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(54) **METHOD OF USING SPINE STABILIZATION SYSTEM WITH DYNAMIC SCREW**

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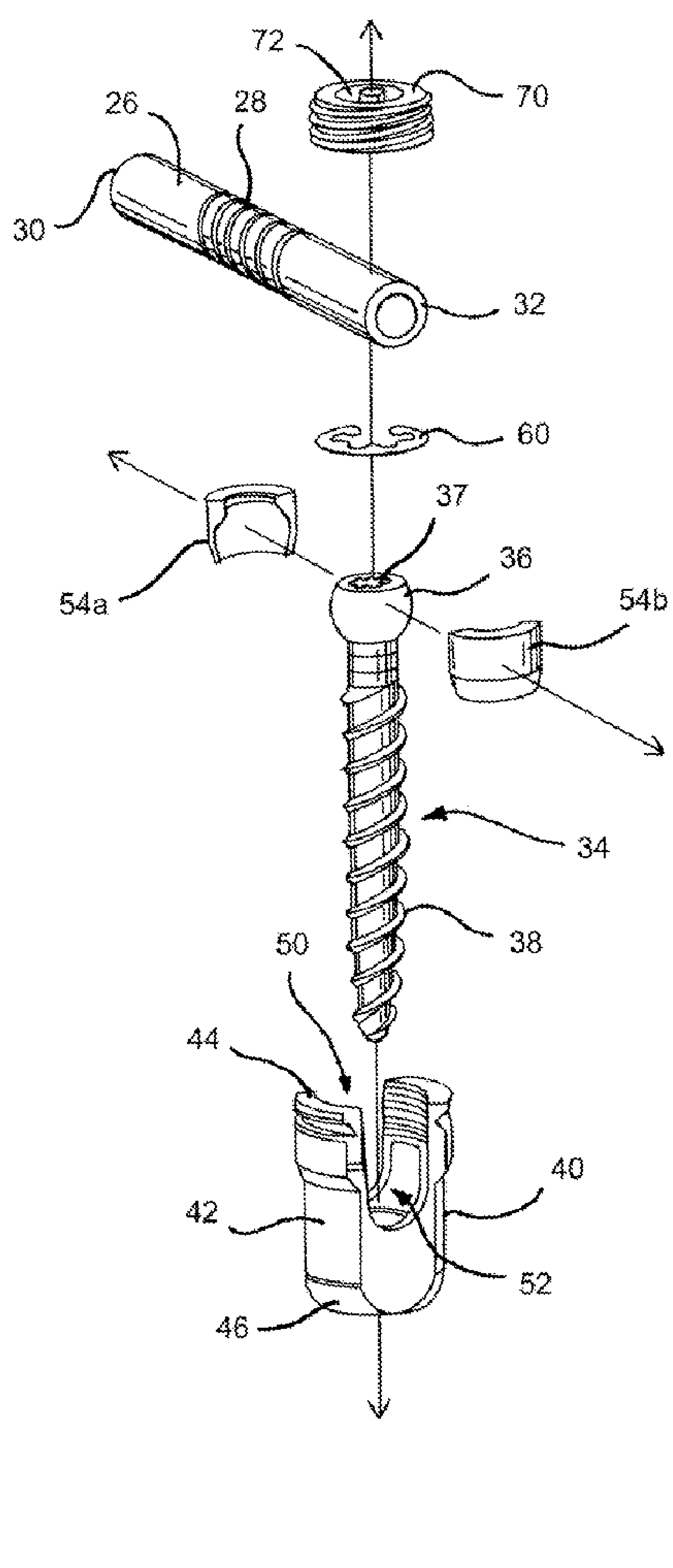
USPC **606/279**

(57) **ABSTRACT**

A method of using a spine stabilization system in one embodiment includes inserting a bone fastener shank through a receiver structure cavity and then through a distal opening of the receiver member, positioning a head of the fastener against a bearing surface of the receiver structure, positioning a bearing member on an upper portion of the head, positioning a first pivot bearing portion of a pivot member above the positioned bearing member, positioning a pivot portion of a connector assembly on the positioned first pivot bearing portion, positioning a second pivot bearing portion of the pivot member on an upper portion of the pivot portion, and threading a fixation screw into a threaded portion of the receiver structure, thereby (i) causing the pivot member to clamp the pivot portion, and (ii) clamping the head of the screw between the first bearing and the bearing surface.



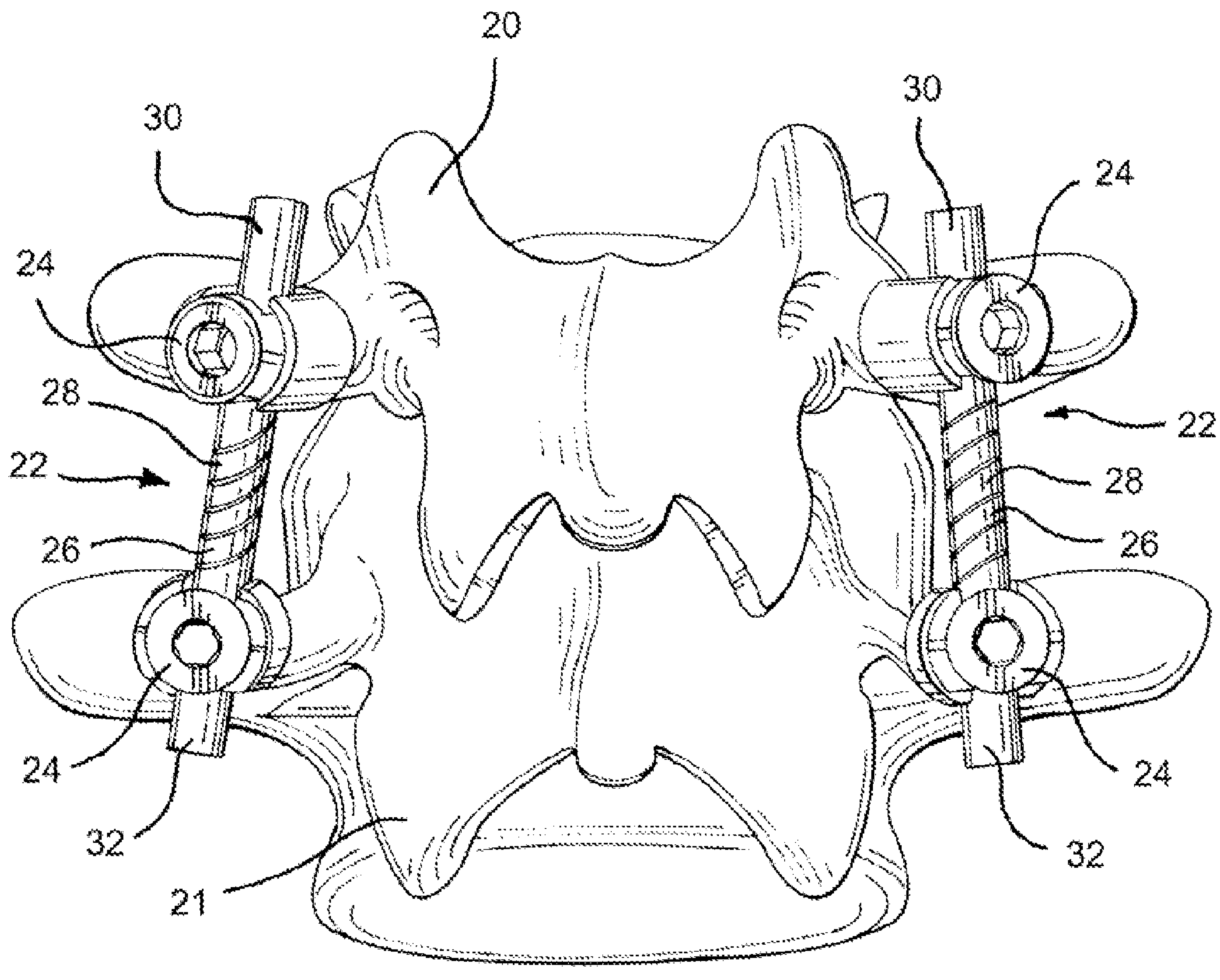


FIG. 1

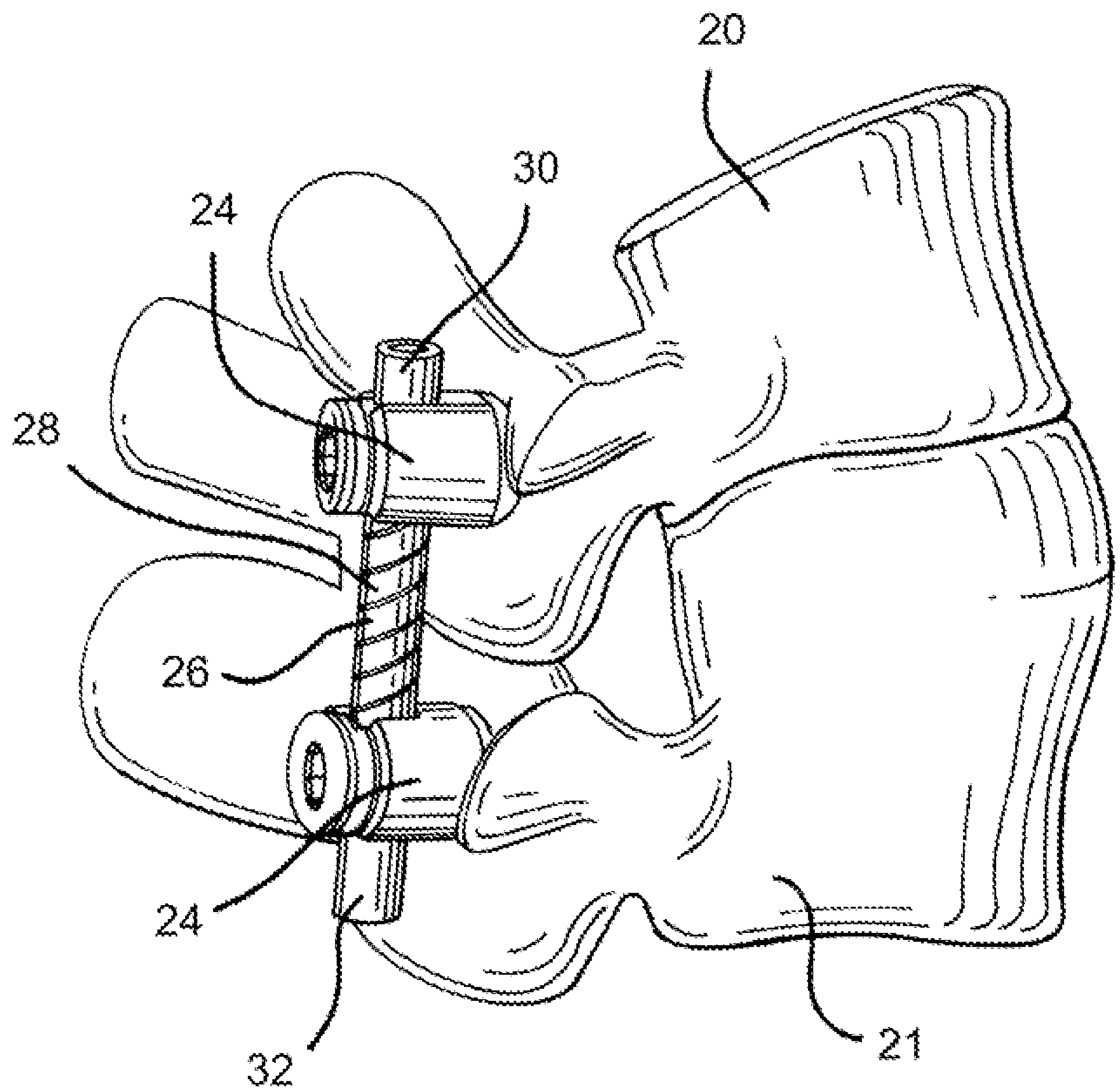


FIG. 2

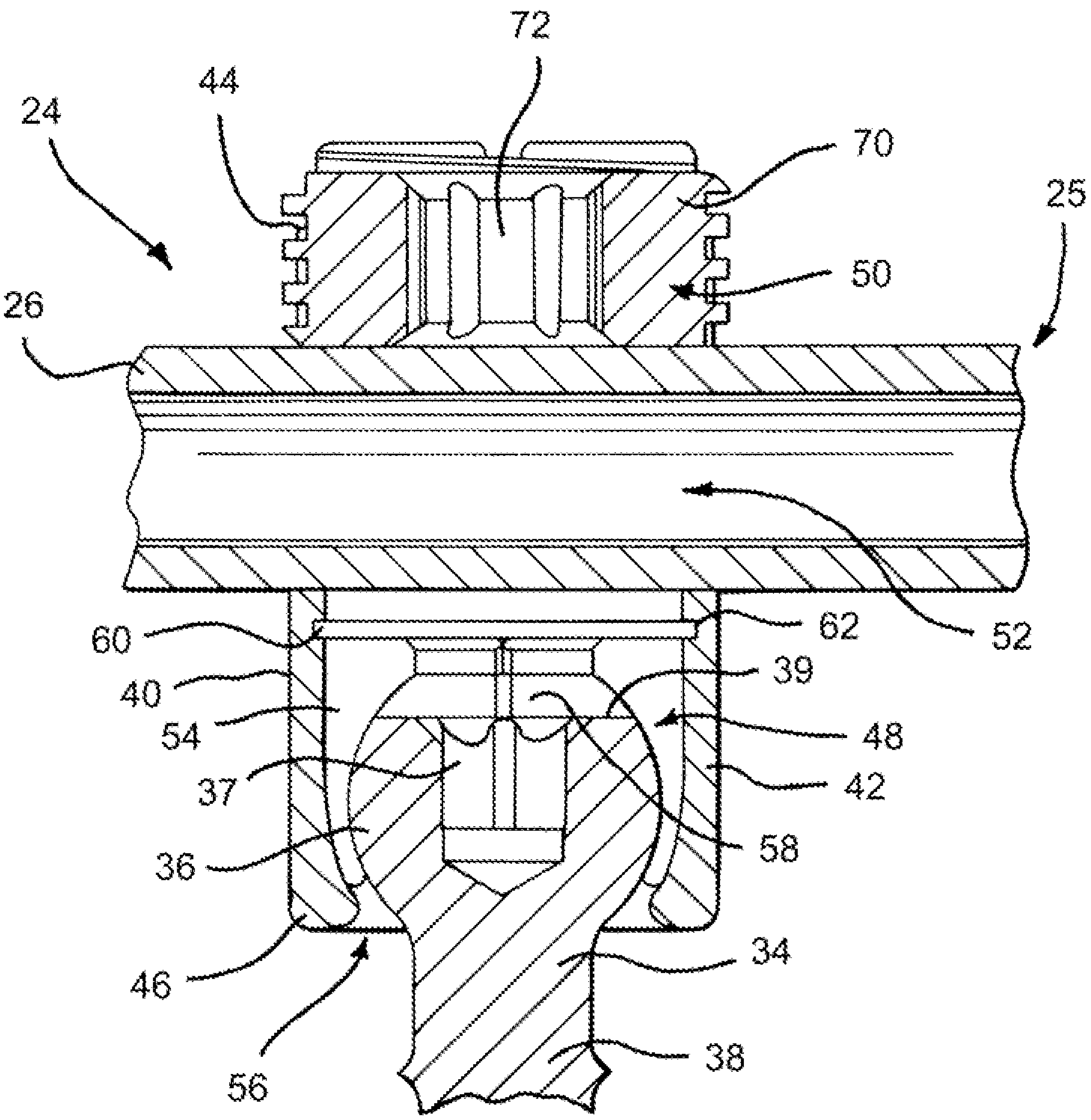


FIG. 3A

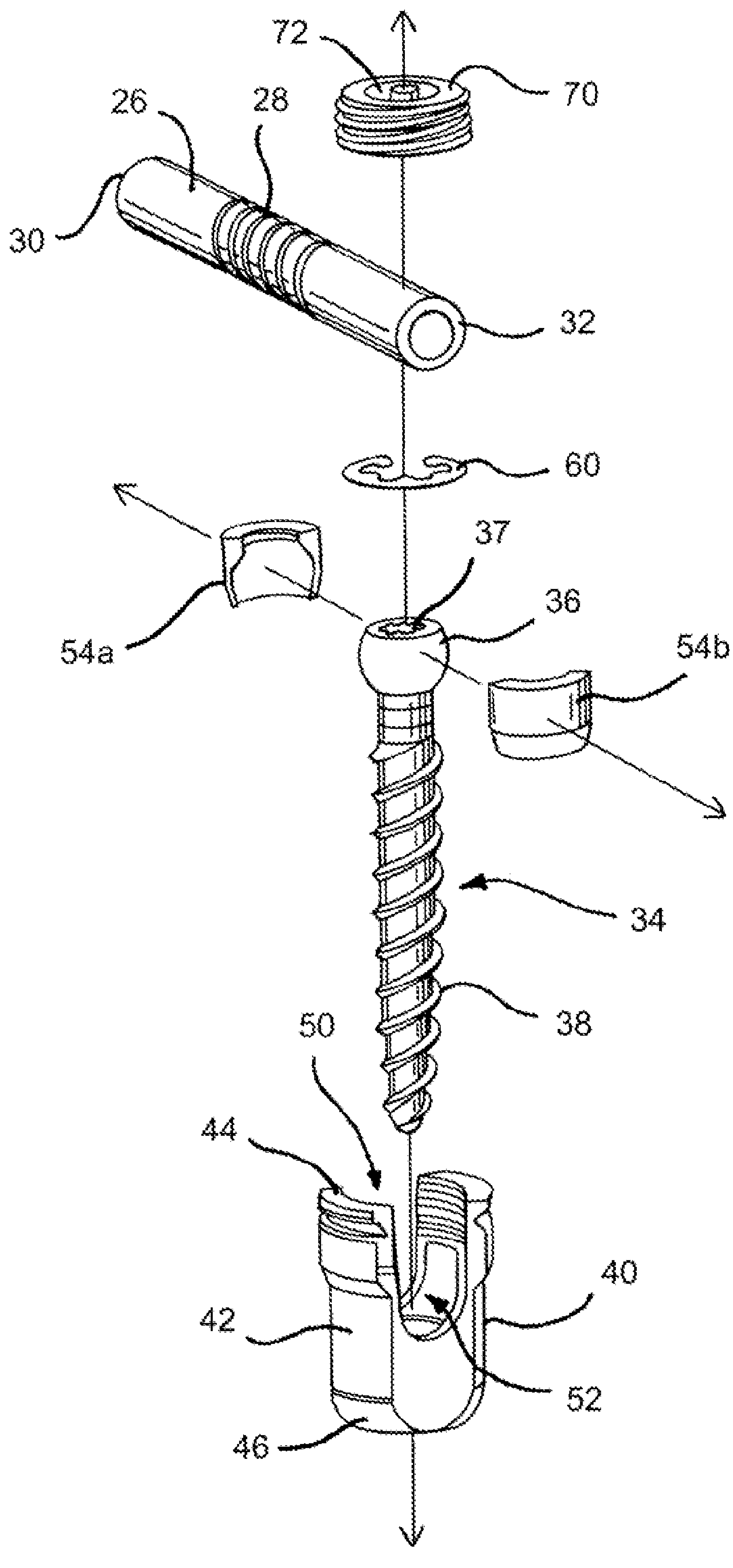


FIG. 3B

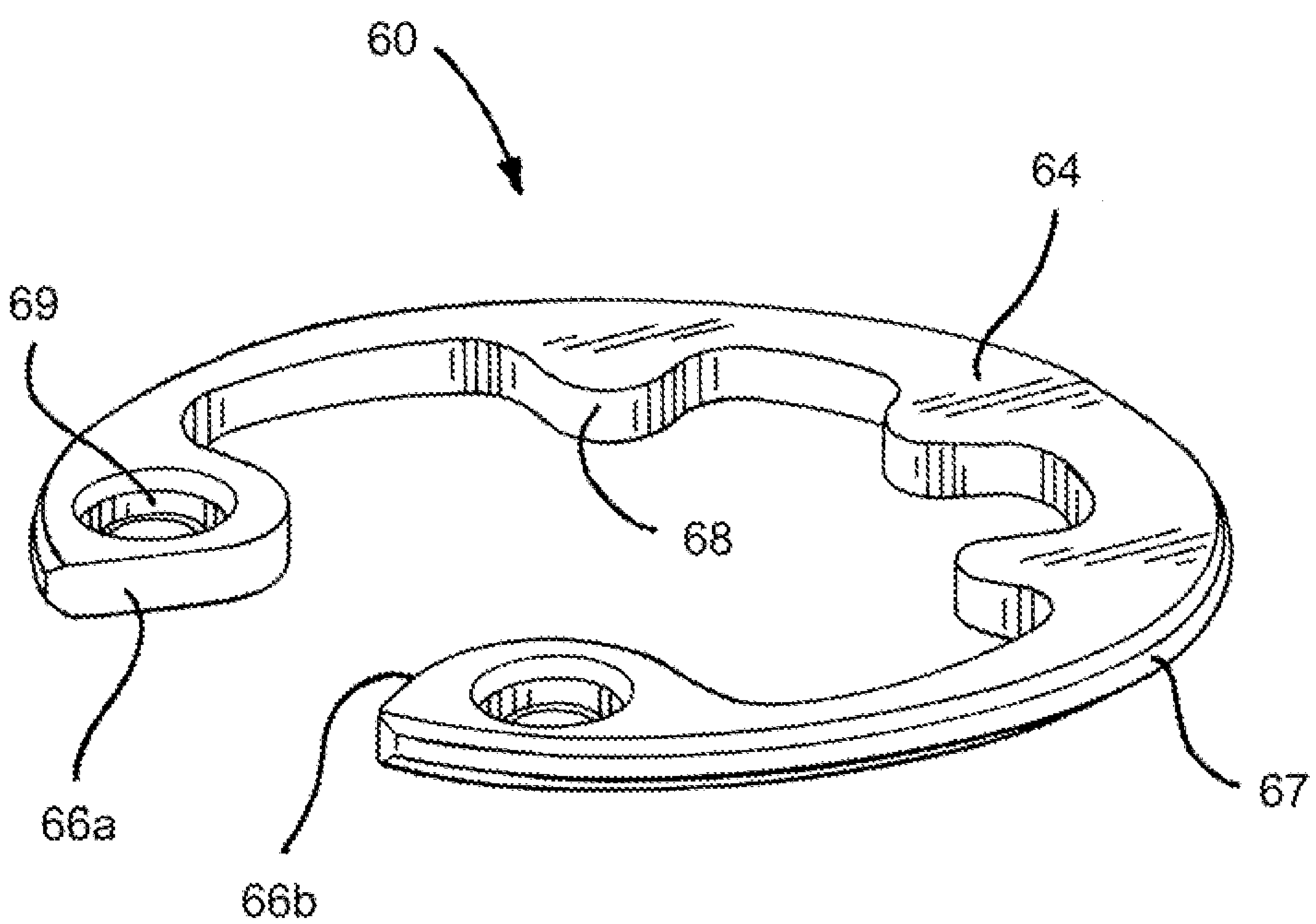


FIG. 3C

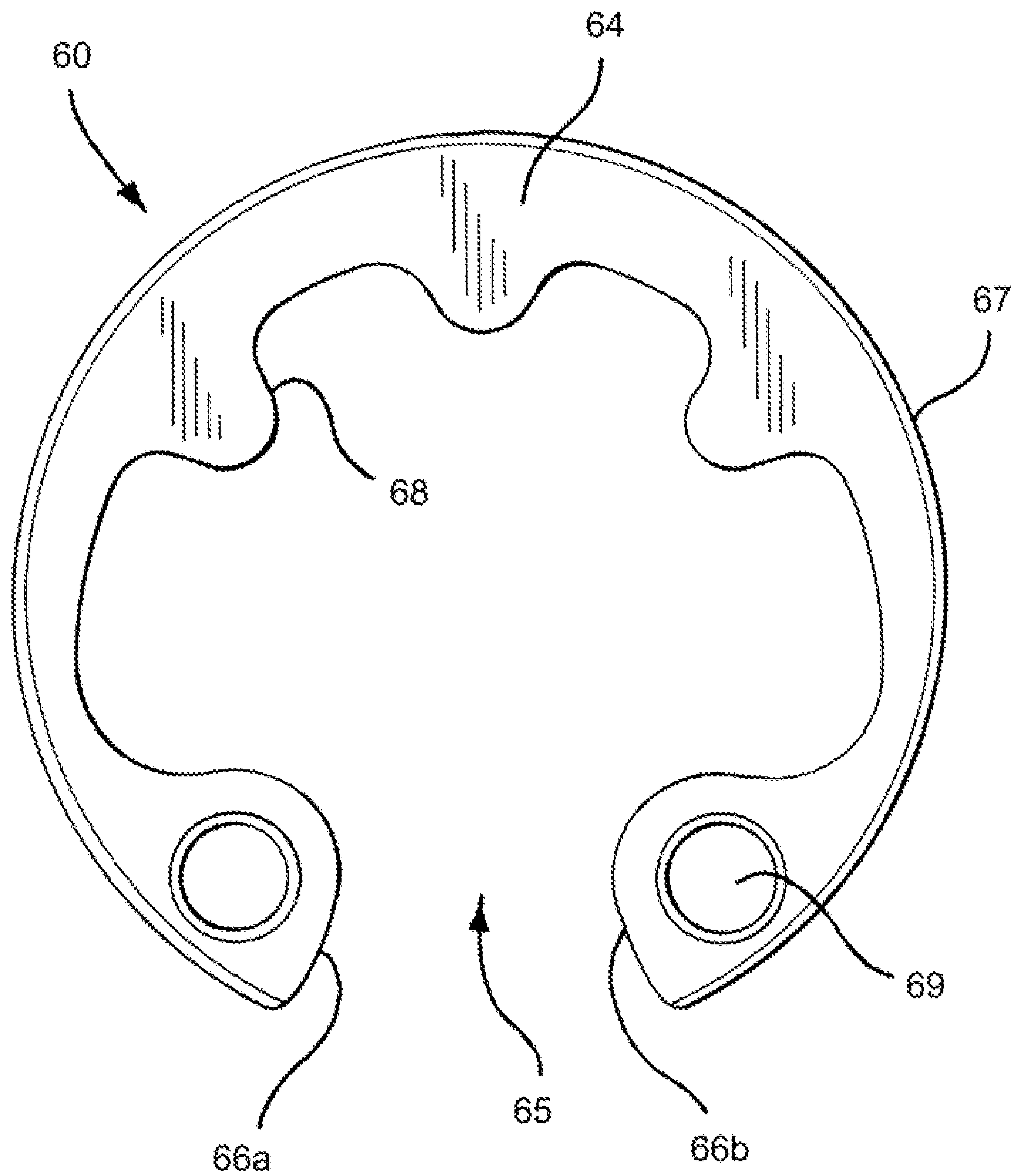


FIG. 3D

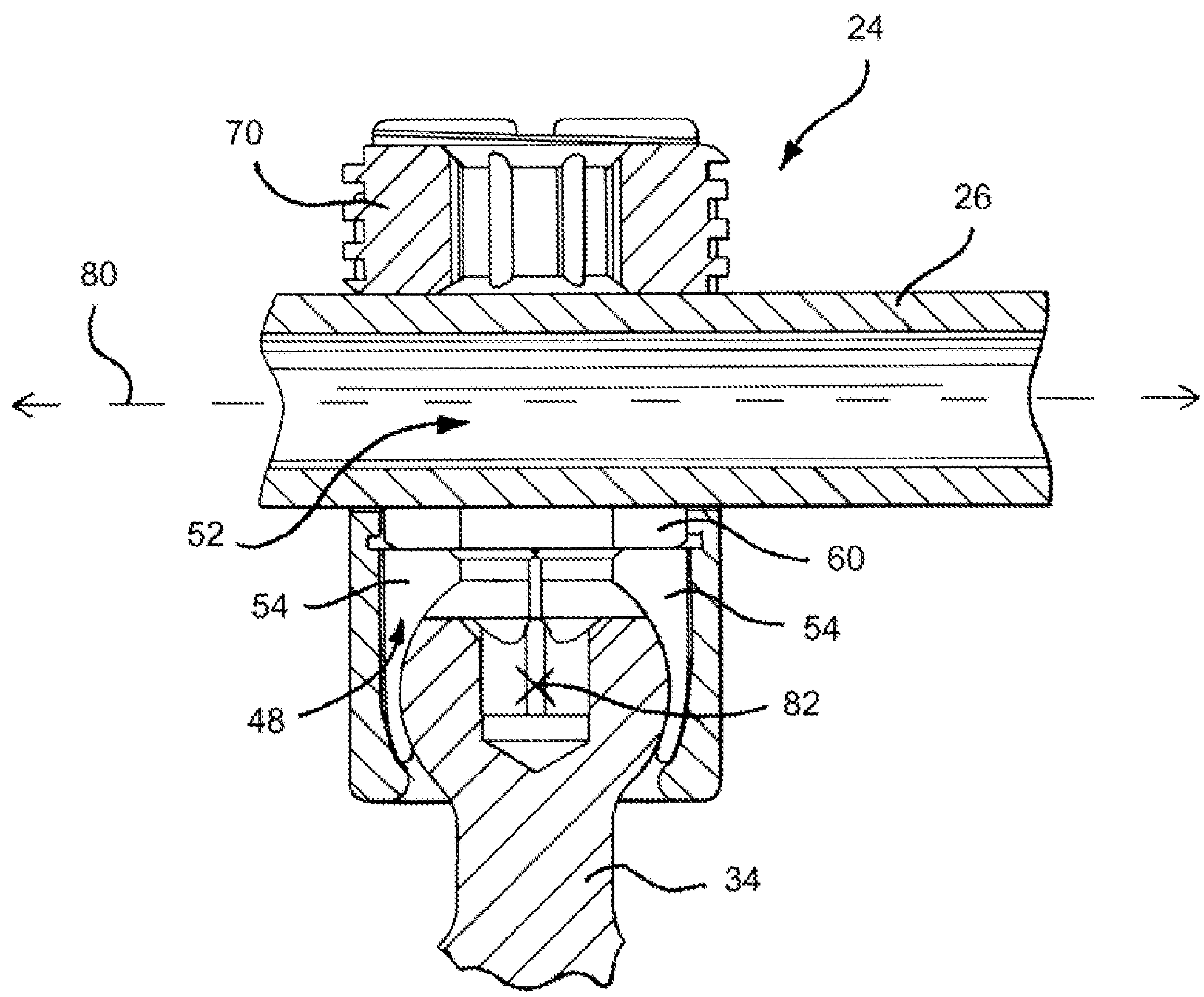


FIG. 4

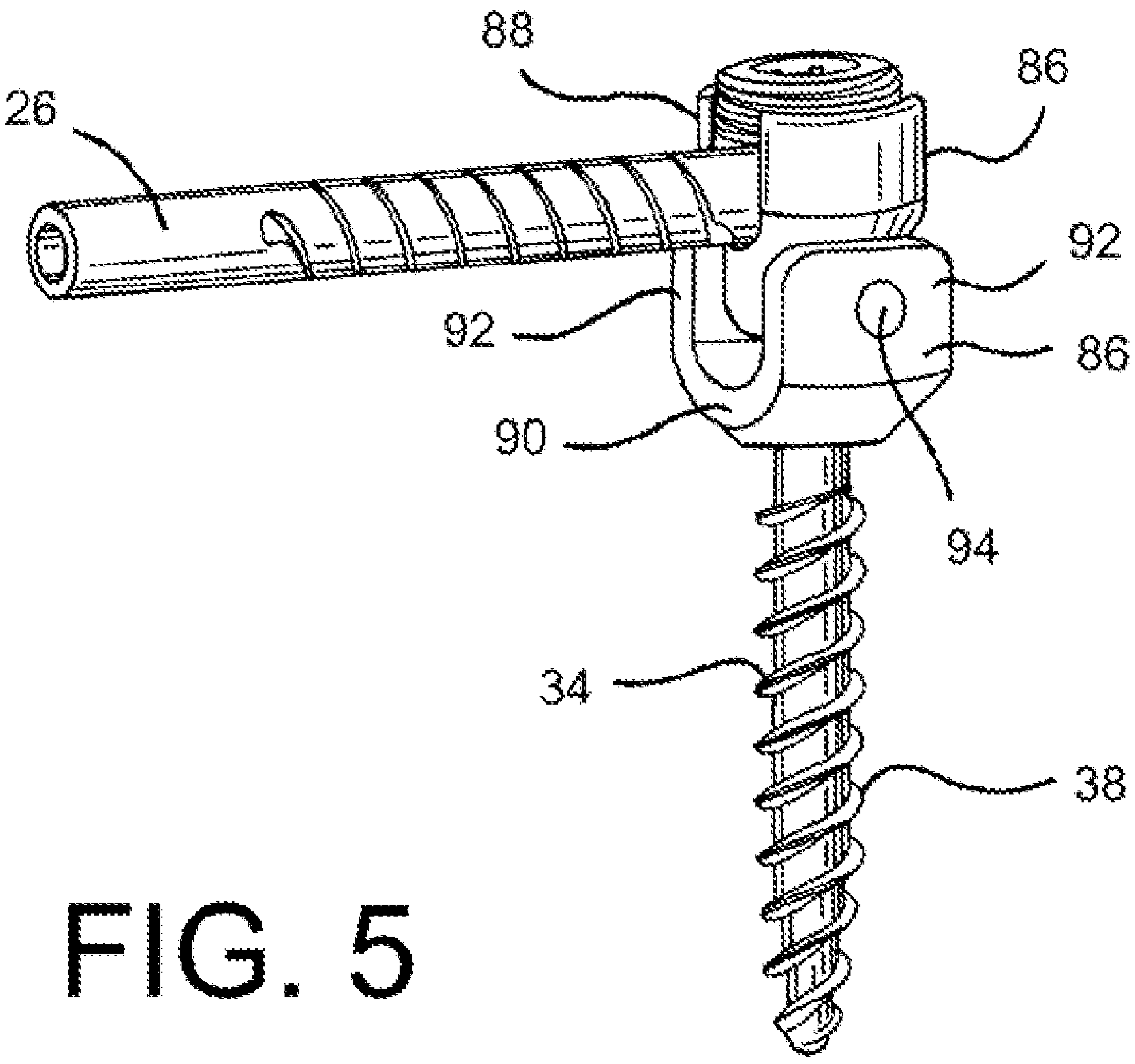


FIG. 5

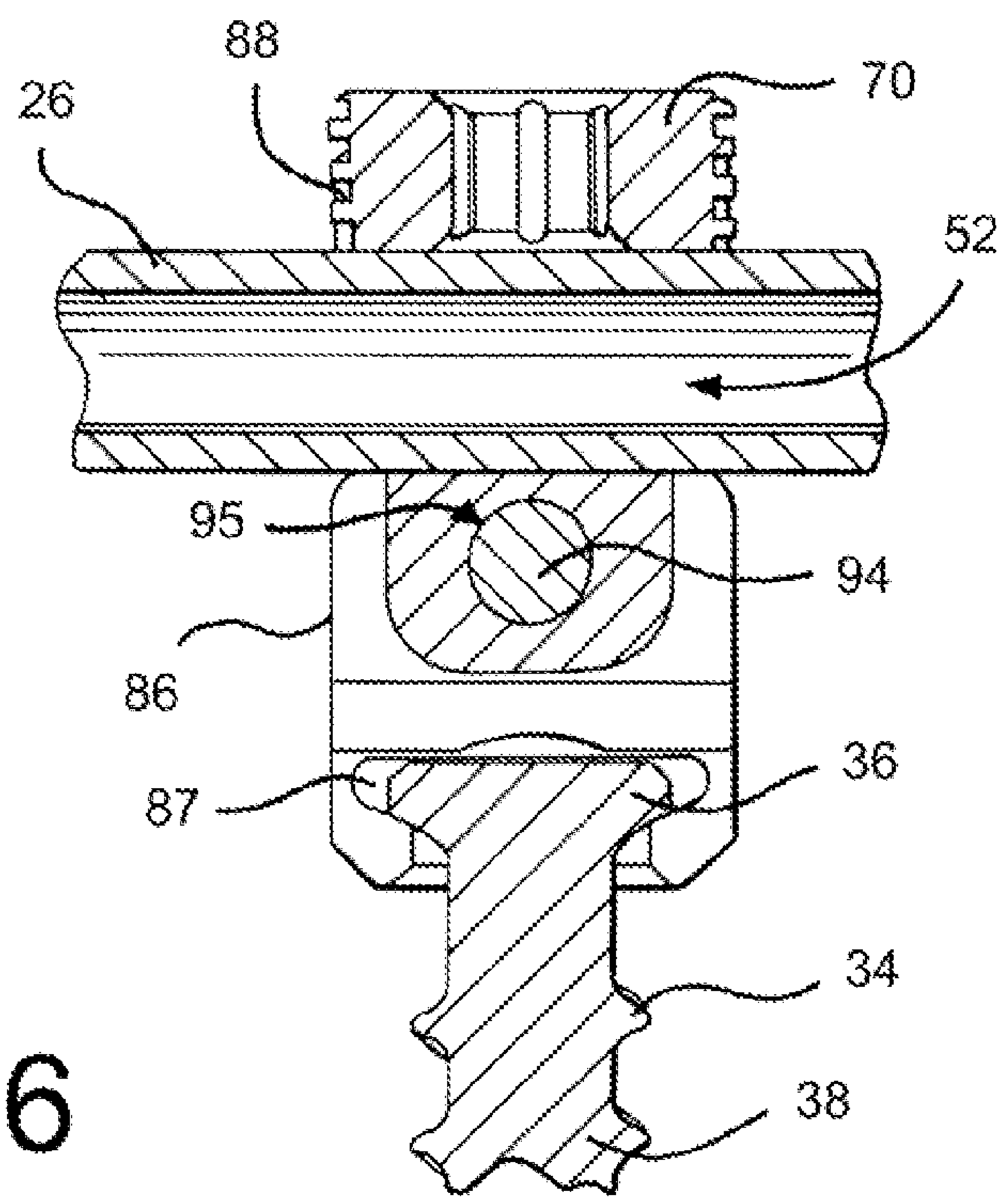


FIG. 6

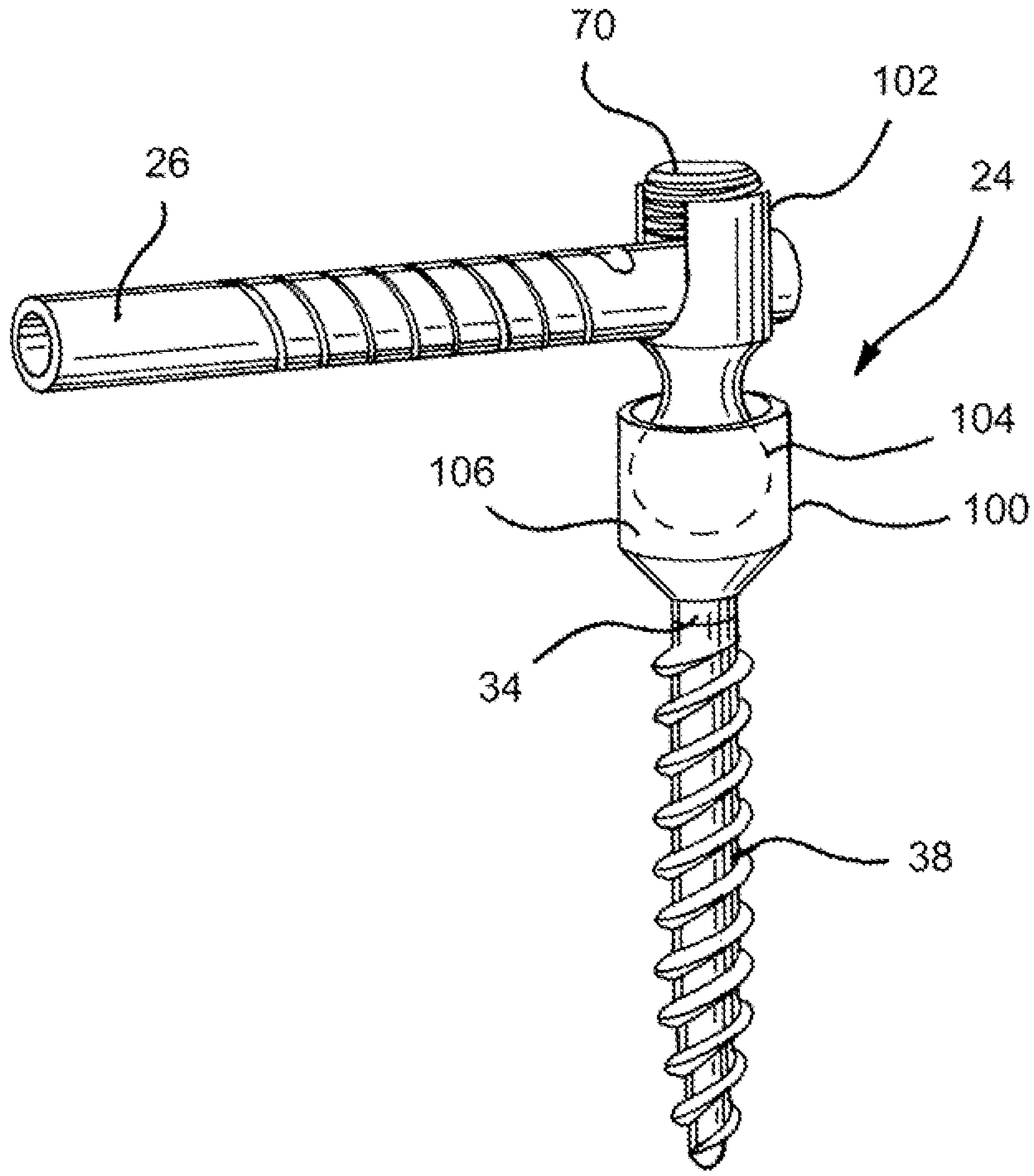


FIG. 7

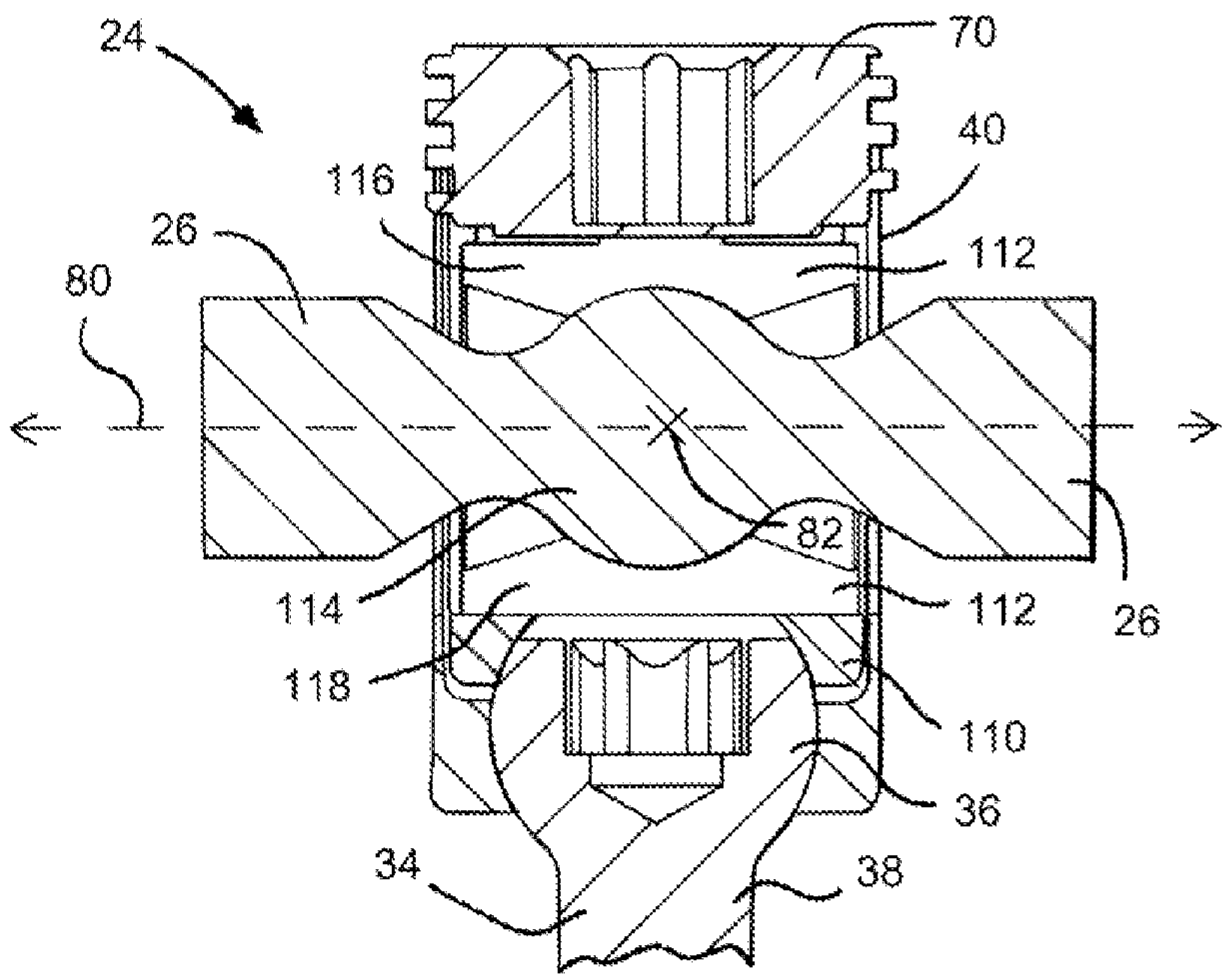

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FIG. 8

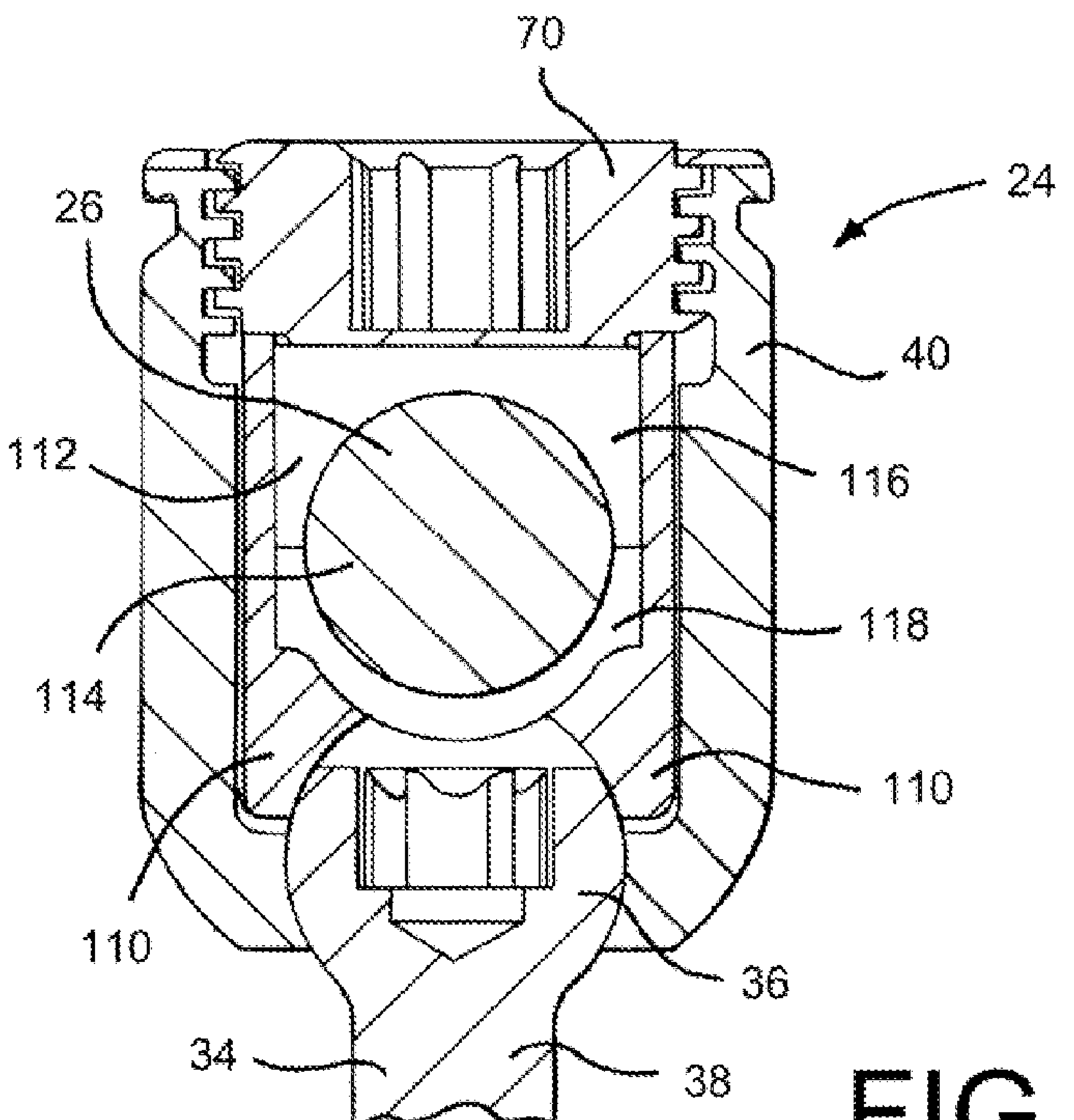
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FIG. 9

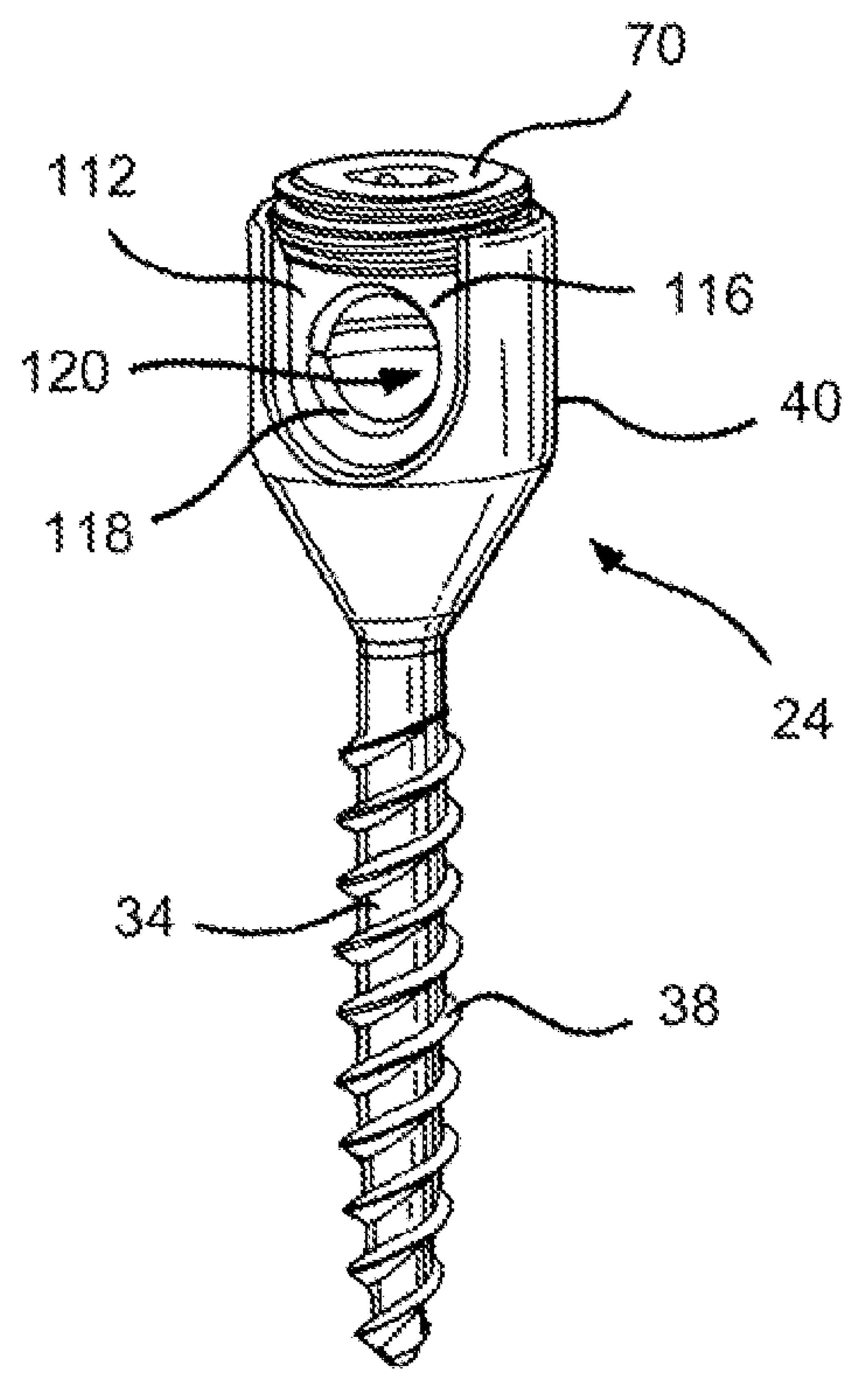

FIG. 10

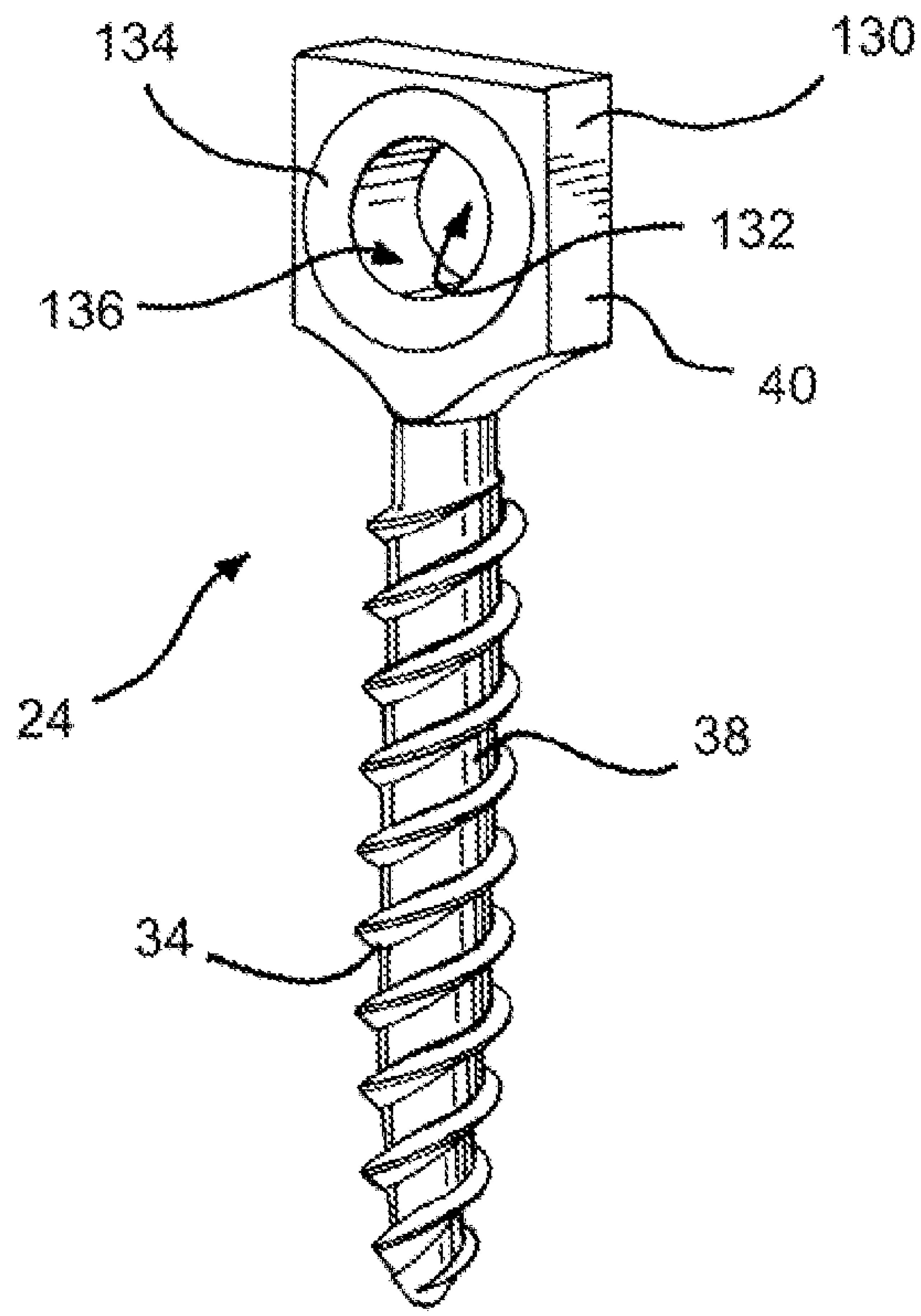

FIG. 11

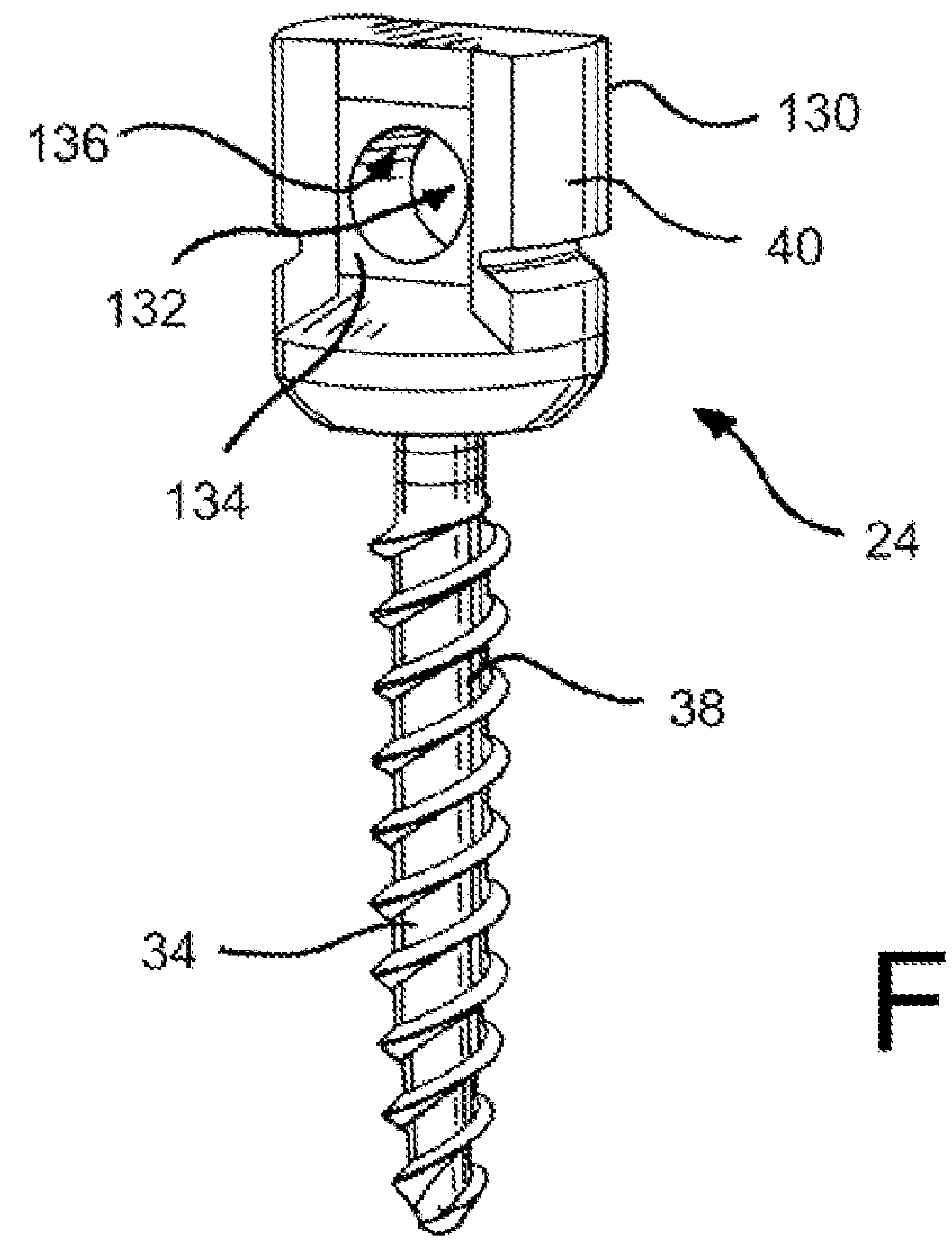

FIG. 12

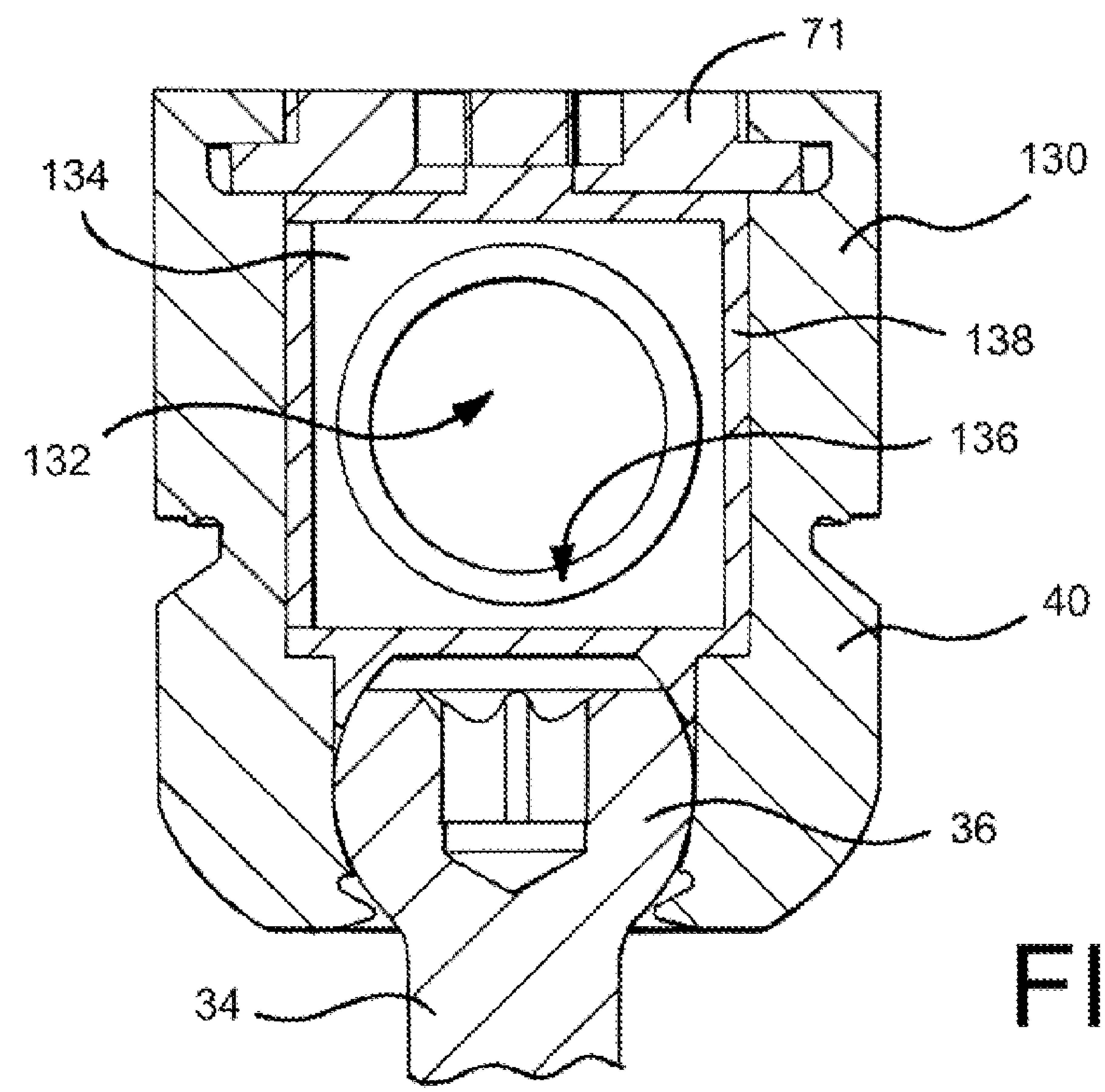

FIG. 13

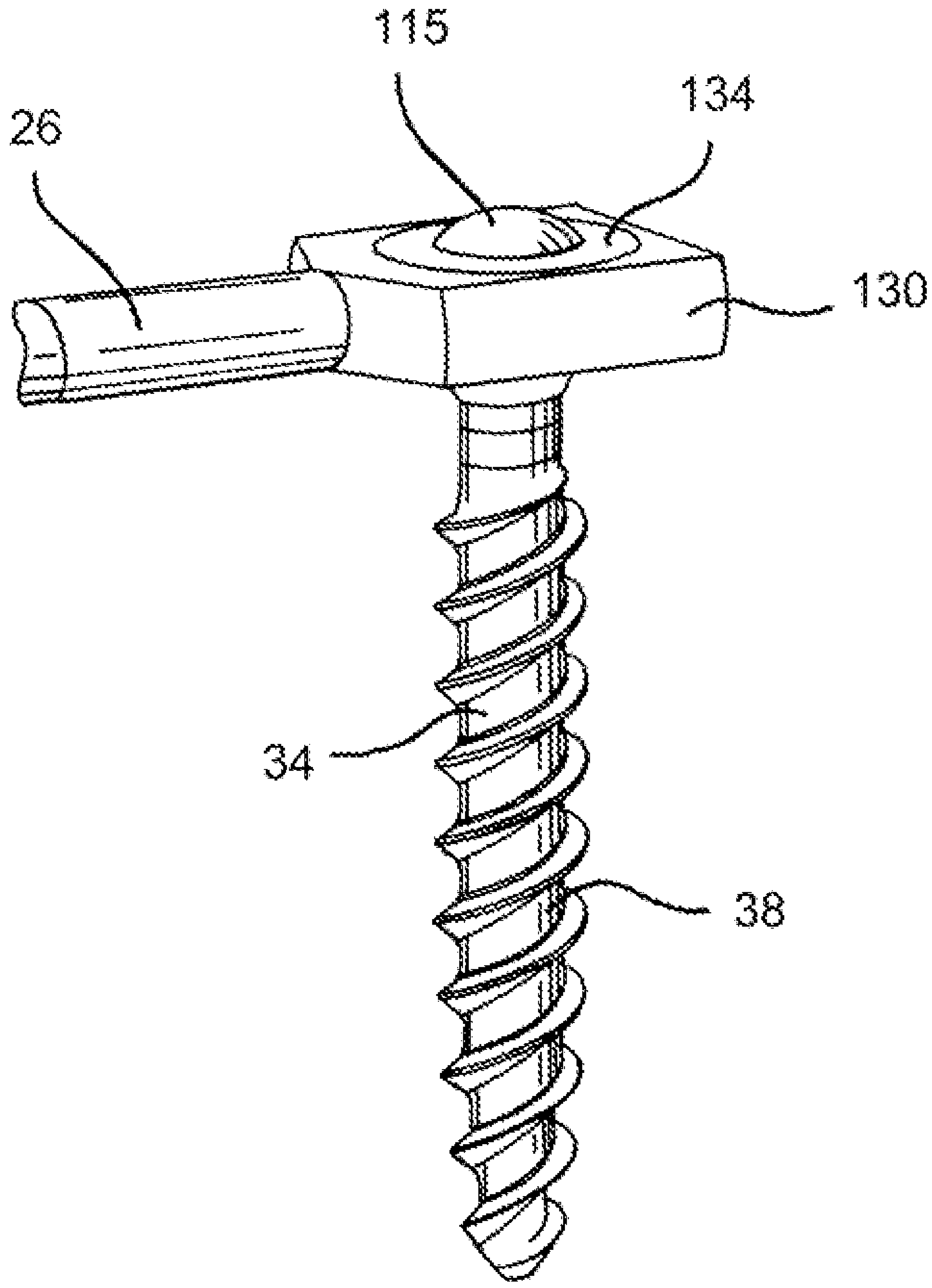

FIG. 14

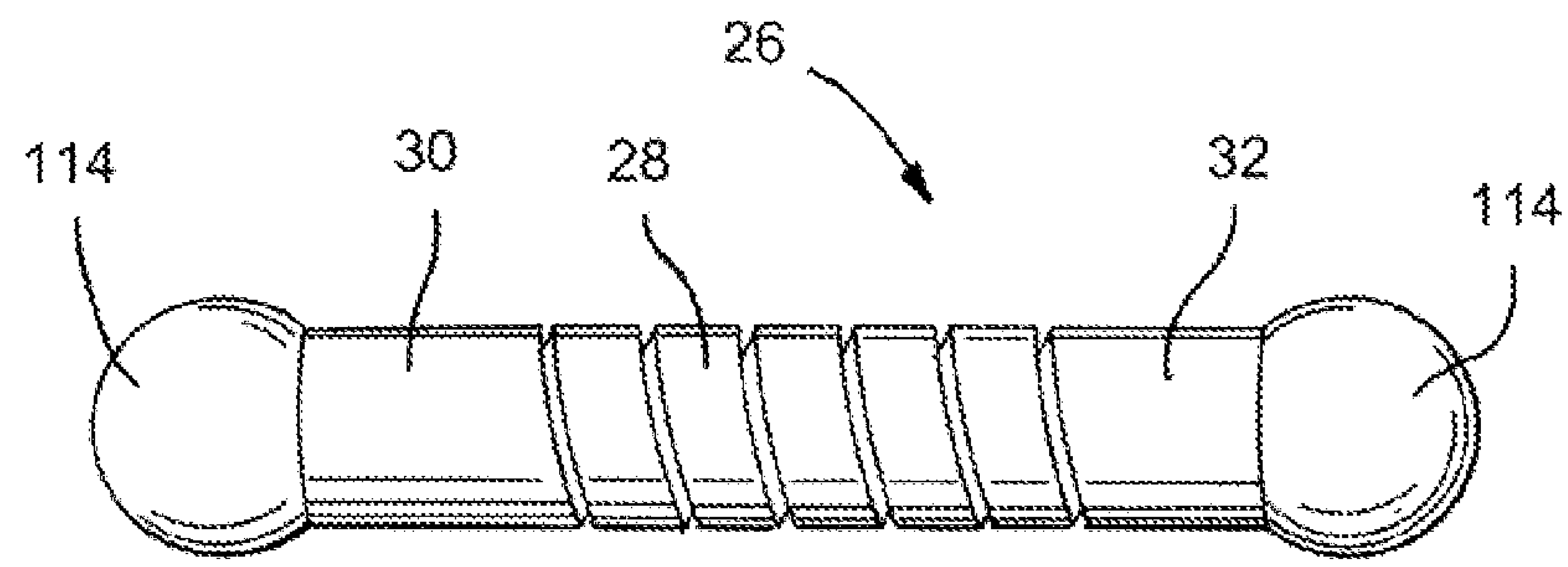

FIG. 15A

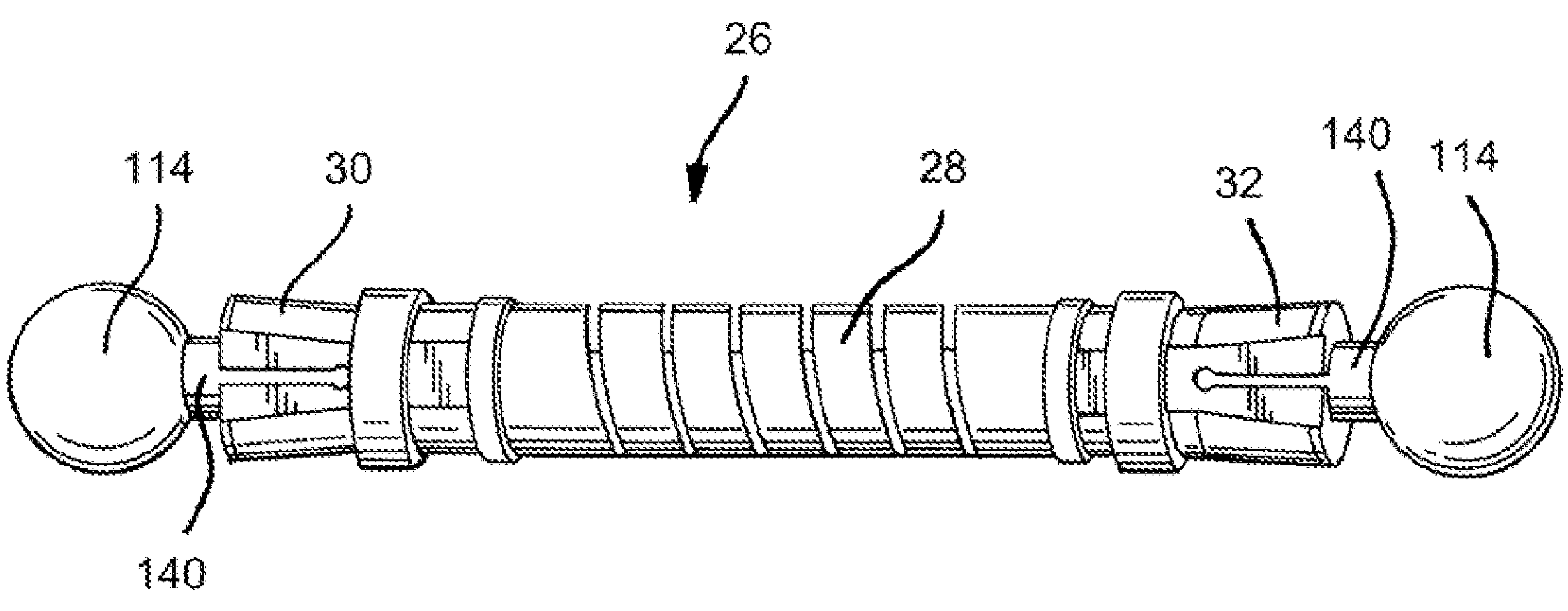

FIG. 15B

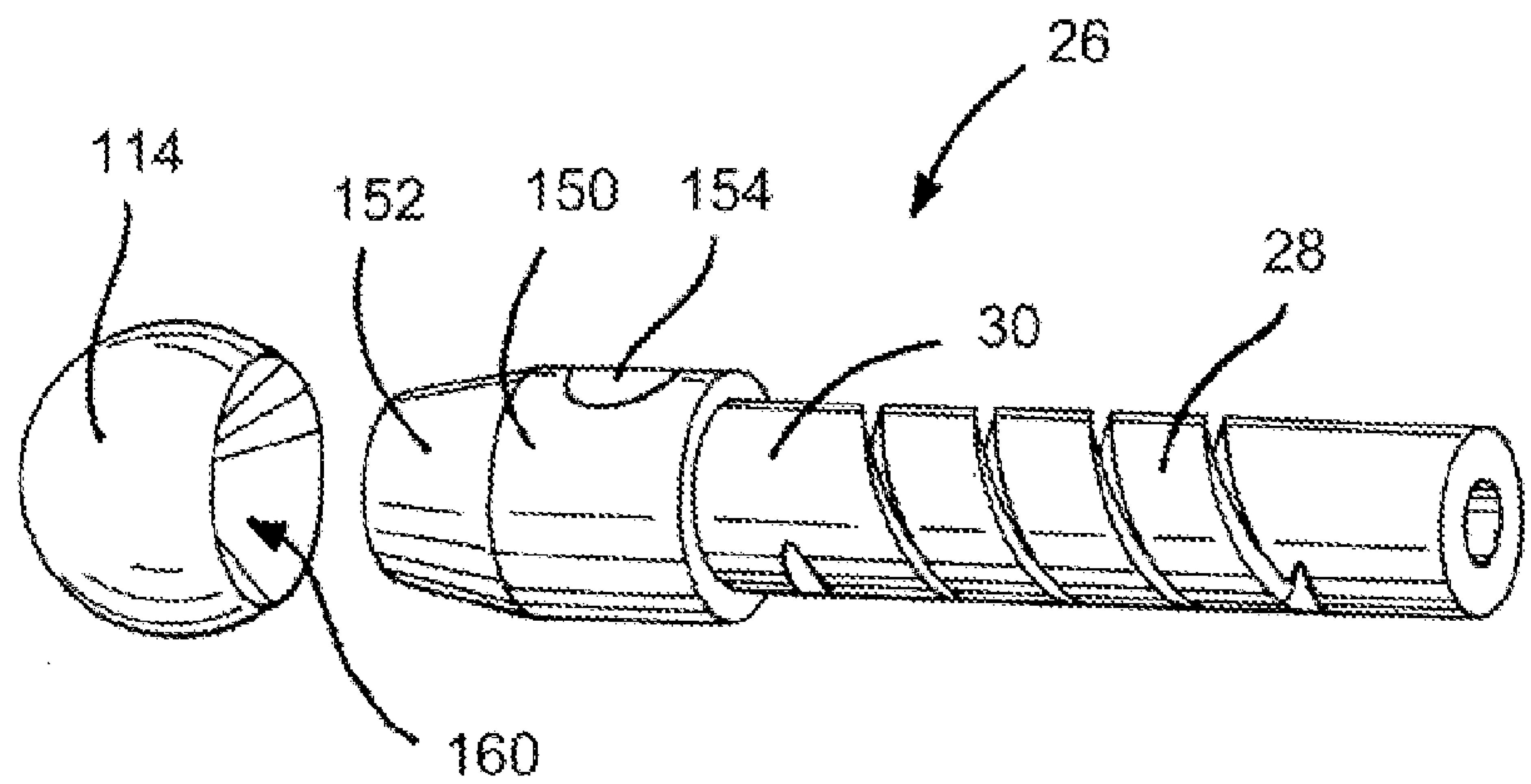

FIG. 15C

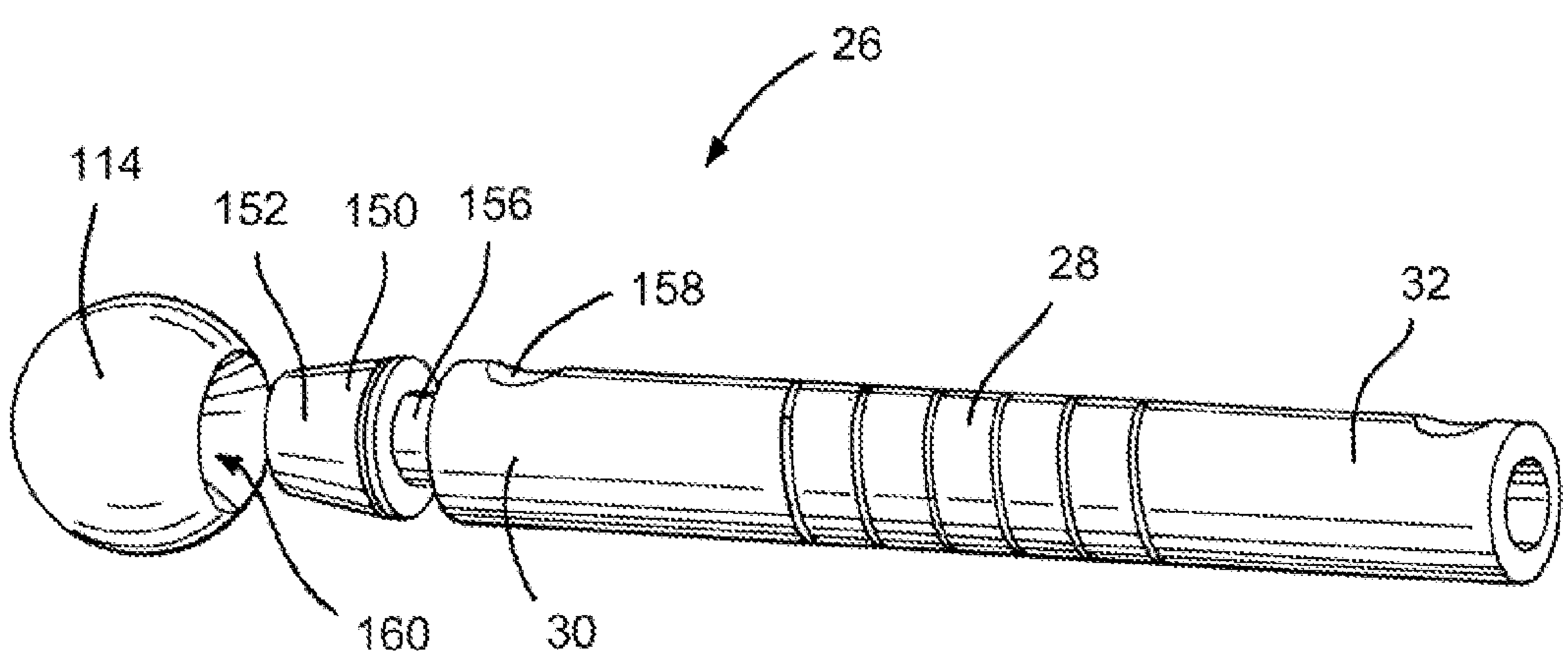

FIG. 15D

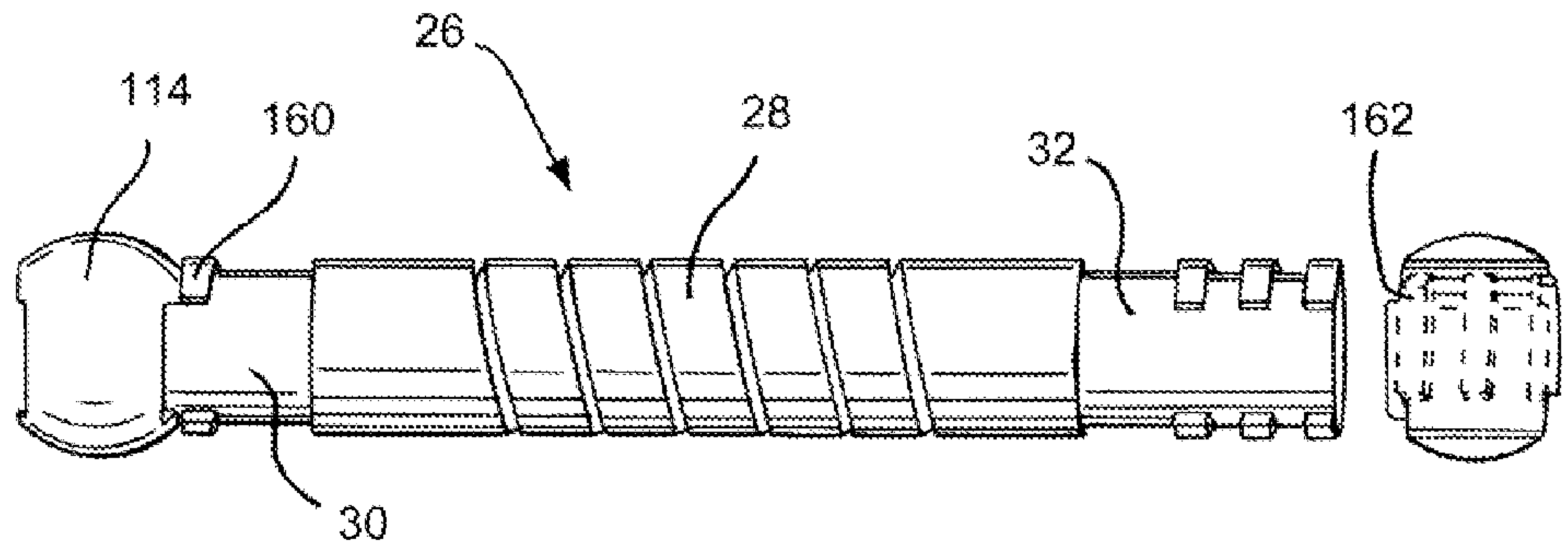

FIG. 15E

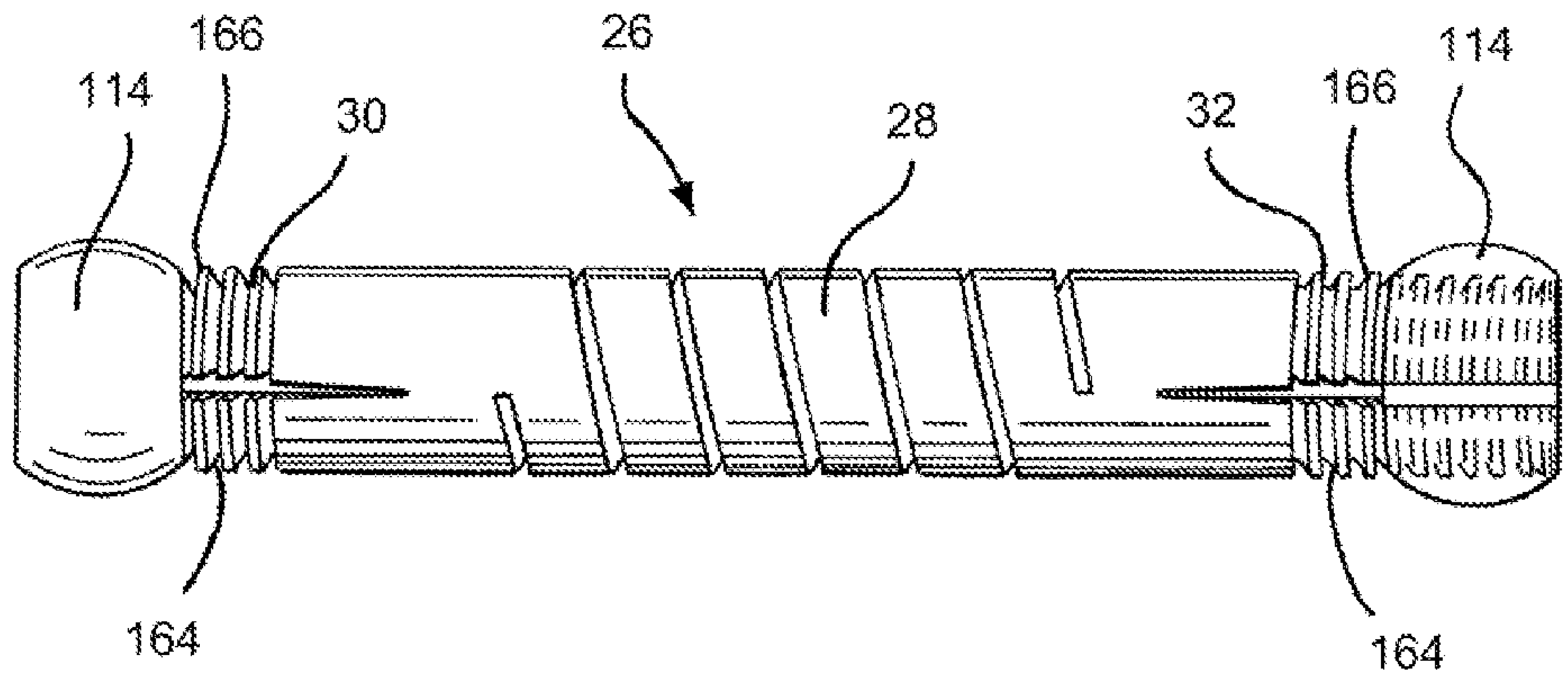

FIG. 15F

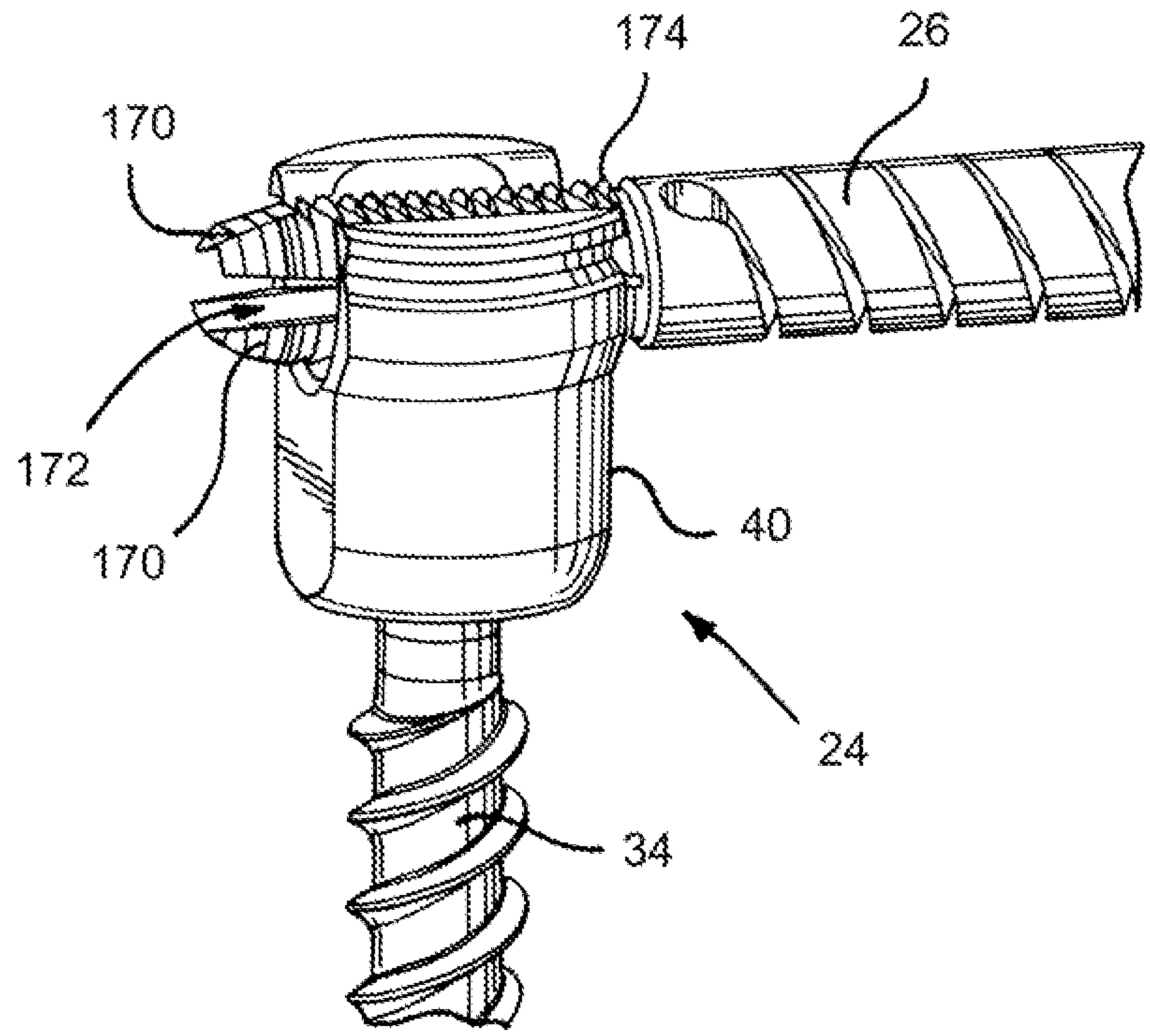

FIG. 16

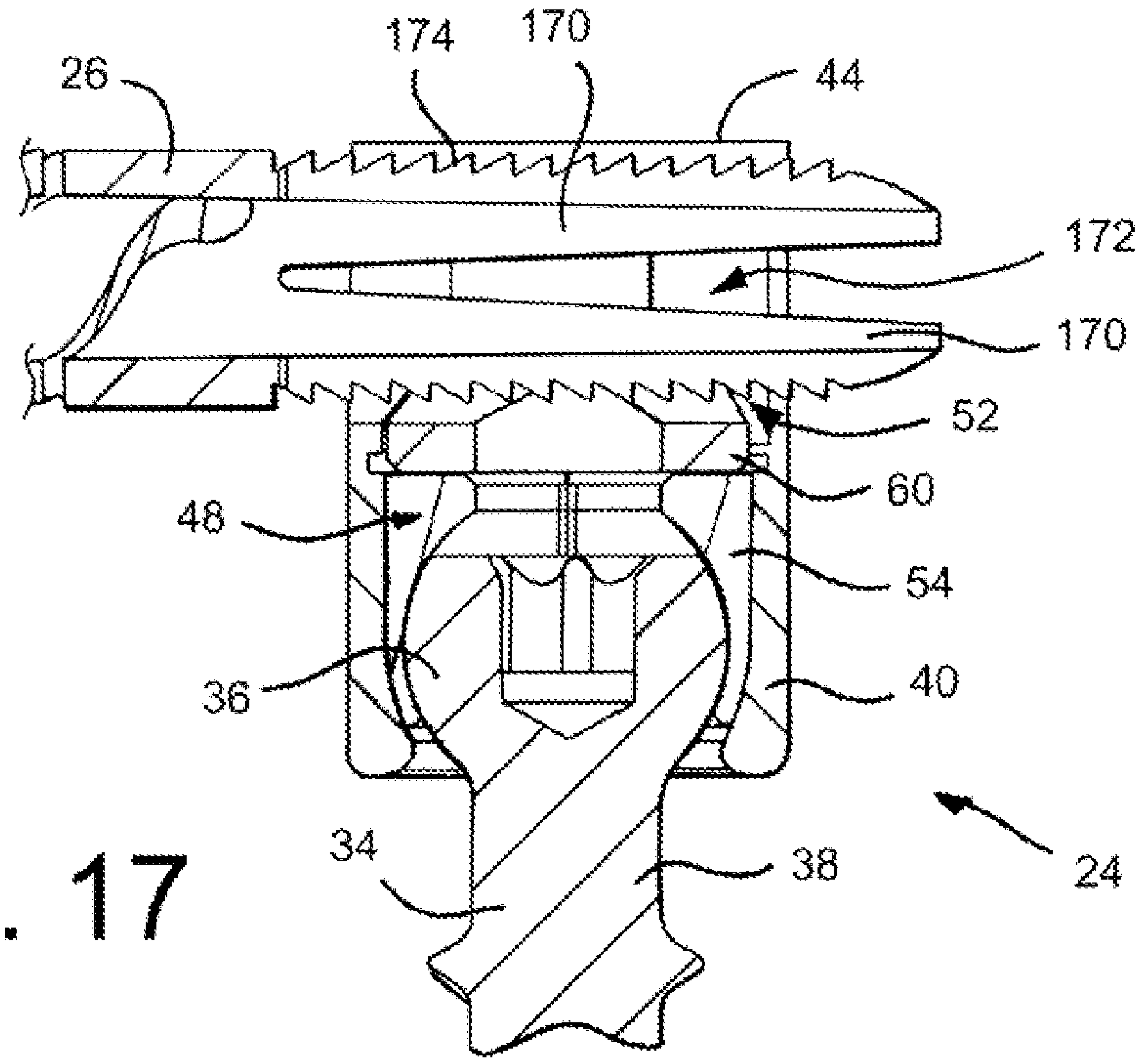
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FIG. 17

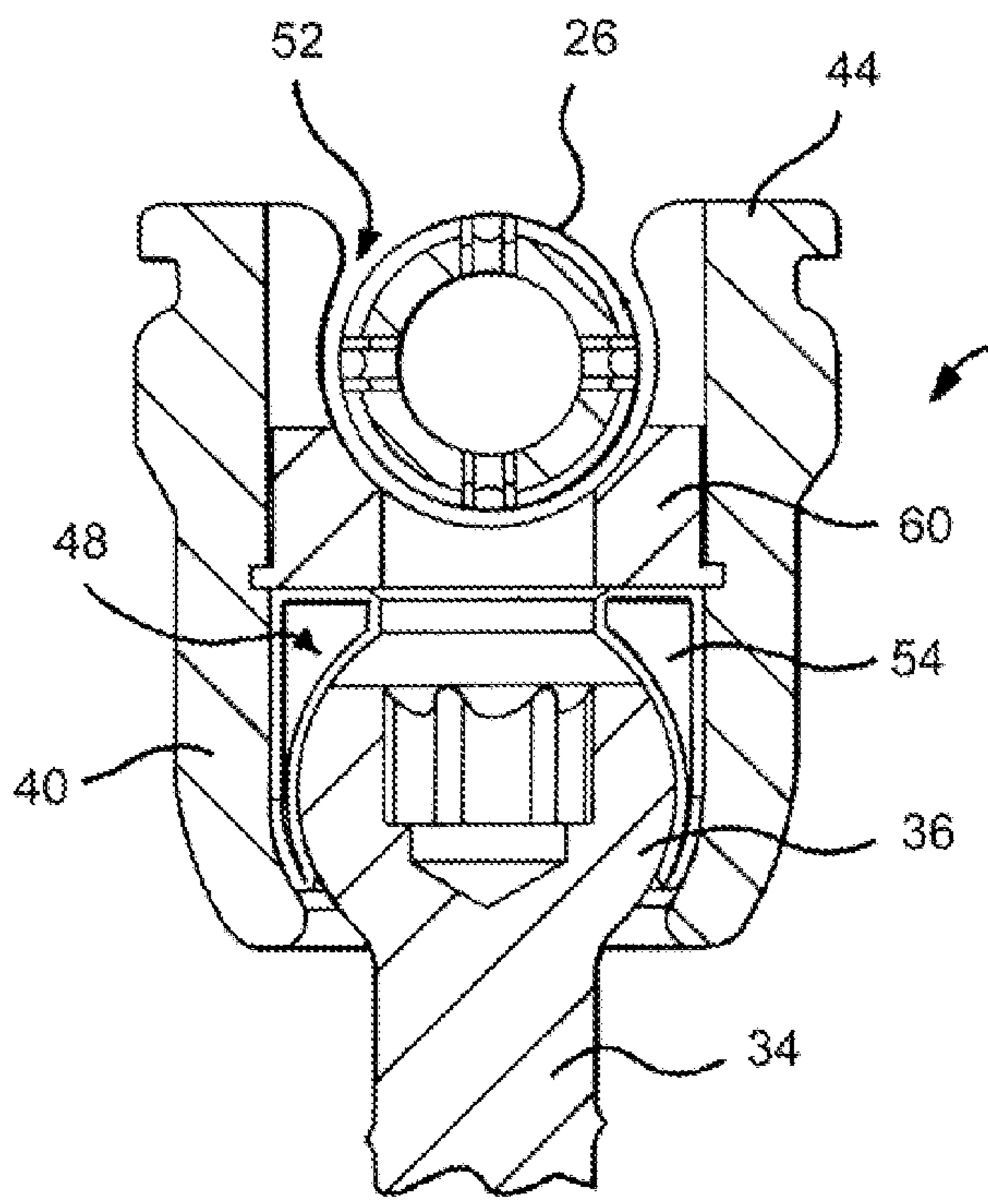
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FIG. 18

METHOD OF USING SPINE STABILIZATION SYSTEM WITH DYNAMIC SCREW

[0001] This application is a divisional of co-pending U.S. application Ser. No. 11/646,877 filed Dec. 28, 2006, the disclosure of which is hereby incorporated herein by reference in its entirety, and related to U.S. patent application Ser. No. 11/646,961, entitled "Spinal Anchoring Screw", which was filed on Dec. 28, 2006.

FIELD

[0002] This application relates to the field of spinal stabilization devices. In particular, this application relates to a method for using a posterior stabilization unit configured for use with a segmental unit of the spine.

BACKGROUND

[0003] Spinal surgeries are commonly used in the medical profession to treat spinal conditions that result when functional segmental units of the spine are moved out of proper position or otherwise damaged. Examples of procedures used to treat spinal conditions include disc replacement, laminectomy, and spinal fusion.

[0004] Following certain spinal procedures, such as spinal fusion, it is typically desirable to stabilize the spine by preventing movement between the vertebrae while the spine heals. This act of stabilizing the spine by holding bones in place during healing has greatly improved the success rate of spinal fusions and other procedures.

[0005] With spinal stabilization procedures, a combination of metal screws and rods creates a solid "brace" that holds the vertebrae in place. These devices are intended to stop movement from occurring between the vertebrae. These metal devices give more stability to the fusion site and allow the patient to be out of bed much sooner.

[0006] During the spinal stabilization procedure, pedicle screws are placed through the pedicles on the posterior portion of two or more vertebrae of the spinal column. The screws grab into the bone of the vertebral bodies, giving them a good solid hold on the vertebrae. Once the screws are placed on the vertebrae, they are attached to metal rods that connect all the screws together. When everything is bolted together and tightened, the assembly creates a stiff metal frame that holds the vertebrae still so that healing can occur.

[0007] Posterior dynamic stabilization (PDS) generally refers to such a stabilization procedure where dynamic rods are positioned between the pedicle screws. These dynamic rods can generally bend, extend, compress, or otherwise deform in order to allow some limited movement between the pedicle screws. By allowing this limited movement between the pedicle screws and the associated vertebrae, less strain is placed on adjoining, non-stabilized functional segmental units during patient movements. In addition, the dynamic rod generally decreases the stresses on the screw shank, minimizing the possibility of screw backout or related screw failures. However, even with dynamic rods, stresses are experienced by the screw shank which could potentially result in screw backout or related failures under the appropriate circumstances. Accordingly, it would be desirable to provide a PDS system capable of further protecting the screw-bone interface and reducing the chances of screw backout. For example, it would be advantageous to provide a PDS system with a flexible stabilization element that offers different kinematics and loading requirements from those stabilization elements found in the prior art. Such a stabilization element would offer additional options to the surgeon when traditional PDS stabilization elements appear problematic.

SUMMARY

[0008] Various embodiments of a dynamic screw for a spine stabilization system are disclosed herein. A dynamic screw for a spine stabilization system comprises at least one bone anchor assembly comprising a bone engaging member and a receiver member. The bone engaging member may comprise a bone screw including a screw head retained within the receiver member and a screw shank extending from the receiver member. The screw head may be pivotably retained within the receiver member. An elongated connecting member is pivotably connected to the bone engaging member. The elongated connecting member may be provided as a rod spanning between two or more bone anchor assemblies. The elongated connecting member is pivotably connected to the receiver member of the bone anchor assembly.

[0009] In one embodiment, the pivotable connection between the elongated connection member and the receiver member is provided by a ball-shaped pivot member on the rod which engages a bearing surface provided within a cavity of the receiver member. Accordingly, the pivot point for the rod may be provided within the cavity in the receiver member. In one such embodiment, the rod may define an axis wherein the axis pivots about a pivot point on the axis when the rod pivots relative to the receiver member. In other embodiments, the pivot point of the rod is offset from the axis defined by the rod.

[0010] The rod may be a fixed length or adjustable to accommodate different segmental units and patients of different sizes. In the adjustable embodiment, the rod comprises a shaft with a flexible central portion and at least one adjustable end. The adjustable end may be provided by various means. For example, the adjustable end may include a post configured to slide within the shaft of the rod. In one embodiment, the adjustable end is configured to threadedly engage the shaft. In another embodiment, the adjustable end is comprised of a shape memory alloy.

[0011] When assembled, the spine stabilization system generally comprises at least two bone anchors with a rod extending between the two bone anchors. As mentioned above, each bone anchor includes a bone screw and a receiver member configured to retain the bone screw. The rod extends between the two receiver members. In one embodiment where the rod is fixed relative to the receiver members, the rod is adapted to bend when the receiver members move relative to one another. In another embodiment, the rod is pivotably connected to both the receiver members, and the rod is adapted to extend or compress when the receiver members move relative to one another.

[0012] In an alternative embodiment, one or more bone anchors of the spine stabilization system include an insert in the form of a retention member that acts to lock a bearing for the bone screw within the receiver member. To this end, the receiver member includes a screw head cavity and a rod cavity with an insert positioned between the screw head cavity and the rod cavity. The screw head cavity is configured to receive a bearing that engages the head of the bone screw with the screw shank extending from the receiver member. In one embodiment, the bone screw bearing is a split bearing. The insert is positioned between the rod cavity and the bearing member and is configured to secure the split bearing within the receiver member. The insert may be provided to fit within a groove formed in an interior sidewall of the receiver member. In this embodiment, the insert comprises a retaining ring that secures the split bearing within the screw cavity. In another embodiment, the insert is comprised of a compressible material positioned between the bearing member and the rod cavity. When the rod is positioned in the rod cavity, the insert is compressed against the bearing member, thus locking the bearing member within the screw cavity.

[0013] In yet another embodiment, the bone anchor assembly is configured with a low profile, wherein the rod is locked within the receiver member without the use of a fixation screw. In this embodiment, the bone anchor assembly includes a head and a screw shank extending from the head. The screw shank is pivotable with respect to the head. Furthermore, a rod cavity is formed within the head. The end of the rod includes features that lock the rod within the rod cavity when the rod is inserted into the rod cavity, thus connecting the rod to the head. For example, in one embodiment, the end of the rod comprises a plurality of fingers that may be flared to lock the rod within the rod cavity. The rod may also include a plurality of teeth that grasp or mesh with the rod cavity to further secure the rod within the cavity.

[0014] In a further embodiment, a method of using a spine stabilization system in one embodiment includes inserting a bone fastener shank through a receiver structure cavity and then through a distal opening of the receiver member, positioning a head of the fastener against a bearing surface of the receiver structure, positioning a bearing member on an upper portion of the head, positioning a first pivot bearing portion of a pivot member above the positioned bearing member, positioning a pivot portion of a connector assembly on the positioned first pivot bearing portion, positioning a second pivot bearing portion of the pivot member on an upper portion of the pivot portion, and threading a fixation screw into a threaded portion of the receiver structure, thereby (i) causing the pivot member to clamp the pivot portion, and (ii) clamping the head of the screw between the first bearing and the bearing surface.

[0015] The above described features and advantages, as well as others, will become more readily apparent to those of ordinary skill in the art by reference to the following detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. **1** shows a posterior view of a spine stabilization system with a plurality of dynamic screws and dynamic rods connected between two vertebrae;

[0017] FIG. **2** shows a side view of the spine stabilization system of FIG. **1**;

[0018] FIG. **3**A shows a cross-sectional view of a bone anchor and rod which form part of the spine stabilization system of FIG. **1**;

[0019] FIG. **3**B shows an exploded perspective view of the bone anchor and rod of FIG. **3**A;

[0020] FIG. **3**C shows a perspective view of a retainer insert of FIG. **3**B;

[0021] FIG. **3**D shows a top view of the retainer insert of FIG. **3**C;

[0022] FIG. **4** shows a cross-sectional view of an alternative embodiment of the bone anchor and rod of FIG. **3**;

[0023] FIG. **5** shows a perspective view of an alternative embodiment of the bone anchor and rod of FIG. **3** wherein the pivot point of the rod is offset from the central axis of the rod;

[0024] FIG. **6** shows a cross-sectional view of the bone anchor and rod of FIG. **5**;

[0025] FIG. **7** shows an alternative embodiment of the bone anchor and rod of FIG. **5**;

[0026] FIG. **8** shows a cross-sectional view of an alternative embodiment of the bone anchor and rod of FIG. **3** wherein the pivot point of the rod is provided on the central axis of the rod;

[0027] FIG. **9** shows another cross-sectional view of the bone anchor and rod of FIG. **8** rotated 90°;

[0028] FIG. **10** shows a perspective view of an alternative embodiment of the bone anchor of FIG. **8**;

[0029] FIG. **11** shows a perspective view of another alternative embodiment of the bone anchor of FIG. **8**;

[0030] FIG. **12** shows a perspective view of another alternative embodiment of the bone anchor of FIG. **8**;

[0031] FIG. **13** shows a cross-sectional view of the bone anchor of FIG. **12**;

[0032] FIG. **14** shows a perspective view of yet another alternative embodiment of the bone anchor and rod of FIG. **8**;

[0033] FIG. **15**A shows a dynamic rod for use with the bone anchor of FIGS. **8-13**, wherein the dynamic rod includes ball shaped members on its ends;

[0034] FIG. **15**B shows an alternative embodiment of the dynamic rod of FIG. **15**A wherein the length of the rod is adjustable;

[0035] FIG. **15**C shows another alternative embodiment of the dynamic rod of FIG. **15**A wherein the length of the rod is adjustable;

[0036] FIG. **15**D shows yet another alternative embodiment of the dynamic rod of FIG. **15**A wherein the length of the rod is adjustable;

[0037] FIG. **15**E shows another alternative embodiment of the dynamic rod of FIG. **15**A wherein the length of the rod is adjustable;

[0038] FIG. **15**F shows yet another alternative embodiment of the dynamic rod of FIG. **15**A wherein the length of the rod is adjustable;

[0039] FIG. **16** shows a perspective view of an alternative embodiment of a bone anchor and rod for use with the spine stabilization system of FIG. **1** wherein the rod is secured to a cavity in the bone anchor without the use of a fixation screw;

[0040] FIG. **17** shows a cross-sectional view of the bone anchor and rod of FIG. **16**; and

[0041] FIG. **18** shows a cross-sectional view of the bone anchor and rod of FIG. **17** rotated 90°.

DESCRIPTION

[0042] With reference to FIGS. **1** and **2**, an exemplary posterior dynamic stabilization (PDS) system **22** is shown arranged between two vertebrae **20**, **21** of a spine. The PDS system **22** comprises a plurality of bone anchors **24** with a plurality of elongated connecting members **26** extending between the bone anchors **24**. The plurality of connecting members **26** may comprise rods, bars, or other elongated connecting members. Each bone anchor **24** is secured to the pedicle of one of the vertebrae **20** or **21**. Each elongated connecting member **26** extends between a first bone anchor fixed to an upper vertebra **20** and a second bone anchor fixed to a lower vertebra **21**.

[0043] The bone anchor **24** is comprised of titanium, stainless steel, or other appropriate biocompatible material. As explained in further detail herein, each bone anchor **24** comprises a bone engaging member **34**, such as a bone screw (as shown in FIG. **3**, for example). However, one of skill in the art will recognize that other bone engaging members **34** are possible, such as posts, pins, cemented surfaces, adhesive surfaces and other bone engaging members as are known in the art.

[0044] In addition to the bone engaging member **34**, each bone anchor **24** also comprises a receiver member **40**. The receiver member **40** is configured to receive a bone engaging member **34** and/or an elongated connecting member **26**. If the bone engaging member **34** is a bone screw, the bone screw **34** includes a screw head **36** and a screw shank **38**. The screw head **36** is retained within the receiver member **40** and the screw shank **38** extends from the receiver member **40**. The screw shank **38** is configured to screw into the bone and secure the bone screw **34** to the pedicle or other portion of bone. The receiver member **40** may be rigidly or pivotably connected to the screw **34**.

[0045] The receiver member **40** is also configured to receive an elongated connecting member, such as the rod **26**. The rod **26** includes two rigid ends **30**, **32** with an elastic/resilient central portion **28** disposed between the rod ends. The elastic central portion **28** allows for some limited flexibility in the rod, while still allowing the rod to spring back to its original shape. Therefore, when opposing forces are applied to the ends **30**, **32** of the rod **26**, the central portion flexes, allowing the rod to bend and/or elongate. When the opposing forces are removed, the rod returns to its original shape. With this configuration, the PDS system generally stabilizes two adjacent vertebrae, while still allowing for some limited movement between the vertebrae **20**, **21**. However, one of skill in the art will recognize that other types of rods are possible, including rigid rods or other flexible rods comprised of elastomeric material, metal, or superelastic material, or other types of PDS rods as are known in the art.

[0046] With reference now to FIGS. **3A-3D**, one embodiment of a bone anchor assembly **24** is shown. In this embodiment, each bone anchor assembly **24** comprises a bone engaging member **34** retained within a receiver member **40**. The bone engaging member is provided in the form of a bone screw **34** (which is also referred to herein as a "pedicle screw"). The bone screw **34** comprises a screw head **36** and a screw shank **38**. The screw head **36** is generally spherical in shape with a flat top **39**. A slot **37** is formed in the top of the screw head **36**. The slot **37** is configured to receive the tip of a screwdriver that may be used to drive the screw **34** into the bone. The screw shank **38** extends from the screw head **36**. The screw shank **38** is threaded to facilitate driving the screw into the bone.

[0047] In the embodiment of FIGS. **3A-3D**, the receiver member **40** is a generally cup-shaped structure configured to hold both the screw **34** and the rod **26**. The receiver member **40** comprises cylindrical sidewalls **42** formed between a superior end **44** and an inferior end **46**. A bone screw cavity **48** is formed within the sidewalls **42** near the inferior end **46**. A fixation screw cavity **50** is formed within the sidewalls **42** near the superior end **44**. A rod cavity and passage **52** is formed in the receiver member between the fixation screw cavity **50** and the bone screw cavity **48**.

[0048] The fixation screw cavity **50** is designed and dimensioned to receive a fixation screw **70** (also referred to herein as a setscrew). Accordingly, the cylindrical sidewalls **42** of the receiver member are threaded at the superior end **44**. These threads are configured to engage the threads on the fixation screw **70**. The fixation screw includes a slot **72** in the top that is adapted to receive the tip of a screwdriver, thus allowing the fixation screw **70** to be driven into the fixation screw cavity **50**.

[0049] The rod passage **52** is provided directly below the fixation screw cavity **50**. The rod passage is designed and dimensioned to receive one of the dynamic rods **26** of the PDS system **22**. In particular, the rod passage **52** is designed to receive one of the rod ends **30**. In the embodiment of FIG. **3**, the rod is loaded into the rod passage from the top of the receiver member by laying the rod within U-shaped dips formed in the superior end **44** of the receiver member **40**. After the rod **26** is positioned in the rod passage **52**, a fixation screw is driven into the fixation screw cavity until it contacts the rod. When the fixation screw it tightened, it locks the rod in place within the receiver member **40**. One of skill in the art will recognize that other appropriate locking features such as cam locks may be used to hold the rod in place.

[0050] The bone screw cavity **48** is designed and dimensioned to retain the screw head **36** of the bone screw **34**, with the shank **38** of the bone screw extending from the receiver member **40**. An opening **56** is formed in the inferior end **46** of the receiver member **40**. In this disclosed embodiment, the diameter of the opening **56** is smaller than the diameter of the screw head **36**, but it is large enough to allow the screw shank **38** to pass through the opening **56**. Accordingly, the cylindrical wall **42** is slightly thicker at the inferior end **46** of the receiver member **40**.

[0051] A bearing member **54** is positioned within the bone screw cavity **48** along with the screw head **36**. The bearing member **54** includes an inner bearing surface that generally conforms to the spherical shape of the screw head **36**. The screw head **36** is configured to rotate and pivot within the bearing member **54**. The outer bearing surface is designed and dimensioned to engage the interior portion of the cylindrical sidewalls **42** of the receiver member.

[0052] In one embodiment, the bearing member **54** is a split bearing that includes a left side member **54*a*** and a right side member **54*b***. The split bearing, **54*a***, **54*b*** provides for easier assembly by allowing the bearing surface to be assembled around the spherical screw head **36**. In addition, the split bearing members **54*a***, **54*b*** facilitate the use of different bearing materials. Appropriate bearing materials will be recognized by those of skill in the art. In the embodiment of FIGS. **3A** and **3B**, the bearing members **54*a***, **54*b*** are comprised of ceramic. Examples of other types of appropriate bearing materials include cobalt chrome, UHMWPE, and other biocompatible materials.

[0053] An insert **60** is provided in the receiver member. The insert **60** acts as a retention member to secure the bearing member **54** in place within the bone screw cavity **48** of the receiver member **40**. In the embodiment of FIGS. **3A-3D**, the insert **60** is C-shaped plate that serves as a retaining ring. As best seen in FIGS. **3C** and **3D**, the insert **60** includes a semicircular wall **64** with a void **65** formed in the wall. Two opposing ends **66*a*** and **66*b*** define the sides of the void **65**. The exterior perimeter **67** of the insert **60** is generally circular in shape, while the interior perimeter **68** is contoured to provide strength to the insert. In addition, the insert may include other structural features such as holes **69**. The insert **60** is generally comprised of a resilient biocompatible material, such as cobalt chrome or UHMWPE. The resilient features of the insert **60** allow the ends **66*a***, **66*b*** to be forced together, reducing the size of the void **65**, and then spring back to their original position.

[0054] As shown in FIG. 3A, the insert **60** is provided within a groove **62** formed in the cylindrical sidewalls **42** of the receiver member **40**. With reference to the exploded view of the anchor assembly **24** shown FIG. 3B, it can be seen that the insert **60** is loaded into the retainer member **40** through a hole **50** in the top of the retainer member. First, the split bearing members **54***a*, **54***b* are positioned about the head of the screw **38** and the screw is inserted into the receiver member **40**. Upon insertion, the split bearing members **54***a*, **54***b* and screw head **36** are seated in the screw head cavity and the shank **38** extends through the hole in the bottom of the receiver member **40**. Next, the insert **60** is compressed and inserted into the receiver member **40**. When properly positioned, the resilient insert snaps into the groove **62** in the receiver member, thus locking the split bearing members **54***a*, **54***b* in place within the retainer member. With the insert **60** locked in the groove **62**, the bearing member **54** is secured in place within the receiver member such that various stresses on the bone screw will not dislodge the bearing member within the anchor assembly **24**. After insertion of the insert **60**, the rod **26** is placed in the rod passage **53** of the receiver member and the fixation screw **70** is threaded in the fixation screw cavity **50** until it compresses against the rod, thus fixing the rod to the receiver member **40**.

[0055] FIG. **4** shows an alternative embodiment of a bone anchor assembly including an insert for securing the bearing **54** within the receiver member **40**. In this embodiment, the insert **60** comprises a polyethylene disc positioned between the rod **26** and the bearing **54**. Before the fixation screw is tightened, the top surface of the polyethylene disc **60** is positioned within the rod cavity **52**. Thus, when the fixation screw **70** is tightened against the rod **26**, the polyethylene insert **60** is slightly compressed by the rod. The force of this compression is then transferred to the bearing member **54**, which is tightly compressed within the bone screw cavity **48**, thus securing the bearing in place. Although FIGS. **3** and **4** show only two methods for holding the bearing **54** in place within the receiver member **40**, one of skill in the art will recognize that variations of the disclosed embodiments may be easily incorporated. For example, in one embodiment, a combination retaining ring and compression disc may be used.

[0056] Rod Fixed to Receiver Member Providing With Pivot Point Offset From Rod Axis

[0057] From FIGS. **3** and **4**, it can be seen that an offset exists between the center axis of the rod and the pivot point of the rod **26** within the anchor assembly **24**. In particular, as shown in FIG. **4**, the center axis **80** of the rod (shown by dotted line **80**) is removed from the pivot point (shown by "X" **82**) of the rod within the anchor assembly **24**. This offset provides one embodiment that may be used to help control the necessary kinematics and loading requirements of the rod. In these embodiments, the rod **26** is fixed to the anchor assembly, and is not allowed to pivot relative to the receiver member **40** which holds the bone screw **34**.

[0058] An alternative embodiment of a bone anchor **24** where the center axis of the rod is offset from the pivot point of the rod within the anchor assembly is shown in FIGS. **5** and **6**. In this embodiment, the anchor assembly includes a bone screw **34**, a U-shaped screw holder **86**, and a rod holder **88**. The bone screw includes a threaded shank **38**, but instead of a spherical head, the head **36** of the bone screw is flat and generally circular or disc-shaped. This flat screw head is designed and dimensioned to fit within a circular cavity formed in the base **90** of the U-shaped screw holder **86**. The circular cavity **87** allows the head **36** to rotate within the cavity **87** about the axis of the screw. A pivot pin **94** extends through the upright portions **92** of the U-shaped screw holder **86**.

[0059] The rod holder **88** is pivotably mounted on the pivot pin **94**. The rod holder **88** is similar to the receiver member **40** described in FIGS. **3** and **4**. However, in place of a screw cavity, the rod holder **88** of FIGS. **5** and **6** includes a pin channel **95** configured to receive the pivot pin **94**. The rod holder **88** is allowed to rotate about the pivot pin **94**, thus allowing the rod holder **88** to pivot relative to the U-shaped screw holder **86**. A rod passage **52** is formed in the rod holder **88** above the pin channel **95**. A fixation screw **70** threadedly engages the interior threaded walls on the top of the rod holder **88**. When the fixation screw **70** is tightened against the rod, the rod is pinned in place within the rod holder **88**.

[0060] In the embodiment of FIGS. **5** and **6**, the rod is allowed only two degrees of freedom. First, the rod **26** is allowed to pivot by radial rotation around an axis defined by the screw shank **38** by virtue of the rotatable engagement between the screw head **36** and the circular cavity **87** of the U-shaped screw holder **86**. Second, the rod **26** is allowed to pivot about the pin **94** which is perpendicular to the screw shank. To facilitate rotation of the screw head **36** and the pin **94** within the U-shaped screw holder, the U-shaped screw holder may be comprised of ultra high molecular weight polyethylene (UHMWPE), cobalt chrome, titanium, stainless steel or other appropriate biocompatible bearing material as will be recognized by those of skill in the art.

[0061] Another alternative embodiment of a bone anchor **24** where the center axis of the rod is offset from the pivot point of the rod is shown in FIG. **7**. The bone anchor **24** of FIG. **7** includes a receiver member in the form of a screw holding member **100** that is fixed to the shank **38** of the bone screw **34**. The rod **26** is secured to a rod holding member **102** which includes a cavity that receives the rod **26**. The rod holding member **102** includes a fixation screw **70** that clamps onto the rod in order to fix to the rod holding member **102** to the rod **26**. The rod holding member further includes a ball-shaped pivot member (shown by dotted lines **104** within the screw holding member **100**). In this embodiment, the screw holding member **100** includes a cavity with a spherical bearing **106** and bearing surface that is also fixed relative to the screw shank **38**. The spherical bearing surface is configured to receive the pivot member **104** which is fixed to the rod **26**. Because the surface of the pivot member **104** is congruent with the bearing surface, the pivot member **104** is allowed to pivot within the screw holding member **100**. Accordingly, the rod **26** is configured to pivot relative to the shank **38**. The pivot point for the rod **26** is defined at the center of the pivot member **104** which is located within the center of the cavity in the screw holding member **100**.

[0062] Rod Pivotably Connected To Receiver Member With Pivot Point on Rod Axis

[0063] With reference now to FIGS. **8-9**, an alternative embodiment of a bone anchor **24** for a PDS system is shown where the rod **26** is pivotably connected to the receiver member **40** of the bone anchor. The bone anchor **24** includes a bone screw **34** having a screw head **36** retained within the receiver member **40** with the screw shank **38** extending from the receiver member **40**.

[0064] Two different bearings are retained within the receiver member **40**. In particular, a first bearing **110** provides a bearing surface for the screw head. The first bearing acts to stabilize the screw head **36** within the receiver member **40** while providing a surface upon which the screw head may pivot relative to the receiver member **40**. In one embodiment, the first bearing may be comprised of a metallic insert that acts to lock the bone screw **34** in place when a fixation screw is tightened, as discussed in further detail below.

[0065] In addition to the first bearing **110**, a second bearing **112** is also provided within the receiver member **40** shown in FIGS. **8** and **9**. The second bearing **112** provides spherical bearing surface for the rod **26**, allowing the rod **26** to pivot relative to the receiver member **40**. Accordingly, the rod **26** includes a pivot member **114** in the form of a spherical ball fixed on at least one end of the rod **26**. The spherical ball **114** engages the spherical bearing surface of the second bearing **112**, thus pivotably retaining the rod **26** within the receiver member **40** and facilitating smooth movement of the rod relative to the receiver member. In this embodiment, the pivot member **114** is fixed to the rod **26**, being integrally formed upon the rod.

[0066] In the embodiment disclosed in FIGS. **8** and **9**, the second bearing **112** is a split bearing that includes a superior bearing member **116** provided above the spherical ball **114** and an inferior bearing member **118** provided below the spherical ball **114**. In another alternative embodiment, the bearing is split into left and right halves such as the bearing shown in FIG. 3B. The split bearing **112** is comprised of UHMWPE, ceramic, cobalt chrome, or any other biocompatible material. In one alternative embodiment, the first bearing **110** and the inferior bearing member **118** of the second bearing **112** may be provided as a single integral component.

[0067] The components of the anchor assembly **24** may all be loaded into the receiver member **40** through a top hole. First, the bone screw **34** is inserted into the receiver member **40** with the screw head **36** seated in the screw head cavity and the shank **38** extending through the hole in the bottom of the receiver member **40**. Second, the first bearing **110** is placed over the screw head. Next, the inferior bearing member **118** of the second bearing **112** is placed on top of the first bearing **110**. The rod **26** is then placed in the receiver member with the spherical ball **114** engaging the bearing surface of the inferior bearing member **118**, and the cylindrical portion of the rod passing through the rod passage formed in the sidewalls of the receiver member. The superior bearing member **116** is then placed over the spherical ball **114**. This provides a superior bearing surface for the spherical ball. Finally, the fixation screw **70** is threaded into the top of the receiver member until it compresses against the second bearing member. Alternatively, the bearing components, screw, and rod may be preassembled and inserted into the receiver member as a unit.

[0068] In the embodiment of FIGS. **8** and **9**, the anchor **24** acts as polyaxial screw that can be locked down by the metal insert **110** that is tightened by the fixation screw **70** when the screw head **36** is in the desired position. The fixation screw **70** functions to lock the bone screw **34** and to slightly compress the second bearing **112**, thus keeping the second bearing in place within the receiver member **40**.

[0069] In the embodiment of FIGS. **8** and **9**, it can also be seen that the rod **26** is configured to pivot relative to the receiver member **40**. Accordingly, as shown in FIG. **8**, the pivot point **82** which the rod **26** pivots about is located on an axis defined by the rod and extending along the rod, such as a central axis **80** or an axis extending axially through the rod or along the surface of the elongated rod **26**. In the case of FIG. **8**, the axis is the central axis **80** of the rod. Because of this, the rod is constrained to motion in the axial direction. In other words, in this embodiment, the dynamic central portion of the rod is elongated or compressed, but is not bent when the receiver member **40** moves. Thus, for a given PDS assembly of two bone anchors and a rod, when the vertebrae move the bone screws **34**, the receiver members **40** also move along with the bone screws. Because the rod **26** is allowed to pivot relative to the receiver members **40** about pivot point **82**, movement of the receiver members **40** imparts axial forces on the rod **26** that cause the rod to either compress or elongate. Advantageously, this arrangement offers different kinematics and loading requirements from those stabilization elements where the pivot point is offset from an axis defined by the rod. These differing kinematics and loading requirements may be advantageous with certain materials and designs or with certain patients.

[0070] One alternative embodiment to that of FIGS. **8** and **9** involves the use of a setscrew nested in the fixation screw, allowing the polyaxial screw to be locked separate from the compression of the bearing surface. Furthermore, although there is a specific shape and locking of the bearing surface shown in FIG. **8**, this could be altered based on materials used and the constraints of the rod. Of course one of skill in the art will recognize that numerous other adaptations of the embodiment of FIGS. **8** and **9** are possible where the pivot point of the rod is located along the central or other axis of the rod.

[0071] Another example of an alternative embodiment for the bone anchor of FIGS. **8** and **9** is shown in FIG. **10**. FIG. **10** shows an embodiment of a bone anchor **24** which acts as a fixed screw instead of a polyaxial screw. In particular, in FIG. **10**, the screw shank **38** is fixed to the receiver member **40**. In this embodiment, the screw shank **38** may be integrally formed with the receiver member **40** such that the receiver member **40** serves as the bone screw head. Alternatively, the screw shank **38** may be otherwise fixed to the receiver member **40** using some locking mechanism or other connection means. In the embodiment of FIG. **10**, the inferior portion **118** of the bearing member **112** is first placed in the cavity **120** formed in the receiver member **40**. The ball shaped portion of the rod **26** is then loaded onto the inferior bearing surface and the superior bearing member **116** is placed on top of the rod within the cavity. Finally, the fixation screw **70** is used to secure the bearing **112** within the cavity **120** of the receiver member **40**.

[0072] FIG. **11** shows another embodiment, similar to FIG. **10**, where the screw shank is fixed to the receiver member **40**, and the screw head is formed as the receiver member **40**. In FIG. **11**, the receiver member **40** is formed as a block **130** with a central cavity **132**. A bearing member **134** with a toroidal bearing surface **136** is positioned within the cavity **132** of the receiver member **40**. Because the receiver member **40** is fixed relative to the screw shank **38**, the bearing **134** is also fixed relative to the screw shank **38**. The toroidal bearing surface is configured to receive a spherical portion on the end of a rod, similar to the rod end in FIGS. **8** and **9** that includes a spherical ball **114**. Engagement of the spherical ball **114** and the toroidal bearing surface **136** allows the rod **26** to pivot relative to the shank **38** of the bone screw **38**. In this embodiment, the bearing **134** is shown as being UHMWPE and as being held in place by a press fit. However, one of skill in the art will recognize that numerous other viable bearing materials and locking mechanisms may be used. Similar to the embodiments of FIGS. **8-10**, the bone anchor disclosed in FIG. **11**

provides an arrangement where the pivot point of the rod is located along the central axis of the rod.

[0073] FIGS. **12** and **13** show another alternative embodiment similar to FIG. **11**. However, in the embodiment of FIGS. **12** and **13**, the bearing **134** is not fixed relative to the screw shank **38**. Instead, the bone anchor **24** acts as a polyaxial screw, and the bone screw head **36** and shank **38** are connected to the block **130**/receiver member **40** in a pivotable relationship. Like the bone screw **34**, the bearing **134** is loaded in the top of the receiver member **40**, and a set screw or other locking member **71** holds the bearing **134** in place within the receiver member **40**. Although the bone anchor acts as a polyaxial screw, the bone screw **34** can be locked in place relative to the block **130** when the locking member **71** is tightened within the block. Accordingly, a metal insert **138** may be provided around the bearing **134**. When the locking member **71** is tightened, the metal insert **138** is locked into the screw head **36**, fixing the bone screw relative to the block **130**. One of skill in the art will recognize that various alternative versions of the embodiments of FIGS. **11-13** are possible. For example, it will be recognized that a dual setscrew could be used and that although the bearing surface is shown as a solid piece, it could be split to allow for easier assembly and to facilitate the use of other materials.

[0074] Yet another embodiment of a bone anchor **24** where the pivot point of the rod is located along the central axis of the rod is shown in FIG. **14**. The embodiment of FIG. **14** is very similar to that of FIG. **11**, but in FIG. **14** the block **130** and bearing **134** is provided on the rod **26** rather than the screw shank **38**. Likewise, a spherical ball **115** is provided on the screw shank **138** rather than on the rod **26**. The spherical ball **115** engages the bearing **134**, allowing the rod **26** to pivot relative to the bone screw **34**. In this embodiment, the bearing **134** is shown as being UHMWPE and as being held in place by a press fit. However, one of skill in the art will recognize that numerous other viable bearing materials and locking mechanisms may be used.

[0075] FIGS. **15**A-**15**F show six possible designs for an adjustable length rod that could be used with the designs of FIGS. **8-13** where the pivot point of the rod is provided along the center axis of the rod. As mentioned above, adjustable length rods are advantageous when providing a PDS system so that different sized systems may be constructed for segmental units of different sizes and patients of different sizes. Accordingly, the rods of FIGS. **15**A-**15**F may be used to provide an adjustable PDS system comprising: a plurality of bone anchors; and at least one connecting member connected to and extending between the plurality of bone anchors, wherein the at least one connecting member is adjustable in length. In one embodiment, the at least one connecting member is fixedly connected to the plurality of bone anchors. In another embodiment, the at least one connecting member is pivotably connected to the plurality of bone anchors. In other embodiments, the adjustable connecting member is provided as a telescoping shaft with two or more portions that slide relative to one another and may be locked to one another. In another embodiment, the adjustable connecting member comprises a shaft with a threaded ball on the end that can be turned to effectively lengthen or shorten the connecting member. These and other embodiments are shown in FIGS. **15**A-**15**F. The embodiments of FIGS. **15**A-**15**F show rods with helical dynamic portions provided in the center of the rod. However, it is intended that the embodiments disclosed herein could be used with any dynamic element, and not just helical dynamic portions.

[0076] FIG. **15**A shows a basic rod **26** that generally comprises a shaft with a flexible elastic central portion **28**, a first end **30**, and a second end **32**. Ball-shaped members **114** are provided on the first end **30** and second end **32** of the rod **26**. The ball-shaped members are substantially spherical in the disclosed embodiment and are configured to engage the bearing surface of the rod bearing **112** retained within the bone anchor **24**. Exemplary bone anchors **24** configured to retain rod bearings for use with rods having ball-shaped ends are disclosed in FIGS. **8-13**. In FIG. **15**A, the ball shaped members **114** are formed integral with the rod in FIG. **15**A. To this end, the ball-shaped members **114** may be molded as a single piece with the central dynamic portion **28** of the rod. Alternatively, the ball-shaped members **114** may be fixed to the dynamic portion **28** by other means, such as welding, adhesion, or other appropriate methods as will be recognized by those of skill in the art. In other alternative embodiments, the ball-shaped members **114** may be releasably connected to the dynamic portion **28**. For example, the ball shaped members **114** may be screwed, snapped, or friction fit onto the rod **26** at the rod ends **30**, **32**. Those of skill in the art will recognize various other possibilities for securing the ball shaped members on the rod. In this embodiment, where the ball shaped members **114** are fixed relative to the dynamic portion **28**, the rod **26** may be provided in numerous discrete lengths to accommodate size differences between different patients and/or different segmental units of the spine.

[0077] In an alternative embodiment, the ball shaped members **114** of the rod may be adjustably connected to the rod. With this arrangement, a single rod may be used to accommodate various size differences between patients and/or segmental units. Examples of rods **26** where the ball shaped member **114** is adjustable relative to the dynamic portion **28** are shown in FIGS. **15**B-**15**F.

[0078] In FIG. **15**B, the ball-shaped members **114** are provided on posts **140**. The posts **140** fit within the rod shaft, and particularly within a mouth **142** formed on the rod ends **30**, **32**. Each mouth **142** includes an upper jaw **144** and a lower jaw **146** that taper outwardly from the central axis of the rod. A passage is formed between the upper jaw **144** and the lower jaw that accepts one of the posts **140**. A locking ring **148** is provided on each rod end **30**, **32**. When the locking ring **148** is moved over the mouth **142**, the upper jaw **144** and lower jaw **146** of the mouth are forced together, thus compressing the post **140** within the mouth **142** and locking the associated ball member **114** on the end of the rod **26**. Because the posts **140** and associated ball members **114** are slideable relative to the central dynamic portion **28** of the rod **26**, the size of the rod may be adjusted to various lengths to accommodate different segmental units of the spine and patients of different sizes.

[0079] In FIGS. **15**C and **15**D, the ball-shaped members **114** are taper-locked to a cap member **150** whose position can be adjusted to the desired length. In both of the embodiments of **15**C and **15**D, the cap member **150** includes a frusto-conical portion **152** that is inserted into a cavity **160** in the ball member **114** to taper-lock the ball member **114** to the cap member **150**. Of course, in the embodiments of FIGS. **15**C and **15**D, another fastening means different from a taper-lock could be used to attach the ball member **114** to the cap member **150**. In both embodiments of FIGS. **15**C and **15**D, the cap member **150** is secured to the rod using a setscrew. In the embodiment of FIG. **15**C, the cap member fits over the cylinder of the rod, and a screw hole **154** is formed in the cap member **150**. In the embodiment of FIG. **15**D, a post **156** is inserted within the rod cylinder and a screw hole **158** is formed in the rod **26**. Again, with both FIGS. **15**C and **15**D, because the ball members **114** are slideable relative to the central dynamic portion **28** of the rod **26**, the size of the rod may be adjusted to various lengths to accommodate different segmental units of the spine and patients of different sizes.

[0080] In the embodiment of FIG. **15**E spaced teeth **160** are provided on the rod ends **30**, **32**. Interlocking teeth **162** are also provided on the inside of the ball members **114**. The teeth **160**, **162** are provided with slight tapers such that the teeth **160** on the rod cylinder interact with the teeth **162** on the inside of the ball members **114**. Depending on which set of spaced teeth **160**, **162** are used, the length of the rod can be adjusted and fixed using a simple turn.

[0081] In the embodiment of FIG. **15**F, the rod ends are comprised of a shape memory alloy (also referred to as "smart metals" or "memory metals"), such as nickel-titanium (NiTi), copper-zinc-aluminum, or copper-aluminum-nickel. Shape memory alloys exhibit temperature dependent memory properties which may be advantageously used to lock the ball members **114** on the ends **30**, **32** of the rod **26**. In the embodiment of FIG. **15**F, the ends **30**, **32** of the rod include nested cups **166** comprised of a shape memory alloy. A slit **164** formed through the cups **166** along the end of the rod. Associated grooves are provided on the inside of the ball members. The ball members **114** are free to slide on the cups **166** on the rod ends **30**, **32** at room temperature. However, at body temperature, the cups **166** splay outward, thus locking the cups **166** into the grooves on the inside of the ball member and securing the ball members in place.

[0082] Low Profile Design

[0083] FIGS. **16**-**18** show an alternative embodiment configured for use with any of the above-described designs where the pivot point of the rod is offset from the central or other axis defined by the rod (e.g., FIGS. **3**-**7**). The advantage addressed in the embodiment of FIGS. **16**-**18** is that of a dynamic screw with a lower profile. In this embodiment, the lower portion of the bone anchor **24** is similar to that of FIGS. **3** and **4**, and includes a bone screw cavity **48** configured to receive a bearing member **48** and the head **36** of a bone screw **34**. An insert **60** is provided above the bearing member **54** that locks the bearing member in the cavity **48**. Also similar to FIGS. **3** and **4**, a rod cavity/passage **52** is provided above the insert. However, unlike FIGS. **3** and **4**, no fixation screw is provided above the rod **26**. Instead, the rod **26** and bone anchor **24** include features that allow the rod **26** to be locked into the rod cavity **52** without the use of a fixation screw.

[0084] In the exemplary embodiment of FIGS. **16**-**18** the locking features provided on the rod **26** include fingers **170** provided on the rod ends with slits **172** cut into each rod end between the fingers **170**. Teeth **174** are also provided on the rod ends.

[0085] The slits **172** allow the fingers **170** to contract toward each other as the end of the rod is forced into the rod cavity **52**. Once the rod is in the cavity **52**, the fingers **170** are flared back outwardly toward or past their original configuration. When the fingers are forced outwardly, they are pressed against the insert **60**, thus locking the rod in place within the rod cavity. Flaring of the fingers may be achieved through the use of a memory metal or by other means, such as a wedge forced into the slits at the end of the rod. With the rod in place within the rod cavity **52**, the rod presses against the insert **60** and receiver member **40**, which locks the bearing **54** in place within the bone anchor **24**. If the insert **60** is comprised of a relatively soft material, the teeth **174** may cut into the insert to assist in securing the rod within the bone anchor. In one alternative embodiment, the teeth **174** are designed to mate with complimentary teeth on insert **60** and receiver member **40** to assist in securing the rod within the bone anchor.

[0086] In one embodiment, a cap is provided over the superior end **44** of the bone anchor. This may be desirable if the rod will be passed through tissue. The cap could either be permanent or temporary. As best seen in FIG. **18**, the distance across the rod cavity **52** generally decreases when moving from the center of the rod cavity toward the superior end **44**. This decreased distance at the superior end **44** is less than the diameter of the rod **26**, and helps in preventing passage of the rod through the top of the receiver member **40**. However, if a cap were provided over the superior end **44** it could be used to further assist in retaining the rod **26** within the receiver member **40**. Furthermore, if this embodiment were used in an minimally-invasive surgery procedure, where it would be more difficult to assure that the receiver members **40** are aligned in the correct configuration to properly engage and lock down the rod, the cap could mate with a feature on the screw head in such a way that it would insure that the heads are placed correctly and that the receiver member is properly secured.

[0087] Although the present invention has been described with respect to certain preferred embodiments, it will be appreciated by those of skill in the art that other implementations and adaptations are possible. For example, although the invention has been disclosed for use with reference to a single segmental spine unit, it could also be adapted for use with multi-level constructions. As another example, the dynamic rods disclosed herein include a helical flexible portion, but different dynamic rods may be used in other embodiments. As yet another example, the connection of the rod to the bone anchor may vary from those embodiments disclosed herein. Moreover, there are advantages to individual advancements described herein that may be obtained without incorporating other aspects described above. Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred embodiments contained herein.

What is claimed is:

1. A method of using a spine stabilization system, comprising:

inserting a bone fastener shank through a receiver structure cavity and then through a distal opening of the receiver member;

positioning a head of the fastener against a bearing surface of the receiver structure;

positioning a bearing member on an upper portion of the head;

positioning a first pivot bearing portion of a pivot member above the positioned bearing member;

positioning a pivot portion of a connector assembly on the positioned first pivot bearing portion;

positioning a second pivot bearing portion of the pivot member on an upper portion of the pivot portion; and

threading a fixation screw into a threaded portion of the receiver structure, thereby (i) causing the pivot member to clamp the pivot portion, and (ii) clamping the head of the screw between the first bearing and the bearing surface.

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