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(54) ARTIFICIAL DISC REPLACEMENT DEVICE

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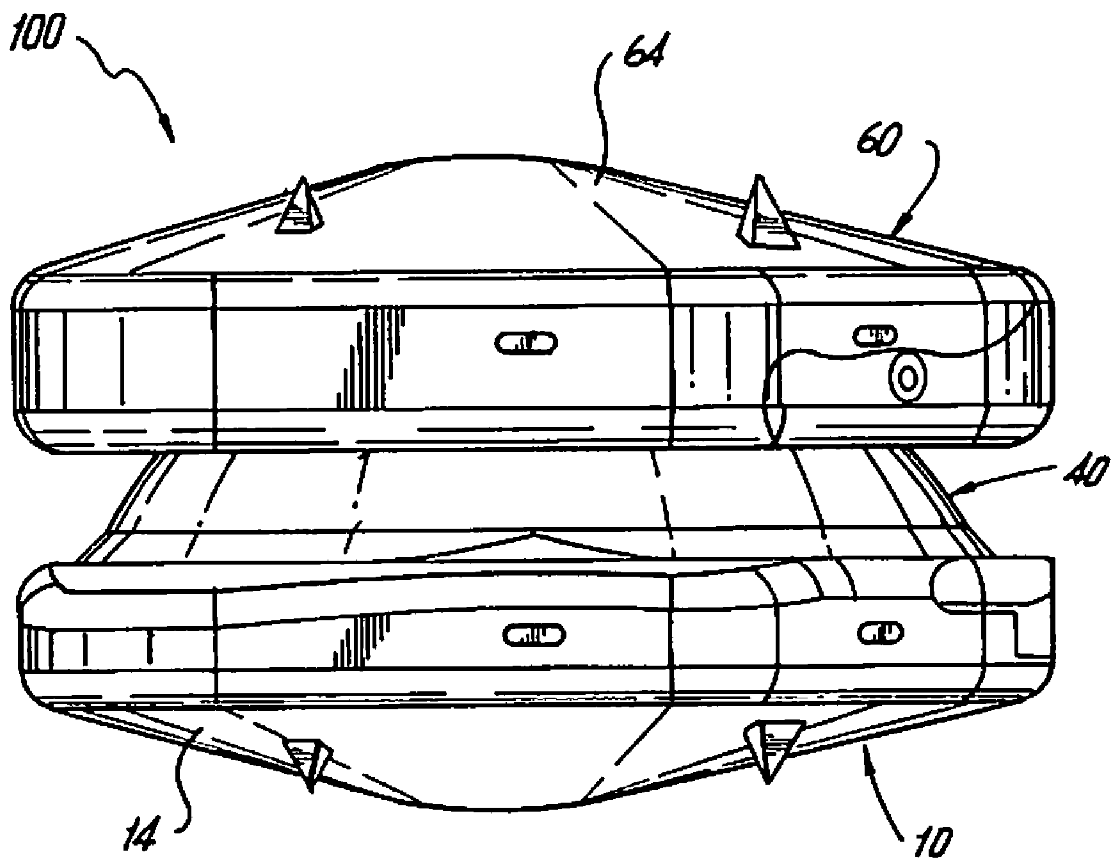
(57) **ABSTRACT**

An artificial disk replacement device includes opposing plate members with a pivoting assembly disposed therebetween. The pivoting assembly allows the plate members to pivot relative to each other in a first direction, but inhibit movement of the plate members in a second direction. The plate members may be installed prior to installing the pivoting assembly. An installation tool for use with the artificial disk replacement device is also disclosed.



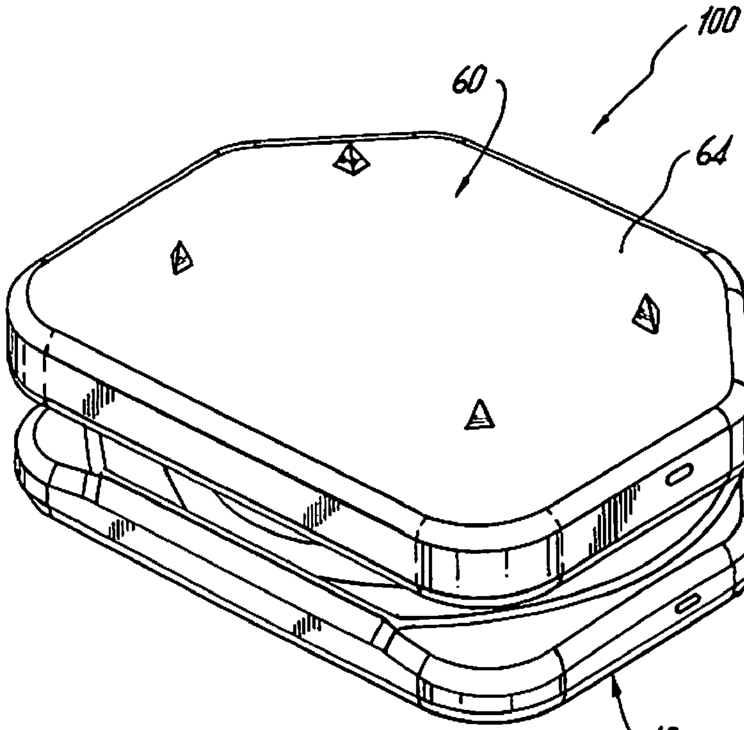


Fig. 1

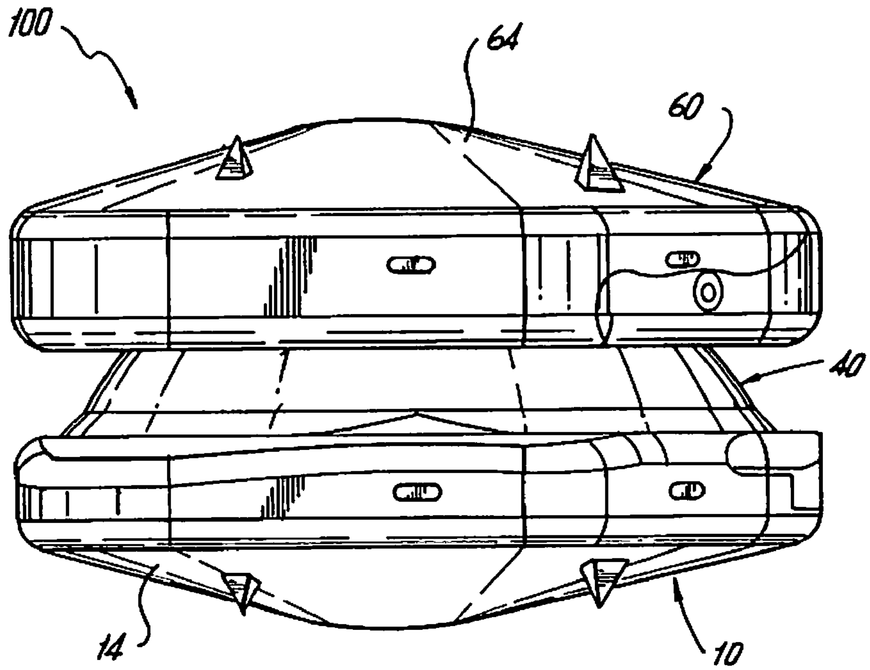
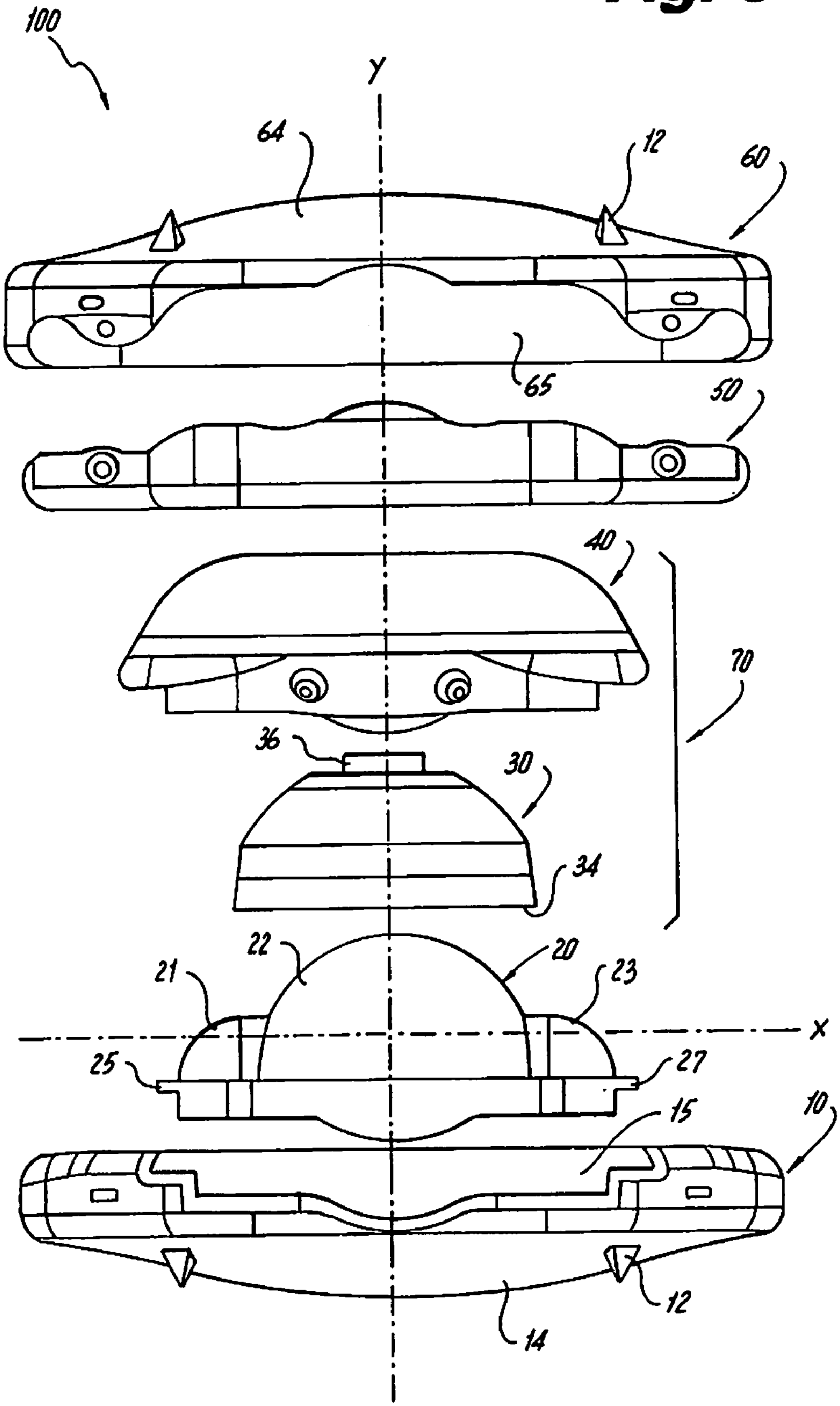


Fig. 2

Fig. 3



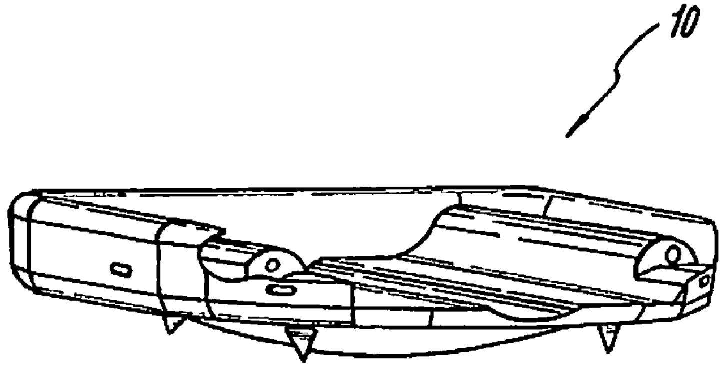


Fig. 4

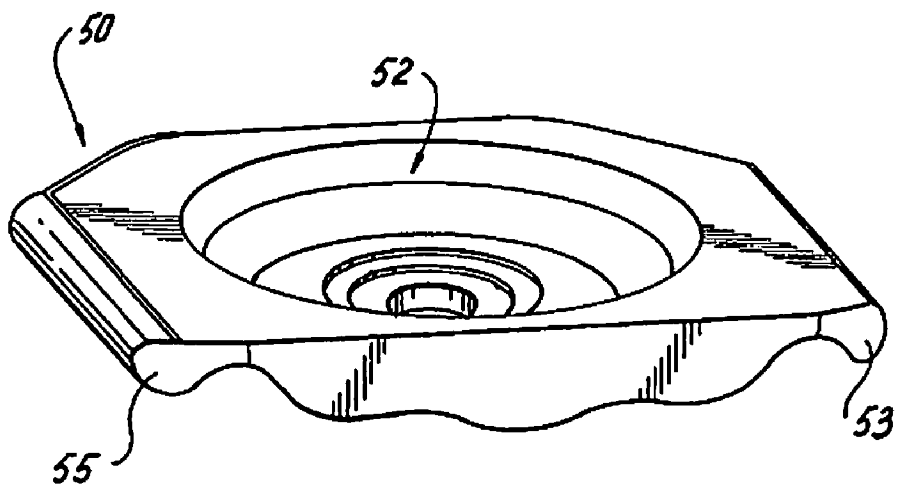


FIg. 5

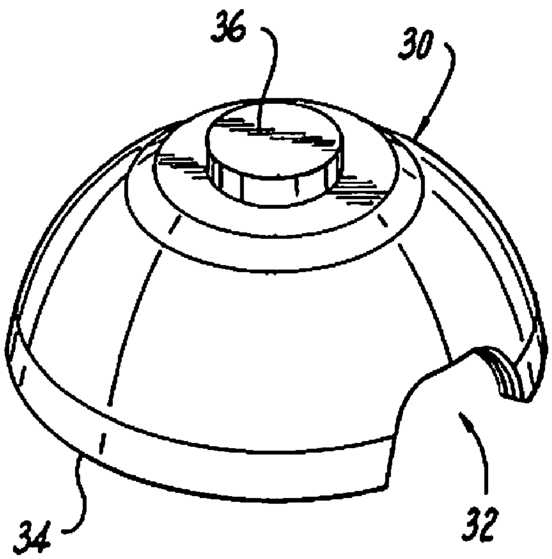


Fig. 6

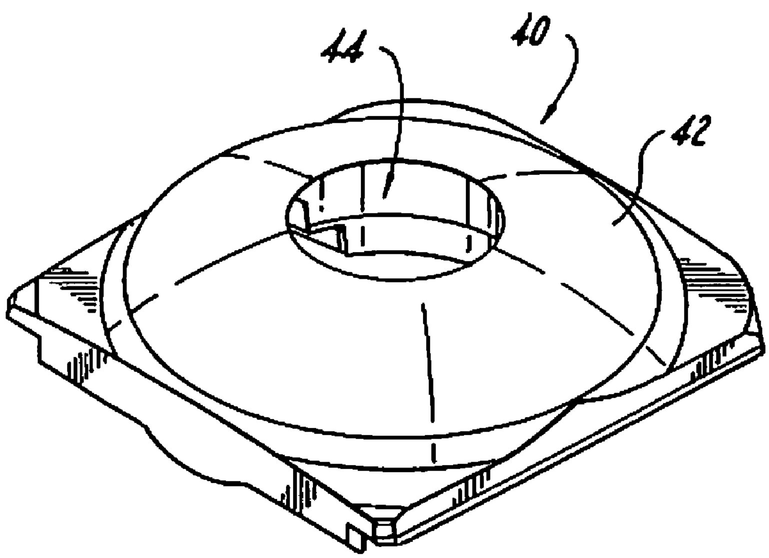


Fig. 7

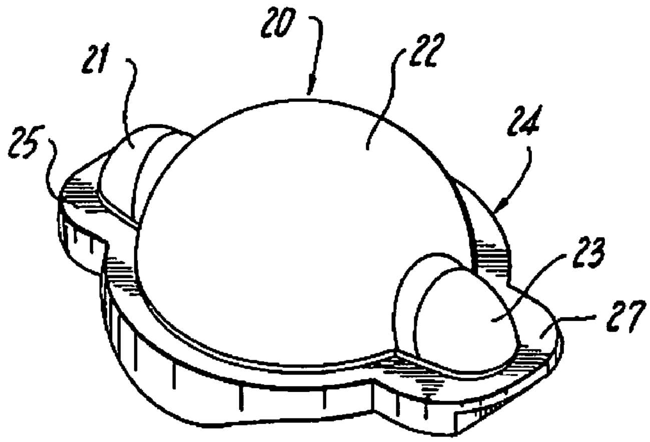


Fig. 8

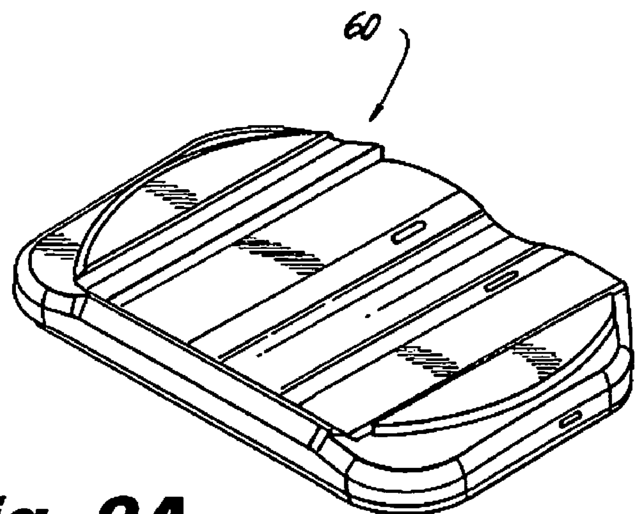


Fig. 9A

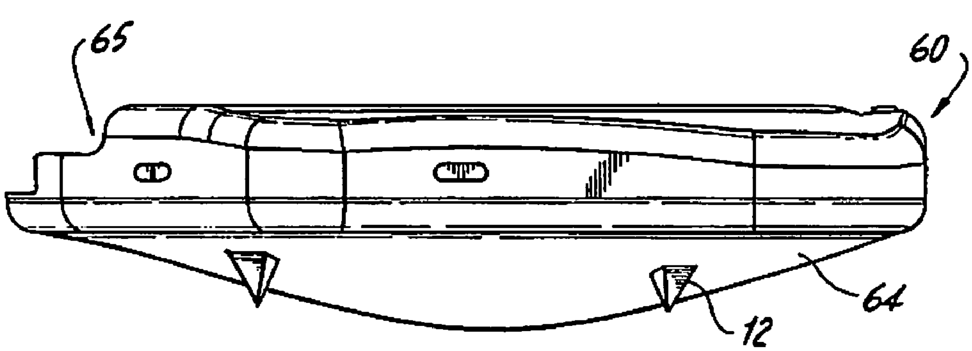


Fig. 9B

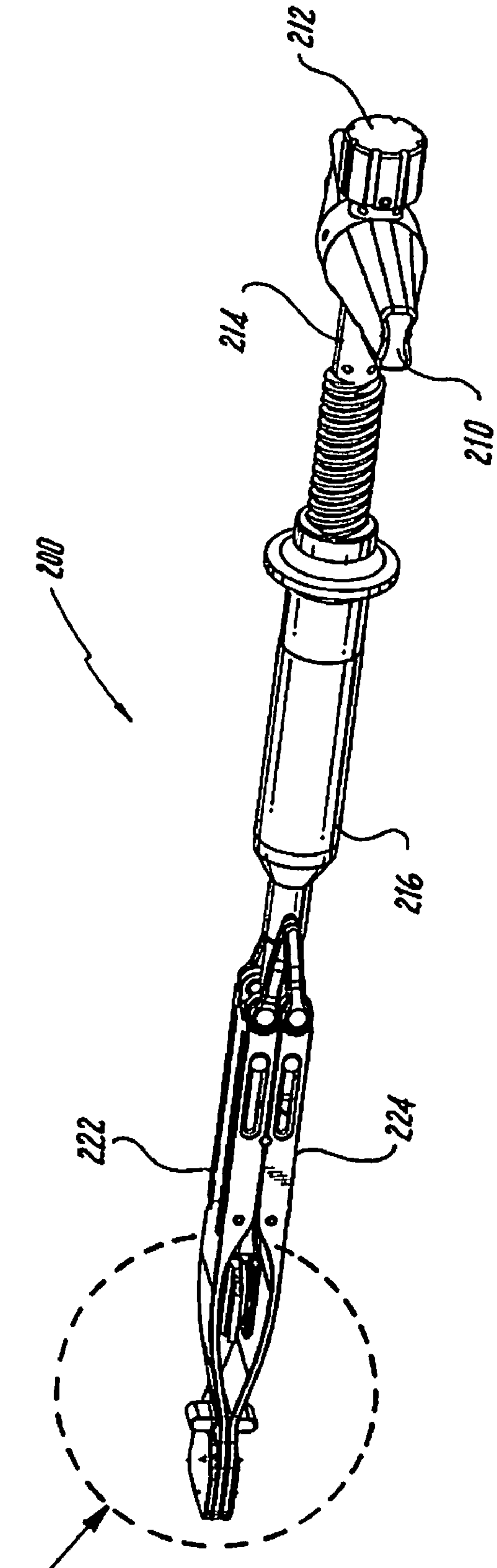


Fig. 10A

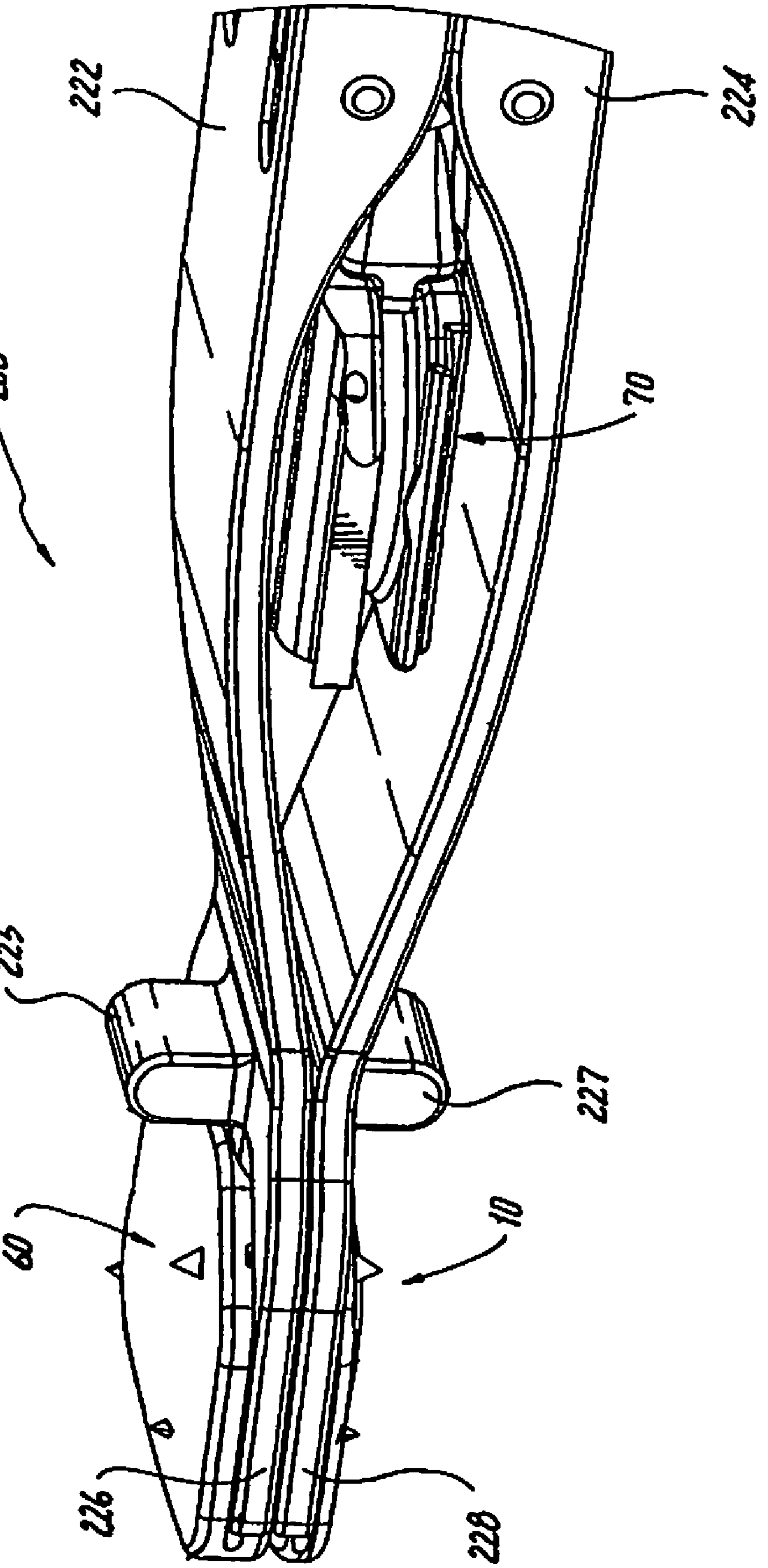


Fig. 10B

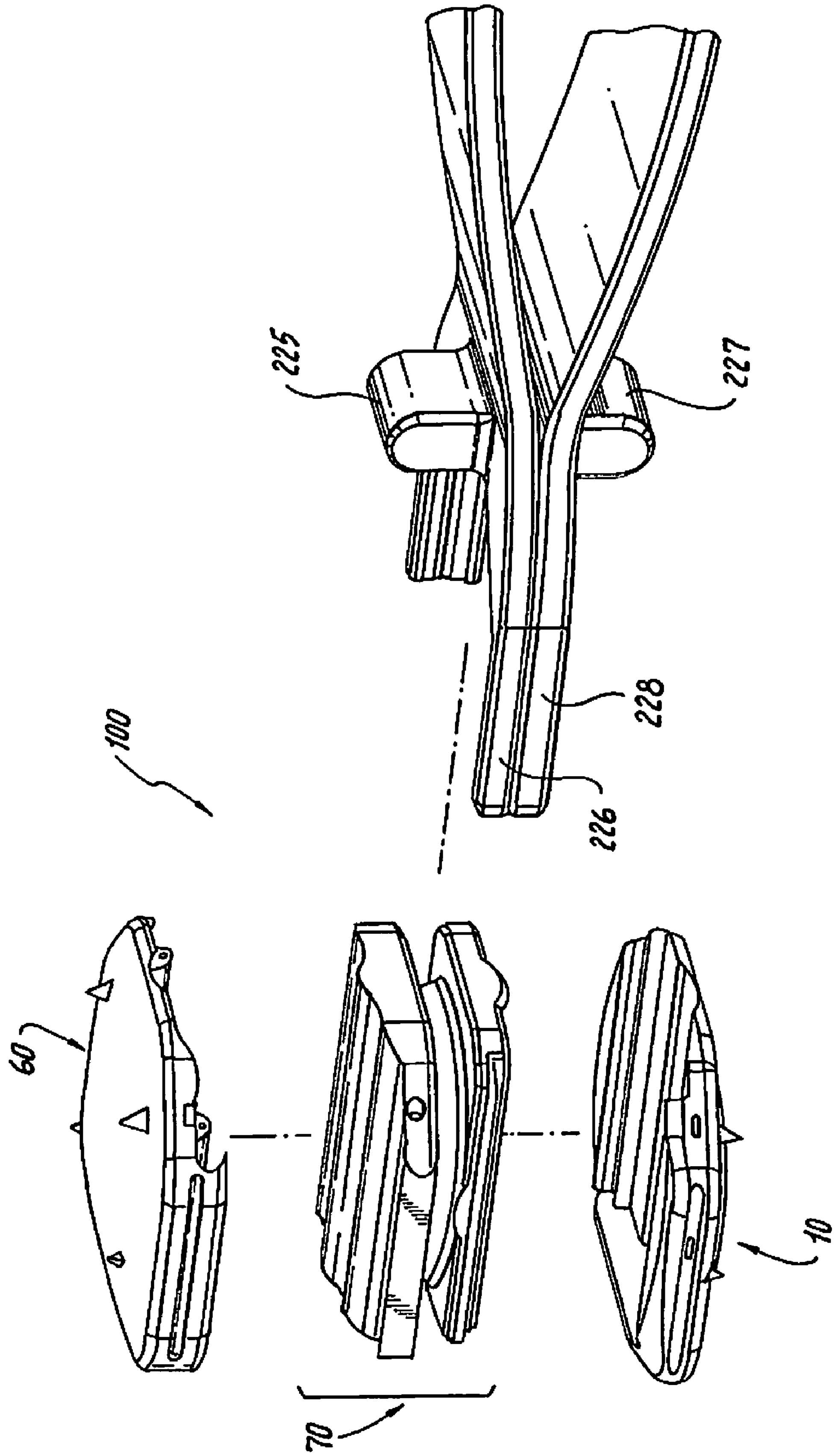


Fig. 10C

ARTIFICIAL DISC REPLACEMENT DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to, and the benefit of, U.S. Provisional Patent Application Ser. No. 61/070,126, filed Mar. 20, 2008, the entire contents of which are hereby incorporated by reference.

BACKGROUND

[0002] 1. Technical Field

[0003] This application relates to a device for use in orthopedic spine surgery. In particular, the present invention relates to an artificial disc replacement device that replaces a damaged or diseased intervertebral disc.

[0004] 2. Background of Related Art

[0005] The human spine is composed of thirty-three vertebrae at birth and twenty-four as a mature adult. Between each pair of vertebrae is an intervertebral disc, which maintains the space between adjacent vertebrae and acts as a cushion under compressive, bending, and rotational loads and motions. A healthy intervertebral disc has a great deal of water in the nucleus pulposus, which is the center portion of the disc. The water content gives the nucleus a spongy quality and allows it to absorb spinal stress. Excessive pressure or injuries to the nucleus can cause injury to the annulus, which is the outer ring that holds the disc together. Generally, the annulus is the first portion of the disc that experiences injury. These injuries are typically in the form of small tears. These tears heal by scar tissue. The scar tissue is not as strong as normal annulus tissue. Over time, as more scar tissue forms, the annulus becomes weaker. Eventually this can lead to damage of the nucleus pulposus. The nucleus begins to lose its water content due to the damage; it begins to dry up. Because of water loss, the discs lose some of their ability to act as a cushion. This can lead to even more stress on the annulus and still more tears as the cycle repeats. As the nucleus loses its water content, it collapses, allowing the vertebrae above and below the disc space to move closer to one another. This results in a narrowing of the disc space between the two vertebrae. As this shift occurs, the facet joints located at the back of the spine are forced to shift. This shift changes the way the facet joints work together and can cause problems in the facet joints as well.

[0006] When a disc or vertebrae is damaged due to disease or injury, standard practice is to remove all or part of the intervertebral disc, insert a natural or artificial disc spacer, and construct an artificial structure to hold the affected vertebrae in place to achieve a spinal fusion. In doing so, while the diseased or injured anatomy is addressed and the accompanying pain is significantly reduced, the natural biomechanics of the spine are affected in a unique and unpredictable way. More often than not, the patient will develop complicating spinal issues in the future.

[0007] To that end, there is an overall need to treat the disease or injury while maintaining or preserving the natural spine biomechanics. Normal spine anatomy, specifically intervertebral disc anatomy, allows one vertebra to rotate with respect to its adjacent vertebra about all three axes. Similarly, the intervertebral disc also allows adjacent vertebra to translate along all three axes with respect to one another.

[0008] For the above stated reasons, a need exits for an implantable device which may be used as an artificial disc replacement thereby maintaining disc height and motion. More specifically, the motion maintained must address at least the principle motions of rotation about all three axes. The device must also have a means to inhibit or minimize expulsion of the device from its installed location. The implantable device has an additional need of having a prolonged life span in the body that can withstand early implantation, as is often indicated for younger patients. In addition, the implantable device will have a limited amount of particulate debris so as to reduce complications over the useful life of the device.

SUMMARY

[0009] The present disclosure relates to an artificial disk replacement device or disk. The disk includes opposing plate members with a pivoting assembly disposed therebetween. The pivoting assembly may include a support member and a cup. Additionally, the pivoting assembly may include an engagement member. The pivoting assembly is configured for slidable insertion into openings in the first and second plate members. Each plate member may include one or more teeth for securely engaging endplates of adjacent vertebral bodies.

[0010] The pivoting assembly is adapted for allowing relative movement of the first and second plate members with respect to each other in a first direction, while inhibiting relative movement of the first and second plate members in a second direction. The first direction is transverse or orthogonal with respect to the first direction.

[0011] One embodiment of the disk is adapted for use in lumbar procedures. In this embodiment, the support member includes a hemispherical dome with opposing arms that lie in the first direction. The cup has opposing openings adapted for pivotally engaging the arms of the support member. As such, the cup moves symmetrically about the axis extending through the arms and the openings.

[0012] In an alternate embodiment, the disk is adapted for use in cervical procedures. In this embodiment, the dome of the support member is eccentric or asymmetric with respect to the axis extending through the opposing arms. Thus, when the cup pivots about the axis extending through the arms, the asymmetric configuration of the dome interacts with the cup causing the plate members of the disk to pivot and lift (i.e. increase the distance between the plate members).

[0013] An installation tool and a method of installing the disk are also disclosed. The installation tool has a handle, a knob, and a shaft. At the distal end of the installation tool, a pair of opposing jaws or blade portions exists. The blade portions releasably engage the first and second plate members. An attachment portion is located at a distal end of the shaft for releasably engaging the pivoting assembly of the disk. With the first and second plate members attached to the blade portions and the pivoting assembly coupled to the attachment portion, the physician inserts the distal end of the installation tool between the adjacent vertebral bodies. Rotating the handle in one direction causes the shaft to translate distally through the installation tool. As the pivoting assembly moves distally, it engages inner surfaces of the blade portions urging them apart. Once the pivoting assembly is fully translated in the distal direction, the support member and the engagement member slide into openings in the respective first and second plate members, thereby securing the pivoting assembly between the first and second plate members and completing the assembly of the disk. Since the

distraction of the adjacent vertebral bodies is performed prior to installing the pivoting assembly, this reduces the installation force necessary to install the disk. Thus, the potential trauma to the patient is reduced and any possibility of deforming the disk is also reduced.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The above and other aspects, features, and advantages of the present disclosure will become more apparent in light of the following detailed description when taken in conjunction with the accompanying drawings in which:

[0015] FIG. **1** is a perspective view of the presently disclosed artificial disc replacement device;

[0016] FIG. **2** is an end view of the artificial disc replacement device of FIG. **1**;

[0017] FIG. **3** is an exploded side view, with parts separated, of the artificial disc replacement device of FIG. **1**;

[0018] FIG. **4** is a perspective view of a first plate member of the artificial disc replacement device of FIG. **1**;

[0019] FIG. **5** is a perspective view of an insert of the artificial disc replacement device of FIG. **1**;

[0020] FIG. **6** is a perspective view of a cup of the artificial disc replacement device of FIG. **1**;

[0021] FIG. **7** is a perspective view of an articulating insert of the artificial disc replacement device of FIG. **1**;

[0022] FIG. **8** is a perspective view of a support member of the artificial disc replacement device of FIG. **1**;

[0023] FIG. **9**A is a perspective view of a second plate member of the artificial disc replacement device of FIG. **1**;

[0024] FIG. **9**B is an end view of the second plate member of the artificial disc replacement device of FIG. **1**;

[0025] FIG. **10**A is a perspective view of a distraction instrument coupled with the artificial disc replacement device of FIG. **1**;

[0026] FIG. **10**B is an enlarged perspective view of a distal end of the distraction instrument of FIG. **10**A with the artificial disc replacement device of FIG. **1** coupled to a jaw assembly of the distraction instrument; and

[0027] FIG. **10**C is an enlarged view of the distal end of FIG. **10**B with the jaws in a closed position and an exploded perspective view of the artificial disc replacement device of FIG. **1**.

DETAILED DESCRIPTION OF EMBODIMENTS

[0028] Particular embodiments of the present disclosure will be described herein with reference to the accompanying drawings. In the drawings and in the description that follows, the term "proximal," will refer to the end of a device or system that is closest to the operator, while the term "distal" will refer to the end of the device or system that is farthest from the operator. In addition, the term "cephalad" is used in this application to indicate a direction toward a patient's head, whereas the term "caudad" indicates a direction toward the patient's feet. Further still, for the purposes of this application, the term "medial" indicates a direction toward the middle of the body of the patient, whilst the term "lateral" indicates a direction toward a side of the body of the patient (i.e., away from the middle of the body of the patient). The term "posterior" indicates a direction toward the patient's back, and the term "anterior" indicates a direction toward the patient's front.

[0029] Referring now to the drawings, in which like reference numerals identify identical or substantially similar parts throughout the several views, FIGS. **1-3** illustrate an embodiment of the presently disclosed artificial disk replacement device or disk **100**. Disk **100** includes a first plate member **10**, a support member **20**, a cup **30**, a coupling member **40**, an engaging member **50**, and a second plate member **60**.

[0030] Each of the first and second plate members **10**, **60** have a superior surface adapted for engaging an endplate of a vertebral body. One or more teeth **12** are disposed on the superior surface **14**, **64** of the first and second plate members **10**, **60**. Each tooth **12** has a generally pyramidal configuration for securely engaging the endplate of the respective vertebral body. It is contemplated that each tooth **12** may have other configurations that are configured and dimensioned for securely engaging the vertebral endplate. The superior surfaces **14**, **64** are curvate surfaces, although other configurations are contemplated. In addition, each plate member **10**, **60** includes an opening **15**, **65** along one side thereof.

[0031] With reference to FIGS. **3** and **8**, the support member **20** includes a dome **22** disposed on a base portion **24**. The dome **22** has a generally spherical shape. The support member **20** includes opposing arms **21**, **23** that are positioned on wing portions **25**, **27** of the base portion **24**. The wing portions **25**, **27** are adapted for slidable engagement with the opening **15** of the first plate member **10** (FIG. **3**). After the support member **20** is inserted into the opening **15**, the first plate member **10** and the support member **20** are securely affixed to one another. Alternatively, the dome **22** may have an alternate configuration such that it is somewhat asymmetrical or eccentric.

[0032] Referring now to FIGS. **3** and **6**, the cup **30** is a generally hemispherical structure with a pair of opposed openings. Although only one opening **32** is shown, the opposing opening is substantially similar to the opening **32**. Each opening **32** is configured and dimensioned for slidable engagement with the arms **21**, **23**. The cup **30** has a configuration that is complementary to that of the dome **22**. In one embodiment, the dome **22** is generally hemispherical and the cup **30** has a complementary configuration. As such, the cup **30** nests atop the support member **20** such that the openings **32** rest atop the arms **21**, **23**. The cup **30** and the dome **22** are configured such that a gap is defined between a bottom lip **34** of the cup **30** and the base portion **24** of the support member **20**. This permits the cup **30** to pivot about an axis X of the disk **100**. An extension **36** is disposed on one end of the cup **30** opposite to the bottom lip **34**.

[0033] The coupling member **40** (FIGS. **3** and **7**) has a curvate upper surface **42** and a central opening **44**. The opening **44** is configured for receiving the extension **36** of the cup **30**. When the coupling member **40** is coupled to the cup **30**, the opening **44** receives the extension **36**.

[0034] The engaging member **50** (FIGS. **3** and **5**) includes a recess **52** and wings **53**, **55**. The wings **53**, **55** are configured for slidably engaging the recess **65** of the second plate member **60**. After sliding the engaging member **50** into the second plate member **60**, the engaging member **50** is securely affixed to the second plate member **60**.

[0035] The disk **100** may be considered as the first and second plate members **10**, **60** having a pivoting assembly **70** (FIG. **3**) disposed therebetween. The pivoting assembly **70** includes the support member **20** and the cup **30**. The pivoting assembly **70** may include the coupling member **40** in one of its embodiments. As assembled, the pivoting assembly **70** permits movement of the first and second plate members **10**, **60** with respect to the axis X (FIG. **3**), while inhibiting movement of the first and second plate members **10**, **60** with respect to axis Y (FIG. **3**). As such, the first and second plate members **10**, **60** are capable of pivoting in a first direction and are inhibited from pivoting in a second direction, wherein the second direction is transverse or orthogonal to the first direction. This arrangement permits a predetermined range of movement of the adjacent vertebral bodies, while simultaneously inhibiting rotational movement of the adjacent vertebral bodies.

[0036] The presently disclosed disk **100** is suitable for use in cervical applications as well as in lumbar applications. When used in cervical applications, the dome **22** of the support member **20** (FIG. **8**) has an eccentric or asymmetrical configuration. Coupling this with the cup **30** having a complementary configuration, allows the disk to pivot about the axis X, and provides a desired amount of lift. As used herein, the term lift refers to displacement of the first and second plate members **10**, **60** with respect to each other along the axis Y. As such, pivoting the first and second plate members **10**, **60** about the axis X, also causes the first and second plate members **10**, **60** to move away from each other along the axis Y, thereby defining the lift of the disk **100**. In lumbar applications, the dome **22** of the support member **20** is generally hemispherical and the cup has a complementary configuration. This arrangement allows the first and second plate members **10**, **60** to pivot about the axis X without the first and second plate members **10**, **60** moving relative to each other along the axis Y.

[0037] An installation tool **200** is shown in FIGS. **10**A and **10**B. The installation tool **200** includes a handle **210** and a knob **212**. A partially threaded shaft **214** is threadably engaged with a housing **216**. The threaded engagement between the shaft **214** and the housing **216** allows the shaft **214** to move longitudinally relative to the housing **216** in response to rotation of the handle **210**. At the distal end of the shaft **214** is an attachment portion **218** that releasably couples the pivoting assembly **70** to the installation tool **200**. The installation tool **200** also includes opposing arms **222**, **224** that have blade or jaw portions **226**, **228** extending distally therefrom. Each blade portion **226**, **228** is generally U-shaped and is further configured and adapted for releasably engaging respective first and second plate members **10**, **60**. Each blade portion **226**, **228** includes respective stop portions **225**, **227** that limit the insertion depth of the blade portions **226**, **228** between the adjacent vertebral bodies. Rotating the handle **210** in a first direction causes distal translation of the shaft **214** relative to the housing **216**. As the shaft **214** advances distally, the pivoting assembly **70** engages inner surfaces of the blade portions **226**, **228** urging them apart. When the pivoting assembly **70** is completely disposed between the first and second plate members **10**, **60**, the shaft **214** is at its distalmost position.

[0038] The disk **100** is installed between adjacent vertebral bodies using the installation tool **200**. With the first and second plate members **10**, **60** attached to respective blade portions **228**, **226** and the pivoting assembly **70** releasably coupled to the attachment portion **218**, the physician inserts the distal end of the installation tool **200** between the adjacent vertebral bodies until the stop portions **225**, **227** engage the exterior of the adjacent vertebral bodies indicating that the maximum insertion depth has been achieved. Subsequently, handle **210** is rotated in a first direction and advances shaft **214** distally, thereby advancing the pivoting assembly **70** distally. During the distal movement of the pivoting assembly **70**, the engaging member **50** and the support member **20** slidably engage inner surfaces of the blade portions **226**, **228** urging them apart and distracting the adjacent vertebral bodies. Continued distal translation of the pivoting assembly **70** positions the pivoting assembly **70** between the first and second plate members **10**, **60** such that the support member **20** and the engaging member **50** are attached to the first and second plate members **10**, **60**. Once the pivoting assembly **70** is attached to the first and second plate members **10**, **60**, the knob **212** is rotated so that the pivoting assembly **70** separates from the attachment portion **218** of the shaft **214**. Subsequently, the installation tool **200** is removed. Since the first and second plate members **10**, **60** are installed prior to any distraction of the adjacent vertebral bodies, inserting the pivoting assembly **70** between the first and second plate members **10**, **60** requires a minimal amount of insertion force. As such, this reduces trauma to the patient and reduces deformation of the disk **100**.

[0039] While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Thus the scope of the embodiments should be determined by the appended claims and their legal equivalents, rather than by the examples given.

What is claimed is:

1. An intervertebral implant comprising:

a first plate member;

a second plate member; and

a coupling disposed between the first plate member and the second plate member, the coupling adapted to allow the first plate member to pivot relative to the second plate member about a first axis extending through the coupling and inhibiting the first end plate from rotating relative to the second plate member about a second axis that is transverse to the first axis.

2. The intervertebral implant of claim **1**, wherein the first plate member and the second plate member are adapted for engaging opposing vertebral endplates.

3. The intervertebral implant of claim **1**, wherein the coupling includes:

a support member having a substantially hemispherical dome and a pair of opposing arms extending therefrom, and

a cup adapted for operative engagement with the support member, the cup having a complementary substantially hemispherical configuration and a pair of opposed openings configured to slidably engage the pair of opposing arms such that the cup is movable relative to the support member in a first direction and is inhibited from moving relative to the support member in a second direction that is orthogonal to the first direction.

4. The intervertebral implant of claim **1**, wherein the coupling includes:

a support member having a substantially asymmetric dome and a pair of opposing arms extending therefrom, and

a cup adapted for operative engagement with the support member, the cup having a complementary substantially asymmetric configuration and a pair of opposed openings configured to slidably engage the pair of opposing arms such that the cup is movable relative to the support member in a first direction and is inhibited from moving relative to the support member in a second direction that is orthogonal to the first direction

5. The intervertebral implant of claim **1**, further including at least one engaging member for attaching the coupling to at least one of the first and second plate members.

6. The intervertebral implant of claim **2**, wherein the first and second plate members include a plurality of extensions, each extension adapted to frictionally engage the endplate of a vertebral body.

7. A method of installing an intervertebral implant comprising the steps of:

providing a distraction device having a jaw assembly with a pair of movable blades;

attaching a first plate member to one of the movable blades and a second plate member to the other of the movable blades;

inserting the first plate member and the second plate member attached to the distraction device between adjacent vertebral bodies;

operating the distraction device to spread apart the adjacent vertebral bodies with the first plate member in contact with one vertebral body and the second plate member in contact with the other vertebral body;

inserting a coupling into a space between the first plate member and the second plate member;

forming the intervertebral implant by securing the coupling to the first end plate and the second end plate; and

removing the distraction device such that the first plate member and the second plate member engage opposing sides of the coupling and the coupling.

8. The method of claim **7**, wherein the step of inserting the coupling includes the coupling having a support member operably coupled to a cup such that the cup is movable relative to the support member in a first direction and inhibited from moving relative to the support member in a second direction.

9. The method of claim **7**, wherein the step of inserting the coupling further includes the support member having a substantially hemispherical surface with a pair of opposing arms extending therefrom and the cup including a complementary configuration with a pair of opposed openings that are adapted for rotatably engaging the arms.

10. The method of claim **7**, wherein the step of inserting the coupling further includes the support member having a substantially asymmetric surface with a pair of opposing arms extending therefrom and the cup including a complementary configuration with a pair of opposed openings that are adapted for rotatably engaging the arms

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