

US00RE49138E

(19) United States

(12) Reissued Patent

Arnin

(10) Patent Number: US RE49,138 E

(45) Date of Reissued Patent: Jul. 19, 2022

(54) RATCHETED SPINAL DEVICES

(71) Applicant: ApiFix Ltd., Carmiel (IL)

(72) Inventor: Uri Arnin, Kiryat Tivon (IL)

(73) Assignee: ApiFix Ltd., Yokneam Ilit (IL)

(21) Appl. No.: 16/989,263

(22) Filed: Aug. 10, 2020

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: 9,980,751
Issued: May 29, 2018
Appl. No.: 15/394,855
Filed: Dec. 30, 2016

U.S. Applications:

- (63) Continuation of application No. 14/370,963, filed as application No. PCT/US2013/020453 on Jan. 7, 2013, now abandoned.
- (60) Provisional application No. 61/743,418, filed on Sep. 4, 2012, provisional application No. 61/690,835, filed on Jul. 6, 2012, provisional application No. 61/631, 667, filed on Jan. 9, 2012.
- (51) Int. Cl.

 A61B 17/70 (2006.01)

 A61B 17/02 (2006.01)

(56) References Cited

U.S. PATENT DOCUMENTS

5,395,371	A	3/1995	Miller				
5,700,263	A	12/1997	Schendel				
7,491,221	B2	2/2009	David				
8,439,914	B2	5/2013	Ross				
8,992,576	B2	3/2015	Keyer et al.				
2002/0183755	A 1	12/2002	Michelson				
2002/0183757	A 1	12/2002	Michelson				
2002/0188296	A 1	12/2002	Michelson				
2003/0114856	A 1	6/2003	Nathanson				
2004/0249380	A 1	12/2004	Glascott				
2005/0070899	A 1	3/2005	Doubler				
2005/0277939	A 1	12/2005	Miller, III				
2006/0241591	A 1	10/2006	Biscup				
2009/0093820	A 1	4/2009	Trieu				
2009/0254123	A 1	10/2009	Pafford				
2009/0306717	A1*	12/2009	Kercher A61B 17/7011				
			606/258				
2010/0004697	A 1	1/2010	Fortin				
2010/0057127	A 1	3/2010	McGuire				
(Continued)							

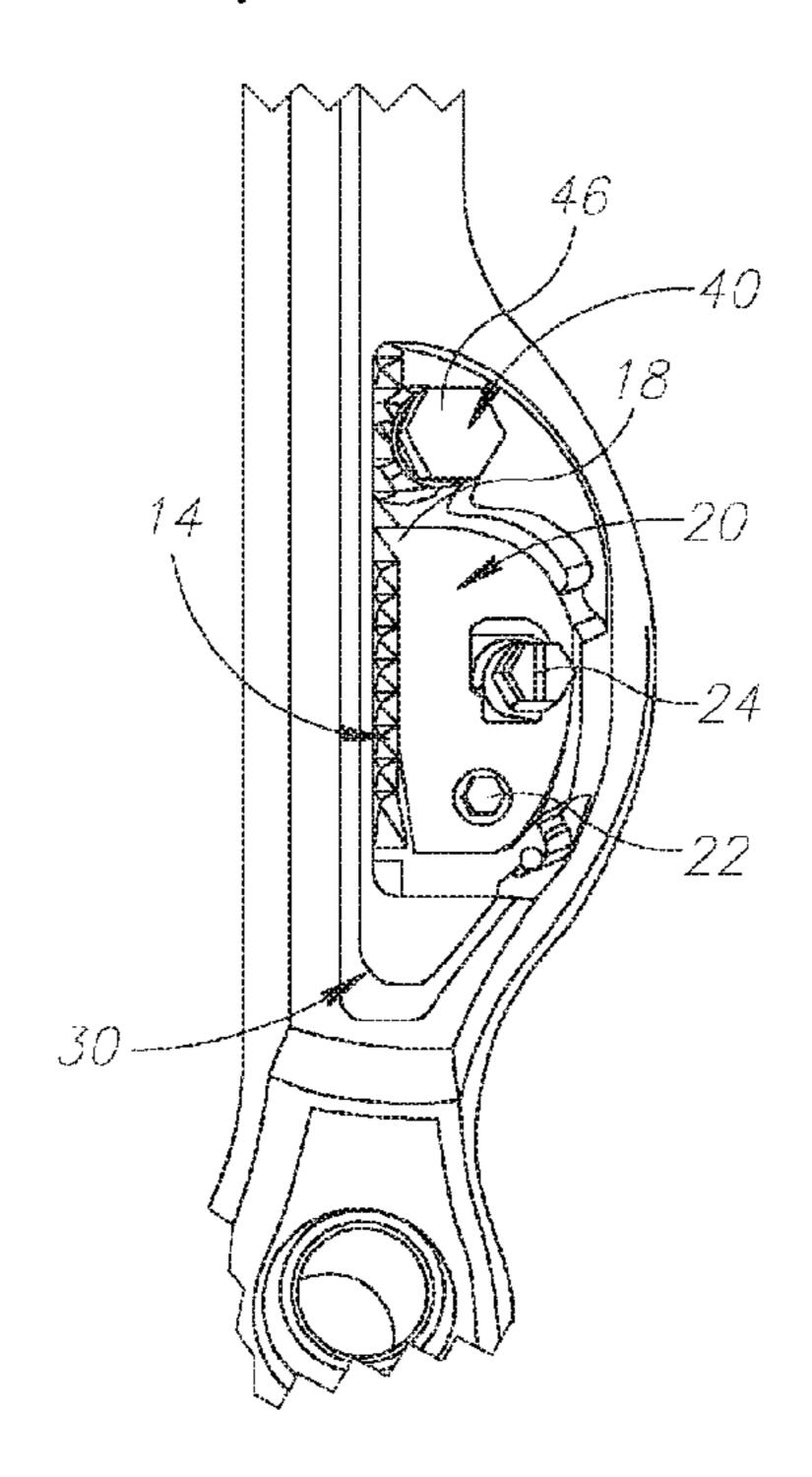
Primary Examiner — David O Reip

(74) Attorney, Agent, or Firm — Gerald W. Roberts; John V. Daniluck; Dentons Bingham Greenebaum LLP

(57) ABSTRACT

A spinal device including a variable-length member including a ratchet mechanism that has an operative configuration that allows a change in length of the variable-length member in one direction and prevents a change in length of the variable-length member in an opposite direction, wherein the variable-length member includes polyaxial-joint attachment members for attachment to bone, which permit pivoting movement of the attachment members about more than one pivoting axis, characterized by a force applicator operative to adjust or advance the ratchet mechanism.

6 Claims, 4 Drawing Sheets



US RE49,138 E

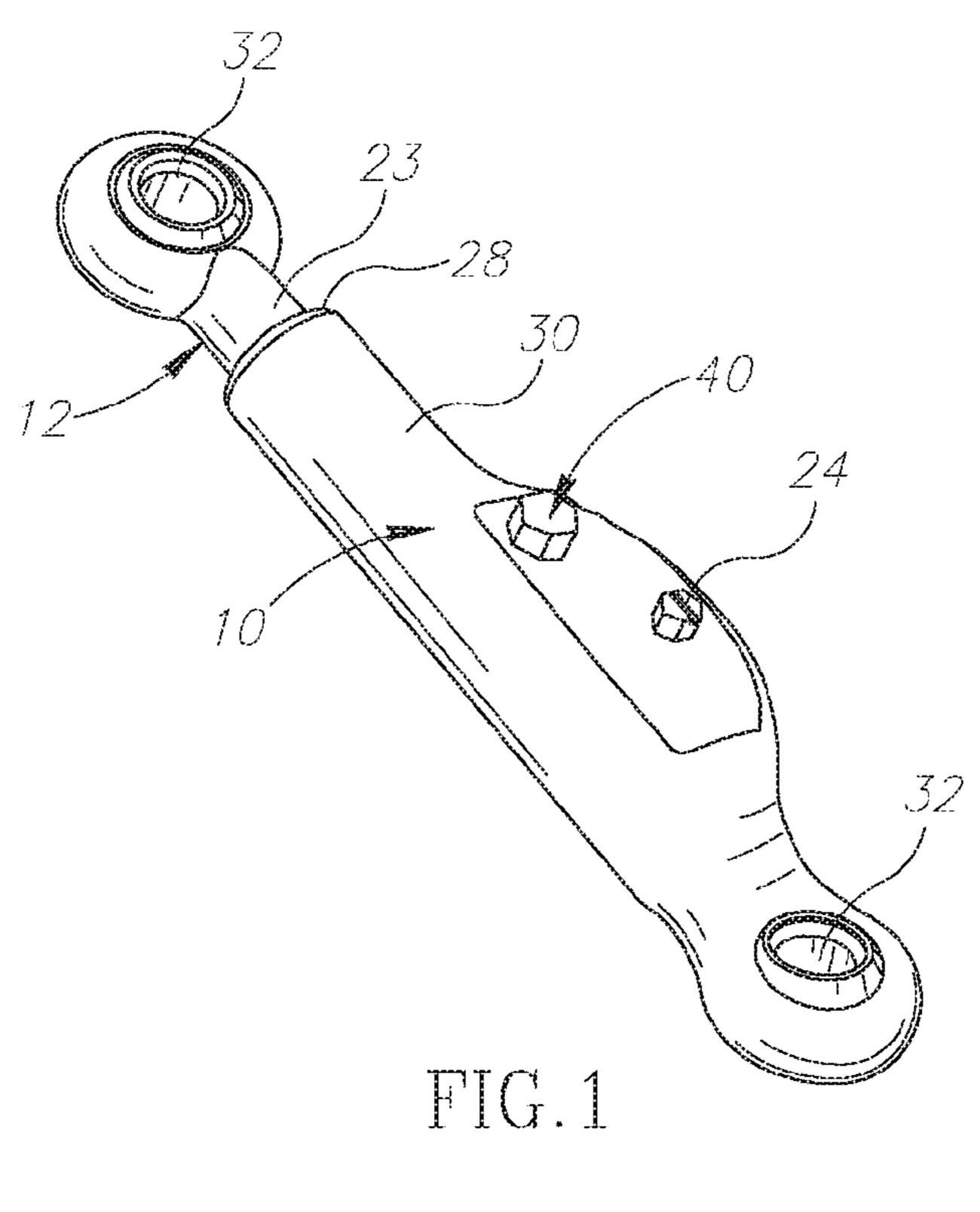
Page 2

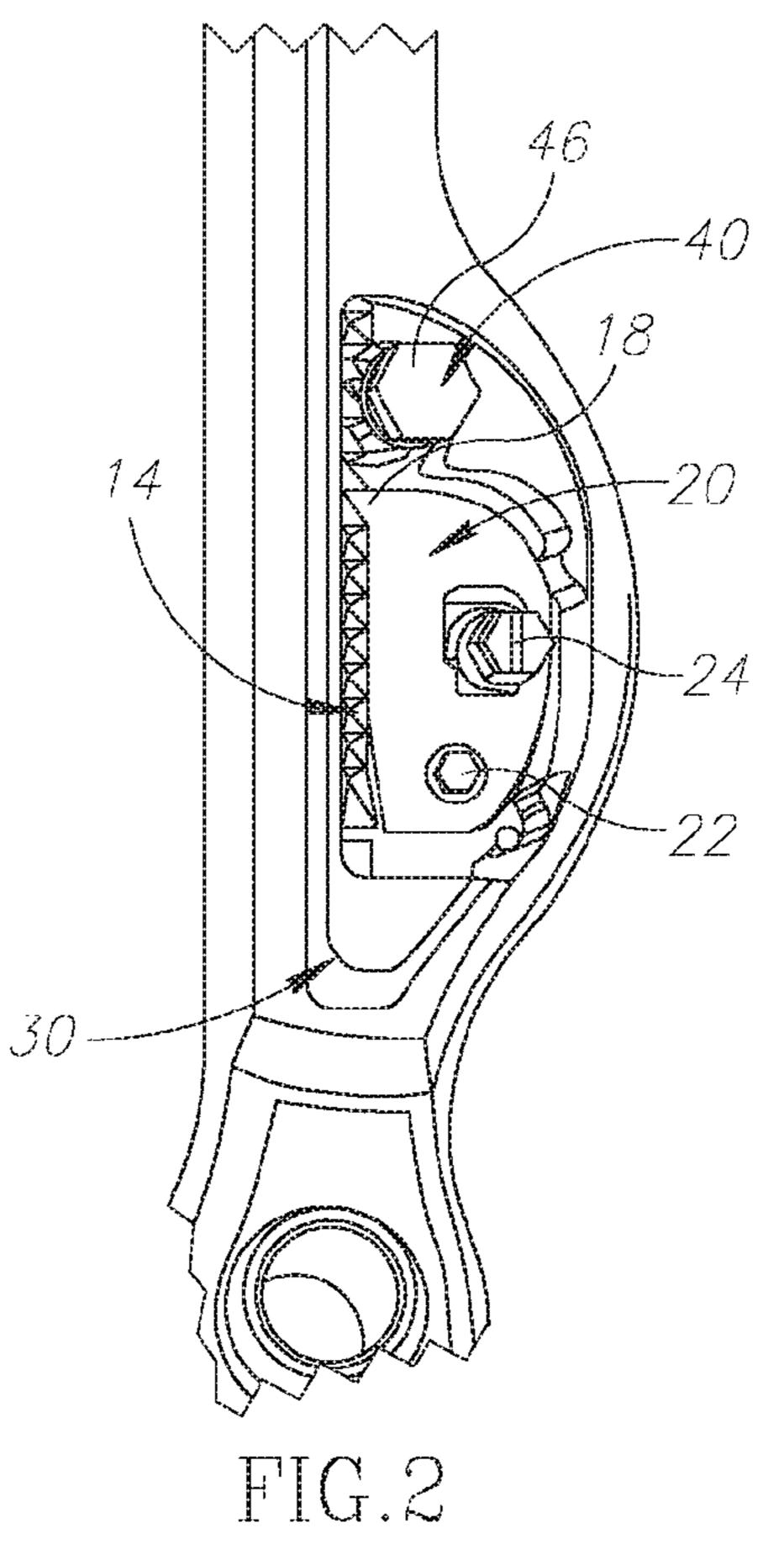
(56) References Cited

U.S. PATENT DOCUMENTS

2010/0152734	A1*	6/2010	Mulone A61B 17/663	
2010/0312243				
2011/0130835 2011/0270314			Mueller A61B 17/704	
2012/0083845	A1*	4/2012	606/264 Winslow A61B 17/7007	
2013/0338713	A 1	12/2013	606/264 Kawakami	

^{*} cited by examiner





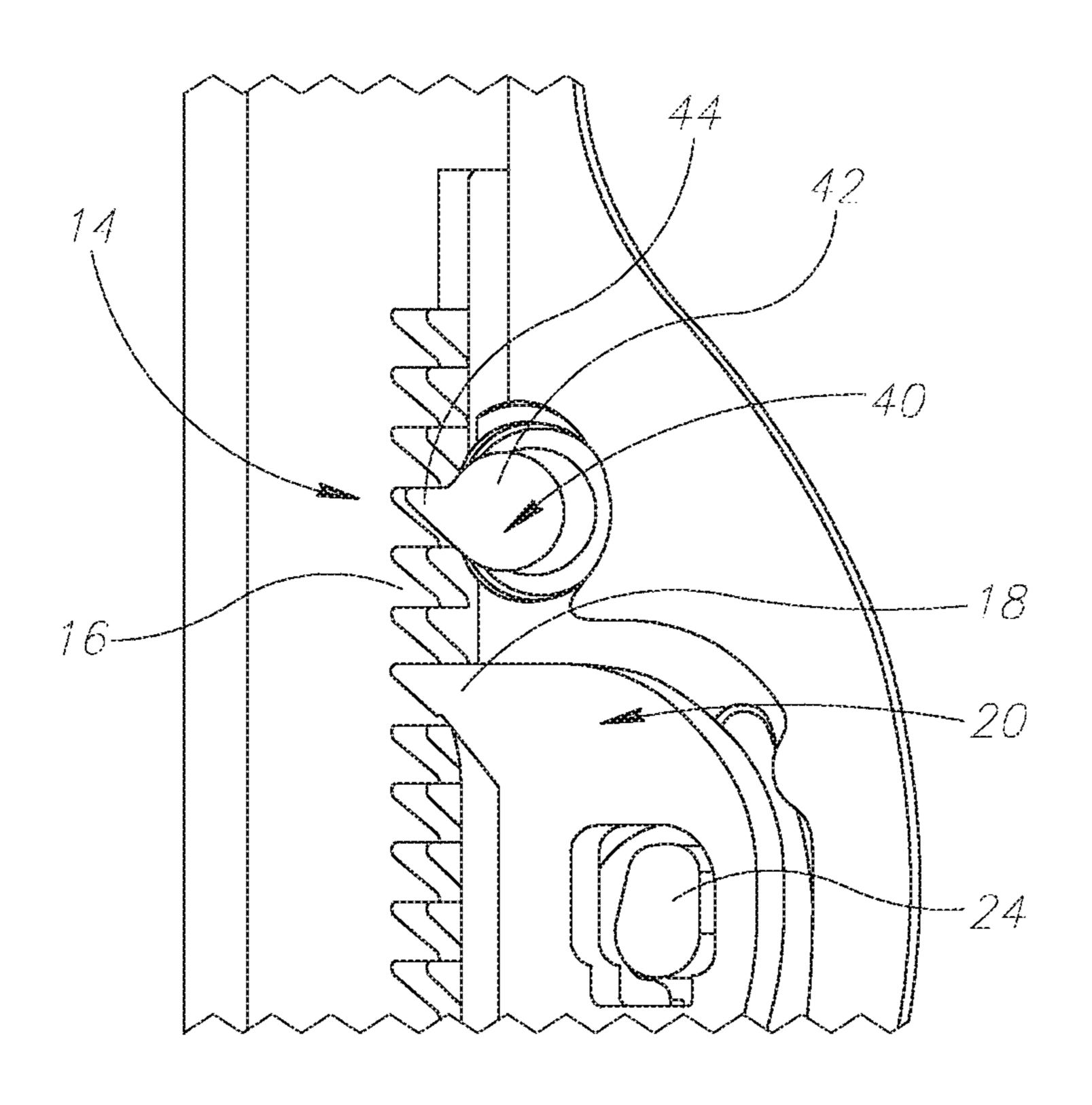


FIG.3

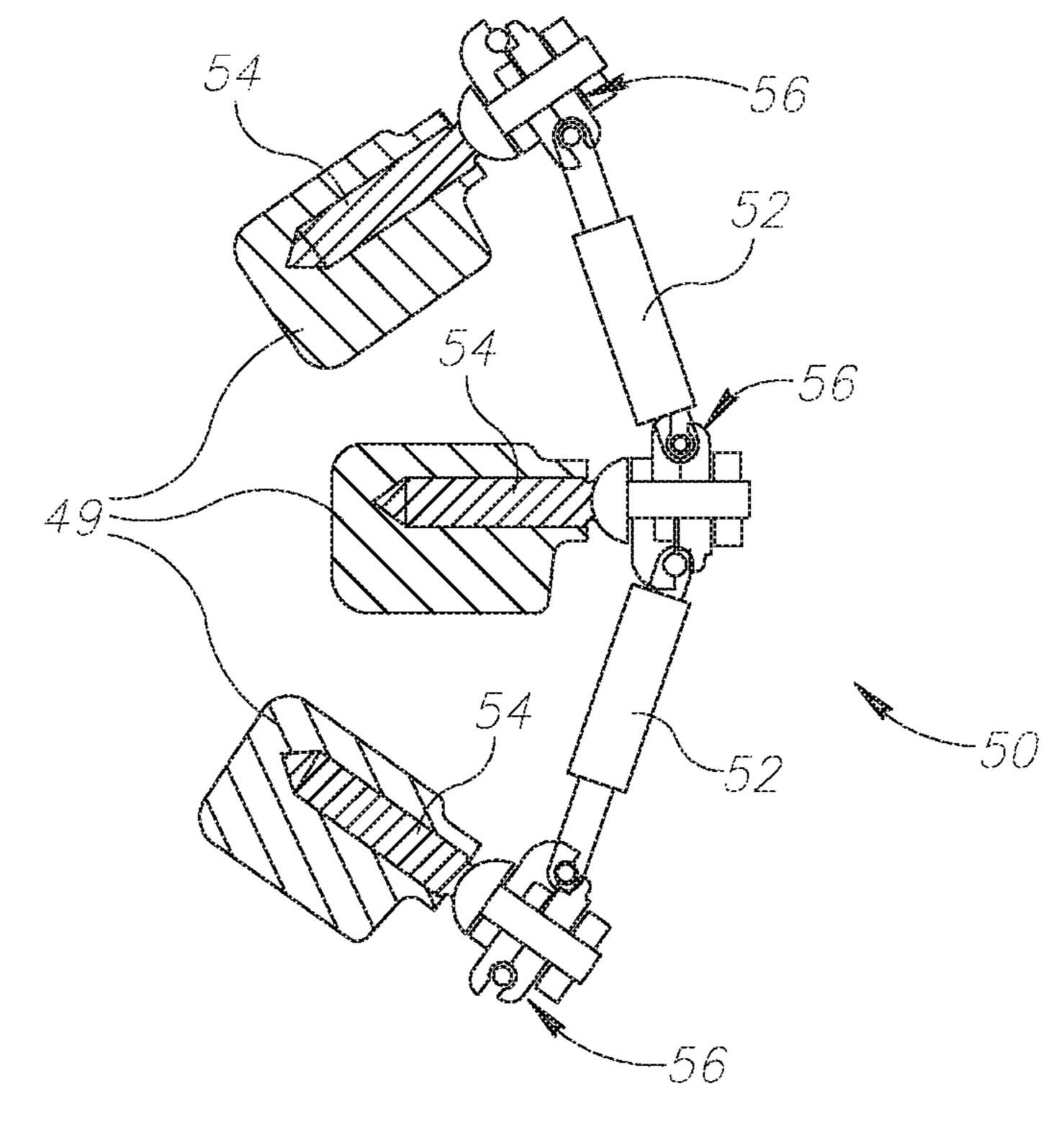


FIG.4

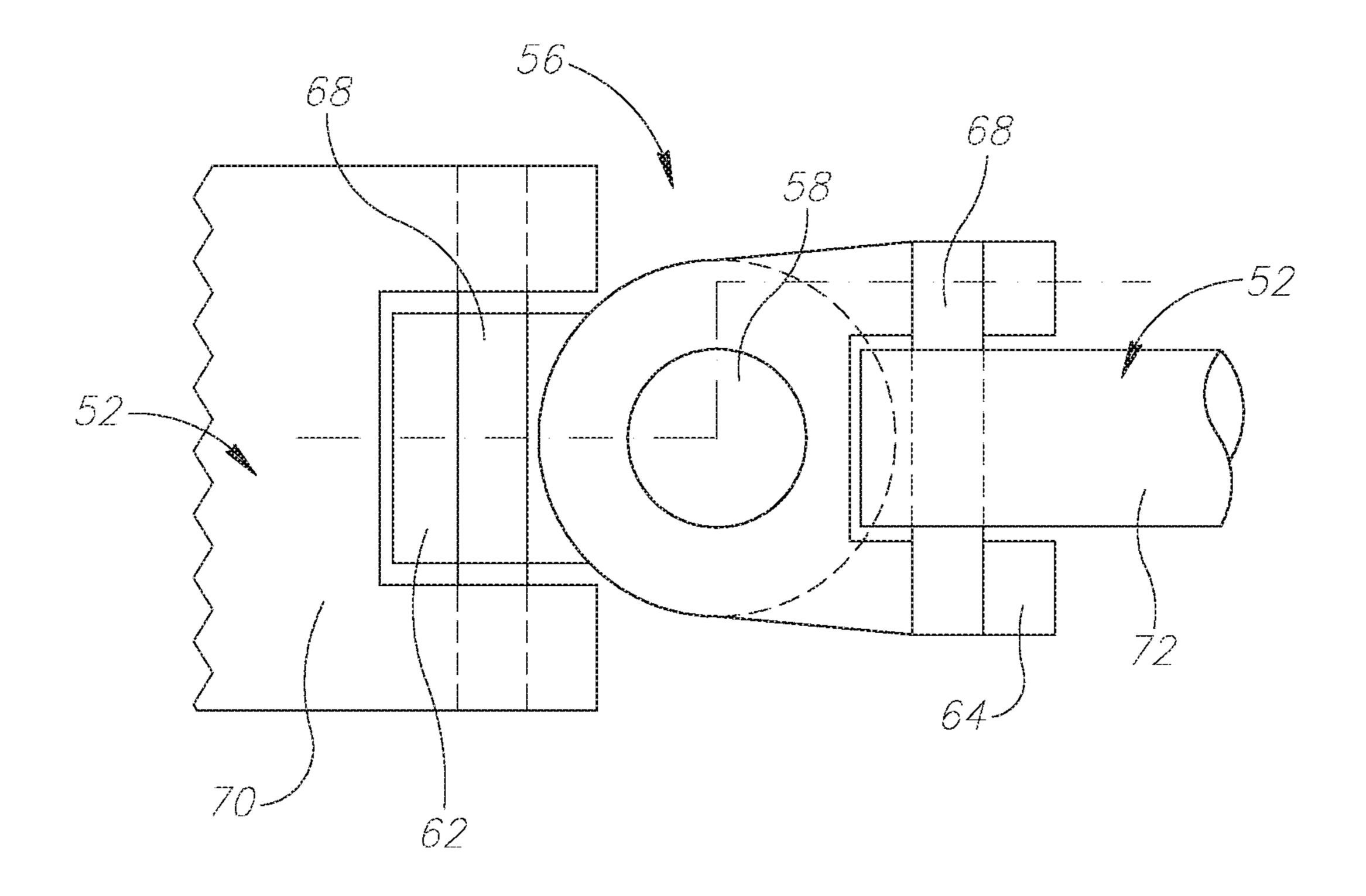
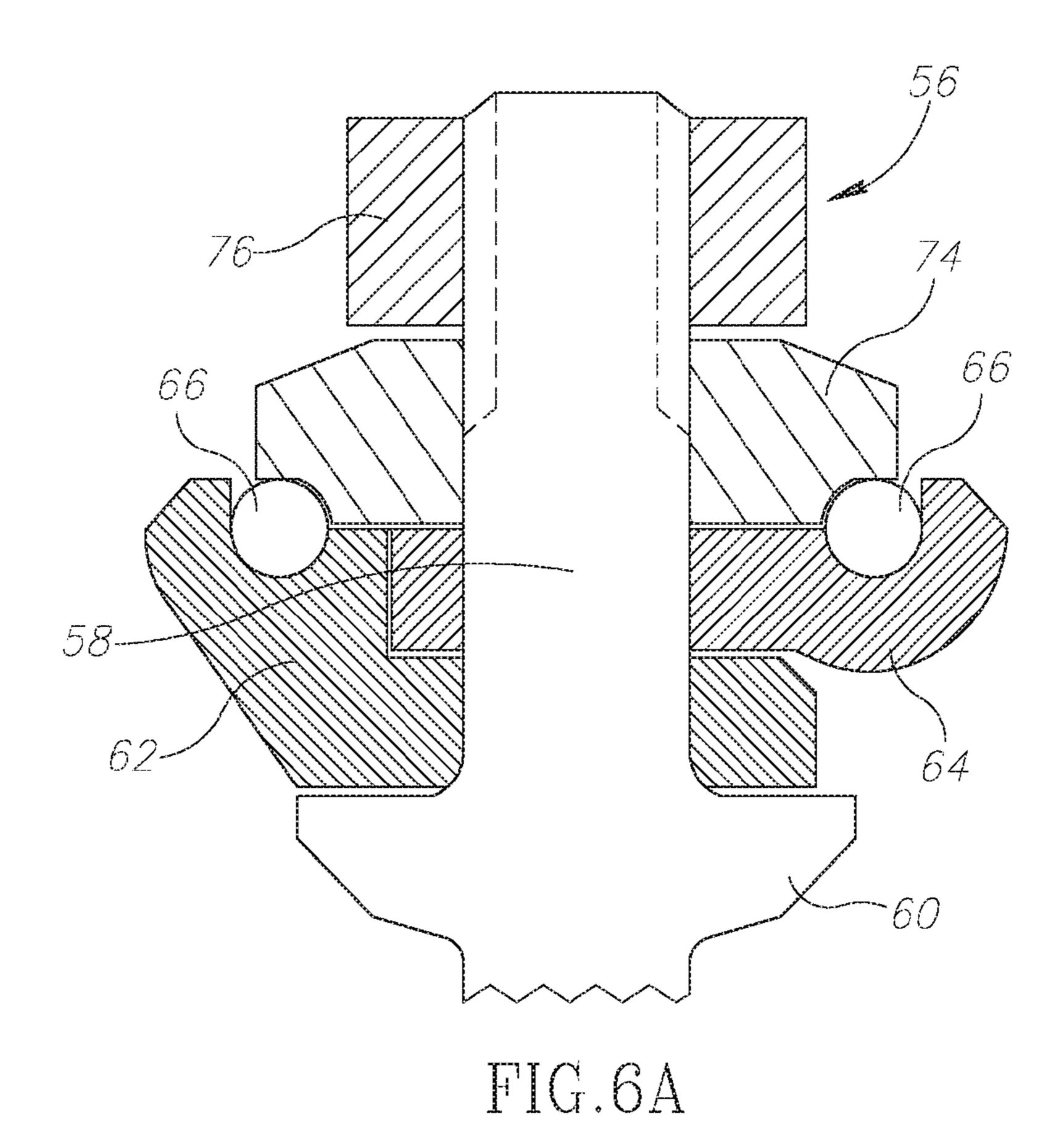
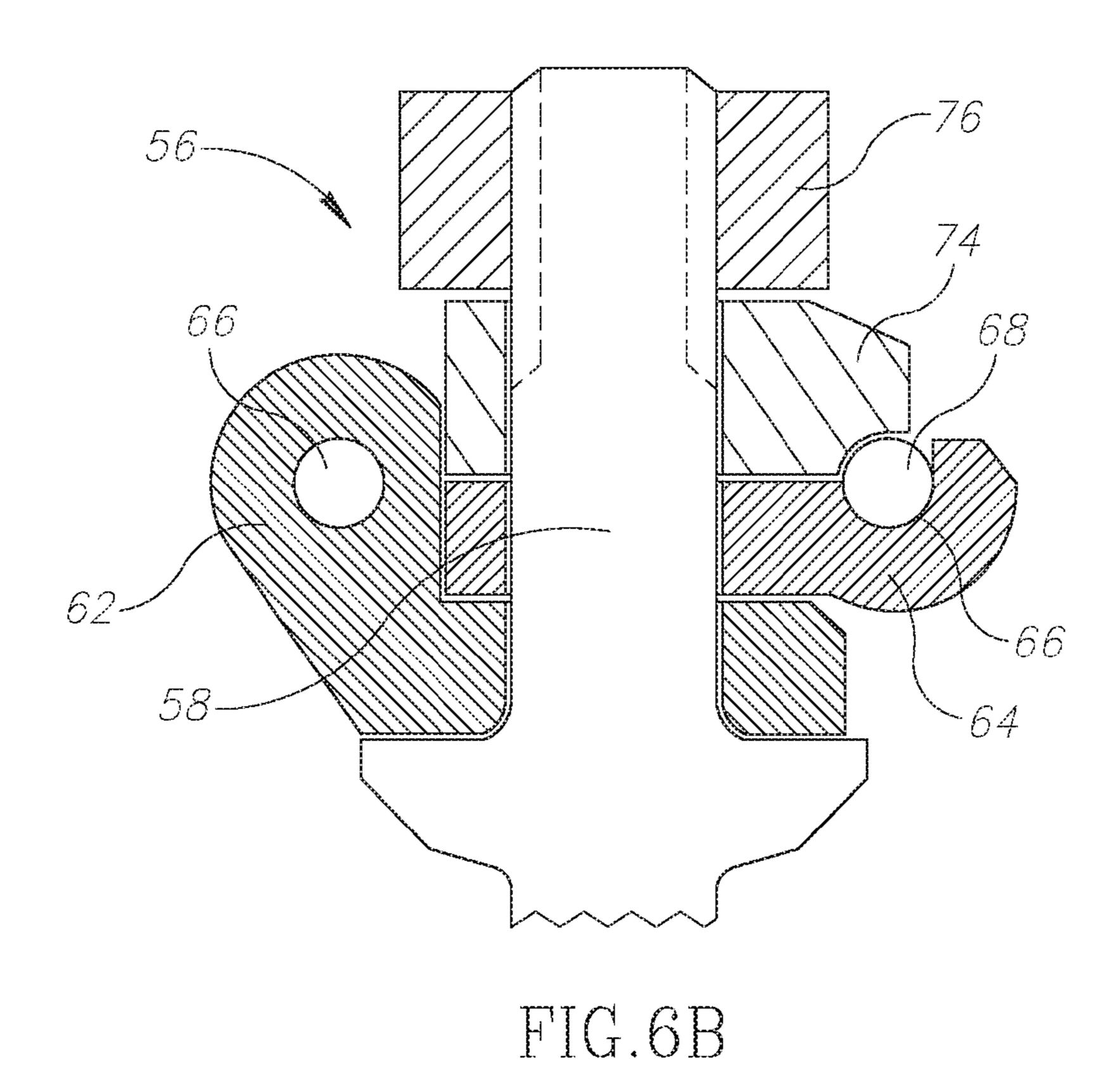


FIG.5

Jul. 19, 2022





RATCHETED SPINAL DEVICES

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

FIELD OF THE INVENTION

The present invention relates generally to spinal implants and prostheses, and particularly to spinal implants having ratchet mechanisms, such as a spinal implant with joints that 15 permit movement in different degrees of freedom, or a spinal implant with a force applicator to control a ratchet mechanism.

BACKGROUND OF THE INVENTION

Scoliosis is a spinal deformity affecting many people. Current surgical treatment involves affixing long fusion rods to the spine by pedicle screws. The rod system is intended to force the deformed spine into a more healthy position. Other spinal disorders which are often treated by fusion include hyperkyphosis and hyperlordosis.

As an alternative to fusion, PCT Patent Application PCT/US2011/035278 of the same inventor describes improved 30 spinal devices that can be lengthened or shortened using a ratchet mechanism. The devices have a variable-length member that can be connected to standard pedicle screws as well as to other spinal rods, using appropriate connectors.

SUMMARY OF THE INVENTION

The present invention seeks to provide further improved spinal devices.

In one embodiment, the spinal device is in the form of a spinal rod (the term rod, or rod assembly, refers to one or more elongate components that together function as a rod and which do not necessarily have a cylindrical shape but can also be bars and other shapes) that can be lengthened or shortened using a ratchet mechanism. The rod is a variable-length member that can be connected to standard pedicle screws as well as to other spinal rods, using appropriate connectors. The variable-length member can also be directly connected to, or be supported by, bony elements of the spine.

In one embodiment of the invention, the device can be set 50 to three different configurations:

- a. Ratchet mechanism active and the variable-length member (rod) can change in length (extend or contract) in one direction.
- b. Ratchet mechanism not active and the variable-length 55 member can move in opposite directions corresponding to the extending and contracting directions.
- c. Locked position, wherein the length of the variable-length member is fixed.

In an embodiment of the invention, the selection of these 60 configurations can be done by rotating an internal element of the assembly. For example, the rotation of the internal element can be done using a worm gear mechanism. The worm gear can be activated by a shaft, through a percutaneous procedure or by an implantable mechanism such as an 65 electric motor, magnet arrangement or other means known to those skilled in the art.

2

In another embodiment of the present invention, the variable-length member can have two portions with different rigidity. For example, the variable-length member can have a flexible portion (e.g., when the ratchet is built such that the rod can be only shortened) like a flexible cable, a rope, a flexible mechanical joint and other means known to those skilled in the art.

In another embodiment of the invention, useful when the rod is supported directly by bone structure of the spine, the hook holding against the bone can have a second hook to fix it to the optimal position.

BRIEF DESCRIPTION OF DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

- FIG. 1 is a simplified pictorial illustration of a ratcheted spinal device, constructed and operative in accordance with a non-limiting embodiment of the invention;
 - FIG. 2 is a simplified pictorial illustration of a ratchet mechanism of the ratcheted spinal device of FIG. 1;
- FIG. 3 is a simplified illustration of a force applicator that can adjust or advance the ratchet mechanism of the ratcheted spinal device of FIG. 1;
 - FIG. 4 is a simplified pictorial illustration of a spinal device, including two rod assemblies that are connected between three vertebrae with three bone screws, constructed and operative in accordance with a non-limiting embodiment of the present invention, wherein there are connector assemblies that permit multiple degree-of-freedom movement;
- FIG. **5** is a simplified top view illustration of one preferred embodiment of the connector assembly, in accordance with an embodiment of the present invention;
 - FIG. **6**A is a simplified cross-sectional illustration of the embodiment of FIG. **5**; and

FIG. **6**B is a simplified cross-sectional illustration of a modified version of the embodiment of FIG. **5**.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to FIGS. 1-3, which illustrates a ratcheted spinal device 10, constructed and operative in accordance with another non-limiting embodiment of the invention.

The ratcheted spinal device 10 includes a variable-length member 12. In the illustrated embodiment, the variable-length member 12 is a rod. The term "rod" encompasses any slender element of any size and cross-sectional shape, such as but not limited to, a rod, bar, wire and the like.

As similarly described in PCT Patent Application PCT/ US2011/035278, spinal device 10 includes a ratchet mechanism 14 (FIG. 2), which has an operative configuration that allows a change in length of variable-length member 12 in one direction and prevents a change in length of the variablelength member 12 in an opposite direction. Ratchet mechanism 14 has ratchet teeth 16 (FIG. 3; also called ratchet rack 16) formed along an axial portion of variable-length member 12, and a pawl 18 (FIGS. 2-3) arranged to catch on one of the teeth 16. Pawl 18 extends from a controller element 20 (FIG. 2) mounted about a pivot 22 (FIG. 2) and provided with an eccentric cam 24 (FIGS. 2-3). Rotation of eccentric cam 24 moves pawl 18 to one of three positions: a) in ratchet engagement with teeth 16 so that variable-length member 12 can incrementally move in one direction, b) in locked engagement with teeth 16 so that variable-length member 12

3

cannot move at all, and c) moved out of engagement with teeth 16 so that variable-length member 12 can move in both directions freely.

As seen in FIG. 1, one end 23 of variable-length member 12 is arranged to linearly move through an aperture 28 formed in a housing 30. Variable-length member 12 includes two polyaxial-joint attachment members 32. Both polyaxial-joint attachment members 32 are used to attach device 10 to available bone structure of the spine.

In contradistinction to PCT Patent Application PCT/ US2011/035278, in the present invention, spinal device 10 includes a force applicator 40 to control ratchet mechanism 14. Force applicator 40 includes, without limitation, a cam 42 which has a tooth 44 (FIG. 3). The head 46 of cam 42 is shown in FIG. 2 (e.g., hexagonal head); head 46 is not shown for simplicity in FIG. 3. By turning head 46 with a suitable tool, such as a wrench (not shown), in the clockwise direction of FIG. 3, the tooth 44 of cam 42 forcefully moves ratchet rack 16 (upwards in the sense of FIG. 3), so that the tooth in which pawl 18 is engaged moves out of engagement with pawl 18 and the next lower tooth of ratchet rack 16 moves into engagement with pawl 18. Accordingly, force applicator 40 adjusts or advances the ratchet mechanism 14.

Reference is now made to FIG. 4, which illustrates a spinal device 50, in accordance with an embodiment of the present invention.

In the illustrated embodiment, spinal device **50** includes two rod assemblies **52** that are connected between three vertebrae **49** with three bone screws **54**. The rod assemblies **52** may be constructed, without limitation, as ratcheted spinal devices **10** or other spinal devices. Connector assemblies **56** form jointed connections between rod assemblies **52**. Connector assemblies **56** permit multiple degree-of-freedom movement of rod assemblies **52** (e.g., variable-35 length members **12**), as will be explained below.

It is noted that any number of vertebrae can be selected, since the design of the system is modular. It is also noted that the middle jointed connection of the two rod assemblies **52** does not have to be connected to any vertebra, meaning one or more vertebrae can be skipped, depending on the application. In the drawing figure, bone screws **54** are inserted in the pedicles, but other insertion locations can be used.

Reference is now made to FIGS. 5 and 6A, which illustrate one preferred embodiment of the connector assembly 56, in accordance with an embodiment of the present invention.

Connector assembly **56** includes a bolt **58** (e.g., a central threaded bolt) having a head **60**, and which passes through a hole formed in a first hinge member **62** and a second hinge member **64**, which may lie on top of, or be adjacent to, first hinge member **62**. Each hinge member is formed with a receiver **66** (FIG. **6A**) for receiving therein a pivot pin **68** (FIG. **5**). One of the pivot pins **68** is pivotally received in an end **70** of one of the rod assemblies **52**, and the other pivot pin **68** is pivotally received in an end **72** of another of the rod assemblies **52** (FIG. **5**). Thus adjacent rod assemblies **52** can pivot with respect to one another by means of connector assembly **56**. A locking element **74** (such as a nut) secures pins **68** in place (FIG. **6A**). Another locking element **76**

4

(such as a nut) is threaded on the end of threaded bolt **58** to complete the assembly (FIG. **6**A).

FIG. 6B illustrates a variation of the embodiment of FIG. 6A. Like elements are designated by like numerals. The main differences are the shape of locking element 74 and the receiver 66 of the first hinge member 62 has a closed aperture instead of the open aperture of FIG. 6A. Other variations are also possible within the scope of the invention.

Connector assemblies **56** permit multiple degree-of-freedom movement of rod assemblies **52**. Rotation is permissible about the longitudinal axis of central threaded bolt **58**, and independently about the longitudinal axis of each pin **68**, which are perpendicular to the longitudinal axis of central threaded bolt **58**.

What is claimed is:

- 1. A system comprising at least one spinal device, said at least one spinal device comprising:
- a variable-length member comprising a ratchet mechanism that has an operative configuration that allows a change in length of said variable-length member in one direction and prevents a change in length of said variable-length member in an opposite direction, wherein said variable-length member comprises polyaxial-joint attachment members for attachment to bone, which permit pivoting movement of said attachment members about more than one pivoting axis, and a force applicator operative to adjust or advance said ratchet mechanism, wherein said force applicator com
 - ratchet mechanism, wherein said force applicator comprises a cam which has a tooth that engages a ratchet rack of said ratchet mechanism, and wherein by turning said cam, said tooth of said cam forcefully moves said ratchet rack so that a tooth of said ratchet rack, in which a pawl of said ratchet mechanism is engaged, moves out of engagement with said pawl and another tooth of said ratchet rack moves into engagement with said pawl.
- 2. The system according to claim 1, wherein said at least one spinal device comprises a pair of said spinal devices and a connector assembly that forms a jointed connection between said pair of spinal devices that permits multiple degree-of-freedom movement of said pair of spinal devices.
- 3. The system according to claim 2, further comprising a connector assembly that forms a jointed connection between said variable-length members that permits multiple degree-of-freedom movement of said variable-length members.
- 4. The system according to claim 3, wherein said connector assembly comprises a bolt which passes through a first hinge member and a second hinge member adjacent said first hinge member, and pivot pins that pivotally connect said spinal devices to said first hinge member and said second hinge member.
- 5. The system according to claim 4, wherein said connector assembly permits rotation about a longitudinal axis of said bolt, and independently about a longitudinal axis of each pivot pin, which are perpendicular to the longitudinal axis of said bolt.
- 6. The system according to claim 1, wherein said cam of said force applicator comprises a head configured for turning with a tool.

* * * * *