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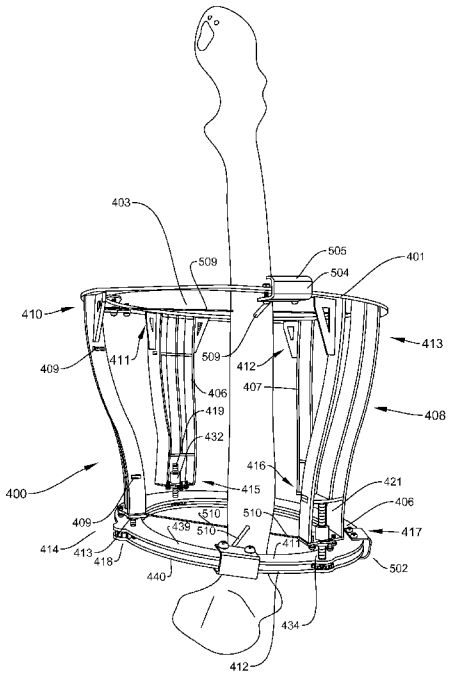



FIG. 4

(57) Abstract: An external fixator for use in limb extension comprising first and second spaced apart rings, a plurality of rigid linkages each extending between said first and second rings; and means to move said plurality of rigid linkages away from each other so as to increase the length of the linkages wherein the movement of said plurality of linkages is in a direction parallel to the main axial direction of a limb being lengthened. Advantageously, the apparatus is ergonomically design to provide an improved fit external fixator device which follows the vertical axis of the bone rather than the vertical axis of the exterior profile of the limb. The provision of an external fixator which works in the same axis as the bone allows a single drive point to move the frame coaxially at a right angle to the limb's axis of work to achieve uniform axial movement.

# EXTERNAL FIXATOR

## Field of the Invention

**[0001]** This invention relates to an external fixator for medical use.

## Background of the Invention

**[0002]** An external fixator is a surgical apparatus comprising a frame which is used to stabilise a bone at a distance remote from an injury site, to temporarily immobilise the bone allowing the injury to heal. External fixators are commonly used for accidental fractures and medically induced fractures for example in the treatment of patients having legs of different length. In order to extend the length of a leg, a patient's leg is fractured in a controlled manner, and the leg is then fitted with an adjustable external frame which is secured to the bone. The frame is adjusted so that the ends of the bone either side of the fracture are kept apart at a substantially constant distance. This promotes bone growth to fill the void between the two bone ends

**[0003]** There are various types of external fixator all of which involve the insertion of wire and pins through bone on either side of a fractures or trauma and the connection of said pins to an external frame. The various external fixators include planar fixators, ring fixators, and hybrid fixators which have properties of both. A ring fixator is so named because it consists of a plurality of circumferential rings to which rods are connected. Pins are inserted from the vertical rods and lie in multiple different horizontal and vertical planes. The most widely used ring fixator is the Ilizarov frame which was designed in the 1920s in Russia and are known as Ilizarov apparatus. Such apparatus comprises either two or three heavy metal stainless steel rings having a plurality of metal stanchions attached via adjustable nuts which hold the rings apart so that when fitted, the rings fit around the patients leg either side of the fracture and the stanchions extend between the rings forming a tubular central passage in which the leg resides.

**[0004]** A plurality of pins and wires, the most common being known as Kirschner wires or "K- wires" are manufactured in heavy gauge metal, usually

stainless steel or titanium alloy, extend inwardly from the rings towards the leg, through the skin and are secured into the bone.. Each ring has a plurality of Kirschner wires, locating the bone substantially coaxially along the central axis of the rings. The pins may also be olive wires, Steinmann pins, and Schanz pins as determined by the anatomical site of the fixator and the degree of force exerted on the pins, with the Steinmann pins and Schanz pins providing the greatest strength.

**[0005]** The Ilizarov frame works via the controlled application of mechanical tension. A pair of upper and lower rings of the Ilizarov frame and their associated pins are in contact with a healthy (trauma free) portion of the bone, whilst optional (middle) rings and associated tensioned wires hold the bone fragments at the site of trauma in the stabilizing their correct alignment during the treatment of compounded fractures. Thus, the upper and lower ring allow pairs force to be transferred from the upper region of trauma free bone through the external fixator ring frame back to the healthy bone to which the lower ring is attached. The Ilizarov apparatus functions to both immobilize the fracture site and to reduce stress at the trauma site, since the upper and lower ring pairs are load bearing and transfer the force from one region of healthy bone down to another region of healthy bone, bypassing the trauma site.

**[0006]** During recovery a fractured bone will grow. Adjusting the frame of the apparatus during this recovery growth phase can result in the controlled lengthening of the bone. Bone lengthening is achieved by incrementally adjusting the space between the upper and lower rings of the Ilizarov device which encourages continued growth of the bone at the fracture site. Typically incremental adjustments are performed periodically and can be optimised to achieve as much as 1mm of new bone growth per day. However, the periodical incremental adjustments are usually performed by the patient or their carer and not by a medically trained individual. To achieve lengthening of the frame, an individual must loosen both the top and bottom nuts which attach the struts to the rings using a spanner. Such adjustments require the manual loosening and then tightening of often in excess of 12 individual screws. This presents a high risk of user error. The Ilizarov frame typically uses steel nuts which can be knocked or slip, and

adjustment of the same can involve a parent or other non-medical person making up to 12 adjustments (turns or half turns) on separate adjustment nuts. Control of the device is therefore delegated to a non-qualified / non-medical persons which can lead to errors. Incorrect tightening of the frame can result in weakened bone structure if the frame is moved too quickly or uneven off axis bone growth if the frame is not adjusted evenly around its circumference. The Ilizarov frame is intended for translational movement in a single direction only.

**[0007]** In addition, the currently available Ilizarov frame is a single size apparatus, which means that the same size Ilizarov frame would be used for a full-grown adult as for a child, and for a man as for a woman. The rings are not designed specifically to fit any one in particular, but are designed to be adapted to fit anyone. They provide a generic “one size fits all” device. Consequentially, external fixators are often oversized to ensure there is adequate clearance surrounding the bone making the fixator clumsy and uncomfortable for the patient. The ring-like structure often alters the gait and posture of an individual wearing the device since the rings are a consistent diameter circumferentially.

**[0008]** An attempt to modify the Ilizarov frame for use in paediatrics and complex fractures was introduced in the form of the Taylor Spatial Frame (TSF). The TSF device comprises two rings joined by 6 struts. Each strut can be independently adjusted to achieve controlled lengthening of compression of the fracture site to lengthen or contract the bone for example in the treatment of bone twisting it may be necessary to construct one side of the bone and lengthen the other. The TSF permits angular and translation adjustment of the bone and by virtue of the six strut structure reduces the number of individual screw and nut joining points which require manipulation to change the position of the device. However, whilst there are fewer physical adjustments, because each strut can be adjusted independently they are often too confusing for a user/carer to operate. Indeed, a specialised computer system is required to calculate the complex strut tightening sequence. Consequently, depending on how the extension nuts are turned this can result in an off - axis movement i.e. not axially along the main length direction of the bone. Incorrect adjustment can result in complications which

actually include worsening the patient's condition e.g. enhancing the twist of the bone.

**[0009]** Furthermore, both the Ilizarov and TSF frames are typically fitted with their rings arranged perpendicularly to the vertical axis of the limb, which isf often not the corresponding working-axis (or load axis) of the limb as a mechanical system since the bone and the exterior profile of the limb are often not parallel for example this occurs with a human femur. Therefore the bone is not being extended or lengthened in a direction along its main length axis, rather the movement is relative to the profile of the exterior of the leg. Thus, each specific orientation of the frame requires different levels of adjustment to account for the angle which the fixator is in contact with the bone.

## Summary of the Invention

**[0010]** It is an object of the present invention to provide an improved fit external fixator device which is tailored to follow the profile of the patient's body and is ergonomically designed not to alter the gait of the patient wearing the device. This is achieved by custom-fit ring profiles and fitting the device with the main plane of the rings of the device arranged to be perpendicular to the bone (and or load axis) rather than to the exterior profile of the patient's limb, allowing the device to follow the ergonomic profile of the patient's body.

**[0011]** Additionally, each ring may be sized to fit the external circumference of the patient's limb, and each ring of the device need not necessarily be the same diameter as the other rings. Further, the rings need not be strictly circular, but in the general case may follow the shape of the patient's limb.

**[0012]** It is a further object of the invention to provide an improved fit external fixator device which is expandable in a direction along a main load axis of the bone rather than the vertical axis of the exterior profile of the limb. The provision of an external fixator which works along a same axis as the main axial direction of the bone allows a single drive point to move the frame coaxially in a direction parallel or substantially parallel with the main length axis of the bone.

Further, because the bone and frame are aligned such that the frame is parallel to the main length axis of the bone and not the exterior of the patient, the present invention permits pre-programmed automated coaxial movement of the external fixator which was not previously possible.

**[0013]** The embodiments disclosed herein provide an external fixator comprising a plurality of rings, which is operable to fit a main plane of each ring substantially perpendicular to the main working axis of the patient's limb rather than to a main length axis the patient's exterior profile, and thereby to permit axial bone lengthening in a direction which is substantially parallel to the main length axis of said bone.

**[0014]** Further, the external fixator embodiments disclosed herein are ergonomically designed to provide as little interference as possible to the wearer's mobility and gait, when in use.

**[0015]** According to one aspect there is provided an external fixator for use in limb adjustment comprising:

first and second spaced apart rings;

a plurality of rigid stanchions each extending between said first and second rings; and

each said stanchion comprises a frame having a first plate member and a second plate member;

said first and second plate members being spaced apart from each other such that a main outer surface of said first plate member lies opposite and facing a main outer surface of said second plate member;

each said stanchion having at least one cross member connecting between said first plate member and said second plate member.

**[0016]** Preferably said first and second plate members are each cut from a substantially flat plate material.

**[0017]** Preferably said first and second spaced apart rings are each cut from a substantially flat plate material.

**[0018]** Preferably said first and second plate members and said at least one cross member are joined together by twist dowel joints.

**[0019]** Preferably said stanchions are joined to a said first or second ring by twist dowel joints.

**[0020]** Preferably each said stanchion has a main length comprising a first curved portion extending along a main length of said stanchion between a first end of said stanchion and a second end of said stanchion; and

a second curved portion extending along said main length of said stanchion between said first end and said second end, said second curved portion being joined to said first curved portion; and

said first curved portion of each said stanchion extends around a first point of curvature, and said second curved portion extends about a second point of curvature, said first and second points of curvature lying on opposite sides of said stanchion to each other.

**[0021]** Said first ring may surround a first aperture and said second ring surrounds a second aperture, an area of said first aperture being greater than an area of said second aperture.

**[0022]** Said first and second spaced apart rings may be of a different diameter or maximum outer dimension to each other.

**[0023]** Preferably a first plurality of fixator pins attached to said first ring wherein said first plurality of fixator pins extend inwardly from said first ring towards a focal point which lies away from a geometrical centre point of said first ring.

**[0024]** Preferably a second plurality of fixator pins attached to said second ring, wherein said second plurality of fixator pins extend inwardly from said second ring towards a focal point which lies away from a geometrical centre point of said second ring.

**[0025]** Preferably said external fixator comprises a plurality of adjustment means for adjusting a distance between said upper ring and said lower ring, each said adjustment means associated with a corresponding respective said stanchion.

**[0026]** There may be provided a separate tightening tool for adjusting said adjustment means.

**[0027]** Said tightening tool may comprise a radio frequency identification device configured to identify an RFID tags located on a said adjustment means.

**[0028]** Preferably said external fixator comprises a control mechanism which is operable to control said plurality of adjustment means to move said first and second rings towards or away from each other whilst maintaining a fixed angle relationship between the main planes passing through each of said first and second rings.

**[0029]** Said control means may comprise a single direction ratchet.

**[0030]** There may be provided a light emitting diode which illuminates to indicate that an adjustment of the distance between the first and second rings is required.

**[0031]** There may be provided an actuation drive to move the first and second rings towards or away from each other.

**[0032]** The actuation drive may be controllable using pre - programmed software to give predetermined axial extension at predetermined times.

**[0033]** The actuation drive may comprise a drive selected from the set: a piezoelectric motor; and electro-mechanical motor; a hydraulic fluid actuation system; a pneumatic fluid actuation system; and a shape-memory alloy mechanism.

**[0034]** The external fixator may further comprise one or more sensors for measuring parameters selected from the set: ring skew; extension between upper and lower rings; position of upper and/or lower rings; and strain.

**[0035]** According to another aspect there is provided an external fixator comprising:

a first ring member;

a second ring member;

a plurality of stanchions extending between said first and second ring members;

a plurality of adjustment mechanisms each located between a said stanchion and a said ring member; and

a plurality of drive means each said drive means being capable of applying a predetermined incremental movement to a corresponding respective said adjustment mechanism; and

a control means for controlling said plurality of drive means.

**[0036]** The external fixator may further comprise

means for coordinating operation of said plurality of drive means to move said plurality of adjustment mechanisms in a predetermined relationship with respect to each other.

**[0037]** Said means for coordinating operation of said plurality of adjustment mechanisms may comprise:

a plurality of rotatable members which altar the distance between the first and second rings; and

a common drive means for rotating said plurality of rotatable members.

**[0038]** Said common drive means may be selected from the set:

a drive belt;

a chain;

a toothed belt;

a wire or cable

a flexible endless web.

**[0039]** Said drive means may comprise a piezoelectric, electro-mechanical, fluid system (i.e. hydraulic or pneumatic) or shape-memory alloy device.

**[0040]** Said common drive means may comprise:

a substantially cylindrical rotatable member; and

at least one piezoelectric device arranged adjacent and in contact with said rotatable member, said at least one piezoelectric device being fixed to a said ring

member, such that said piezoelectric electric device when electrically activated urges against an outer surface of said rotatable member in order to rotate said rotatable member.

**[0041]** Said common drive means may comprise:

a rod or bar extending in a direction which intersects a main plane of said ring; and

a manually operable ratchet device attached to a said ring,

wherein said manually operated ratchet device is arranged to incrementally urge said rod or bar in said direction intersecting said main plane of said ring.

**[0042]** Preferably said at least one stanchion comprises:

a first plate member;

a second plate member extending alongside and spaced apart from said first plate member; and

a plurality of cross plate members extending between said first plate member and said second plate member.

**[0043]** A said stanchion may comprise:

a first curved portion extending along a main length of said stanchion between a first end of said stanchion and a second end of said stanchion; and

a second curved portion extending along said main length of said stanchion between said first end and said second end,

said second curved portion being joined to said first curved portion;

wherein said first curved portion extends about a first point of curvature; and

said second curved portion extends about a second point of curvature,

wherein said first and second points of curvature lie on opposite sides of said stanchion from each other.

**[0044]** There may be provided a plurality of adjustment mechanisms each located between a said stanchion and a said ring member.

**[0045]** Each said stanchion is preferably rigidly secured to said first ring by one or a plurality of twist dowel joints.

**[0046]** The embodiments include an external fixator for use in limb adjustment comprising first and second spaced apart rings, a plurality of rigid linkages each extending between said first and second rings; and means to move said first and second rings apart or towards one another to increase or decrease the length of the linkages respectively; wherein said means to move said first and second rings apart from one another comprises a mechanism configured to attach to the plurality of rigid linkages and to allow said first ring to move towards or away from said second ring in a uniform manner along a main axial direction of the fixator, and which maintains the relationship of the main plane of the second ring relative to the overall axial direction of the second ring relative to the first ring.

**[0047]** Preferably the external fixator is for use in limb extension and said means to move said first and second rings apart from one another comprises a mechanism configured to attach to the plurality of rigid linkages and to allow said first ring to move away from said second ring in a uniform manner along a main axial direction of the fixator, and which maintains the relationship of the main plane of the second ring relative to the overall axial direction of the second ring relative to the first ring.

**[0048]** The means to move said plurality of adjacent linkages may be an adjustable threaded screw and correspondingly threaded nut.

**[0049]** Preferably each plurality of rigid linkages comprise four struts arranged as two pairs to permit equal distribution of tension across the frame. However, the plurality of rigid linkages may comprise more than four struts, or in some embodiments three struts.

**[0050]** In some embodiments the is provided means to move said first and second rings apart from or towards one another to increase or decrease the length of the linkages comprising at least one thumbwheel.

**[0051]** Alternatively, the means to move said first and second rings apart from one another or towards one another to increase or decrease the length of the linkages is a single direction ratchet arrangement. By limiting the range of movement of the adjustment means accidental adjustment in the wrong direction can be eliminated.

**[0052]** Preferably the external fixator device further comprises an LED to indicate that an adjustment to the apparatus if required, thus providing a clear visual indication as to when adjustment is required.

**[0053]** The first and second spaced apart rings may be of the same diameter, but advantageously the first and second spaced apart rings are of a different diameter and their fit can be anatomically tailored to enhance the ergonomic fit of the device.

**[0054]** Preferably the device is ergonomically shaped to the natural shape of a leg or other limb rather than being arranged in the overall format of an over - sized straight circular cylindrical architecture.

**[0055]** It is envisaged that the apparatus is constructed from laser cut sheet plate, and comprises including twist dowel and / or slot rivet joints which reduce the number of complex parts required for assembly and reduce manufacturing times.

**[0056]** Preferably the construction of the apparatus from laser cut sheet plate using twist dowel and / or slot rivet joints allows for speedy manufacture in a range of different customizable sizes, rather than a “one size fits all” prior art solution.

**[0057]** Preferably the means to move said plurality of rigid linkages away from each other is driven by powered actuation, be that an electro-mechanical motor, an electric motor, a stepper motor, piezo-electric drive, a shape-memory alloy driven system, a fluid motor (hydraulic or pneumatic) or other suitable method.

**[0058]** The actuation motor may be controllable using pre - programmed software to give predetermined axial extension at predetermined times. Thus the device also provides the ability for feedback of extension data to a control computer for monitoring and analysis of the patient and the treatment progression.

**[0059]** Advantageously an actuation approach to adjusting the plurality of rigid linkages offers the possibility to prevent turning of wrong screw and to only permit turning in one direction. The activity of the electric drive motor may be automated and computer driven. Thus removing the dependency on a non – medically trained person manually adjusting the spacing between the rings.

**[0060]** It is envisaged that the device further comprises position sensors, load-cells, strain gauges, accelerometers and the like for data collection and reporting of various parameters including ring skew, extension data, etc. which can be fed into a computer control/analysis unit.

**[0061]** There may be provided a tightening tool for tightening the adjustment mechanisms to adjust the spacing distance between the first and second rings to move those further apart gradually during limb extension.

**[0062]** It is envisaged that the tightening tool comprises a radio frequency identification device configured to identify RFID tags on the adjustment means. By

automating the procedure through the use of RFID tags only the correct degree of adjustment can be administered thus reducing user error.

**[0063]** The invention includes an external fixator comprising:

a first ring member;

a second ring member;

a plurality of stanchions separating said first and second ring members;

a plurality of adjustment mechanisms each located between a said stanchion and a said ring member; and

control means for coordinating operation of said plurality of adjustment mechanisms to move said plurality of adjustment mechanisms in a predetermined relationship with respect to each other.

**[0064]** For example the control means may coordinate movement of the first and second rings to move apart from each other by a predetermined distance each day or each predetermined period, keeping the main plane of the upper ring parallel to the main plane lower ring.

**[0065]** The invention includes an external fixator comprising:

first and second rings;

a plurality of rigid stanchions each extending between said first and second rings;

at least one said ring comprises a mechanism which links to said rigid stanchions and which allows the one of said first or second rings to move towards or away from the other one of said first or second rings in a uniform manner along

a main axial direction, and which maintains the angle relationship of the main plane of said second ring relative to the main plane of said first ring.

**[0066]** The invention includes an external fixator for use in limb adjustment comprising:

first and second spaced apart rings;

a plurality of stanchions each extending between said first and second rings; and

a plurality of adjustment means each said adjustment means being associated with a corresponding said stanchion;

a plurality of mechanisms, configured to effect movement of a corresponding respective said adjustment means to increase or decrease the distance between said first and second spaced apart rings;

wherein each stanchion comprises a frame having a first plate member and a second plate member;

each said stanchion having a main length comprising a first curved portion extending along a main length of said stanchion between a first end of said stanchion and a second end of said stanchion; and a second curved portion extending along said main length of said stanchion between said first end and said second end, said second curved portion joined to said first curved portion; and

said first curved portion of each said stanchion extends about a first point of curvature and said second curved portion of said each stanchion extends about a second point of curvature and said first and second points of curvature lie on opposite sides of said stanchion from one another.

**[0067]** In the embodiments rather than being a circular or annular ring, each ring may shaped to follow more closely the outer profile or circumference of a patient's limb, meaning that each ring may be slightly off circular, ovoid, or egg - shaped. Preferably the area of a main central aperture bounded by an upper ring of the external fixator is larger than the area of a main central aperture bounded by a lower ring of the external fixator. The pins or wires connected to the upper ring may be arranged to focus around a point or region which is not at the geometric centre of the aperture area surrounded by the upper ring. Similarly, the pins or wires which connect to the lower ring may focus at a point which is not at the geometric centre of the aperture surrounded by the lower ring.

**[0068]** In the embodiments, first and second rings need not be of the same outer dimension, but in preferred embodiments, an upper ring may have a larger outer diameter plate and surround a larger diameter aperture than a lower ring to account for the different circumferential distances around the patient's limb at different lengths along the limb, for example where persons inner thigh has a larger circumference than their leg at a position lower down the leg, and for example immediately above the knee, where the circumference around the persons knee may be smaller than the circumferential distance around their thigh.. The use of differently sized rings and a non-circular cylindrical architecture of the overall framework of the external fixator may better fit the patient and take into account the gait of the patient and that the main length direction of the femur is angled to the vertical rather than being vertically upright in normal human standing date.

**[0069]** In embodiments described herein in which extension or contraction of the fixator is effected by an actuator, said actuator may be controllable by pre-programmed software to give predetermined axial extension at predetermined times. The process may be automated so that it is not rely on the person adjusting the spacing between the rings.

**[0070]** In various embodiments described herein, there is the ability and functionality for (preferably wireless) control from a remote computer which may be operated by qualified medical practitioner. There is also the ability for daily or

periodic reporting of extension data measuring how far the external fixator has extended in a particular period to be remotely reported to a remote computer or analysis apparatus.

**[0071]** The external fixator may be supplemented by addition of position sensors, strain gauges, or other sensors which may report physical parameters remotely over a digital communication link to a remote monitoring apparatus. Parameters measured may include extension data, ring skew, adjustment mechanism rotation and/or strain or bend on the K wires. The digital communications link may comprise a wireless link.

**[0072]** Specific embodiments described herein provide an external fixator frame, the inner cavity of which is contoured to fit the external shape of a patient's limb, and the outer surfaces of which fit within a virtual surface which is contoured so as to be less intrusive to a patient than known Ilizarov or Taylor spatial frame devices.

**[0073]** Other aspects are as set out in the claims herein, the content of which is incorporated into the summary of invention by reference.

## Brief Description of the Drawings

**[0074]** For a better understanding of the invention and to show how the same may be carried into effect, there will now be described by way of example only, specific embodiments, methods and processes according to the present invention with reference to the accompanying drawings in which:

Figure 1 herein illustrates a prior art exterior fixator device of the Ilizarov frame type.

Figure 2 herein illustrates a prior art Taylor Spatial Frame (TSF).

Figure 3 herein illustrates the fit of prior art frames relative to the longitudinal axis of a human femur.

Figure 4 herein, shows a front view of an external fixator in accordance with one embodiment of the present invention.

Figure 5 herein, shows a perspective view of the embodiment external fixator of Figure 4 herein.

Figure 6 herein, shows a close up view of an adjustment means of the external fixator of Figures 4 and 5 herein.

Figure 7 herein shows in plan view from above a detail of the lower plate showing a toothed belt or chain drive for driving a plurality of adjustment means of the external fixator.

Figure 8 herein shows in schematic view, an actuator and control mechanism for the actuator for driving a toothed belt or chain for adjustment of a plurality of attachments of a lower ring of the external fixator to a plurality of stanchions of the external fixator.

Figure 9 herein, shows a close up perspective view of a first alternative adjustment mechanism of the external fixator of Figure 4 herein.

Figure 10 herein shows in cut away view a second alternative adjustment mechanism which can be used with an external fixator shown in Figures 4 to 6 herein, incorporating a piezoelectric drive.

Figure 11 herein, shows a close up view of a third alternative adjustment mechanism which can be used with the external fixator of Figure 4 herein.

Figure 12 herein, shows a schematic illustration of a part of an external fixator in combination with a radio-frequency identification (RFID) equipped tightening tool, according to a second specific embodiment of the present invention.

Figure 13 herein illustrates schematically a further modification of the second embodiment described in Figure 12 herein by addition of an electric motor comprising an adjustment means.

Figure 14 herein illustrates schematically in cutaway view from one side and electromagnetic drive means for rotating a threaded rod comprising an adjustment means.

Figure 15 herein illustrates in a further stage of operation the electromagnetic drive means of Figure 14 herein.

Figure 16 herein illustrates schematically a modular motor position sensor as applicable to any of the embodiments described herein.

Figure 17 herein describes a spherical module amount for mounting a threaded rod to a ring or stanchion cross member of any of the external fixator embodiments described herein.

Figure 18 illustrates schematically a further variation embodiment of a piezoelectric motor drive comprising part of an adjustment means which may be applied to the first or second external fixator embodiments described herein.

Figure 19 illustrates schematically in perspective view from above the plates electric motor drive as shown in Figure 18 herein.

**Detailed Description of the Embodiments**

**[0075]** There will now be described by way of example a specific mode contemplated by the inventors. In the following description numerous specific details are set forth in order to provide a thorough understanding. It will be apparent however, to one skilled in the art, that the present invention may be practiced without limitation to these specific details. In other instances, well known

methods and structures have not been described in detail so as not to unnecessarily obscure the description.

**[0076]** In the present specification, the term “rings” is used to denote a structure which is placed around a limb. A “ring” as described herein includes both a continuous closed circuit ring, and an open ring in the form of a “C” shaped ring which is not necessarily a fully continuous closed circuit.

**[0077]** In this specification, the terms “stanchion”, “linkage” and “strut” are used interchangeably each to mean the same thing as the other.

**[0078]** Referring to Figure 1 herein, there is shown a prior art Ilizarov frame 100. The frame consists of four stainless steel rings 101 - 104, vertically aligned with each other along a common axis, and a plurality of metal stanchions 105 - 116 holding the rings apart so that when fitted, the rings fit around the patients leg either side of a fracture or trauma site such that the stanchions 105 - 116 extend between the rings to form a tubular central passage in which the leg or other limb resides.

**[0079]** A plurality of pins, the most common known as Kirschner wires or “K-wires” 117 of heavy gauge stainless steel extend inwardly from the rings towards the leg, through the subject’s skin and soft tissue, and are secured into the bone in known manner. Each ring has a plurality of Kirschner wires, locating the bone substantially coaxially along the central axis of the plurality of rings.

**[0080]** In use, in a leg lengthening treatment, a human femur is fractured at a fracture site between two spaced apart rings, the two spaced apart rings being separated and rigidly held apart by a plurality of adjustable length stanchions 109 - 112. In this example, there are four adjustable stanchions 109 - 112 extending between the inner most two rings. The length of each stanchion is independently adjustable with the result that the inner most rings separated by the adjustable stanchions may be moved apart either with the planes of the two inner most rings being held parallel to each other, or with the main planes of each of the two inner most rings being skewed or tilted with respect to each other, depending upon the

relative adjustments to each of the four adjustable stanchions 109 - 112 applied by a patient or user.

**[0081]** Problems with the known Ilizarov frame include (1) because the frame uses nuts both above and below the ring, the patient or carer can adjust frame incorrectly; (2) a patient or carer must loosen both the top and bottom nuts on each threaded stanchion or linkage rod, to adjust the length of the frame; and (3) the Ilizarov frame is a "one size fits all" solution, with the same set of rings and stanchions being used irrespective of the size of the patient; (4) the geometry of the Ilizarov frame means that extension of the frame does not necessarily occur in a same axial length direction of the bone or working axis of the limb; and (5) the rings can easily be skewed by incorrect adjustment of the stanchions by the user, patient or carer.

**[0082]** Referring to Figure 2 herein, there is shown one example of a prior art Taylor Spatial Frame 200. In this example, the frame comprises three stainless steel rings 201, 202, 203 vertically aligned along a common central axis. Six individual struts 204 - 209 each extend between upper ring 201 and middle ring 202. A further six metal rod stanchions 210 - 215 hold the middle ring 202 and lower ring 203 apart. When fitted to a limb of a patient or subject, the entire ring structure fits around the patient's either side of a fracture or trauma site T to form a tubular central passage within which the limb resides.

**[0083]** A plurality of pins, known as half-pins 216 extend inwardly from a plurality of rancho cubes 217 fitted on the middle ring 202 towards the leg, through the skin and are secured into the bone near the trauma site. A further plurality of fine wires or pins e.g. Kirschner wires 218 attach to a healthy (trauma free) region of the bone to stabilise the device.

**[0084]** In the Taylor spatial frame, the use of separate adjustable nuts above and below each ring is avoided by the use of adjustable struts between rings. This reduces the amount of adjustments which needs to be made by a user.

**[0085]** However, there are remaining problems with the Taylor spatial frame which include: (1) the frame is a "one size fits all" solution which applies to different sized patients; (2) there are still 6 manual adjustments to be made on the 6 struts between adjacent rings; (3) there is still the possibility that the adjacent rings will become skewed relative to each other resulting in the bone being bent off its main natural length axis; (4) the geometry of the Taylor spatial frame is based on a circular cylindrical form still such as to promote the user to adjust their gait when walking; (5) the rings are the same diameter as each other, and do not follow the natural contours of the outer surface of a patient's limb.

**[0086]** Referring to Figure 3 herein there is illustrated schematically the fit of ring members 300 of prior art frames relative to a longitudinal axis 301 of a femur 302 in terms of the main planes **A** of those rings which intersect said prior art ring members. The prior art frames are fitted such that their main planes **A** lie substantially perpendicularly to the long or working axis **A'** of the exterior profile of a patient's leg when the patient is standing upright. The long / working axis of the leg passes through the centre of femoral head (ball joint) and the anterolateral attachment of the posterior cruciate ligament (approximately the centre of the knee joint). This long axis usually lies at an angle of around 5° to the vertical when the person is standing, but this angle varies on average with the race. Thus, the angle of intersection of the main planes of the rings of the prior art frame apparatus and the plane perpendicular to the main longitudinal axis 301 of the patient's femur creates an acute angle **Θ**. The prior art rings are not fitted perpendicular to the main axial length **B'** of the shaft of the femur (shaft axis).

**[0087]** In contrast, axis **B** illustrates the fit of a main plane of a ring of an external fixator in accordance with an embodiment of the present invention. The angle of intersection between the rings of the apparatus of the present invention and the main axial length 301 **B'** of the shaft of the patient's femur 302 is substantially $90^0$C. Consequentially, the apparatus of the present invention is not fitted perpendicular to the long axis **A'** of the patient's femur, but rather is normal or perpendicular to the main femoral shaft axial length direction **B'** 301. In the specific embodiments described herein, each ring is secured to the bone such that

the main plane of each ring is substantially perpendicular or normal to the main femoral shaft axial length 301 of the main longitudinal section of the femur.

**[0088]** Figure 4 herein, shows a front view of an external fixator 400 in accordance with a specific embodiment of the present invention. The embodiment shown comprises upper and lower metal rings 401, 402 each having respective substantially circular upper and lower inner apertures 403, 404 in which a bone and part of a patient's leg or other limb is located. The two stainless steel rings 401, 402 are aligned with each other along a common axis, and are separated by a plurality of metal stanchions 405 - 408 each said stanchion extending between said upper and lower metal rings.

**[0089]** Each said stanchion 405 - 408 comprises a frame structure made from laser cut sheet plate metal assembled together by twist dowel, slot rivets and other jointing methods 409. Each frame-like stanchion 405 - 408 is directly connected at a corresponding respective first end 410 - 413 to said upper stainless steel ring 401 by a corresponding respective joint such that the upper ring 401 provides an upper end boundary of each stanchion. Each stanchion is indirectly connected at its respective second end 414 - 417, to said lower stainless steel ring 402 via a corresponding respective screw threaded lead-screw 418 - 421 which is received in an corresponding respective aperture in a lower end of the stanchion. Each threaded bolt is secured in position by a corresponding lead-screw nut 431 - 434 which the threaded lead-screw passes through -. Each threaded lead-screw is rotatable with respect to the stanchion and said lower ring. Each lead-screw nut is secured to a lower cross member of a corresponding respective stanchion such that the lead-screw nut does not rotate when the threaded lead-screw is rotated. Rotation of a threaded lead-screw relative to its stanchion and relative to the lower ring is achieved by rotation of a corresponding respective gear or pinion or cog 435 - 438 which is integrally located between first 439 and second 440 ring plates comprising said lower ring 402, said first and second ring plates being joined by one or a plurality of slot rivet joints such that said first and second plates are rigidly held in a spaced apart relationship to each other with a void or gap there-between.

**[0090]** Looking at each individual stanchion, the respective thumbwheel 435 - 438 is secured to the corresponding respective threaded lead-screw 423 - 426 each of which runs through a corresponding respective aperture at the lower end of each stanchion. Movement of the thumbwheel in a clockwise direction advances the lower ring 402 toward the lower end of the stanchion to reduce the overall distance between the first and second rings 401 and 402 respectively. A spacer on the underside of each stanchion 439 - 443 prevents the lower ends of the stanchions from being in direct contact with the upper surface of the second ring 402.

**[0091]** All stanchions 405 - 408 are ergonomically shaped to the natural shape of a leg or other limb rather than being arranged in the overall format of an over - sized straight circular cylindrical architecture. In the general case, the curvature of each stanchion can be custom made to fit an individual patient.

**[0092]** In the embodiment shown, the frame structure of each stanchion comprises a first sheet plate bar member; a second sheet plate bar member spaced apart from said first sheet plate bar member; optionally, an intermediate sheet plate bar member spaced between said first and second sheet bar members; an upper cross plate extending between said first and second bar members; an intermediate cross plate extending between said first and second bar members; and a lower cross plate extending between said first and second bar members, said intermediate cross plate being positioned between said upper and lower cross plate members; a main plane of each said cross plate member being arranged substantially perpendicular to a main plane of each said sheet plate bar member; the main planes of the plurality of cross plate members being substantially parallel to each other; and the main planes of each of the plurality of sheet plate bar members being substantially parallel to each other.

**[0093]** In the same stanchion, the main planes of each of the bar members of the stanchion extend in a direction which is substantially parallel to the main planes of each of the other bar members of that stanchion. Similarly, in the same stanchion, the main planes of the cross plate members extend in a direction which

intersects the main planes of each of the bar members, so that the overall construction of a stanchion is of first and second flat bar members spaced apart from each other with a plurality of cross plates there between, wherein the main planes coincident with the outer surfaces of the cross members lie across the main planes coincident with the outer surfaces of the bar members. Within the same stanchion, the bar members are spaced apart from each other, and the plates of the bar members lie opposite each other, with their relatively larger surfaces facing each other across a space there between, with the cross members extending across the distance between the opposing first and second bar members.

**[0094]** In each stanchion, a main outer surface of the first plate member faces opposite the main outer surface of the second plate member with a gap or void there between, with the cross members extending across gap. The main inwardly facing outer surface of the first or second plate member is the surface of the plate member having the largest or equal largest surface area of that plate member, and which faces opposite the other one of the first or second plate members across the void in the centre of the stanchion.

**[0095]** Each sheet plate bar member is cut in a double curvature with the extent of curvature differing between different stanchions. As seen from one side, the first stanchion 405 comprises a first relatively straight portion which curves around in a first direction with the first radius of curvature, and transitions into a second curved portion which curves in an opposite direction to said first curved portion so as to give a shallow double curve shaped stanchion component.

**[0096]** Each stanchion comprises a frame having a main length comprising a first curved portion extending along a main length of said stanchion between a first end of said stanchion and a second end of said stanchion; and a second curved portion extending along said main length of said stanchion between said first end and said second end, said second curved portion joined to said first curved portion; wherein said first curved portion extends about a first point of curvature; and said second curved portion extends about a second point of

curvature, wherein said first and second points of curvature lie on opposite sides of said stanchion from each other.

**[0097]** The upper ends of each sheet plate bar member are joined to the upper ring by a corresponding respective slot rivet. A main plane of each sheet plate bar member is substantially perpendicular to a main plane of said upper ring 401. Upper ends of the first and second said bar members of each stanchion are buttressed to the underside of the upper ring 401 to add additional rigidity and strength, by a plurality of sheet plate buttress members 412 fabricated from laser cut sheet metal. Each buttress plate 412 is joined to the upper ring by one or more slot rivets, and is joined to an adjacent said first or second bar member by at least one further slot rivet per buttress member.

**[0098]** The result is said upper ring member which extends in a first plane, and a plurality of said stanchions which each extend in a corresponding respective plane each of which is perpendicular to said first plane of said upper ring member.

**[0099]** As shown in Figure 4, the upper and lower rings are of different dimensions to each other, and each may be asymmetric, in that they need not be perfect circular or perfect annular rings. Rather, the shape of each ring may be determined by the shape of the outer skin surface at the position along the limb at which the individual ring surrounds the limb. In the general case, the upper ring may have a larger maximum width dimension, or a larger maximum internal and external diameter than the corresponding maximum width dimensions or diameters of the lower ring on the same external fixator. Further, the area bounded by the inner perimeter of the upper ring, in general will be different to the area bounded by the inner perimeter of the lower ring, so that in general the upper ring encloses a larger area in a plane coincident with an upper surface of the upper ring ring than the corresponding area bounded by the inner perimeter of the lower ring in a plane coincident with an upper surface of the lower ring.

**[0100]** As viewed in plan view in a direction perpendicular to a plane coinciding with the main upper surface of the upper and/or lower rings, the upper and lower rings may be of different maximum outer widths to each other in the main

plane of each ring, and may enclose different central areas to each other. In the example shown, the upper ring bounds a larger internal area than the lower ring, due to the shape of a human thigh having a greater circumference nearer the groin than nearer the knee. The main central aperture surrounded by the upper ring has a larger area than the main central aperture surrounded by the lower ring.

**[0101]** In the example shown in Figures 4 and 5, where the external fixator is fitted to a human femur bone, because the external fixator is shaped to follow the outer shape of a person's thigh, and because the upper and lower rings are maintained to move towards or away from each other in a direction along a main length axis of the bone to which they are connected, this means that the plurality of pins of the upper ring extend from the upper ring inwardly into the aperture surrounded by the upper ring to focus at a point of connection to the bone which is not at the geometric centre of the upper ring. That is to say, the geometric centre of the bone does not lie at the geometric centre of the upper ring, and therefore the focal point towards which the plurality of K wires / fixator pins of the upper ring point does not lie at the geometrical centre of the aperture surrounded by the ring.

**[0102]** Similarly, at the position of the lower ring, if the bone itself is not at the geometrical centre of the soft tissue such as muscle, skin and fat in the plane perpendicular to the main axial length of the bone at the location of the lower ring, the geometric centre of the bone where the bone is fixed to the lower ring by the second set of fixator pins or k wires will not coincide with the geometric centre of the aperture surrounded by the lower ring.

**[0103]** In the general case, because each external fixator is custom-made to suit a particular patient, the spatial relationship between the focal point of the fixator pins of the upper ring within the aperture surrounded by the upper ring and the geometric centre of the aperture surrounded by the upper ring will vary between individual fixators. Similarly for the lower ring, for the reason that each fixator is custom-made, which means that the shape of the lower ring may vary from patient to patient and the location of the bone within the outer perimeter of the soft tissue will vary from patient to patient, in general the focal point of the plurality

of lower fixator pins or K wires connected to the lower ring may vary relative to the geometric centre of the aperture surrounded by the lower ring. The focus point of the pins or K wires connected to the lower ring may lie eccentric and off centre from the main geometric centre point of the lower ring.

**[0104]** Referring to Figure 5 herein, there is shown in perspective view from another side the external fixator as shown in Figure 4 herein. Clamps 501, 502 are present on the upper and lower rings 401 and 402 respectively. The clamps perform multiple functions. Firstly, said clamps act as anchor points for the radially outwardly projecting ends of the Kirchner wires to secure the ends of the Kirchner wires to the upper and lower rings. Each clamp secures and end of an individual K wire to the upper or lower ring. The opposite end of the K wire is screwed into the bone in conventional manner.

**[0105]** Upper clamps 501 comprises a flat sheet of metal, typically originally of rectangular shape prior to bending, and which is bent over in a substantially “C” shape or “L” shape, comprising a first plate portion 503 occupying a first plane, and a second plate portion 504 occupying a second plane, said first plane and said second plane intersecting each other, and preferably but not essentially arranged perpendicular to each other. The lower plate comprises first and second apertures, through which a bolt can be passed in order to secure the lower plate to the underside of a said ring, such that an end of a said K wire can be clamped between the lower plate of the clamp and the flat ring, thereby securing the proximal end of said K wire securely to the ring. The second plate portion extends in a plane which intersects the plane of the first plate portion and in use locates radially outward of the ring to which the clamp is attached so that the end of the K wire is covered in the radial direction outwardly of the central bone. At the opposite end of the second plate portion of the clamp to which the first plate portion is connected, there is provided a bent over plate portion 505 which occupies a plane which lies at an angle of around 45° to the plane occupied by the first plate portion and which lies at an angle of around 45° to the plane occupied by the second plate portion. This angle may be varied by ± 5°.

**[0106]** Lower clamps 502 each comprise a substantially "C" or "L" shaped bent over flat rectangular sheet of metal each comprising a first plate portion 506 extending in a first plane; a second plate portion 507 extending in a second plane; and the third plate portion 508 extending in a third plane, wherein said first and second planes lie across each other and are preferably substantially perpendicular to each other, and the third plane lies at an angle of approximately 45° to the first plane and the second plane, with a variation of ± 5°.

**[0107]** A third function of the upper or lower clamps 501, 502 is that they may be used to connect multiple rings to be connected to one another to build a modular external fixator device. A lower ring of an upper external fixator may be connected to an upper ring of a lower external fixator by said clamps.

**[0108]** Lower clamps 502 also maintain the configuration of the lower ring 402 which comprises first and second ring plates and a plurality of thumbwheels 410 located there between.

**[0109]** The upper ring 401 has an irregular outer profile, having a linear edge 520 which is ergonomically designed to reduce the extent of which the device protrudes from a patient's limb. The ergonomic fit reduces the impact of wearing the device on the patient's posture and gait when walking. As shown in Figure 5, the upper ring 401 need not be a pure annular circular plate. In the embodiment shown, the a substantially flat part 520 of the outer perimeter of the upper ring in use is situated adjacent the patient's inner thigh, and in this embodiment reduces the obtrusiveness of the upper ring to the patient's opposite leg by reducing the lateral extent to which the upper ring extends towards the patient's opposite leg.

**[0110]** The external fixator device has a plurality of upper pins, Kirchner wires or "K- wires" 509, which extend substantially radially within the area bounded by the upper ring 401, and a plurality of lower pins, Kirchner wires or K-wires 510 which extend substantially radially within the area bounded by the lower ring 402. The Kirchner wires, pins or K-wires are of heavy gauge stainless steel

and extend inwardly from each of the upper 401 and lower rings 402 towards the leg, through the skin and are secured at a substantially $90^0$C angle to the main central longitudinal axis **B'** of the femoral shaft.

**[0111]** Said metal buttresses or flanges 412 provide additional support to the structure and reinforce the attachment of the frame-like stanchions 405 - 408 to the upper ring 401.

**[0112]** In general, the upper and lower rings need not be of the same size or shape, but rather are custom made to suit the patient's limb to which the external fixator is being fitted. The projected intersection point of the ends of the K wires or pins with the bone, that is, the axial centre line of the bone at the position along a length of the bone where the K pins of an upper or lower ring are fixed may be offset from the geometrical centre of the ring, for both the pin intersection point of the upper ring and/or the lower ring. This means that either the upper and/or the lower ring may be located eccentrically with respect to the position within the ring which represents the centre line axis of the bone, and the nominal intersection point of the K wires. Thus, in use, the upper ring and lower ring may appear to be laterally offset from each other, whilst a main outer surface of the upper ring occupies a plane which is substantially perpendicular to a plane which intersects with a main outer surface of the lower ring, so that the upper and lower rings are substantially parallel to each other, but the perimeter around the outside of the upper ring does not necessarily overlie, and in the general case does not overlie the perimeter around the outside of the lower ring when viewed in a direction perpendicular to a main plane occupied by a main outer surface of the upper ring, or a main plane occupied by a main outer surface of the lower ring.

**[0113]** In general during extension of the external fixator, the main planes of the upper and lower rings will remain in fixed angular relationship to each other, under control of the adjustment means. A line between the male focal point of the upper ring, corresponding to a main central length axis of the bone to which the fixator is attached, should remain as a straight line during extension, with the external fixator expanding so that the upper and lower rings remains parallel to

each other, and the angle between the line connecting the focal points of the upper set of pins and the lower set of pins remaining at a same angle to both the upper plane through the upper ring, and the lower plane through the lower ring.

Slot rivet or twist dowel construction

**[0114]** The individual metal components of the external fixator can be assembled using either slot rivets or twist dowels, or by a combination of slot rivets and twist dowels.

**[0115]** Slot rivets 409 each comprise a rectangular aperture in a first sheet of metal, and a corresponding shaped projection in a second piece of metal. The projection is passed through the rectangular aperture in the first sheet metal and a portion of the projection which extends through the aperture to other side of the first piece of metal is pressed or flattened to form a rivet which joins the two pieces of metal together. Slot rivets are known in the art.

**[0116]** A twist dowel comprises a rectangular aperture in a first sheet of metal and a corresponding rectangular shaped projection at the end of the second piece of metal. The projection passes through the from one side to the other of the first sheet of metal, and protrudes beyond the other side of the first sheet of metal. The portion of the projection which protrudes on the other side of the first sheet is then twisted so that the projection cannot be pulled back through the aperture, and the end of the projection is locked on the other side of the aperture, thereby joining the second sheet of metal to the first sheet. Twist dowels are known in the art, for example in EP2246147, the contents of which are incorporated herein by reference.

**[0117]** The use of slot rivet and / or twist dowel joining on the frame construction of the stanchions, on the buttresses and to join the upper ends of stanchions to the upper ring enable the fixator to be fabricated from laser cut sheet metal. The use of laser cut sheet metal means that the shape of the stanchions, and the size and shape of the rings can be designed on a computer aided design package and then cut automatically using a laser cutting machine from a sheet of

metal. This means that there is a high degree of flexibility and design variation in terms of size and shape which can be applied and that an individual external fixator can be customised to fit closely an individual patient, whilst at the same time enabling quick and efficient fabrication.

**[0118]** An inner passage or cavity bounded by the inner surfaces of the novel external fixator disclosed herein is contoured to follow more closely the outer skin surface of the portion of limb of the patient to which the fixator is individually designed to fit. As shown in Figure 5, the upper ring 401 surrounds a slightly larger dimensional upper aperture than the relatively smaller dimensional lower aperture bounded by the inner surfaces of the lower ring. Further, the inner faces of the rings and stanchions which present facing radially inwardly follow at roughly a fixed distance to the contours of the external surface of human patients thigh at a position between the patients the hip joint and their knee joint. Since each patient is of slightly different build and has a slightly different limb shape, due to the use of laser cut metal plate construction for the stanchions and rings, and the use of slot rivets and/or twist dowels in construction, this enables relatively easy manufacture of a custom-made external fixator to suit the limb dimensions of each individual patient, rather than in the prior art case where a one size fits all standard off-the-shelf Ilizarov or Taylor spatial frame is used. Specific embodiment custom-made fixators as disclosed herein may be able to be produced to suit an individual patient within one day, including initial measurement of the three-dimensional outer skin surface of the patient, laser cutting of the individual components for the frame, including rings and stanchions, and assembly of the individual stanchions using slot rivet or twist dowel construction and including fitting the stanchions to the upper ring and construction of the lower frame and attachment means and fitting of the lower ring and attachment means to the lower ends of the stanchions.

**[0119]** In some applications, fast turnaround times for measuring and manufacture of customised external frames are desirable, because if a patient arrives in casualty after experiencing a traumatic fracture, for example a car accident, the patient needs to be put into surgery at the earliest opportunity and an external support frame needs to be fitted without delay. For less urgent elective or

semi elective surgery such as leg lengthening, support frame manufacturing turnaround times are less critical but are till desirable for reasons of improved efficiency and reducing hospital operation waiting times.

**[0120]** Figure 6 herein, shows a close up view of an adjustment means 600 of the external fixator of Figures 4 and 5 herein. The adjustment means 600 comprises threaded bolt 421 which is secured in position by a lead-screw nut 434, the nut having a reciprocally threaded core which receives the threaded lead-screw 421 such that the lead-screw is axially rotatable with respect to the nut increase or decrease the distance between the lower ring and the lower part of the stanchion, and thereby increase or decrease the distance between the upper and lower rings of the external fixator.

**[0121]** One or a plurality of sheet metal spacers 603 are located between the first ring plate 439 and second ring plate 440 which comprise the lower ring 402 either side of the pinion gear or cog 435 ensuring that there is sufficient clearance for the pinion gear or cog wheel 435 to rotate without obstruction. The lead-screw nut 434 is secured to the lower cross member 607 of the stanchion by one or a plurality of screws 609. The screws 609 provide an outermost limit which functions as a stop to prevent the underside 607 of the upright bar 608 from contacting the first surface 604 of the lower ring, and also prevent the nut 435 from rotating relative to the stanchion.

**[0122]** In the embodiment shown, rotation of the pinon cog or gear 435 in a first rotational direction causes the lead-screw thread 421 to draw the nut 434 closer towards the lower ring 402, and rotation of the pinion cog or gear 435 in an opposite second direction causes the nut 434 to travel in the opposite direction along the lead-screw thread thereby pushing the nut 434 and the lower end of the stanchion away from the lower ring 402. Therefore, by rotating the cog or gear wheel 435 either in the first rotational direction or the second rotational direction, the distance between the upper and lower rings 401, 402 can either be shortened or extended. Typically in use in a leg extension, the gear wheel will be rotated in

the second rotational direction, extending the distance between the upper ring 4 one and the lower ring 402 in order to incrementally extend the patient's leg.

**[0123]** When all adjustment means are adjusted at the same time and by the same increment as each other, the lower ring 402 extends substantially along the main axis **B'** of the femoral shaft. However, if extension of the bone in a direction other than along the main axis of the femoral shaft is required, this can also be accommodated by varying the adjustment means. For example the pitches of the screws 421 may be varied such that at different positions around the lower ring, the adjustment screws have thread pitches which are selected so that for the same number of turns of each screw, some individual adjustment means extend further than other individual adjustment means on the same lower ring, so that the ring moves off in path which carries the lower part of the femur in a direction which is not a straight axial extension along the main femoral shaft axis **B'** of the upper part of the femur. In this way, the apparatus is versatile enough to be adapted for movement across other corrective axes not along or parallel to the main femoral shaft axis **B'**. The modification of different threaded pitches for different individual adjustment means may also be applied to other embodiments described in this specification.

**[0124]** Referring to Figure 7 herein, there is illustrated schematically in plan view from above, a second plate 440 of second lower ring 402 of the external fixator, without the first plate 439, showing the interior of the lower plate 402, of the external fixator as shown in Figures 4 to 6 herein.

**[0125]** There are shown the plurality of cogs, wheels or pulleys 418 - 421 which rotate about their corresponding respective rotational axes. There is further provided a continuous toothed belt, chain, cable or wire 700 which extends around the perimeter of the lower ring, passing through the voids between the lower clamps 502 and the outer perimeter of the lower ring and which engages with the teeth on each of the individual cogs or gears, thereby ensuring that the threaded rods 418 - 421 are in locked or synchronised rotational relationship to each other.

**[0126]** By moving the belt in a first belt direction, the plurality of pinon gears or cogs 418 – 421 each rotate in their first rotational directions in synchronisation with each other, and vice versa, by rotating the belt in a second belt direction, the plurality of gears or cogs 418 - 421 each rotate in coordinated synchronisation in their respective second rotational directions. By synchronising the rotation of the plurality of individual threaded lead-screws of the individual adjustment means between the lower end stanchions and the second ring, it can be ensured that the movement of the lower ring with respect to the upper ring in a direction further away from or closer to the upper ring occurs such that the main plane of the lower plate is always substantially parallel to the main plane of the upper plate, and that the lower plate extends away from the upper plate along a movement of direction which is substantially parallel to the main working axis of the limb.

**[0127]** The external toothed belt or chain connecting the plurality of pinion gears or cogs of the respective plurality of adjustment means may be driven manually by means of a separate rotatable thumbwheel (not shown) located on the lower ring and engaging with the toothed belt or chain via a separate drive cog or drive gear 701 located between the first and second plates of the lower ring.

**[0128]** Alternatively, the toothed belt or chain may be driven by a small electric motor or other actuator mounted on the lower ring, to drive the toothed belt or chain via a separate toothed drive wheel or gear 701 located between the first and second plates of the lower ring in order to drive the belt in the first and/or second belt rotational directions. In this modification, the actuator may be controlled locally by a small control unit mounted on the lower ring, the control unit being in communication via a radio transmitter/receiver over a short range communications systems such as Wi-Fi or Bluetooth to a local controller or user interface. The user interface may be implemented as an app on for example a mobile phone, tablet, personal computer or like device.

**[0129]** Referring to Figure 8 herein, there is illustrated schematically a motorised drive mechanism and control apparatus for the adjustment means. An actuator 800 drives a drive gear wheel or toothed wheel 701 which is in direct

contact with a toothed belt or chain as described herein above to drive the individual cogs or gears 418 – 421 of the lower ring adjustment mechanisms. The electric motor, which may be a stepper motor drives the drive wheel 701 optionally via a gearbox 801.

**[0130]** A motor control unit 802 receives signals from a transmitter/receiver 803. The control unit and transmitter/receiver 803 and the electric motor 800 are powered by a small battery pack or cabled mains transformer 804 which can be mounted anywhere which is convenient and least intrusive on the external fixator.

**[0131]** The transmitter/receiver unit 803 may communicate with a remote device, for example a mobile phone, laptop computer, personal computer or handheld tablet computer device 805 via a short range communications systems such as Wi-Fi or Bluetooth or via a wired protocol such as USB or Ethernet. A computer program on the remote computer device 805 may control operation of the motor 800 through an automated program to determine the amount of rotation of the toothed wheel 701 to be applied on a daily basis. Rotation of the toothed wheel 701 causes all of the adjustment means to rotate by a same rotational amount and therefore causes the whole of the lower plate to extend further away from the whole of the upper plate in a direction transverse to the main planes of the upper and lower plates, and substantially parallel to a main axial length direction of the bone, thereby providing an automated and controlled extension of the bone of the limb which can be controlled through the remote device 805.

**[0132]** In a variation of the adjustment means shown in Figures 4 to 7 herein, rather than having a plurality of adjustment means which are driven by a single belt or chain drive, each individual adjustment means at the base of each stanchion may be individually driven by its own corresponding respective actuator, which may be for example a stepper motor, or an electric motor, and each individual actuator may be individually and independently controlled so that each actuator may be operated independently or in conjunction with each other actuator to achieve a range of paths of travel of the lower ring relative to the main femoral shaft axis **B'** of the femur, either in parallel and along the femoral shaft axis, or

travelling off away from the shaft axis by a few degrees. The provision of a plurality of independently controllable extendable adjustment means arranged around the lower ring gives the opportunity and ability to "point" the direction of travel of the lower ring at any direction within a cone of possible directions, where the cone of possible directions is centred around the main femoral shaft axis.

**[0133]** Figure 9 herein, show in close up view part of an alternative embodiment external fixator comprising an alternative adjustment mechanism 900. All other features of the external fixator as described with reference to Figures 4 to 6 herein are present, except that the adjustment means of the first embodiment external fixator are replaced by the adjustment means as shown in Figure 9, and each stanchion adjustment means is manually operated independently of each other stanchion adjustment means.

**[0134]** The alternative adjustment means 900 includes a threaded bolt 901 co-operably received into a rotatable threaded nut 902, said nut 902 spanning first 903 and second 904 plates of a ring frame member 905 which are joined together to form said ring frame member.

**[0135]** Movement of the threaded bolt 901 relative to the ring is effected by movement of rotatable threaded nut 902. The rotatable threaded nuts is formed with a protruding thumbwheel portion 906 which is accessible on the side of the ring and protrudes enough such that a human user can rotate the thumbwheel with their finger or thumb. The rotatable nut and thumbwheel 906 rotates within a circular cylindrical passage inside the ring but are prevented from moving axially with respect to the ring by virtue of being located between the first and second plates 903, 904 of the ring. The threaded rod 901 can move axially in response to rotation of the rotatable nut. A distal end of the threaded rod 901 is fitted to the lower part of a stanchion frame in a manner where it can rotate relative to the lower part stanchion, but cannot move axially with respect to the lower part of the stanchion.

**[0136]** In the embodiment shown in Figure 9, there may also be provided a rotary position encoder, being a small semiconductor device fitted within the frame which measures the position of the knot and/or thumbwheel, and which may be electrically connected to a wireless transmitter to send a digital position signal over a wired or wireless link, for example wifi or Bluetooth to a receiving device. The receiving device may comprise a computer device such as a smart phone, laptop computer, tablet computer, personal computer or the like or a specifically manufactured electronic monitoring unit which generates a display to give the user an indication of the amount of rotation of each rotatable nut and/or a calculation of extension of the threaded rod based upon the number of measured rotations of the nut.

**[0137]** Figure 10 herein, shows in cut away view of a third and alternative adjustment means 1000 which can be fitted to the first embodiment external fixator as described herein with reference to Figures 4 to 6 herein, in replacement of the adjustment means described with respect to that external fixator. All other aspects of the external fixator of 4 to 6 herein are retained.

**[0138]** The third adjustment means comprises a threaded rod member 1001 which is received into an aperture of a threaded bore, passage or nut 1002 rotatably secured between first and second plates1003, 1004 of the lower ring. The rotatable member 1002 when rotated moves the threaded rod 1001 rotationally, in a direction along a main length axis of said threaded rod, thereby drawing the rod through the rotatable member 1002 and drawing the lower ring 1005 towards the upper ring if the rotatable member 1002 is rotated in a first direction, and pushing the lower ring away from the upper ring if the rotatable member 1002 is rotated in a second, opposite rotational direction.

**[0139]** The rotatable member comprises a circular cylindrical outer surface 1006 of a diameter larger than the diameter of upper and lower portions 1007, 1008 respectively both above and below the central larger diameter section. Placed adjacent the outer surface of the larger diameter section 1006 there is provided a piezoelectric (PZT) drive 1009 or piezoelectric motor. The piezoelectric

drive operates by expansion and contraction of a piezoelectric material in response to electronic pulses. The piezoelectric device can be driven such that along its circular cylindrical surface, the surface can be made to move in a wave motion which, when in contact with the outer surface of the circular cylindrical larger diameter section 1006 urges the rotatable member 1002 in the direction of the waves along the surface of the piezoelectric material.

**[0140]** Similarly, by driving the concave circular cylindrical surface of the piezoelectric material with a further electronic pulse drive, and expansion/contraction way of the piezoelectric material can be made to move along the concave surface of the piezoelectric material in the opposite rotational direction.

**[0141]** Therefore, depending upon the electrical drive signal applied to the piezoelectric material, moving waves in either a first rotational direction, or in an opposite second rotational direction can be achieved. Since the piezoelectric material is in contact with the outer surface of the larger diameter central portion 1006 of the rotatable member 1002, the surface waves of the piezoelectric material urges that rotatable member either in a first rotational direction or a second, opposite rotational direction. This allows accurate rotational control of the rotatable member 1002 using a piezoelectric drive.

**[0142]** In an external fixator having a plurality of piezoelectric driven adjustment mechanisms connecting the lower ring to the lower ends of the stanchions, if all piezoelectric driven adjustment mechanisms are driven similarly by a substantially same drive signal, there can be coordinated movements of the 4 adjustment means at the same time and such that the rotatable members 1002 rotate in a same rotational sense as each other to urge the lower ring towards or away from the upper ring (depending upon the rotational sense of the rotatable member selected).

**[0143]** Alternatively, by applying a slightly different drive signal to each piezoelectric driven adjustment mechanism, if there occurs any misalignment of the main plane of the lower ring with respect to the main plane of the upper ring, then

such misalignment can be corrected by applying slightly different drive signals to each of the plurality of piezoelectric driven adjustment mechanisms in order to correct for any such misalignment.

**[0144]** In the third adjustment mechanism, the mechanism may be varied such that the other ends of the threaded rods 1001 which are connected to the lower ends of the stanchions are rotatable with respect to the stanchions. The other ends of the rods may be connected to the lower ends of the stanchions such that rotation of the threaded rods does not move the lower end of the stanchion axially with respect to the main axis of the rod, so that the threaded rods maintain a same axial relationship to the stanchions and the lower ring moves along the threaded rods, in which case all movement of the lower ring relative to the stanchion is a result of movement of the threaded rod within the rotatable member 1002.

**[0145]** In another and alternative variation, the rotatable member 1002 may be rotatably fixed to the rotatable rod 1001 such that the rotatable rod 1001 does not move axially with respect to the plane of the lower ring when rotated. However at the upper end of the rotatable rod 1001, this is connected into a rotatable vertically fixed threaded nut on the lower end of the stanchion so that rotation of the rotatable nut 1002 moves the rotatable rod upwards or downwards relative to the lower end stanchion thereby moving the lower ring towards or away from the lower ends of the stanchions.

**[0146]** Referring to Figure 11 herein, there is illustrated schematically in perspective view a third adjustment mechanism which can be applied to the lower ring of an external fixator as described with reference to Figures 4 to 6 herein.

**[0147]** The third adjustment mechanism comprises a threaded rod or bar 1101 which passes through an aperture in a lower ring of the external fixator, such that rotation of the rod or bar 1101 relative to the lower ring moves the rod or bar 1101 rotationally in a first rotational direction. Another end of the rotational rod or bar may be fixed to a lower end of the stanchion for described with reference to

Figures 4 to 6 herein so that rotation of the rod or bar causes axial movement of the rod or bar with respect to the stanchion and thereby pushes the lower ring of the fixator away from the lower ends of the stanchions and pushes the lower ring away from the upper thereby expanding the fixator.

**[0148]** The rotatable rod or bar 1101 is in fixed relationship axially i.e. along the axial direction of the rod or bar to the lower ring so that rotation of the rod or bar simply rotates the rod or bar in the lower ring but does not move it lengthwise with respect to the lower ring. Within the lower ring, between first and second plates of said lower ring, there is provided a larger diameter wheel which is rigidly connected to the rotatable rod or bar 1101 and which is acted upon by a ratchet mechanism operated by an externally protruding pivoted pushbutton or lever 1103 which can be activated by manually pressing the lever.

**[0149]** Movement of the threaded bolt 901 in its axial direction transverse to the main plane of the lower ring is effected by a ratchet “click” device which is manually activated. The spring-loaded ratchet device is pressed in a direction downwardly or upwardly with respect to the lower ring and pushes the threaded bolt or rod 1101 axially along its length, and in a direction transverse to the main plane of the lower ring. Each activation of the ratchet mechanism moves the threaded bar 1101 a predetermined distance, dictated by the pitch of the thread of the bolt 1101.

**[0150]** Using an external fixator having this alternative adjustment means, a user would typically apply a predetermined number of “clicks” or presses of the ratchet lever per day to each adjustment means. By applying the same number of activations or “clicks” to each separate adjustment mechanism means that each separate adjustment mechanism moves the corresponding respective stanchion relative to the lower ring by a same distance in the axial direction, i.e. in a direction parallel to the main length axis of the bone. Use of this device is therefore simple user. All the user needs to know is that for example a single click needs to be applied to each adjustment mechanism daily. This moves the lower ring away from

the upper ring by a predetermined distance each day and ensures that the main plane intersecting the lower ring remains parallel to the main plane intersecting the upper ring once each adjustment mechanism has been activated.

**[0151]** Optionally, a light emitting diode 1104 provides a visual indication of whether the device needs adjustment. When the LED 804 is illuminated the device requires adjustment. The light-emitting diode may be controlled by a separate microprocessor control unit so as to illuminate after a certain predetermined time period, for example every 8 hours. The light-emitting diode may be deactivated by a signal, for example created by rotation of the threaded rod or bar 1101 which then turns the light-emitting diode off indicating that an adjustment has been made.

**[0152]** Using this adjustment mechanism, expansion of the external fixator is simplified for a user or carer since they will know that when the LED is lit, a single push of the ratchet mechanism is required in order to effect the correct amount extension of the external fixator.

**[0153]** Referring to Figure 12 herein there is shown a schematic illustration of a second apparatus 1200 according to a second specific embodiment.

**[0154]** The second apparatus includes a second external fixator 1201 and a radio frequency identification (RFID) equipped tightening tool 902. The second external fixator may be substantial described herein with reference to the first fixator as shown in Figures 4 to 6 herein, but with a modified adjustment mechanism as hereinafter described.

**[0155]** Adjustment of a plurality of threaded rods or bars through a ring of the external fixator is made by rotation of a corresponding plurality of adjustable threaded nuts 1203. The RFID tool employs electromagnetic fields to identify the specific identification labels 1204 on the individual adjustment nuts of the second external fixator.

**[0156]** Each rotatable adjustable means 1203 has its own individual identification tracker in the form or an RFID chip 1204. The RFID tightening tool

comprises an RFID detector which can individually recognise each individual RFID chip 1204. An RFID sensor or detector in the spanner or wrench 1202 detects and recognises each individual RFID rotatable adjuster 1203. The sensor or detector sends a signal back to a computerised monitoring and control unit 1205 which keeps a record of each individual adjustment means 1203 and a record of the number of terms and the rotational sense of each turn of each adjustment means from an initial set up or start-up condition.

**[0157]** An algorithm programmed into the computerised control unit 1205 calculates how many turns off each adjustment means 1203 is required, and a visual display may be displayed on a visual display unit to instruct a user how many turns off the adjustment mechanism and in which direction need to be applied.

**[0158]** The control unit may operate via a website interface to provide a visual on-screen indication of the level of adjustment required for each individual adjustment means 1203. The RFID system prevents adjustment means from being incorrectly tightened and allows complex adjustment plans to be programmed into an interface and easily executed by a patient or their carer.

**[0159]** Alternatively, the external fixator apparatus may comprise motor driven adjustment means which are preprogrammed via a computer interface which has been preprogrammed by a clinician to employ a specific adjustment program.

**[0160]** Referring to Figure 13 herein, there is illustrated schematically in perspective view a motorised variation of the second external fixator apparatus shown in Figure 12 herein. Instead of having manually adjustable draw – nuts as shown in Figure 12 and individual motor 1300 may be attached at or adjacent the point at which each threaded bar 1301 attaches to the lower ring 1302. An arrangement in which an electric motor is positioned immediately adjacent to the side of the threaded bar, being off axis from threaded bar may be provided and where the output shaft of the motor drives an annular threaded ring which fits around the threaded bar so that rotation of the annular threaded ring causes axial movement of the annular bar. Alternative motor arrangements are possible, for

example the motor may be designed such that the threaded bar passage through a central substantially circular cylindrical passage in the motor, and locates in a threaded rotatable annular driven wheel which is directly driven by the motor. The motor may comprise a stepper motor and the motor may include position sensors so that the position of the rotations of the motor can be detected and can be transmitted wirelessly to a remote monitoring device, which may also control the motor via a small motor controller integrated circuit located on the external fixator frame or on the motor itself. In such an arrangement, a plurality of motors may be individually controllable by a remote controller and/or may be controlled in unison, to apply the same amount of rotation each motor, thereby ensuring that the ring is drawn towards or away from the rest of the external fixator frame maintaining its relative angular position of the plane of the ring compared to the rest of the frame.

**[0161]** Referring to Figures 14 and 15 herein, there is illustrated schematically yet another option for rotation of the threaded rods. As with previous options, the remainder of the external fixator is substantially as shown with reference to Figures 4 to 6 herein, with the optional variation being the manner in which the threaded rods are rotated.

**[0162]** In Figure 14, rotatable rod 1401, has one end attached to the lower part of a stanchion so as to be rotatable with respect to the stanchion, and such that rotation of the rod moves the end of the stanchion relative to the threaded rod in a direction along the main length axis of the threaded rod. The main length of the rod is located in the lower ring and passes through an aperture in the lower ring. Within the lower ring there is provided a rotatable threaded member 1402 at a fixed axial location on the threaded rod 1401 the nut, being located between upper and lower plates of the lower ring so that it cannot move in the axial direction of the rod. The threaded rod 1401 is rigidly fixed to the rotatable member 1404 so that rotation of the rotatable member 1404 causes rotation of the threaded rod but without any axial movement relative to the ring. Movement of the ring relative to the lower end stanchion is caused by the other end of the threaded rod 1401 moving axially with respect to the lower end of the stanchion.

**[0163]** Rotational movement of the threaded rod is by rotation of the captive nut 1404 on the lower ring. Rotation of the captive rotational member 1404 is by application of a permanent magnet 1405 which engages with the outer surface of the rotational member causing the rotational member to rotate. The permanent magnet 1405 moves in a plane which intersects the main axial direction of the threaded rod and acts on the outer surface of the rotational member 1404 so as to rotate that member, when a signal is applied to an external electromagnet 1403 which has a magnetic field which overlaps the magnetic field of the permanent magnet 1405.

**[0164]** As with other embodiments described herein, activation of the electromagnet may be made from a remote location by provision of a localised electromagnet controller circuit located on the external fixator frame. Similarly, position sensors may be applied to the rotational member and/or the threaded bar and a digital position signal may be transmitted from the external fixator to a remote controller to provide information on the amount of rotation of each threaded bar and/or an amount of movement either towards or away of the ring relative to the rest of the external fixator frame.

**[0165]** Referring to Figure 16 herein, there is illustrated schematically in perspective view a modular motor position sensor which may be used in any of the embodiments described herein which include an electric motor.

**[0166]** Referring to Figure 17 herein, there is illustrated schematically in cutaway view a spherical module amount which may be used to mount a threaded rod or bar to an external fixator ring or to the bottom of the stanchion and which can be applied to any of the embodiment external fixator is described herein.

**[0167]** Referring to Figures 18 and 19 herein, there is illustrated schematically in cutaway view from one side yet a further embodiment variation of a piezoelectric drive mechanism for rotating a threaded rod, and which may be fitted in to a ring of an external fixator, or into the lower part of a stanchion of external fixator substantially as described with reference to Figures 4 to 6 herein

with appropriate modifications as would be understood by the person skilled in the art.

**[0168]** The piezoelectric drive is shown as being located in an external fixator ring member 1800 comprising an upper plate 1801 and a lower plate 1802, said upper and lower plates being spaced apart from each other with a gap there between; a substantially circular or tablet shaped rotatable central portion 1803 mounted to the ring plates via an annular bearing 1804.

**[0169]** A threaded rod 1805 is rigidly secured to the central rotatable member 1803 such that as the rotatable member 1803 rotates either in a first rotational or in an opposite second rotational direction, the threaded rod rotates with it. The annular bearing 1804 prevents the threaded rod from moving in a direction axially with respect to the ring plates 1801, 1802 and movement of the ring relative to the remainder of the frame is effected by axial movement of the other end of the rod where it meets a stanchion of the fixator frame substantially as hereinbefore described with reference to Figures 4 to 6.

**[0170]** The central rotatable member comprises two spaced apart circular discs 1806, 1807 rigidly fixed together by a central cylindrical circular annular collar 1808 through which the threaded rod passes and which is rigidly secured to said threaded rod.

**[0171]** In the annular circular void created between the upper and lower circular discs 1806, 1807 there is provided first and second piezoelectric devices 1809, 1820, each mounted on a corresponding respective printed circuit board 1821, 1822. The piezoelectric devices 1809, 1820 may be driven by an electric signal to create a moving surface wave on the surfaces of the piezoelectric devices, depending upon the drive signal applied, the surface wave moves in either a first rotational direction, or a second directional rotation.

**[0172]** In a simplification of the adjustment mechanism shown in Figures 18 and 19, the piezoelectric devices may be driven only one direction, such that there surface waves flow only in one rotational direction. This means that the rotational

direction of the central rotational drive member 1803 would only be a single direction.

**[0173]** As shown in Figure 19, and optional ratchet device may be incorporated into the central rotatable member to ensure that the central rotatable member only moves in one direction and prevents accidental reverse rotation which may loosen the fitting of the external fixator frame to the patient. As shown in Figure 19, the bearing may comprise a substantially solid ring of bearing material, for example nylon or brass, having one or a plurality of notches in which a spring-loaded ratchet mechanism may engage. The spring-loaded ratchet mechanism may be disengaged by pushing the pawl 1900 of the ratchet which engages a notch 1901 inwardly towards the central axis of the rotational member thereby allowing the pawl to move in the opposite rotational direction without being held by the notch.

**[0174]** Central rotational member 1803 may be provided with a releasable ratchet mechanism which normally allows rotation of the rotatable member only in one rotational direction, but which can be manually overridden by an operative to allow reverse direction rotation.

**[0175]** In each of the above-described alternative adjustment mechanisms, an object is to ensure that a non - medically skilled user can apply a predetermined amount of extension or contraction of the external fixator in an easy-to-use and easy to understand manner with the minimum risk of error. It is an object that all adjustment mechanisms are designed to enable the lower ring of the external fixator to move with respect to its upper ring such that a main plane passing through the lower ring remains parallel to a main plane passing through the upper ring, and such that the main plane of the lower ring moves in a direction transverse to its main plane and parallel to a main length axis of the bone to which the external fixator is secured.

**[0176]** – In a further modification to the fixators disclosed herein, there may be provided one or more cosmetic customisable panels to be secured to the struts, and which can snap on and off the struts. This enables the patent opportunity to

change the colour to match their outfit – or in the case of the children have cartoon characters to make the device less intimidating and "cooler". Also these covers shroud any working mechanisms or electrical components. The design of the external fixator embodiments described herein is particularly suitable for fitment of such external cover panels.

**[0177]** Advantages of the invention and the above-described embodiments include, amongst other advantages mentioned herein:

- Avoiding skew adjustments of the rings relative to each other.

- The advantages include avoiding off skew adjustment of the rings.

- Lower errors and less risk of making the wrong adjustment to a ring.

- Less user skill is required in making adjustments to the rings in use.

- Automation of adjustments to the ring spacings.

- Automatic reporting of extension of the distance between rings.

- Possible remote monitoring of one or a plurality of devices by a single monitoring apparatus operated by a qualified medical personnel.

- Customisation of an external fixator to fit a specific patient, improved / reduced manufacturing times, and ease of manufacture.

- Additionally, the fixator can be shaped more closely to fit the user, and can be shaped so that there is better alignment between the main axis of movement and the main longitudinal axis of the bone.

- There may be medical instances where the bone may need extending along another corrective axis angle – this can be designed in with the specific embodiments disclosed herein.

**[0178]** Whilst specific embodiments herein have been described in relation to treatment of a human patient's leg and in particular a leg lengthening treatment, in the general case the embodiments herein are not restricted to use with a human leg, but may be applied to a human arm or in the general case, to any suitable animal or human limb in which an accurate controlled fixation and/or positioning and/or extension of first and second skeletal members with respect to each other is to be achieved.

**[0179]** In the above description, any joint which can be achieved by a slot rivet may be replaced by a twist dowel joint or other mechanical fastening method (e.g. bolted joint) and vice versa unless specifically stated otherwise.

**[0180]** In the embodiments described herein, any feature described in relation to one embodiment may be incorporated into any other embodiment described herein except as specifically stated otherwise in this document, or except as being technically mutually exclusive alternatives.

**Claims**

1. An external fixator for use in limb adjustment comprising:

first and second spaced apart rings;

a plurality of rigid stanchions each extending between said first and second rings; and

each said stanchion comprises a frame having a first plate member and a second plate member;

said first and second plate members being spaced apart from each other such that a main outer surface of said first plate member lies opposite and facing a main outer surface of said second plate member;

each said stanchion having at least one cross member connecting between said first plate member and said second plate member.

2. An external fixator according to claim 1, wherein said first and second plate members are each cut from a substantially flat plate material.

3. An external fixator as claimed in any one of the preceding claims, wherein said first and second spaced apart rings are each cut from a substantially flat plate material.

4. An external fixator as claimed in any one of the preceding claims, wherein said first and second plate members and said at least one cross member are joined together by twist dowel joints.

5. An external fixator as claimed in any one of the preceding claims, wherein said stanchions are joined to a said first or second ring by twist dowel joints.

6. An external fixator according to any one of the preceding claims, wherein each said stanchion has a main length comprising a first curved portion extending along a main length of said stanchion between a first end of said stanchion and a second end of said stanchion; and

a second curved portion extending along said main length of said stanchion between said first end and said second end, said second curved portion being joined to said first curved portion; and

said first curved portion of each said stanchion extends around a first point of curvature, and said second curved portion extends about a second point of curvature, said first and second points of curvature lying on opposite sides of said stanchion to each other.

7. An external fixator as claimed in any one of the preceding claims, wherein said first ring surrounds a first aperture and said second ring surrounds a second aperture, an area of said first aperture being greater than an area of said second aperture.

8. An external fixator according to any one of the preceding claims, wherein said first and second spaced apart rings are of a different diameter or maximum outer dimension to each other.

9. An external fixator as claimed in any one of the preceding claims, comprising a first plurality of fixator pins attached to said first ring;

wherein said first plurality of fixator pins extend inwardly from said first ring towards a focal point which lies away from a geometrical centre point of said first ring.

10. An external fixator as claimed in any one of the preceding claims, comprising a second plurality of fixator pins attached to said second ring;

wherein said second plurality of fixator pins extend inwardly from said second ring towards a focal point which lies away from a geometrical centre point of said second ring.

11. An external fixator according to any one of the preceding claims comprising a plurality of adjustment means for adjusting a distance between said upper ring and said lower ring, each said adjustment means associated with a corresponding respective said stanchion.

12. An external fixator according to claim 11, further comprising a separate tightening tool for adjusting said adjustment means.

13. An external fixator according to claim 11 or 12, wherein said tightening tool comprises a radio frequency identification device configured to identify an RFID tags located on a said adjustment means.

14. An external fixator according to any one of claims 11 to 13, comprising a control mechanism which is operable to control said plurality of adjustment means to move said first and second rings towards or away from each other whilst maintaining a fixed angle relationship between the main planes passing through each of said first and second rings.

15. An external fixator according to claim 14, wherein said control means comprises a single direction ratchet.

16. An external fixator according to any one of claims 11 to 15, wherein the means to move said plurality of rigid linkages away from or towards each other comprises an actuation drive.

17. An external fixator according to any one of the preceding claims, further comprising a light emitting diode which illuminates to indicate that an adjustment is required.

18. An external fixator according to claim 17 wherein the actuation drive is controllable using pre - programmed software to give predetermined axial extension at predetermined times.

19. An external fixator according to claim 17 or 18 wherein the actuation drive comprises a drive selected from the set: a piezoelectric motor; and electro-mechanical motor; a hydraulic fluid actuation system; a pneumatic fluid actuation system; and a shape-memory alloy mechanism.

20. An external fixator according to any one of preceding claims further comprising a one or more sensors for measuring parameters selected from the set: ring skew; extension between upper and lower rings; position of upper and/or lower rings; and strain.

21. An external fixator comprising:

a first ring member;

a second ring member;

a plurality of stanchions extending between said first and second ring members;

a plurality of adjustment mechanisms each located between a said stanchion and a said ring member; and

a plurality of drive means each said drive means being capable of applying a predetermined incremental movement to a corresponding respective said adjustment mechanism; and

a control means for controlling said plurality of drive means.

22. The external fixator as claimed in claim 21, further comprising:

means for coordinating operation of said plurality of drive means to move said plurality of adjustment mechanisms in a predetermined relationship with respect to each other.

23. The external fixator as claimed in claim 22, wherein said means for coordinating operation of said plurality of adjustment mechanisms comprises:

a plurality of rotatable members; and

a common drive means for rotating said plurality of screw threaded members.

24. The external fixator as claimed in claim 23, wherein said common drive means is selected from the set:

a drive belt;

a chain;

a toothed belt;

a wire or cable

a flexible endless web.

25. The external fixator as claimed in any one of claims 21 to 24, wherein said drive means comprises a piezoelectric, electro-mechanical, fluid system (i.e. hydraulic or pneumatic) or shape-memory alloy device.

26. The external fixator as claimed in claim 25, wherein said drive means comprises:

a substantially cylindrical rotatable member; and

at least one piezoelectric device arranged adjacent and in contact with said rotatable member, said at least one piezoelectric device being fixed to a said ring member, such that said piezoelectric electric device when electrically activated urges against an outer surface of said rotatable member in order to rotate said rotatable member.

27. The external fixator as claimed in claim 21, wherein said drive means comprises:

a rod or bar extending in a direction which intersects a main plane of said ring; and

a manually operable ratchet device attached to a said ring,

wherein said manually operated ratchet device is arranged to incrementally urge said rod or bar in said direction intersecting said main plane of said ring.

28. The external fixator as claimed in claim 21, wherein said at least one stanchion comprises:

a first plate member;

a second plate member extending alongside and spaced apart from said first plate member; and

a plurality of cross plate members extending between said first plate member and said second plate member.

29. The external fixator as claimed in any one of claims 21 to 28, wherein a said stanchion comprises:

a first curved portion extending along a main length of said stanchion between a first end of said stanchion and a second end of said stanchion; and

a second curved portion extending along said main length of said stanchion between said first end and said second end,

said second curved portion being joined to said first curved portion;

wherein said first curved portion extends about a first point of curvature; and

said second curved portion extends about a second point of curvature,

wherein said first and second points of curvature lie on opposite sides of said stanchion from each other.

30. The external fixator as claimed in any one of claims 21 to 29, further comprising:

a plurality of adjustment mechanisms each located between a said stanchion and a said ring member.

31. The external fixator as claimed in any one of claims 21 to 30, wherein said plate members are each formed as laser cut metal plates.

32. The external fixator as claimed in any one of claims 21 to 31, wherein said first and second rings are each formed from laser cut plate.

33. The external fixator as claimed in any one of claims 21 to 32, wherein each said stanchion is rigidly secured to said first ring by one or a plurality of twist dowel joints.

AMENDED CLAIMS
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1. An external fixator for use in limb adjustment (400) comprising:

first (401) and second (402) spaced apart rings;

a plurality of rigid stanchions (406, 407, 408) each extending between said first and second rings; and

each said stanchion comprising a frame having a first plate member and a second plate member;

said first and second plate members being spaced apart from each other such that a main outer surface of said first plate member lies opposite and facing a main outer surface of said second plate member;

the external fixator comprising a plurality of adjustment means (600) for adjusting a distance between said first and second rings, each said adjustment means associated with a corresponding respective said stanchion; and

characterised in that said plurality of adjustment means (600) comprises an actuation drive (800) operable to move the first and second rings towards or away from each other;

wherein the actuation drive is controllable using pre - programmed software to give predetermined axial extension at predetermined times

2. An external fixator according to claim 1, wherein each said stanchion has at least one cross member (607) connecting between said first plate member and said second plate member.

3. An external fixator according to any preceding claim, wherein said first and second plate members are each cut from a substantially flat plate material.

4. An external fixator as claimed in any one of the preceding claims, wherein said first and second spaced apart rings are each cut from a substantially flat plate material.

5. An external fixator as claimed in any one of the preceding claims, wherein said first and second plate members and said at least one cross member (607) are joined together by twist dowel joints.

6. An external fixator as claimed in any one of the preceding claims, wherein said stanchions are joined to a said first or second ring by twist dowel joints.

7. An external fixator according to any one of the preceding claims, wherein each said stanchion has a main length comprising a first curved portion extending along a main length of said stanchion between a first end of said stanchion and a second end of said stanchion; and

a second curved portion extending along said main length of said stanchion between said first end and said second end, said second curved portion being joined to said first curved portion; and

said first and second points of curvature lying on opposite sides of said stanchion to each other.

8. An external fixator as claimed in any one of the preceding claims, wherein said first ring surrounds a first aperture and said second ring surrounds a second aperture, an area of said first aperture being greater than an area of said second aperture.

9. An external fixator according to any one of the preceding claims, wherein said first and second spaced apart rings are of a different diameter or maximum outer dimension to each other.

10. An external fixator as claimed in any one of the preceding claims, comprising a first plurality of fixator pins attached to said first ring;

wherein said first plurality of fixator pins extend inwardly from said first ring towards a focal point which lies away from a geometrical centre point of said first ring.

11. An external fixator as claimed in any one of the preceding claims, comprising a second plurality of fixator pins attached to said second ring;

wherein said second plurality of fixator pins extend inwardly from said second ring towards a focal point which lies away from a geometrical centre point of said second ring.

12. An external fixator according to any preceding claim, further comprising a separate tightening tool for adjusting said adjustment means.

13. An external fixator according to claim 12, wherein said tightening tool comprises a radio frequency identification device configured to identify an RFID tags located on a said adjustment means.

14. An external fixator according to any preceding claim, comprising a control mechanism which is operable to control said plurality of adjustment means to move said first and second rings towards or away from each other whilst maintaining a fixed angle relationship between the main planes passing through each of said first and second rings.

15. An external fixator according to claim 14, wherein said control mechanism comprises a single direction ratchet.

16. An external fixator according to any one of the preceding claims, further comprising a light emitting diode which illuminates to indicate that an adjustment is required.

17. An external fixator according to any preceding claim wherein the actuation drive comprises a drive selected from the set: a piezoelectric motor; and electro-mechanical motor; a hydraulic fluid actuation system; a pneumatic fluid actuation system; and a shape-memory alloy mechanism.

18. An external fixator according to any one of preceding claims further comprising a one or more sensors for measuring parameters selected from the set: ring skew; extension between upper and lower rings; position of upper and/or lower rings; and strain.

19. An external fixator comprising:

a first ring member;

a second ring member;

a plurality of stanchions extending between said first and second ring members;

a plurality of adjustment mechanisms each located between a said stanchion and a said ring member; and

a plurality of drive means each said drive means being capable of applying a predetermined incremental movement to a corresponding respective said adjustment mechanism; and

a control means for controlling said plurality of drive means.

20. The external fixator as claimed in claim 19, further comprising:

means for coordinating operation of said plurality of drive means to move said plurality of adjustment mechanisms in a predetermined relationship with respect to each other.

21. The external fixator as claimed in claim 20, wherein said means for coordinating operation of said plurality of adjustment mechanisms comprises:

a plurality of rotatable members; and

a common drive means for rotating said plurality of screw threaded members.

22. The external fixator as claimed in claim 21, wherein said common drive means is selected from the set:

a drive belt;

a chain;

a toothed belt;

a wire or cable

a flexible endless web.

23. The external fixator as claimed in any one of claims 19 to 22, wherein said drive means comprises a piezoelectric, electro-mechanical, fluid system (i.e. hydraulic or pneumatic) or shape-memory alloy device.

24. The external fixator as claimed in claim 23, wherein said drive means comprises:

a substantially cylindrical rotatable member; and

at least one piezoelectric device arranged adjacent and in contact with said rotatable member, said at least one piezoelectric device being fixed to a said ring member, such that said piezoelectric electric device when electrically activated

urges against an outer surface of said rotatable member in order to rotate said rotatable member.

25. The external fixator as claimed in claim 19, wherein said drive means comprises:

a rod or bar extending in a direction which intersects a main plane of said ring; and

a manually operable ratchet device attached to a said ring,

wherein said manually operated ratchet device is arranged to incrementally urge said rod or bar in said direction intersecting said main plane of said ring.

26. The external fixator as claimed in claim 19, wherein said at least one stanchion comprises:

a first plate member;

a second plate member extending alongside and spaced apart from said first plate member; and

a plurality of cross plate members extending between said first plate member and said second plate member.

27. The external fixator as claimed in any one of claims 19 to 26, wherein a said stanchion comprises:

a first curved portion extending along a main length of said stanchion between a first end of said stanchion and a second end of said stanchion; and

a second curved portion extending along said main length of said stanchion between said first end and said second end,

said second curved portion being joined to said first curved portion;

wherein said first curved portion extends about a first point of curvature; and

said second curved portion extends about a second point of curvature,

wherein said first and second points of curvature lie on opposite sides of said stanchion from each other.

28. The external fixator as claimed in any one of claims 19 to 27, further comprising:

a plurality of adjustment mechanisms each located between a said stanchion and a said ring member.

29. The external fixator as claimed in any one of claims 19 to 28, wherein said plate members are each formed as laser cut metal plates.

30. The external fixator as claimed in any one of claims 19 to 29, wherein said first and second rings are each formed from laser cut plate.

31. The external fixator as claimed in any one of claims 19 to 30, wherein each said stanchion is rigidly secured to said first ring by one or a plurality of twist dowel joints.

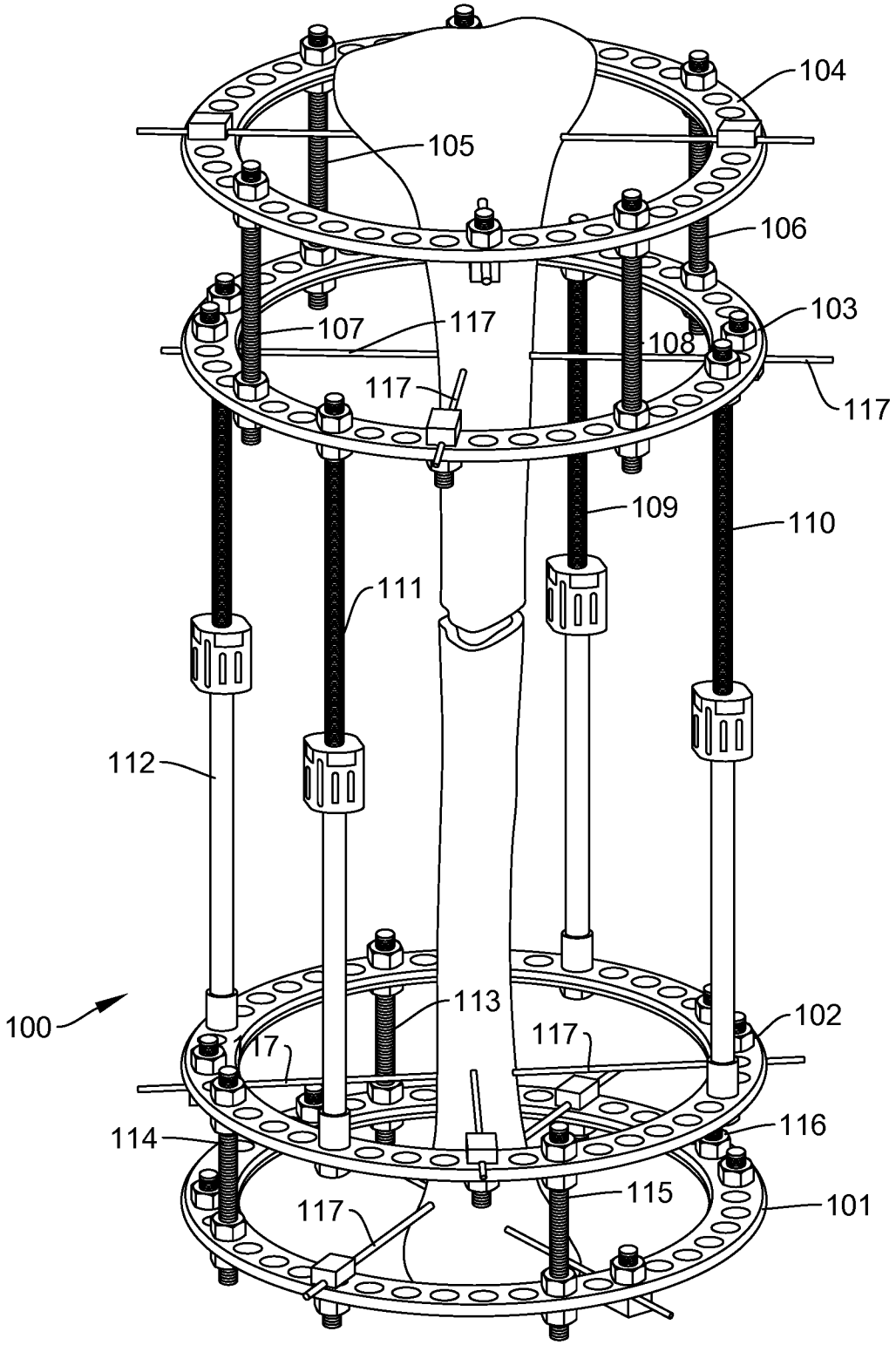

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FIG. 1

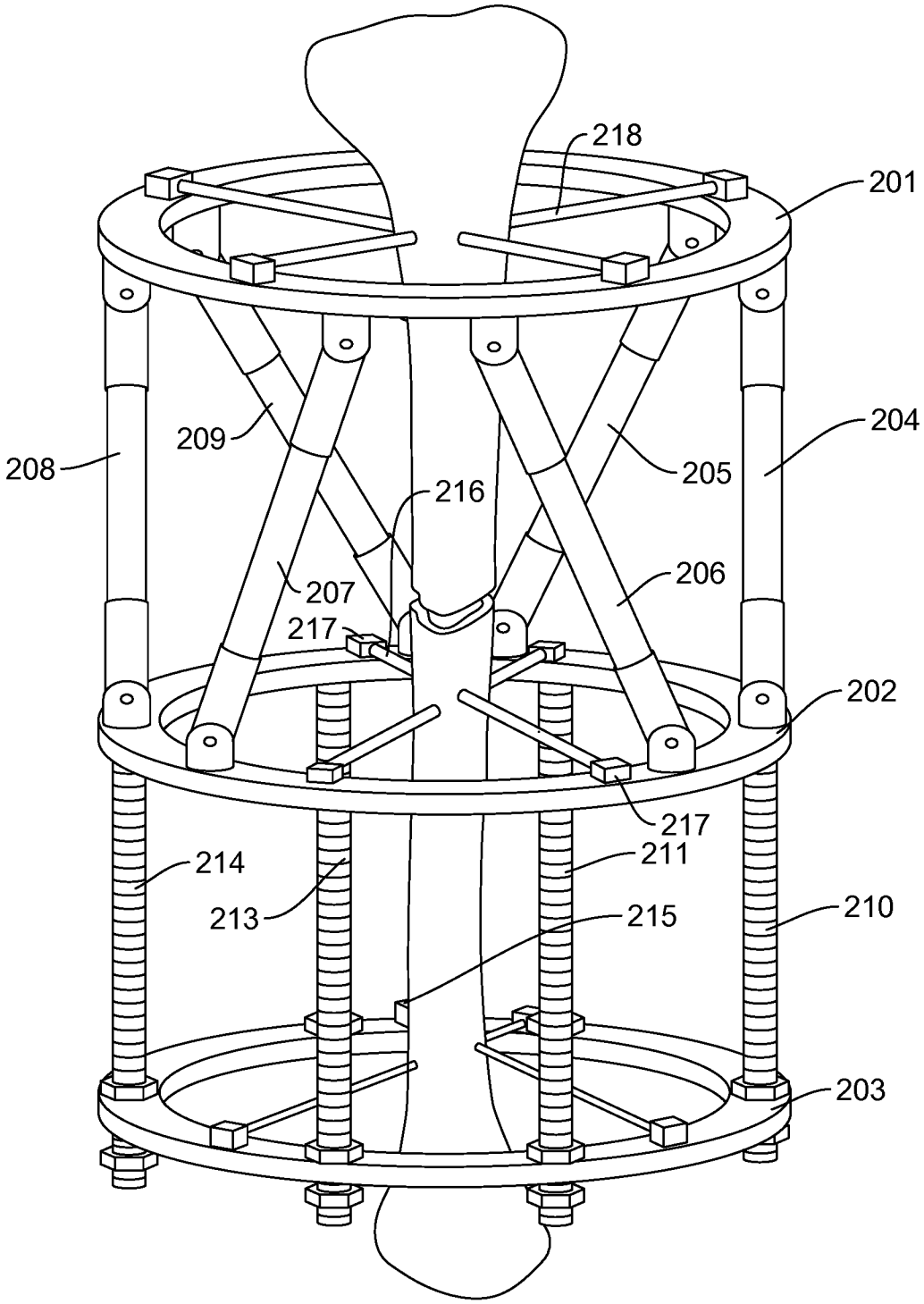

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FIG. 2

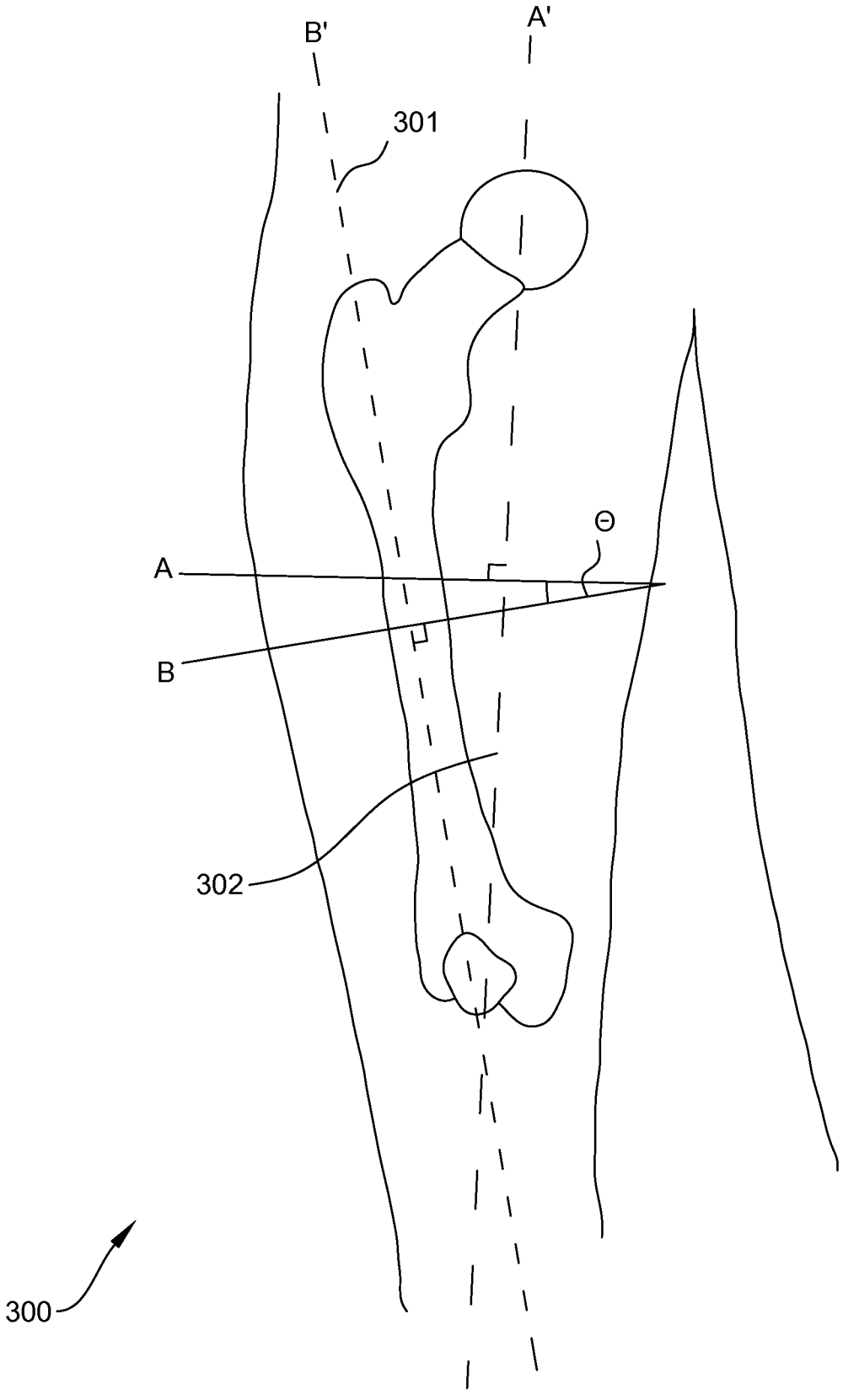



FIG. 3

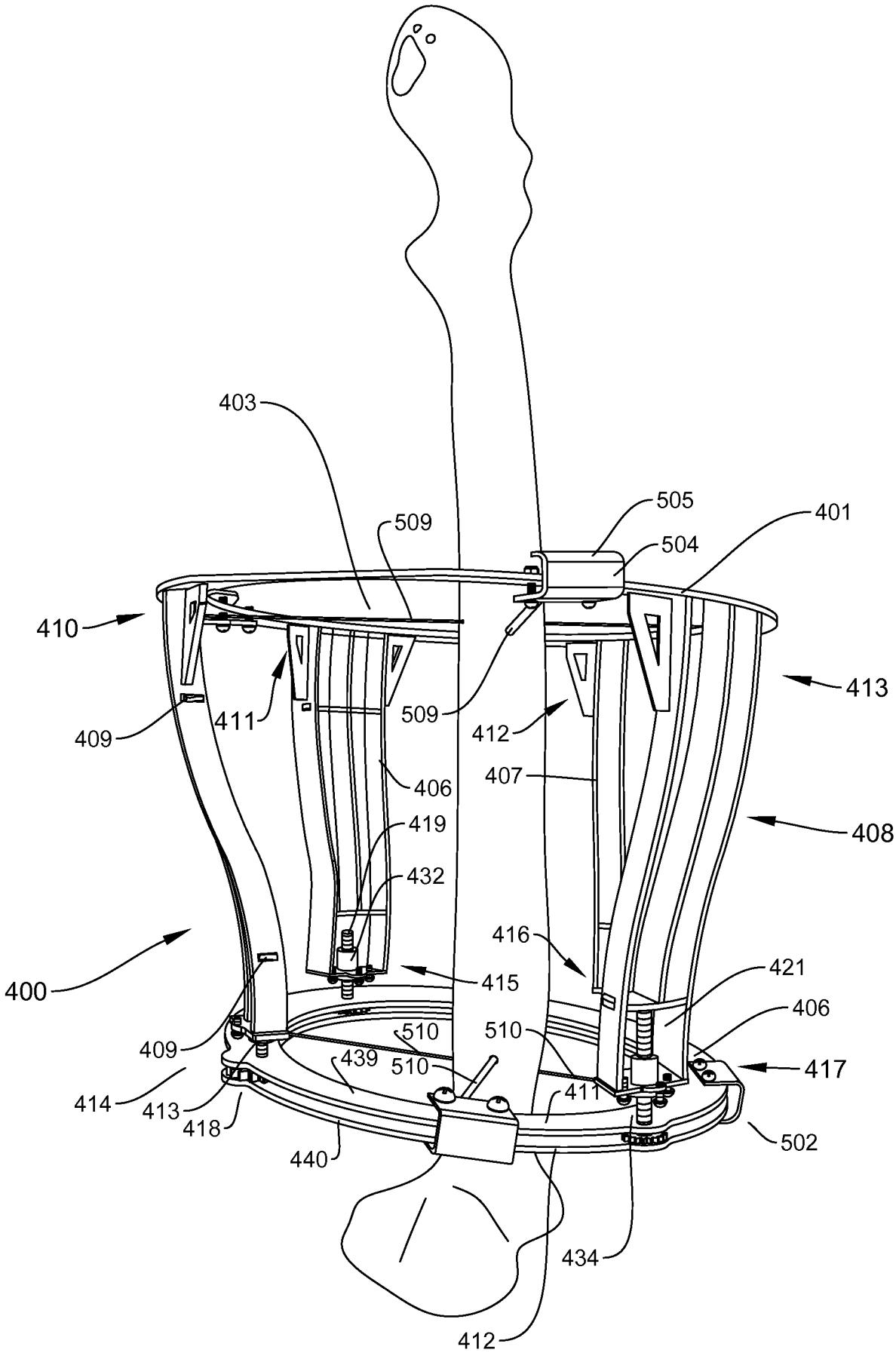

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FIG. 4

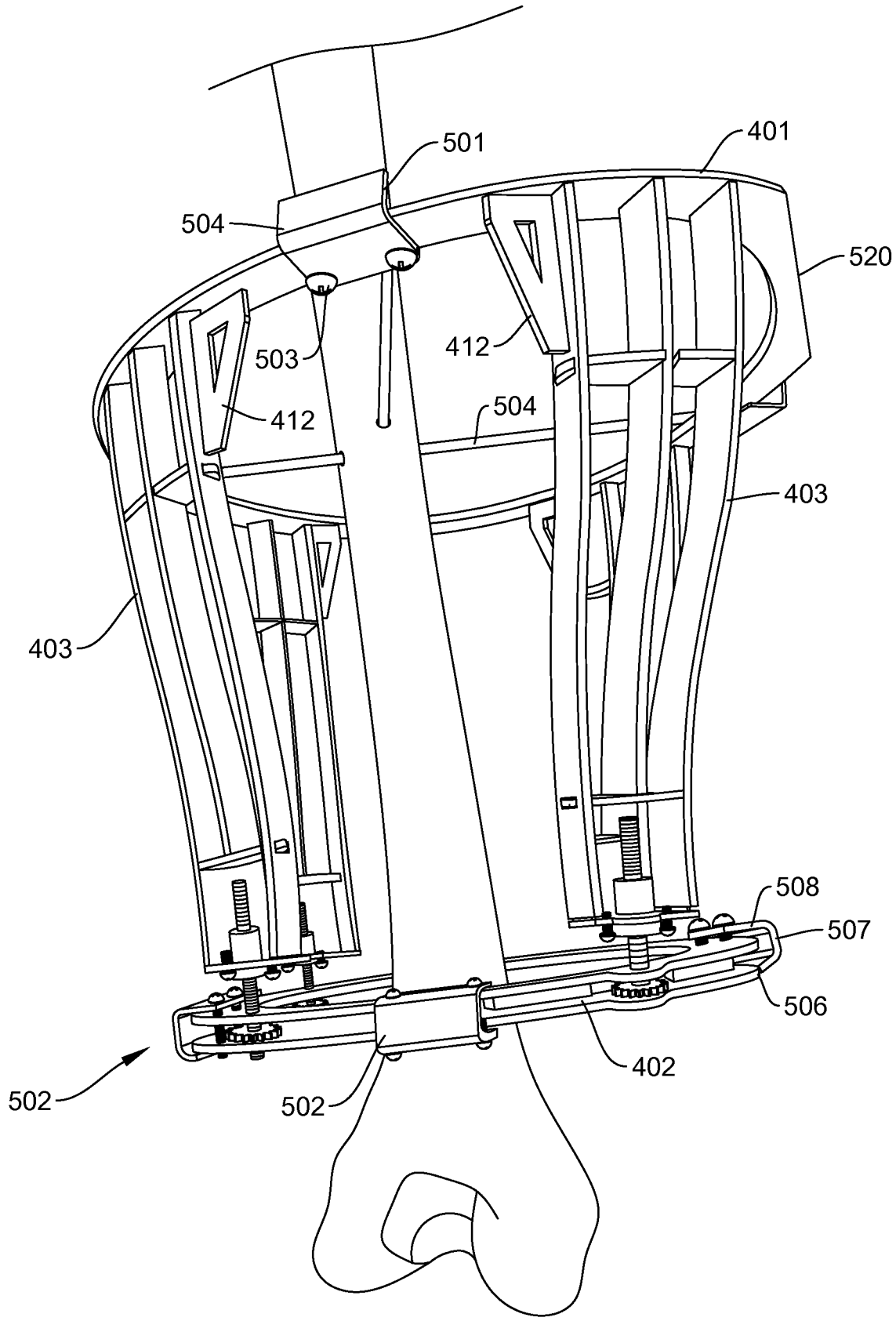



FIG. 5

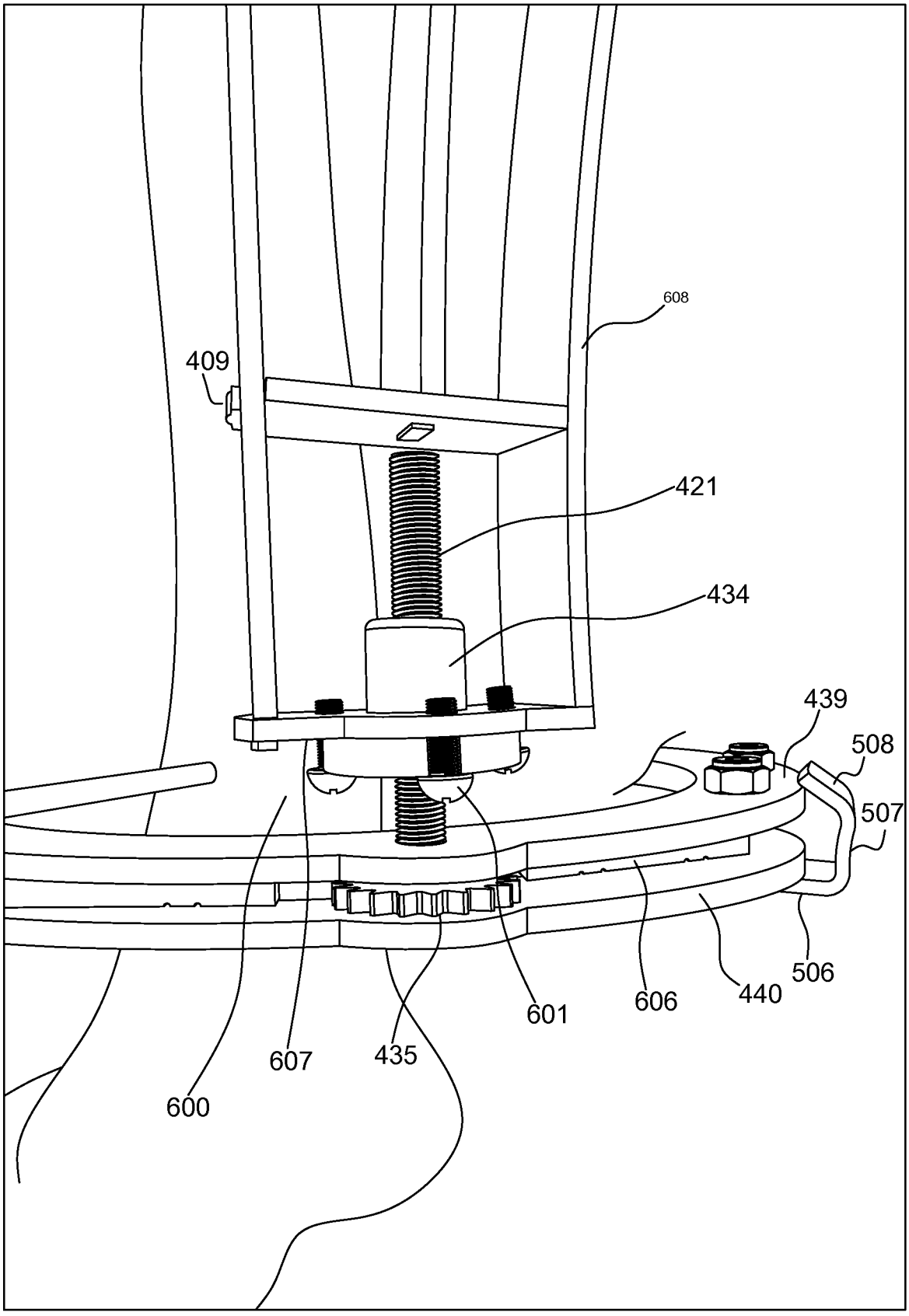



FIG. 6

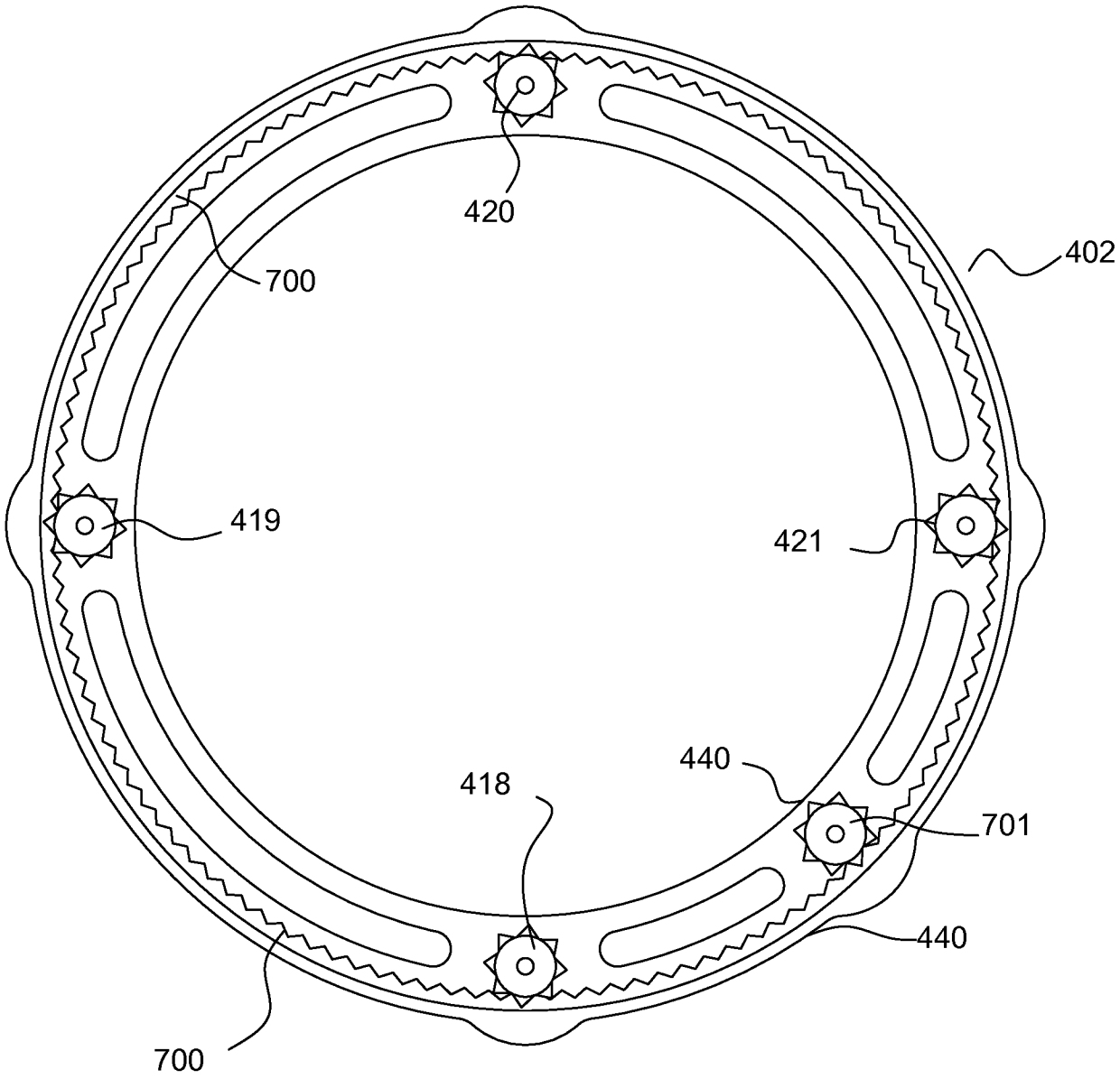
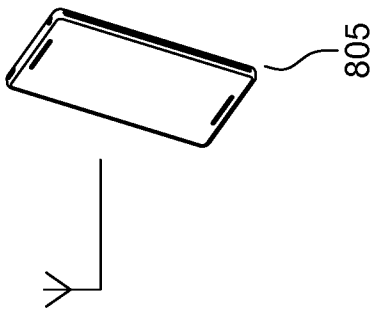



FIG. 7



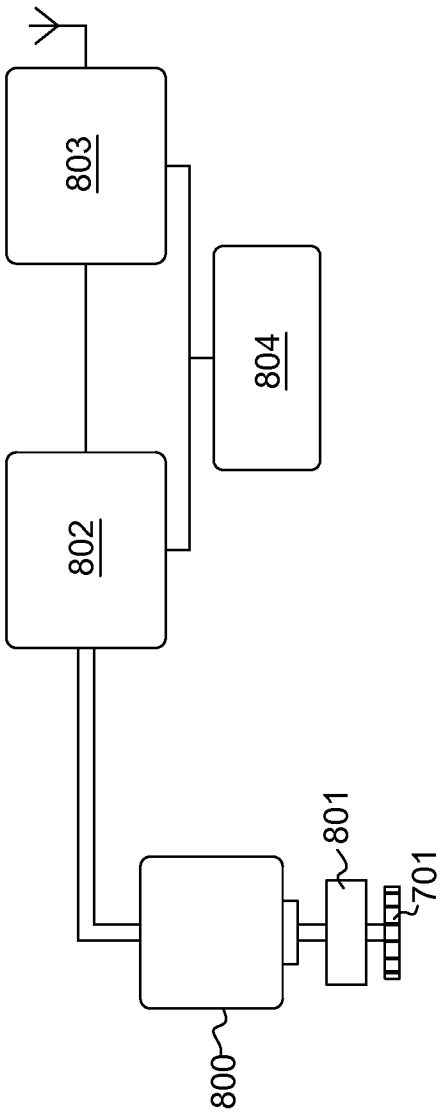




FIG. 8

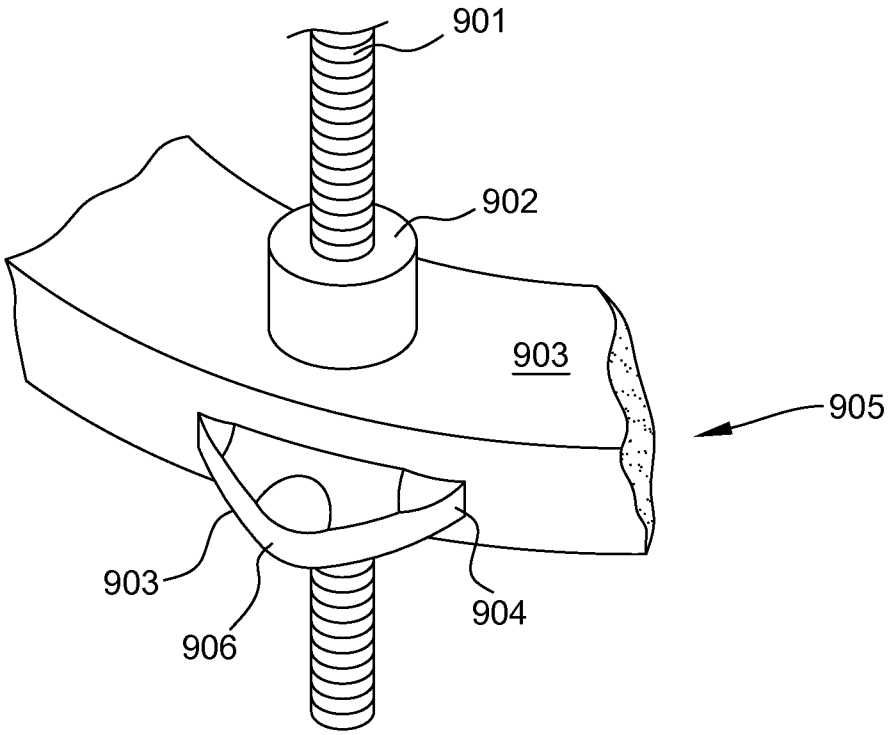

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FIG. 9

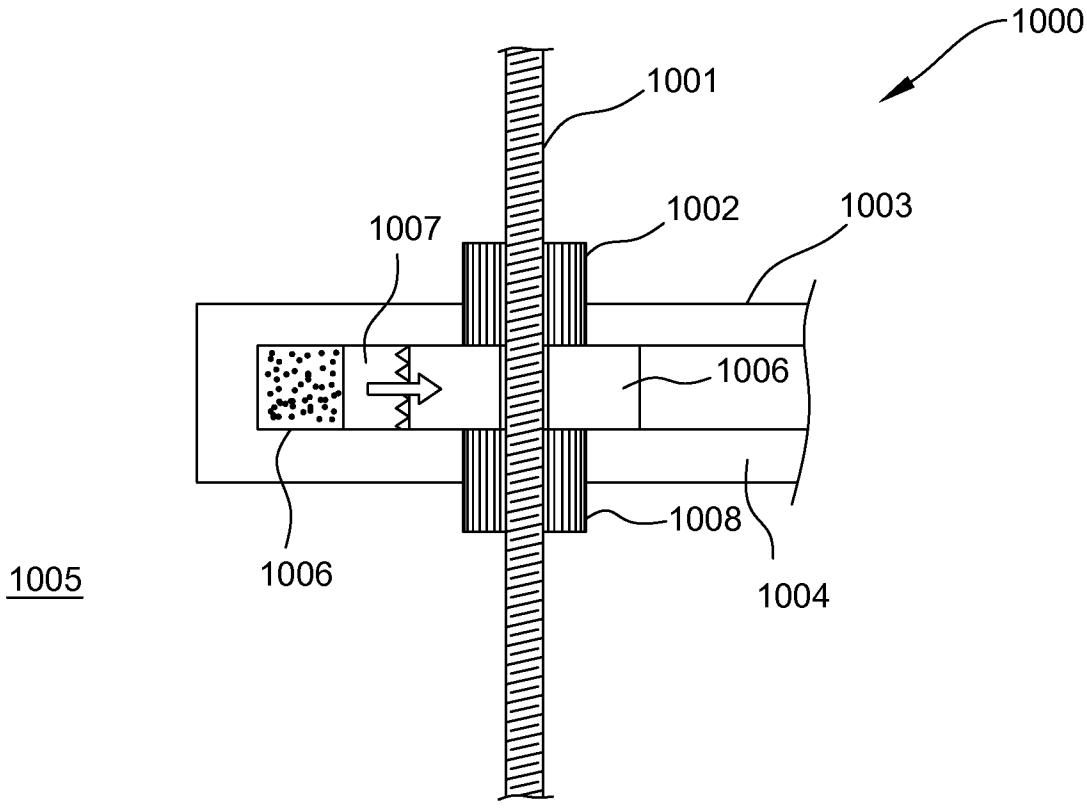

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FIG. 10

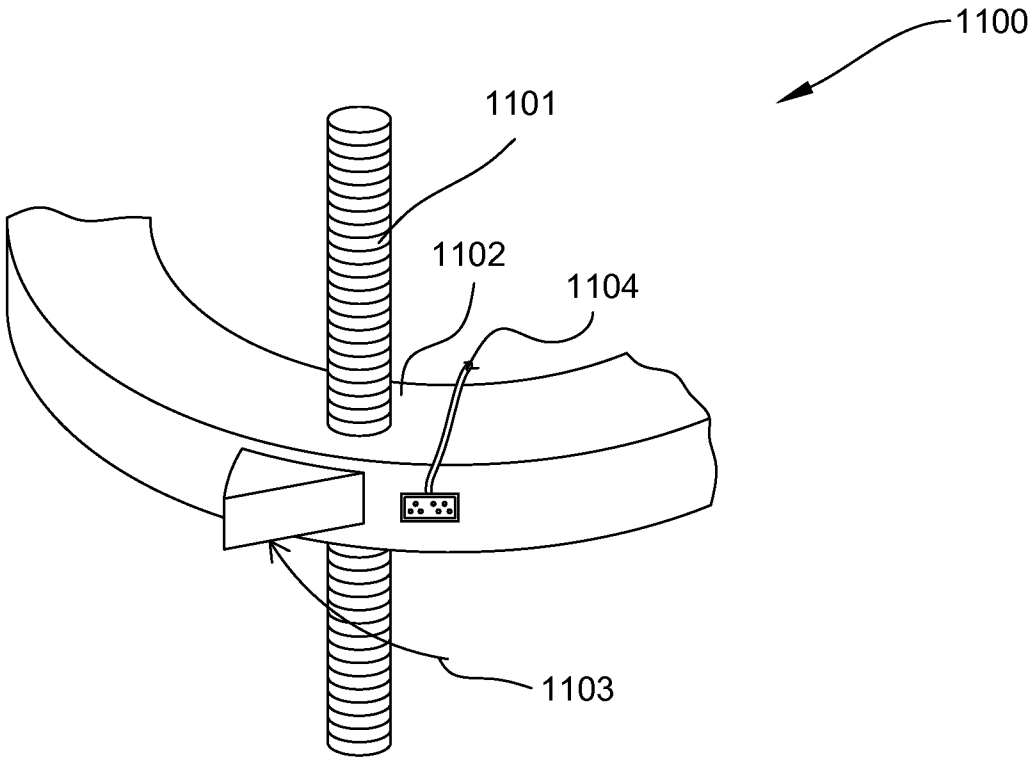



FIG. 11

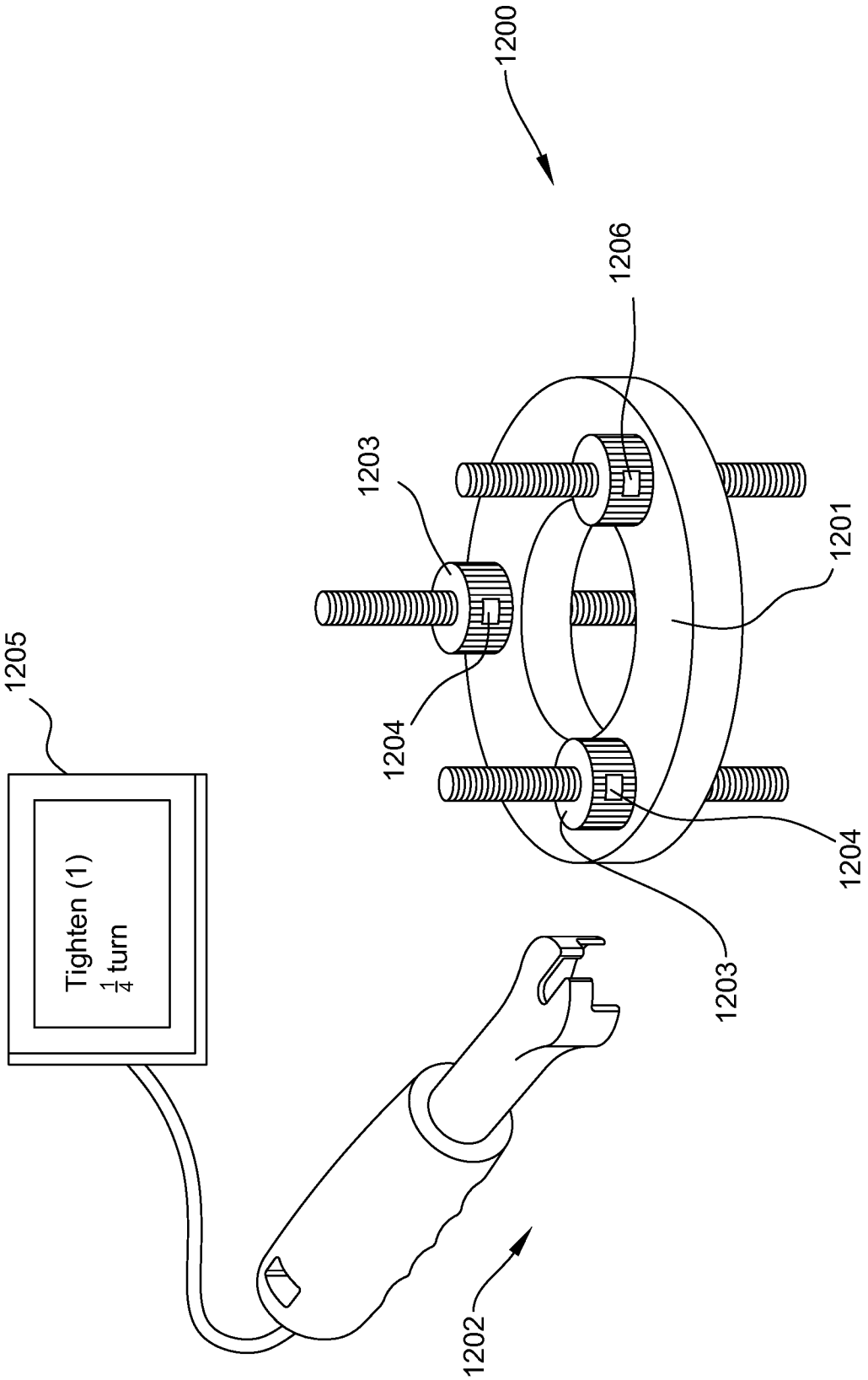

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Tighten (1)
$\frac{1}{4}$ turn
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FIG. 12

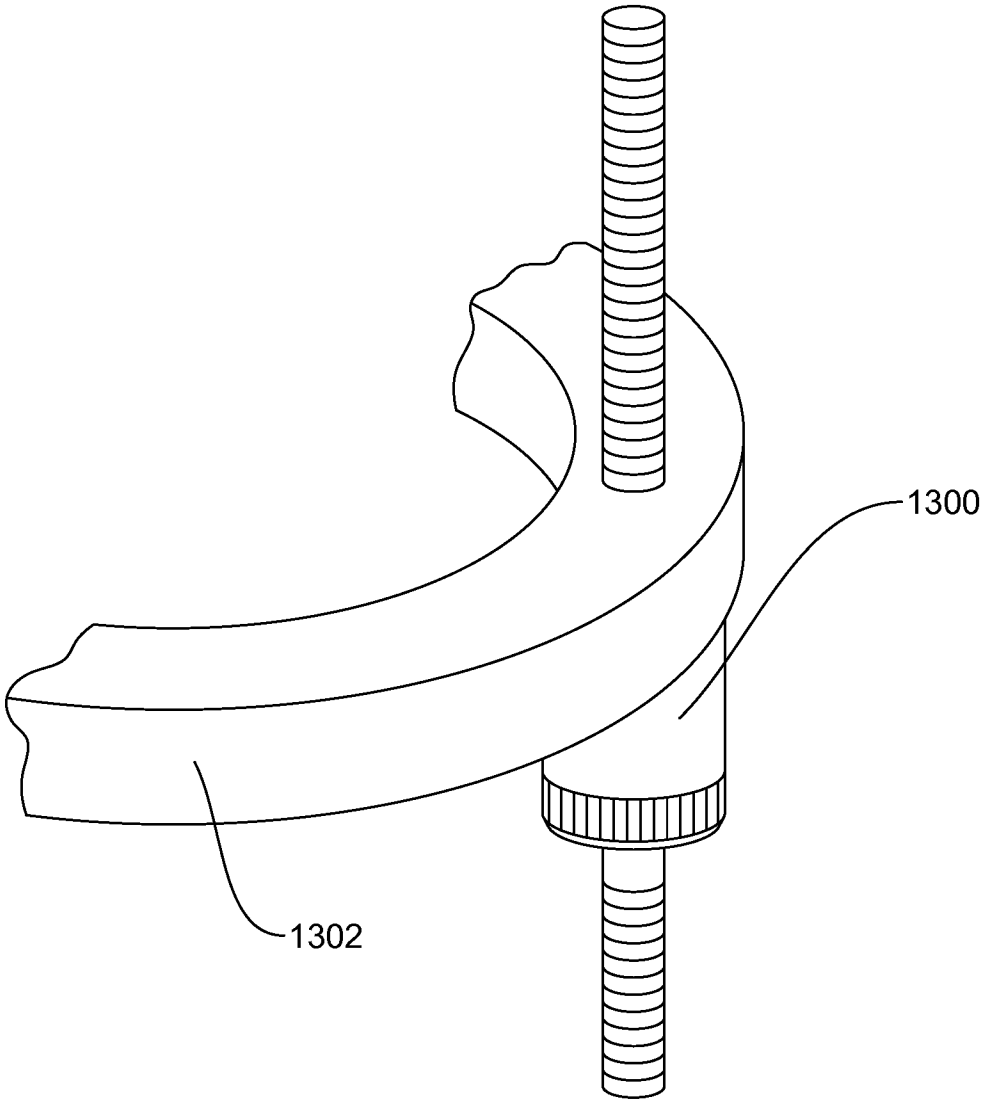



FIG. 13

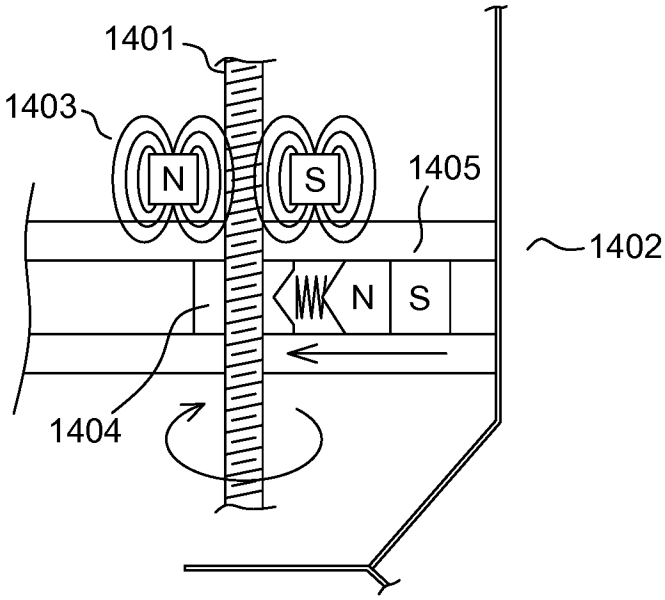



FIG. 14

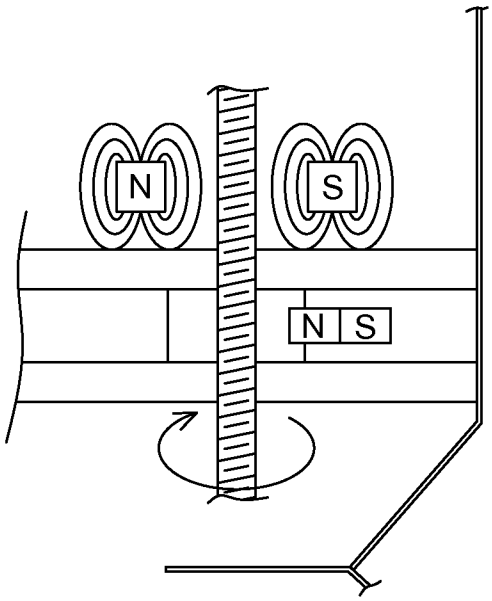



FIG. 15

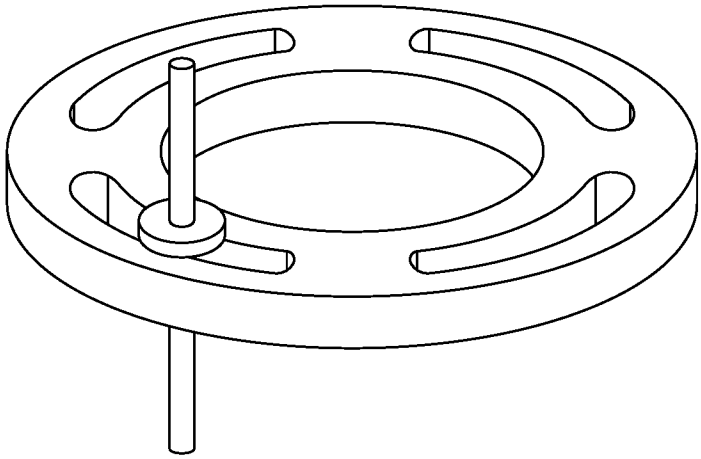


FIG. 16

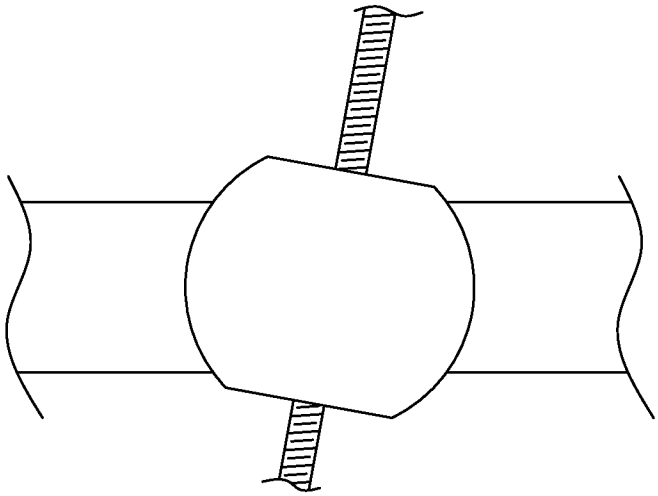


FIG. 17

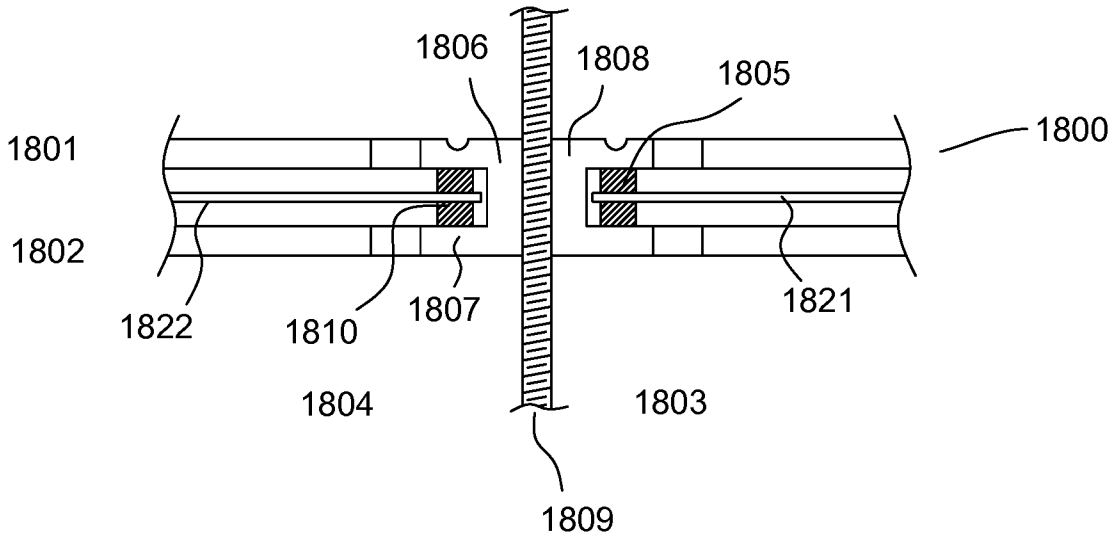



FIG. 18

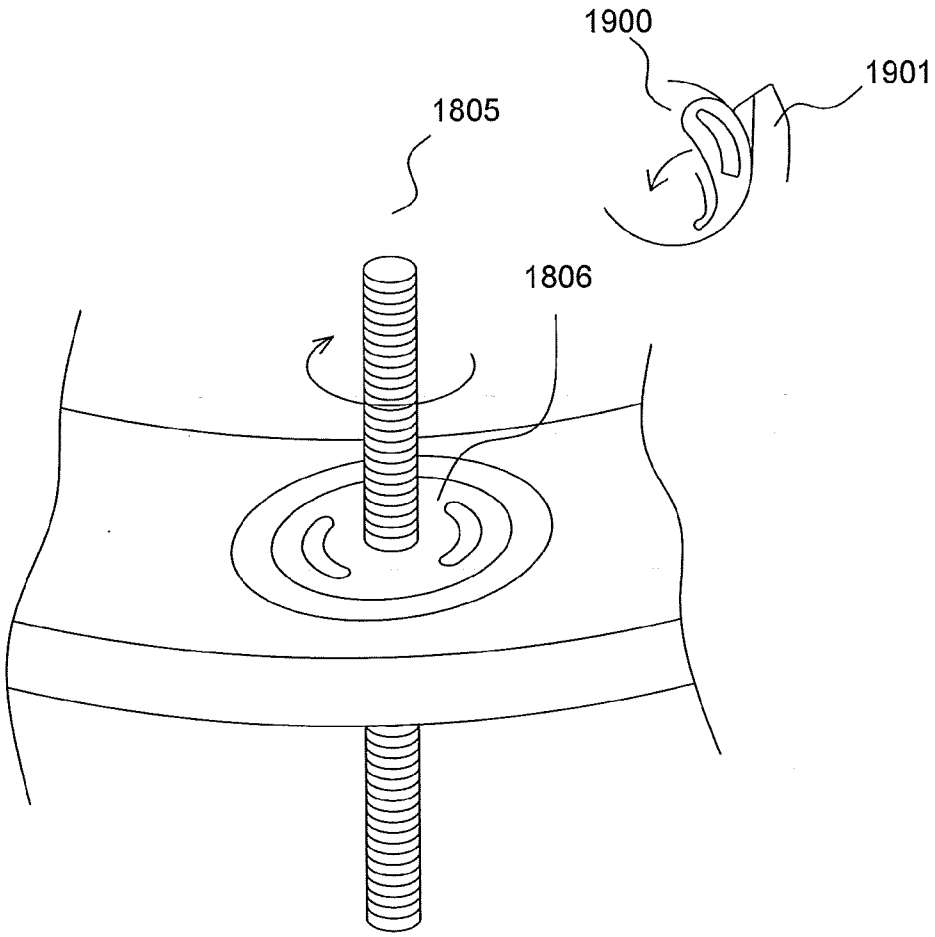



FIG. 19

# INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2019/077538

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/62
ADD.

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

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)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>A | US 5 074 866 A (SHERMAN MICHAEL C [US] ET AL) 24 December 1991 (1991-12-24)<br>figures 1-3,6 | 1-3,<br>7-12,20<br>4,5,<br>13-19 |
| | ----- | |
| X | US 2018/243007 A1 (JARAMILLO JYMER MAX [CA]) 30 August 2018 (2018-08-30)<br>figures 2,3 | 1-3,6,<br>9-12,20 |
| | ----- | |
| X | US 2016/256194 A1 (WONG KIAN-MING [US] ET AL) 8 September 2016 (2016-09-08)<br>figures 1A-3 | 1-3,9,<br>10,20 |
| | ----- | |

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

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"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

"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

"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

"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

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 5 June 2020 | 06/08/2020 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Hamann, Joachim |

1

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2019/077538

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-20

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/** 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-20

An external fixator, wherein each said stanchion comprises a frame having a first plate member and a second plate member and a cross member.

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2. claims: 21-33

An external fixator, comprising a plurality of adjustment mechanisms each located between a said stanchion and a said ring member.

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2019/077538

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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