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(54) Title: JOINT DISTRACTION DEVICE FOR ARTHROSCOPIC SURGERY

(57) Abstract: A joint distraction device for use in an arthroscopic surgery is provided. The device has a joint distraction mechanism, situated in between two bone fixation surfaces, and is capable of changing the relative distance between these two surfaces. The force generated by the mechanism should be sufficient to insert bone spikes affixed to the surfaces into bone, as well as distract the joint to create a sufficient enough gap to allow the intended procedure. With the surfaces and spikes engaged to bone at opposite sites of a joint, an increase in distraction force results in an increase in the relative distance results, hence increasing the space within the joint. Embodiments of this invention, compared to fracture table approaches, effectively eliminate the risk of pudendal nerve injury, allow for longer surgical times, and allow for much more controllable joint distraction.

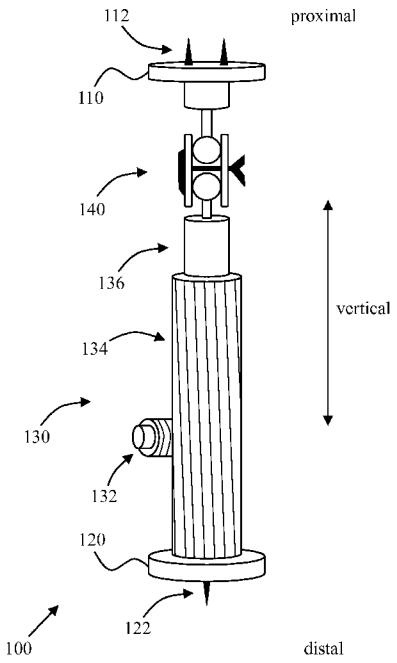


FIG. 1

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# JOINT DISTRACTION DEVICE FOR ARTHROSCOPIC SURGERY

## FIELD OF THE INVENTION

The invention relates to joint distraction devices and surgical procedures.

## BACKGROUND OF THE INVENTION

Hip arthroscopy is becoming an increasingly common and effective surgery as it allows for the repair and resurfacing of various parts of the hip with minimal surgical trauma to the patient. However, such a procedure requires distraction of the femoral head from the acetabulum of the pelvis to allow for arthroscopic access to the tissues within the joint.

The hip is a constrained joint, and has an anatomical structure similar to a 'tight' ball and socket joint. Therefore, distraction requires, relatively speaking to other joints, a fairly large amount of traction force to create a space in the joint that is adequate for the surgical procedure.

The current distraction device standard for hip arthroscopy is the fracture table where the femoral head is distracted from the acetabulum by pulling the leg away from the pelvis to create sufficient joint space. Counter-traction is achieved by placing a fixed post placed at the patient's groin. The fracture

table procedure is a crude and imprecise mechanism that may give risk to postoperative complications such as pudendal nerve injury and other joint (e.g. ankle or knee) damage. Accordingly, there is a need in the art to develop a technology with the goal to reduce such postoperative complications for the patients while maintaining adequate joint space in the hip for arthroscopic surgery. The present invention addresses this need.

## SUMMARY OF THE INVENTION

The present invention provides a joint distraction device for use in an arthroscopic surgery. The device can be arthroscopically inserted within a body or inserted via an open incision. A joint distraction mechanism is situated in between a proximal and distal bone fixation surface. The proximal end and the distal end of the joint distraction mechanism are affixed respectively to a proximal fixation surface and a distal fixation surface.

The proximal fixation surface has an outer facing surface facing away from the joint distraction device. This outer facing surface has two or more bone spikes for engagement with a proximal bone segment proximally located to a joint. The distal fixation surface has an outer facing surface facing away from the joint distraction device. In one embodiment, this distal fixation surface has one bone spike for engagement with a distal bone segment distally located

from the joint. In another embodiment, this distal fixation surface could have two or more bone spikes. The bone spikes, screws or other projections to allow fixation (temporary or permanent) are typically connected substantially perpendicular to the respective outer surfaces of the fixation surfaces.

The joint distraction mechanism has a force driving mechanism for changing the relative distance between the proximal fixation surface and the distal fixation surface. Examples are provided of a worm gear force driving mechanism or a pneumatic force driving mechanism. This joint distraction mechanism is useful to change the relative distance between the proximal bone segment and the distal bone segment. The force generated should be sufficient to insert the bone spikes (in case they are not screws and do not have to be screwed into the bone), as well as sufficient to distract the joint (i.e. create a sufficient gap to allow the intended surgical procedure). With the surfaces and spikes engaged to bone at opposite sites of a joint, an increase in distraction force results in an increase in the relative distance results, hence increasing the space within the joint. The device is preferably in its shortened position during insertion into and removal from (e.g. arthroscopically) a patient's body.

The joint distraction device could further have: (i) an articulating joint or (ii) a fixed joint angle for aligning the relative position of the proximal fixation surface with the proximal bone segment. In other words, this is used for pointing two segments of the device in between the bone surfaces for better alignment. In one example, the articulating joint is a three-dimensional articulating joint. The articulating joint can be locked or fixed in a position useful when the distraction takes place.

Embodiments of the invention pertain to joint distraction devices and the use/application of such devices, which are described herein with distinct advantages when compared to, for example, the use of the fracture table approach. One advantage pertains to the use of the device as it effectively eliminates the risk of pudendal nerve injury common with the fracture table approach. Currently, using the fracture table, surgical time is limited (usually to less than 2 hours) due to the risk of nerve injury from the pressure resulting from the traction-counter traction of the fracture table. With the device of this invention, it is conceivable that the duration of surgery would no longer be limited by fear of complications associated with the fracture table. This would allow for the development and practice of more advanced and complex surgical techniques and procedures. In addition, the device could be placed lateral to the joint and therefore does not obstruct the operating space of the surgeon. Furthermore, in contrast with the fracture table approach, the device

allows for controllable distraction. Yet another advantage in the application to the hip joint is that by applying the distraction force along a line closer to parallel with the femoral neck, the overall force required to distract the hip is reduced.

## BRIEF DESCRIPTION OF THE DRAWINGS

**FIG. 1** shows according to an exemplary embodiment of the invention a joint distraction device with a worm gear drive mechanism and a three-dimensional articulating joint connecting the worm gear drive mechanism and the proximal fixation surface.

**FIG. 2** shows according to an exemplary embodiment of the invention a joint distraction device with a fixed angle in the rod connecting the worm gear drive mechanism and the proximal fixation surface.

**FIG. 3** shows according to an exemplary embodiment of the invention a pneumatic cylindrical force driving mechanism.

## DETAILED DESCRIPTION

Joint distraction devices according to the invention are intended to arthroscopically distract a joint by applying opposing forces to a proximal and distal bone segment crossing the joint. Specific examples herein relate to the

hip joint, but the invention is not limited as such since these devices can be used for distraction of other joints as well, such the knee joint for meniscus or osteochondral grafting. It could also be used for the elbow joint for osteochondral grafting or soft tissue resurfacing. Further, the ankle joint is a candidate for the use of the device for open ankle surgery.

In the example of the hip joint, the device distracts the hip joint by applying opposing force to non-cartilagenous areas such as the anterior inferior iliac spine (AIIS) and the piriformis fossa. More generally speaking, the forces could be applied to areas on the pelvis and the proximal femus. For example, the device could be applied within the joint capsule or exterior to it. The device is inserted through a cannula under arthroscopic and fluoroscopic visualization starting in the peripheral compartment of the joint space. Fluoroscopic visualization is useful to ensure proper insertion and placement of the device. Fluoroscopy is especially useful for the placement to the piriformis fossa. Arthroscopy could be sufficient for the placement to the AIIS.

The device is inserted in a shortened position and expanded inside the patient. Removal of the device is the reverse order of the insertion procedure meaning that the expansion is reversed and the device is removed from the cannula in the shortened position. During the procedure, the cannula could be free for other instruments needed during surgery.

The expansion and shortening of the joint distraction device could either be done with a helical worm gear drive mechanism, a pneumatic cylindrical mechanism or a combination thereof. Once the device is inside the peripheral compartment (e.g. under muscle and can be in or outside the capsule), a proximal portion of the device goes on to the AIIS and a distal portion of the device goes into the piriformis fossa. Once this happens, distraction occurs as the device continues to be expanded and apply opposing forces to the AIIS and piriformis fossa.

**FIG. 1** shows an exemplary joint distraction device **100** with a proximal fixation surface **110** and a distal fixation surface **120**, both preventing migration into bone. A joint distraction mechanism **130** is situated in between both fixation surfaces, **110**, **120**. The proximal end of joint distraction mechanism **130** is affixed to proximal fixation surface **110**, and the distal end of joint distraction mechanism **130** is affixed to distal fixation surface **120**.

Proximal fixation surface **110** has an outer facing surface facing away from joint distraction device **100**. Outer facing surface of proximal fixation surface **110** has two or more bone spikes for engagement with a proximal bone segment (e.g. AIIS) proximally located to a joint.

Distal fixation surface **120** has an outer facing surface facing away from joint distraction device **100**. Outer facing surface of distal fixation surface **120** has one or more bone spikes for engagement with a distal bone segment (e.g. piriformis) distally located from the joint.

Joint distraction mechanism **130** has a force driving mechanism for changing the relative distance between proximal fixation surface **110** and distal fixation surface **120**, and therewith the relative distance of proximal bone segment and distal bone segment, thus changing the space within the joint (e.g. hip). It is noted that joint distraction mechanism **130** is also used for changing the length of device **100** for insertion into and retraction from the patient's body.

In one example, joint distraction mechanism **130** has a worm gear drive mechanism. Worm gear **132** is a special type of helical gear whose helix angle is close to perpendicular with the axis of the gear's drive shaft. Resembling a corkscrew, worm gears **132** are usually produced by wrapping a single tooth around the gear's central axis at a given helix angle.

As worm gear **132** is turned, the tooth is advanced in a direction parallel to the gear's central axis. Worm gears could be meshed with either spur gears or helical gears with a complimentary helix angle to create a drive mechanism. Using this arrangement of gears, rotation about a horizontal axis is translated into rotation about a vertical axis, while using minimal space.

In one example, in place of an ordinary helical gear to mesh with the worm gear, gear teeth with a complimentary helix angle could be formed onto about a 72 mm (about 3 inch) long cylinder **134**. A tap hole could be drilled through the length of cylinder **134** and threaded to allow distal fixation surface (or stud) **120** and a threaded rod **136** to be screwed into its opposing ends. The exposed end of threaded rod **136** could then be fixed to an articulating joint or head **140** used to attach to the AIIS. This allows cylinder **134** to unscrew from threaded rod **136** when articulating joint **140** is held fixed. When worm gear **132** is turned along a horizontal axis, it meshes with cylinder **134** and causes it to rotate about its vertical axis.

With articulating joint **140** at one end of device **100** held in a fixed position (i.e. simulating attachment to the AIIS), rotation causes cylinder **134** to unscrew from threaded rod **136**. As cylinder **134** is unscrewed, the displacement that this creates presses against a distal fixation surface **120** and creates a force in the vertical direction. When this force is applied across the AIIS and the piriformis, distraction will be produced at the hip joint. Since cylinder **134** can be driven by worm gear **132**, but not vice-versa, the worm gear drive mechanism in device **100** is self-locking and will hold the generated distraction until worm gear **132** is turned in reverse to release distraction.

It is noted that worm gear **132** could be driven by something outside the patient's body and stays fairly fixed in space other than rotating to generate the force and therefore separation between proximal and distal points.

The mechanism of attachment to the proximal bone segment (e.g. AIIS) has two features. The first feature is proximal fixation plate **110** with two or more bone spikes **112**, similar to bones screws or nails, on the outer facing surface that will engage the proximal bone segment. The second feature is the articulating head **140**.

When device **100** is inserted through the cannula and proximal fixation plate **110** is pressed against the AIIS, spikes **112** on the plate's surface will insert a short distance into the AIIS and fix it to the bone. As long as two or more spikes are used on the fixation plate surface, a rigid attachment to the surface of the bone is provided which will help stabilize device **100** during joint distraction. Once proximal fixation plate **110** has been fixed to the AIIS, articulating joint **140** can be maneuvered to direct device **100** toward the piriformis fossa and then locked in a fixed position for hip distraction by a friction or set screw mechanism. Articulating joint **140** can also be loosened and adjusted during distraction to change the orientation of the patient's leg and give the surgeon access to different surfaces within the hip during the procedure.

It is noted that articulating joint **140** is shown with an exemplary two ball mechanisms that can be clamped together with e.g. a screw or similar fastening mechanism. As a person skilled in the art would appreciate articulating joint **140** could be established with various (joint) mechanisms like a single ball mechanism and is not limited to these examples. In general, the intent of using articulating joint **140** is to align proximal fixation surface **110** against the proximal bone segment (e.g. AIIS) and/or to allow maneuvering of device **100** to point to the opposing bone surfaces. Articulating joint **140** is preferably a three-dimensional articulating joint. However, articulating joint **140** could also have fewer degrees of rotation freedom or even have just a fixed angle (**142** in **FIG. 2**) for aligning the relative position of proximal fixation surface **110** with a proximal bone segment, depending on the type of surgical procedure and/or joint to be distracted.

The mechanism of attachment to the distal bone segment (e.g. piriformis fossa) features a distal fixation plate **120** with one or more bone spikes **122**, similar to bones screws or nails, on the outer facing surface that will engage the distal bone segment (i.e. piriformis fossa).

As cylinder **134** unscrews from threaded rod **136** to create distraction, bone spike **122** is pressed into the distal bone segment and holds device **100** in

place.

Since the attachment mechanism at the distal end of device **100** is made up of a single point **122**, device **100** will be free to rotate with respect to the distal bone segment after bone spike **122** has been pressed into the bone. This will allow device **100** to continue producing a distraction force after both proximal and distal ends have been fixed securely to the bone. Since a larger surface of the distal fixation surface/stud will press against the piriformis fossa once the bone spike has been inserted, the force required to produce distraction will be spread over a larger area and decrease the contact pressure at the proximal femur or piriformis fossa.

In another embodiment, joint distraction mechanism **130** could have a pneumatic cylindrical force driving mechanism shown in **FIG. 3**. Pneumatic cylinder **300** is powered through a connection to a pressurized air tank or line. The two air inlets **310**, **312** are connected to two isolated chambers within the cylinder. When pressurized air is channeled to air inlet **310** via an external switch valve, a piston **320** is extended. When air is channeled to inlet **312**, the piston is retracted. This extension of the piston by pressurized air is the mechanism that generates the force applied across the piriformis fossa and the AIIS to generate distraction at the hip.

The mechanism to attach pneumatic cylinder driving mechanism **300** to the AIIS is the same as the one described above in the worm gear device description. Here, the articulating head is instead bonded to the back of the pneumatic cylinder and can be maneuvered to point the piston in the direction of the piriformis fossa. The mechanism to attach pneumatic cylinder **300** mechanism to the piriformis fossa is also similar to the one detailed in the worm gear device description. Here, a bone spike similar to a bone screw or nail is attached to the piston of the pneumatic cylinder. As air pressure pushes the piston toward the piriformis fossa, this spike will embed in the piriformis fossa and fix that end of the device to the bone during distraction.

**Exemplary Details**

Devices according to the invention could display various physical measurements depending on the type of surgical procedure, patient size, morphology of the patient's hip (e.g., gender variations), joint or even species. The following is merely an example of measurements for use of the device in hip arthroscopy procedures. It is noted that the invention should not be limited to these exemplary details.

- The cannula for insertion and removal of the device could be about 8.25 mm (about .32 inches).

- The size of the device in shortened position is about 70 mm (about 2.75 inches) and extended position about 102 mm (about 4 inches). These sizes could vary about 20% and are based on anatomical differences and device design.
- The device attaches to bone using small bone spikes on each end. The force generated through the joint distraction mechanism is sufficient to insert these spikes into bone, which for an exemplary and common cross-section area of screw/pin is about or less than 267 N (60 lbs).
- The one (or more) bone spikes or pins for the piriformis fossa could be about 2-4 mm long and about 1-2 mm in diameter.
- The two or more bone spikes or pins on the AIIS side could be about 1 mm long and about 1 mm in diameter.
- The proximal and distal joint facing fixation surfaces for the AIIS and proximal femur could each be about 50 $mm^2$.
- In one variation, the number of bone spikes at the proximal fixation surface could be one or more provided sufficient fixation (where the articulating mechanism could play a role) to hold the proximal end of the device in place during expansion/distraction.
- The force distraction vector generated by the device onto the bone surfaces is preferably as close as possible and as close to be parallel to the joint axis that is being distracted. This would reduce the amount of force required to distract the hip as well as further improve safe distraction.

# CLAIMS

What is claimed is:

1. A joint distraction device for use in an arthroscopic surgery, comprising:

(a) a proximal fixation surface;

(b) a distal fixation surface; and

(c) a joint distraction mechanism, situated in between said proximal and distal surfaces, having a proximal end affixed to said proximal fixation surface and having a distal end affixed to said distal fixation surface,

wherein said proximal fixation surface has an outer facing surface facing away from said joint distraction device, and wherein said outer facing surface of said proximal fixation surface has two or more bone spikes for engagement with a proximal bone segment proximally located to a joint,

wherein said distal fixation surface has an outer facing surface facing away from said joint distraction device, wherein said outer facing surface of said distal fixation surface has one or more bone spikes for engagement with a distal bone segment distally located from said joint, and

wherein said joint distraction mechanism comprises a force driving mechanism for changing the relative distance between said proximal fixation surface and said distal fixation surface, and wherein the force generated by said force driving mechanism should be sufficient to insert said bone spikes into said respective bone segments, as well as distract said joint to create a sufficient enough joint gap to allow an intended procedure.

2. The joint distraction device as set forth in claim 1, wherein said joint distraction mechanism comprises (i) an articulating joint or (ii) a fixed joint angle for aligning the relative position of said proximal fixation surface with said proximal bone segment.

3. The joint distraction device as set forth in claim 2, wherein said articulating joint is a three-dimensional articulating joint.

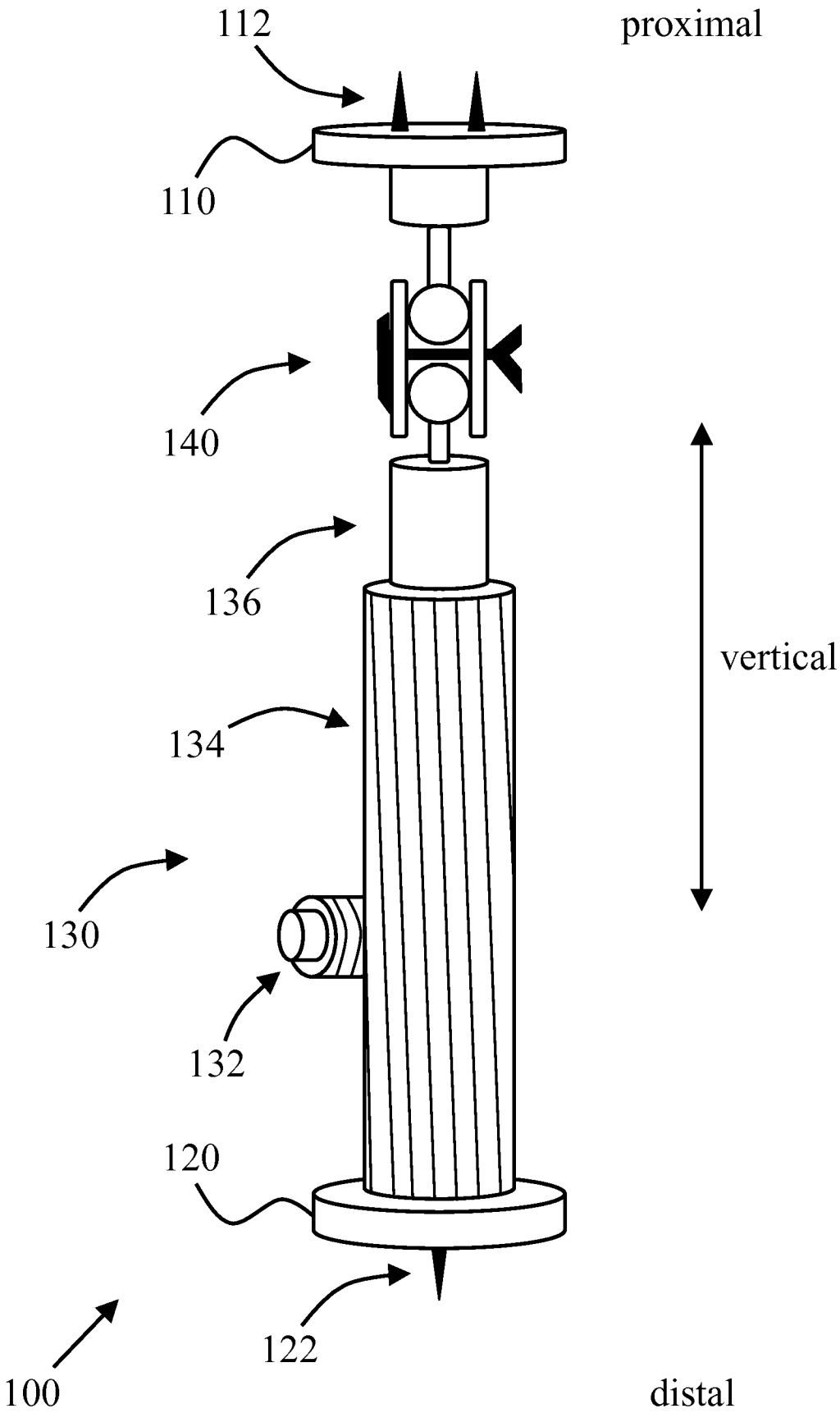
4. The joint distraction device as set forth in claim 1, wherein said articulating joint can be locked or fixed in a position.

5. The joint distraction device as set forth in claim 1, wherein said joint distraction device can be arthroscopically inserted within a body or inserted via an open incision.

6. The joint distraction device as set forth in claim 1, wherein said spikes are connected substantially perpendicular to said respective outer surfaces of said fixation surfaces.

7. The joint distraction device as set forth in claim 1, wherein said force driving mechanism comprises a worm gear force driving mechanism or a pneumatic force driving mechanism.

8. The joint distraction device as set forth in claim 1, wherein said joint is a hip joint, said proximal bone segment is an area on a pelvis and said distal bone segment is an area on a femur.


112
proximal
110
140
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134
130
132
120
122
100
distal

FIG. 1

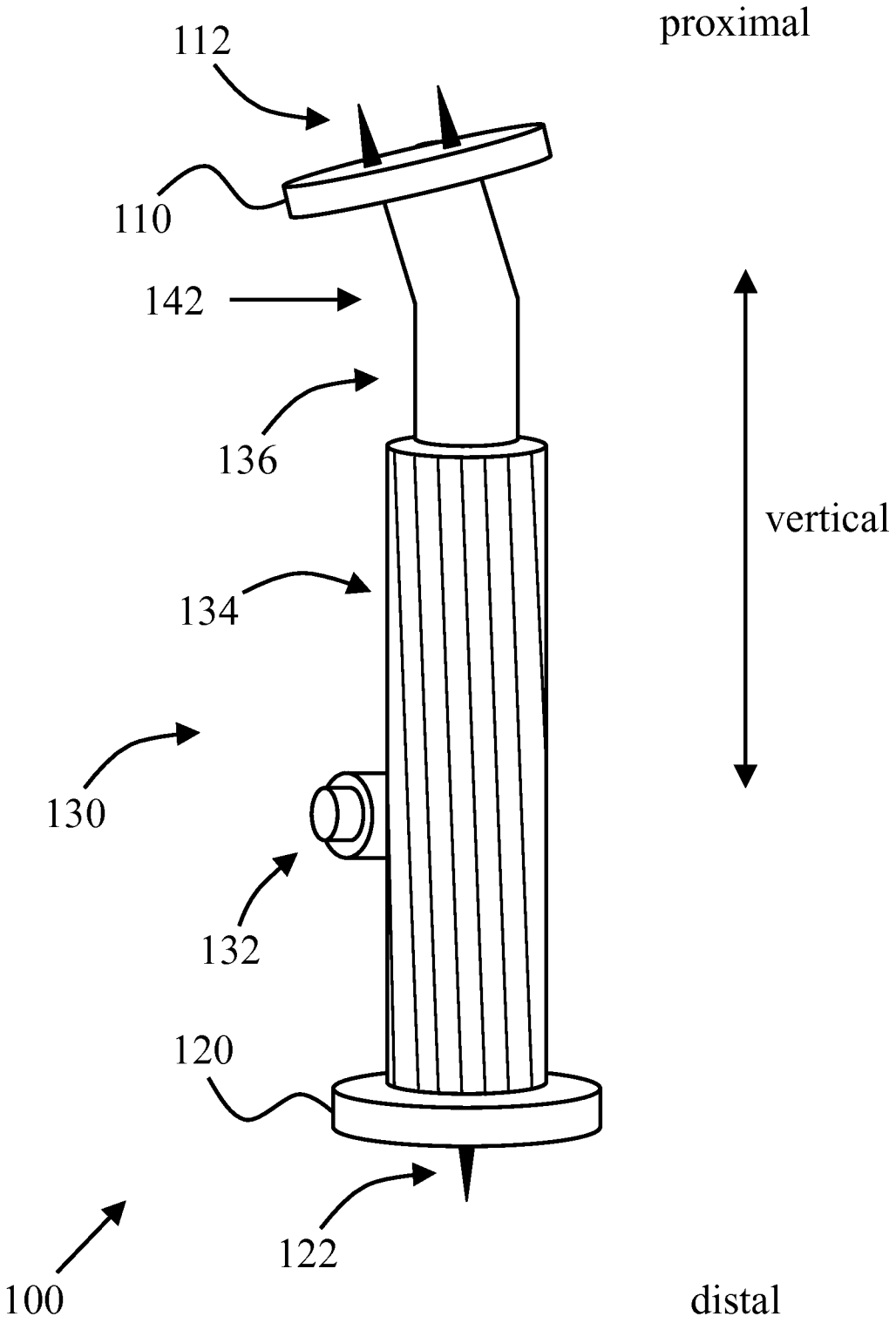
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FIG. 2

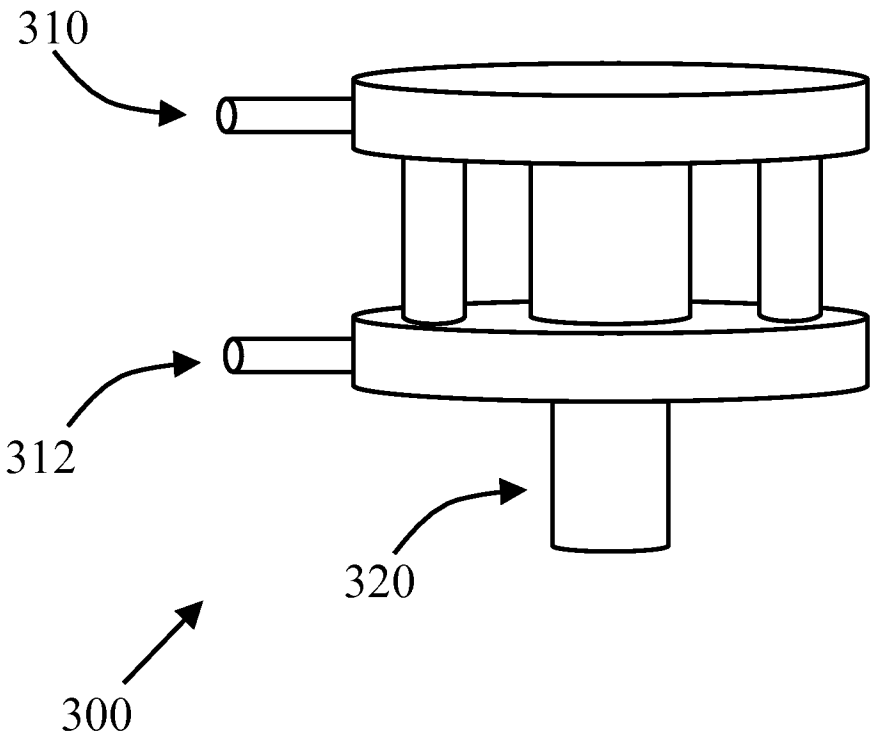


FIG. 3

**INTERNATIONAL SEARCH REPORT**

International application No.
PCT/US 2013/039117

A. CLASSIFICATION OF SUBJECT MATTER

***A61B 17/02*** *(2006.01)*
***A61B 17/56*** *(2006.01)*
***A61B 1/317*** *(2006.01)*

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)

A61B 1/317, 17/02, 17/56

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSearch (RUPTO internal), Esp@cenet, PAJ, USPTO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 6102928 A1 (GENERAL SURGICAL INNOVATIONS, INC.) 15.08.2000, col. 9, line 42-col. 10, line 12, fig. 11, 12 | 1-8 |
| A | RU 92781 U1 (GOSUDARSTVENNOE OBRAZOVATELNOE UCHREZHDENIE VYSHEGO PROFFESSIONALNOGO OBRAZOVANIYA MOSKOVSKAYA MEDITSINSKAYA AKADEMIYA IM. I.M.SECHENOVA FEDERALNOGO AGENTSTVA PO ZDRAVOOKHRANENIYU I SOTSIALNOMY RAZVITIYU) 10.04.2010 | 1-8 |
| A | US 6616673 B1 (BIOMET, INC.) 09.09.2003 | 1-8 |
| A | US 7828727 B2 (EBI, LLC) 09.11.2010 | 1-8 |
| A | US 7766918 B2 (WARSAW ORTHOPEDIC, INC.) 03.08.2010 | 1-8 |

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

☐ See patent family annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 20 June 2013 (20.06.2013) | 22 August 2013 (22.08.2013) |
| Name and mailing address of the ISA/ FIPS<br>Russia, 123995, Moscow, G-59, GSP-5,<br>Berezhkovskaya nab., 30-1<br><br>Facsimile No. +7 (499) 243-33-37 | Authorized officer<br><br>R. Fedorova<br><br>Telephone No. 8(495)531-64-81 |

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