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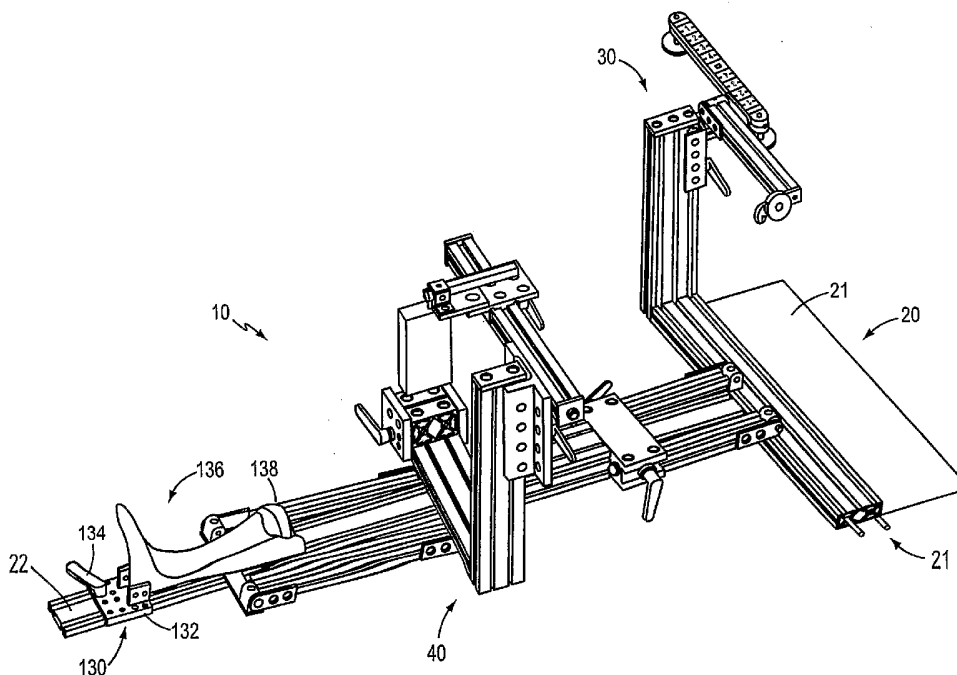
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(54) Title: METHOD AND APPARATUS FOR ALIGNING A KNEE FOR SURGERY OR THE LIKE



(57) Abstract: Generally described the invention relates to methods and apparatuses for aligning the lower extremities of a patient with a mechanical axis. More specifically, the present invention provides an exoskeleton or external framework that positions a patient's leg into a desired mechanical axis in preparation for surgery or other medical treatment.



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METHOD AND APPARATUS FOR ALIGNING A KNEE FOR SURGERY OR THE LIKE

Field of the Invention

The present invention is generally related to the manipulation of a leg to
5 provide surgery thereon or other medical attention thereto. More specifically, the
present invention provides an external frame, or “exoskeleton” to position the leg
into a desired axis in preparation for surgery or other treatment on the knee.

Background of the Invention

Damage to the weight-bearing surfaces of the knee as a result of arthritis
10 and/or trauma can be isolated to one compartment, or can be global (involving two
or more of the three compartments of the knee). The three compartments of the
knee are the patellofemoral compartment, the medial compartment and the lateral
compartment. When damage to the knee results in a change in the shape of the
underlying bone of the knee, the damage is permanent. Surface replacement
15 procedures such as a total knee arthroplasty (TKA) and a unicompartmental knee
arthroplasty (UKA) are typical corrective measures for this damage.

The natural biomechanics of the knee places the weight-bearing axis in a
position to allow approximately 60% of the weight bearing by the medial
compartment and 40% by the lateral compartment of the knee. This weight-
20 bearing axis is measured in the frontal plane and is a line drawn from the center of
the femoral head to the center of the ankle. Therefore, this line must fall slightly to
the medial side of the center of the knee to accomplish this weight-bearing
distribution. Load distribution across the knee corresponds to the relative surface
area of each compartment. That is to say, the medial compartment is generally
25 60% of the total bearing surface area of the knee. The body distributes this weight
optimally to maintain a certain amount of load per square inch of surface area.
When this load exceeds a certain level in one or the other compartment, overload
in that compartment occurs and damage ensues. The damage begins with articular
cartilage wear and can progress to flattening of the condyle with its resultant shape
30 change in the condyle.

When only one compartment in the knee has been damaged permanently, a unicompartmental knee arthroplasty or UKA is used to replace the damaged bone surface. This type of prosthesis has several common failure modes: 1) the side with the UKA fails due to poly wear or interface failure; 2) the opposite
5 compartment fails due to a substantial increase in arthritis; and 3) the femoral component impinges on the patella creating an impingement syndrome. Each of these failures can be attributed to misalignment of the implant. Therefore, there is great need when performing a UKA to implant the device such that the proper mechanical axis within the knee is recreated. Since every lower extremity is
10 unique, the mechanical axis must be uniquely reproduced for the best chance at long-term success. When installed in alignment with the proper axis, the UKA survival rate is greatly improved.

Total Knee Arthroplasty or TKA is a surgical procedure wherein both the lateral and medial compartments are replaced. The proper mechanical axis for
15 these procedures is also important to the long-term success of the implant.

Several prior art devices have been used for the purpose of establishing an axis for partial and total knee replacement surgery. One procedure involves forcing a metal rod into the end of the thighbone. The surgeon then uses this rod to estimate the proper angle for cutting the bone and installing the prosthesis. This
20 procedure has numerous disadvantages including inaccurate cutting of the bone resulting in incorrect placement of the prosthesis and blood clots that may occur from forcing the rod into the marrow of the thighbone to estimate the mechanical axis.

An additional method for aligning the bones for a knee replacement surgery
25 is a device called an intramedullary guidance system. This device takes measurements of the leg and calculates the proper alignment. However, the measurements tend to be inaccurate because they are taken from the somewhat deformable tissue covering the bone rather than the more rigid bone itself. As a result, the alignment measurements vary based on the amount of tissue covering
30 the bone.

Once the axis is estimated using one of the techniques described above, a cutting guide is secured to the bone, which requires multiple incisions. The securing process may weaken the bone and increase the recovery time.

An additional factor in the placement of a knee prosthesis is the natural amount of 'play' in the joint. This 'play' is defined as the natural amount of motion between the two bones of the joint allowed by the ligaments. In a knee joint with a lot of "play," incongruous joint surfaces will still allow full flexion and extension. On the other hand, a knee joint with very little 'play' must have perfectly shaped joint surfaces to allow full flexion and extension. One job of the surgeon during implantation of either a TKA or a UKA is the need to recreate the patient's normal amount of joint 'play'. This means the appropriate amount of ligament release and implant size must be used to allow for both the appropriate amount of 'play' and correction of the mechanical axis. The current known methods do not provide a method of determining the natural play of a joint.

Therefore there is a need for methods and apparatuses for the alignment of a leg for surgery or other medical attention that address deficiencies in the art, some of which are discussed above.

Summary of the Invention

The present invention provides improvements over the prior art by providing a method and apparatus for aligning a leg in order to facilitate surgery or medical treatment thereon.

Therefore it is an object of the present invention to provide an improved medial device and technique of using same.

It is a further object of the present invention to provide an improved method and apparatus for aligning a knee joint of a patient.

It is a further object of the present invention to provide an improved method and apparatus for aligning a knee of a patient for the purposes of knee replacement surgery.

It is a further object of the present invention to provide an improved method and apparatus for assessing the natural play associated with a knee joint.

It is a further object of the present invention to provide an improved method and apparatus for aligning the knee while in a bent condition.

It is a further object of the present invention to provide a method and apparatus to increase the speed of knee replacement surgery.

It is a further object of the present invention to provide an improved method and apparatus to reduce the number of persons required to perform a UKA or TKA.

It is a further object of the present invention to provide an improved method and apparatus to reduce the need for drilling into bone to secure cutting guides during knee replacement surgery.

5 It is a further object of the present invention to provide an inflatable bladder under the thigh to provide distraction of the knee joint when the leg is in the bent or flexion position.

10 In an aspect of the present invention, an apparatus is provided for identifying the mechanical axis of a leg of a patient to facilitate medical treatment thereon, the leg including a femoral head, and a foot portion which itself includes an ankle portion, the mechanical axis having a portion extending from the center of the femoral head to the center of the ankle, the apparatus including a base member including a spine portion and a head portion, the spine portion being substantially elongate and having a longitudinal axis, the head portion attached proximate one longitudinal end of the spine portion, a pelvic location assembly attached relative to the base member proximate the head portion, the pelvic location assembly including a femoral head location member configured to identify the approximate location the femoral head of the leg, the pelvic location assembly also configured to establish a first reference point positioned at a known location relative to the center of the femoral head, a carriage moveably attached relative to the spine portion and configured to be moved along a carriage path having a portion being substantially parallel to the longitudinal axis of the spine, and the carriage further configured to be selectively secured relative to the spine so as to discourage the relative movement between the carriage and the spine, a boot assembly pivotably attached relative to the carriage and configured to accept the foot portion of the leg and to establish a second reference point at a known location relative to the center of the ankle portion, and a mechanical axis indicator providing a visual indication of a portion of a reference axis passing through from the first reference point and through to the second reference point, such that the reference axis is within substantially the same plane as the mechanical axis.

30 In a further aspect of the present invention, an apparatus is provided for aligning a leg of a patient with a mechanical axis to facilitate medical treatment thereon, the leg including a femoral head, a thigh portion and a foot portion which itself includes an ankle portion, the mechanical axis having a portion extending from the center of the femoral head to the center of the ankle, the apparatus

including a base member including a spine portion and a head portion, the spine portion being substantially elongate and having a longitudinal axis, the head portion attached proximate one longitudinal end of the spine portion, a pelvic location assembly attached relative to the base member proximate the head portion, the pelvic location assembly including a femoral head location member configured to identify the approximate location the femoral head of the leg, the pelvic location assembly also configured to establish a first reference point positioned at a known location relative to the center of the femoral head, a carriage moveably attached relative to the spine portion and configured to be moved along a carriage path having a portion being substantially parallel to the longitudinal axis of the spine, and the carriage further configured to be selectively secured relative to the spine so as to discourage the relative movement between the carriage and the spine, a boot assembly pivotably attached relative to the carriage and configured to accept the foot portion of the leg and to establish a second reference point at a known location relative to the center of the ankle portion, a mechanical axis indicator providing a visual indication of a portion of a reference axis passing through from the first reference point and through to the second reference point, such that the reference axis is within substantially the same plane as the mechanical axis; a leg manipulation assembly attached relative to the spine portion between the pelvic location assembly and the boot assembly, the leg manipulating assembly having a first lateral force assembly and a second lateral force assembly the force assemblies being proximate the thigh portion and spaced apart to accept the leg therebetween and located proximate the knee joint, the first lateral force assembly being adjustable and selectably securable along an axis substantially perpendicular to the longitudinal axis of the spine and configured to urge discourage the leg into from moving away from a desired alignment with the mechanical axis identifier.

In another aspect of the present invention, an apparatus is provided for aligning a leg of a patient with a mechanical axis to facilitate medical treatment thereon, the leg including a femoral head, a thigh portion, a knee portion and a foot portion which itself includes an ankle portion, the mechanical axis having a portion extending from the center of the femoral head to the center of the ankle, the apparatus including a base member including a spine portion and a head portion, the spine portion being substantially elongate and having a longitudinal axis, the head portion attached proximate one longitudinal end of the spine portion, a pelvic

location assembly attached relative to the base member proximate the head portion, the pelvic location assembly including a femoral head location member configured to establish a first reference point positioned at a known location relative to the center of the femoral head, a carriage moveably attached relative to the spine portion and configured to move along a carriage path having a portion being substantially parallel to the longitudinal axis of the spine and further configured to be selectively secured relative to the spine so as to discourage the movement, a boot assembly pivotably attached relative to the carriage and configured to accept the foot portion of the leg and to establish a second reference point at a known location relative to the center of the ankle portion, a upper pivoting assembly having a first end pivotably attached relative to the spine portion proximate the head portion, a second end pivotably and moveably attached relative to the spine portion and a hinged portion positioned proximate the patient's knee between said first end and said second end such that when said patient's knee is in a bent condition, said second end moves relative to said spine portion and said hinge portion follows said knee such that said thigh support member also provides support to said thigh portion of said leg, a mechanical axis indicator providing a visual indication of a reference axis passing through said first reference point and through the second reference point, such that the reference axis is within substantially the same plane as the mechanical axis, and a leg manipulation assembly attached relative to the spine portion between the pelvic location assembly and the boot assembly, the manipulating assembly having a first lateral force assembly and a second lateral force assembly being spaced apart to accept the leg therebetween and located proximate the knee joint, the first lateral force assembly being adjustable and selectably securable in an axis substantially perpendicular to the longitudinal axis of the spine and configured to urge the leg into alignment with the mechanical axis identifier.

In a further embodiment of the present invention, an apparatus is provided that is configured to measure the clearance between the mating surfaces of the femur and a tibia at the knee joint, the apparatus being elongate with a substantially wedge shaped tip portion, the wedged shaped tip portion including indicia associated with a width at a distance spaced apart from the end of the wedge shaped tip.

It is to be understood that the inventions are not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the present invention. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

Other objects, features, and advantages of the present invention will become apparent upon reading the following detailed description of the preferred embodiment of the invention when taken in conjunction with the drawing and the appended claims.

10

Description of the Drawings

Fig. 1 illustrates certain bones in a typical human leg. As may be seen, the femur 2 extends from a pelvis 9, to a knee joint. A tibia 3 extends from the knee joint to an ankle (not shown). The mechanical axis (MA) is created by a line running through the femoral head and the center of the ankle 4.

Figs. 2A and 2B are other illustrative views of a leg of a patient and a portion of an embodiment of the present invention. This view may be considered a side plan view of a patient in a prone position and looking at the patient from the patient's right side.

20 Figs. 3A, B is an illustrative views of a portion (from the waist down) of a patient and a portion of an embodiment of the present invention. This view may be considered a top plan view of a patient in the prone position, looking down from above the operating table the patient is lying on.

Fig. 4 is a simplified drawing of a portion of apparatus 10 in accordance with one embodiment of the present invention.

Fig. 5 is a drawing of apparatus 10 shown in an extended configuration in accordance with an embodiment of the present invention.

Fig. 6 is a drawing of the pelvic location assembly 30 according to the present invention.

30 Fig. 7 is a drawing of a portion of the pelvic location assembly 30 showing the alignment line assembly 40 in accordance with one embodiment of the present invention.

Fig. 8 is a drawing of a portion of the apparatus 10 focusing on the upper pivoting assembly 50 in accordance with an embodiment of the present invention.

Fig. 9 is a drawing of a portion of the apparatus **10** focusing on the lower pivoting member **80** in accordance with an embodiment of the present invention.

Fig. 10 is a drawing of a portion of the apparatus **10** focusing on the support column **70** and the cutting guide mounting assembly **71** in accordance with
5 an embodiment of the present invention.

Fig. 11 is another view showing the cutting guide mounting assembly **71** similar to Fig. 10, but shows the cutting guide mounting assembly **71** in an extended state.

Fig. 12 is a drawing of the foot cradle assembly **136** without the carriage **90**
10 in accordance with one embodiment of the present invention.

Figs. 13A and 13B are drawings illustrating two embodiments of the measurement tool **150** in accordance with the present invention.

Fig. 14 is a drawing of an embodiment of the bladder assembly **160** in accordance with the present invention.

Fig. 15 is a flow diagram illustrating the steps of a method to align a leg in
15 accordance with an embodiment of the present invention.

Fig. 16 is a drawing of a portion of a tibia **300** illustrating two cut lines for an osteotomy procedure.

Figs. 17A and 17B illustrate cutting guides having slots therein in
20 accordance with an embodiment of the present invention.

Fig. 18 is a drawing of a tibia and a retention rod **330** in accordance with an embodiment of the present invention.

Fig. 19 is a drawing of a retention rod in accordance with an embodiment
of the present invention.

25

Detailed Discussion of the Present Embodiment

The present inventions now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the invention are shown. Indeed, these inventions may be embodied in many
30 different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like numbers refer to like elements throughout.

Many modifications and other embodiments of the inventions set forth herein will come to mind to one skilled in the art to which these inventions pertain having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the inventions are not to be limited to the specific embodiments disclosed and that modifications and other
5 embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

General Construction and Operation

10 Generally described, the invention relates to a method and apparatus for manipulating a human leg into a desired alignment in preparation for surgery or other medical treatment. Referring generally to Fig. 1, the mechanical axis MA of a patient's leg is created by a line stretching from the femoral head 1 of the femur 2 to the center of the ankle 4. In a preferred embodiment, an external framework, or
15 "exoskeleton" provides a visual indication of a reference axis which is within the same vertical plane as the proper mechanical axis MA. This framework also provides a means for manipulating the patient's leg into a desired alignment with the visual indication.

Preferably, a patient's leg is aligned with its mechanical axis when the
20 reference axis created by the present invention is positioned slightly to the medial side of the patient's knee. This alignment achieves an optimum weight distribution at the knee joint when the patient is standing. However, as one of ordinary skill will appreciate, any desired alignment with respect to the reference axis may be achieved using the present invention.

25 In addition to positioning the patient's leg into proper alignment, an embodiment of the present invention also provides an alignment feature for surgical cutting guides. In this embodiment, a patient's leg and a surgeon's cutting guides are held in an optimal relative position by an external framework. In the prior systems, the leg is manually restrained in its current position, which may or
30 may not be the proper mechanical axis. The surgeon then estimates the adjustment angle necessary to place the knee in its proper mechanical axis when the prosthesis is installed and adjusts the cutting guides accordingly. The success of the surgery is directly related to estimate made by the surgeon, which is dependent on the skill and experience of the surgeon. With embodiments of the present invention, the

surgeon no longer has to estimate the cut angle on the femur and tibia to achieve the proper mechanical axis **MA** to facilitate proper installation of a knee prosthesis because the optimum angle is established by the external framework. Thus, the consistency and accuracy of the cutting operation is improved with the use of
5 embodiments of the present invention.

Reference is now made to Figs. 3A and 3B to further discuss the general operation of the invention. This figure shows a patient's legs in a prone position; the leg designated as **5** has a thigh portion **6**, an ankle portion **7** and a foot portion **8**. The preferred mechanical axis **MA** for the patient's leg **5** is created by a line
10 running through the femoral head **1** and the center of the ankle **4**. Because the femoral head **1** is not detectable from outside the body, a skeletal reference point that is detectable from outside the body is chosen to aid in locating the femoral head **1**. Preferably, the anterior superior iliac spine, which is the bony prominence of the pelvis (i.e. edge of the pelvis **9**), is chosen as the skeletal reference point.
15 An X-ray of the patient is used to determine the distance "d" from the skeletal reference point to the femoral head **1**. This distance "d" is used to approximate the location of the femoral head based on the skeletal reference point on the patient's body. A reference axis is then created using a cable, string, or laser that is within the same plane as the mechanical axis **MA** which passes through the femoral head
20 and the center of the ankle.

As best shown in Fig. 3A, the patient's leg **5** may not be in alignment with the mechanical axis **MA** prior to treatment. To place the leg in proper alignment, a force is applied in the direction of vector "F." Fig. 3B illustrates an aspect of the present invention where an inflated bladder creates a lateral force in the direction
25 of vector **F** to urge the leg into alignment with the reference axis and therefore the preferred mechanical axis.

Turning to Figs. 2A and 2B, a further aspect of the present invention is illustrated where the leg **5** of the patient may be bent without losing alignment with the mechanical axis **MA**. As illustrated, leg support is provided by the external
30 framework proximate the thigh portion of the leg thereby securing the knee in both the straight and bent positions. Additionally, an inflatable bladder may be positioned under the thigh to allow the surgeon to selectively distract the knee joint by inflating/deflating the bladder. These features allow the surgeon to bend the

knee to a desired degree to provide access to the cut portions of the tibia and femur as discussed in greater detail elsewhere in this application.

When a surgeon is performing a partial knee replacement, it is important that the distance between the bearing surfaces of the femur 2 and the tibia 3 is
5 consistent. Therefore, a surgeon measures the distance between the undamaged bearing surfaces of the knee and replicates that distance with the prosthesis. In an additional aspect of the present invention, a tool is provided for measuring this distance.

Referring to Fig. 13A, a measurement tool 150 is provided for measuring
10 the natural play in a knee joint. The measurement tool 150 is generally elongate and has a wedge-shaped measuring portion 152 wherein indicia representing the width of the wedge at different distances from the tip are provided.

In use, the leg of the patient is positioned in straight condition and distracted by applying a force proximate the foot directed away from the patient's
15 torso. The detraction preferably extends the ligaments of the knee to their maximum length. The wedge-shaped measuring portion 152 of the measuring tool 150 is placed between the bearing surfaces of the femur and tibia until the surfaces of the wedge contact both bearing surfaces. The surgeon reads the indicia corresponding with the depth of the wedge to determine the distance between the
20 bearing surfaces. From this measurement, the surgeon can calculate the amount of bone to remove to achieve the same "play" with the prosthetic joint. Fig. 13B illustrates an alternative embodiment of the measurement tool 150 where the tool takes a more ergonomic shape.

More Detailed Discussion

25 **Apparatus 10**

The apparatus 10 is shown generally in Figs. 4 and 5. This apparatus 10 is used to manipulate a leg of a user (not shown) in order to provide medical attention thereto. Generally described, the apparatus 10 includes a stationary base 20, a pelvic location assembly 30, a leg manipulation assembly 40, an upper pivoting
30 assembly 50, a lower pivoting member 80, a carriage 90, and a foot assembly 130.

Stationary Base 20

The stationary base 20 is configured to be positioned atop a stationary, substantially horizontal surface, which may be a floor, a suitable medical table, or the like. This stationary base 20 is substantially rigid, and includes a planar head portion 21 fixed to a spine member 22. The planar head portion 21 is configured to support the posterior of a patient (not shown). Padding or the like may be positioned atop the planar head portion as desired. The spine member 22 is essentially elongate, and is configured to accept various carriages to slide along at least a portion of its length as discussed later in this application.

10 Pelvic Location Assembly 30

Turning to Fig. 6, the pelvic location assembly 30 is attached to the planar portion 21 of the base 20, and is generally configured to provide the surgeon with a means for locating a point proximate the pelvic region of the patient. The pelvic location assembly 30 is attached to the base 20 on the side corresponding with the leg requiring treatment using locating pins 24 and fixing member 25. In the embodiment shown in Fig. 6, the pelvic location assembly 30 is attached to the right side of the base 20. But, as one of ordinary skill in the art will appreciate, the location assembly 30 may be positioned on the opposite side of the base 20 as desired.

20 The vertical support member 32 of the pelvic location assembly 30 is substantially elongate and has a vertical longitudinal axis. The lower end of the vertical support member 32 is rigidly attached to the stationary base 20, although it may be removed and reattached to the other side as necessary. Proximate the upper end of the vertical support member 32 is attached an adjustable frame member 34. This adjustable frame member 34 is configured to be rigidly attached relative to the vertical support member 32, but also adjustable along a portion of its length. Various members, including a skeletal reference location bar 36 and an alignment line assembly 40 are supported by the vertical support member 34. A skeletal reference locator 38 is located at each end of the skeletal reference location bar 36. As discussed elsewhere in this application, the skeletal reference locators 38 are configured to contact a certain portion of the body directly above a skeletal reference point, such as the anterior superior iliac spine.

As shown in Fig. 7, the alignment line assembly 40 includes an elongate member 41, an alignment reel 42, and an alignment line 43. The elongate member 41 has one end pivotably attached relative to the adjustable frame member 34, and has its opposing end attached to and supporting the alignment reel 42 and associated alignment line 43.

As discussed in detail later, the alignment line 43 when extended is used to provide a visual indication of a reference axis that is preferably substantially within the same vertical plane as the mechanical axis of the leg requiring treatment. An X-ray is taken of the patient and the distance between a skeletal reference point and the femoral head 1 is determined. The location bar 36 is adjusted according to the determined distance using the scale positioned thereon. After the patient is positioned in the apparatus with their skeletal reference point adjacent the reference locator 38, the alignment reel 42 will be positioned proximate the center of the femoral head of the leg receiving treatment. In other words, the skeletal reference locator 38 is positioned a distance "d" from the alignment reel 42 using the scale located on the location bar 36.

Leg Manipulation Assembly 40

As shown in Fig. 5, the leg manipulation assembly 40 is configured to provide at least two functions. One function is to allow for suitable alignment of the leg, and the second function is to allow the leg to be bent into a position for surgical treatment while maintaining alignment. Referring generally to Fig. 4, for example, the leg manipulation assembly 40 generally includes an upper pivoting assembly 50, a lower pivoting member 80, and a carriage 90.

Upper Pivoting Assembly 50

Turning to Fig. 8, the upper pivoting assembly 50 is configured to be pivotably attached relative to the base 20 at pivot points P1. The upper pivoting assembly 50 is generally T-shaped. This member 50 includes a pair of lower parallel frame elements 54, an upper frame element 56, a connecting plate 58, a pair of length adjustment members 60 and a transverse member 62. The lower parallel frame elements 54 are each substantially elongate and have parallel longitudinal axes. The upper frame element 56 is likewise substantially elongate and has a longitudinal axis substantial parallel to those of the lower parallel frame elements 54. The connecting plate 58 attaches to the upper ends of the lower parallel frame elements 54. The length adjustment members 60 are configured to

provide selective gripping between the lower frame elements **54** and the upper frame element **56**, such that the overall length of the T-shaped upper pivoting assembly **50** may be varied as desired.

As shown in Fig. 10, the upper pivoting assembly **50** also includes an adjustable lateral force member **64** that includes a carriage **66**, a padded flange **67** and a fixing member **68**. As will be discussed elsewhere in this application, the carriage **66** allows for adjustment of the support member **64** relative to the transverse member **62** to facilitate manipulation of the leg. The fixing member **68** fixes the carriage **66** relative to the transverse member **62**. Preferably, the longitudinal position of the lateral force member **64** is above the knee joint proximate the thigh portion of the patient's leg as is generally shown in Fig. 2A and 2B.

In a preferred embodiment, the lateral force member **64** is selectively locked in a position proximate the patient's leg and an inflatable bladder is positioned between the lateral force member **64** and the leg. The leg is urged away from the lateral force member **64** and into a desired alignment with the reference axis when the bladder is inflated, as will be discussed in greater detail later. Alternatively, a force may be applied to the lateral force member **64** in an axis parallel to the transverse member **62** and in the direction of the leg. This force will urge the leg is into a desired alignment with the reference axis after contact is made. At this point, the lateral force member may be selectively locked in place.

The upper pivoting assembly **50** also includes a support column **70** that extends from one end of the transverse member **62**. Supported by the support column **70** is a cutting guide mounting assembly **71**. This assembly **71** includes a cross member **72**, an adjustment bracket **73**, and a cutting guide mounting member **74**. The cutting guide mounting member **74** will be discussed in more detail elsewhere in this application, as it provides a mounting structure for a cutting guide that aids the surgeon is cutting the femur and tibia in a desired axis and contour relative to the preferred mechanical axis.

30

Lower Pivoting Member 80

Referring to Fig. 9, the lower pivoting member **80** has one end pivotably attached to the upper pivoting assembly **50** at pivot point **P2** and has an opposite end attached relative to a carriage **90** at pivot point **P3**. The lower pivoting member **80** could be considered "H-shaped," in that it includes two parallel frame members **81** and a connecting cross member **82**.

The lower pivoting members **80** are pivotably attached relative to the carriage **90** at pivot point **P3**. This carriage **90** is slidably mounted along the longitudinal axis of the spine member **22** of the stationary base **20**. Alternatively, a ball bearing construction could be used as illustrated by the exemplary ball bearing **91**. As may be understood, as the carriage **90** moves along the length of the spine member **22**, a pivoting action is provided between the upper pivoting assembly **50** and the lower pivoting member **80**, such as is illustrated by reference to the positions shown in Figs. 4 and 5. This allows the leg positioned thereon to be bent to a greater or lesser degree as desired.

Foot Support Assembly 130

Returning to Figs. 4 and 5, the foot support assembly **130** is adjustably attached relative to the spine member **22**, such that it can be slid relative to, yet fixed to, the spine member **22** as desired. The foot support assembly **130** includes a carriage **132**, a fixing member **134**, a pivot pin **135**, and a foot cradle assembly **136**.

The carriage **132** provides a sliding action intermediate the foot support assembly **130** and the spine member **22**. The fixing member **134** provides a fixing feature to fix the carriage **132** relative to the spine member **22**.

Turning to Fig. 12, the foot cradle assembly **136** is configured to accept a foot of a patient (not shown) and includes a retention strap **138** configured to retain the foot as and an attachment bracket **140**. The attachment bracket **140** is configured to engage a pivot pin **135** on the carriage **132** such that a pivoting action is provided. By using a hook configuration, retention of the foot is provided while still allowing the foot to rotate about the axis of the pivot pin **135** when the leg is moved from its extended to its bent position. Furthermore, this attachment means also facilitates the application of a force on the leg of the patient along the axis of the spine away from the torso of the patient in order to stretch the knee joint ligaments and distract the knee joint.

Bladder Assembly 160

Working in conjunction with the rigid elements described above, a bladder assembly 160 provides a force to position a patient's leg into alignment as shown in Figs. 3A and 3B.

5 Turning to Fig. 14, the bladder assembly 160 generally includes a bladder 162, a retention sleeve 163, a tube 164, a bulb 165 and a valve 166. The bladder 162 is generally rectangular with the retention sleeve 163 attached thereto. The retention sleeve 163 is configured to slide over the padded flange 67 or attach to the support column 70. The tube 164 provides fluid communication between the
10 bladder 162 and the bulb 165. Valve 166 controls the flow of air into and out of the bulb 165. As one of skill in the art will recognize, to inflate the bladder 162, the valve 166 is adjusted to allow air to flow in one direction into the bulb 165. As the bulb 165 is squeeze and released, air is forced into the bladder 162. To deflate the bladder 162, the valve 166 is adjusted to allow air to escape. The selective
15 inflation and deflation of the bladder 162 allows the surgeon to position the patient's leg as desired.

Method of Operation

As previously described, the present invention is generally used to position a patient's leg into a desired alignment for surgery and/or treatment of the knee
20 joint. The following paragraphs will describe the method of operation for an embodiment of the present invention.

With reference to Fig. 15, the process begins at Step 200 where an X-ray of the patient is taken to determine the distance from a skeletal reference point to the femoral head of the leg requiring treatment. Preferably, the skeletal reference point
25 is the anterior superior iliac spine.

Meanwhile, the apparatus 10 is placed on a substantially horizontal support surface such as the floor, a hospital bed or table at Step 210. Preferably, the weight of the patient will secure the device to the support surface. Alternatively, the device may be secured to the support surface with attachment brackets, straps or
30 any other method of securing known in the art. The pelvic location assembly 30 is secured to the planar head 21 of the stationary base 20 on the side corresponding with the leg to be treated using securing member 25 and locating pins 24. In other words, if the right leg of the patient is being treated, the pelvic location assembly 30 is secured to the right side of the planar head 21. Then, the skeletal location bar 36

is adjusted according to the distance measurement from Step 200 using the scale located thereon.

At Step 220, the patient is positioned with his posterior on planar head 21 of the stationary base 20. The leg to be treated is positioned substantially parallel to the spine member 22 and between the adjustable lateral force member 64 and the support column 70. The patient is positioned such that the skeletal reference point on the patient's body is positioned proximate the skeletal locator 38. The upper pivoting assembly 50 is adjusted along its length such that the pivot axis PA2 is positioned proximate the knee of the patient.

10 The foot support assembly 130 is moved along the spine member 22 to allow the patient's foot 8 to be position therein. The patient's foot 8 is secured to the foot cradle assembly 136 using retention strap 138. The knee joint is then placed in tension by exerting a force on the foot support assembly 130 in a direction away from the patient's torso along the axis of the spine 22 and the foot
15 cradle assembly 136 is secured to the spine member 22. This tension preferably extends the knee ligaments to their maximum length. At this point, the setup of the apparatus is complete and ready for determining the proper mechanical axis MA of the patient's leg 5.

At Step 230, the proper mechanical axis of a human leg is determined. To
20 establish a reference axis within substantially the same vertical plane of the mechanical axis of the patient's leg, the elongate member 41 is pivoted towards the body and stops parallel with the skeletal reference location bar 36. Because the patient is positioned with the skeletal reference locator 38 proximate the skeletal reference point, the alignment reel 42 at the end of the elongate member 41 is
25 located proximate the center of the femoral head of the leg receiving treatment when rotated into place. The alignment line 43 is then extended from the alignment reel 42 to the foot cradle assembly 136 to provide a visual indication of the reference axis. This reference is substantially within the same plane as the mechanical axis MA for the patient.

30 After identifying the proper mechanical axis MA for the patient's leg 5, the leg 5 is urged into a desired alignment with this visual axis at Step 240. To accomplish this alignment, a bladder assembly 160 is positioned on the lateral force member 64 and the support column 70. The bladder assemblies 160 are selectively inflated and contact a portion of the leg above the knee and proximate

the thigh. The selective inflation urges the leg into alignment with reference axis and therefore into a desired alignment with the mechanical axis. Preferably, the patient's leg is positioned in a desired alignment with the reference axis when the reference axis is slightly to the medial side of the knee portion of the leg. At this
5 step in the process, the leg is held in the proper mechanical axis as indicated by the reference axis established in Step 230. After the leg is secured in the proper mechanical axis by the external framework, the alignment line 43 may be retracted into the alignment reel 42 and the surgical procedure and/or treatment may begin.

As discussed earlier in this application, a typical surgical procedure on the
10 knee joint is the application of a prosthesis for all or a portion of the bearing surfaces. To accommodate a prosthesis, all or a portion of the bearing surfaces of the femur and tibia must be removed as shown in Fig. 1.

The Unicompartmental knee or partial replacement requires that a portion of the medial tibia and the medial femoral condyle be removed to accommodate
15 the new bearing surface. The cuts in the end of the tibia and the end of the femur are preferably perpendicular to the mechanical axis and thus necessarily parallel to each other when the knee is in full extension. Further cuts in the end of the femur may be necessary to accommodate the typically curved femoral bearing surface or femoral prosthesis which is typically made from metal but could be fashioned from
20 other materials including human tissue. With a unicompartmental knee replacement there is always a sagittal or side cut which extends from the usual planar cut at the end of the bone into the joint such that only half of the distal femur and half of the proximal tibia is cut.

The Total Knee Replacement requires that the entire proximal tibia and the
25 entire distal femur be cut in order to accommodate for the new tibial and femoral bearing surface or prosthesis. Again there may be necessary cuts in the femur to bevel the end of the femur to accommodate for a bearing surface or prosthesis that is curved in nature. Certainly, the cutting guide mounting assembly 71 could accommodate other cutting guides for removal of small portions of the joint for
30 smaller or partial surface bearing replacements to occur.

Before making any cuts to the bone, the surgeon will determine the amount of clearance in the joint needed for proper operation of the prosthesis. At Step 250, the clearance between the femur and the tibia of an undamaged portion of the knee is measured using the measurement tool 150. If the surfaces of the knee requiring

treatment are damaged for example for a total knee replacement, the surgeon may measure the spacing in the other knee to use as a reference.

To check the “play” in the knee joint, the patient is positioned in the apparatus 10 with the leg receiving treatment aligned with the proper mechanical axis and distracted. The measurement tool 150 is positioned between the bearing surfaces of the femur and tibia to determine the distance between the bearing surfaces. From this measurement, the surgeon can calculate the amount of bone that needs to be removed from the ends of the femur and tibia for proper positioning of the prosthesis. This calculation includes the space required by the prosthesis plus the distance measured between the bearing surfaces. For example if one millimeter of joint clearance is desired and the overall thickness of the prosthesis is twenty millimeters, then ten millimeters of tibia and eleven millimeters of femur will be removed to achieve the desired 1 mm clearance.

To assist the surgeon in determining the proper amount of bone to remove, a spacer having the thickness of the desired joint play may be inserted between the bearing surfaces of the prosthesis joint. Using this technique, the surgeon simply measures the prosthesis with the spacer in place to obtain the space necessary to receive the prosthesis and to create the optimum joint play. The spacer itself may be made of a conventional dissolvable material and attached to one of the bearing surfaces of the prosthesis joint. In this embodiment, the desired joint play will be present when the spacer dissolves shortly after the surgery. Additionally, the dissolvable space may include an antibiotic or other factors that release as the spacer is dissolved to promote the healing of the knee. Alternatively, the spacer may be made of a non-dissolvable material such as metal or plastic and remove by the surgeon after insertion of the prosthesis.

In preparation for removing bone, the cutting guide mounting member 74 and the adjustment bracket 73 are adjusted to position cutting guides proximate the proximal end of the tibia at Step 260. These cutting guides are preferably held perpendicular to the mechanical axis MA. A cutting saw or routing tool is then used to remove the desired amount of bone from the tibia. This procedure is repeated for the distal end of the femur.

After the cuts are made, the cut surfaces must be shaped to accept the prosthesis at Step 270. Typically this requires beveling the cut surfaces of the bone. To accomplish this task, the leg is positioning by the apparatus 10 in the bent condition. The fixing member 134 of the foot support assembly 130 is release
5 and the leg manipulation assembly 40 is pivoted upwardly by directing a force at pivot point PP2 in an upward direction. This causes the foot support assembly 130 and the carriage 90 to slide along the spine member 22 toward the patient's torso. After the desired degree of bend is achieved, the fixing member 134 secures the foot cradle assembly 130 to the spine member 22 while still allowing the foot
10 cradle assembly 130 to pivot relative the pivot pin 135. As may be understood, a bladder may be positioned under the thigh when the leg is in the bent position in order to provide distraction to the knee to allow for finishing cuts on the bone and/or installation of various prosthetic devices.

A conventional beveling tool is then used to shape the cut ends of the bone
15 to accept the prosthesis. These tools typically use the cut surface as a guide for the beveling operation. After beveling and with the knee in a bent position, the prosthesis is positioned on the cut surfaces of the tibia and femur. The leg is then returned to a straight condition and the ligaments of the knee compress the prosthesis.

20 Variations

As may be understood, the present invention contemplates variations in configuration and use. For example, instead of using bladders to position the knee, a force may be applied directly to the adjustable lateral force member 64 and therefore onto the leg until the leg is in alignment with the proper mechanical axis
25 MA. In this embodiment, lateral force members 64 are slideably attached to transverse member 62 such that the patient's leg would be positioned between the two support members 64. Referring briefly to Fig. 3A, the two padded flanges 67 are placed against the medial and lateral aspect of the distal femur. Using these two padded flanges the knee is pushed or pulled such that the leg is urged into
30 alignment with its proper mechanical axis MA. Each flange is then locked into place on the transverse member 62 using fixing members 68. This assures that the knee will remain in the patient's optimal mechanical position. It also allows the cross member 72 of the apparatus 10 to remain in a plane perpendicular to the patient's knee allowing surgical cuts to be made accurately with respect to the

mechanical axis MA. Additionally, during the surgical procedure, conventional skin and/or soft tissue retractors can be attached to these medial and lateral pads to allow easy and assistant-free access to the inside of the knee.

In a further variation, a routing tool may be to the external frame instead of cutting guides as described elsewhere in this application. In this embodiment, the knee is positioned in the apparatus 10 such that the leg is fully extended and aligned with the mechanical axis as described above. Once the knee is properly aligned in the device, an operating arm supporting the routing tool is attached to the support column 70 such that the arm is fixed in a plane perpendicular to the mechanical axis MA and lies anterior to the knee. This operating arm can be moved superiorly and inferiorly along the MA. It can also move anterior and posterior relative to the knee. During these movements, the arm preferably remains perpendicular to the MA of the leg.

Generally, a "flat walled" drill or router bit is used which has a substantially round and constant cutting circumference. By rotating the router bit about its longitudinal axis and moving it along an axis perpendicular to its rotational axis, a flat wall may be formed on the bone if the router is drawn past an uneven surface.

An end and side cutting bit attached to a high speed drill or router can be attached to the operating arm such that it can slide medial and lateral along the line of the arm. When the drill is lowered to a bone in the knee and the drill is moved along the operating arm medial and lateral, the end and side cutting bit will create a flat surface cut in the bone along the plane that is perpendicular to the mechanical axis. As the bit is lowered more and more posteriorly the bone can be cut in two leaving the end of the bone perfectly flat with a surface that is perpendicular to the MA. Thus, when the patient is standing the flat cut at the end of the tibia and the end of the femur will be generally parallel to the floor.

As an alternative, the routing tool could be made to rotate about a fixed position on the operating arm thereby creating a cutting arc which is preferably perpendicular to the MA.

Typically, the tibia is cut first followed by the femur. The exact distance between the distal femoral cut and the proximal tibia cut should equal the thickness of the knee prosthesis to be inserted plus the amount of normal play desired in the joint.

Once the end of the femur is cut in the above fashion it must be shaped to fit the prosthesis. In the apparatus 10, the femur is lifted up and the knee bent and rigidly fixed. Once in this position, the foot support assembly 130 is secured to the spine member 22. A bladder is inflated underneath the thigh such that the thigh is moved away from the upper pivoting assembly causing the femur to be lifted away from the proximal tibia. This creates a distraction force that lifts the end of the femur off of the tibia.

Once the knee is bent and distracted, the cut ends of the femur and tibia can be shaped or a secondary cut made so the cut surfaces of the bone conform to the mating surfaces of the prosthesis. For example, an end and side cutting bit can be positioned in a routing tool to create the necessary flat surfaces relative to the original cut surface of the femur for any and all varieties of knee prosthesis.

In some situations, a patient may not be able to extend the knee completely, resulting in a condition known as "flexion contracture." Assuming that the knee has a 10 degree bend in it, the surgeon can bisect the remaining bend and pivot the router about the operation arm 5 degrees in order to provide a cut on the tibia. Typically the leg will then fall into a straight position and the surgeon can continue as described elsewhere. The initial cut to the tibia can, if needed, be revisited and re-cut if needed.

In addition to total or unicompartmental knee arthroplasty, the present invention may be used in an osteotomy procedure which is performed to correct a varus or valgus deficiency. With reference to Fig. 16, a conventional osteotomy procedure includes removing a wedge portion 304 from the tibia 300 at a location space apart from the bearing portion 302 of the tibia 300. After the wedge portion is removed, the bearing portion 302 is reattached to the remaining tibia 300 using a metal plate and screws. To facilitate the proper wedge shape, a cutting guide providing a wedged shaped template as shown in Fig. 17A may be positioned using an embodiment of the present invention.

In addition to the wedge shaped cut, domed or arcuate cut osteotomy procedures have been performed, but with limited success due to the difficulty in achieving an arcuate cut manually. An embodiment of the present invention provides a cutting guide with an arcuate slot as shown in Fig. 17B and an external frame to position the cutting guide to improve the accuracy of the domed or arcuate cut.

In the domed cut osteotomy, an arcuate cut **321** is made in tibia **320** as best shown in Fig. 18. The bearing surface portion **322** of the tibia **321** is then rotated into the desired location. To secure the two portions of the tibia in a desired location, a retention rod **330** is used.

5 Referring to Fig. 19, the retention rod is a generally "T" shaped member having a transverse head portion **331** and an elongate portion **332**. The transverse portion **331** is configured to accept convention fasteners. The elongate portion **332** includes a plurality of slots **333** configured to accept convention fasteners while still allowing movement in a direction parallel with the elongate axis of the
10 retention rod **330**. As one of ordinary skill in the art will appreciate, any number of fasteners may be used to secure the rod **330** to the bone. Furthermore, the rod shape may be formed to follow more closely the contour of the bone as desired.

After the two portions of the tibia are positioned in a desired location, the elongate portion of the retention rod **330** is partially inserted into the tibia as
15 generally shown by dashed lines in Fig. 18. Fasteners **336** are driven into the tibia **320** and through the slots **333** to secure the retention rod **330** to the tibia **320** while still allowing movement of the rod in its longitudinal axis. The bearing surface portion **322** of the tibia **320** is secured to the head portion **331** of the retention rod **330** using convention fasteners.

20 The domed cut osteotomy procedure is beneficial because there is minimal loss in tibia length and there is greater surface contact area for healing than with the wedge cut procedure. Furthermore, the retention rod attachment discourages relative movement of the tibia **320** and the bearing surface portion **322** both rotationally and laterally in a plane perpendicular to the longitudinal axis of the
25 rod. However, this attachment method allows some movement in the axis parallel to the retention rod **332** due to the use of slots **333** to attach the rod to the tibia **320**.

Adjustments

The present invention has several adjustments to accommodate a variety of patient sizes and shapes. During the initial setup, the foot cradle assembly **130**
30 may be adjusted along the length of the spine member **22** to accommodate varying leg lengths. Similarly, the length of the upper pivoting assembly **50** may be adjusted to position the pivot point PP2 under the knee. This allows the invention to accommodate patients with different femur lengths.

The pelvic location assembly **30** also provides adjustments for varying waist measurements. As discussed earlier in this application, the adjustable frame member **34** allows for vertical adjustment of the skeletal reference location bar **36** along the length of the vertical support member **32** to accommodate girth variations between patients.

The present invention also includes provisions for adjusting the location of cutting guides. These provisions include a vertical adjustment of the cutting tool mounting assembly **71** that allows the surgeon to position the guides at a desired distance above the knee joint. The cutting guide mount assembly **74** itself also provides adjustments laterally (i.e. perpendicular to the elongate axis of the leg) and longitudinally (i.e. parallel elongate axis of the leg) allowing the surgeon to position the guides as desired.

Additionally, the apparatus may be configured for use on either leg. This is accomplished by moving the pelvic location assembly **30** from one side of the planar head **21** to the other. In other words, if the right leg of the patient is being treated, the pelvic location assembly **30** is secured to the right side of the planar head **21**.

To position the pelvic locating assembly **30**, the present invention provides two locating pins **24** on each side of the planar head **21** as best shown in Fig. 6. The pelvic location assembly is configured to accept the locating pins and provides a securing member **25** to retain the pelvis location assembly **30** to the planar head **21** of the stationary base **20**.

That which is claimed:

1. An apparatus for identifying the mechanical axis of a leg of a patient to facilitate medical treatment thereon, said leg including a femoral head, and a foot portion which itself includes an ankle portion, said mechanical axis having a portion extending from the center of said femoral head to the center of said ankle, said apparatus comprising:

a base member including a spine portion and a head portion, said spine portion being substantially elongate and having a longitudinal axis, said head portion attached proximate one longitudinal end of said spine portion;

a pelvic location assembly attached relative to said base member proximate said head portion, said pelvic location assembly including a femoral head location member configured to establish a first reference point positioned at a known location relative to the center of said femoral head;

a carriage moveably attached relative to said spine portion and configured to be moved along a carriage path having a portion being substantially parallel to said longitudinal axis of said spine, said carriage further configured to be selectively secured relative to said spine so as to discourage said relative movement between said carriage and said spine;

a boot assembly pivotably attached relative to said carriage and configured to accept said foot portion of said leg and to establish a second reference point at a known location relative to the center of said ankle portion; and

a mechanical axis indicator providing a visual indication of a portion of a reference axis passing from said first reference point to said second reference point, said reference axis is within substantially the same plane as said mechanical axis.

2. The apparatus of Claim 1, wherein said mechanical axis indicator comprises a retractable wire configured to have a free end attachable to said boot assembly at a location proximate said second reference point.

3. The apparatus of Claim 1, wherein said mechanical axis indicator comprises a visible laser.

4. The apparatus of Claim 1, wherein said moveable attachment is a sliding attachment allowing said carriage to slide relative to said spine portion such that the knee bends.

5 5. The apparatus of Claim 1, wherein said moveable attachment is a rolling attachment allowing said carriage to roll relative to said spine portion such that the knee bends.

6. The apparatus of Claim 1, wherein said base member defines a support surface for the posterior of said patient that is substantially horizontal, and wherein said plane containing said reference axis and said mechanical axis is substantially vertical.

7. The apparatus of Claim 1, wherein said carriage includes a pin oriented in a plane perpendicular to said longitudinal axis of said spine portion, and wherein said boot assembly includes an attachment bracket with a hook portion that is configured to engage said pin on said carriage such that said boot assembly pivots as said carriage moves relative to said spine portion.

20

8. An apparatus for aligning a leg of a patient with a mechanical axis to facilitate medical treatment thereon, said leg including a femoral head, a thigh portion and a foot portion which itself includes an ankle portion, said mechanical axis having a portion extending from the center of said femoral head to the center of said ankle, said apparatus comprising:
- 5 a base member including a spine portion and a head portion, said spine portion being substantially elongate and having a longitudinal axis, said head portion attached proximate one longitudinal end of said spine portion;
- 10 a pelvic location assembly attached relative to said base member proximate said head portion, said pelvic location assembly including a femoral head location member configured to establish a first reference point positioned at a known location relative to the center of said femoral head;
- 15 a carriage moveably attached relative to said spine portion and configured to be moved along a carriage path having a portion being substantially parallel to said longitudinal axis of said spine, said carriage further configured to be selectively secured relative to said spine so as to discourage said relative movement between said carriage and said spine;
- 20 a boot assembly pivotably attached relative to said carriage and configured to accept said foot portion of said leg and to establish a second reference point at a known location relative to the center of said ankle portion;
- a mechanical axis indicator providing a visual indication of a portion of a reference axis passing from said first reference point to said second reference point, such that said reference axis is within substantially the same plane as said mechanical axis; and
- 25 a leg manipulation assembly attached relative to said spine portion between said pelvic location assembly and said boot assembly, said leg manipulating assembly having a first lateral force assembly and a second lateral force assembly said force assemblies being proximate said thigh portion and spaced apart to accept said leg therebetween, said first lateral force assembly being
- 30 adjustable and selectably securable along an axis substantially perpendicular to said longitudinal axis of said spine and configured to discourage said leg from moving away from a desired alignment with said mechanical axis identifier.

9. The apparatus of Claim 8, wherein said first lateral force assembly includes a first post member and a first inflatable bladder, said first inflatable bladder being positioned between said first post member and said leg such that inflation of said first bladder tends to cause said first bladder to bias against said leg proximate said knee such that said knee tends to move away from said first post member;

wherein said second lateral force assembly includes a second post member and a second inflatable bladder, said second inflatable bladder being positioned between said second post member and said leg such that inflation of said second bladder tends to cause said second bladder to bias against said leg proximate said knee such that said knee tends to move away from said second post; and

wherein said first and second bladders are configured such that selectively inflating said first and said second bladders tends to provide a bias between said leg proximate said thigh portion and at least one of said first and said second bladders, thus urging said knee into a desired alignment with said mechanical axis identifier.

10. The apparatus of Claim 9, wherein selectively inflating said first and said second bladders discourages movement of said leg relative to said first and said second post members.

11. The apparatus of Claim 8, wherein said first lateral force assembly includes a first force member moveably attached relative to said base member such that said first post member is adjustable and selectively securable in an axis substantially perpendicular to the longitudinal axis of said spine portion;

wherein said second lateral force assembly includes a second post member moveably attached relative to said base member such that said second force member is adjustable and selectively securable in an axis substantially perpendicular to the longitudinal axis of said spine portion and spaced apart from said first post member to accept said leg therebetween; and

wherein further said force members contact said leg and urge said knee into alignment with said mechanical axis identifier.

12. The apparatus of Claim 8 further comprising a cutting guide mounting assembly attached relative to said first post and configured to position a cutting guide proximate a knee portion of said leg.

5 13. The apparatus of Claim 12, wherein said cutting guide mounting assembly is adjustable in at least two orthogonal axes.

14. The apparatus of Claim 12, wherein said cutting guide mounting assembly is configured to facilitate bone removal in an axis perpendicular to said
10 mechanical axis.

15. The apparatus of Claim 8 further comprising an operating arm configured to secure a cutting tool and to provide movement of said cutting tool in at least two axes.

15

16. The apparatus of Claim 15, wherein said operating arm is configured to pivotably secure said cutting tool, wherein further said cutting tool pivots about an axis substantially parallel to said longitudinal axis of said spine portion.

20

17. An apparatus for aligning a leg of a patient with a mechanical axis to facilitate medical treatment thereon, said leg including a femoral head, a thigh portion, a knee portion and a foot portion which itself includes an ankle portion, said mechanical axis having a portion extending from the center of said femoral head to the center of said ankle, said apparatus comprising:

a base member including a spine portion and a head portion, said spine portion being substantially elongate and having a longitudinal axis, said head portion attached proximate one longitudinal end of said spine portion;

a pelvic location assembly attached relative to said base member proximate said head portion, said pelvic location assembly including a femoral head location member configured to establish a first reference point positioned at a known location relative to the center of said femoral head;

a carriage moveably attached relative to said spine portion and configured to move along a carriage path having a portion being substantially parallel to said longitudinal axis of said spine and further configured to be selectively secured relative to said spine so as to discourage said movement;

a boot assembly pivotably attached relative to said carriage and configured to accept said foot portion of said leg and to establish a second reference point at a known location relative to the center of said ankle portion;

a upper pivoting assembly having a first end pivotably attached relative to said spine portion proximate said head portion, a second end pivotably and moveably attached relative to said spine portion and a hinged portion positioned proximate said patient's knee between said first end and said second end such that when said patient's knee is in a bent condition, said second end moves relative to said spine portion and said hinge portion follows said knee such that said thigh support member also provides support to said thigh portion of said leg;

a mechanical axis indicator providing a visual indication of a reference axis passing through said first reference point and through said second reference point, such that said reference axis is within substantially the same plane as said mechanical axis; and

a leg manipulation assembly attached relative to said spine portion between said pelvic location assembly and said boot assembly, said manipulating assembly having a first lateral force assembly and a second lateral force assembly being spaced apart to accept said leg therebetween and located proximate said knee joint,

said first lateral force assembly being adjustable and selectably securable in an axis substantially perpendicular to said longitudinal axis of said spine and configured to urge said leg into alignment with said mechanical axis identifier.

5 18. The apparatus of Claim 17, wherein said thigh support is configured to allow free movement of a calf portion of said leg when said leg is in said bent condition.

10 19. The apparatus of Claim 17 further comprising an inflatable bladder positioned intermediate said thigh portion and said upper pivoting assembly to encourage distraction of said knee joint when knee is in a bent condition and said bladder is selectively inflated.

15 20. The apparatus of Claim 17 further comprising a cutting guide mounting assembly attached relative to said first post and configured to position a cutting guide proximate a knee portion of said leg.

20 21. The apparatus of Claim 20, wherein said cutting guide mounting assembly is adjustable in at least two orthogonal axes.

22. The apparatus of Claim 20, wherein said cutting guide mounting assembly is configured to facilitate bone removal in an axis perpendicular to said mechanical axis.

25 23. The apparatus of Claim 20, wherein said cutting guide includes an arcuate slot configured to provide a path for a bone cutting tool to follow.

30 24. The apparatus of Claim 20, wherein said cutting guide includes a wedge shaped slot configured to provide a path for a bone cutting tool to follow.

25. A method for preparing a patient's leg having a femur with a femoral head, a thigh portion, a knee portion, a femur, a tibia, and an ankle portion, for treatment thereon, said method comprising the steps of:

providing a first reference point proximate said femoral head;

5 providing a second reference point proximate the center of said ankle portion; and

providing a visual indication of a reference axis passing from said first reference point to said second reference point such that said visual indication is within substantially the same plane as the mechanical axis of said leg, said
10 mechanical axis having a portion extending from the center of said femoral head to the center of said ankle.

26. The method of Claim 25, wherein said step of providing a first reference point comprises the steps of:

15 taking an Xray of said patient showing at least the location of a skeletal reference and said femoral head;

identifying said skeletal reference on said patient; and

positioning said first reference point proximate said femoral head of said patient responsive to said distance obtained from said Xray.

20

27. The method of Claim 25 further comprising the steps of:

urging said leg into a desired alignment with said reference axis; and

providing an external frame configured to secure said leg in said desired alignment.

25

28. The method of Claim 25 further comprising the steps of:

providing a cutting guide mounting assembly attached relative to said external frame and configured to position a cutting tool proximate to said knee joint;

30 removing at least a portion of the distal end of said femur; and

removing at least a portion of the proximal end of said tibia.

29. The method of Claim 28 further comprising the steps of:

providing an upper pivoting assembly configured to support said leg proximate said thigh and having an inflatable bladder positioned intermediate said leg and said thigh support;

- 5 positioning said leg in with said knee in a bent condition such that said thigh support is positioned proximate said thigh portion of said leg; and
selectively inflating said bladder such that said thigh is urged away from said upper pivoting assembly tending to cause distraction at the knee.

10 30. The method of Claim 28 further comprising the steps of:

distracting said knee portion of said leg by applying a force to said foot portion in a direction away from said torso of said patient in a direction substantially parallel to the longitudinal axis of said leg;

- providing a wedged shaped measuring tool configured to contact the
15 bearing surfaces of said femur and said tibia at said knee portion and provide indicia of a clearance between said bearing surfaces.

31. The method of Claim 30 further comprising the steps of:

- providing a prosthesis assembly having a first member configured to be
20 secured to said femur of said leg, and a second member configured to be secured to said tibia of said leg, each of said first and second members having a bearing portion configured to cooperated to provide movement at said knee portion.

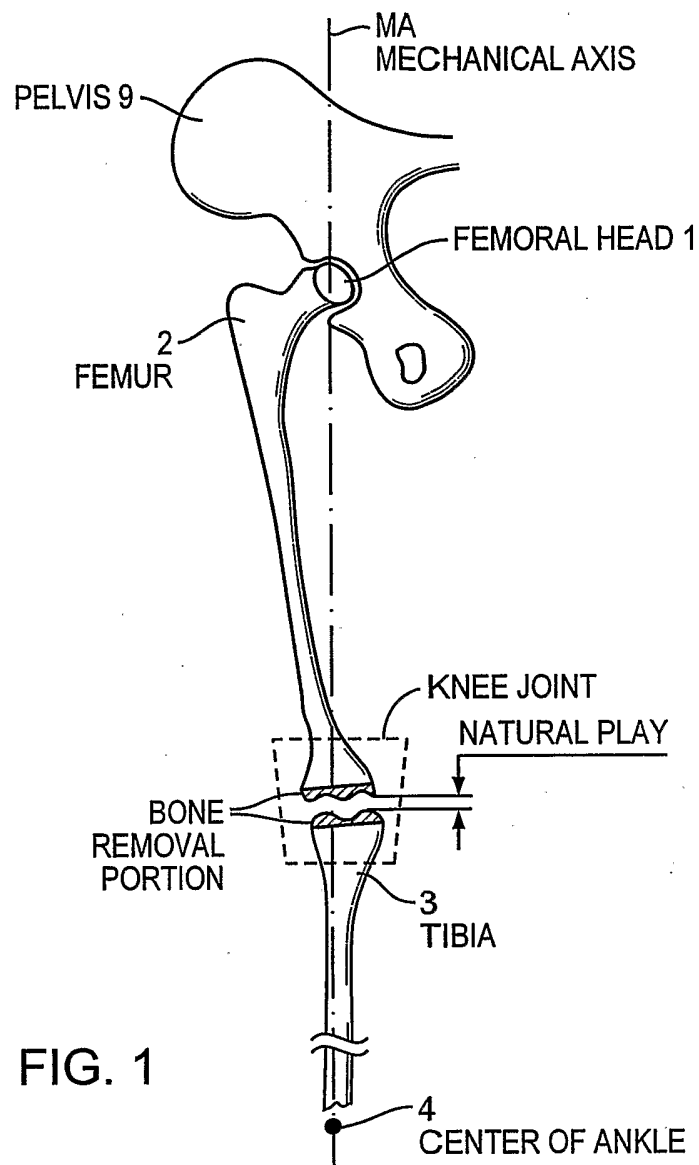
providing a dissolvable spacer between said bearing surfaces, said space
having a thickness substantially the same as said measured clearance.

25

32. The method of Claim 30, further comprising the step of releasing an antibiotic from said spacer when said spacer dissolves.

33. An apparatus configured to measure the clearance between the
30 mating surfaces of the femur and a tibia at the knee joint, said apparatus being elongate with a substantially wedge shaped tip portion, said tip portion including indicia associated with a width at a distance spaced apart from the end of said tip.

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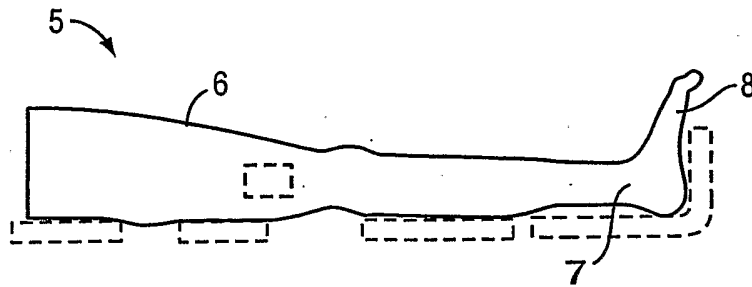


FIG. 2A

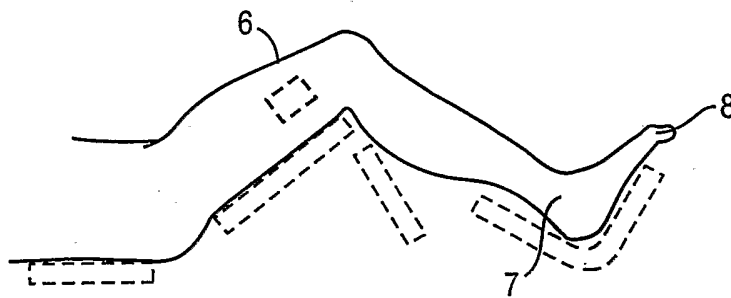


FIG. 2B



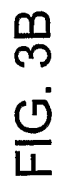
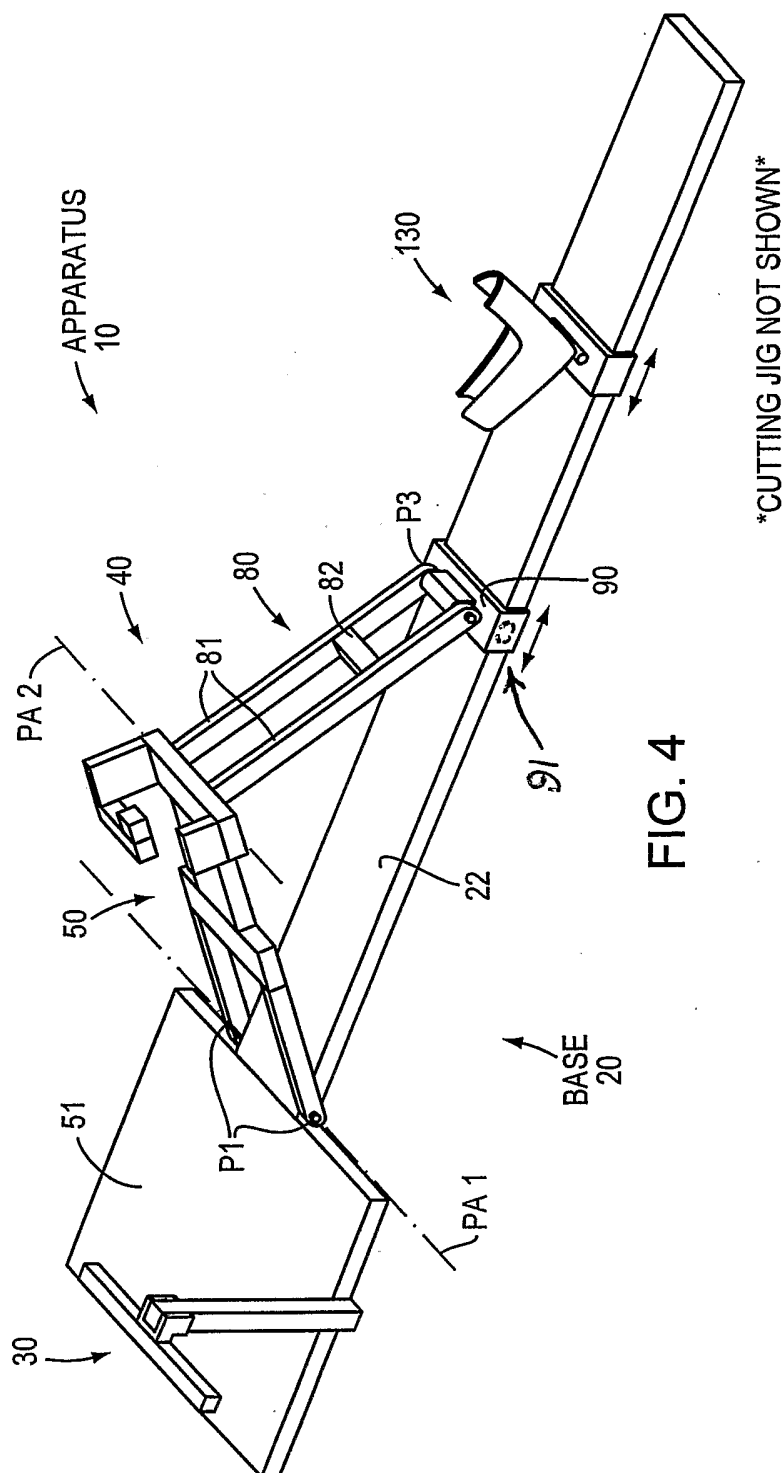
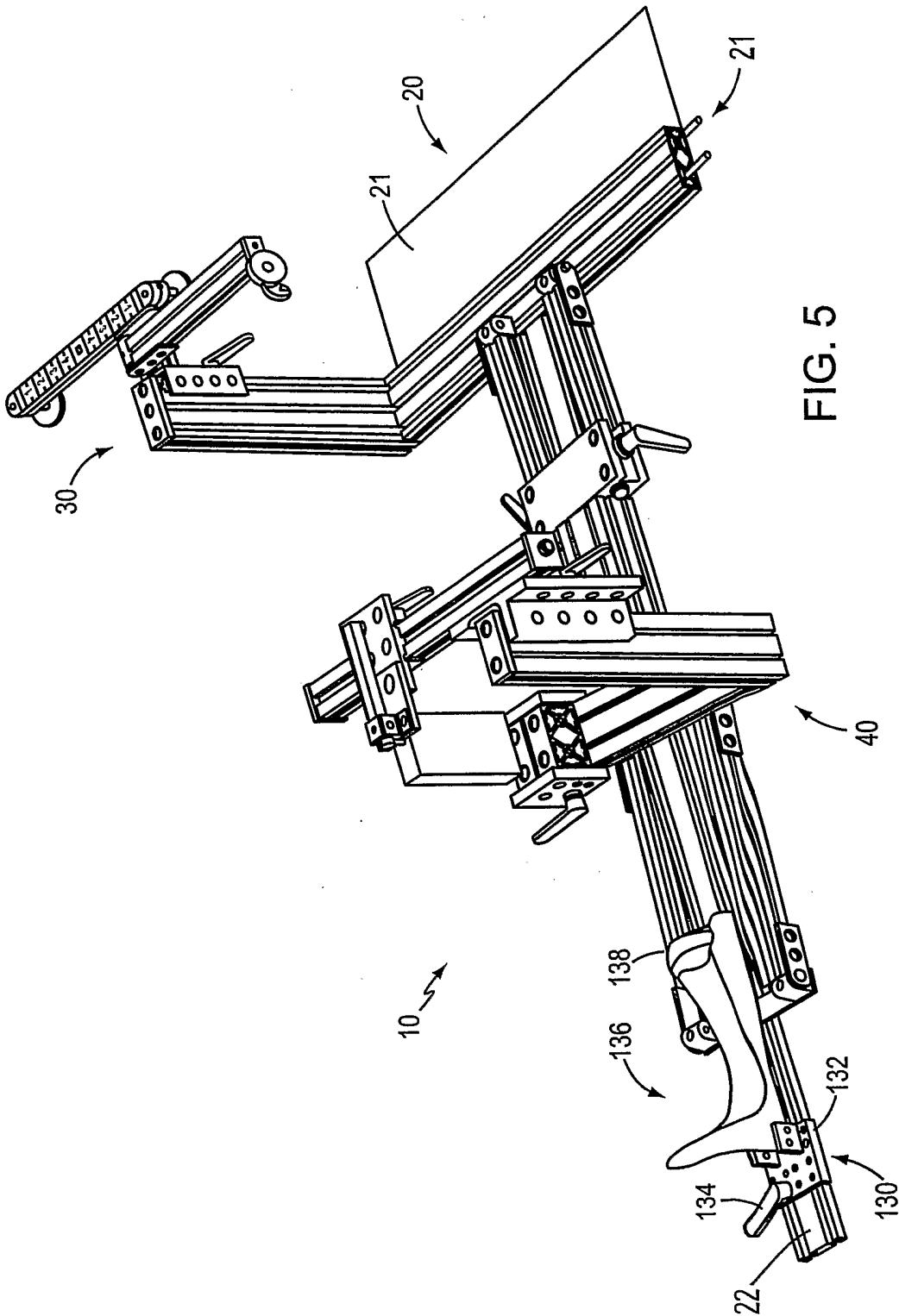


FIG. 3A





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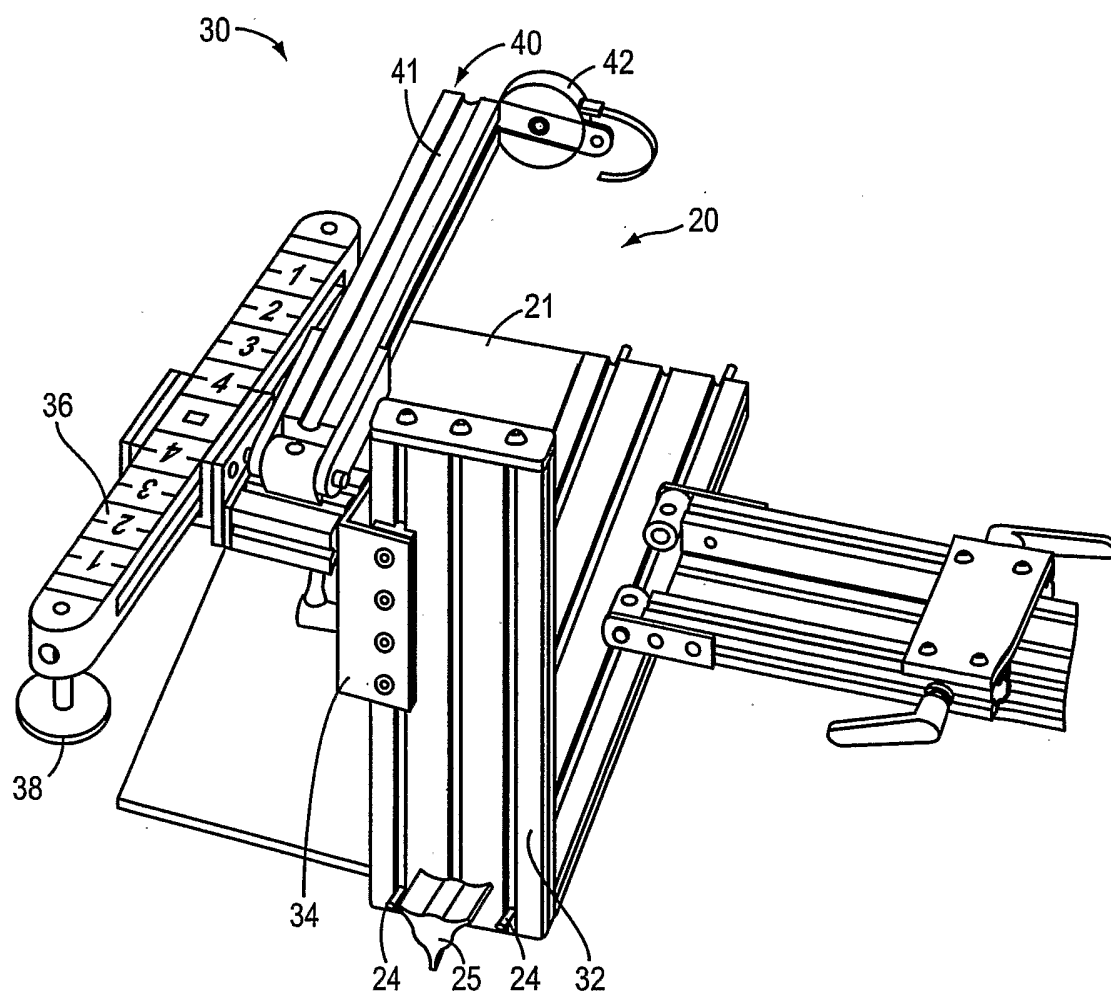


FIG. 6

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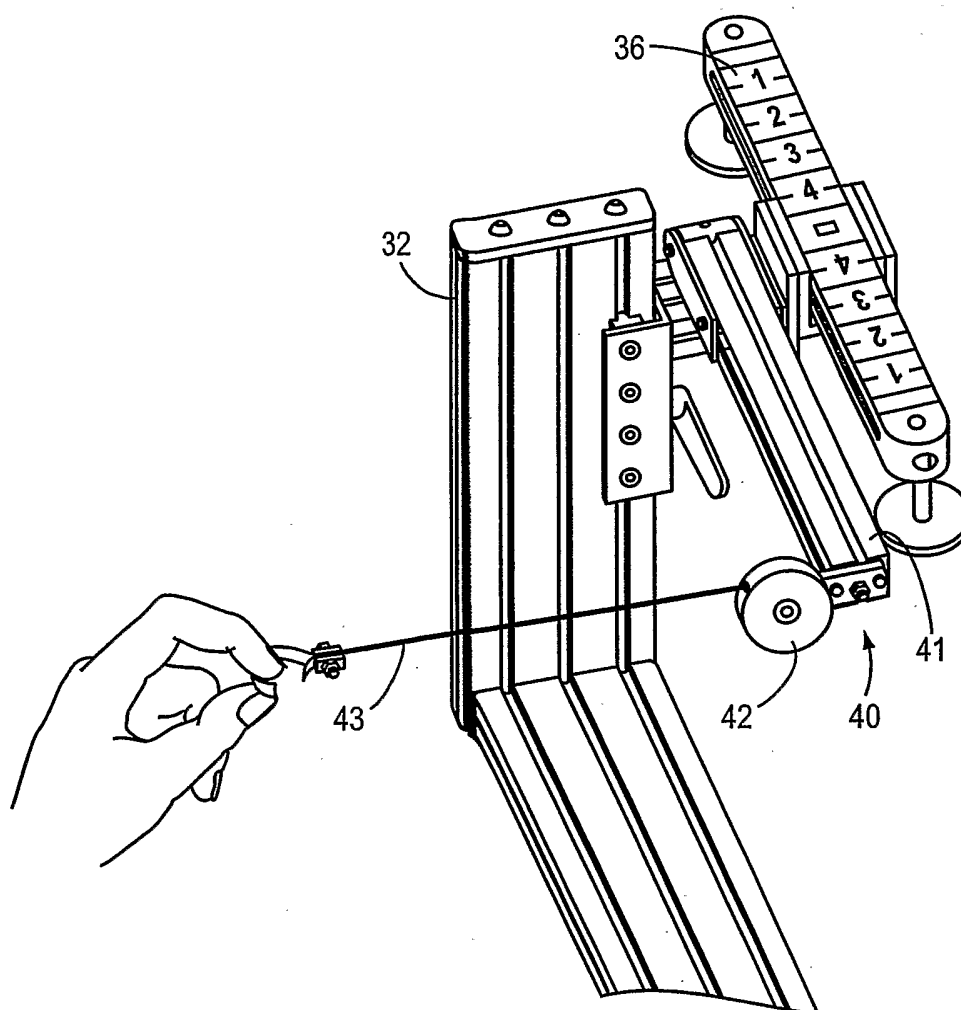
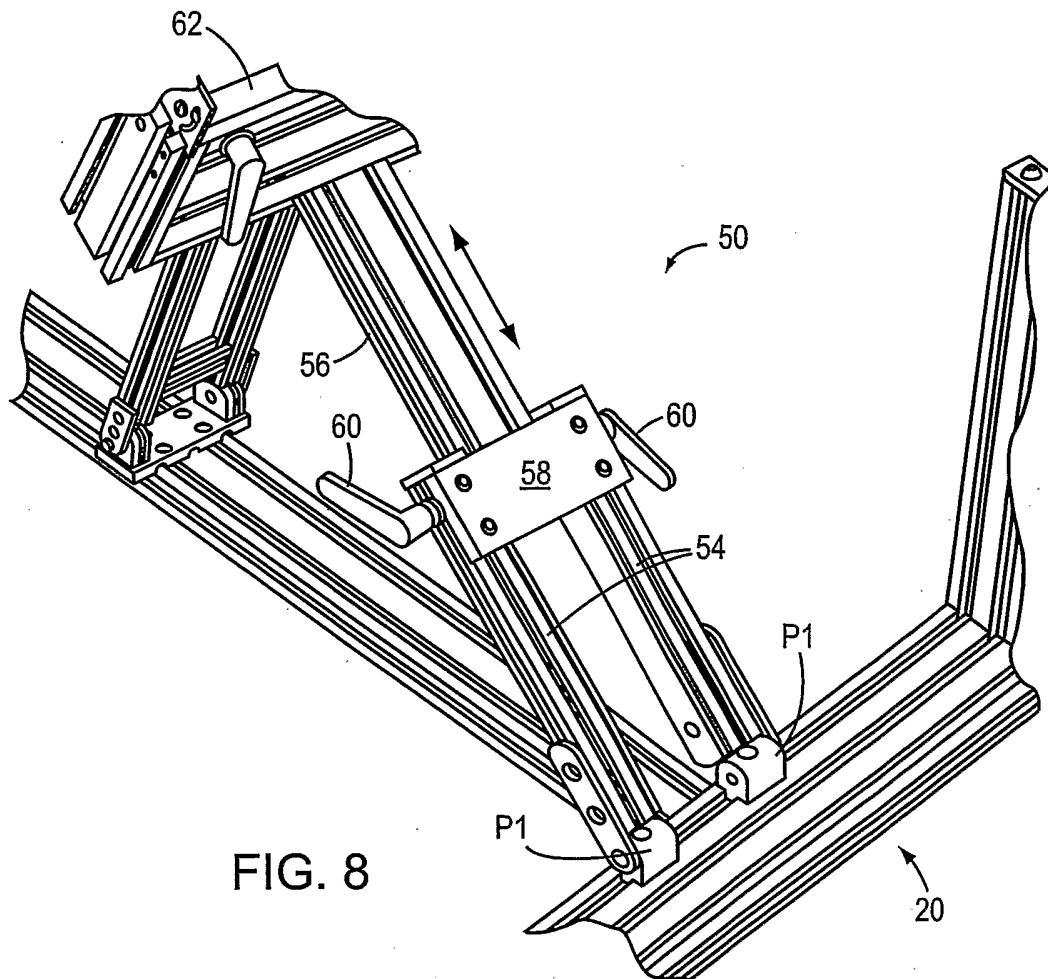


FIG. 7

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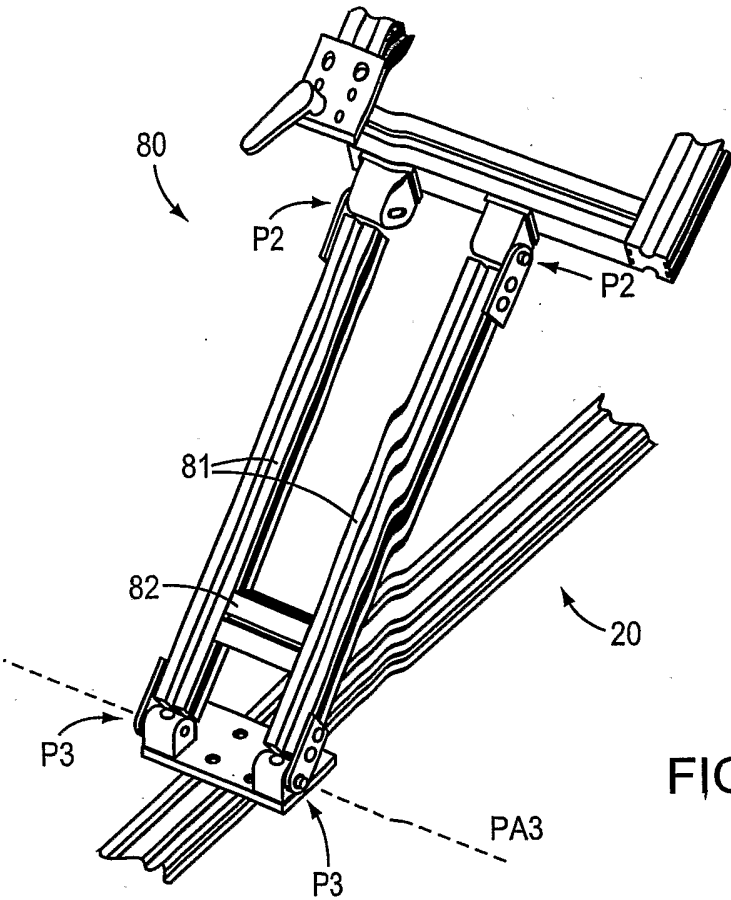


FIG. 9

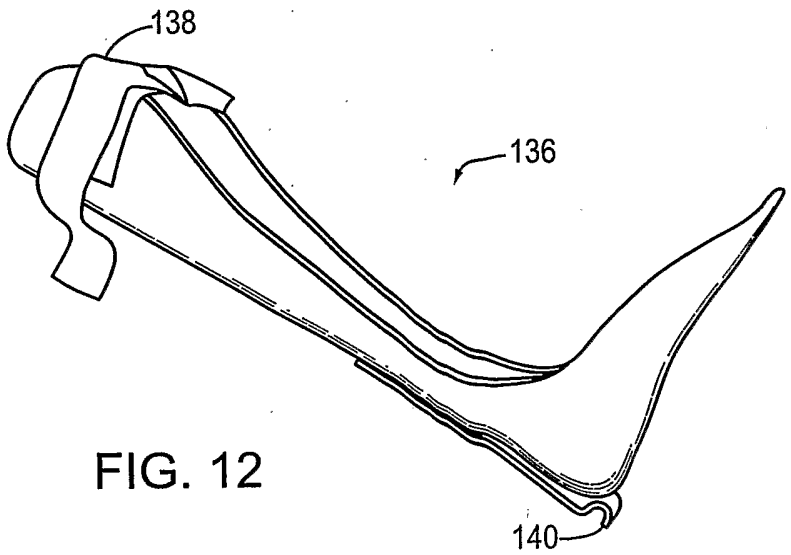


FIG. 12

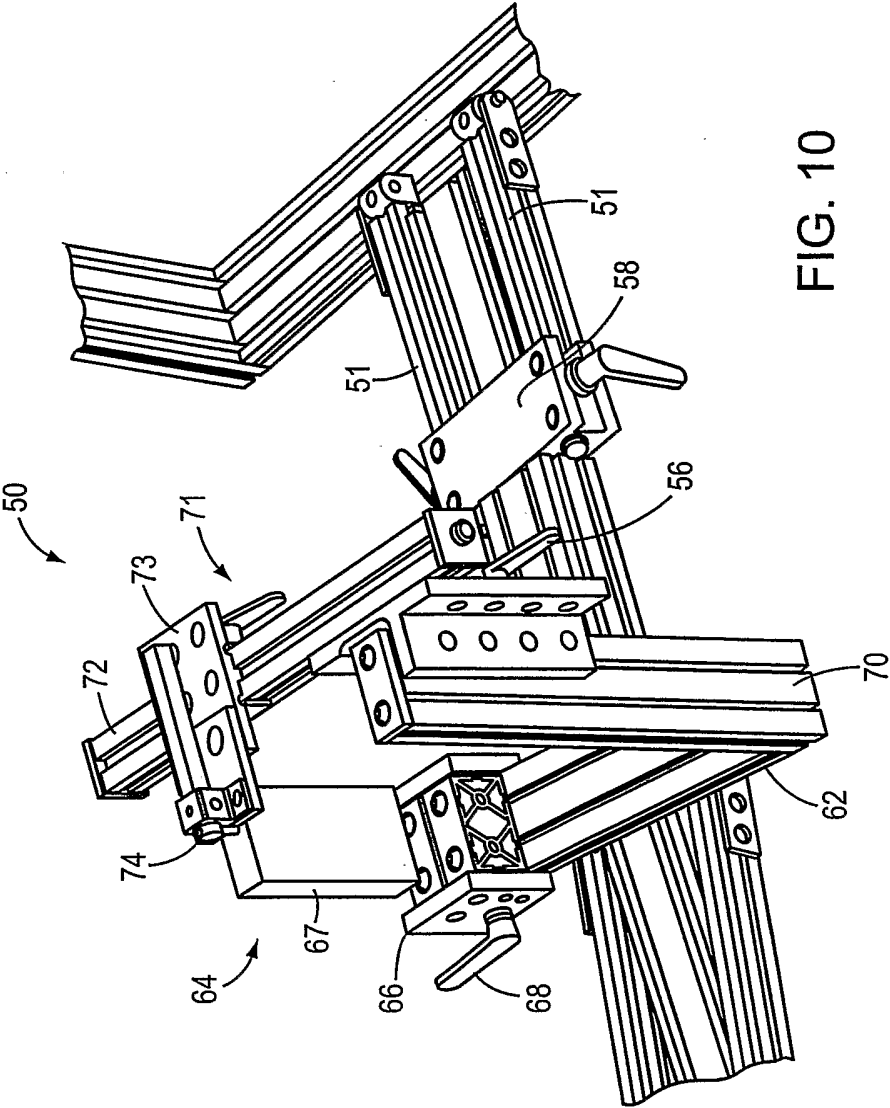
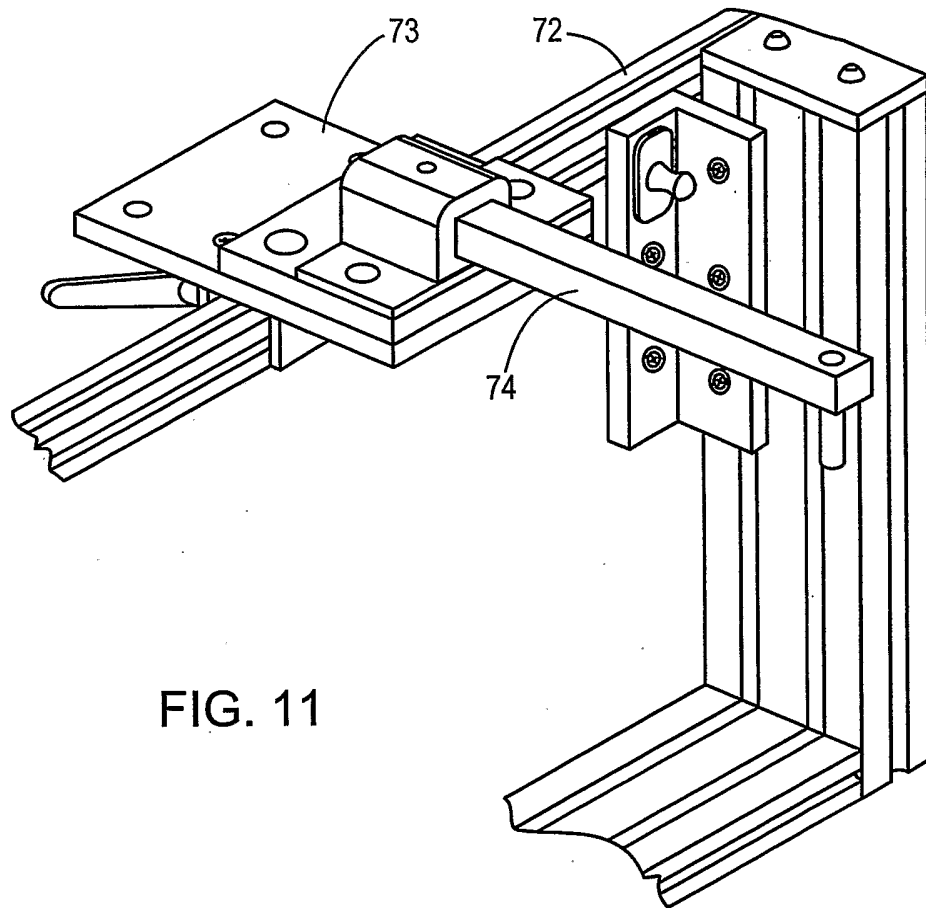


FIG. 10



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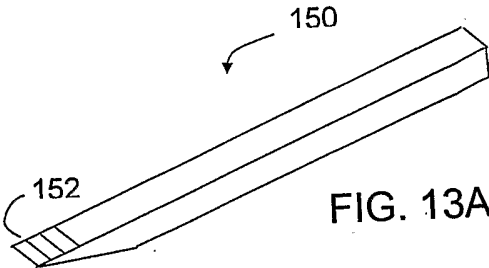


FIG. 13A

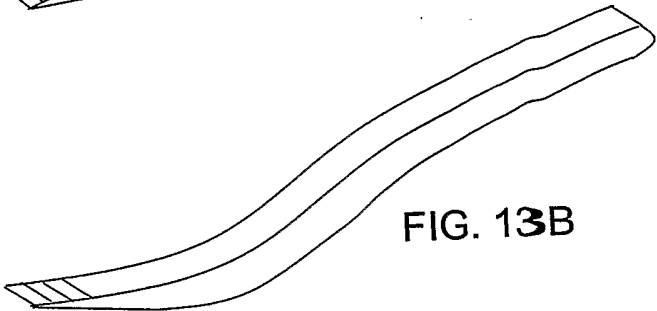


FIG. 13B

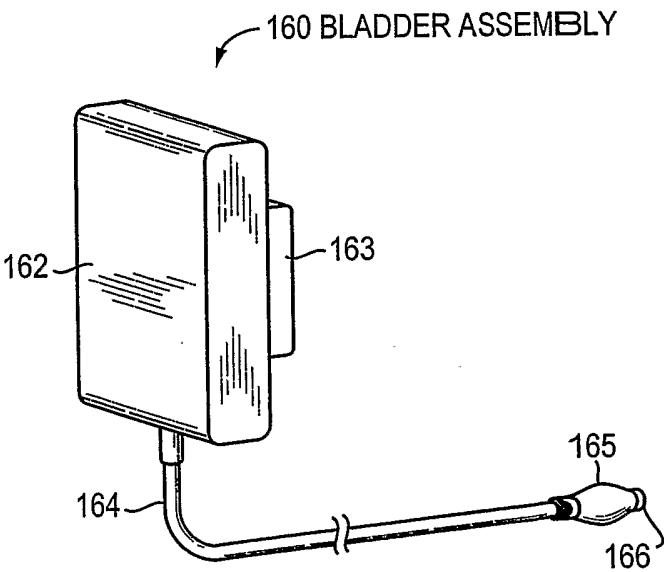


FIG. 14

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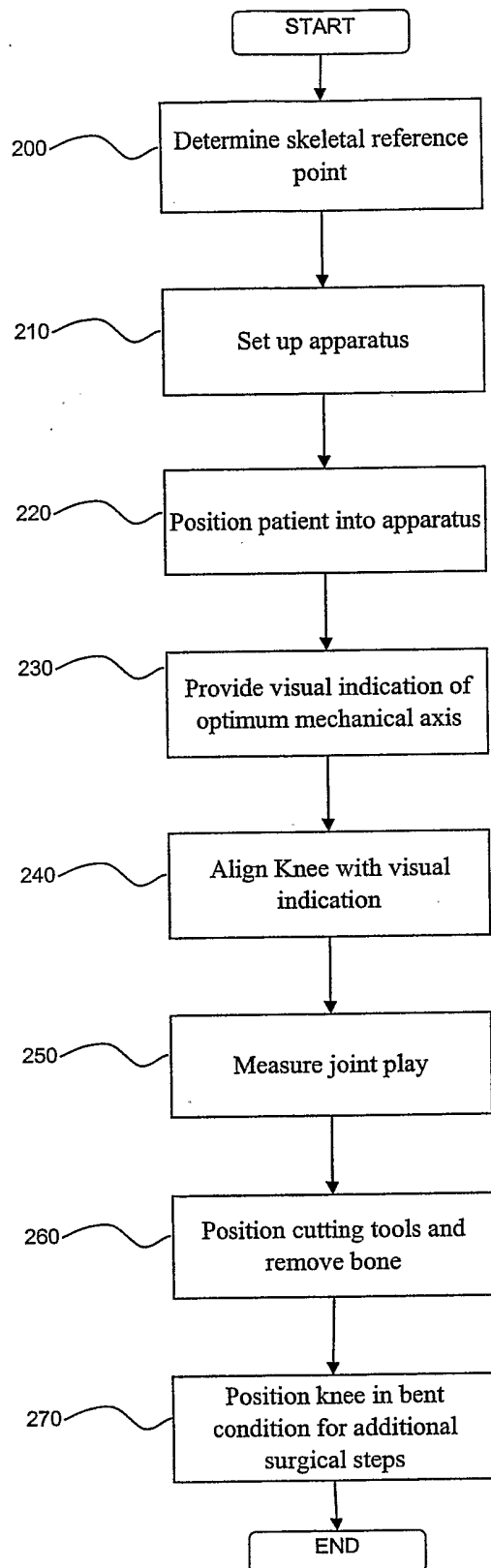
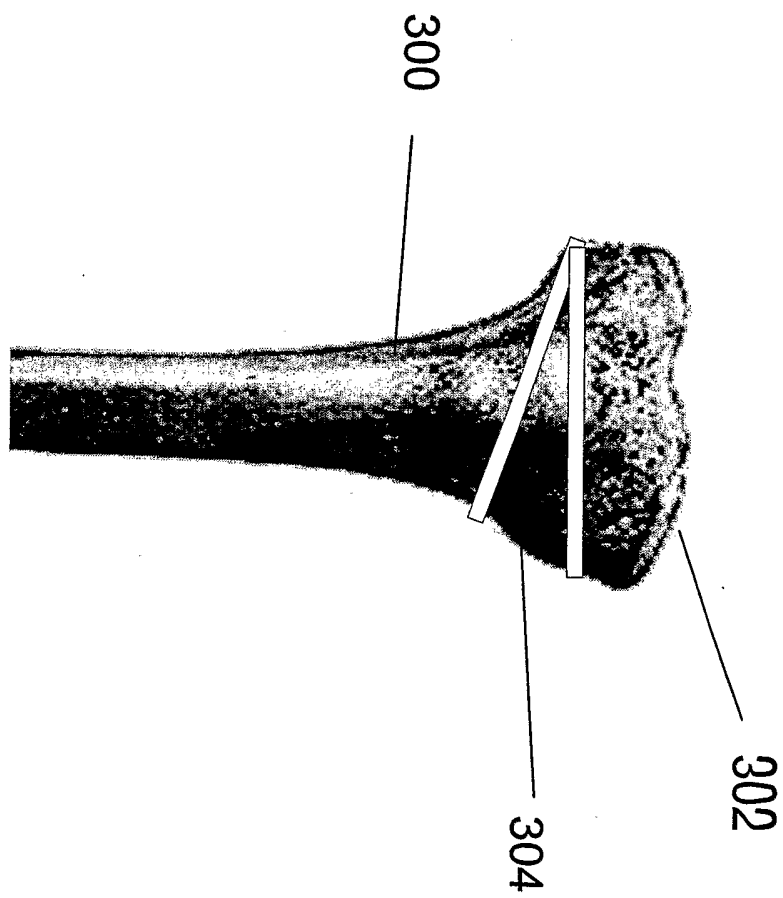


Fig. 15

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FIG. 16



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FIG. 17A

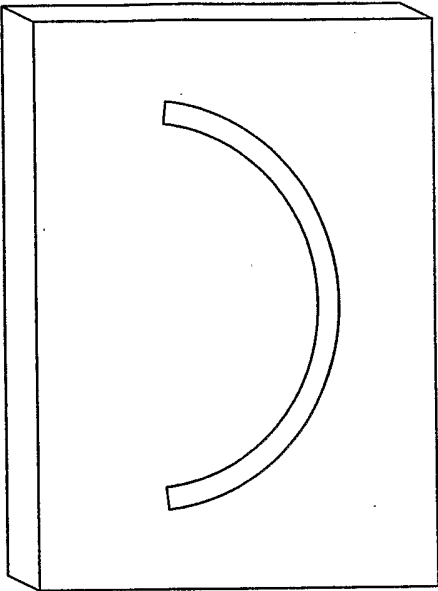


FIG. 17B

