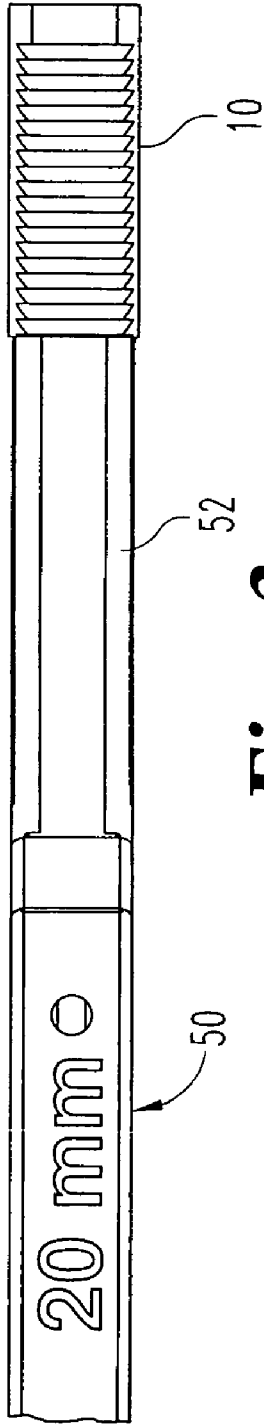


Fig. 3

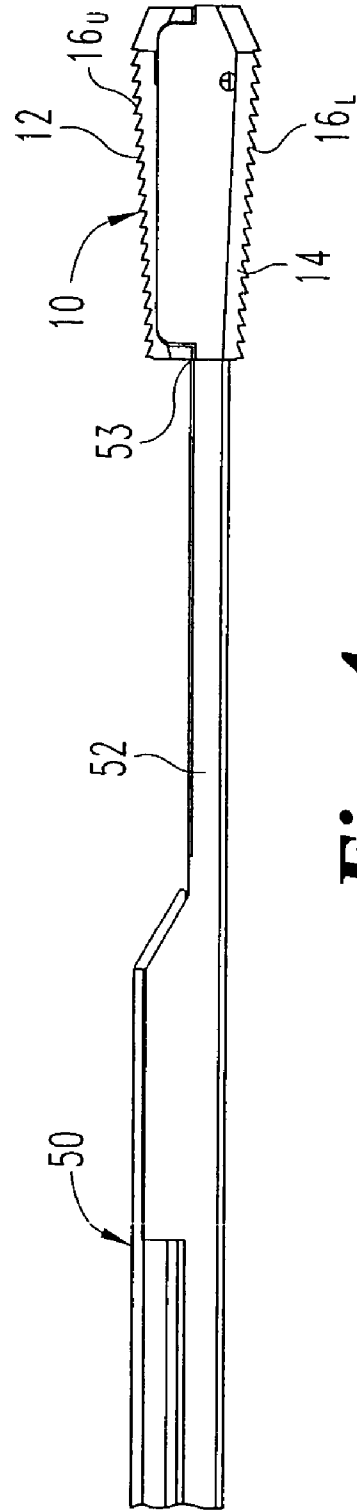


Fig. 4

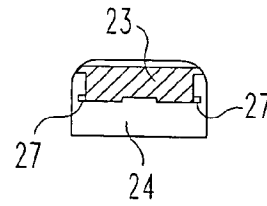


Fig. 5a

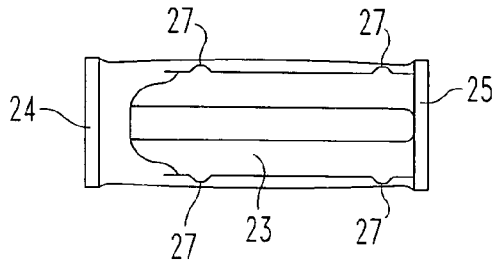


Fig. 5b

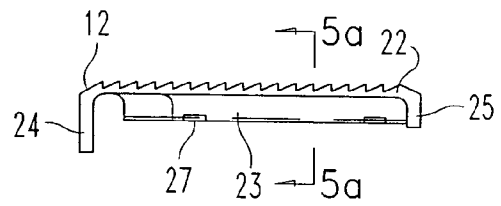


Fig. 5c

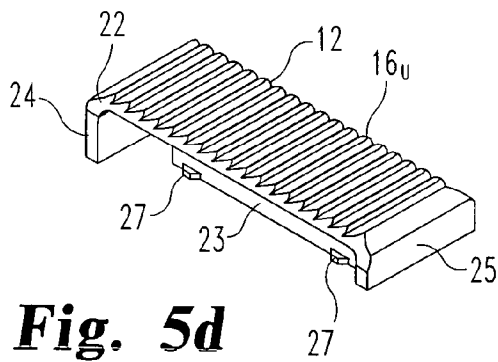


Fig. 5d

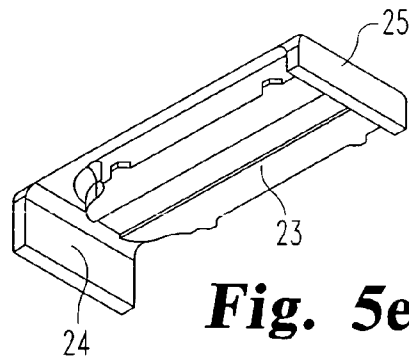


Fig. 5e

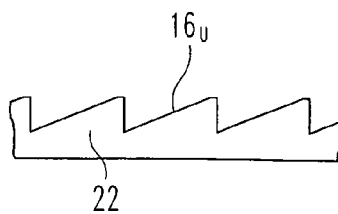


Fig. 5f

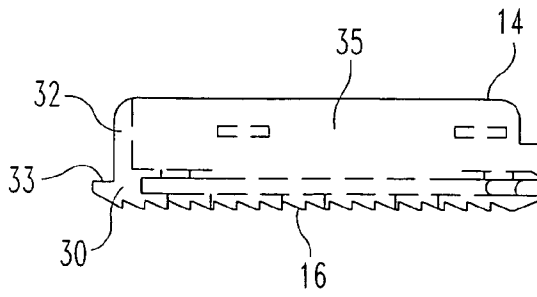


Fig. 6a

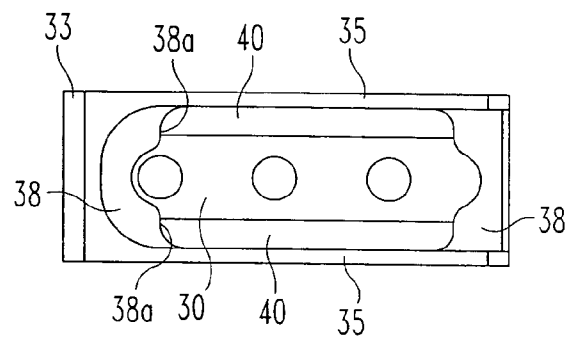


Fig. 6b

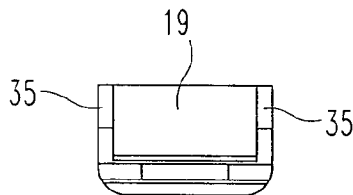


Fig. 6c

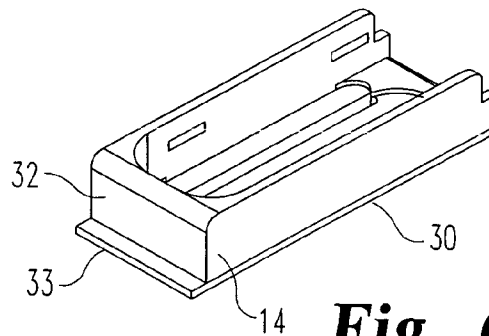


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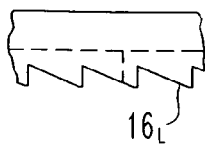


Fig. 6e

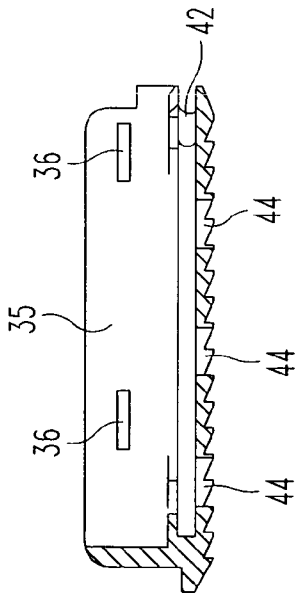


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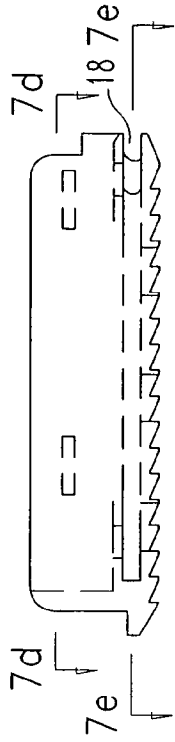


Fig. 7b

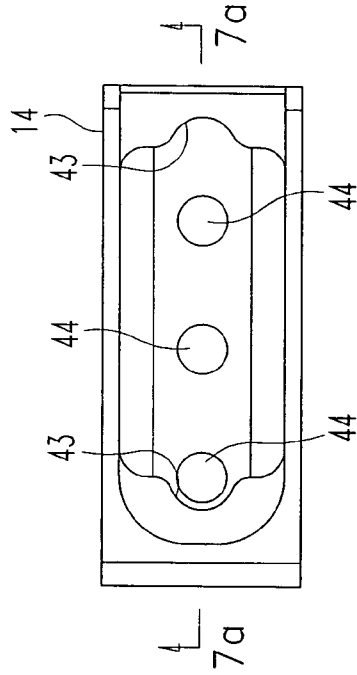


Fig. 7c

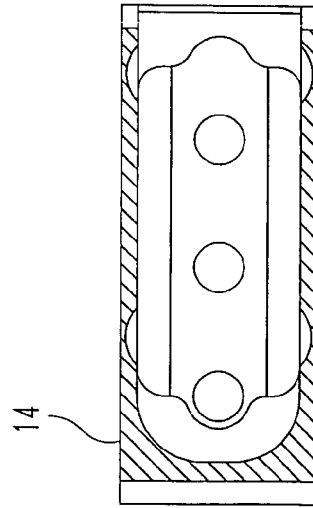


Fig. 7d

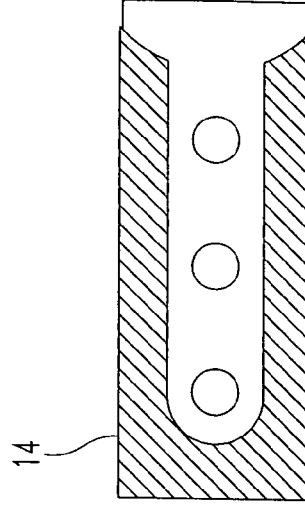


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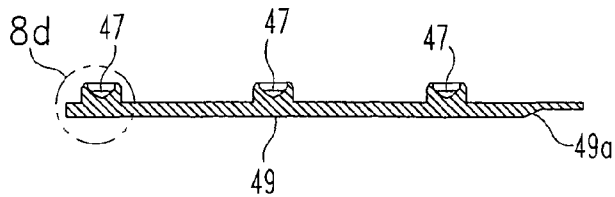


Fig. 8a

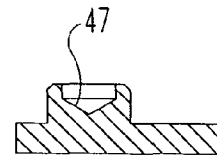


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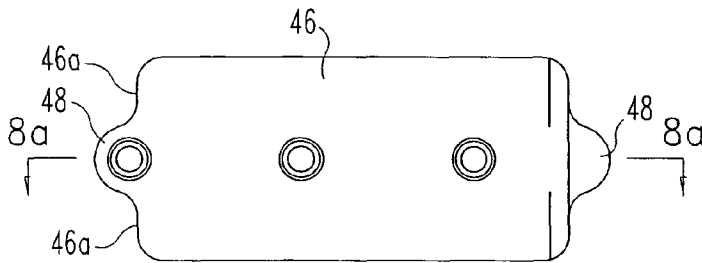


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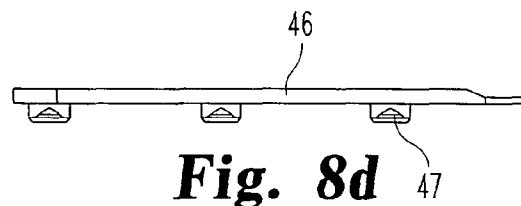


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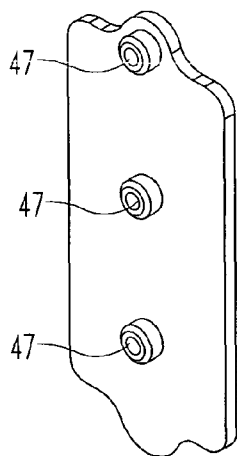


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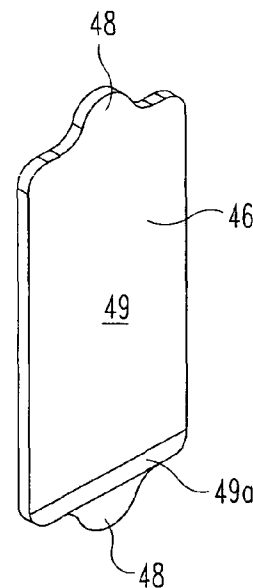


Fig. 8f

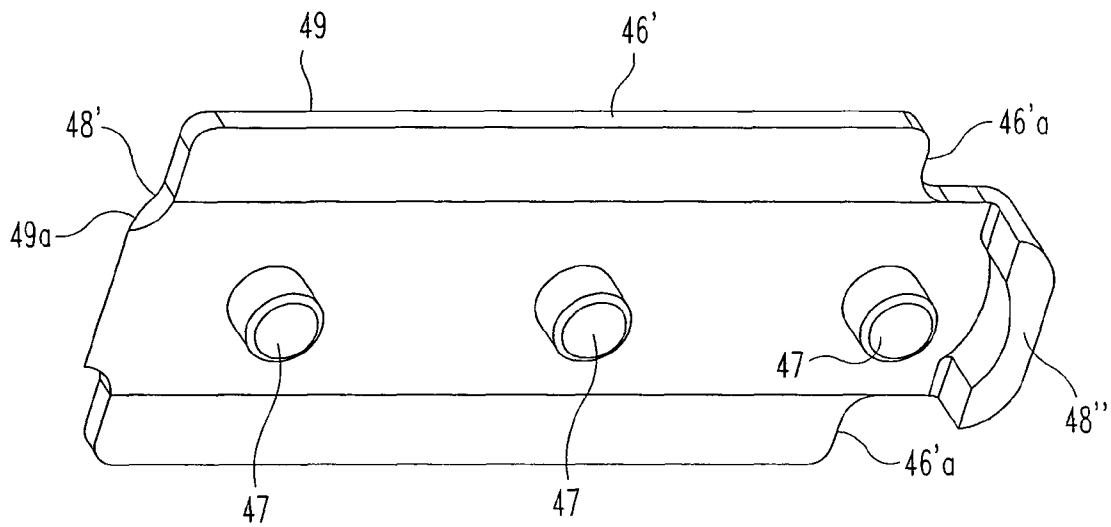


Fig. 8g

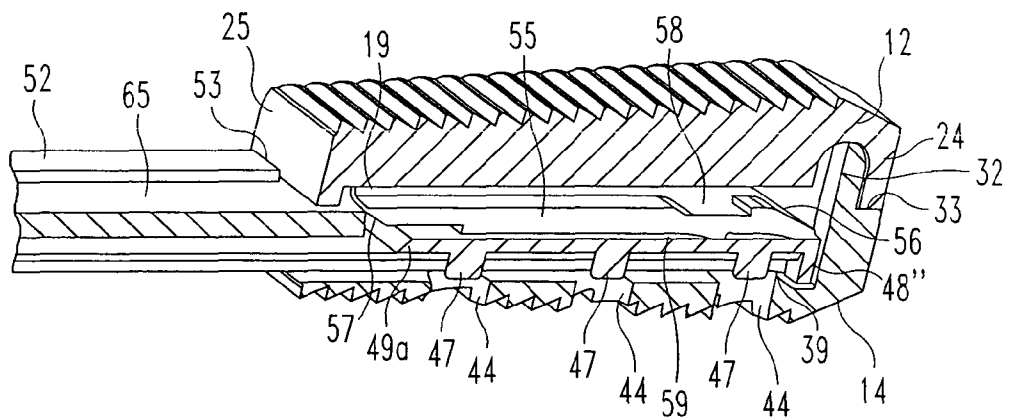


Fig. 9

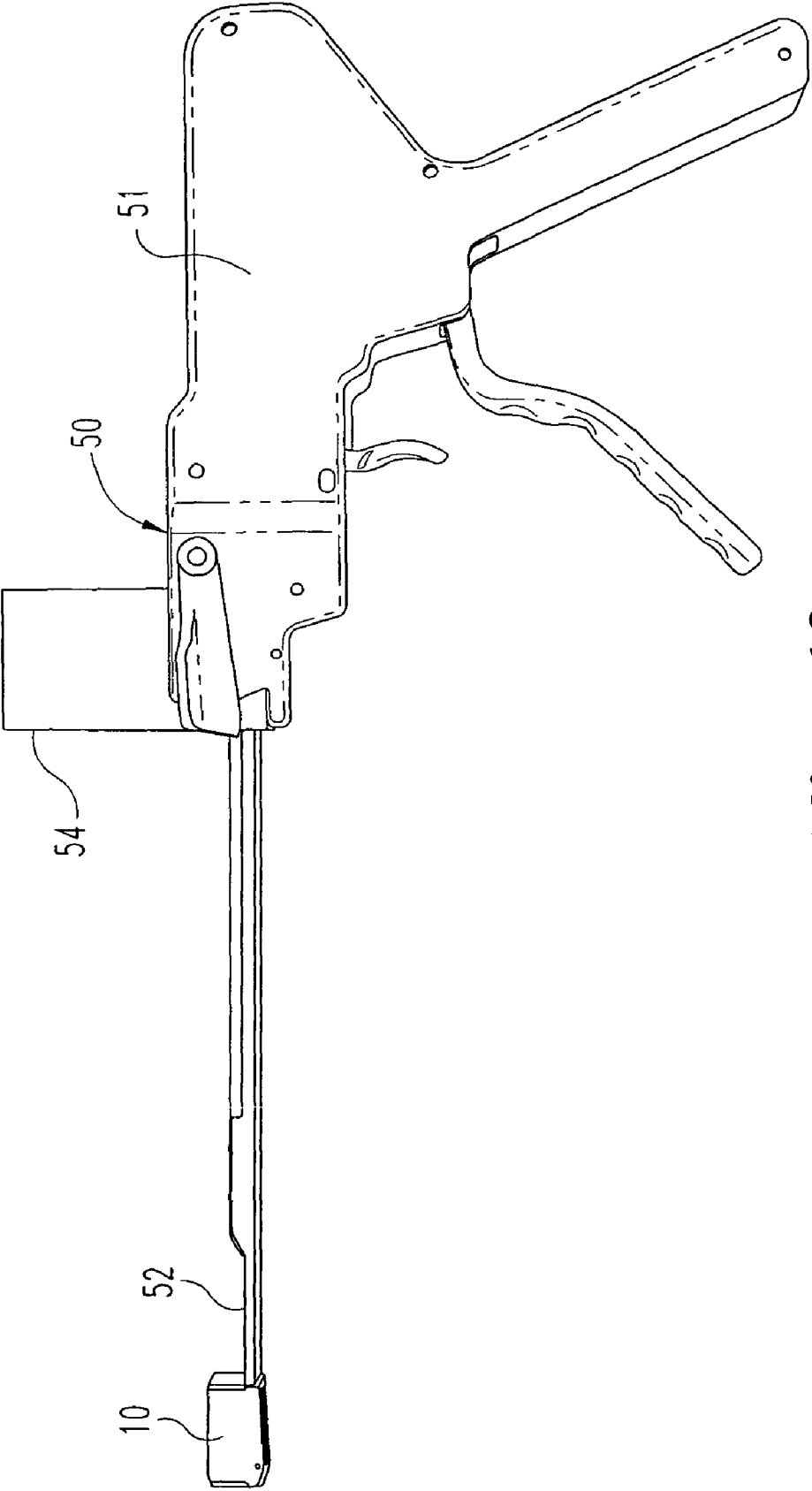


Fig. 10

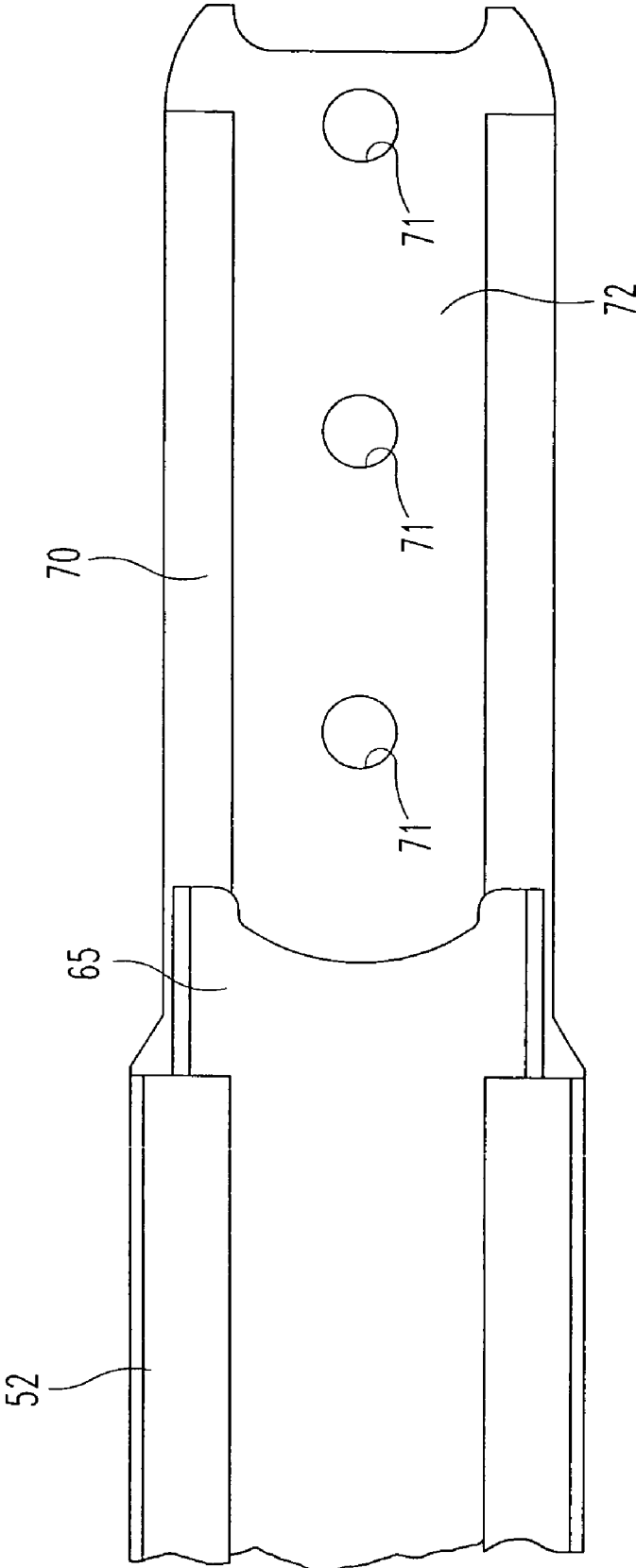


Fig. 13

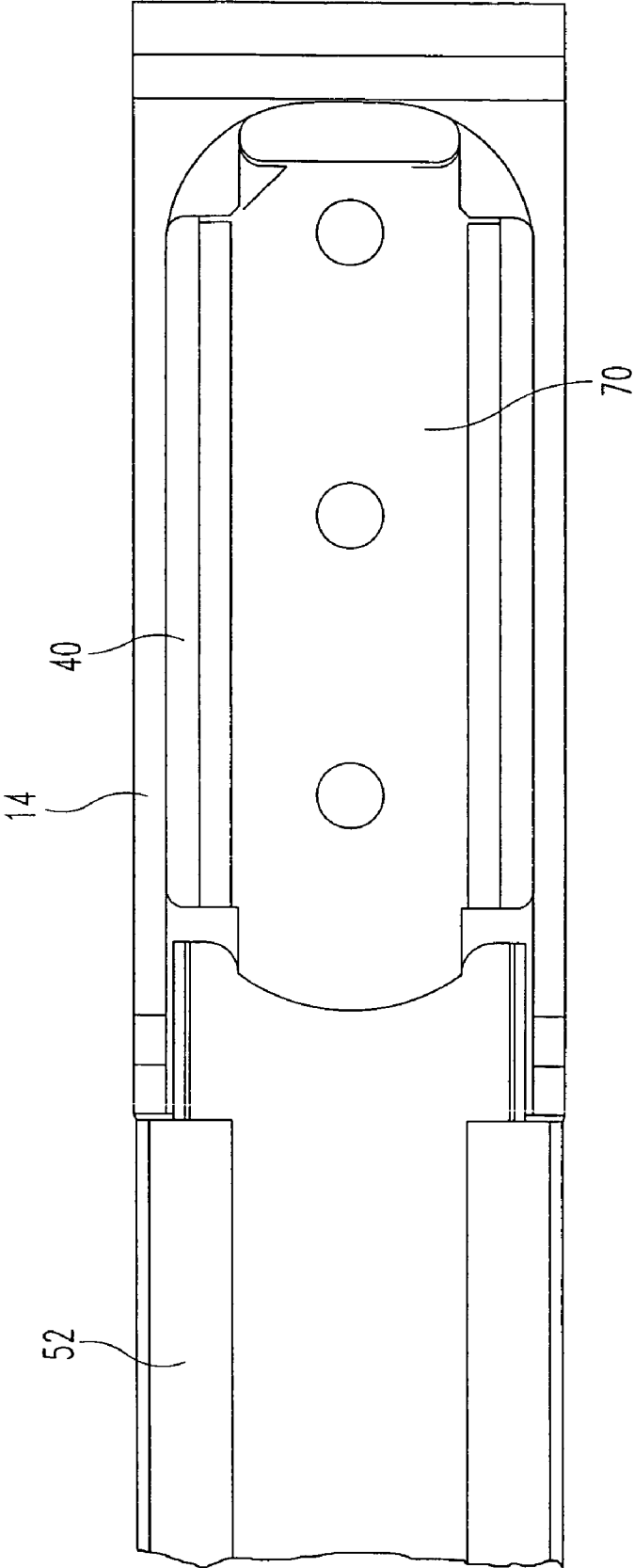


Fig. 14a

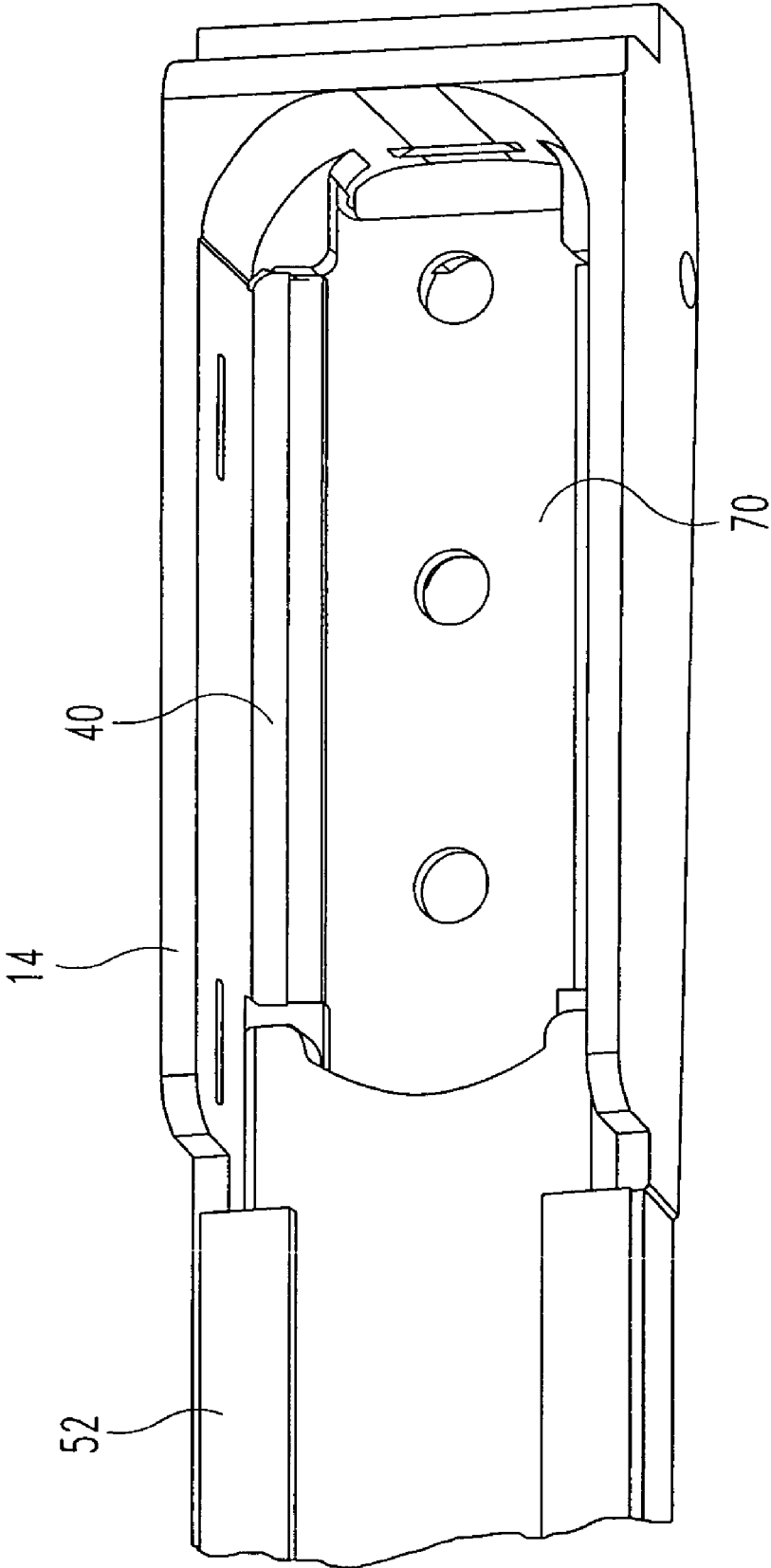


Fig. 14b

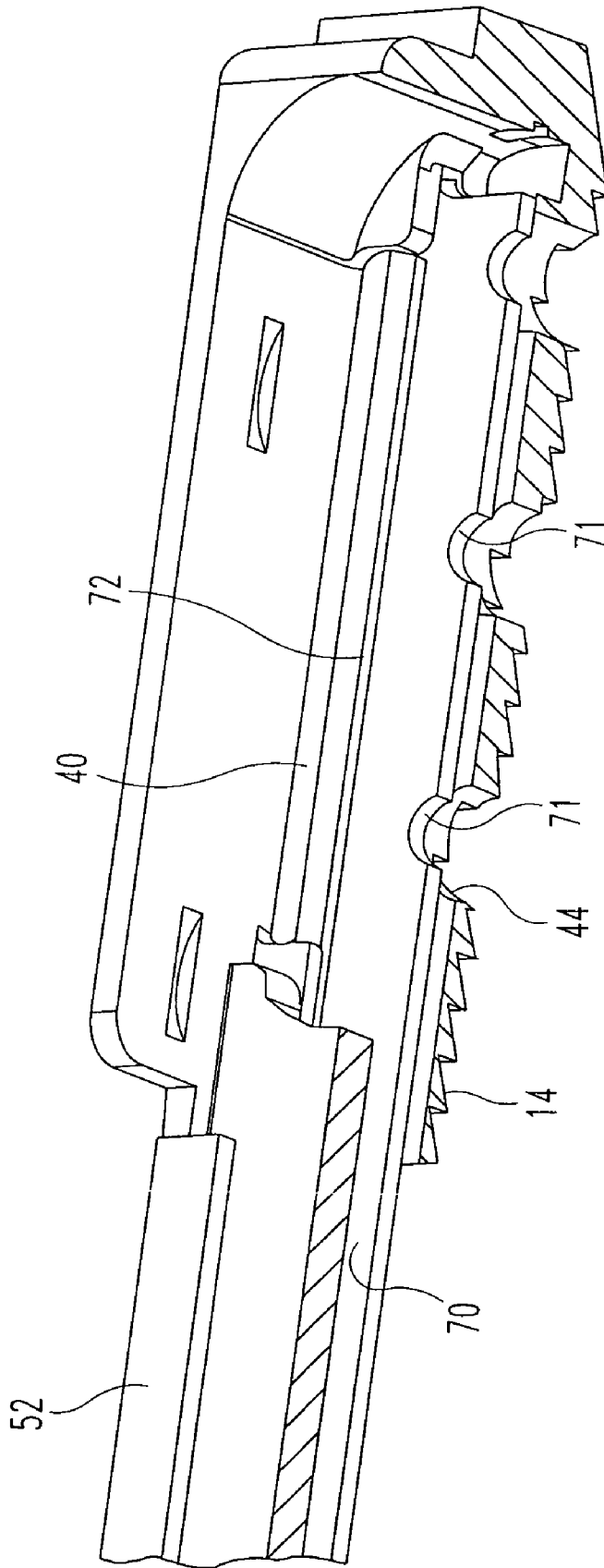


Fig. 14c

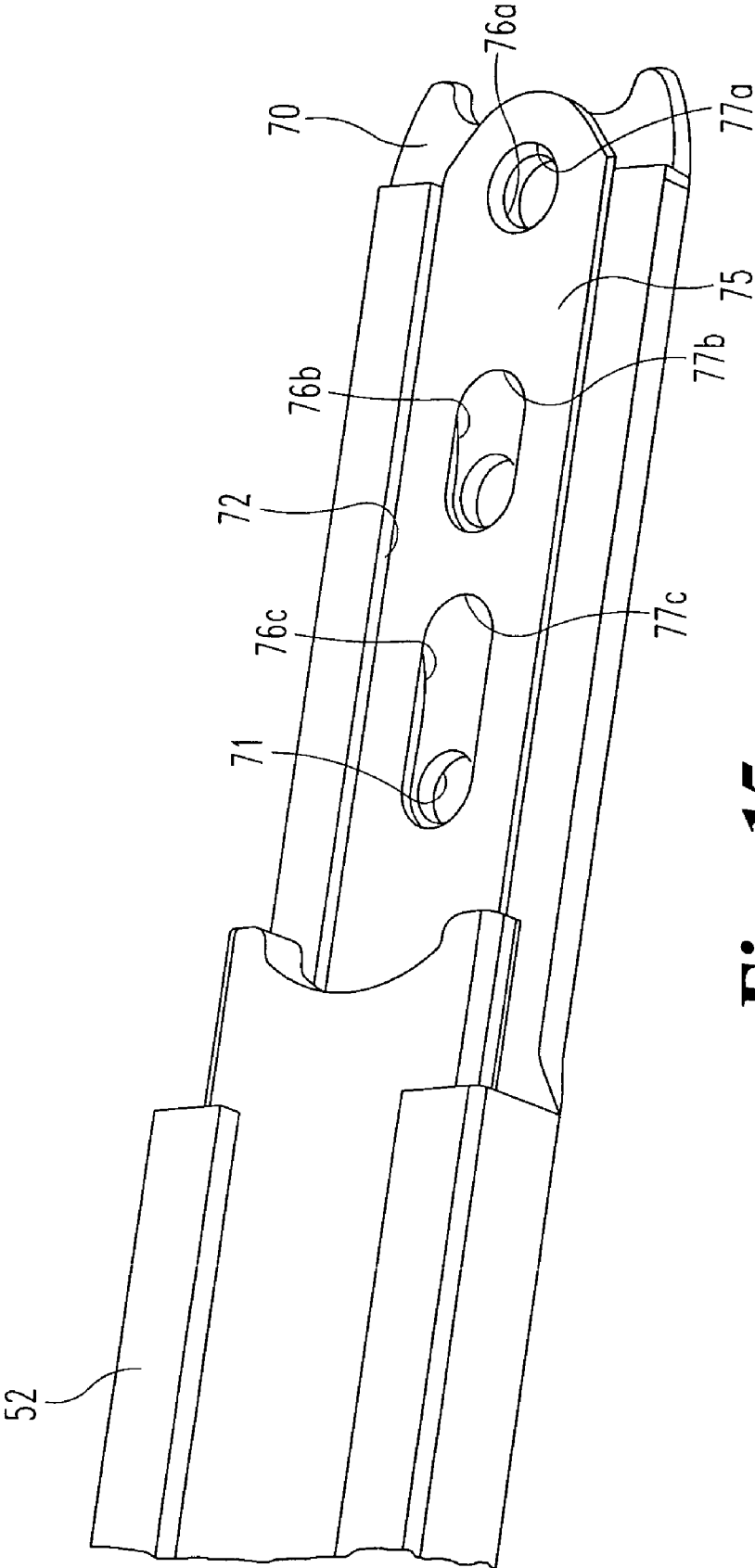


Fig. 15a

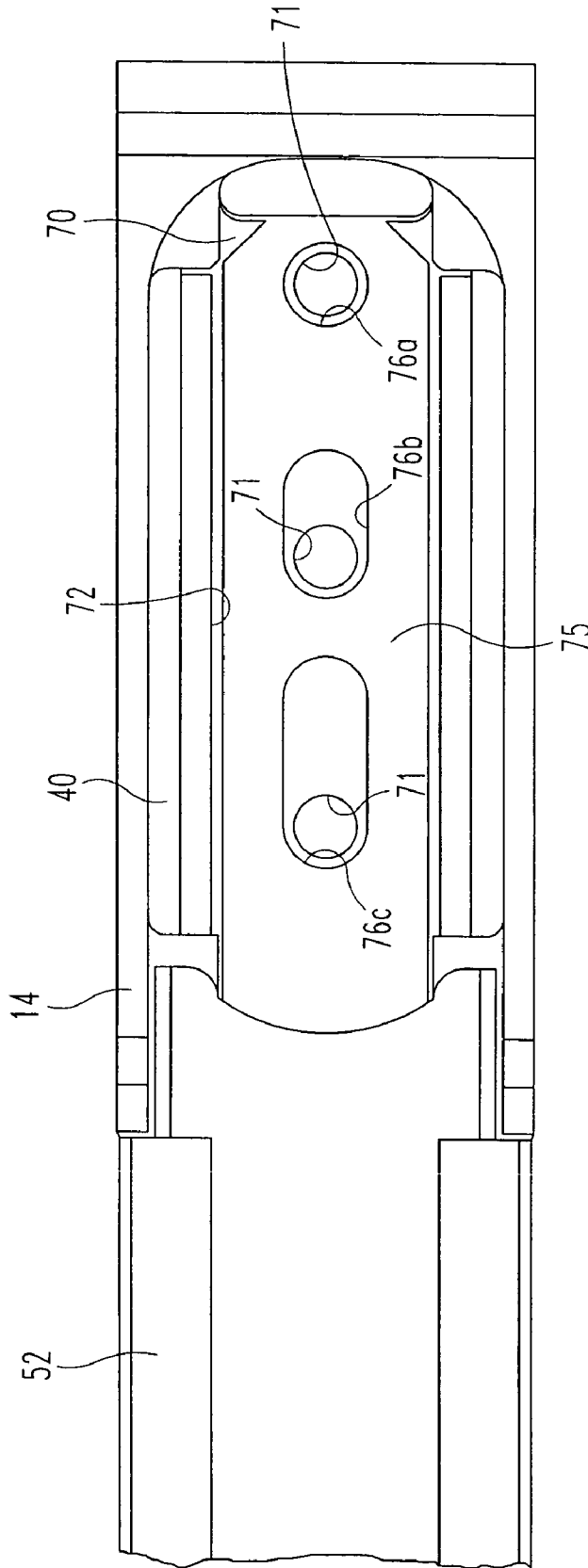


Fig. 15b

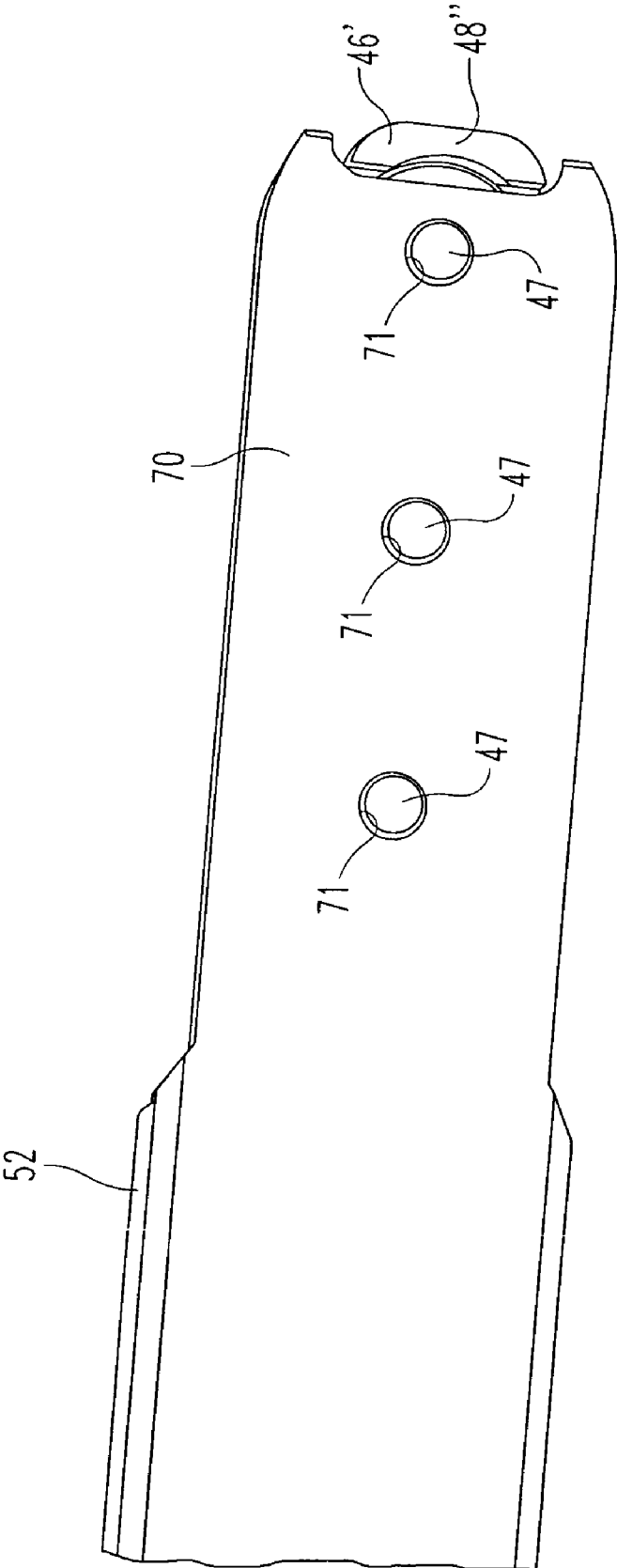


Fig. 16a

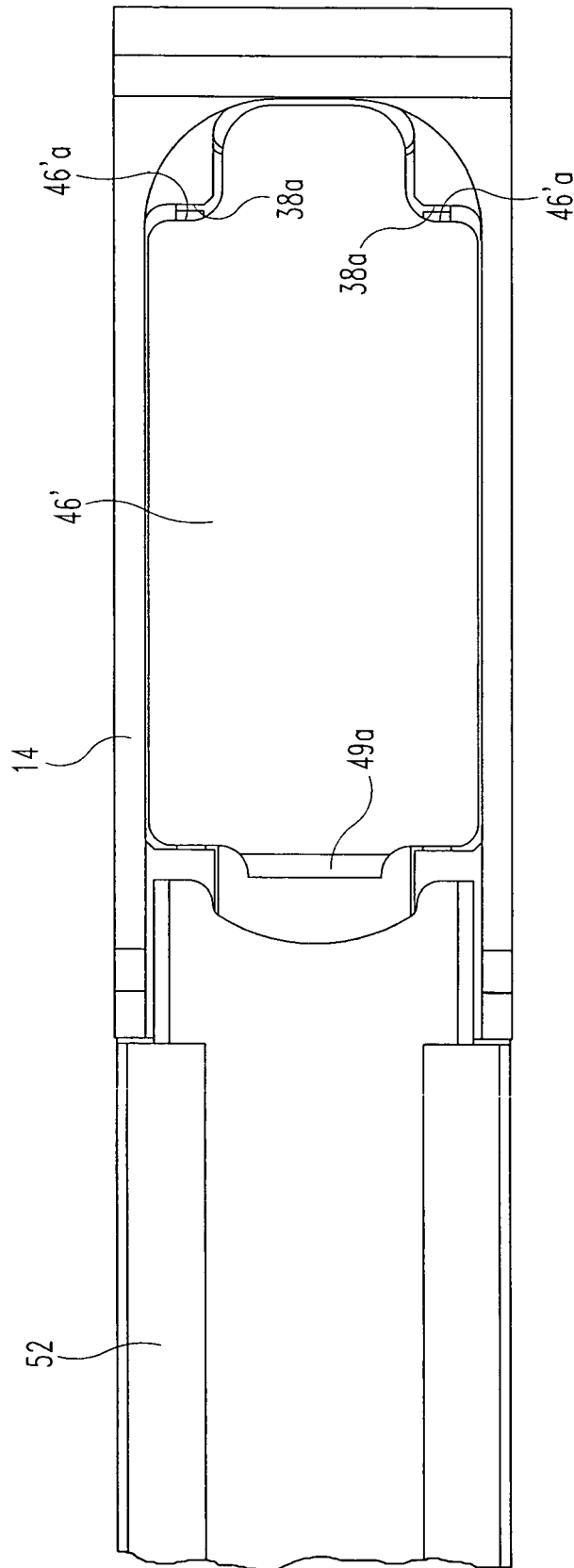


Fig. 16b

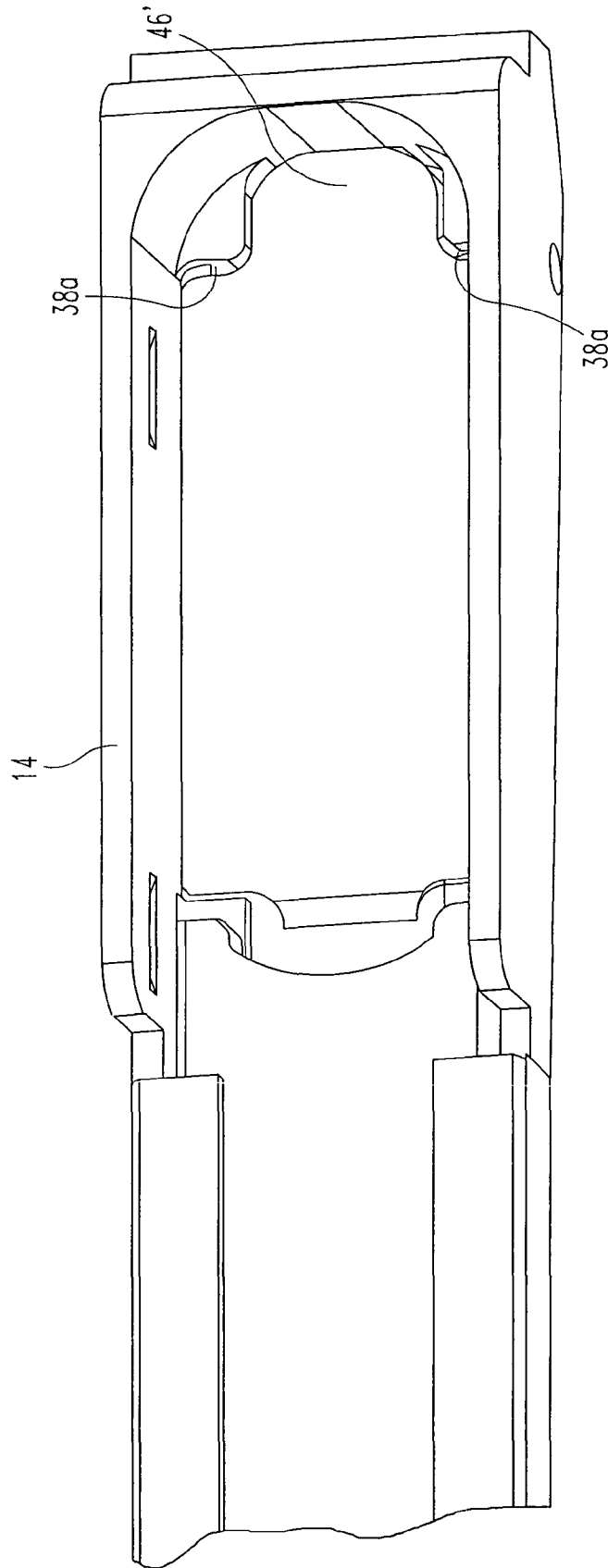


Fig. 16c

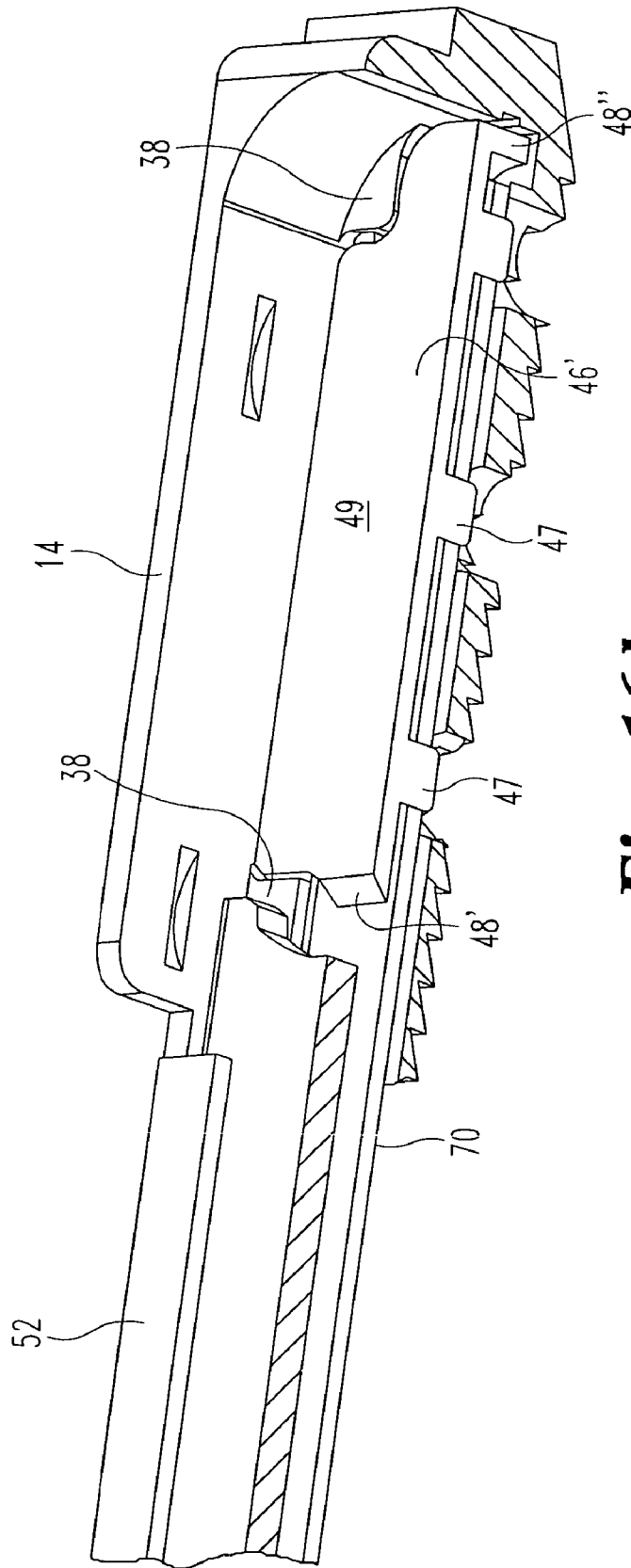


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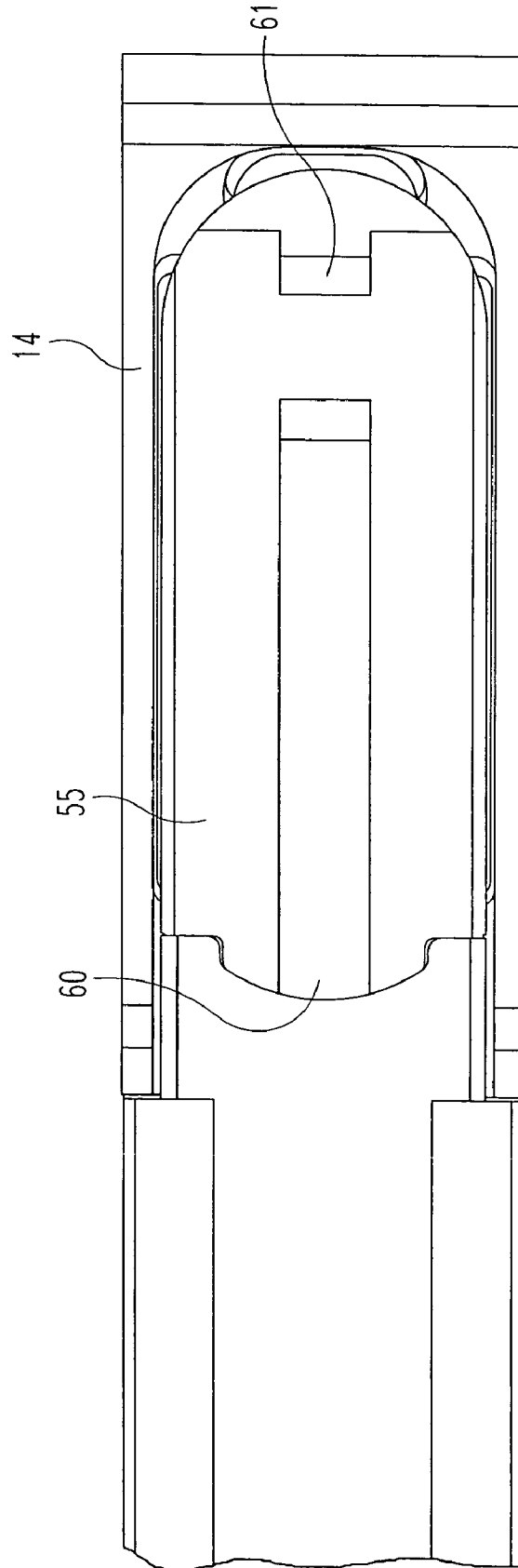


Fig. 17

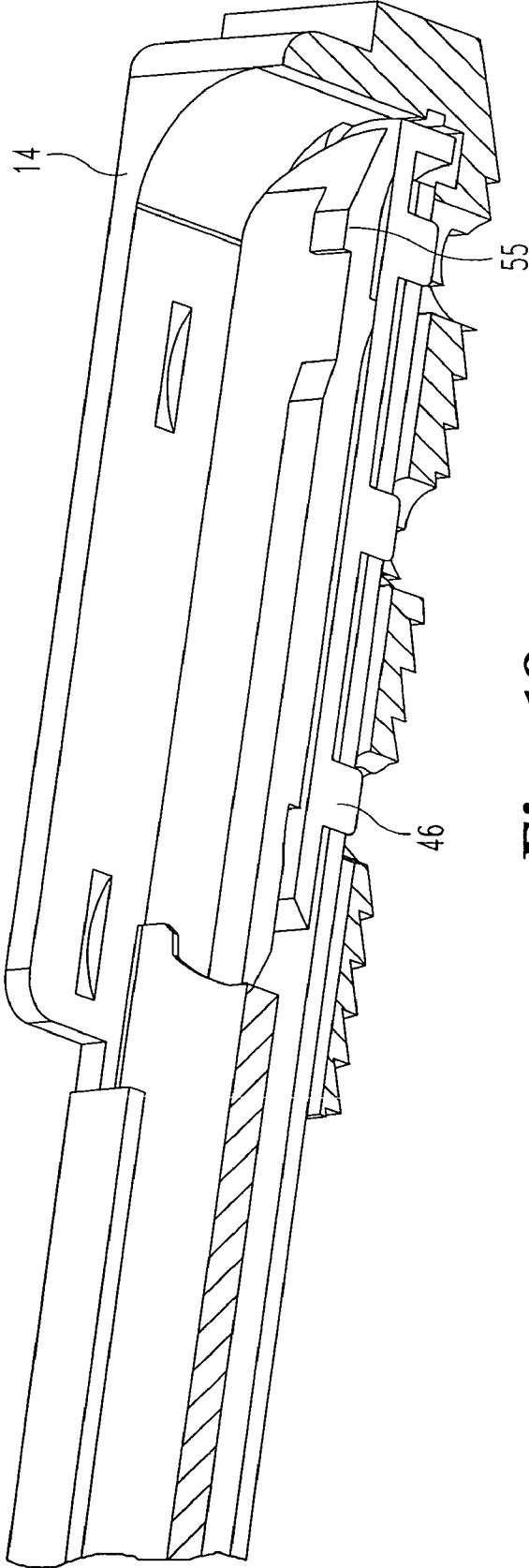


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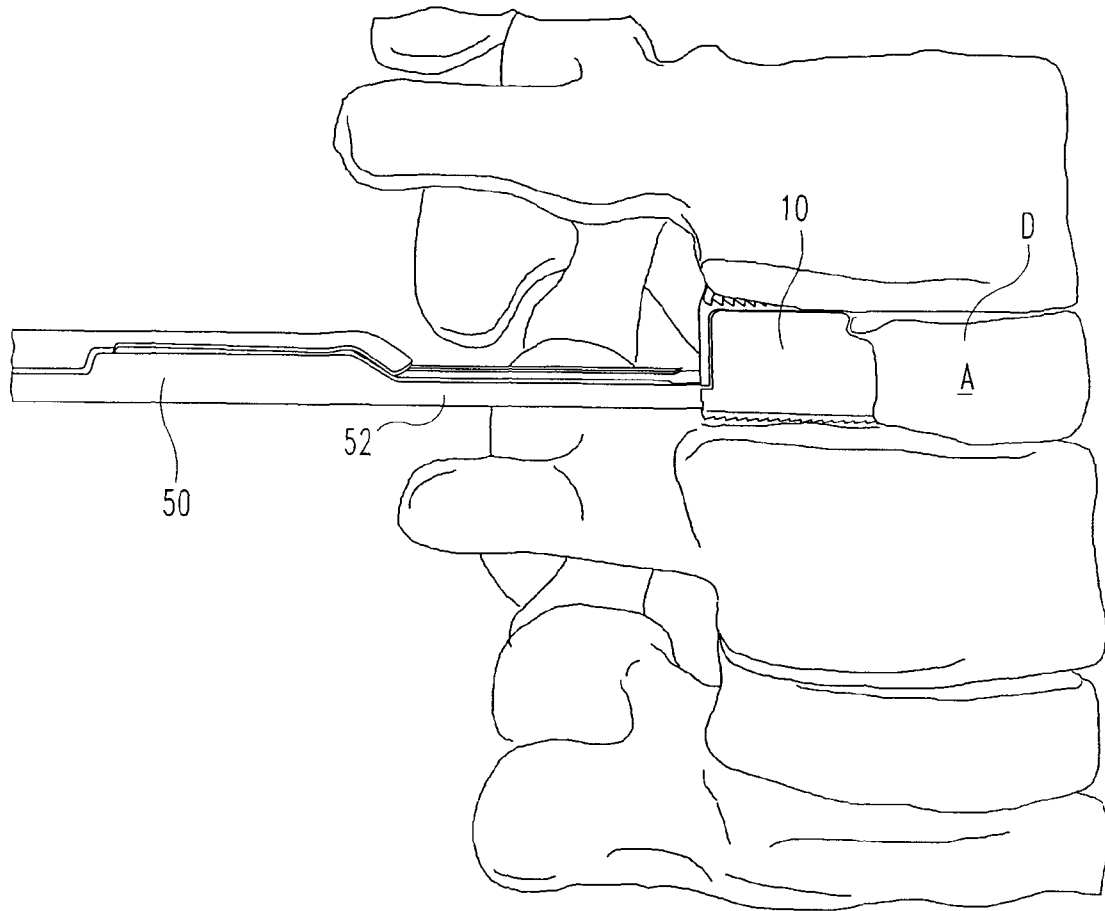


Fig. 19

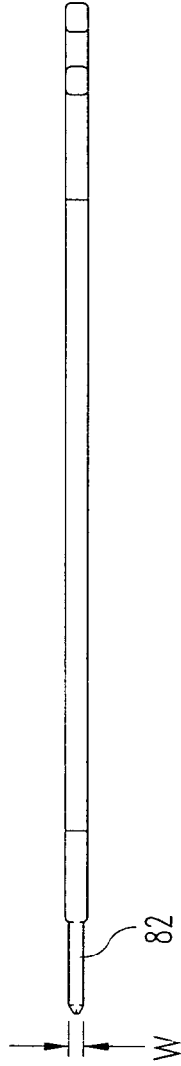


Fig. 20a

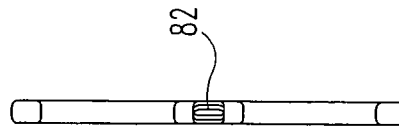


Fig. 20c

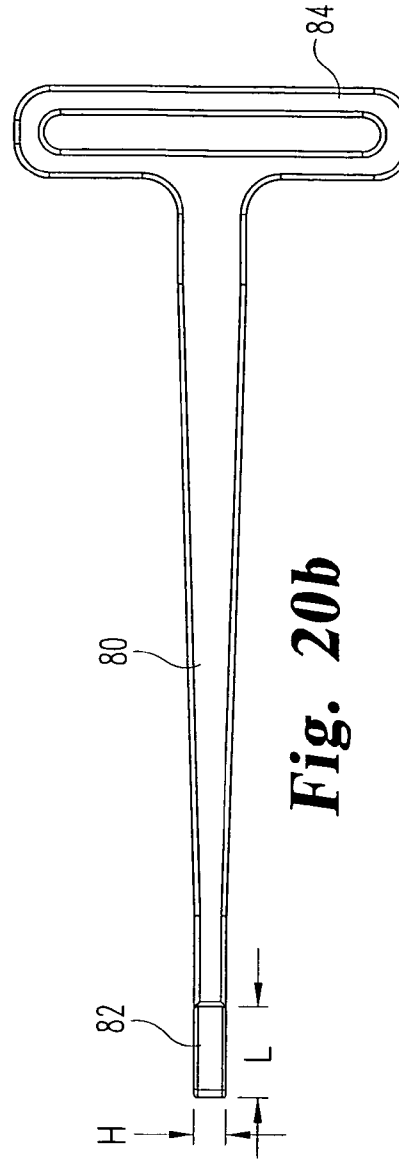


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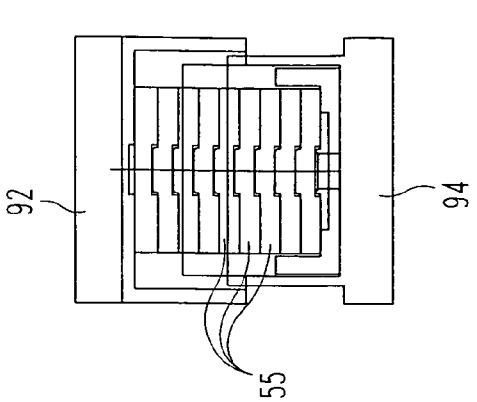


Fig. 21b

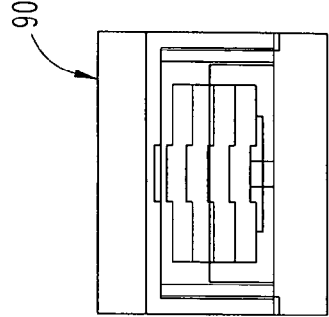


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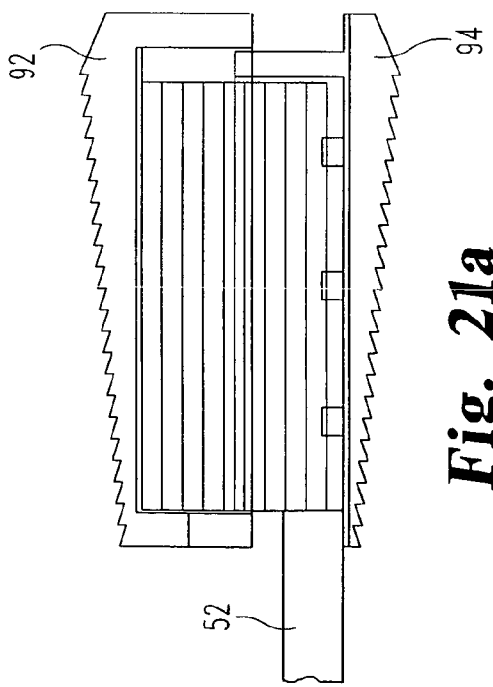


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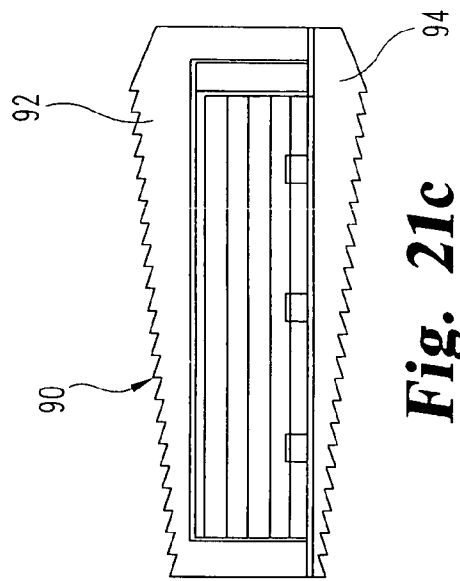


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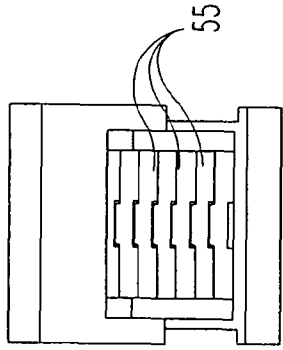


Fig. 22b

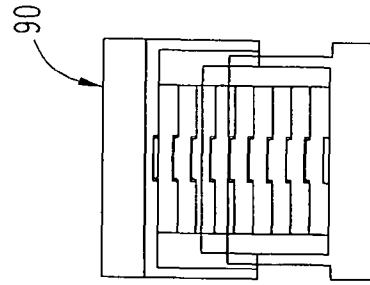


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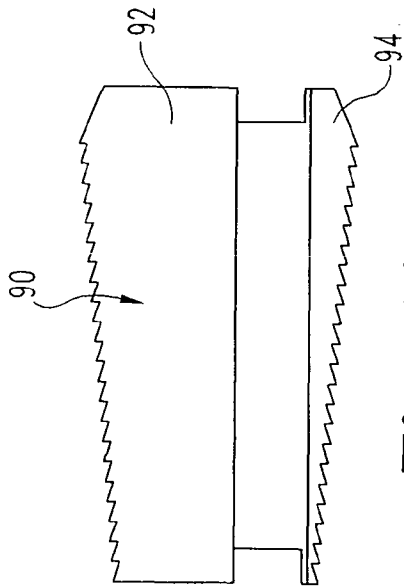


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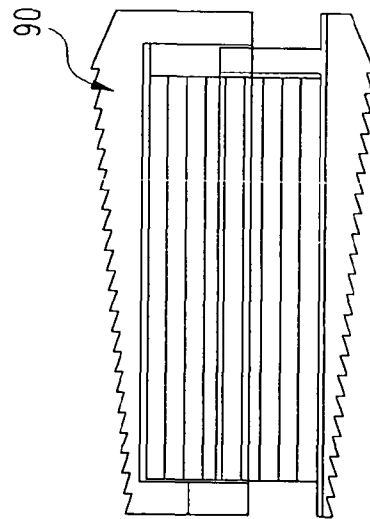


Fig. 22c

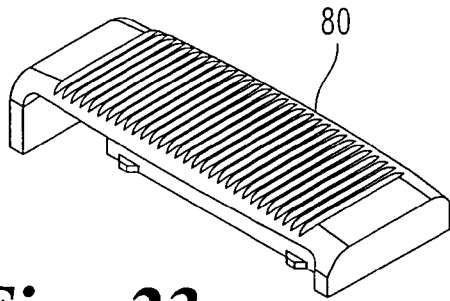


Fig. 23a

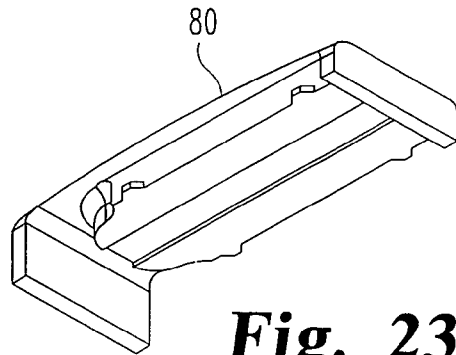


Fig. 23b

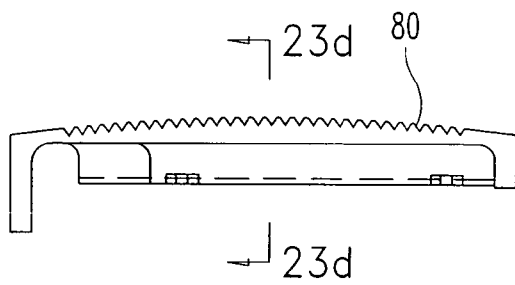


Fig. 23c

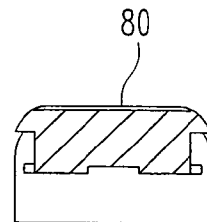
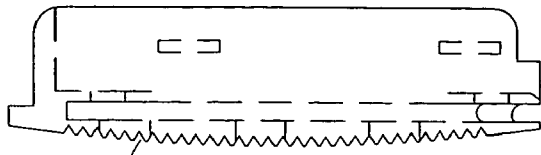
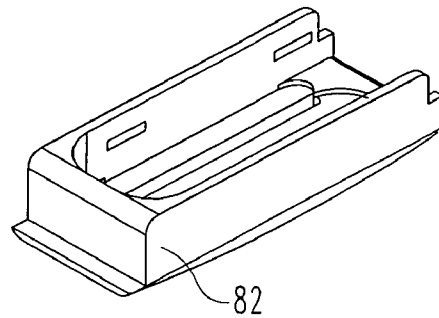


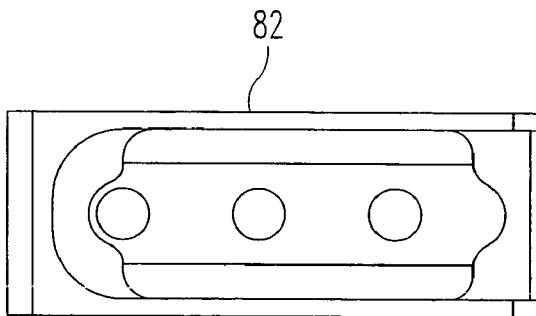
Fig. 23d



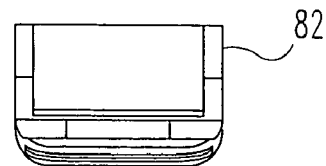
82 **Fig. 24a**



82 **Fig. 24b**



82 **Fig. 24c**



82 **Fig. 24d**

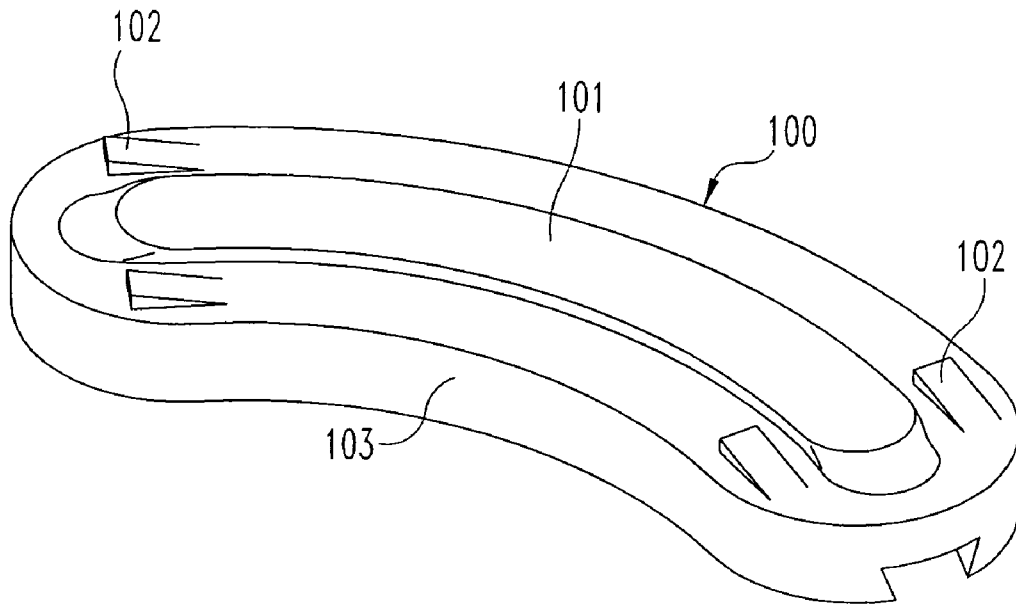


Fig. 25a

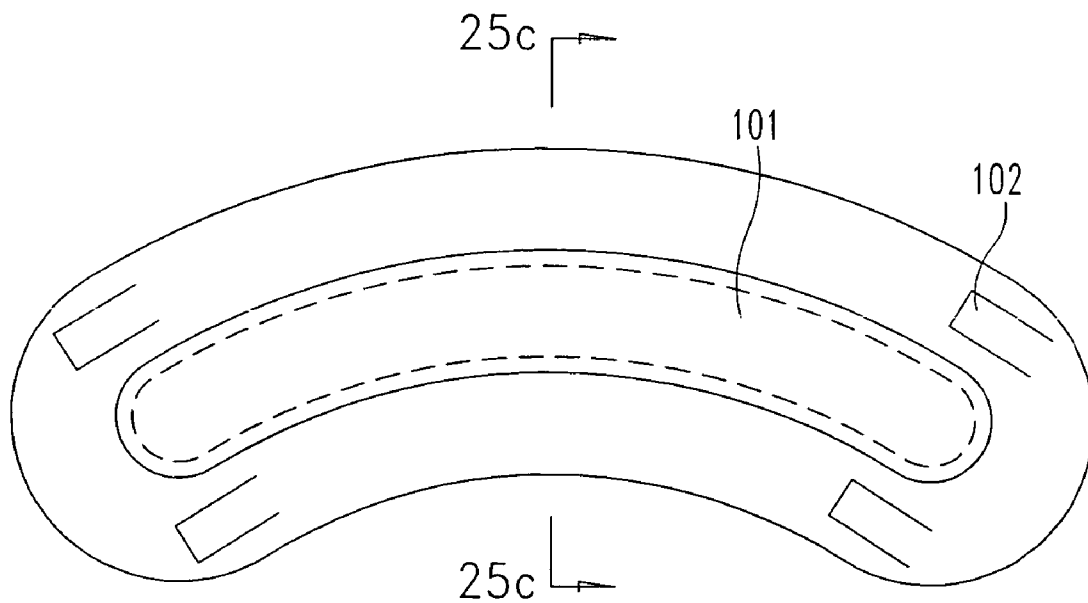


Fig. 25b

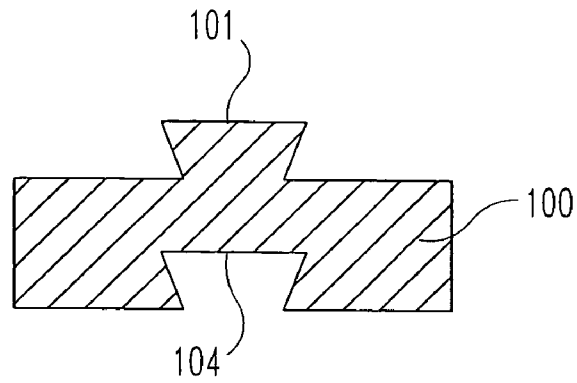


Fig. 25c

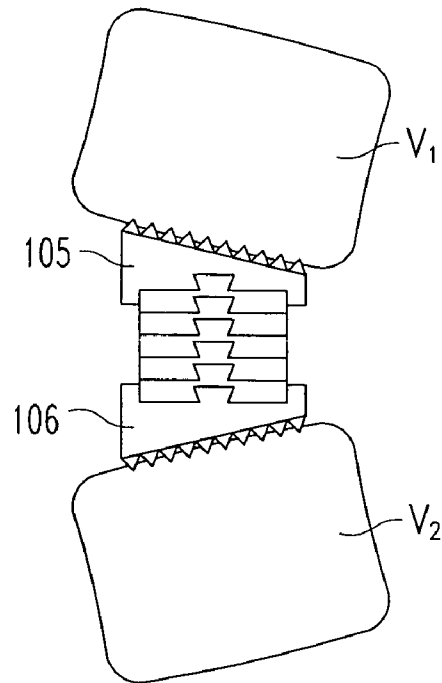


Fig. 26

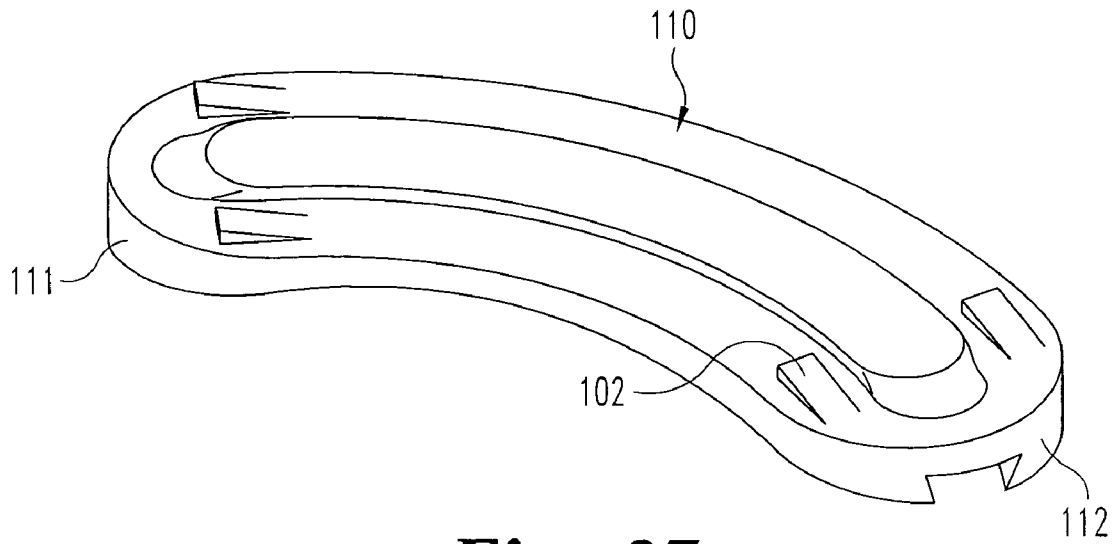


Fig. 27a

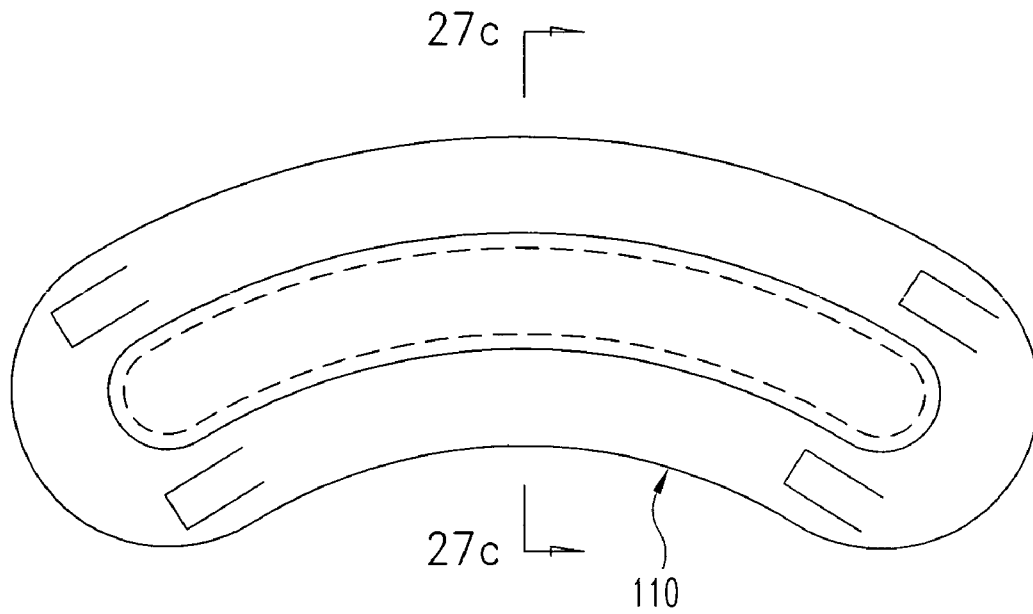


Fig. 27b

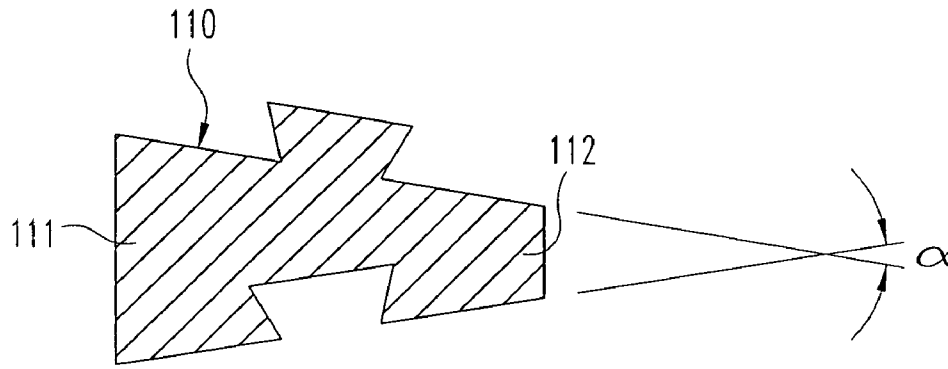


Fig. 27c

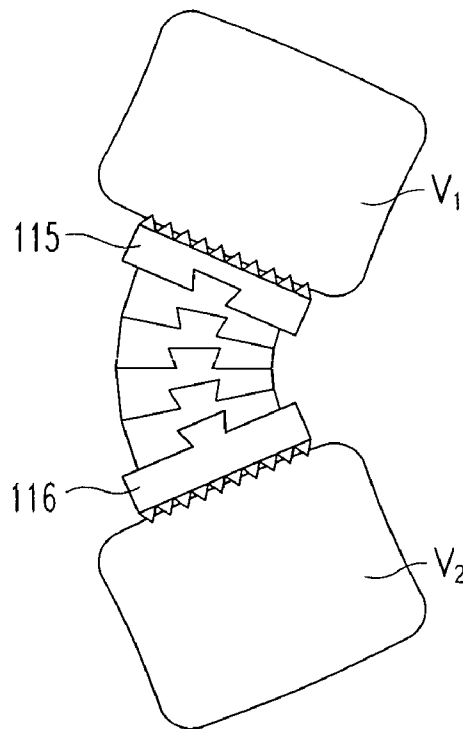


Fig. 27d

EXPANDABLE INTERBODY FUSION DEVICE

REFERENCE TO RELATED APPLICATION

This application claims priority to co-pending provisional application No. 60/604,422, filed on Aug. 25, 2004, and entitled "Expandable Interbody Fusion Device". The disclosure of this provisional application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to devices and methods for stabilization of spinal motion segments and most particularly for stabilization of the intervertebral disc space.

The number of spinal surgeries to correct the causes of low back pain has steadily increased over the last several years. Most often, low back pain originates from damage or defects in the spinal disc between adjacent vertebrae. The disc can be herniated or can be suffering from a variety of degenerative conditions, so that in either case the anatomical function of the spinal disc is disrupted. The most prevalent surgical treatment for these types of conditions has been to fuse the two vertebrae surrounding the affected disc. In most cases, the entire disc will be removed, except for the annulus, by way of a discectomy procedure. Since the damaged disc material has been removed, something must be positioned within the intradiscal space, otherwise the space may collapse resulting in damage to the nerves extending along the spinal column.

In order to prevent this disc space collapse, the intra-discal space has been filled with bone or a bone substitute in order to fuse the two adjacent vertebrae together. In early techniques, bone material was simply disposed between the adjacent vertebrae, typically at the posterior aspect of the vertebrae, and the spinal column was stabilized by way of a plate or a rod spanning the affected vertebrae. With this technique once fusion has occurred the hardware used to maintain the stability of the segment became superfluous. Moreover, the surgical procedures necessary to implant a rod or plate to stabilize the level during fusion were frequently lengthy and involved.

It was therefore determined that a more optimum solution to the stabilization of an excised disc space is to fuse the vertebrae between their respective end plates, most optimally without the need for anterior or posterior plating. There have been an extensive number of attempts to develop an acceptable intra-discal implant that could be used to replace a damaged disc and yet maintain the stability of the disc interspace between the adjacent vertebrae, at least until complete arthrodesis is achieved. These "interbody fusion devices" have taken many forms, but many have had difficulty in achieving fusion, at least without the aid of some additional stabilizing device, such as a rod or plate. Moreover, some of these devices are not structurally strong enough to support the heavy loads and bending moments applied at the most frequently fused vertebral levels, namely those in the lower lumbar spine.

The interbody fusion devices (IBFDs) that have overcome these difficulties are typically bulky, at least with respect to the intervertebral space. In particular, these devices have been configured to completely fill the space and to restore the normal spinal anatomy at the instrumented level. One drawback of this approach is that the implant device is not exactly sized to the anatomy of the particular patient, thus typically requiring pre-distraction of opposed vertebrae in order to increase the disc space for device implantation. While a collection of differently sized IBFDs can be provided, it is

unwieldy and impractical to provide an IBFD sized for every intervertebral disc space height.

Another drawback of these prior devices is that the surgical insertion site must be at least as big as the IBFD. Minimally invasive and working channel surgical techniques have been recently developed that have significantly reduced the surgical invasion, but even more improvement is needed. The present invention provides an IBFD that achieves all of the benefits of prior IBFD designs, while also addressing the above-noted drawbacks.

SUMMARY OF THE INVENTION

In order to address these drawbacks, the present invention contemplates an expandable interbody fusion device for implantation into the intradiscal space between two opposing vertebral bodies of a spine which comprises a superior endplate member having an upper surface for engaging a superior vertebral body in a spine and an inferior endplate member having a lower surface for engaging an inferior vertebral body in the spine, the superior endplate member and the inferior endplate member being releasably coupled and defining a cavity therebetween. The device is further provided with at least one expansion member configured to be introduced into the cavity to move the superior endplate and the inferior endplate member relatively apart upon introduction and to thereby decouple the superior endplate member and the inferior endplate member. In one embodiment, the superior endplate member has a pair of opposing spaced apart sidewalls depending downwardly from the upper surface, while the inferior endplate member has a pair of opposing spaced apart sidewalls projecting upwardly from the lower surface. The depending sidewalls of the two endplate members are configured to overlap for an extent as the superior endplate member and the inferior endplate member are moved apart.

In one feature, at least one of the sidewalls on one of the superior endplate member or the inferior endplate member comprises a projecting prong while an overlapping sidewall of the other of the superior endplate member or the inferior endplate member defines a complementary notch for receipt of the prong. The prong and the notch thus form a releasable coupling between the superior endplate member and the inferior endplate member.

In a further embodiment, the superior endplate member has at least one end wall depending downwardly from the upper surface and the inferior endplate member has at least one end wall projecting upwardly from the lower surface. The depending end walls are configured to overlap for an extent as the superior endplate member and the inferior endplate member are moved apart.

In certain embodiments of the invention, the upper surface of the superior endplate member and the lower surface of the inferior endplate member each comprise gripping surfaces for engagement with the respective superior and inferior vertebral bodies. These gripping surfaces may be defined by ribs having a generally saw-toothed configuration. Furthermore, at least one of the upper surface of the superior endplate member or the lower surface of the inferior endplate member may be angled to provide a particular angle between the opposing vertebral bodies. At least one of the upper surface of the superior endplate member or the lower surface of the inferior endplate member may be curved to provide anatomical support of the vertebral bodies.

In accordance with certain features of the invention, the at least one expansion member is a generally flat wafer configured for sliding insertion into the cavity under sufficient pressure to move the superior endplate member and the inferior

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endplate member apart. The wafer may comprise a surface for cooperative engagement with at least the superior endplate member. Preferably, the device comprises a plurality of wafers slidably received in contact to form a stack of wafers within the cavity and to separate the superior plate from the inferior plate when the height of the stack exceeds the size of the cavity in the device.

In one specific embodiment, each of the wafers has an upper generally flat surface and a lower generally flat surface. In another specific embodiment, a lower flat surface of a wafer in the stack and an upper flat surface of a contacting wafer comprise complementary interdigitating configurations to provide at least lateral and rotational stability to the stack of wafers. These complementary configurations may be defined by a ridge on at least one of the wafer surfaces and a trough for receiving the ridge on a surface of a contacting wafer.

In a further embodiment of the invention, an expandable interbody fusion device is provided for implantation into the intradiscal space between two opposing vertebral bodies of a spine, in which the device comprises a superior endplate member having an upper surface for engaging a superior vertebral body in a spine and an inferior endplate member having a lower surface for engaging an inferior vertebral body in the spine, the superior endplate member and the inferior endplate member defining a cavity therebetween. The device further comprises at least one expansion member configured to be introduced into the cavity and upon introduction to move the superior endplate member and the inferior endplate member relatively apart. The superior endplate member and the inferior endplate member define cooperative surfaces that overlap for an extent as the superior endplate member and the inferior endplate member move apart to thereby provide stability to the device upon expansion.

In accordance with other features of the invention, an apparatus is provided for use in restoring the anatomical height of a damaged or diseased disc space between two opposing vertebral bodies in a spine. The apparatus comprises an expandable interbody fusion device according to embodiments described above, together with an inserter releasably connected to the fusion device. The inserter may comprise a track along which the expansion element is conveyed for introduction into the cavity of the fusion device. In one aspect, a separable interface is provided between the track and the fusion device. That interface may be a connector plate supported by the inferior endplate member. The connector plate includes a support surface on one side for supporting the expansion member and at least one severable member on the other side for temporarily holding the track to the fusion device. The connector plate may interface with a movable release plate supported by the track and having a cutting surface operable upon movement to sever the at least one severable member on the connector plate, to thereby allow removal of the track from the fusion device.

An expandable interbody fusion device for implantation into the intradiscal space between two opposing vertebral bodies of a spine comprises a curved superior endplate member and a curved inferior endplate member, wherein at least one of the superior endplate member or the inferior endplate member has a thickness at one side different from the thickness at the opposite side, thereby defining a lordotic angle between opposing vertebral bodies. A plurality of wafers may be stacked between the superior endplate member and the inferior endplate member, the wafers each being of relatively constant thickness from one side to the other. In certain embodiments, both the superior endplate member and the

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inferior endplate member have a thickness on one side different from the thickness on the other side.

In one feature, the device defines cooperative interlocking surfaces between the wafers. Cooperative interlocking surfaces may also be defined between the wafers and the superior and inferior endplate members. The cooperative interlocking surfaces may constitute dovetail configurations.

Additional embodiments of the invention reside in an expandable interbody fusion device for implantation into the intradiscal space between two opposing vertebral bodies of a spine that comprises a superior endplate member, an inferior endplate member, and a plurality of wafers stacked between the superior endplate member and the inferior endplate member, wherein each of the wafers has a different thickness from side to side to thereby provide upon disposition between the superior endplate member and the inferior endplate member a lordotic angle between the vertebral bodies. Again, the device may define cooperative interlocking surfaces between the wafers, as well as between the wafers and the endplate members.

In a further embodiment, a device is provided for distracting a body tissue space between opposing tissue surfaces which comprises an upper plate having an outer surface configured to contact one of the opposing surfaces and a lower plate having an outer surface configured to contact the other of the opposing surfaces, the lower plate having opposite side walls configured to removably support the upper plate thereon. The upper and lower plates define a cavity when the upper plate is supported on the lower plate. The lower plate defines a wafer support surface for supporting at least one wafer within the cavity, and a channel communicating with the cavity and configured to receive a wafer conveyed there-through for placement on the surface of the lower plate. In one feature of this embodiment, the upper plate defines a contact surface for contacting a wafer within the cavity to displace the upper plate from the lower plate.

It is one object of the invention to provide an expandable device that may be manipulated percutaneously to distract the space between two tissue surfaces, such as the intervertebral disc space. Another object resides in features of the invention that provides for controlled expansion of superior and inferior plates configured to engage the tissue surfaces.

One benefit of the various embodiments disclosed herein is that all of the components are configured for easy introduction to the surgical site through a working channel cannula and without the need for traditional open surgical procedures. Another benefit is that the overall height of the expandable device, and thus the amount of distraction applied to the tissue surfaces, may be easily controlled during the distraction procedure. Other objects and benefits of the invention will become apparent from the following written description and accompanying figures.

DESCRIPTION OF THE FIGURES

FIG. 1 is a bottom perspective view of an interbody fusion device (IBFD) according to one embodiment of the invention.

FIG. 2 is a side view of the IBFD shown in FIG. 1.

FIG. 3 is a top view of the IBFD of FIGS. 1-2 mounted on an insertion apparatus in accordance with one aspect of the invention.

FIG. 4 is a side view of the IBFD and insertion apparatus shown in FIG. 3.

FIGS. 5a-5f include perspective, side, end, top and bottom views of a superior endplate portion of the IBFD shown in FIGS. 1-2, and including a cross-sectional and enlarged view of portions thereof.

FIGS. 6a-6e include perspective, side, end, top and bottom views of an inferior endplate portion of the IBFD shown in FIGS. 1-2, including an enlarged view of a portion thereof.

FIGS. 7a-7e include side, top and cross-sectional views of the inferior endplate portion of the IBFD shown in FIGS. 6a-6e.

FIGS. 8a-8f include side, top, bottom and perspective views of a track connector used in connection with the insertion apparatus shown in FIGS. 3-4, including cross-sectional views of portions thereof.

FIG. 8g is a bottom perspective view of an alternative embodiment of a track connector used in connection with the insertion apparatus shown in FIGS. 3-4.

FIG. 9 is a side perspective partial cut-away view of the IBFD and insertion apparatus shown in FIGS. 3-4 with the track connector shown in FIG. 8b in accordance with one embodiment of the invention.

FIG. 10 is a side view of the IBFD and insertion apparatus shown in FIGS. 3-4.

FIGS. 11a, 11b are top perspective and bottom views of a wafer for introduction into the IBFD of FIGS. 1-2 using the insertion apparatus as shown in FIGS. 3-4 and 9.

FIG. 12 is a side cut-away view of the structure shown in FIG. 9.

FIG. 13 is a top view of the distal end of the wafer-track portion of the insertion apparatus shown in the prior figures.

FIGS. 14a-c are top, top perspective and top-perspective cut-away views of components of the insertion apparatus engaged with the inferior endplate portion of the IBFD illustrated in FIGS. 6-7 and including the distal end of the wafer track shown in FIG. 13.

FIG. 15a is a top perspective view of a release plate, driver and the distal end of the wafer track of FIG. 13.

FIG. 15b is a top view of components of the insertion apparatus engaged with the inferior endplate, including the release plate of FIG. 15a. The track connector is removed to show the position of the release plate and the distal end of the wafer track in the inserter cavity.

FIG. 16a is a bottom perspective view of the distal end of the wafer track of FIG. 13 with the track connector of FIGS. 8a, 8b mounted thereon.

FIGS. 16b-d are top, top perspective and top perspective cut-away views of components of the insertion apparatus engaged with the inferior endplate portion and including the track connector of FIG. 8b prior to wafer insertion.

FIG. 17 is a top view of the insertion apparatus with a wafer situated within the inferior endplate portion of the IBFD. The superior endplate is removed to show the position of the wafer in the wafer cavity.

FIG. 18 is a perspective cut-away view of the insertion apparatus, the inferior endplate portion of the IBFD, including the track connector, and wafer shown in FIG. 17.

FIG. 19 is a side pictorial view of the insertion apparatus being used to insert an IBFD in accordance with the present invention into an intervertebral space.

FIGS. 20a-20c include side, top and end views of a disc space distractor for use with the insertion apparatus shown in the above identified figures.

FIGS. 21a-21b are side and end cross-sectional views of an IBFD in accordance with one embodiment of the present invention with a stack of wafers introduced therein to one pre-determined height.

FIGS. 21c-21d are side and end cross-sectional views of the IBFD shown in FIGS. 21a-21b stacked to a different height in which all of the wafers are contained within the endplates.

FIGS. 22a-d include side and end views of the IBFD shown in FIGS. 21a-21b.

FIGS. 23a-23d include top and bottom perspective views, a side view and a cross-sectional view of a superior endplate for a sagittally curved embodiment of an IBFD of the present invention.

FIGS. 24a-24d include side, top perspective, top and end views of an inferior endplate for a sagittally curved embodiment of an IBFD of the present invention.

FIGS. 25a-c are perspective, top and cross-sectional views of a transversely curved wafer for use with an IBFD of the present invention.

FIG. 26 is a side representation of an IBFD implanted in an intervertebral space with wafers as shown in FIGS. 25a-c.

FIGS. 27a-c are perspective, top and cross-sectional views of a transversely curved and angled wafer for use with an IBFD of the present invention.

FIG. 27d is a side representation of an IBFD implanted in an intervertebral space with wafers as shown in FIGS. 27a-c.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.

In accordance with one embodiment of the invention, an interbody fusion device (IBFD) 10 includes a superior endplate 12 and an inferior endplate 14 that define a wafer cavity 19, as shown in FIGS. 1-2. The superior and inferior surfaces of the endplates define engagement ribs 16_U and 16_L that are configured to engage or grip the vertebral endplates of opposed vertebrae in a spine. Preferably, the ribs 16_U and 16_L are configured to prevent expulsion of the IBFD under normal spinal loads. For instance, the ribs may have a saw tooth shape that is inclined toward the opening through which the IBFD is inserted into the interbody space. Angling the ribs toward the opening also angles them away from the direction of insertion so that the IBFD can be easily inserted into a collapsed space.

The IBFD 10 also defines an inserter cavity 18 that engages a portion of an inserter apparatus 50, as shown in FIGS. 3-4. The inserter apparatus 50 defines a wafer track 52 along which a plurality of expansion members, or wafers, are conveyed to fill the wafer cavity 19.

In accordance with one aspect of the invention, the IBFD 10 has a height across the superior and inferior endplates 12, 14 that is less than the normal anatomic height of a typical intervertebral disc space. The invention contemplates that a series of expansion members, such as wafers, are introduced into the wafer cavity 19 to at least fill all or part of the cavity, and to distract the opposing vertebrae, separating the superior and inferior endplates. Insertion of the wafers separates the endplates to expand the height of the IBFD within the intervertebral or interbody space and to ultimately restore the normal anatomic height of the instrumented disc space.

Details of the superior and inferior endplates can be seen in FIGS. 5-7. Referring to FIGS. 5a-5f, and in particular to FIG. 5d, the superior endplate 12 includes an upper wall 22 on which the engagement ribs 16_U are defined. The interior face of the upper wall is thickened in a reinforcement region 23.

This region helps maintain the integrity of the superior endplate **12** and provides a strong surface against which a lifting force can be applied by successive insertion of the wafer. Region **23** is also configured to contain and to cooperate with the wafers, as described below, to provide lateral and torsional stability to the wafer stack.

The upper wall terminates in an anatomically anterior end wall **24** and an anatomically posterior end wall **25** that integrate with the inferior endplate **14** as described below. In addition, the reinforcement region **23** defines outwardly and laterally projecting prongs **27** that engage cooperating notches **36** defined in the interior of the inferior endplate **14**. Details of the inferior endplate are shown in FIGS. 6-7. The endplate **14** includes a bottom wall **30** on which the engagement ribs **16_z** are defined. The bottom wall **30** terminates in an end wall **32** and a ledge **33**. As shown in FIGS. 2 and 9, the anterior end wall **24** of the superior endplate **12** overlaps the end wall **32** and end ledge **33** when the endplates are initially assembled. The two end walls **24** and **30** overlap over the majority of the height of the end wall **32** so that as the superior and inferior endplates are pushed apart the two endplates remain in contact and continue to define the wafer cavity **19**, providing stability to the IBFD as it expands.

The inferior endplate **14** also includes side walls **35** that define the wafer cavity and ultimately help retain the wafers within the cavity as they are sequentially inserted. The inner face of the side walls define notches **36** that are aligned for engagement by the prongs **27** in the superior endplate **12**. Thus, when the IBFD is initially assembled prior to insertion into the interbody space, the prongs and notches **27**, **36** hold the two endplates together. The interface between the prongs and notches is adequate to hold the IBFD together as it is inserted into the space, but is sufficiently weak to be dislodged under pressure from the inserted wafers.

The interior of the inferior endplate **14** includes opposite surfaces **38** that structurally reinforce the IBFD under large compressive loads. Slightly offset from the walls **38** are support rails **40** (FIG. 6b) that support the track connector **46** shown in FIGS. 8a-8f. The top surface **49** of the track connector **46** is configured to be superior to surface **38** such that any compressive load from the wafer stack is transmitted through the bottom surface of the track connector to the support rails **40**. The end walls **38** of the endplate **14** also form end notches **43** (FIG. 7c) that are complementary to the end edges of the track connector **46** in one embodiment of the invention. The end walls **38** and rails **40** of the endplate **14** define a connector channel **42**, as shown in FIG. 7a, which is configured to receive the distal end of the wafer track of inserter apparatus **50**, as described below.

The superior and inferior endplates **12**, **14** can be formed of a biocompatible material with sufficient strength to support the adjacent vertebrae without fatigue and fracture. Preferably, the two endplates are molded from a biocompatible polymeric material, such as, for example, PEEK or a biocompatible composite material, such as, for example carbon-fiber-reinforced PEEK. The material may also be selected to permit tissue ingrowth to integrate with the vertebral endplates. The endplates can further be formed from a moldable or formable biologic material, such as bone.

In accordance with one aspect of this invention, the IBFD **10** is configured to be introduced into the interbody space by an introducer or inserter apparatus **50**. The inserter can be constructed and operated like the insertion apparatus disclosed in U.S. Pat. No. 6,595,998, entitled "Tissue Distraction Device", which issued on Jul. 22, 2003, to the assignee of the present invention. The disclosure of this patent, and particularly its discussion of the wafer inserter, is incorporated

herein by reference. Alternatively, the inserter can be constructed and operated like the insertion apparatus disclosed in co-pending application Ser. No. 10/813,819, entitled "Tissue Distraction Device", filed on May 31, 2004, and assigned to the assignee of the present invention. The disclosure of this co-pending application is incorporated herein by reference.

For purposes of illustration, certain details of the inserter **50** will be explained herein. As shown in FIG. 3, the apparatus includes a wafer track **52** along which wafers are conveyed to fill the wafer cavity **19** within the IBFD and ultimately to expand the height of the IBFD. Once the last wafer has been introduced into the IBFD it is necessary to remove the inserter **50**. The preferred embodiment of the invention contemplates a track connector **46** that helps to integrate the wafer track **52** with the interior cavity of the IBFD and to provide a support surface for the wafer stack within the IBFD.

Details of the track connector **46** are shown in FIGS. 8a-8f and FIG. 9. In particular, the connector **46** includes connector posts **47** that project downward with the IBFD, as best seen in FIG. 9. These posts engage corresponding openings **71** in an insertion plate **70** (see FIG. 12) to provide an interface between the inserter apparatus **50** and the IBFD. In one embodiment, the track connector **46** defines interface edges **48** at its opposite ends that are configured to conform to wall **38** in the inferior endplate **14** (see FIG. 6b). The track connector may also include end edges **46a** flanking the interface edges that contact wall edges **38a** of the endplate **14** to limit the movement of the track connector into the endplate. The track support includes a ramp **49a** that helps direct incoming wafers upward from the wafer track **52** to the wafer support surface **49** within the IBFD.

In an alternative embodiment shown in FIG. 8g, a track connector **46'** includes a modified proximal end **48'** and distal end **48''**, but still retains the connector posts **47**, wafer support surface **49** and ramp **49a**. The modified distal end **48''** catches against a lip **39** formed in the inferior endplate, as shown in FIGS. 9, 12 to prevent removal of the track connector **46'** once it is positioned with the assembled IBFD. The distal end of the track connector **46'** further defines end edges **46'a** that contact the wall edges **38a**, as depicted in FIG. 16b, in the same manner as the end edges **46a** described above.

As shown in FIGS. 9, 10 and 12, the wafer inserter apparatus **50** provides an avenue for passage of wafers **55** from a wafer cartridge **54** into the IBFD. The inserter apparatus includes a cartridge gun that extracts wafers **55** consecutively from a stack within the cartridge **54** and conveys them along the track **52** to the IBFD. As shown in FIGS. 11a-b, the wafers **55** are configured for transition along the track **52** and for interlocking engagement within the IBFD. In particular, the wafers include a leading bevel **56** and an opposite trailing bevel **57** to facilitate movement of each successive wafer underneath the immediately prior inserted wafer. The bevels **56**, **57** help the incoming wafer dislodge and slide underneath the wafer stack already resident within the IBFD. In certain embodiments, a wafer driver **65** may be provided within the wafer track **52** to advance each wafer into the wafer cavity. The driver **65** can also help hold the lowermost wafer of the stack in position as the inserter apparatus **50** is removed.

The wafers **55** also include interdigitating upper and lower surfaces **58**, **59**, respectively. The surfaces can assume a variety of configurations intended to prevent relative longitudinal movement between wafers in the stack as well as for lateral and rotational stability. The wafers **55** and their respective surfaces can be constructed as disclosed in U.S. Pat. No. 6,595,998 cited above. The disclosure of this patent, and most particularly its discussion of the construction of the wafers, is incorporated herein by reference. In the preferred embodi-

ment, the upper surface **58** defines a ridge **60** and spaced rib **61** extending along the longitudinal axis of the wafer. Similarly, the lower surface defines a linear trough **62** that receives the ridge **60**, and a notch **63** that receives the rib **61**.

The insertion configuration for the IBFD and wafer inserter apparatus is generally depicted in FIG. **12**. The wafer track **52** of the inserter apparatus engaged the IBFD with the track end **53** contacting the proximal faces of both the inferior endplate **14** and the superior endplate **12**. A wafer **55** is shown resting on the wafer support surface **49** of the track connector **46**. The track connector **46** rests on the support rail **40** (see FIG. **6**) with its posts **47** projecting downward toward the post openings **44** in the inferior endplate **14**. As shown in the figures, the posts do not necessarily extend into the openings **44**. Instead, the post openings **44** facilitate the assembly of insertion apparatus to the track connector prior to use.

Beneath the track connector **46** reside an insertion plate **70** and a release plate **75** immediately adjacent the connector **46**. Both plates provide openings to receive the connector posts **47** therethrough, including openings **71** in the insertion plate and openings **76a-c** in the release plate. The insertion plate **70** may define a release track **72** (as shown in FIG. **14c**) within which the release plate **75** slides. The release track may be provided to increase the stiffness of the insertion plate, or may be eliminated to permit a reduction in width of the components.

The assembly of the components of the inserter apparatus **50** within the IBFD **10** is depicted sequentially in FIGS. **13-18**. The insertion plate **70** is shown in FIG. **13**. Preferably, the plate **70** is integral with the wafer track **52**. As shown in FIG. **12**, the insertion plate **70** essentially supports the IBFD with the plate **70** extending into the wafer cavity and the track end **53** abutting the IBFD. This plate **70** will be removed with the inserter apparatus **50**, leaving the IBFD within the interbody space. The post openings **71** are sized to receive the connector posts **47** therethrough. As can be seen in FIGS. **14a-c**, the insertion plate **70** sits below the support rail **40** in the inferior endplate **14** with its post openings **71** aligned with the post openings **44** in the endplate **14**.

The release plate **75**, as shown in FIGS. **15a-b**, is slidably disposed within the release track **72** in the insertion plate **70**. In an alternate embodiment, the release plate **75** is slidably disposed on top of the insertion plate **70** without any release track **72**. The release plate **75** includes openings **76a-c** corresponding to each of the connector posts **47**. The distal edge **77a-c** of each opening is sharpened so that they will sever the posts **47** from the connector plate **46** when the release plate is pulled proximally, or out of the IBFD. The opening **76a** is generally sized slightly larger than the post **47**, while the other two openings **76b-c** are increasingly elongated. This configuration allows the distal-most post to be cleanly severed before the middle post is severed, and the middle post to be severed before the proximal post. This approach reduces the force needed to sever the posts. Once the posts are severed, they are retained within the post openings **71** via an interference fit, since they are no longer needed to hold the track connector within the IBFD. When the posts are severed, the inserter apparatus **50** can be removed from the implanted IBFD without risk of retracting the IBFD.

The next series of figures, FIGS. **16a-d**, show the placement of the track connector on top of the insertion plate **70** and release plate **75**. As can be seen in FIG. **16d**, the wafer support surface **49** is generally contiguous with wall **38** of the inferior endplate **14**. In an alternate embodiment the wafer support surface **49** is superior to wall **38** of the inferior endplate **14**. This alternate embodiment ensures that the compressive load from the wafer stack is transmitted through the

wafer support surface **49** and not through wall **38**. A first wafer **55** is added in FIGS. **17-18**.

The inserter apparatus **50** and the IBFD **10** are shown in position for implanting the IBFD within an interbody space. It is contemplated that the interbody or intradiscal space will be prepared in a known manner. In particular, the disc nucleus is removed by known means, preferably leaving the disc annulus **A** relatively intact. A portal is formed in the annulus that is sized to the dimensions of the IBFD **10** in its unexpanded configuration (as shown in FIGS. **1-2**).

In the preferred arrangement, the IBFD is sized to be received in the unexpanded state through the portal into the disc space without any pre-distraction. In certain situations where the disc space height is smaller than the height of the unexpanded IBFD, pre-distraction may be used to slightly elevate the disc space so as to allow receipt of the unexpanded IBFD through the portal. Such pre-distraction, which can occur using conventional techniques, is not intended to achieve the final disc space height. One approach is to use the distractor **80** shown in FIGS. **20a-20c**. This distractor includes a distal end **82** having a height **H** greater than its width **W**. The height **H** of the distal end **82** is substantially constant over the insertion length **L**. The distractor is inserted into the disc space at a location adjacent to but laterally spaced from the location where the IBFD is to be inserted with its larger dimension parallel to the vertebral endplates. As such, no distraction occurs during insertion of the distractor **80**. The handle **84** is used to rotate the distractor **80** until the larger dimension contacts and pushes apart the vertebral endplates. The distractor **80** can be held in position as the IBFD is maneuvered into the interbody space using the inserter apparatus **50**. After removal of the distractor, a second IBFD may be inserted adjacent to the first implanted IBFD.

As shown in FIGS. **21a-d** and FIGS. **22a-d**, the IBFD can be expanded to a specific height, with its height being determined by the number of wafers **55** inserted into the IBFD. In the preferred embodiment, the superior and inferior endplates **12, 14** and the wafers have a pre-determined height or thickness. As explained above, the endplates include overlapping portions to help stabilize the stack, in particular the end walls **24** and **32**. After implanting the IBFD a biomaterial, such as bone chips or other osteogenetic materials, such as bone morphogenic proteins or adipose-derived adult stromal cells, may be introduced adjacent to or in contact with the IBFD so as to promote fusion between the opposing vertebrae.

As indicated in the figures, in certain embodiments of the invention, the stack height will change when the inserter apparatus is dislodged from the IBFD and removed. In particular, the wafer stack will shift slightly downward when the insertion plate and release plates are removed, allowing the track connector **46** to drop down.

The IBFD **90** shown in FIGS. **21a-d** and FIGS. **22a-d** includes superior and inferior endplates **92, 94** that are angled. These endplates are configured to restore or maintain a particular angle of the vertebral motion segment. For instance, if the IBFD **90** is used in the lumbar spine, the endplates are defined at a lordotic angle. The endplates **80, 82** in FIGS. **23a-d** and FIGS. **24a-d** are also configured to have arcuate upper and lower surfaces for introduction into and anatomical support of the lumbar spine.

Alternative concepts for the endplates and the wafers are shown in FIGS. **25a-27d**. In FIGS. **25a-c**, a curved wafer **100** is provided. The wafer includes interlocking dovetail features **101** and **104** and locking notches **102** to help hold the wafer stack together. As shown in FIG. **26**, the endplates **105, 106** can be angled to restore the lordotic angle of the motion segment with the wafer stack therebetween.

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As an alternative, the wafers can provide the lordotic angle, such as the wafer **110** shown in FIGS. **27a-c**. The wafer **110** includes one end **111** that is thicker than the opposite end **112**. The wafers can be contained within endplates **115**, **116** that are planar—i.e., that do not incorporate the lordotic angle.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. It is understood that only the preferred embodiments have been presented and that all changes, modifications and further applications that come within the spirit of the invention are desired to be protected.

This invention contemplates an interbody fusion device configured for implantation within an interbody space that incorporates a cavity for receipt of bio-compatible wafers. The wafers can be used to fill the cavity and provide additional strength for the IBFD components, and to increase the height of the IBFD. In this way, a smaller IBFD can be initially introduced into the interbody space, preferably minimally invasively, and then a series of wafers can be introduced to incrementally increase the height of the IBFD in situ, to thereby increase the disc space substantially to its natural height.

What is claimed is:

1. An apparatus for use in restoring the anatomical height of a damaged or diseased disc space between two opposing vertebral bodies in a spine, comprising:

a) an expandable interbody fusion device comprising:

a superior elongate endplate member having an upper surface for engaging a superior vertebral body in a spine, an opposite lower surface and opposing side surfaces;

an inferior elongate endplate member having a lower surface for engaging an inferior vertebral body in said spine and spaced opposing side surfaces, said superior endplate member and said inferior endplate member being releasably coupled to each other along said side surfaces of each said member; and

at least one expansion member configured to be introduced between said superior endplate member and said inferior endplate member to move said members relatively apart upon introduction and to thereby decouple the side surfaces of said superior endplate member and said inferior endplate member, said at least one expansion member having an upper surface and together with said lower surface of said superior endplate member further defining a cooperative engagement interlocking said expansion member and said superior endplate member upon said introduction of said expansion member; and

b) an inserter releasably connected to said fusion device, said inserter including a track defining a channel through which said expansion element is conveyed for introduction into said fusion device, there being a separable interface between said track and said fusion device, said interface comprising a connector plate supported by said inferior endplate member, said connector late including a support surface on one side for supporting said expansion member and at least one severable member on an opposite side for temporarily holding said track to said fusion device.

2. The apparatus of claim 1, wherein said opposing side surfaces of said inferior endplate member are respectively defined by a pair of opposing spaced apart sidewalls projecting upwardly from said lower surface, said projecting sidewalls of said inferior endplate member configured to decouple with the side surfaces of said superior endplate

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member as said superior endplate member and said inferior endplate member are moved apart.

3. The apparatus of claim 2, wherein said opposing side surfaces of said superior endplate member are respectively defined by a pair of opposing spaced apart sidewalls depending downwardly from said upper surface.

4. The apparatus of claim 2, wherein said inferior endplate member has at least one end wall projecting upwardly from said lower surface.

5. The apparatus of claim 1, wherein said releasable coupling includes at least one of said side surfaces of one of said superior endplate member or said inferior endplate member having a projecting prong and the side surface of the other of said superior endplate member or said inferior endplate member defining a complementary notch for receipt of said prong.

6. The apparatus of claim 5, wherein said superior endplate member has at least one end wall depending downwardly from said upper surface.

7. The apparatus of claim 1, wherein said upper surface of said superior endplate member and said lower surface of said inferior endplate member each comprise gripping surfaces for engagement with the respective superior and inferior vertebral bodies.

8. The apparatus of claim 7, wherein said gripping surfaces are defined by ribs having a generally saw-toothed configuration.

9. The apparatus of claim 1, wherein at least one of said upper surface of said superior endplate member or said lower surface of said inferior endplate member is angled to provide a particular angle between said opposing vertebral bodies.

10. The apparatus of claim 9, wherein both said upper surface of said superior endplate member and said lower surface of said inferior member are angled.

11. The apparatus of claim 1, wherein at least one of said upper surface of said superior endplate member or said lower surface of said inferior endplate member is arcuate to provide anatomical support of the vertebral bodies.

12. The apparatus of claim 11, wherein both of said upper surface of said superior endplate member and said lower surface of said inferior member are arcuate.

13. The apparatus of claim 1, wherein said at least one expansion member is a generally flat wafer configured for sliding insertion under sufficient pressure to move said superior endplate member and said inferior endplate member apart.

14. The apparatus of claim 13, wherein the apparatus comprises a plurality of wafers slidably received in contact to form a stack of wafers between said superior endplate member and said inferior endplate member.

15. The apparatus of claim 14, wherein each of said wafers has an upper generally flat surface and a lower generally flat surface.

16. The apparatus of claim 15, wherein the lower flat surface of a wafer in said stack and the upper flat surface of a contacting wafer comprise complementary interdigitating configurations to provide at least lateral and rotational stability to said stack of wafers.

17. The apparatus of claim 16, wherein said complementary configurations are defined by a ridge on at least one of said wafer surfaces and a trough on the other of said wafer surfaces for receiving said ridge.

18. The apparatus of claim 14, wherein said wafers comprise complementary interdigitating configurations to provide at least lateral and rotational stability to said stack of wafers.

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19. The apparatus of claim 1, wherein said superior endplate member and said inferior endplate member are each formed of biocompatible material.

20. The apparatus of claim 1, wherein said opposing side surfaces of said superior endplate member overlap with said spaced opposing side surfaces of said inferior endplate member and define said releasable coupling therebetween.

21. The apparatus of claim 20, wherein said releasable coupling is defined by a prong on one of said overlapping side surfaces and a complementary notch on the other of said overlapping side surfaces.

22. The apparatus of claim 1, further including a movable release plate supported by said track and having a cutting surface operable upon movement to sever said at least one severable member on said connector plate, to thereby allow removal of said track from said fusion device.

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23. The apparatus of claim 22, wherein there are at least two severable members on said connector plate and wherein said release plate has at least two openings for respectively receiving said severable members.

24. The apparatus of claim 23, wherein the edges of said openings in said release plate define said cutting surfaces.

25. The apparatus of claim 24, wherein one of said openings is elongate relative to the other of said openings to thereby cause cutting of said severable members in a sequential manner upon movement of said release plate.

26. The apparatus of claim 1, wherein said device comprises a plurality of expansion members, each being a generally flat wafer and configured for slidable receipt to form a stack of wafers within said device.

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