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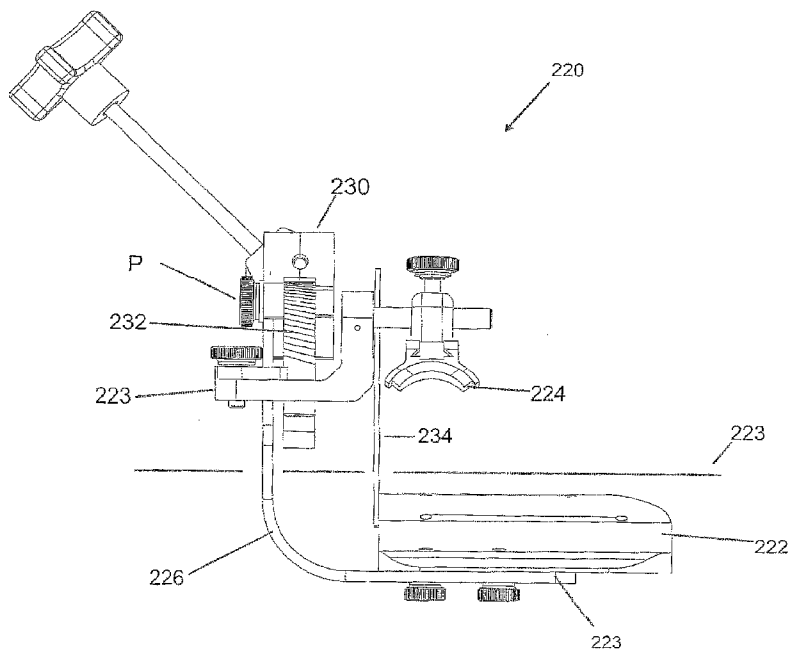
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(54) Title: RANGE OF MOTION DEVICE



(57) Abstract: The present invention provides an orthosis for stretching tissue around a joint of a patient between first and second relatively pivotable body portions. The orthosis includes a first member affixable to the first body portion and including a first extension member extending therefrom. A second member affixable to the second body portion is also included and has a second extension member having an arcuate shape extending therefrom. The second extension member is operatively connected to the first extension member and travels through the first extension member along an arcuate path when the second arm member is moved from a first position to a second position relative to the first arm member.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## RANGE OF MOTION DEVICE

### 5 FIELD OF THE INVENTION

The present invention relates to an adjustable orthosis for stretching tissue in the human body. In particular, the present invention relates to an adjustable orthosis which can be used for stretching tissue such as ligaments, tendons or muscles around a joint during flexion or extension of the joint.

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### BACKGROUND OF THE INVENTION

In a joint, the range of motion depends upon the anatomy and condition of that joint and on the particular genetics of each individual. Many joints primarily move either in flexion or extension, although some joints also are capable of rotational movement in varying  
15 degrees. Flexion is to bend the joint and extension is to straighten the joint; however, in the orthopedic convention some joints only flex. Some joints, such as the knee, may exhibit a slight internal or external rotation during flexion or extension.

Most people do not appreciate the complexity of joint motion until something goes wrong, such as when an injury results in lost range of motion. When a joint is injured, either  
20 by trauma or by surgery, scar tissue can form or tissue can contract and consequently limit the range of motion of the joint. For example, adhesions can form between tissues and the muscle can contract itself with permanent muscle contracture or tissue hypertrophy such as capsular tissue or skin tissue. Lost range of motion may also result from trauma such as exposure to extreme temperatures, chemical burns, or surgical trauma so that tissue planes  
25 which normally glide across each other may become adhered together to markedly restrict motion. The adhered tissues may result from chemical bonds, tissue hypertrophy, proteins such as Actin or Myosin in the tissue, or simply from bleeding and immobilization. It is

often possible to mediate, and possibly even correct this condition by use of a range-of-motion (ROM) orthosis, but the longer the period of stiffness or loss of motion the greater the time interval and the force required to regain lost range of motion. Therefore, it is beneficial to treat the tissue or joint as early as possible. For example, a ROM orthosis may be applied  
5 immediately after surgery or as soon as the stiffness problem is diagnosed.

ROM orthoses are devices commonly used during physical rehabilitative therapy to increase the range-of-motion over which the patient can flex or extend the joint.

Commercially available ROM orthoses are typically attached on opposite members of the joint and apply a torque to rotate the joint in opposition to the contraction. The force is  
10 gradually increased to increase the working range or angle of joint motion. Exemplary orthoses include U.S. Patent Nos.: 6,921,377 ("Finger Orthosis"), 6,770,047 ("Method of using a neck brace"), 6,599,263 ("Shoulder Orthosis"), 6,113,562 ("Shoulder Orthosis"), 6,503,213 ("Method of using a neck brace"), 6,502,577 ("Finger Orthosis"), 5,848,979 ("Orthosis"), 5,685,830 ("Adjustable Orthosis Having One-Piece Connector Section for  
15 Flexing"), 5,611,764 ("Method of Increasing Range of Motion"), 5,503,619 ("Orthosis for Bending Wrists"), 5,456,268 ("Adjustable Orthosis"), 5,453,075 ("Orthosis with Distraction through Range of Motion"), 5,395,303 ("Orthosis with Distraction through Range of Motion"), 5,365,947 ("Adjustable Orthosis"), 5,285,773 ("Orthosis with Distraction through Range of Motion"), 5,213,095 ("Orthosis with Joint Distraction"), and 5,167,612  
20 ("Adjustable Orthosis"), and U.S. Publication No. 20040215111 ("Patient monitoring apparatus and method for orthosis and other devices"), all to Bonutti and herein are expressly incorporated by reference in their entirety.

In the past, many ROM orthoses required manual operation, may not have been capable of accurately simulating the natural range of motion of a healthy joint, or may not

have allowed for easy adjustment of the treatment protocol (e.g., force applied, range of motion exercised, duration of treatment, etc.).

#### SUMMARY OF THE INVENTION

5           The present invention provides an orthosis for stretching tissue around a joint of a patient by causing the joint to flex or move through a range of motion. In some cases, the range of motion through which the joint is moved is predetermined and well controlled. That is, the range of motion a joint experiences as it moves through one cycle of movement may be substantially the same as the range of motion that the joint travels through in a second  
10 cycle of movement during a treatment session. The range of motion through which the joint is exercised may be accomplished through flexion or extension of the joint, or through combinations of both flexion and extension.

          Alternatively, the range of motion may be predetermined and well controlled by being capable of duplicating or at least approximating the range of movement a joint experiences in  
15 a treatment session, even if the range of motion varies between individual cycles of motion during a session. For example, the range of motion a joint experiences may vary in a predetermined and well controlled manner under this invention by gradually increasing or decreasing the range of motion the joint passes through over time, or by introducing motion in a different plane or direction, such as by combining flexing or bending movement with  
20 rotational movement, such as with an ankle, knee, elbow, or shoulder joint. Thus, even if there are some variations of range of motion in a treatment session, it may still be carried out in a predetermined and well controlled manner if a physician, technician, or patient could perform a second treatment session that was so similar to the first to be considered a repeated treatment session.

In some cases, the invention may be configured such that the range of motion through which the joint moves during a treatment session may be controlled to some extent, but not predetermined. For instance, while one or more components of a device operating according to this aspect of the invention may travel through a predetermined path, other components  
5 may be designed to allow for flexibility of the overall system in response to joint stiffness, limited range of motion, adhesions, or other patient-related factors. This may happen, for instance, if cushioning or flexibility is provided in the invention to account for differences in joint flexibility over time or between patients. Thus, while the settings of the device may be established to recreate substantially the same underlying movement of some component parts,  
10 changes in the treated joint over time may mean that the range of motion through which it moves may change.

For example, a patient fitted with a joint treatment apparatus according to the present invention is expected to gradually increase range of motion in the joint over time. Initially, however, the joint and surrounding tissue may not be capable of a wide range of motion  
15 without risking damage to the joint or surrounding tissue. To account for this, a force absorber or cushioning device may be used to limit the amount of force exerted on a joint, or at least reduce it to a lower level than may have been exerted if the device did not utilize a force absorber or cushioning device. As the resistive forces in the joint and surrounding tissue reach a threshold amount, the force absorber or cushioning device may bend, deflect,  
20 compress, or otherwise absorb some of this energy. As flexibility in the joint and surrounding tissue increases, operation of the force absorber or cushioning device will decrease and the range of motion the joint travels through will increase.

In one embodiment of the invention, the orthosis includes a first member affixable to a first body portion, such as a foot of a user. The first member has a first extension member  
25 extending therefrom. A second member affixable to the second body portion, such as on at

least one toe on the foot is also included. The second member includes a second extension member having an arcuate shape extending therefrom. The second and first members are operatively connected, such that the second extension member travels through the first extension member along an arcuate path when the second member is moved from a first  
5 position to a second position relative to the first member.

The range of motion generated by an orthosis of the present invention may be created or carried out in several ways. In the embodiment described above, for instance, a portion of the device follows an arcuate path. For purposes of the present invention, the term arcuate path is to be interpreted broadly to include, for example, known or defined geometric paths,  
10 such as all or part of an arc of a circle, ellipse, oval, parabola, or other mathematically definable curves or portions of geometrically defined curved shapes. Relative movement of component parts of an orthosis of the present invention may utilize cams and followers, inter-connecting gears, or other structures or systems to cause the joint to move at least partially through a desired range of motion. As explained in greater detail below, however, some  
15 alternative embodiments described below may utilize one or more components moving in a linear or even in an angular direction. Additionally, two or more components may be moveable such that the net effect of these movements results in forces being exerted on the joint generally in the direction of the natural movement of the joint.

In some embodiments, the orthosis may also have a drive assembly that provides for  
20 continuous, cyclic operation of the orthosis through ranges of motion over time. The length of time or number of cycles that the orthosis exercises the range of motion of the joint may be varied according to a desired treatment protocol, patient comfort, or other factors. Likewise, the amount of movement or force exerted on the joint may be varied during operation of the drive assembly. The drive assembly may be mounted onto the first extension member,  
25 thereby engaging the second extension member. The drive assembly can be manually or

automatically actuated to selectively move the second extension member relative to the first extension member.

#### BRIEF DESCRIPTION OF THE DRAWINGS

5 A more complete understanding of the present invention, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a schematic diagram of an orthosis of the present invention;

FIG. 2 is a schematic diagram of the orthosis of FIG. 1 in an extended position;

10 FIG. 3 is a schematic diagram of the orthosis of FIG. 1 in a flexed position;

FIG. 4 is an isometric view of an orthosis of the present invention;

FIG. 5 is a front view of the orthosis of FIG. 4;

FIG. 6 is a side view of the orthosis of FIG. 4;

FIG. 7 is a sectional view of a drive assembly of the orthosis of FIG. 4;

15 FIG. 8 is a sectional view of an adjustable second cuff for the orthosis of FIG. 4;

FIG. 9 is an expanded view of the drive assembly connection to the first member of the orthosis of FIG. 4;

FIG. 10 is a top view of the drive assembly of the orthosis of FIG. 4;

20 FIG. 11 is an expanded view of another drive assembly connection to the first member of the orthosis of FIG. 4;

FIG. 12 depicts a bottom view of the orthosis of FIG. 4.

FIG. 13 depicts a bottom view of a first cuff of the orthosis of FIG. 4;



FIG. 14 is a schematic diagram of an embodiment of an orthosis of the present invention;

FIG. 15 illustrates another embodiment of the invention utilizing a cushion or spring;

FIG. 16 is an embodiment of the invention illustrating the use of a cam surface;

5 FIG. 17 is an embodiment of the invention utilizing a slideable arcuate surface;

FIG. 18 illustrates features of an orthosis of the invention where the relative positions of component parts of the orthosis are adjustable;

FIG. 19 is an illustration of the use of gears with an arcuate or cam surface of an orthosis of the invention;

10 FIG. 20 is a schematic diagram of an embodiment of the invention using an arcuate path and gear or cam follower;

FIG. 21 illustrates the use of a multi-slotted component to control movement of the orthosis; and

15 FIG. 22 illustrates an embodiment of the invention where linear movement of a component is translated into rotational and translational movement of another component of the orthosis.

#### DETAILED DESCRIPTION OF THE INVENTION

20 The present invention relates to an orthosis for causing a joint to flex or move through a range of motion. One exemplary application of an orthosis of the present invention is in treatment of a toe of a patient's foot. While the invention is believed to provide significant improvements in this area of treatment, it may likewise be of benefit in treating other joints, such as ankles, knees, hips, fingers, wrists, elbows, shoulders, or the spine.

Furthermore, while many examples provided herein may illustrate the invention used to treat the metatarsal and proximal phalanx of the toe, these examples are non-limiting on other joints of the toe that also may be treated by the present invention. It is understood by those skilled in the art that the other joints of the toe may be flexed or extended, without departing from the spirit and scope of the invention. Additionally, the present invention is described in use on the "big" toe or hallux on the foot. Thus, it should be understood by those skilled in the art that the present invention is equally applicable for use on the second, third, fourth and minimus toes of the foot.

Each toe in the foot extends from the metatarsal bone and is formed by the proximal phalanx, middle phalanx, and distal phalanx, each of which is respectively pivotally connected to form a joint there between. The orthosis of the present invention may be configured to flex or extend (or both) a toe joint, where the joint defines an inner sector on the flexor side that decreases in angle as the joint is flexed (bent) and an outer sector on the extensor side that decreases in angle as the joint is extended (straightened).

Referring now to the figures in which like reference designators refer to like elements, there is shown in FIG. 1, a schematic of the orthosis 200 of the present invention. The orthosis 200 includes a first member 202 attachable to a first body portion, such as a user's foot. The shape and configuration of the first member 202 may be selected to support or conform generally to a patient's foot. For example, the first member 202 may be a platform that contacts or supports the underside of a user's foot. Sidewalls or curved edges may be provided to help position, cradle, or securely hold the foot in proper position.

Alternatively, the first member 202 may have a profile or shape that generally conforms to a user's arch, shoe size, or foot width so that it fits more comfortably, holds the foot securely in place, or improves alignment of the device so that the range of motion imparted by the device corresponds to a joint's healthy range of motion. This conforming

shape or profile may be accomplished, for instance, by providing interchangeable platforms corresponding to different foot sizes and shapes. The interchangeable platform may be selectively removed and replaced by an interchangeable platform of a different size.

Alternatively, the first member 202 may have adjustable surfaces that can be resized or repositioned to better support or correspond to a patient's foot. For example, the overall length of the first member 202 may be adjustable, or the width of the first member 202 near the toes may be adjusted to account for different foot widths. In addition, raised walls or edges that support the feet may be selectively moveable so that they can be moved to accommodate different foot sizes. Once the foot is in place and the edges are moved to their desired position, they may be selectively locked or secured in place to help hold the foot in place. Additionally, the first member 202 may be configured with an arch, which in some instances also may be adjustable such as by having interchangeable arch inserts, by configuring the arch to be inflatable, or the like.

The first member 202 is operatively associated with or connected to a second member 204 so that the first and second members 202 and 204 may move or rotate with respect to each other. As shown in FIG. 1, the supporting surface of the first member 202 may be offset from the supporting surface of the second member 204. This amount of offset provided may vary from patient to patient or from joint to joint, and in some cases an offset may not be provided. Thus, it may be advantageous to allow the offset of the orthosis 200 to be adjustable so that a physician or user may change its size as needed to improve comfort, fit, or operation of the orthosis 200.

In use, the second member 204 may be attachable to a second body portion, such as at least one toe on the foot so that the relative movement of the two members also causes movement of the joint. As shown in FIG. 2, the orthosis 200 may have an axis of rotation 206 that is aligned with the axis of rotation of the joint. In this manner, the instantaneous axis

of rotation (IAR) of the first and second members 202 and 204 may better match the IAR of the treated joint. As will be discussed in greater detail below, while the axis of rotation 206 of the device is illustrated in FIGS. 1-3 as occurring only along a single line, the axis of rotation 206 may also shift or move depending on the relative positioning of the first and second members 202 and 204 in a manner that corresponds to changing axis of rotation that a joint may experience through its range of motion. The first and second members 202 and 204 are operatively connected to each other, offset from the orthosis axis 206.

The first member 202 of the orthosis 200 includes a first extension member 208 extending therefrom. The second member 204 of the orthosis 200 includes a second extension member 210 extending therefrom and having an arcuate shape. The first and second extension members 208 and 210 are operatively connected at point "P," such that in operation the second extension member 210 travels along an arcuate path about and substantially through point "P." The arcuate shape of the second extension member 210 results in the toe rotating about the orthosis axis 206, or alternatively about a moving IAR, when the second member 204 is moved from a first position to a second position relative to the first member 202.

The first extension member 208 can extend substantially vertically from the first member 12 or extend at an angle  $\alpha$  from the first member 202. In one embodiment of the invention, the angle  $\alpha$  and the radius of curvature of the second extension member 210 are configured such that of the orthosis axis 206 is aligned with the axis of rotation of the joint.

The previous description of the first member 202 depicts a first extension 208 having a substantially linear shape, extending at an angle  $\alpha$  from the first member 202. However, it is within the scope of the present invention that the first extension member 208 can be any shape extending from the first member 202 which aligns orthosis axis 206 with the axis of rotation of the joint. Furthermore, as mentioned previously and again below, in some

instances the axis of rotation of the joint may change or move slightly. Therefore, in some instances it may be desirable for the orthosis to mimic the IAR of the joint. As will be illustrated in detail below, this can be accomplished in several ways. One modification of the embodiment of the invention shown in FIG. 1, for instance, may be for the second extension  
5 member 210 not to have a constant radius of curvature.

The orthosis 200 further includes a drive assembly 212, which is illustrated in FIG. 1 at or near point "P." In this embodiment, the drive assembly 212 is operably connected to the first and second extension members 208 and 210 for applying force to the first and second members 202 and 204 to pivot the second body portion about the orthosis axis 206. As will  
10 be shown below in additional embodiments, the drive assembly 212 may be configured or disposed to interact with or operate on one of the first or second members 202 and 204 independently.

Referring to FIG. 2, in order for the orthosis 200 to extend the joint the first and second members 202 and 204 may be affixed to the first and second body portions,  
15 respectively, tightly enough so that the first and second members 202 and 204 can apply torque to extend the joint. The second extension member 210 is moved through the drive assembly 212 from a first position to a second position, relative to the first extension member 208, rotating the second member 204 and the second body portion about the orthosis axis 206 stretching the joint. As the second member 204 is rotated to the second position, the second  
20 extension member 210 travels at least partially through point "P" and may travel substantially through this point for a large range of motion. Because the first and second members 202 and 204 are affixed to the first and second body portions, the outward pivoting movement of the second member 204 causes the joint to be extended as desired. The orthosis 200 may then be maintained in the second position for a predetermined treatment time providing a constant  
25 stretch to the joint. The orthosis may alternatively be configured to impart a constant force or

load on the joint or may utilize the techniques of Static Progressive Stretch as described in co-pending application serial no. 11/203,516, entitled "Range of Motion System and Method", and filed on August 12, 2005, the entirety of which is incorporated by reference.

Returning to the example where the orthosis is maintained in the second position,  
5 after the expiration of the treatment time, the second member 204 may then be moved back to the first position, relieving the joint. Optionally, the second member 204 can be rotated to a third position, increasing the stretch on the joint, or partially reducing it to allow limited relaxation of the surrounding tissue. The second member 204 can be rotated at discrete time intervals to incrementally increase, reduce, or vary the stretch of the joint through the  
10 treatment cycle. After completion of the treatment cycle, the second arm 204 is returned to the first position for removal of the orthosis 200.

Referring to FIG. 3, operation of the orthosis 200 to flex the joint is shown. The first and second members 202 and 204 are affixed to the first and second body portions, respectively, tightly enough so that the first and second members 202 and 204 can apply  
15 torque to extend the joint. A cuff, strap, laces, or other retaining device may be used to securely associate respective body portions of the joint with the first and second members 202, 204. The second extension member 210 is moved through the drive assembly 212 from the first position to a second position, relative to the first extension member 208, rotating the second member 204 and the second body portion about the orthosis axis 206 stretching the  
20 joint. As the second member 204 is rotated to the second position, the second extension member 210 travels substantially through point "P." Because the first and second members 202 and 204 are affixed to the first and second body portions, the inward pivoting movement of the second member 204 causes the joint to be flexed as desired. The orthosis 200 is maintained in the second position for a predetermined treatment time providing a constant  
25 stretch to the joint.

After the expiration of the treatment time, the second member 204 is moved back to the first position, relieving the joint. Optionally, the second member 204 can be rotated to a third position, thereby increasing, decreasing, or otherwise varying the stretch on the joint. The second member 204 can be rotated at discrete time intervals to incrementally increase the stretch of the joint through the treatment cycle. After completion of the treatment cycle, the second arm 204 is returned to the first position for removal of the orthosis 200.

FIGS. 4-6 further illustrate several aspects of the invention more concretely. An orthosis 220 of the present invention includes a first member 221 having a first cuff 222 attachable to a user's foot and a second member 223 having a second cuff 224 attachable to a toe of the user's foot, wherein the second member 223 is rotatable with respect to the first member 221 about an axis of rotation 226. The first and second members 221 and 223 are attached to the foot and toe of the user with the first and second cuffs 222 and 224, such that as the second member 223 is rotated about the axis of rotation 226, the toe is rotated about a joint axis.

A first extension member 228 is affixed to and extends from the first member 221, wherein a drive assembly 230 is positioned on an end portion of the first extension member 228. A second extension member 232 is similarly affixed to and extends from the second member 223, wherein the second extension member 232 has an arcuate shape. The second extension member 232 engages the drive assembly 230 of the first extension member 228 at a point "P." An actuation of the drive assembly 230 operates to move the second extension member 232 through the drive assembly 230, such that the second cuff 224 travels along an arcuate path "A" with respect to the first member 221. The arcuate shape of the second extension member 232 results in the toe rotating about the joint axis, as the second cuff 224 is moved along the arcuate path "A." The drive assembly 230 can be actuated to move the second cuff 224 and toe from a first position to a second position relative to the first cuff 222.

Once again, the term "cuff" as used herein means any suitable structure for transmitting the force of the orthosis 220 to the limb portion it engages.

The first extension member 228 can extend substantially vertically from the first member 221 or extend at an angle  $\alpha$  from the first member 221, where the angle  $\alpha$  and the radius of curvature of the second extension member 232 (if constant) can be configured such that of the axis of rotation 226 is aligned with the joint axis of rotation. As previously discussed, the curvature of the second extension member 232 need not be constant, and therefore the axis of rotation may shift or move in a manner that preferably mimics or approximates the moving IAR the joint would normally have. Another potential benefit of the orthosis 220 having the capability of a moving IAR is when multiple joints are being treated by the device. For instance, the range of motion of the tip of a toe or finger may involve cooperative motion of two or more joints. If the combined bending of the multiple joints causes the overall motion to rotation about a moving axis, it would be beneficial for the orthosis to approximate this moving IAR. Thus, the curvature of the second extension member 232 may be complex in order to better approximate a moving IAR.

Referring to FIG. 7, the drive assembly 230 can include a housing 240 having a worm gear 242 therein. A first miter gear 244 is attached to the worm gear 242 such that a rotation of the first miter gear 244 rotates the worm gear 242. The drive assembly 230 further includes a drive shaft 246 having a knob 248 at one end and a second miter gear 250 at an opposite end. The second miter gear 250 is positioned within the housing 240, in engagement with the first miter gear 244. A rotation of the knob 248 rotates the drive shaft 246 and the second miter gear 250, which in turn rotates the first miter gear 244 and the worm gear 242.

A gear surface 252 of the second extension member 232 includes a plurality of teeth 254. The second extension member 232 is positioned throughout the housing 240, such that



the worm gear 242 engages the teeth 254 of the second extension member 232. A rotation of the knob 248 rotates the worm gear 242, which in turn moves the second extension member 232 through the housing 240.

In an alternative embodiment, the drive assembly 230 for orthosis 230 in accordance  
5 with the present invention can be actuated by a motor instead of by a manually actuatable member, such as the knob 248. Likewise, the motor may be configured and adapted with  
gearing that causes the orthosis to cycle through a range of motion in a predetermined manner, or alternatively may be controlled by a programmable logic controller (PLC).

In an embodiment, an electric motor is mounted to the drive shaft 246 for rotation of  
10 the second miter gear 250. A battery or other source of energy provides electric power to the motor. Alternatively, the motor can be supplied with external power. A microprocessor controls the operation of the motor. The microprocessor and motor together can be used to cycle the second cuff 224 through a plurality of positions that cause the joint to undergo a range of motion, either by extension, by flexion, or both. For example, the microprocessor  
15 may be used to move the second cuff 224 in one pivotal direction a certain amount, hold there while tissue stretches, then move further in that direction; or in any other manner.

In another manner of use, the orthosis can be set to cycle to one end of the joint's range of motion and hold there for a predetermined period of time, then cycle to the other end of the joint's range of motion and hold there. The programming and control of the  
20 microprocessor is within the skill of the art as it relates to driving the motor to control the second cuff 224 to move in known manners. This embodiment is ideally suited for continuous passive motion exercise, because the orthosis is portable and because the motor can be programmed with the desired sequence of movements.

It should be understood that the particular physical arrangement of the motor, the power source, and the microprocessor is not the only possible arrangement of those elements. The invention contemplates that other arrangements of these or similarly functional elements are quite suitable, and thus, the invention is intended to cover any such arrangement.

5 Additionally, another type of power source, other than an electric motor, can also be used. For example, the use of a hydraulic or pneumatic motor as the drive mechanism is contemplated.

The present invention can further include a monitor for use with the orthosis 220, which provides assurances the patient is properly using the orthosis 220 during his/her  
10 exercise period. For instance, the monitor can have a position sensor, a temperature sensor, a force sensor, a clock or timer, or a device type sensor for monitoring the patient's implementation of a protocol. The information obtained from these monitoring devices may be stored for later analysis or confirmation of proper use or may be transmitted in real-time during use of the device. The data obtained from the monitor can be analyzed by a healthcare  
15 professional or technician and the protocol can be adjusted accordingly.

This analysis may be conducted remotely, thereby saving the time and expense of a home visit by a healthcare professional or technician. An exemplary monitoring system is provided in U.S. Publication No. 20040215111 entitled "Patient Monitoring Apparatus and Method for Orthosis and Other Devices," to Bonutti et al., the content of which is herein  
20 expressly incorporated by reference in its entirety.

In an exemplary use, the orthosis 220 is operated to rotate a toe about a joint axis in the following manner. The first cuff 222 is fastened about the foot with one or more straps, laces, or similar retaining device. Similarly, the second cuff 224 is fastened securely to the toe of the user, such that the joint and joint axis 226 is interposed between the first and  
25 second cuffs 222 and 224. The orthosis 220 is attached to the foot and toe in a first position.

The drive assembly 230 is actuated to move the second extension member 232, such that the second cuff 224 travels along an arcuate path from the first position to a second position, relative to the first cuff 222, rotating the toe about the joint axis stretching the joint. The orthosis 220 is maintained in the second position for a predetermined treatment time  
5 providing a constant stretch to the joint. After the expiration of the treatment time, the second cuff 224 is moved back to the first position, relieving the joint. Optionally, the second cuff 224 can be rotated to a third position, thereby increasing or decreasing the stretch on the joint. The second cuff 224 can be rotated at discrete time intervals to incrementally increase the stretch of the joint through the treatment cycle. After completion of the  
10 treatment cycle, the second arm member is returned to the first position for removal of the orthosis 220.

Referring to FIG. 8, the second member 223 can include an attachment bracket 260 for adjustably attaching the second cuff 224 to the second extension member 232. The attachment bracket 260 can include a toe rod 262 extending therefrom. The second cuff 224  
15 can be slideably mounted on the toe rod 262 to position second cuff 224 over the toe. Alternatively, the toe rod 262 can be of sufficient length such that the second cuff 224 can be slidingly positioned on a selected toe on the foot of the user, for example, the big toe, minimus toe, or any toe therebetween.

The second cuff 224 can be positioned on the toe rod 262 with a first bracket 264,  
20 where the toe rod 262 passes through a passage 266 in the first bracket 264. A set screw 268 is provided to secure the first bracket 264 to the toe rod 262. When the set screw 268 is loosened, the first bracket 264 is free to slide along the toe rod 262. A tightening of the set screw 268 secures the first bracket 264 in place on the toe rod 272.

The second cuff 224 can further include a second bracket 270, where the second  
25 bracket 270 can be pivotally mounted to the first bracket 264. For example, the second

bracket 270 can be attached to the first bracket 264 with a pin or screw connector, allowing the second bracket 270 to rotate with respect to the first bracket 264.

Additionally, when a joint is flexed or extended a compressive force may be applied to the connective tissue surrounding the joint. It may be desirable to control the compressive force, distracting the joint as the joint is flexed or extended. "Distraction" is defined by one dictionary as "Separation of the surfaces of a joint by extension without injury or dislocation of the parts." (Taber's Cyclopedic Medical Dictionary, 16th Edition, 1989, page 521), and involves stretching rather than compressing the joint capsule, soft tissue, ligaments, and tendons.

Additionally, the second bracket 270 can be slideably mounted to the first bracket 264. For example the second bracket 270 can be mounted to the first bracket 264 with a dovetail joint 272, allowing the second bracket 270 to slide with respect to the first bracket 264. The sliding movement of the second cuff 224 helps to limit the distractive or compressive forces which can be imparted on the joint by the rotation of the second cuff 224 with respect to the first cuff 222.

The attachment bracket 260 can be pivotally mounted to the second extension member 232. For example, the attachment bracket 260 can be attached to the second extension member 232 with a pin or screw connector 274, allowing the attachment bracket 260 to rotate with respect to the second extension member 232. The second extension member 232 further includes an extension bracket 276 having a slotted portion 278. A set screw 280 is positionable through the slotted portion 278, engaging the attachment bracket 260, such that the set screw 280 can be used to control the pivotal position of the attachment bracket 260 with respect to the second extension member 232.

The adjustable connection of the second cuff 224 to the attachment bracket 260 and the pivotal connection of the attachment bracket 260 to the second extension member 232 can be used to align the second cuff 224 with the toe. The alignment of the second cuff 224 on the toe can be used to substantially limit the force applied to the toe to that of a torque about  
5 the joint axis 226.

#### Bending a Joint in Extension:

In operation of the orthosis 220 to extend the joint, the orthosis starts at a more flexed position. The first and second cuffs 222 and 224 are clamped onto the foot and toe portions,  
10 respectively, by straps 234, tightly enough so that the first and second members 221 and 223 can apply torque to extend the joint. The second extension member 232 is moved through the drive assembly 230 from the first position to a second position, relative to the first extension member 228, rotating the second cuff 224 and the toe about the orthosis axis 226 stretching the joint. As the second cuff 224 is rotated to the second position the second extension  
15 member 232 travels along an arcuate path "A" about and substantially through point "P." The orthosis 220 is maintained in the second position for a predetermined treatment time providing a constant stretch to the joint.

As the orthosis 220 is rotated from the first position to the second position, extending the joint, the second cuff 224 moves along the first bracket 64. Because the first and second  
20 members 221 and 223 are clamped onto the foot and toe as described above, the outward pivoting movement of the second cuff 224 causes the joint to be extended as desired. However, this extension of the joint can place strong distractive forces on the soft tissues around the joint. The sliding movement of the second cuff 224 helps to limit these distractive forces by counteracting the outward movement. Thus, the detrimental effects of strong

distractive forces normally generated in forced extension of a joint are avoided, being replaced with the beneficial effects of limited and controlled distraction.

#### Bending a Joint Flexion:

5           In operation of the orthosis 220 to flex the joint, the orthosis 220 starts at a more extended position. The first and second cuffs 222 and 224 are clamped onto the foot and toe portions, respectively, by straps 234, tightly enough so that the first and second members 221 and 223 can apply torque to extend the joint. The second extension member 232 is moved through the drive assembly 230 from the first position to a second position, relative to the  
10 first extension member 228, rotating the second cuff 224 and the toe about the orthosis axis 226 stretching the joint. As the second cuff 224 is rotated to the second position the second extension member 232 travels along an arcuate path "A" about and substantially through point "P." The orthosis 220 is maintained in the second position for a predetermined treatment time providing a constant stretch to the joint.

15           As the orthosis 220 is rotated from the first position to the second position, flexing the joint, the second cuff 224 moves along the first bracket 264. Because the first and second members 221 and 223 are clamped onto the foot and toe as described above, the inward pivoting movement of the second cuff 224 causes the joint to be flexed as desired. However, this flexion of the joint can place strong compressive forces on the soft tissues around the  
20 joint. The sliding movement of the second cuff 224 helps to limit these compressive forces by counteracting the inward movement. Thus, the detrimental effects of strong compressive forces normally generated in forced flexion of a joint are avoided, being replaced with the beneficial effects of limited and controlled compression.

          Referring to Fig. 9, the drive assembly 230 can be adjustable mounted to the first  
25 extension member 228. The first extension member 228 includes a longitudinal slotted

section 282. A threaded member 284 is positioned through the longitudinal slotted section 282, where the threaded member 284 is threaded into a threaded hole 286 in the drive assembly 230. The position of the drive assembly 230 is secured on the first extension member 228 by tightening the threaded member 284, compressing the first extension member 228 between the threaded member 284 and the drive assembly 230. The position of the drive assembly 230 can be adjusted by loosening the threaded member 284 and sliding the drive assembly 230 along the longitudinal slot 282. In this manner the position of the drive assembly 230 can be adjusted to align the axis of rotation 226 with the joint axis.

The drive assembly 220 can further include an indented portion 288. The indented portion 288 is sized to receive the first extension member 228 therein, such that the first extension member 228 slides through the indented portion 288 as the drive assembly 230 is moved along the first extension member 230. The indented portion 288 is configured to align the drive assembly 230 with respect to the first extension member 228. The indented portion 288 provides the further benefit of resisting a rotation of the drive assembly 230 with respect to the first extension member 228 when the orthosis 220 is in use.

Referring to FIG. 10, the drive assembly 230 can include a pair of indented portions 288 and 290, positioned on opposite sides on the drive assembly 230. As shown in FIG. 9, the first indented section 288 can be used to position the drive assembly 230 in an outer position on the orthosis 220, where the drive assembly 230 is positioned on an outside surface 292 of the first extension member 228.

Alternatively, as shown in FIG. 11, the second indented section 290 can be used to position the drive assembly 230 in an inner position on the orthosis 220, where the drive assembly 230 is positioned on an inner surface 294 of the first extension member 228. The threaded member 284 is positioned through the longitudinal slotted section 282, where the threaded member 284 is threaded into a second threaded hole 296 in the drive assembly 230.

In an embodiment, the first member 221 can be adjustable mounted to the first cuff 222, such that the position of the second cuff 224 can be adjusted to align the second cuff 224 with a toe of interest and the joint axis of the toe. In instances where the joint of a toe is misaligned, for example for toe deformations such as hammer toe, bunion, etc, the linear and angular position of the second cuff 224 can be adjusted with respect to the first cuff 222 aligning the second cuff 224 with the misaligned toe such that the axis of rotation 226 of the orthosis 220 is aligned with the axis of rotation of the toe joint. In the manner, the orthosis 220 can be adjusted to prevent the unwanted application of torsional forces to the toe joint.

Referring to FIG. 12, the first member 221 is adjustably attached to a bottom surface of the first cuff 222. The first member 221 can include a longitudinal slot 300, through which a pair of threaded members 302 and 304 are positioned, attaching the first member 221 to the first cuff 222. The first member 221 can be moved along the longitudinal slot 300 to laterally adjust the position of the first member 221 with respect to the first cuff 222. The first member 221 is secured in position by tightening the threaded member 302 and 304, compressing the first member 221 between the threaded members 302 and 304 and the bottom surface 298 of the first cuff 222.

The first member 221 can further include a second longitudinal slot 306, parallel and offset from the first longitudinal slot 300. The first member 221 can be attached to the first cuff 222, using the second longitudinal slot 306 to longitudinally adjust the position of the first member 221 with respect to the first cuff 222. Similarly, the first member 221 can be moved along the second longitudinal slot 306 to laterally adjust the position of the first member 221 with respect to the first cuff 222.

It is also contemplated that the angular position of the first member 221 can be adjusted with respect to the first cuff 222. In an embodiment, as shown in FIG. 13, the bottom surface 298 of the first cuff 222 includes a center threaded hole 308 and an arcuate



slot 310. An internally threaded fastener 312 is slidingly positioned in the arcuate slot 310, opposite the bottom surface 298. The first member 221 is attached to the first cuff 222 by positioning the threaded members 302 and 304 through a longitudinal slot 300 or 306 of the first member 221 and engaging the threaded hole 308 and the internally threaded fastener 312  
5 in the arcuate slot 310. The angular position of the first member 221 can be adjusted with respect to the first cuff 222 by pivoting the first member 221 about threaded member 302 in the center threaded hole 308, such that the internally threaded fastener 312 and the second threaded member 302 travel along the arcuate slot 310. The first member 221 is secured in position by tightening the threaded members 302 and 304, compressing the first member 221  
10 between the threaded members 302 and the bottom surface 298 of the first cuff 222, and compressing the first member 221 and first cuff 222 between threaded member 304 and internally threaded fastener 312.

The bottom surface 298 of the first cuff 222 can further include a second arcuate slot 314, where an internally threaded fastener 316 is slidingly positioned in the second arcuate  
15 slot 314, opposite the bottom surface 298 of the first cuff 222. Similar to arcuate slot 310, second arcuate slot 314 can be used to angularly adjust the position of the first member 221 with respect to the first cuff 222.

Specifically, the first member 221 is attached to the first cuff 222 by positioning the threaded members 302 and 304 through a longitudinal slot 300 or 306 of the first member  
20 221 and engaging the threaded hole 308 and the internally threaded fastener 316 in arcuate slot 314. The angular position of the first member 221 can be adjusted with respect to the first cuff 222 by pivoting the first member 221 about threaded member 302 in the center threaded hole 308, such that the internally threaded fastener 316 and the second threaded member 304 travel along the arcuate slot 314. The first member 221 is secured in position by  
25 tightening the threaded member 302 and 304, compressing the first member 221 between the

threaded members 302 and the bottom surface 298 of the first cuff 222, and compressing the first member 221 and first cuff 222 between the threaded member 304 and internally threaded fastener 316.

It is also contemplated that the first member 221 can be attached to the first cuff 221  
5 using the arcuate slots 310 and 314 and the respected internally threaded members 312 and 316. Specifically, the first member 221 is attached to the first cuff 222 by positioning the threaded members 302 and 304 through a longitudinal slot 300 or 306 of the first member 221 and engaging the internally threaded fastener 312 in the arcuate slot 310 and the internally threaded fastener 316 in arcuate slot 314. The angular position of the first member  
10 221 can be adjusted with respect to the first cuff 222 by pivoting the first member 221 such that the internally threaded fasteners 312 and 316 travel along the arcuate slots 310 and 314. The first member 221 is secured in position by tightening the threaded member 302 and 304, the first member 221 and first cuff 222 between the treaded members 302 and 304 and internally threaded fastener 312 and 316.

15 While the embodiment discussed above utilize a second extension member having an arcuate shape to control movement of the second member relative to the first, it should be understood that skilled artisans having the benefit of this disclosure will appreciate that other configurations may likewise provide similar relative movement.

FIG. 14, for example, schematically illustrates an embodiment of an orthosis 330 of  
20 the invention having a first member 332 and a second member 334, both of which preferably having sufficient structure or component parts to hold body members near the treated joint or joints. In the embodiment illustrated in FIG. 14 the second member has a first pivoting contact point 336 about which the geared body member may rotate. In this embodiment, the first pivoting contact 336 does not move in relation to the first body member 330, but as  
25 indicated in FIG. 12 one alternative embodiment may allow relative movement that can be

resisted by a flexible device 338 such as a spring, compressed gas, foamed material, elastomer or the like.

Returning once again to FIG. 14, the second member may have an additional pivot contact 340, preferably disposed at a location at or near the opposite end of the second member 334 from where the first pivoting contact 336 is located. The second pivoting contact 340 may be configured with a drive assembly 344 that causes the second member 334 to follow a predetermined path. Thus, the second pivoting contact 340 in the embodiment of FIG. 14 is configured to move relative to the first member 332 in order to cause the joint to move from a first position to second one.

10 The drive assembly 344 illustrated in FIG. 14 is an arm or linkage 346 connected between the second pivot connection 340 and a rotating wheel 348. The wheel 348 may be configured so that the linkage 346 can be selectively connected to it in different radial distances from the center of rotation of the wheel. This allows the range of motion to be adjustable by the care provider, physician, or patient. As the wheel 348 is rotated, the linkage  
15 346 moves in a manner that causes the second member 334 to move in a particular way.

The second member 334 (or alternatively the first member 332) may also have a sliding contact surface 342. The sliding contact surface 342 allows the joint to rotate or move according to its natural instantaneous axis of rotation. Thus, if the second pivot contact 340 moves in a manner that does not always exactly correspond to the axis of rotation of the joint,  
20 the sliding contact surface 342 may move or adjust accordingly. Another potential advantage of the sliding contact surface 342 is that it may help facilitate proper alignment of the joint in the orthosis during initial setup.

FIG. 14 illustrates some variations that may also be used in orthosis of the invention. For instance, the first and or second pivot contact may be configured with a cushion or spring

338 that allows one or both ends of the second member to impart some flexibility in the force imparted to the joint. As noted above, the cushion or spring 338 may be made of a variety of suitable materials and constructions to permit some flexibility in the movement of the pivot points 336, 340.

5           The use of a spring or cushion allows the orthosis 330 to be used in different treatment protocols than just by holding the joint in a prescribed location for a period of time. Instead, the orthosis can utilize the principles of static progressive stretch as described in copending application no. 11/203,516, entitled "Range of Motion System and Method", and filed on August 12, 2005, the entirety of which is incorporated by reference.

10           Thus, an orthosis 330 configured with a spring or cushion 338 can be moved from an initial position to a second position that is determined not by position of the joint but instead by the amount of force the orthosis 330 imparts on the joint. The joint may then be subjected to this loading, and over time as the surrounding tissue stretches the joint will move and the imparted forces will be reduced. It should be noted that while Fig. 15 illustrates the cushion  
15           or spring 338 associated with the first pivot contact 336, it is not required to be associated with it. Instead, for example, the cushion or spring 338 may be associated with the second pivot 340 so that it can flex or move in response to resistive forces of the joint and nearby tissue. Likewise, there may be a spring or cushion 338 associated with both pivot contacts 336, 340.

20           Another notable variation between the embodiments of FIGS. 14 and 15 is that the rotating wheel 348 in FIG. 14 has multiple single point connections for connecting the linkage 346 at different distances from the center of rotation of the wheel. In contrast, the embodiment of FIG. 15 illustrates that an elongated slot 350 may be used to connect the linkage 346. The advantage of utilizing multiple single point connections may be ease of use  
25           and the ability to quickly confirm the orthosis 330 is properly configured for a prescribed

treatment protocol, whereas one potential advantage of utilizing an elongated slot 350 is the ability to quickly adjust the settings without disassembling the device.

FIG. 16 illustrates an embodiment of the invention where the rotating wheel 348 is a cam surface 352. This embodiment is similar to the use of cams and followers as described in U.S. Patent No. 5,514,143, which is incorporated herein in its entirety. As shown, the cam surface 352 may have varying distance from the center or rotation of the wheel 348. If the wheel 348 is circular, for example, the center of rotation may be located somewhere different from the geometric center of the circle or at the center or rotation of the shape. As it rotates, the circumferential outer surface causes the linkage 346 to move to the second member 340 in a desired manner. Additionally, the outer edge of the "wheel" 348 need not be round, but instead may be a cam surface 352 of varying distance from the center or rotation. Likewise, the outer surface may have varying radii of curvature as shown in FIG. 16.

The embodiments of FIGS. 17 and 18 further illustrate that a cam surface 352 may be used to move the second member 332 in a desired, perhaps complex way. As is the case for other embodiments described herein, performance of the cam surface 352 may be enhanced because of the ability to better mimic or replicate a moving axis of rotation of the treated tissue and joint.

In FIG. 17, the cam surface 352 is associated with the first member 332. Linkages or arms 346 of the second member 334 have cam followers 354 that trace the cam surface 352 and cause the second member 334 to move in a more complex manner than just by rotation around a fixed axis.

The cam surface 352 of FIG. 17 also is associated with a slot 356 that allows the relative location of the first and second members 332 and 334 to be adjusted or moved without decoupling the cam followers 354 from the cam surface 352. As shown, the slot 356

allows for horizontal adjustment repositioning. Although not shown, vertical slots may also be provided, either alone or in combination with a horizontal slot.

FIG. 18 illustrates an example where the linkage 346 is a cam surface 352 that passes through two or more points 358, 360 that are stationary or fixed relative to the first member 332 when the orthosis 330 is in use (i.e. after alignment is completed). Once again, this embodiment may be configured to permit horizontal adjustment, such as by providing slot 368, and likewise may be configured to be vertically adjustable. In addition, this embodiment also illustrates that the first and second members 332 and 334 may be represented by rotation about a pivot 370. Thus, the use of horizontal, vertical, and rotational adjustment of the relative positions of the first and second members 332 and 334 may allow greater fitting of the orthosis 330 to the treated tissue and joint.

FIG. 19 is an exploded view of how the cam surface 352 and cam followers 354 may utilize a geared surface 372. Utilizing a geared surface 372 may allow for a drive assembly 344 to automate the movement of the orthosis 330.

FIGS. 20 and 21 schematically illustrate other ways in which potentially complex movement of the second member 334 may be controlled. FIG. 20 illustrates that the cam surface may not be directly formed from a component part of either the first or second members, but instead maybe associated with some other structure. For instance, the orthosis 330 may be operatively connected to a base unit 374 having a plurality of cam surfaces 376 corresponding to different ranges of motion for related joints, such as when the orthosis 330 can be used to treat a plurality of different toes or a patient. Once the orthosis 181 is placed on the patient, the second member 334 will be positioned to securely hold one of the toes on the patient's foot and to engage with the cam surface 376 corresponding to that toe.

FIG. 21 shows that multiple cam surfaces or slots 378 may be formed in a side panel 380. The side panel 380 may have a sliding engagement of the second member 334. As the second member 334 moves, the engagement with the side panel 380 controls position and movement. Moreover, one or more sides or edges of a slot 316 of the embodiment of FIG. 21  
5 may be geared to allow implementation of a drive assembly 344.

FIG. 22 illustrates an embodiment where movement of at least part of a linkage 346 may be linear, but when combined with a rotational pivot 382, sliding slot 384, and possibly other components or combinations described herein, the net effect on the second member 334 is once again a controlled movement in a desired manner.

10 The components of the present invention are rigid members made of, for example, aluminum, stainless steel, polymeric, or composite materials. The member and extensions are sufficiently rigid to transmit the necessary forces. It should be understood that any material of sufficient rigidity might be used. For example, some components can be made by injection molding. Generally, for injection molding, tool and die metal molds of the  
15 components are prepared. Hot, melted plastic material is injected into the molds. The plastic is allowed to cool, forming components. The components are removed from the molds and assembled.

Furthermore, it is contemplated that the components can be made of polymeric or composite materials such that the device can be disposable. For example, at least some or all  
20 of the components can be made of a biodegradable material such as a biodegradable polymer. Among the important properties of these polymers are their tendency to depolymerize relatively easily and their ability to form environmentally benign byproducts when degraded or depolymerized. One such biodegradable material is poly (hydroxyacids) ("PHA's") such as polyactic acid ("PLA") and polyglycolic acid ("PGA").

Additionally, the device can be made of a nonmagnetic material. In such instance, the device can be used as a positioning device for use in imaging devices, such as a MRI device. It is also contemplated that the device can be used as a positioning device for use during surgical procedures, where it may be necessary to adjust and hold the position of the joint.

5 All references cited herein are expressly incorporated by reference in their entirety.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described herein above. For example, although the examples presented identify the toe joint, the present invention can be used for any joint in the body of the patient. In addition, unless mention was made above to the  
10 contrary, it should be noted that not all of the accompanying drawings are to scale. A variety of modifications and variations are possible in light of the above teachings without departing from the scope and spirit of the invention, which is limited only by the following claims.



## The Claims

What is claimed:

- 5 1. An orthosis for stretching tissue around a foot and toe, the orthosis comprising:  
a first member affixable to the foot and including a first extension member extending  
therefrom; and  
a second member affixable to the toe and including a second extension member,  
wherein the second extension member comprises an arcuate shape extending  
10 therefrom, the second extension member is operatively connected to the first extension  
member so that relative movement between the first and second affixable members is  
determined by movement along the arcuate shape.
2. The orthosis of claim 1 wherein the arcuate shape associated with the second  
15 extension member is convex.
3. The orthosis of claim 2 wherein the arcuate shape has a constant radius of curvature.
4. The orthosis of claim 2 wherein the arcuate shape has a variable radius of curvature.  
20
5. The orthosis of claim 1 wherein the arcuate shape of the second extension member is  
a cam surface, and wherein the first extension member comprises cam followers that control  
the relative movement between the affixable members.
- 25 6. The orthosis of claim 1 wherein a plurality of gear teeth are disposed on the arcuate  
shape of the second extension member.
7. The orthosis of claim 6 further comprising:  
a motor-operated drive assembly in communication with the arcuate shape of the  
30 second extension member; and  
a programmable control system capable of automatically cycling relative movement  
between the first and second affixable members according to predetermined parameters.

8. The orthosis of claim 1 wherein the relative movement between the first and second affixable members is about an axis of rotation that corresponds to an axis of rotation of relative movement between the toe and foot.
- 5 9. The orthosis of claim 8 wherein the location of the axis of rotation of movement between the first and second affixable member is not constant.
10. The orthosis of claim 1 wherein the relative movement between the first and second affixable members is about a fixed axis of rotation.
- 10 11. The orthosis as set forth claim 1 further comprising a drive assembly on the first extension member, the drive assembly engaging the second extension member for selectively moving the second member with respect to the first member.
- 15 12. The orthosis of claim 1 wherein the second affixable member further comprises a base and a sliding contact surface that allows for relative movement between the toe and the base of the second affixable member.
- 20 13. The orthosis of claim 1 wherein the second affixable member has a first end distal to the first affixable member and a second end proximate to the first affixable member and wherein the second affixable member further comprises a cushion that allows one or both ends to flex as forces from relative movement of the first and second affixable members are imparted to the toe.
- 25 14. The orthosis of claim 13 wherein the cushion comprises one or more of a spring, compressed gas, an elastic material, or a foamed material.
- 30 15. The orthosis of claim 11 wherein the drive assembly includes a worm gear rotatably mounted therein and wherein the worm gear is manually rotatable for selectively moving the second member with respect to the first member.
16. The orthosis of claim 1 further comprising means for securing the foot to the first affixable member and means for securing the toe to the second affixable member.

17. An orthosis for stretching tissue around a foot and a toe, the orthosis comprising:  
a first member affixable to the foot;  
a second member affixable to the toe and including an extension member; and  
5 an arcuate shape operatively communicating with the extension member so that  
relative movement between the first and second affixable member is determined by  
movement of the extension member along the arcuate shape.
18. The orthosis of claim 17 wherein the arcuate shape is disposed on the first affixable  
10 member, the curvature of the arcuate shape is convex and has a constant radius of curvature.
19. The orthosis of claim 17 wherein the curvature of the arcuate shape is concave.
20. The orthosis of claim 17 further comprising:  
15 a drive assembly on the first extension member, the drive assembly engaging the  
second extension member for selectively moving the second member with respect to the first  
member; and  
a motor operatively connected to the drive assembly for selectively moving the  
second member with respect to the first member,  
20 wherein the relative movement between the first and second affixable members is  
about an axis of rotation that corresponds to an axis of rotation of relative movement between  
the toe and foot.
21. The orthosis of claim 20 wherein the second affixable member further comprises a  
25 base and a sliding contact surface that allows for relative movement between the toe and the  
base of the second affixable member.
22. The orthosis of claim 20 wherein the second affixable member has a first end distal to  
the first affixable member and a second end proximate to the first affixable member and  
30 wherein the second affixable member further comprises a cushion that allows one or both  
ends to flex as forces from relative movement of the first and second affixable members are  
imparted to the toe.

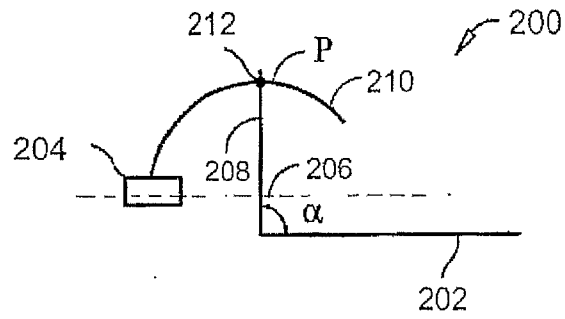


FIG. 1

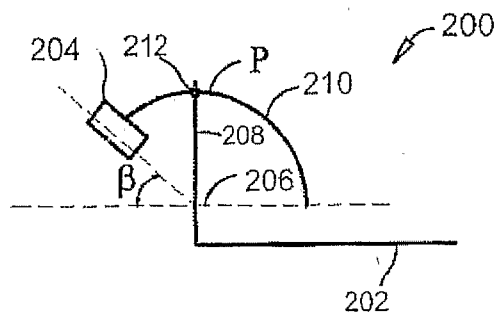


FIG. 2

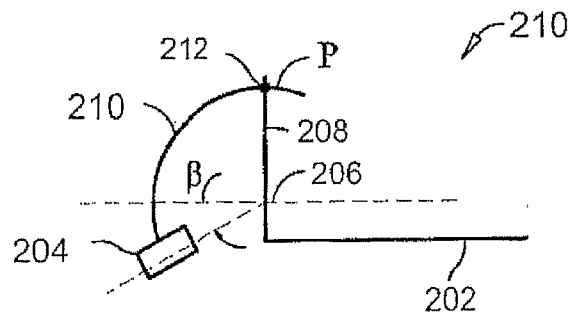


FIG. 3

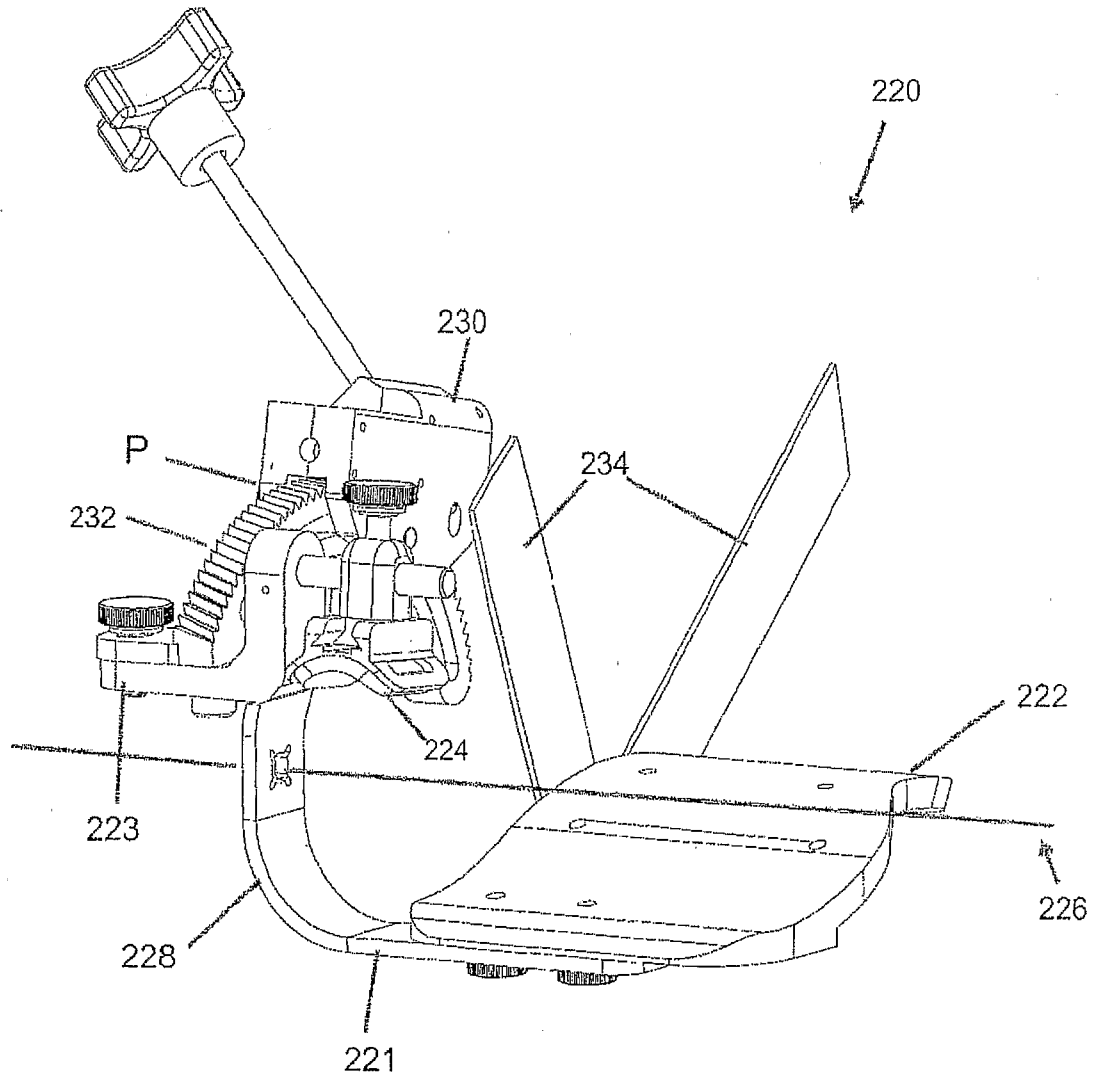


FIG. 4

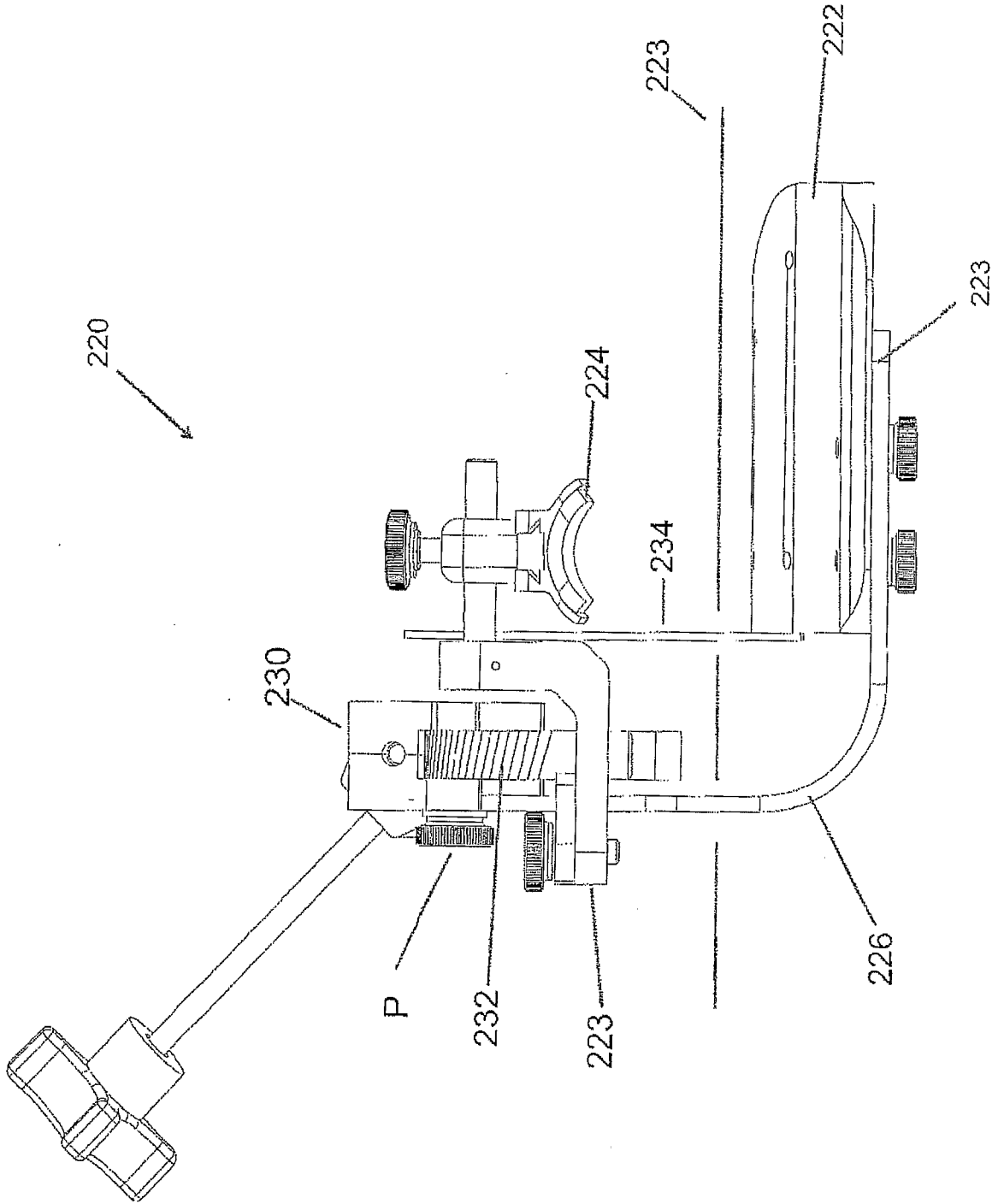


FIG. 5

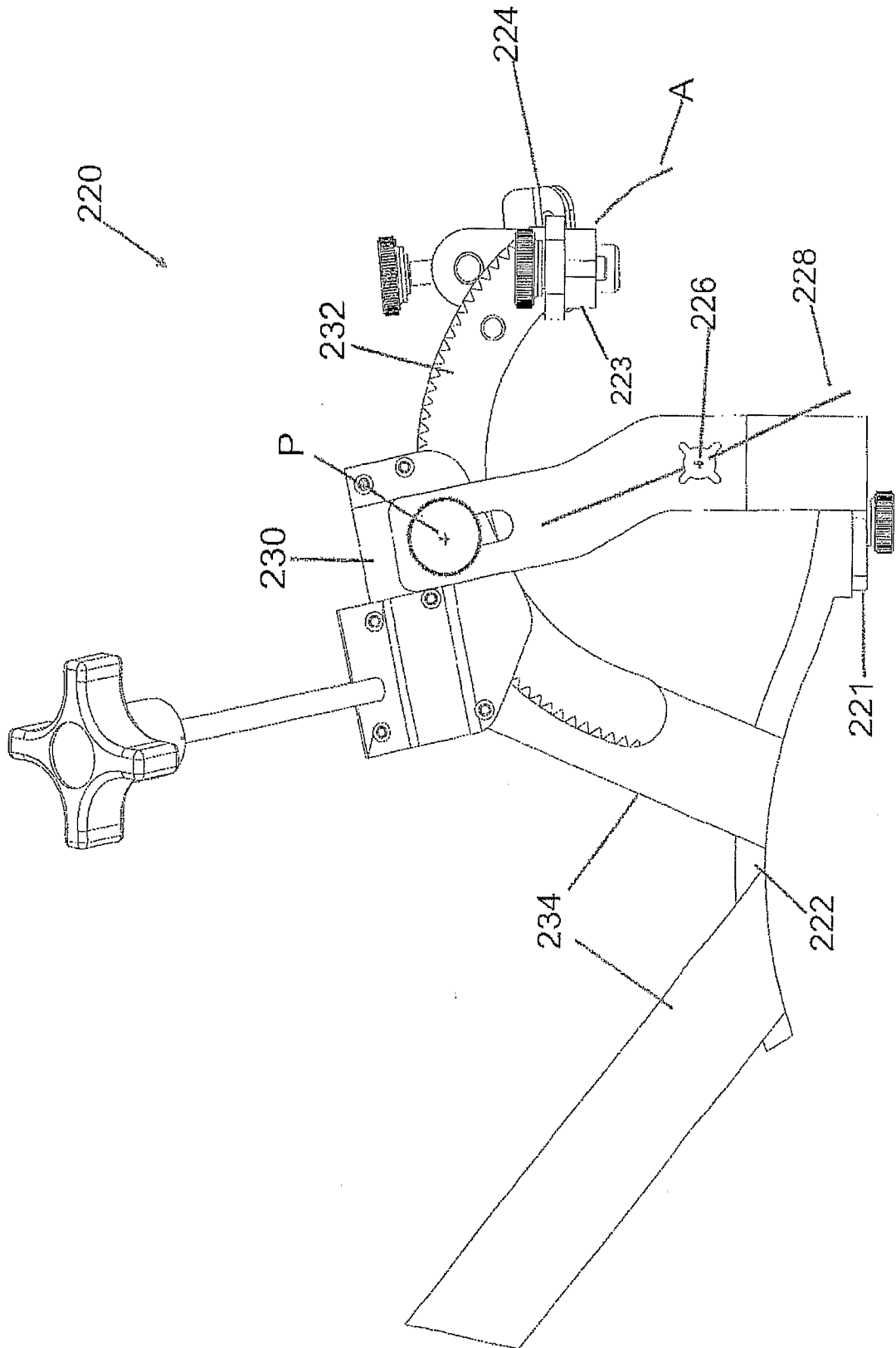


FIG. 6

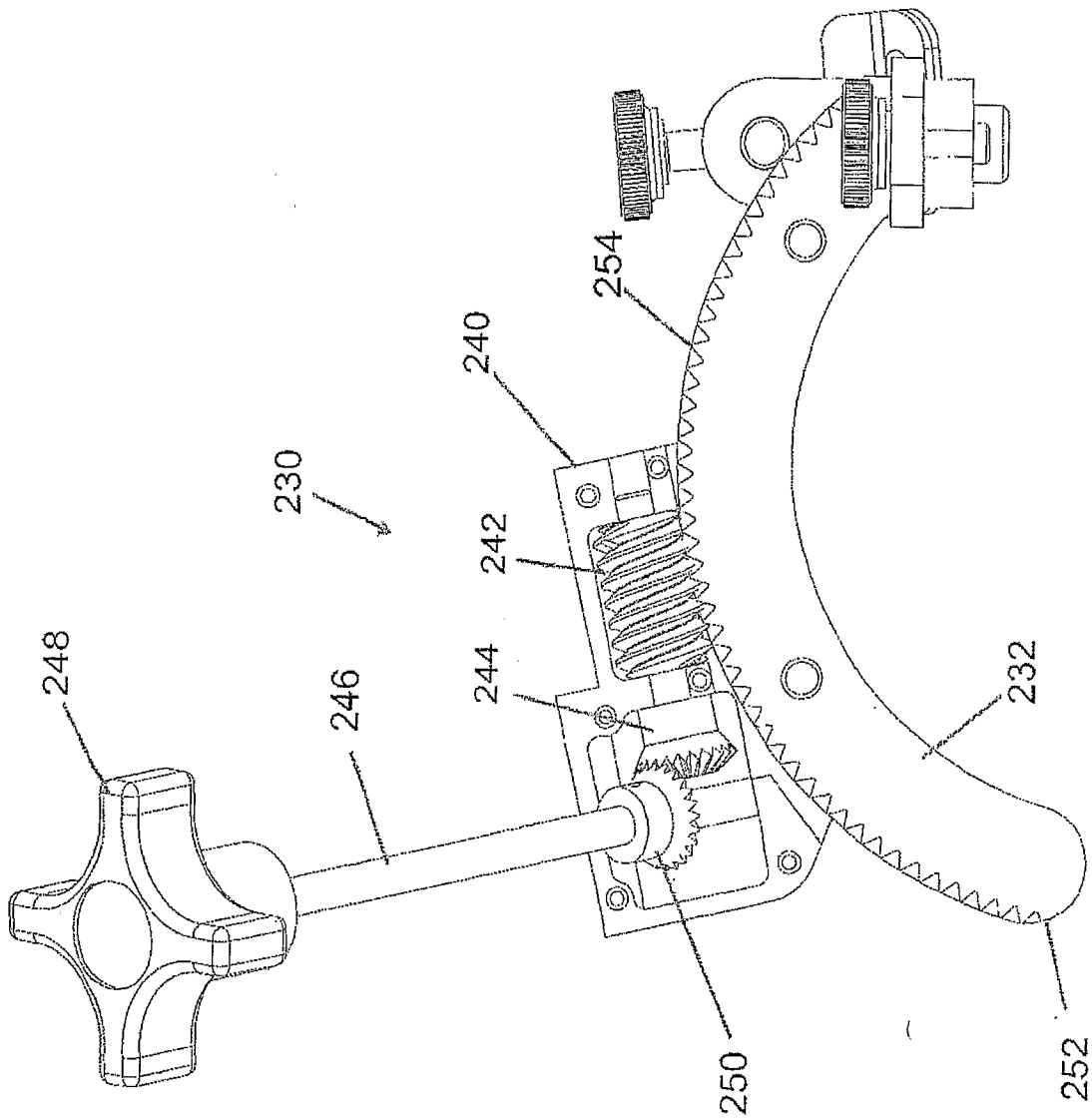


FIG. 7



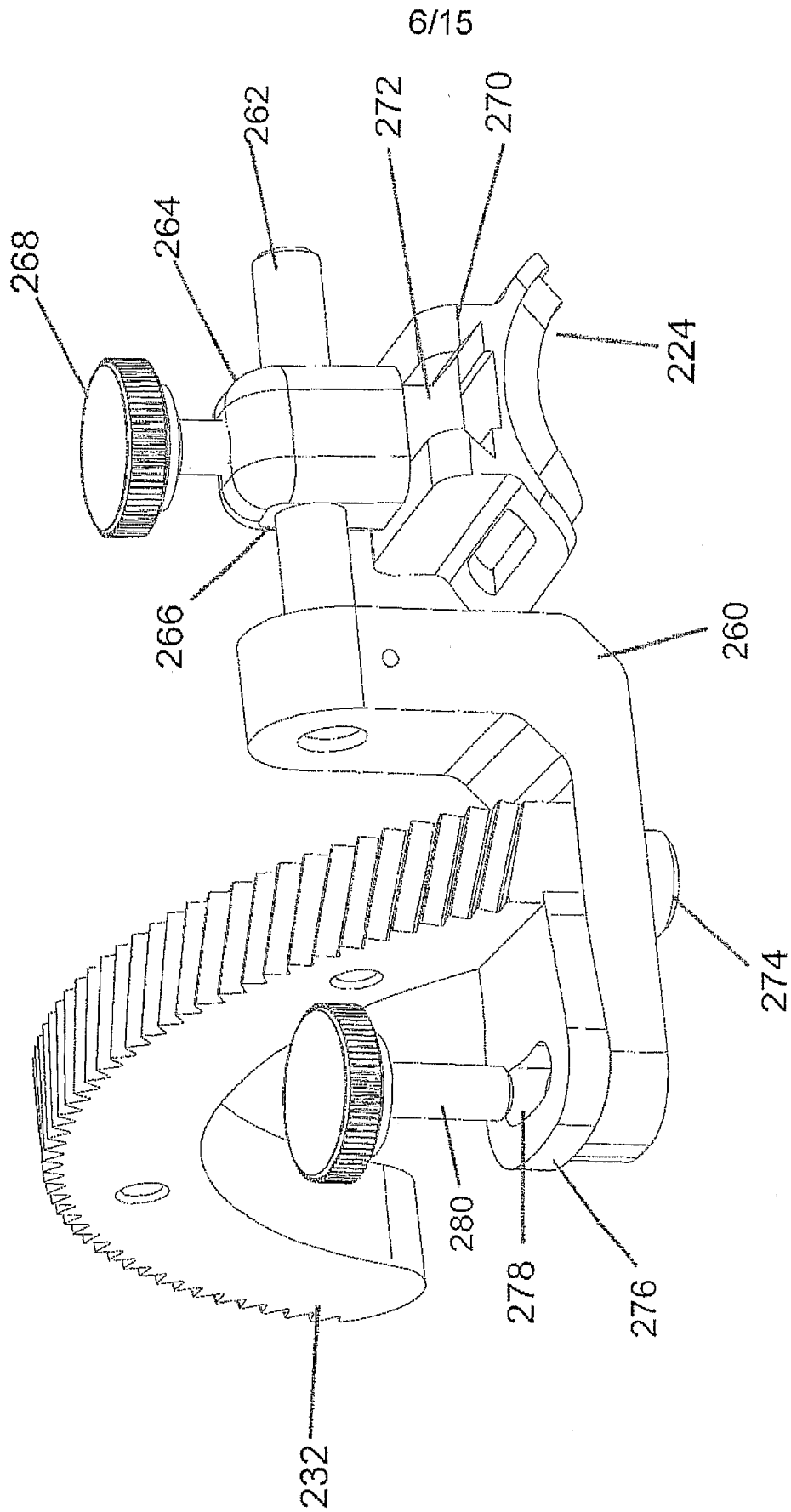


FIG. 8

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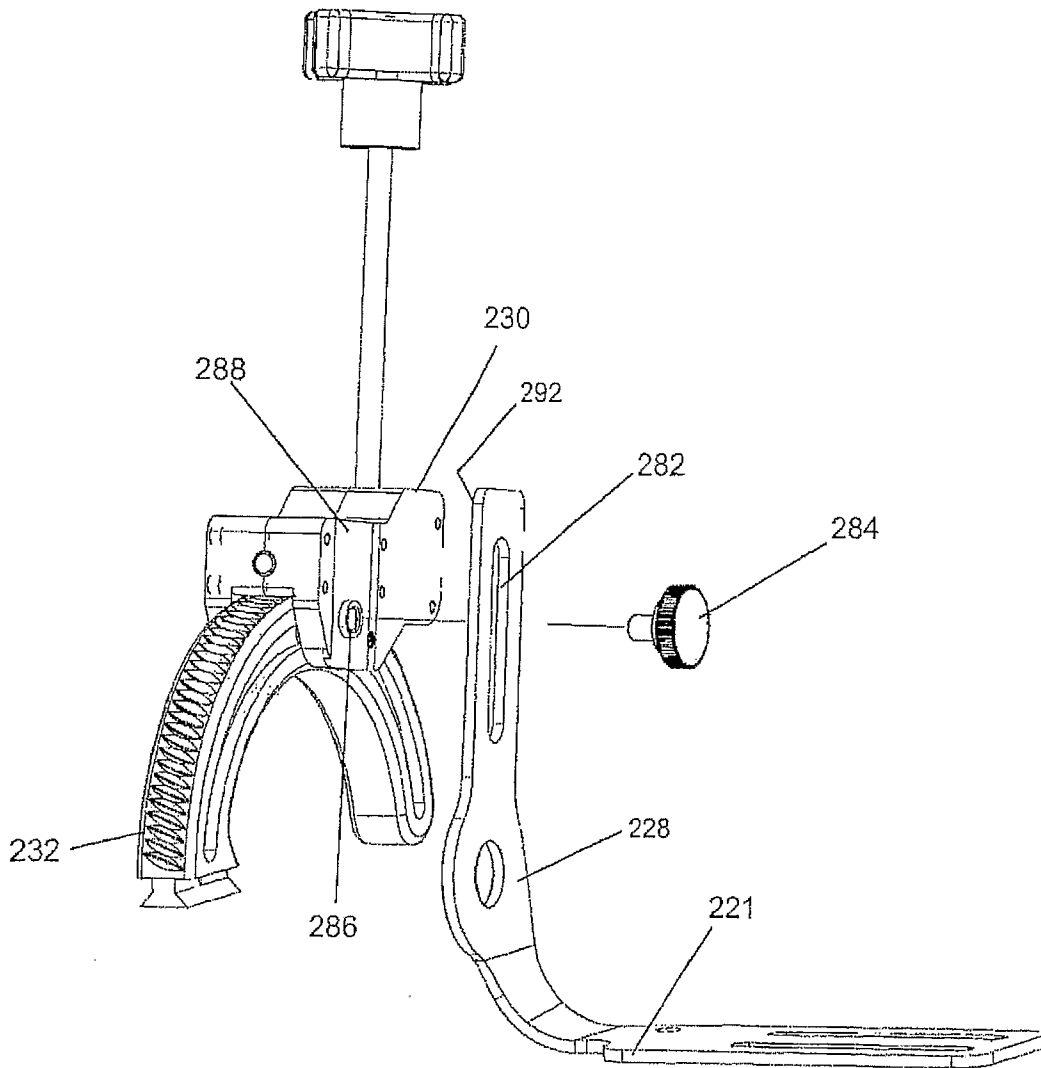


FIG. 9

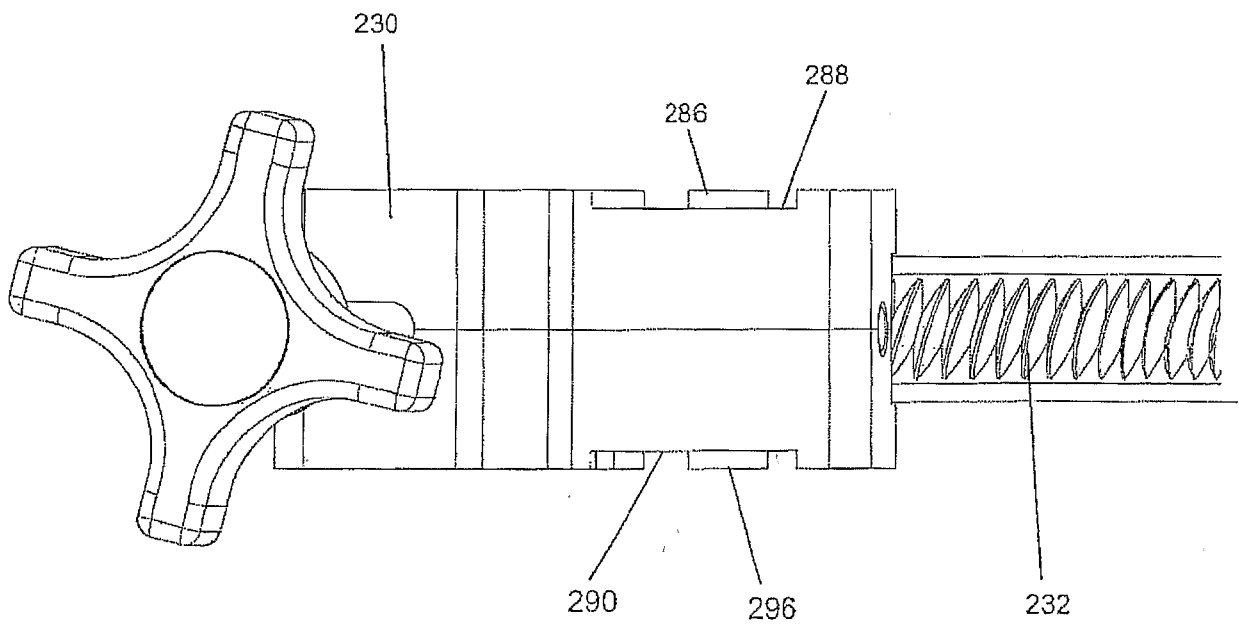


FIG. 10

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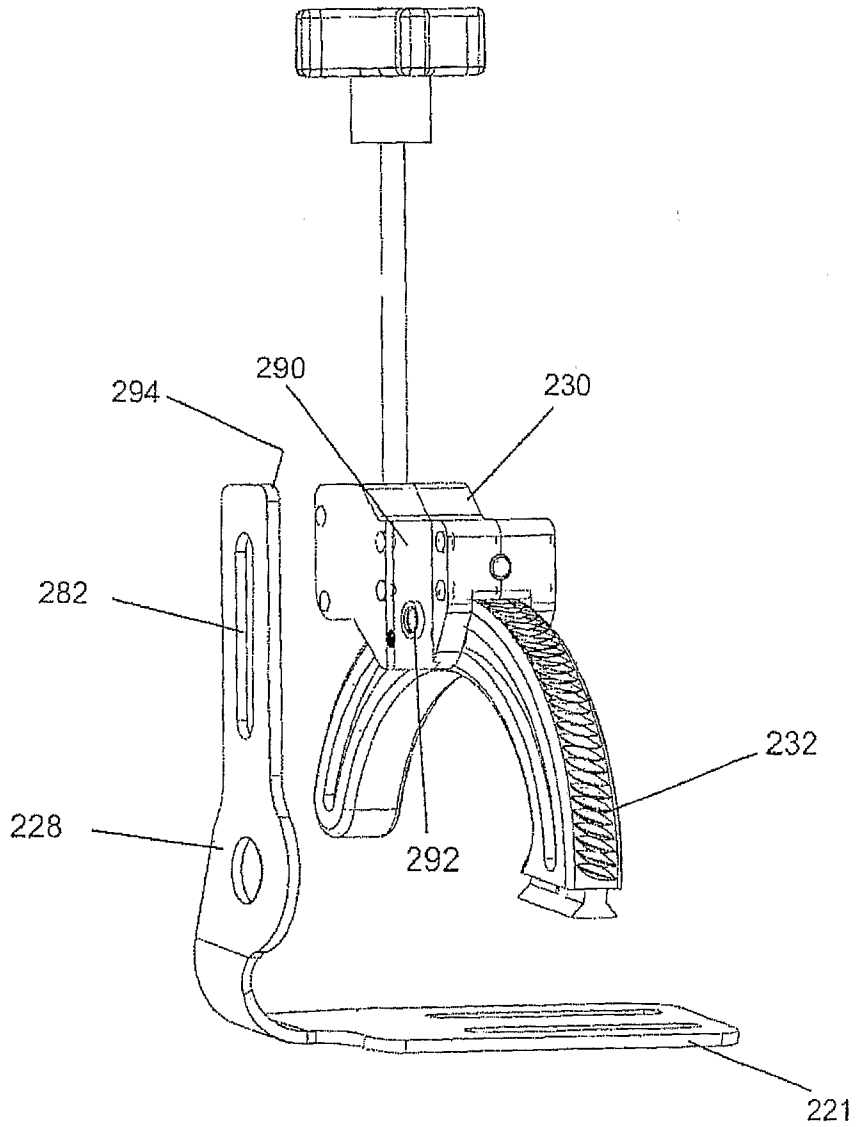


FIG. 11

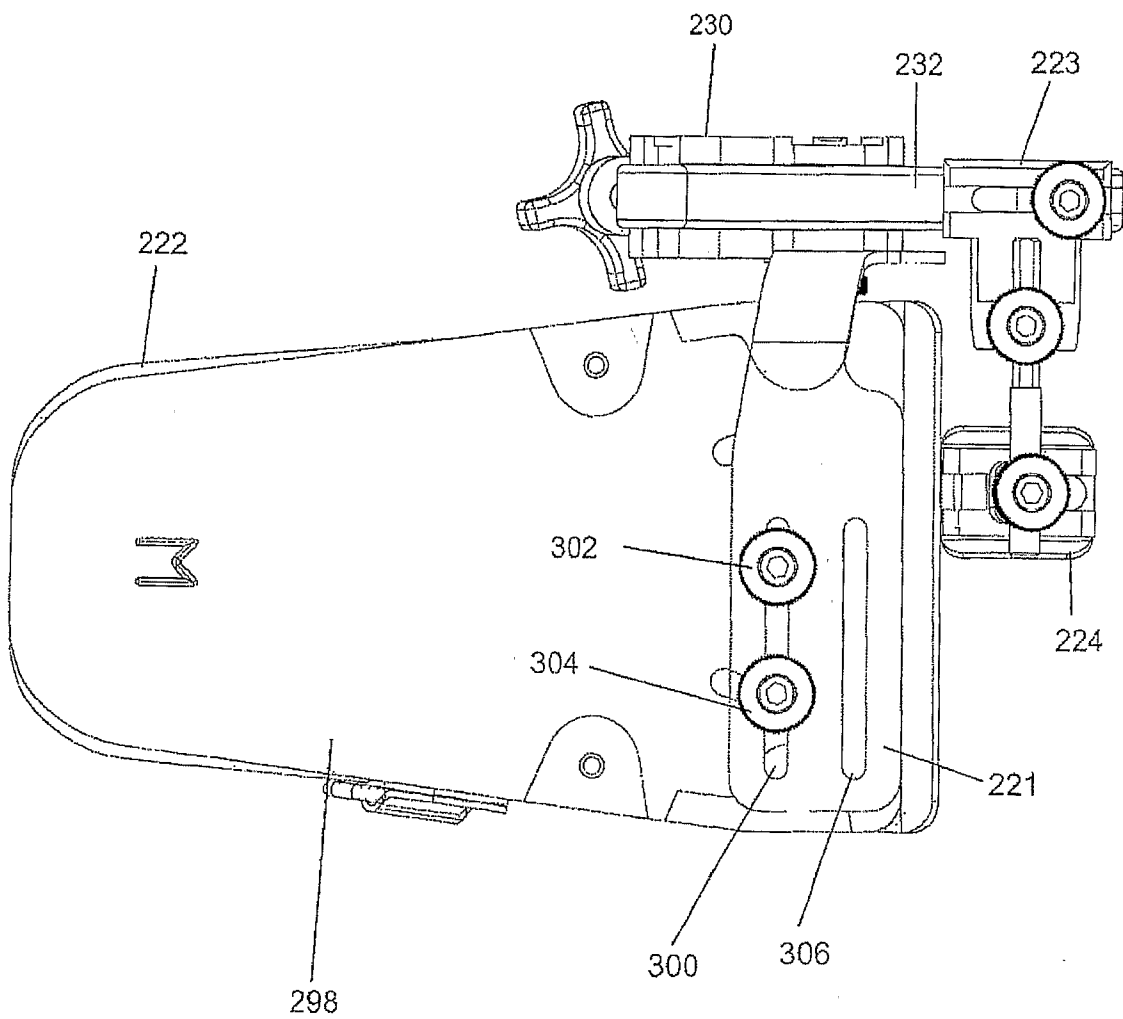


FIG. 12

11/15

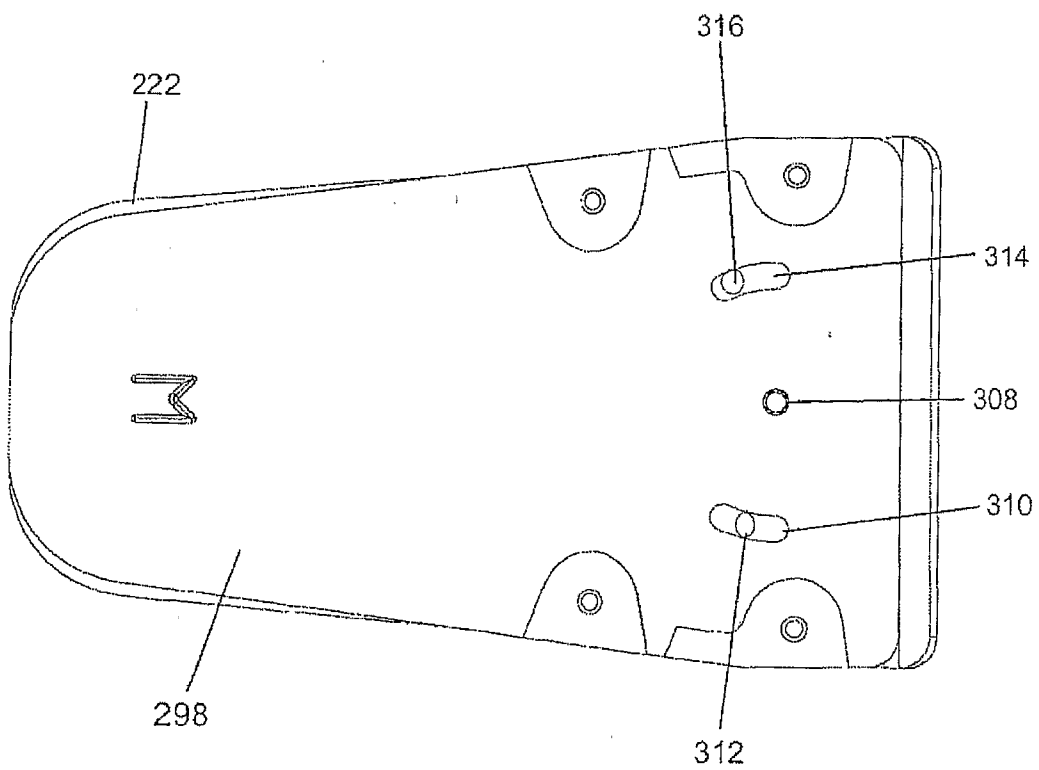


FIG. 13

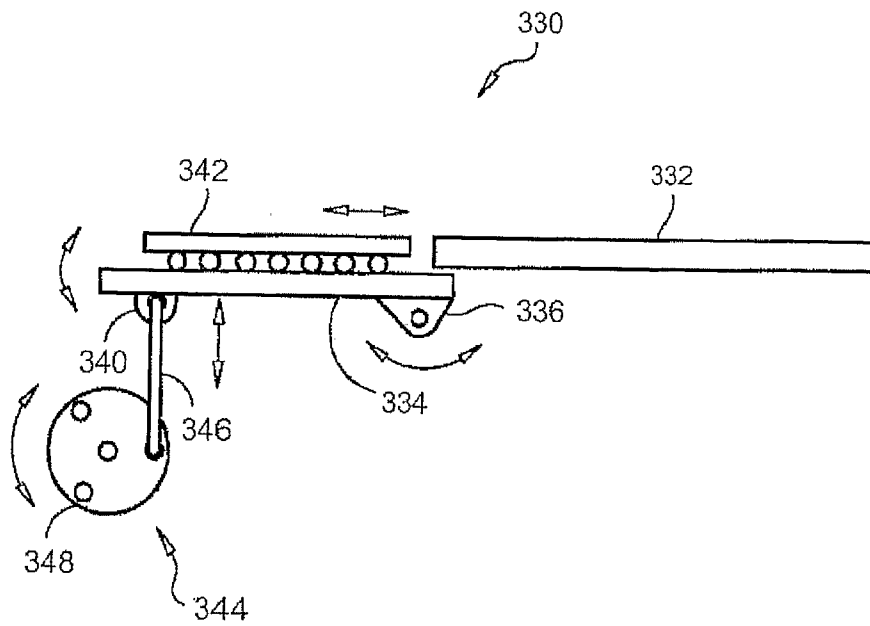


FIG. 14

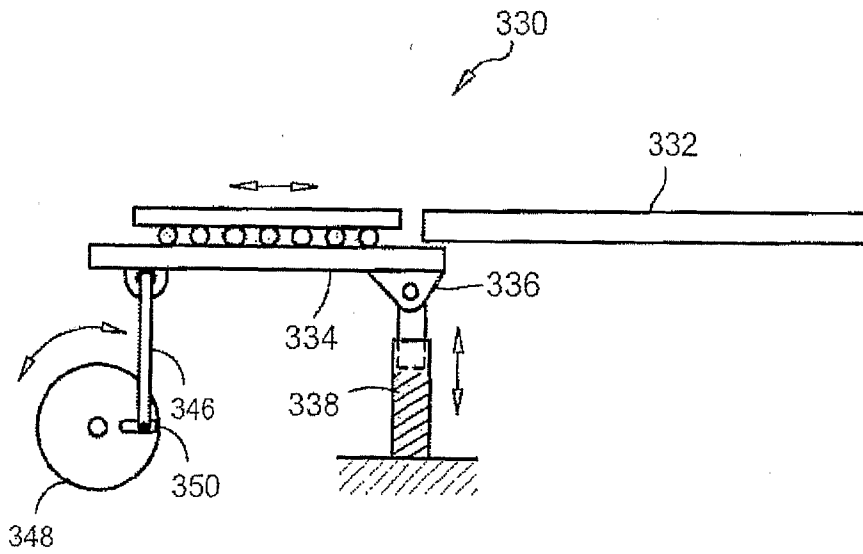


FIG. 15

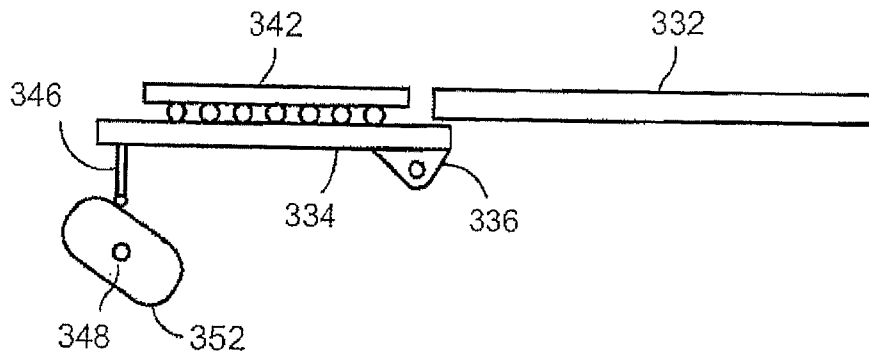


FIG. 16

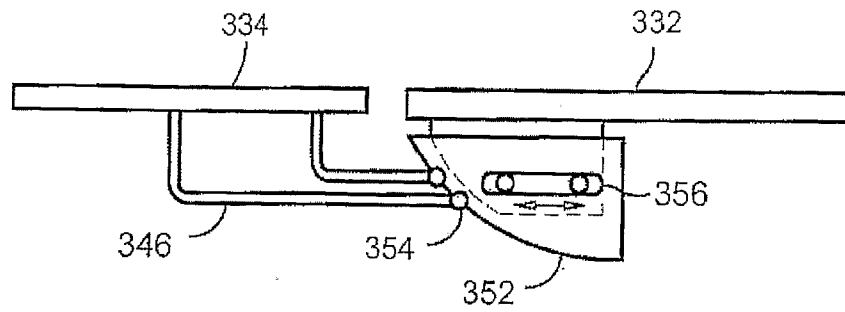


FIG. 17



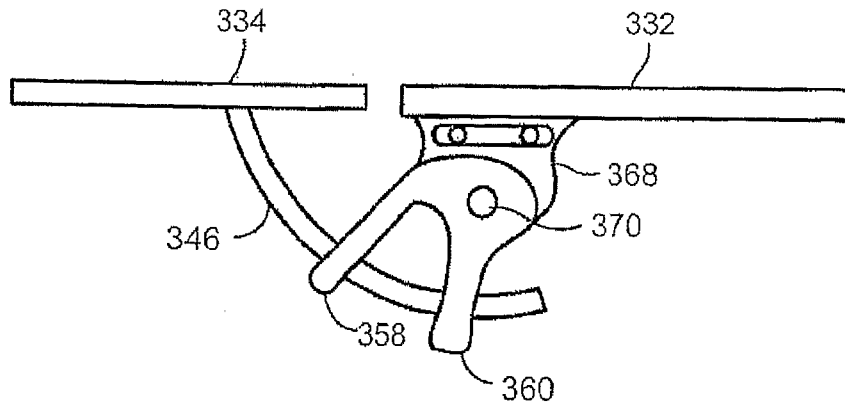


FIG. 18

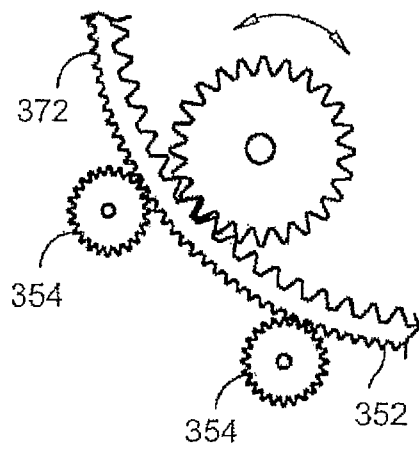


FIG. 19

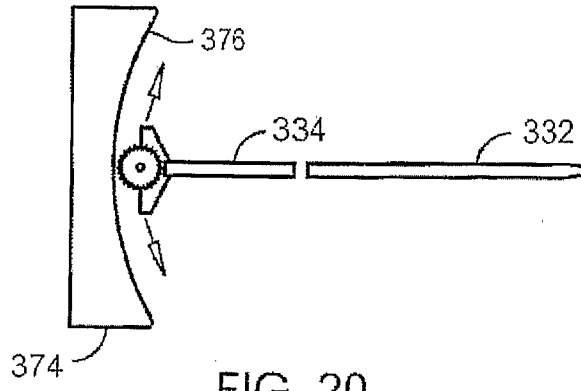


FIG. 20

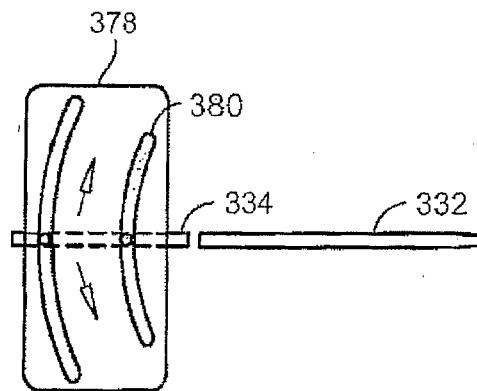


FIG. 21

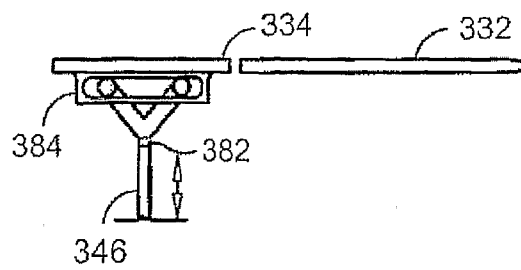


FIG. 22