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(54) **Title**: EXTERNAL FIXATION SYSTEM

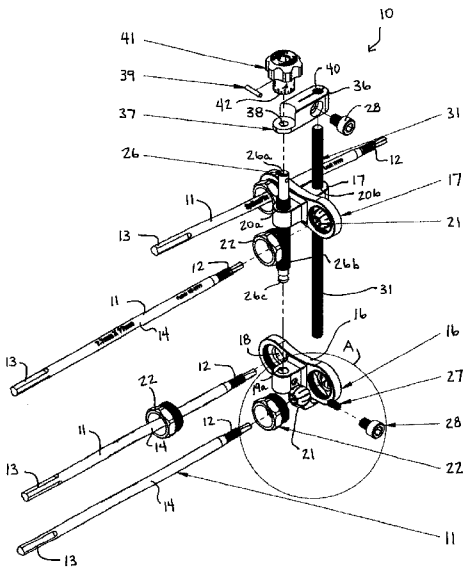


FIG. 1

(57) Abstract: An external fixation system having at least one ball collet pivotably mounted within a movable clamp and at least one ball collet pivotably mounted within a fixed clamp, wherein a surgical pin is mounted within each ball collet. In operation, the surgical pins are screwed into bone and passed through openings through the fixed clamp, movable clamp, and ball collets. A drive knob is operable to rotate a drive screw and thereby move the movable clamp either towards or away from the fixed clamp and concomitantly move the pins secured in the movable clamp either towards or away from the pins secured in the fixed clamp. A connecting rod prevents axial rotation of the movable clamp and fixed clamp relative to each other.

EXTERNAL FIXATION SYSTEM

TECHNICAL FIELD

The present invention relates to medical devices, and more particularly, to an external fixation system for stabilizing a bone fracture.

BACKGROUND ART

External fixation systems are used for a number of medical purposes, such as to treat certain bone fractures, for bone lengthening procedures, and to correct certain bone deformations. These fixation systems are used by inserting a plurality of surgical pins through the skin and into the bone on each side of a bone fracture. The pins are attached to an external frame assembly to provide stability and proper alignment of bone fragments during the healing process. These surgical pins may remain in position for several days, weeks, or even months, depending upon the severity of the fracture and other factors. The present invention is an improvement to such external fixation systems.

DISCLOSURE OF THE INVENTION

According to a preferred embodiment of the present invention, the invention is an external fixation system comprising a plurality of surgical pins, a plurality of ball collets, a plurality of collet caps, a drive screw, a connecting rod, a cap clamp having a first hole for receiving the upper end of the drive screw therethrough and a second hole for receiving the connecting rod therethrough, a movable clamp having a first hole for receiving the body of the drive screw therethrough and a second hole for receiving the connecting rod therethrough and a first opening for receiving a surgical pin therethrough, a fixed clamp having a first hole for receiving the lower end of the drive screw therein and a second hole for receiving the connecting rod therethrough and a first opening for receiving a surgical pin therethrough, and a drive knob having a hole for receiving the upper end of the drive screw therein wherein the drive knob is secured to the drive screw for concomitant rotation therewith.

A first ball collet is pivotably mounted within the movable clamp first opening, wherein the first ball collet is secured within the movable clamp first opening by a first

collet cap reversibly attached to the movable clamp, and wherein a first surgical pin is pivotably mounted within the first ball collet. A second ball collet is pivotably mounted within the fixed clamp first opening, wherein the second ball collet is secured within the fixed clamp first opening by a second collet cap reversibly attached to the fixed clamp, and wherein a second surgical pin is pivotably mounted within the second ball collet. A third ball collet is pivotably mounted within a movable clamp second opening, wherein the third ball collet is secured within the movable clamp second opening by a third collet cap reversibly attached to the movable clamp, and wherein a third surgical pin is pivotably mounted within the third ball collet. A fourth ball collet is pivotably mounted within a fixed clamp second opening, wherein the fourth ball collet is secured within the fixed clamp second opening by a fourth collet cap reversibly attached to the fixed clamp, and wherein a fourth surgical pin is pivotably mounted within the fourth ball collet.

In operation, first ends of the surgical pins are preferably screwed into fractured bone and the second ends of the pins are passed through openings through the fixed clamp and movable clamp, the ball collets, and the collet caps. The collet caps are tightened to compress the ball collets and thereby secure the pins within the ball collets. The drive knob can be rotated clockwise or counterclockwise to rotate the drive screw and thereby move the movable clamp either towards or away from the fixed clamp and concomitantly move the pins through the movable clamp either towards or away from the pins through the fixed clamp.

A principal feature of the invention is the connecting rod. The connecting rod is preferably splined to provide excellent transport geometry and prevent the movable and fixed clamps from axial rotation relative to each other. This novel feature has application in other external fixation systems, such as simple unilateral frame assemblies utilizing single pin clamps and/or double pin clamps, or in a ring-type frame assembly (e.g., an "Ilizarov" device). Another principal feature of the invention is the collet feature, wherein use of the ball collets allows for an expanded area for surgical pin placement and enhances the accuracy of pin placement, with each pin having an independent range of motion.

These and other features of the invention will become apparent from the following detailed description of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded front perspective view of the present invention.

FIG. 2 is a detail view of area A in FIG. 1.

FIG. 3 is a right front perspective view of the present invention.

FIG. 4 is a right side elevational view of the present invention.

FIG. 5 is a top plan view of the present invention.

FIG. 6 is a front elevational view of the present invention.

FIG. 7 is a sectional view taken along line B-B in FIG. 6.

FIG. 8 is a side elevational view of the splined connector.

FIG. 9 is a sectional view of the splined connector taken along line C-C in FIG. 8.

FIG. 10 is a perspective view of the ball collet.

FIG. 11 is a top plan view of the ball collet.

FIG. 12 is a side elevational view of the ball collet.

FIG. 13 is a sectional view of the ball collet taken along line D-D in FIG. 12.

FIG. 14 is a right front perspective view of an alternate embodiment of the present invention.

FIG. 15 is a left front perspective view of the embodiment of FIG. 14.

FIG. 16 is a left side elevational view of the embodiment of FIG. 14.

FIG. 17 is a top plan view of the embodiment of FIG. 14.

FIG. 18 is a front elevational view of the embodiment of FIG. 14.

FIG. 19 is a right front perspective view of an alternate embodiment of the present invention.

FIG. 20 is a front elevational view of the embodiment of FIG. 19.

BEST MODES FOR CARRYING OUT THE INVENTION

The present application claims priority to U.S. Provisional Patent Application No. 61/582,996, filed January 4, 2012, the disclosure of which is incorporated herein by reference. The preferred embodiments of the present invention are shown in FIGS. 1-20, wherein the invention comprises an external fixation apparatus **10** having a plurality of surgical pins **11,** wherein each pin **11** has a first end **12** that is secured directly to bone, an

opposing second end **13,** and an elongated body **14** that is secured within an external frame assembly **15.** The frame assembly **15** preferably comprises a fixed clamp **16** and a movable clamp **17,** wherein each clamp **16, 17** has at least one opening **18** therethrough with a ball collet **21** pivotably mounted therein and secured therein by a collet cap **22.** The ball collet **21** has an opening **23** therethrough that aligns with an opening **24** through the collet cap **22.** The fixed clamp **16** and movable clamp **17** are secured to each other on a front side with a drive screw **26** and on a rear side with a connecting rod **31** preferably having a plurality of splines **32** extending the length thereof ("splined connector"). The drive screw **26** and splined connector **31** are maintained in parallel relationship to each other.

The drive screw **26** has an unthreaded upper end **26a,** a threaded body **26b,** and an unthreaded lower end **26c.** The fixed clamp **16** has an unthreaded first channel or hole **19a** for receiving the unthreaded lower end **26c** of drive screw **26** therein and a grooved second hole **19b** for receiving the splined connector **31** therethrough. The fixed clamp **16** can be secured to the unthreaded lower end **26c** of drive screw **26** with a drive screw retainer **27** and a socket head cap screw **28** that allows the drive screw **26** to rotate within fixed clamp **16.** The movable clamp **17** has a threaded first hole **20a** for receiving the threaded body **26b** of the drive screw **26** therethrough and a grooved second hole **20b** for receiving the splined connector **31** therethrough. The movable clamp **17** can be threadably secured to the threaded body **26b** of drive screw **26.** A cap clamp **36** has a ring member **37** with an unthreaded first hole **38** for receiving the upper end **26a** of drive screw **26** therethrough, wherein a dowel pin **39** preferably secures the cap clamp **36** to the drive screw **26.** The cap clamp **36** has a grooved second hole **40** for receiving the splined connector **31** therethrough, wherein the cap clamp **36** can be immovably secured to the splined connector **31** with a socket head cap screw **28.** A drive knob **41** has a hole **42** for receiving the unthreaded upper end **26a** of drive screw **26** therein, wherein the drive knob **41** can be secured to the unthreaded upper end **26a** of drive screw **26** for concomitant rotation therewith. The fixation apparatus **10** is MRI compatible, lightweight, and has a low profile design for convenient use.

In operation, the first ends **12** of the pins **11** are preferably screwed into fractured bone and the second ends **13** of the pins **11** are passed through the openings **18, 23, 24**

through the fixed clamp **16** and movable clamp **17,** the ball collets **21,** and the collet caps **22.** The collet caps **22** are tightened to compress the ball collets **21** and thereby secure the pins **11** within the ball collets **21.** The drive knob **41** can be rotated clockwise or counterclockwise to rotate the drive screw **26** and thereby move the movable clamp **17** either towards (e.g. compression procedure) or away from (e.g. lengthening procedure) the fixed clamp **16** and concomitantly move the pins **11** through the movable clamp **17** either towards or away from the pins **11** through the fixed clamp **16.** The splined connector **31** prevents the movable clamp **17** and the fixed clamp **16** from axial rotation relative to each other.

A principal feature of the invention is the splined connection feature. The splined connector **31** provides excellent transport geometry and prevents the clamps **16** and **17** from rotating relative to each other. This novel feature has application in other external fixation systems, for example, in simple unilateral frame assemblies utilizing single pin clamps **51** and/or double pin clamps **52** (see FIGS. 19 and 20), or in a ring-type frame assembly (e.g., an "Ilizarov" device) such as that described in U.S. Patent No. 4,890,631 to Hardy, the disclosure of which is incorporated herein by reference.

Another principal feature of the invention is the collet feature, wherein use of the ball collets **21** allows for an expanded area for surgical pin **11** placement and enhances the accuracy of pin placement, with each pin having an independent range of motion. For example, FIG. 4 is a right side elevational view of the fixation apparatus **10** wherein pin **100** has been pivoted relative to the other pins **11** and is thus no longer in parallel relationship with them. Thus, the pins do not need to be held in parallel relationship with each other and in perpendicular relationship with the external frame assembly.

While the invention has been shown and described in some detail with reference to specific exemplary embodiments, there is no intention that the invention be limited to such detail. On the contrary, the invention is intended to include any alternative or equivalent embodiments that fall within the spirit and scope of the invention as described and claimed herein.

CLAIMS

1. An external fixation apparatus, comprising:
   a. a surgical pin having a first end for connecting to bone and an opposing second end;
   b. a ball collet having an opening for receiving said surgical pin therethrough;
   c. a collet cap having an opening for receiving said surgical pin therethrough;
   d. a connecting rod; and
   e. a clamp having a hole for receiving said connecting rod therethrough and an opening for receiving said surgical pin therethrough;
   f. wherein said ball collet is pivotably mounted within said opening of said clamp, wherein said ball collet is secured within said opening of said clamp by said collet cap reversibly attached to said clamp, wherein said surgical pin is pivotably mounted within said ball collet.

2. An external fixation apparatus according to claim 1, wherein said connecting rod has a plurality of splines extending the length thereof.

3. An external fixation apparatus, comprising:
   a. a plurality of surgical pins, wherein each surgical pin has a first end for connecting to bone and an opposing second end;
   b. a plurality of ball collets, wherein each ball collet has an opening for receiving a surgical pin therethrough;
   c. a plurality of collet caps, wherein each collet cap has an opening for receiving a surgical pin therethrough;
   d. a connecting rod having a plurality of splines extending the length thereof; and
   e. a plurality of clamps, wherein each clamp has a hole for receiving said connecting rod therethrough and an opening for receiving a surgical pin therethrough;
   f. wherein a first ball collet is pivotably mounted within a first opening of a first clamp, wherein said first ball collet is secured within said first opening of said

first clamp by a first collet cap reversibly attached to said first clamp, wherein a first surgical pin is pivotably mounted within said first ball collet; and

g. wherein a second ball collet is pivotably mounted within a first opening of a second clamp, wherein said second ball collet is secured within said first opening of said second clamp by a second collet cap reversibly attached to said second clamp, wherein a second surgical pin is pivotably mounted within said second ball collet.

4. An external fixation apparatus according to claim 3, wherein a third ball collet is pivotably mounted within a second opening of said first clamp, wherein said third ball collet is secured within said second opening of said first clamp by a third collet cap reversibly attached to said first clamp, wherein a third surgical pin is pivotably mounted within said third ball collet.

5. An external fixation apparatus according to claim 4, wherein a fourth ball collet is pivotably mounted within a second opening of said second clamp, wherein said fourth ball collet is secured within said second opening of said second clamp by a fourth collet cap reversibly attached to said second clamp, wherein a fourth surgical pin is pivotably mounted within said fourth ball collet.

6. An external fixation apparatus, comprising:

a. a plurality of surgical pins, wherein each surgical pin has a first end for connecting to bone and an opposing second end;

b. a plurality of ball collets, wherein each ball collet has an opening for receiving a surgical pin therethrough;

c. a plurality of collet caps, wherein each collet cap has an opening for receiving a surgical pin therethrough;

d. a drive screw having an upper end, a body, and a lower end;

e. a connecting rod;

f. a cap clamp having a first hole for receiving said upper end of said drive screw therethrough and a second hole for receiving said connecting rod therethrough;

g. a movable clamp having a first hole for receiving said body of said drive screw therethrough, a second hole for receiving said connecting rod therethrough, and a first opening for receiving a surgical pin therethrough;

h. a fixed clamp having a first hole for receiving said lower end of said drive screw therein, a second hole for receiving said connecting rod therethrough, and a first opening for receiving a surgical pin therethrough; and

i. a drive knob having a hole for receiving said upper end of said drive screw therein; wherein said drive knob is secured to said drive screw for concomitant rotation therewith;

j. wherein a first ball collet is pivotably mounted within said first opening of said movable clamp, wherein said first ball collet is secured within said first opening of said movable clamp by a first collet cap reversibly attached to said movable clamp, wherein a first surgical pin is pivotably mounted within said first ball collet;

k. wherein a second ball collet is pivotably mounted within said first opening of said fixed clamp, wherein said second ball collet is secured within said first opening of said fixed clamp by a second collet cap reversibly attached to said fixed clamp, wherein a second surgical pin is pivotably mounted within said second ball collet; and

l. wherein said drive knob is operable to rotate said drive screw and thereby move said movable clamp along the length of said body of said drive screw.

7. An external fixation apparatus according to claim 6, wherein said drive screw has an unthreaded upper end, a threaded body, and an unthreaded lower end.

8. An external fixation apparatus according to claim 6, wherein said connecting rod has a plurality of splines extending the length thereof.

9. An external fixation apparatus according to claim 6, wherein a third ball collet is pivotably mounted within a second opening of said movable clamp, wherein said third ball collet is secured within said second opening of said movable clamp by a third collet cap reversibly attached to said movable clamp, wherein a third surgical pin is pivotably mounted within said third ball collet.

10. An external fixation apparatus according to claim 9, wherein a fourth ball collet is pivotably mounted within a second opening of said fixed clamp, wherein said fourth ball collet is secured within said second opening of said fixed clamp by a fourth collet cap reversibly attached to said fixed clamp, wherein a fourth surgical pin is pivotably mounted within said fourth ball collet.

11. An external fixation apparatus, comprising:

a. a plurality of surgical pins, wherein each surgical pin has a first end for connecting to bone, an opposing second end, and an elongated body;

b. a plurality of ball collets, wherein each ball collet has an opening for receiving a surgical pin therethrough;

c. a plurality of collet caps, wherein each collet cap has an opening for receiving a surgical pin therethrough;

d. a drive screw having an unthreaded upper end, a threaded body, and an unthreaded lower end;

e. a connecting rod having a plurality of splines extending the length thereof;

f. a cap clamp having an unthreaded first hole for receiving said unthreaded upper end of said drive screw therethrough and a grooved second hole for receiving said connecting rod therethrough;

g. a movable clamp having a threaded first hole for receiving said threaded body of said drive screw therethrough, a grooved second hole for receiving said connecting rod therethrough, and a first opening for receiving a surgical pin therethrough;

h. a fixed clamp having an unthreaded first hole for receiving said unthreaded lower end of said drive screw therein, a grooved second hole for receiving

said connecting rod therethrough, and a first opening for receiving a surgical pin therethrough; and

i. a drive knob having a hole for receiving said unthreaded upper end of said drive screw therein; wherein said drive knob is secured to said drive screw for concomitant rotation therewith;

j. wherein a first ball collet is pivotably mounted within said first opening of said movable clamp, wherein said first ball collet is secured within said first opening of said movable clamp by a first collet cap reversibly attached to said movable clamp, wherein a first surgical pin is pivotably mounted within said first ball collet;

k. wherein a second ball collet is pivotably mounted within said first opening of said fixed clamp, wherein said second ball collet is secured within said first opening of said fixed clamp by a second collet cap reversibly attached to said fixed clamp, wherein a second surgical pin is pivotably mounted within said second ball collet;

l. wherein a third ball collet is pivotably mounted within a second opening of said movable clamp, wherein said third ball collet is secured within said second opening of said movable clamp by a third collet cap reversibly attached to said movable clamp, wherein a third surgical pin is pivotably mounted within said third ball collet;

m. wherein a fourth ball collet is pivotably mounted within a second opening of said fixed clamp, wherein said fourth ball collet is secured within said second opening of said fixed clamp by a fourth collet cap reversibly attached to said fixed clamp, wherein a fourth surgical pin is pivotably mounted within said fourth ball collet; and

n. wherein said drive knob is operable to rotate said drive screw and thereby move said movable clamp along the length of said threaded body of said drive screw.

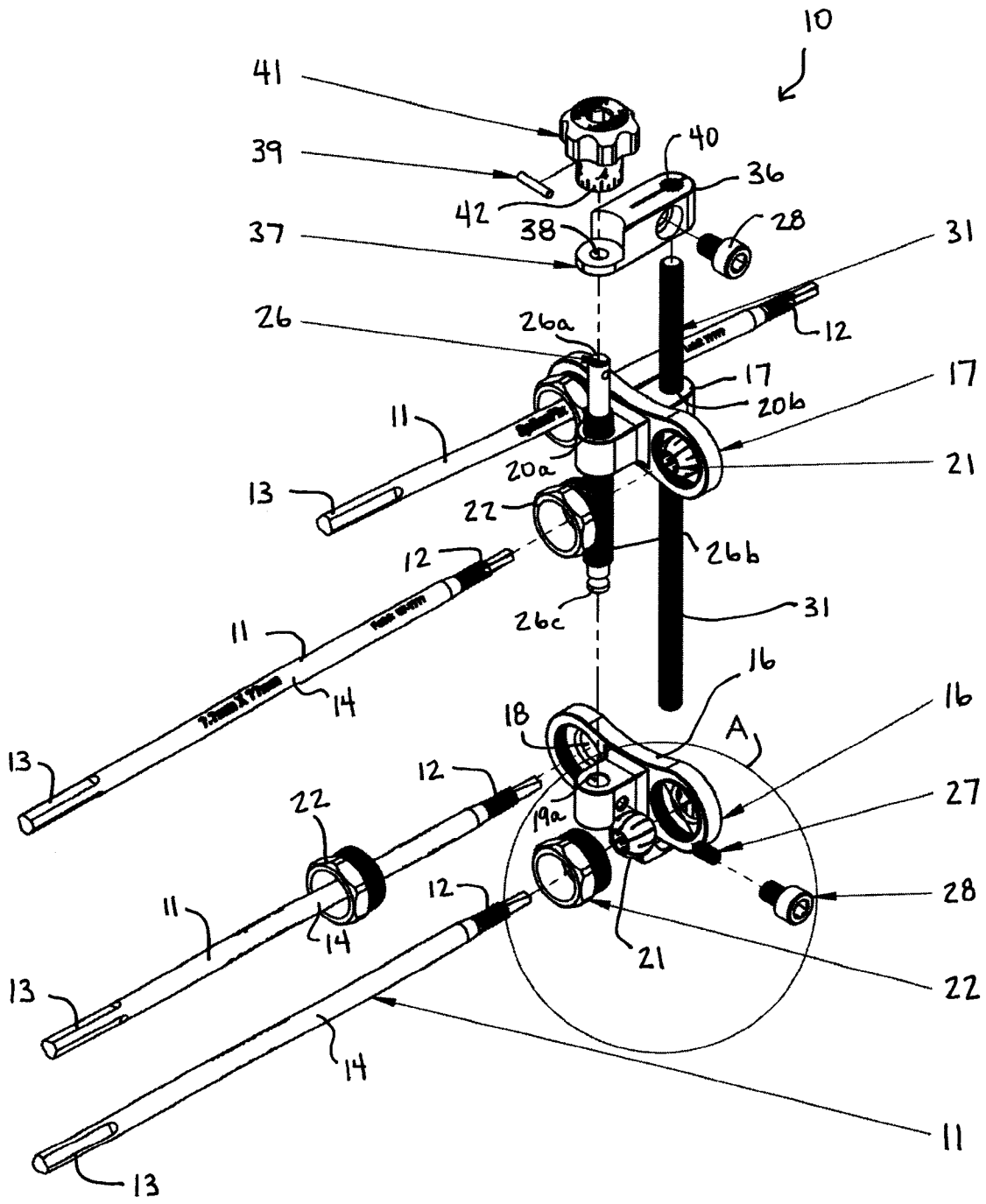

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FIG. 1

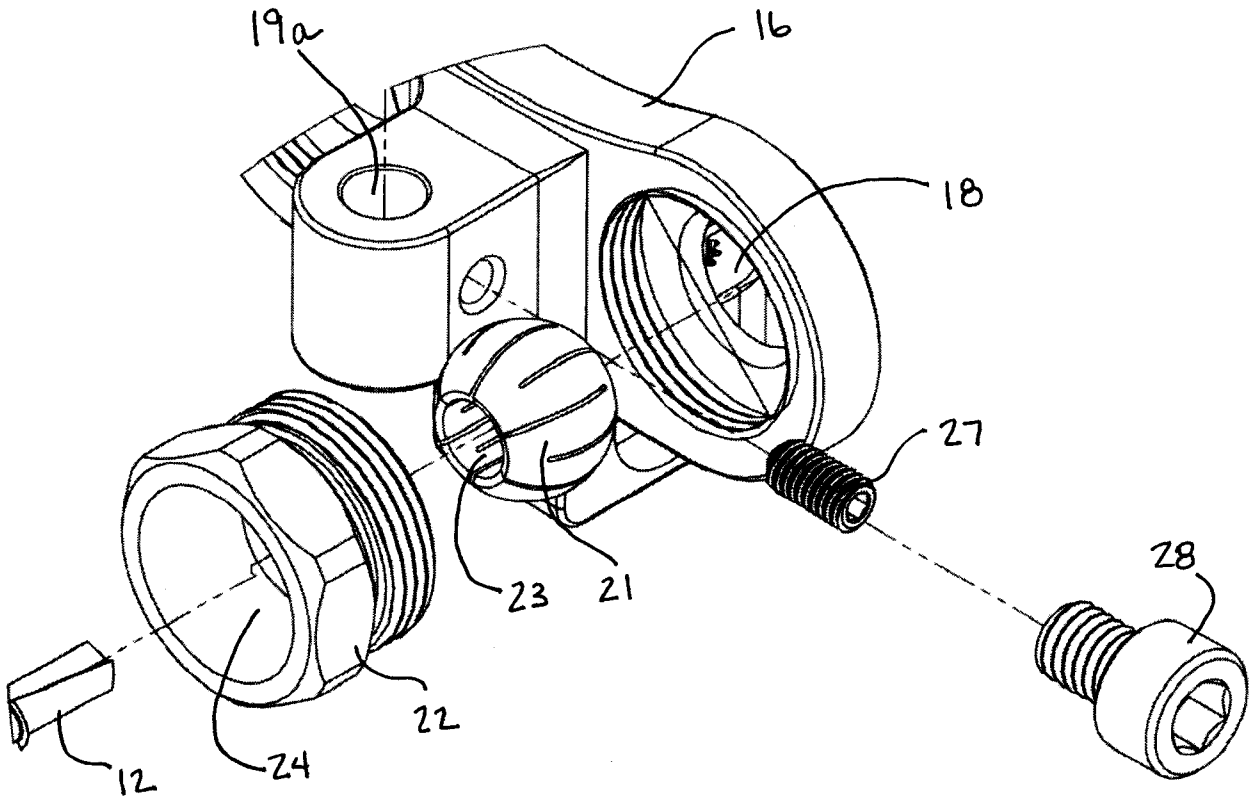


FIG. 2

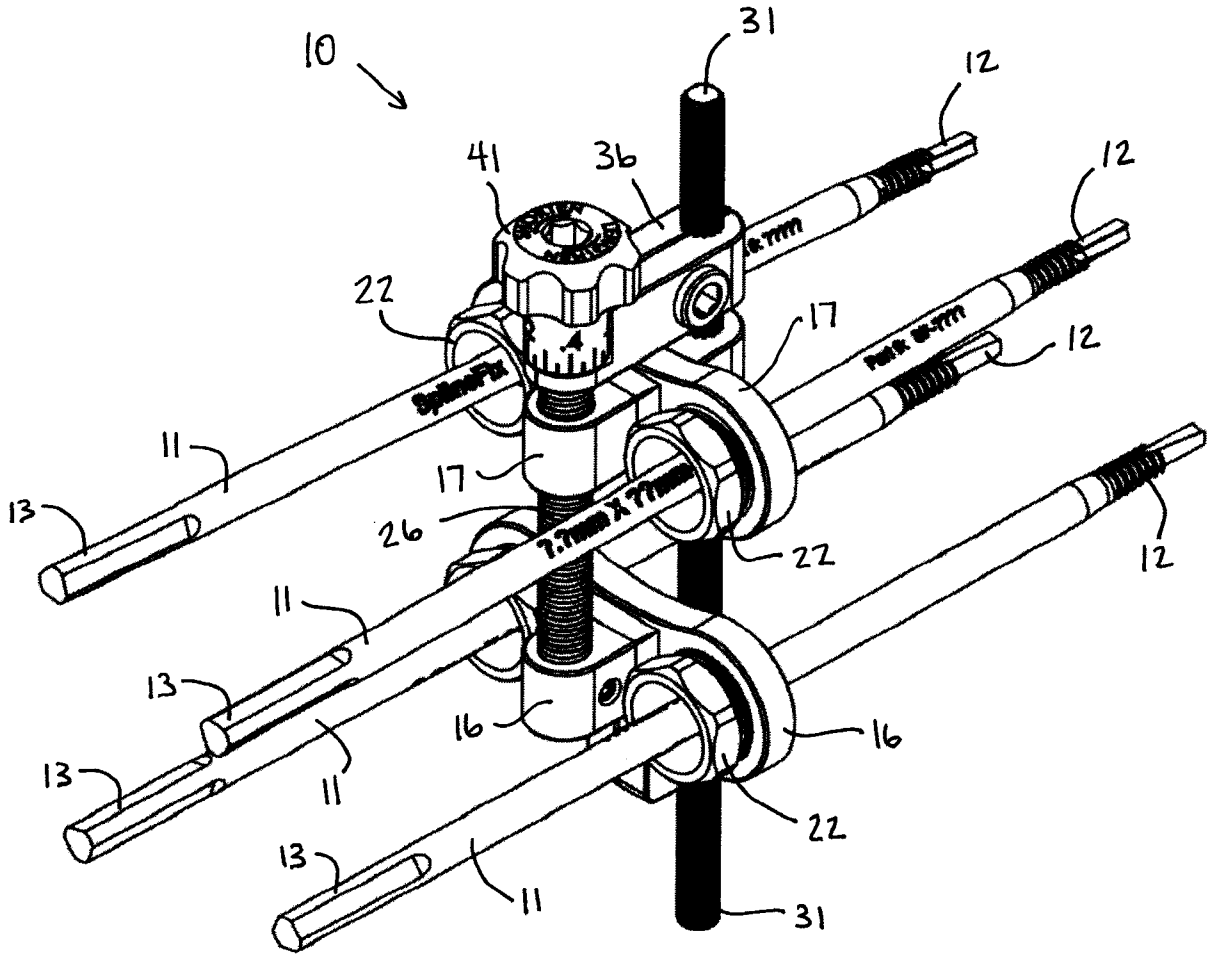

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FIG. 3

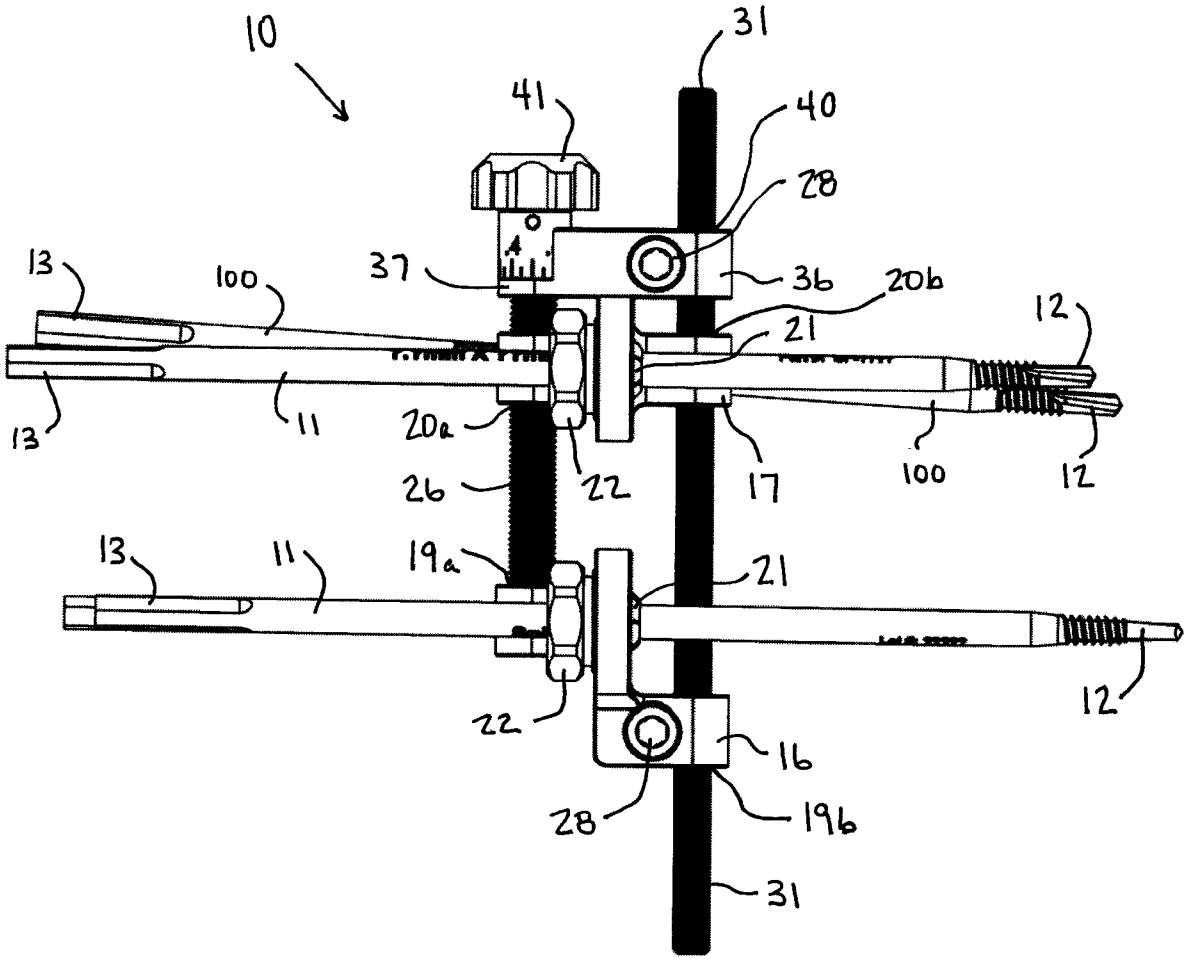

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FIG. 4

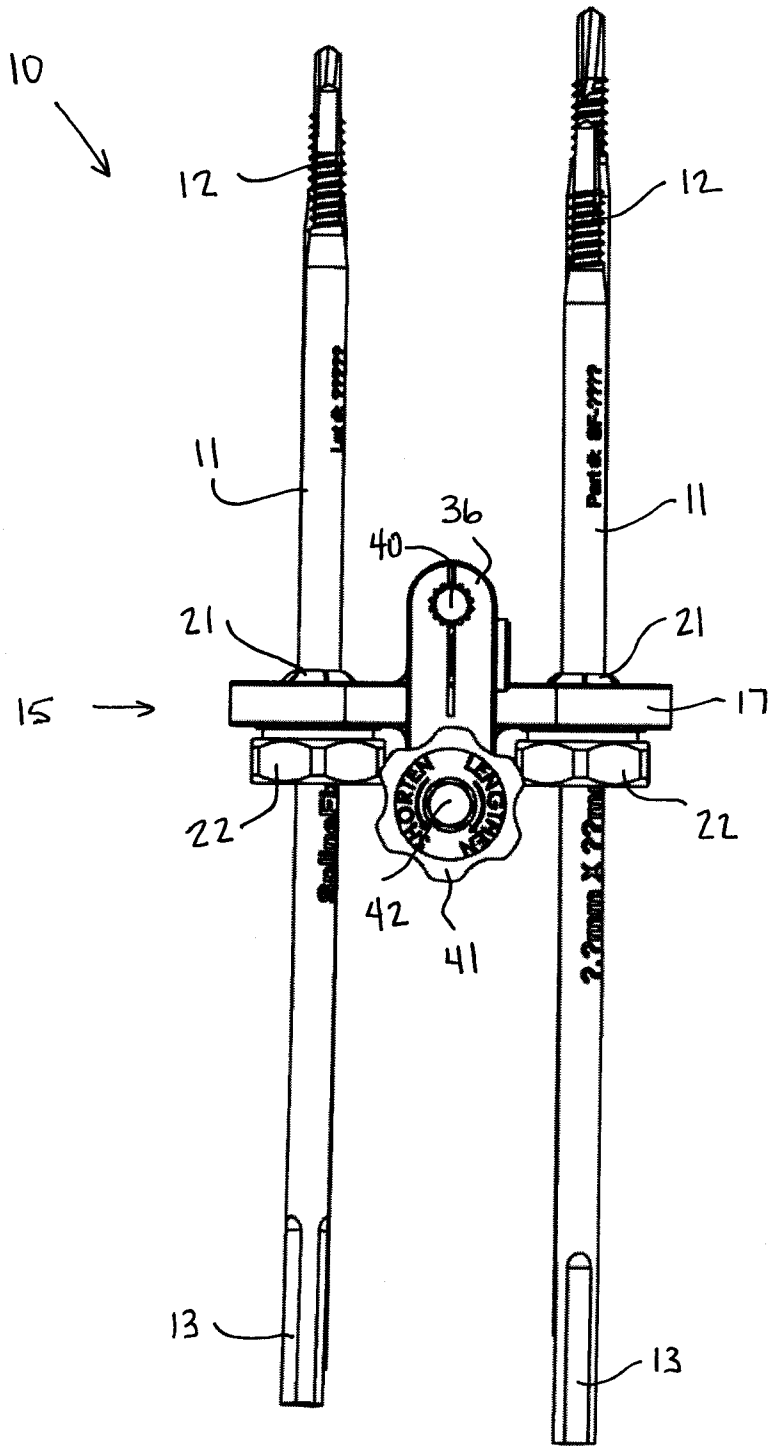


FIG. 5

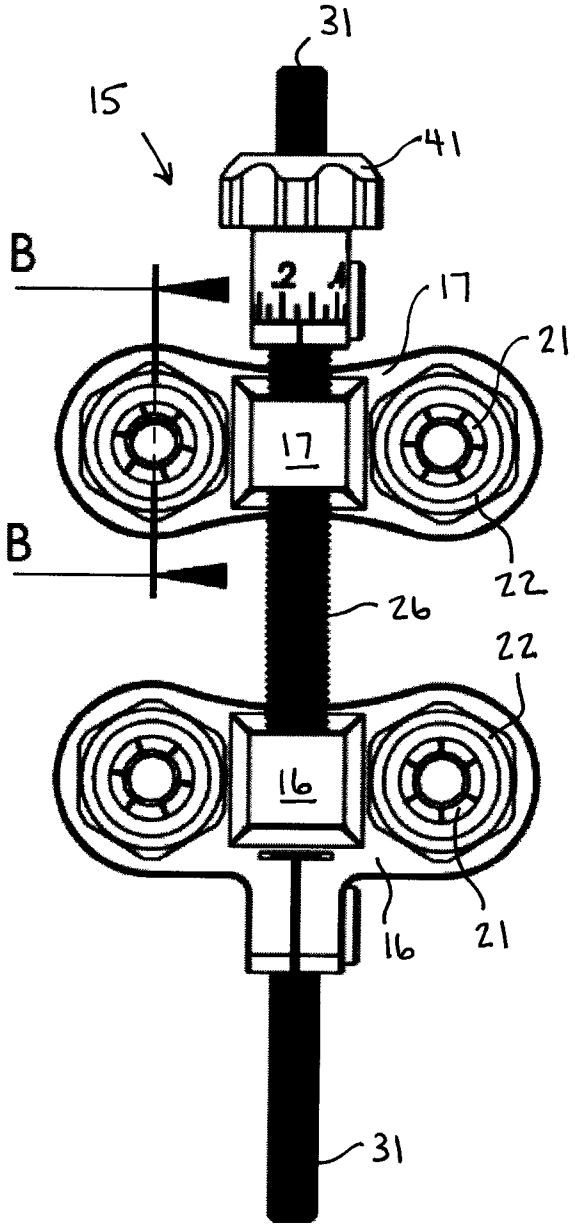


FIG. 6

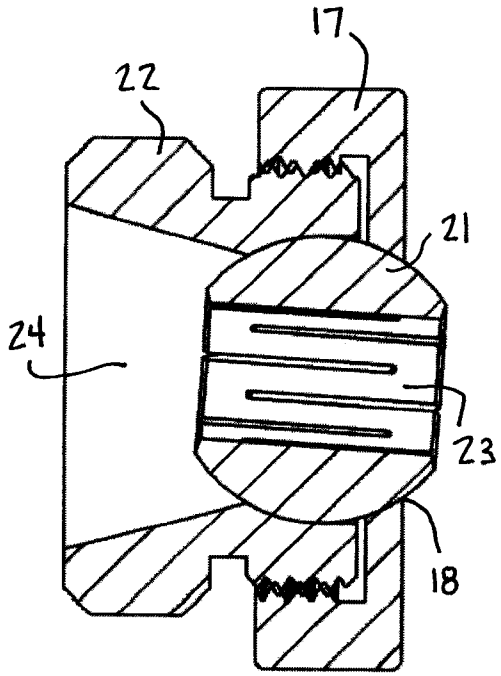


FIG. 7



FIG. 8

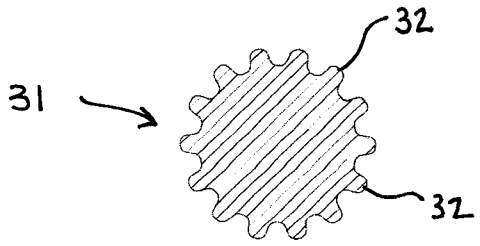


FIG. 9

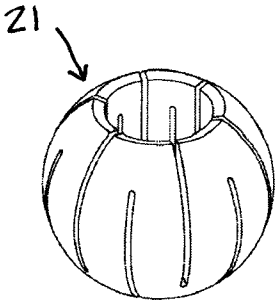


FIG. 10

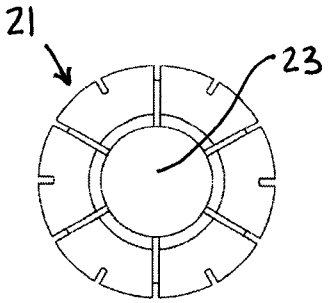


FIG. 11

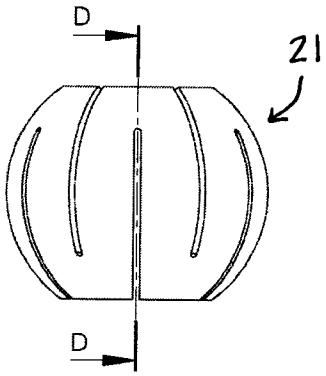


FIG. 12

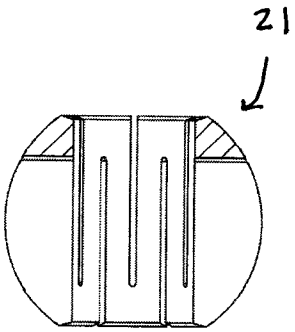


FIG. 13

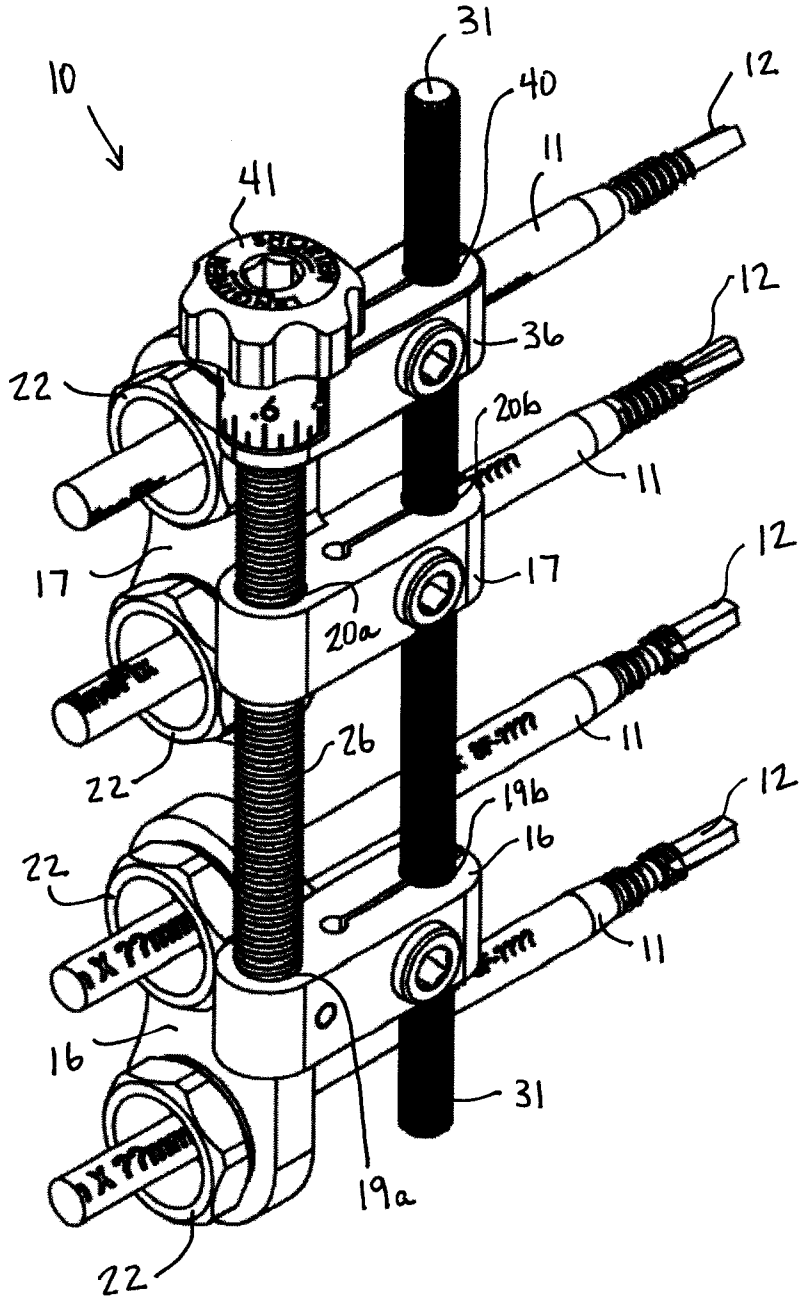

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FIG. 14

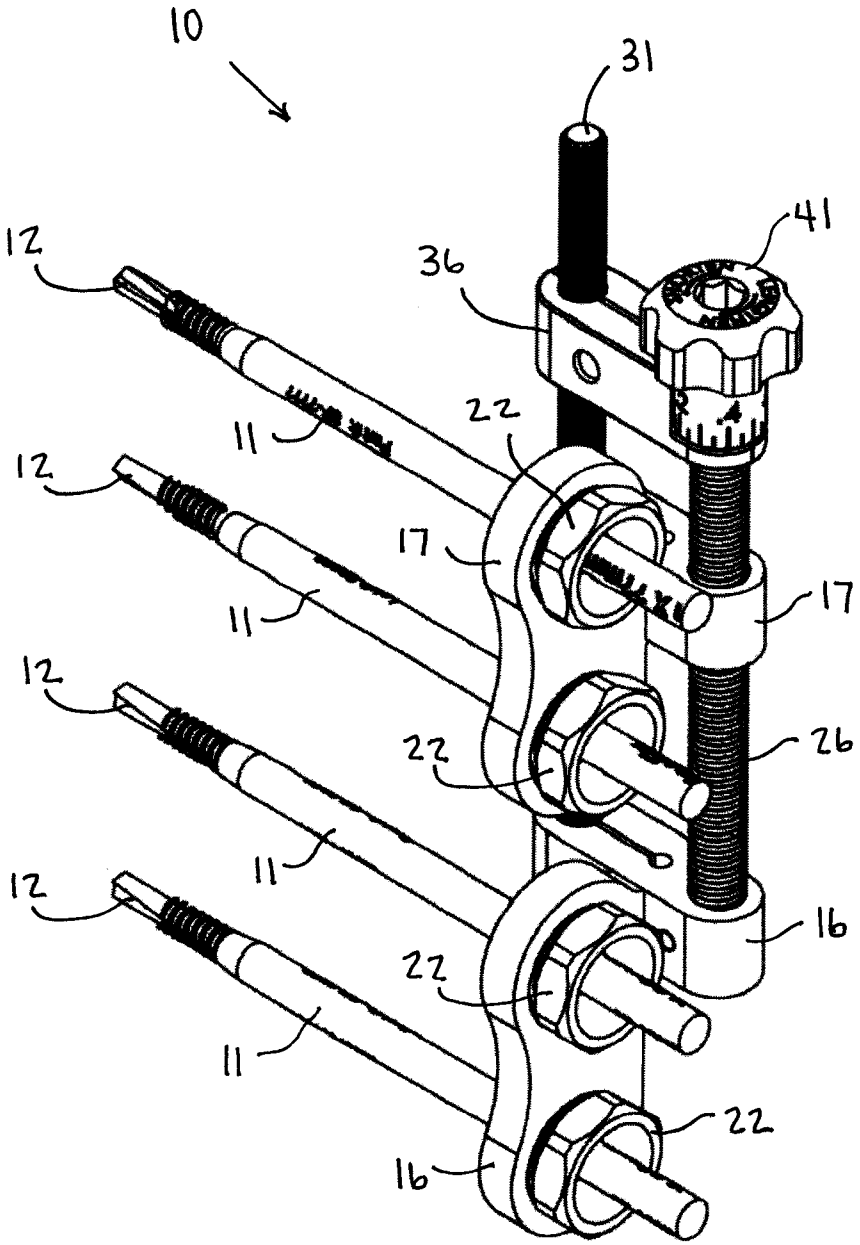


FIG. 15

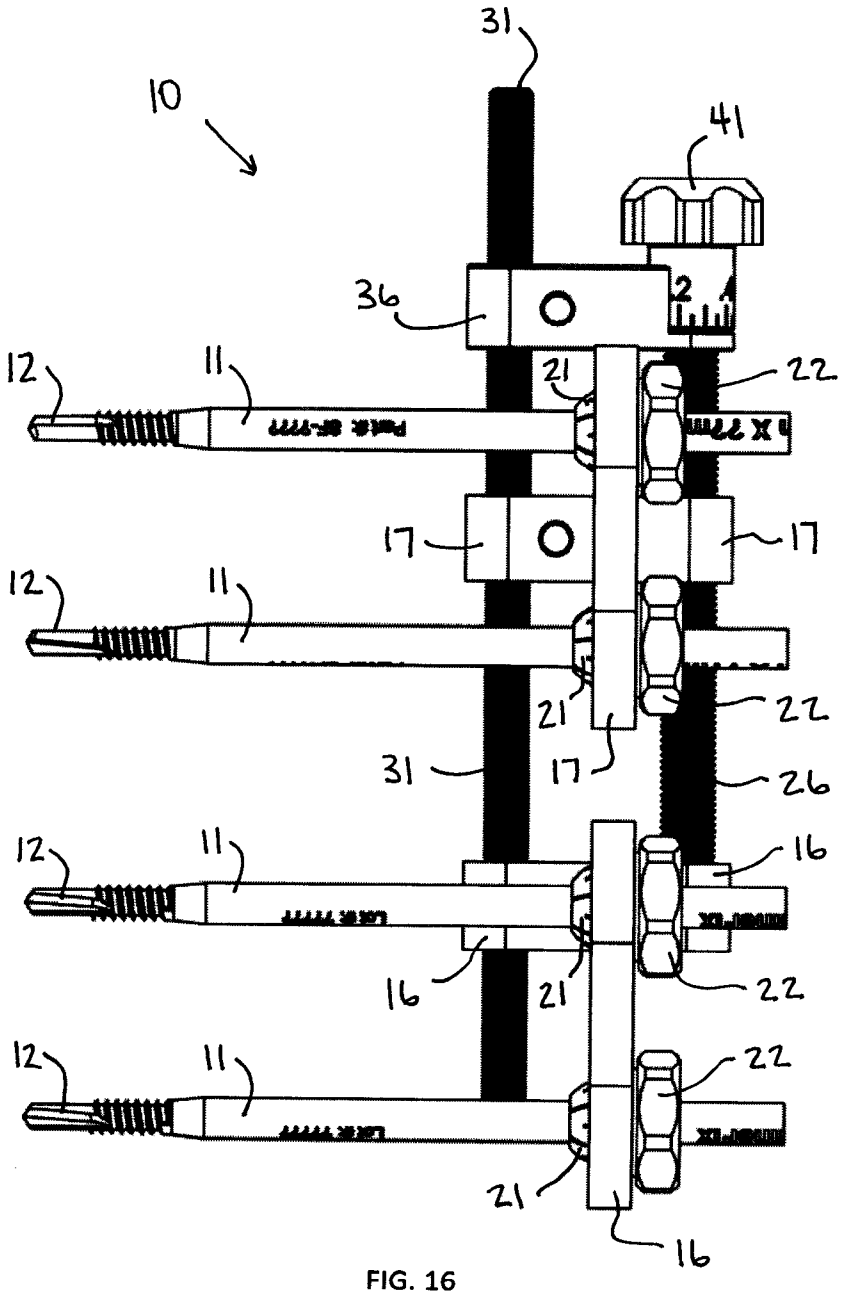

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FIG. 16

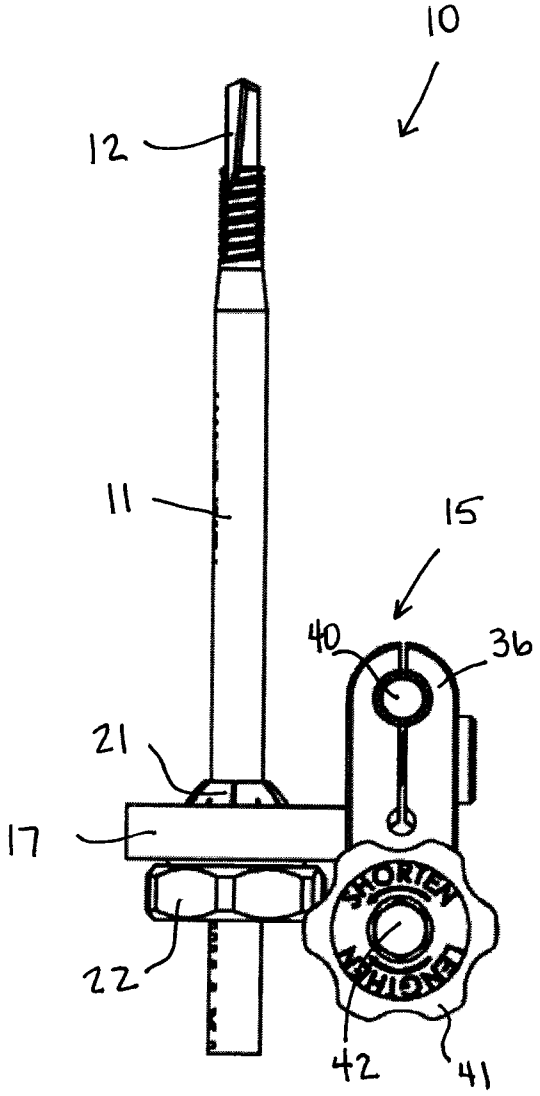

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FIG. 17

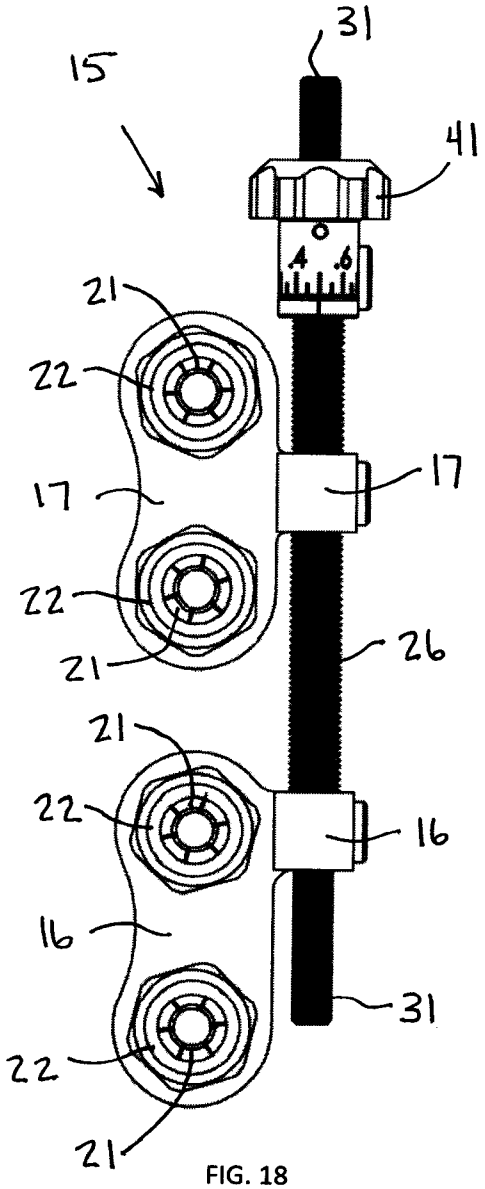

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FIG. 18

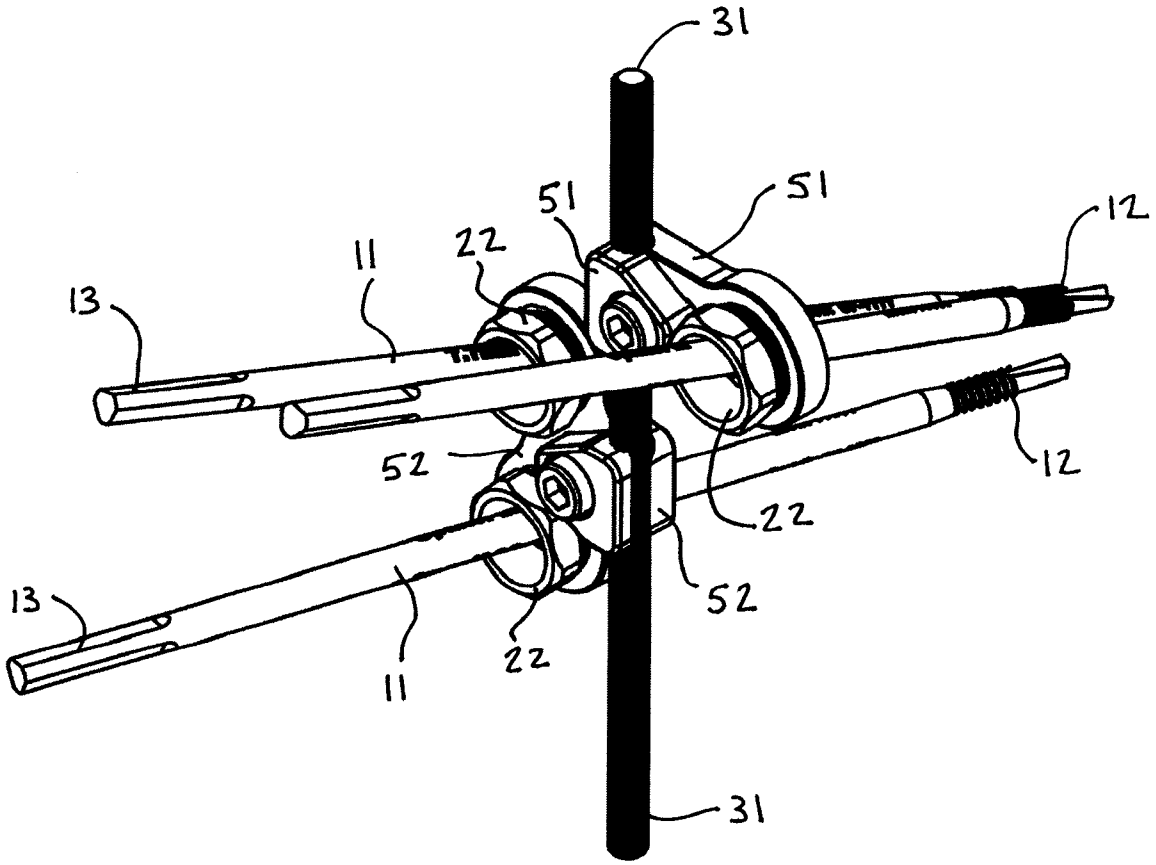


FIG. 19

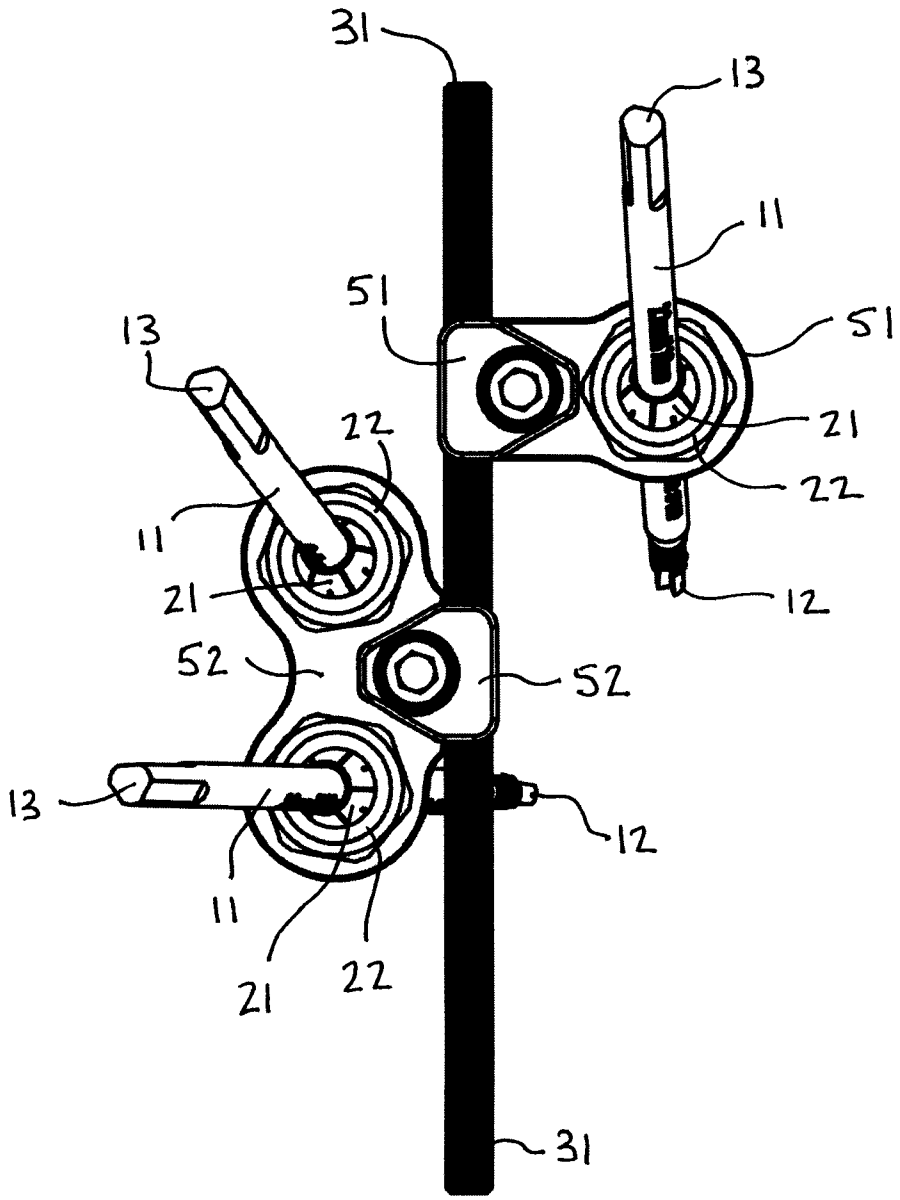


FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 13/20133

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/00 (2013.01)
USPC - 606/59, 54
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/00 (2013.01)
USPC - 606/59, 54

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
606/54-59
(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Patbase (All); Google
Search Terms: External fixation, fixation, set, setting, distraction, extend, spacing, bone, ball, spher*, globe, collet, bar, rod, spline *, move, movable, moving, translat *, clamp, spacing, rotating, anti-rotation

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y -- A	US 5,443,464 A (RUSSELL et al.) 22 August 1995 (22.08.1995) Entire document, especially Abstract, col 2, ln 21-43, col 3, ln 46- col 4, ln 50 and FIGS. 1-6.	1-5 ---- 6-10 ------ 11
Y -- A	US 4,730,608 A (SCHLEIN) 15 March 1988 (15.03.1988) Entire document, especially Abstract, col 2, ln 21-43, col 3, ln 46- col 4, ln 42 and FIGS. 1-3.	6-10 ------ 11
A	US 2,391,693 A (ETTINGER) 25 December 1945 (25.12.1945) Entire document.	1-11
A	US 5,451,225 A (ROSS Jr. et al.) 19 September 1995 (19.09.1995) Entire document.	1-11
A	US 5,403,316 A (ASHMAN) 04 April 1995 (04.04.1995) Entire document.	1-11
A	US 5,676,664 A (ALLARD et al.) 14 October 1997 (14.10.1997) Entire document.	1-11
A	US 2005/0101959 A1 (MITKOVIC) 12 May 2005 (12.05.2005) Entire document.	1-11

☐ Further documents are listed in the continuation of Box C.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier application or patent but published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 14 March 2013 (14.03.2013)	Date of mailing of the international search report 12 APR 2013
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCTOSP: 571-272-7774