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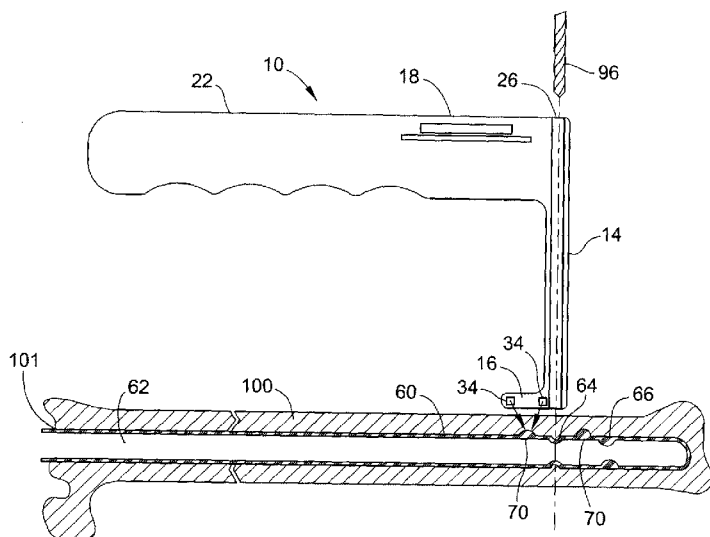


FIG. 5

(57) Abstract: An intramedullary nail targeting apparatus for targeting and drilling screw openings in the intramedullary nail is provided herein. A preferred version of the targeting apparatus includes a magnetic targeting device (116), a nail extension (110) for connecting to an intramedullary nail (60), and a magnet member (70), preferably in a "bucking configuration," for affixing to the intramedullary nail at a defined position relative to the screw openings in the nail. The nail extension includes a targeting arm (120) with one or more bores which align with the screw openings in the nail when the targeting arm is aligned with the intramedullary nail. The magnetic targeting device includes a support member with a sensor array (33) that extends through one of the bores on the targeting arm to target the magnet member, thereby aligning the targeting arm with the intramedullary nail. A second bore on the targeting arm can then be used for drilling through the bone at the position of an aligned screw opening. Methods for using the targeting apparatus for targeting and drilling screw openings in intramedullary nails or openings in bone plates are also described herein.

INTRAMEDULLARY NAIL TARGETING DEVICE

Alfred A. Durham

5 CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 USC §119(e) to U.S. Provisional Patent Application 61/214,060 filed April 20, 2009, and is a continuation-in-part under 35 USC §120 of U.S. Patent Application 12/552,726 filed September 2, 2009, which claims priority under 35 USC §119(e) to U.S. Provisional Patent Application 61/190,709 filed
10 September 2, 2008 and is a continuation-in-part under 35 USC §120 of U.S. Patent Application 10/679,166 filed October 3, 2003, which claims priority under 35 U.S.C. §119(e) to U.S. Provisional Patent Application 60/415,952 filed October 3, 2002, all of which are incorporated herein by reference in their entirety.

15 FIELD OF THE INVENTION

The present invention is directed to a targeting device in general and specifically relates to an intramedullary nail targeting device and method for positioning locking screws for intramedullary nails.

20 BACKGROUND

Devices for targeting of distal holes or openings in orthopedic hardware such as intramedullary nails include mechanical targeting devices and magnetic targeting devices.

Examples of conventional mechanical targeting devices for intramedullary nails include those described in U.S. Patent Nos. 4,622,959 to Marcus; 4,913,137 to Azer et al.;
25 5,281,224 to Faccioli et al.; 6,039,739 to Simon; 7,060,070 to Anastopoulos et al.; 7,077,847 to Pusnik et al.; 7,147,642 to Robioneck et al.; 7,311,710 to Zander; 7,232,443 to Zander et al.; and 7,549,994 to Zander et al. These devices typically include rigid arms that extend from the intramedullary nail that guide a drill bit toward an opening in the intramedullary nail. However, these devices fail to provide the degree of accuracy
30 required for locating and drilling openings in intramedullary nails due to the inherent flexure in these devices. Furthermore, the flexure increases as the length of the arm increases, which renders them impractical for drilling distal openings in the nails. These

devices can be deflected as much as a centimeter or more off the distal openings of an intramedullary nail.

The earliest successful magnetic targeting was accomplished by Durham et al. and was described in a succession of patents covering a mechanical magnetic targeting system using a mechanically balanced cannulated magnet (U.S. Patent Nos. 5,049,151; 5,514,145; 5,703,375; and 6,162,228). Hollstien et al. (U.S. Patent No. 5,411,503) followed with an electrically based system of stacked flux finders connected to a PC display. These devices, however, operate at the level of the skin. The magnets used in these devices may not be strong enough to accurately position the drill bit as even the fields of the strongest magnets diminish to that of the earth's magnetic field at distance of about 10 cm.

As a result, all of the prior devices have yet to be practical in surgical use.

SUMMARY OF THE INVENTION

The present invention provides an intramedullary nail targeting apparatus.

A preferred version of the targeting apparatus includes a nail extension. The nail extension is capable of being connected to an end of an intramedullary nail and includes a targeting arm configured to extend along a longitudinal axis of the intramedullary nail when connected thereto. The targeting arm on the nail extension includes one or more bores.

The targeting apparatus also includes a magnetic targeting device capable of detecting a magnet for attaching to the targeting arm. The targeting arm provides support and stability for the magnetic targeting device. The magnetic targeting device includes a support member having a proximal end and a distal end and is structured to fit through at least one of the bores in the targeting arm, a sensor array disposed on the distal end of the support member, and a positional indicator. The support member has a length sufficient to place the sensor array against a bone comprising the intramedullary nail when the nail extension is connected to the intramedullary nail and the magnetic targeting device is connected to the targeting arm.

The targeting apparatus also includes a magnet member disposed in fixed relation to the intramedullary nail. Targeting of the magnetic targeting device to the magnet member in the intramedullary nail aligns the targeting arm on which the magnetic targeting device is supported with the intramedullary nail. This, in turn, aligns bores in

the targeting arm with screw openings in the intramedullary nail. The bores can then be used for accurate drilling of the bone to secure the intramedullary nail thereto.

A preferred version of the invention further includes a magnet member that produces a radial magnetic field. This includes, for example, a magnet member comprising individual magnets in a "bucking configuration," wherein the magnet member includes a first magnet and a second magnet arranged coaxially with like poles placed head-to-head. In other versions of the invention, the magnet member includes a third magnet interposed between the first and the second magnets and oriented orthogonally to the first and the second magnets.

Some versions of the invention further include an orthogonal targeting guide for targeting and drilling orthogonal screw openings in intramedullary nails. A preferred version of the orthogonal targeting guide includes a lateral support base for attaching to the targeting arm or other support structures, orthogonal support arms extending from the lateral support base, and a mechanical targeting arm with orthogonal guide bores for use in drilling the orthogonal screw openings. The orthogonal targeting guide also preferably includes a straight-edge guide for aligning the orthogonal guide bores over the orthogonal screw openings.

The invention also provides a method of targeting screw openings in an intramedullary nail for the internal fixation of a bone within a limb, wherein the intramedullary nail includes first and second screw openings. In a preferred version, the method includes placing the intramedullary nail in a medullary cavity of the bone, wherein the intramedullary nail includes a magnet member positioned at a known, fixed position relative to the second screw opening, attaching a nail extension comprising at least a first bore and a second bore to a proximal end of the intramedullary nail, attaching a magnetic targeting device to the targeting arm, aligning the magnetic targeting device with the magnet member, drilling a first hole in the bone at a position of the first screw opening, stabilizing the targeting arm to the first screw opening, and drilling a second hole in the bone at a position of the second screw opening. In this version, the second screw opening is targeted with the magnetic targeting device inserted through the second bore while the first screw opening is drilled using the first bore.

In some versions, the targeting arm is stabilized to the first and second screw openings after drilling the second hole. The targeting arm is preferably stabilized to the screw openings with drill guides. The stabilizing is followed by attaching an orthogonal

targeting guide to the stabilized targeting arm and drilling holes in the bone through the orthogonal targeting guide.

Other versions further include un-stabilizing the targeting arm after drilling the second hole, rotating the nail extension orthogonally, targeting orthogonal openings in the intramedullary nail with the magnetic targeting device, and drilling holes in the bone through the orthogonal openings.

The invention further provides a bone plate targeting apparatus for targeting a bone plate including holes. The apparatus comprises a magnet member disposed a defined distance from at least one of the holes in the bone plate, and a magnetic targeting device.

The invention further provides a method of targeting holes in a bone plate for the external fixation of a bone within a limb. The method comprises placing the bone plate against the bone, placing a magnetic targeting device against the bone plate, aligning the magnet member with a sensor array in the magnetic targeting device, wherein aligning the magnet member with the sensor array aligns the lower opening of the drill guide with the at least one of the holes, and drilling a hole in the bone through the hole in the bone plate.

The present invention advantageously provides magnet members that provide larger magnetic fields in the same space confines, a targeting system that is unaffected by incidental rotation of a magnet member within an intramedullary nail, the ability to use smaller sensor arrays that can be used percutaneously while still attaining accurate targeting, a targeting system that can be used for a variety of bone sizes and intramedullary nail sizes, and a stable system that minimizes erroneous degrees of freedom while targeting and drilling.

The objects and advantages of the invention will appear more fully from the following detailed description of the preferred embodiments of the invention made in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the magnetic targeting device of the present invention.

FIG. 2 is a cross-sectional view of the magnetic targeting device of **FIG. 1** taken along lines 2 – 2 of **FIG. 1**.

FIG. 3 is a cross-sectional view of the sensor foot of the magnetic targeting device of **FIG. 1** taken along lines 3 – 3 of **FIG. 2**.

FIGS. 4A and 4B are partial side plan views of the magnetic targeting device of **FIG. 1** comprising a hinged sensor foot.

FIG. 5 is a side plan view of the magnetic targeting device illustrating its operation with respect to a long bone.

5 **FIG. 6** is a top view of the intramedullary nail of the present invention.

FIG. 7 is a top plan view of the magnetic targeting device of **FIG. 1** with the cover (i.e., upper body portion) removed.

FIG. 8 is a block diagram illustrating the operation of the magnetic targeting device of the present invention.

10 **FIG. 9** is a top plan view of the magnetic targeting device of **FIG. 1** illustrating the display.

FIG. 10 is a diagram illustrating the amplitude output of the sensors.

FIG. 11 is a diagram illustrating the flux density of the magnetic field at various distances from the magnet.

15 **FIG. 12A** is a side cutaway view of a magnet member on a magnet insertion rod in a “bucking” configuration within an intramedullary nail.

FIG. 12B is a cross-sectional view taken across line 12B – 12B of **FIG. 12A**.

FIG. 12C is a side cutaway view of a magnet member comprising both longitudinally and orthogonally oriented magnets on a magnet insertion rod.

20 **FIG. 13** is a perspective view of a magnetic targeting device mounted on a nail extension of the present invention.

FIG. 14 is a perspective view of a magnetic targeting device mounted on a nail extension with an orthogonal targeting guide mounted on the nail extension.

25 DETAILED DESCRIPTION OF THE INVENTION

Definitions

Unless explicitly stated otherwise, “x axis,” “y axis,” and “z axis” used in reference to the intramedullary nail **60** or the magnet member **70** inserted in the intramedullary nail **60** are defined relative to the intramedullary nail **60** having screw openings **64,66,68** shown in **FIGS. 5** and **6**. “X axis” refers to an axis defined by the long axis of the intramedullary nail **60**. “Y axis” refers to an axis defined by the central axis of screw opening **68**, which is substantially orthogonal to the long axis of the intramedullary nail **60** and to screw openings **64,66**. “Z axis” refers to an axis defined by the central axis

of screw openings **64,66**, which are substantially orthogonal to the long axis of the intramedullary nail **60** and to screw opening **68**. Thus, in **FIGS. 5 and 6**, the x axis runs the length of the depicted intramedullary nail **60** from its left-hand side to its right-hand side; the y axis runs perpendicular to the length of the depicted intramedullary nail **60** through screw opening **68**; and the z axis runs perpendicular to the length of the depicted intramedullary nail **60** through screw openings **64,66**.

Magnetic Targeting Device 10

Referring now to **FIG. 1**, the present invention includes a magnetic targeting device **10** which, in an exemplary version, includes a body **12** with a handle portion **22**, a support member **14**, a button **20**, a sensor foot **16** connected to a distal end of the support member **14**, a display **18**, and a drill sleeve **26** constituting or extending through the support member **14**. The magnetic targeting device **10** places the sensor foot **16** of the support member **14** directly on the bone **100**, illustrated in **FIG. 5**, for more accurate reading.

Body 12

The body **12** can be made of a variety of materials known to the medical arts, including plastic and metal as appropriate for durability and reusability of the magnetic targeting device **10**. As illustrated in **FIG. 1**, the body **12** is designed to be handheld and comfortable with finger grips **24** in the handle portion **22**. The body **12** also holds the battery **32**, the comparator circuit **86** and the display **18**, as illustrated in **FIGS. 2 and 7**. The magnetic targeting device **10** can operate on two AAA batteries, have rechargeable cells, or be wired for electrical operation.

The body **12** of the magnetic targeting device **10** is amenable to several non-limiting design variations, each with various advantages.

In some versions, the body **12** and support member **14** are provided as a single unit.

In the exemplary version, the body **12** and support member **14** are provided as separate units and are separable, for example, at line **38** (see **FIGS. 1 and 2**). Connecting elements are known in the art for joining the support member **14** to the body **12** in a manner to enable the electrical connection between the two units. In the exemplary version, the body **12**, which contains the electronic circuitry (such as the comparator circuit **86**), may be provided in a sterile bag (not illustrated) and would not have to be sterilized prior to use. During use, the plastic bag containing the body **12** could be

perforated by the sensor-support member **14** portion of the device to connect to the electronic circuitry in the body **12** to render the magnetic targeting device **10** ready for use. Alternatively, the electronics can be made to withstand sterilization, including but not limited to gas sterilization, autoclaving, CIDEX® disinfecting solutions (Johnson & Johnson Corporation, New Brunswick, NJ) or other similar chemical soaks, or any equivalent thereof. This permits the support member **14** to attach to the body **12** at line **38** and be used without a sterile bag.

Having the support member **14** and the body **12** as separate units also allows for different interchangeable support member **14** options for the same body **12**. One advantage of having different support member **14** options is that they can be used for different applications such as humeral or tibial nail-locking, which might use smaller diameter locking screws and require narrower drill sleeves **26**. A second advantage is that support members **14** having different lengths may be used. Shorter support members **14** would allow more efficient use of the magnetic targeting device **10** when deep soft tissues do not have to be avoided. A third advantage is that different sensor array **33** configurations (see below) may be used for different applications. The ability to use different support member **14** options therefore prevents the necessity of making a different magnetic targeting device **10** for each application.

Providing the body **12** and support member **14** as separable units also permits the support member **14** to be made of disposable materials for simple disposal after use.

In another version, the magnetic targeting device **10** is connected wirelessly between the sensor foot **16** and the display **18** to transfer targeting or display information wherever needed. The sensing information may be transmitted by radio, infrared, or equivalent thereof from the sensor foot **16** to the display **18**. The display **18** may be separate from the body **12** and can comprise any medium, including virtual projections, heads-up glasses, a personal computer, or a television screen. Such a display **18** can be made from any compatible non-magnetic material.

The body **12** may also be separable along line **39**, as shown in **FIG. 2**, to divide the body **12** into an upper body portion **12A** and a lower body portion **12B**. The upper and lower body portions **12A,B**, may be connected by screws **13A** that insert into threaded holes **13B**, the latter of which extend from the lower body portion **12B** into the upper body portion **12A**. Other mechanisms of connecting the upper and lower body portions **12A,B** may be used. The ability to separate the upper and lower body portions **12A,B**

allows the user to access internal parts of the device **10**, such as the battery **32** and the comparator circuit **86**.

The body **12** may be provided with or without a handle portion **22**.

5 The button **20** is provided generally on the top surface of the body **12** at a convenient location for the surgeon to power and calibrate the device **10**. The button may also turn off the device **10**. The button **20** is positioned for comfortable use. There may be a button **20** on either side of the handle portion **22** activating the same functions, to allow for left- or right-handed use.

Support Member 14 and Sensor Foot 16

10 The preferred design of the present invention includes a support member **14** about 10 cm in length. While the length of the support member **14** is variable, a length of 10 cm incorporates most distal femoral soft tissue sleeves. For tibial and humeral applications, the support member **14** can be as short as 3-4 cm.

The sensor foot **16** is preferably disposed on a distal end of the support member
15 **14** and comprises the sensor array **33**. In a version shown in **FIG. 3**, the sensor foot **16** resembles a foot wherein the toe portion **17** contains the sensor array **33** and the heel portion **19** contains the lower opening **30** of the drill sleeve **26**. In another version, the sensor foot **16** comprises the same shape as the distal end of the support member **14**. A smaller sized sensor foot **16** on the support member **14** is more practical to use.

20 In some versions, the sensor foot **16** can be separated from the support member **14**. This enables sensor feet **16** having different sensor arrays **33** to be used on the support member **14**.

As shown in **FIGS. 4A** and **4B**, some versions of the sensor foot **16** include a swivel design wherein the sensor foot **16** is hingedly attached to the support member **14**
25 by means of a hinge unit **40**. This configuration eases insertion of the sensor foot **16** into the soft tissues at the point of insertion. The hinge unit **40** can be made of a number of materials and designs to incorporate the swivel functioning of the unit. Prior to insertion into an opening in a limb for positioning next to a bone **100**, the sensor foot **16** is rotated by means of the hinge **40** and pointed in parallel alignment with the support member **14**
30 for ease of movement toward the bone **100**, as illustrated in **FIG. 4A**. As the toe portion **17** comes in contact with the bone **100**, the foot **16** will rotate in an arc approximating arrow **42** until the sensor foot **16** rests on the bone **100** approximately perpendicular to the support member **14**, as illustrated in **FIG. 4B**.

Sensor array 33

The sensor array **33** is preferably included within the sensor foot **16** of the support member **14** near the lower opening **30** of the drill sleeve **26** (see **FIG. 3**). In one version of the invention, the sensor array **33** is dimensioned and configured such that each sensor **34** in the array **33** is capable of being excited by the same magnitude and angle of flux when centered about the magnet member **70**. As used herein, “angle of flux” refers to the angle of the magnetic field **74** flux lines **78** relative to the orientation of the sensor **34** and does not refer to the direction through which the flux lines **78** run through the sensor **34**. For example, sensors **34** positioned equidistantly from and on either side of a center line of flux **75** extending from a magnet member **70** would have the same magnitude and angle of flux even though the flux lines **78** would extend through the sensors **34** in opposite directions. An exemplary version of an array **33** that is excited by the same magnitude and angle of flux when centered about the magnet member **70** is shown in **FIG. 3**. The sensor array **33** in this version includes four magnetic sensors **34** arranged in a substantially planar, symmetrical array. Other exemplary substantially planar arrays include those described in U.S. Pub. No. 2005/0075562 to Szakelyhidi et al.

Other sensor arrays **33** may be symmetrical about the magnetic field **74** but not planar. For example, the sensor array **33** may include a pyramidal arrangement. Such an arrangement may include one or two additional, “z-axis” sensors positioned equidistantly from sensors **34** arranged in a planar, symmetrical arrangement. The z-axis sensors may be placed anywhere along an axis running through the center of the planar, symmetrical arrangement of sensors **34**. In one version, the sensor array **33** includes one z-axis sensor positioned outside the plane defined by the sensors **34** arranged in the planar, symmetrical arrangement. In a second version, the sensor array **33** includes a first z-axis sensor positioned outside the plane defined by the sensors **34** in the planar arrangement and a second z-axis sensor positioned within the plane defined by the sensors **34** in the planar arrangement. The z-axis sensor positioned outside the plane in these versions is preferably disposed on a side of the planar sensors **34** opposite the magnet member **70**. A sensor array **33** in a pyramidal arrangement provides both translational and rotational positional information with respect to the magnet member **70**. When the sensor array **33** is aligned over the field, the z-axis sensors detect the field at maximum strength.

In sensor array **33** configurations comprising z-axis sensors, a magnet **72** placed at a distance from the sensor foot **16** may dispose the z-axis sensors between collinear flux

lines **78**. Targeting in such a case may be achieved when the sensors detect flux lines **78** parallel to the magnetic field **74**.

The sensor array **33** may include any number of sensors **34** in any configuration, provided that each sensor **34** in the array **33**, in combination with other elements of the invention, is capable of detecting the magnetic field **74** in a manner that predictably indicates the translational and/or rotational position of the magnetic targeting device **10** relative to the magnet member **70**. For example, in preferred versions, the system permits translational alignment in either the x-y and/or x-z planes in addition to rotational alignment about the x, y, and z axes.

The individual sensors **34** in the sensor array **33** are preferably polarized sensors. As used herein, “polarized sensors” are sensors **34** capable of detecting the magnetic field **74** in all three dimensions (as defined by the sensor), thereby providing a readout of the magnitude and direction of the flux lines **78** comprising the magnetic field **74** at a given position. A preferred example of a polarized sensor that may be used in the sensor array **33** is a Honeywell HMC 1052 (Morristown, NJ) magneto resistive sensor. Magneto resistive sensors advantageously have an internal magnetic reset function that can reverse the magnetizing effect of a permanent magnet when brought too close to the sensor array **33**. This feature works well and is used to reset the sensors **34** upon every calibration operation (described below). The sensor reset driver pushes a large current pulse through all sensors at once to perform the reset.

The sensor array **33** is connected to the comparator circuit **86** in the body **12** by printed circuit wiring, wires **36** extending within the support member **14** beside the drill sleeve **26** (see **FIG. 2**), or through wireless communication. In the exemplary version shown in **FIG. 2**, the sensor array **33** is molded in a plastic support member **14** with the wires **36** from the sensor array **33** ascending the support member **14** to the comparator circuit **86** and linked to a display **18**.

The magnetic targeting device **10** is preferably configured such that each individual sensor **34** in the sensor array **33** detects multiple flux lines **78** for high resolution in targeting. This is a difficult hurdle in conventional magnetic intramedullary nail targeting devices. All magnets obey the inverse square rule, wherein the strength of the magnetic field drops off at the square of the distance. Doubling the distance decreases the magnetic field strength to 25%. If the distance between a sensor and a magnet is 10 cm, the magnetic field is 1% the strength and field density of a sensor array 1 cm from the

magnet. Conversely, the strength of the magnetic field at 1 cm from the magnet would be 100 times stronger than the same magnetic field measured at 10 cm.

As shown in **FIG. 11**, the lines of flux **78** of a magnetic field **74** are so diffuse at a distance of 10 cm **80** from a magnet member **70** that a sensor would detect only one or fewer flux lines **78** at a time. This is insufficient for accurately locating the center of a 5 mm hole. At a distance of 1.5 cm **82** or other distances closer to the magnet member **70**, multiple flux lines **78** can be detected and translated into targeting information. This applies even for relatively small sensors.

Disposing the sensor array **33** on the sensor foot **16** in the present invention allows the sensor array **33** to be placed at the surface of the bone **100** and in close proximity to the magnet member **70**. As a non-limiting example, a sensor array **33** suitable for detecting multiple flux lines **78** in the current system includes individual sensors **34** 1-2 mm square and arranged in an array **33** about 5-8 mm across and 2-5 mm thick. A preferred distance between the sensor array **33** and the magnet member **70** is a distance of about 1.5 cm, typically the average thickness of the side of the bone **100**. At that distance, the field density is about 30 times the density at a distance of 10 cm. Other acceptable distances include about 1 cm, about 2 cm, about 3 cm, about 4 cm, about 5 cm, about 6 cm, or more. The center line of flux **75** of the magnetic field **74** can be offset as little as 6-10 mm from the center axis of the hole to be drilled. To date the most difficult distal targeting goal has been the distal femur. The working distances from the annular cavity **62** of an intramedullary nail **60** in a distal femur to the surface of the bone is typically no more than 3 cm and is usually 1-2 cm. Thus, the magnetic targeting device **10** described herein is capable of accurately targeting the distal femur. This makes targeting nearly any other bone, *i.e.*, the tibia, humerus, or any other long bone, even easier with the magnetic targeting device **10** described herein because of smaller cortex to nail distances.

In a preferred version, the sensors **34** in the array **33** are positioned so that they are perpendicular to the maximum density flux lines when the array **33** is centered over the magnet member **70**.

Intramedullary Nail 60

Referring to **FIG. 5**, the magnetic targeting device **10** is illustrated in association with a long bone **100**, such as a broken femur, tibia, or humerus bone. Within the bone **100**, there is illustrated an intramedullary nail **60**, known in the art. Examples of intramedullary nails are prevalent in the prior art. For example, reference is made to U.

S. Patent 6,503,249 to Krause and the patents to Durham (cited herein), the contents of which are incorporated herein for a description of intramedullary nail and manners of use. The intramedullary nail **60** is an elongated metal rod typically having an annular cavity **62**; although, as described with respect to the intramedullary nail **60** in **FIG. 6**, the intramedullary nail **60** may also be a solid body. The intramedullary nail **60** typically includes a first, proximal screw opening **64** and a second, distal screw opening **66**. The screw openings **64,66** of typical intramedullary nails **60** are transverse, *i.e.*, having center axes about ninety degrees to the long axis of the nail **60**, as illustrated in **FIGS. 5** and **6**. However, intramedullary nails **60** may contain non-transverse or oblique screw openings, *i.e.*, having center axes at angles other than at about ninety degrees in relation to the long axis of the intramedullary nail **60**. Intramedullary nails **60** also typically include one or more screw openings **68** positioned orthogonally to both the longitudinal axis of the nail **60** and screw openings **64,66**, as illustrated in **FIG. 6**. As used herein, screw openings **64,66** are referred to as “lateral” screw openings **64,66**, and screw opening **68** is referred to as an “orthogonal” screw opening **68**.

Prior to placement of the intramedullary nail **60** within a bone **100**, a reaming rod known to the art is worked through the medullary cavity **101** of the bone **100**, such as a broken femur, tibia, or humerus bone. The intramedullary nail **60** is then placed within the medullary cavity **101** for securing within the bone **100** by means of cross-locking screws or bolts positioned through the screw openings **64,66,68**.

Magnet Member 70

The magnetic targeting device **10** of the present invention targets an intramedullary nail **60** by aligning the sensor array **33** on the magnetic targeting device **10** with a magnet member **70** in fixed relation to the intramedullary nail **60**. The magnet member **70** comprises one or more individual magnets **72**.

In a version of the invention shown in **FIG. 12A**, the magnet member **70** is attached to a magnet insertion rod **73** or other like device. The magnet insertion rod **73** is inserted into the annular cavity **62** of the intramedullary nail **60**, typically in a specified orientation, to a locking point at a set distance from at least one of the screw openings **64,66,68**. A reaming rod, known in the art, can be adapted for use as a magnet insertion rod **73**. The adaptation requires a mechanism for attaching the magnet member **70** to the distal end of the rod **73**, with provisions for maintaining correct depth, rotation, and

centering of the magnet member **70** within the intramedullary nail **60**. Such an attachment mechanism can include threads on a proximal end of the magnet insertion rod **73** that connect to a threaded portion of the annular cavity **60**. The magnet insertion rod **73** can also be secured to an end of a nail extension **110** (see below). Magnet insertion rods **73** of
5 different lengths can be included for placement of the magnet member **70** relative to different screw openings **64,66,68** along the length of the nail.

In another version of the invention, as illustrated in **FIGS. 5** and **6**, the intramedullary nail **60** has magnet members **70** embedded directly on the surface of the intramedullary nail **60**. An intramedullary nail **60** with a magnet member **70** embedded
10 therein does not require an annular cavity **62** and can be solid.

In another version (not shown), a magnetic ring is placed around the periphery of the screw openings **64,66,68** or to placed in the center of the screw opening **64,66,68** as a displaceable “bull’s-eye.”

In yet another version (not shown), the magnet member **70** can be located at the
15 screw opening **64,66,68** on a swivel that retracts when the drill enters the screw opening **64,66,68**. The magnet member **70** is centered within the intramedullary nail **60** by a circular spring mechanism or equivalent.

In order to align and advance a drill bit **96** through the bone **100** accurately, a surgeon must have accurate knowledge of the position of the lower opening **30** of the drill sleeve **26** in relation to the axes of the screw openings **64,66,68**. The magnetic targeting device **10** described herein accomplishes this by employing magnet member-sensor array **30-34** combinations that provide translational and/or rotational positioning information. For example, the magnet member-sensor arrays **30-34** described herein provide translational positioning alignment along planes orthogonal to the targeted screw
25 openings **64,66,68**, together with rotational positioning alignment about the central axis defined by the screw openings **64,66,68**. Alternatively, the magnetic targeting device **10** employs magnet member-sensor array **30-33** combinations together with additional elements, such as a nail extension **110** (see below), to provide this alignment for targeting.

30 One version of the magnet member **70**, shown in **FIG. 11**, employs a polarized magnet **72** with either its north or south pole facing an axis orthogonal to the x axis of the intramedullary nail **60** such that it projects a magnetic field **74** having a central line of flux **75** parallel to the axis of one of the screw openings **64,66,68**. Such a magnet **70** may

be dimensioned and configured to produce either circular or non-circular flux lines. Non-circular flux lines produce a non-circular field shape that uniquely defines each axis. This produces a field shape and polarity that potentially affords unique targeting information in all possible planes, such as the three-dimensional orientation of the intramedullary nail's
5 60 x-axis, y-axis, and z-axis. See U.S. Pub. No. 2005/0075562 to Szakelyhidi et al. regarding non-circular flux lines.

Another version of the magnet member 70, shown in FIGS. 12A and 12B, includes two individual magnets 72 with like poles placed head-to-head in a "bucking" arrangement. For example, a north pole of a first magnet 72 is connected to a north pole
10 of a second magnet 72, and south poles of the first and second magnets 72 extend coaxially therefrom. The same arrangement can be achieved by placing the south poles head-to-head. The magnet member 70 in such an arrangement is preferably longitudinally oriented within the annular cavity 62 along the longitudinal axis (x axis) of the intramedullary nail 60. The bucking arrangement is advantageous in that it compresses
15 the flux lines and produces a radial magnetic field 74 projecting orthogonally to the long axis of the intramedullary nail 60. Because the magnetic field 74 is radially projected, it always has a component perpendicular to the targeted screw openings 64,66,68, regardless of the amount of rotational deflection while inserting the magnet member 70 in the annular cavity 62 of the intramedullary nail 60. The condensed, radially projected
20 magnetic field 74 also permits the sensor array 33 to be compressed, which, in turn, permits a smaller-sized sensor foot 16. This allows for placement of the sensor foot 16 directly against the bone 100 with less damage to surrounding tissue. Another advantage of the bucking arrangement is that the central lines of flux 75 emanating from the like poles of the magnet member 70 (FIGS. 12A and 12B) are at least twice the strength of
25 central lines of flux 75 emanating from a magnet member 70 with its pole aligned orthogonally to the longitudinal axis of the intramedullary nail 60 (FIG. 11). This increases the strength of the magnetic field 74 at any given position on the z axis of the intramedullary nail 60.

The magnets 72 used in the bucking arrangement have cross-sectional dimensions
30 and shapes that enable them to fit within the annular cavity 62 of the intramedullary nail 60. Most intramedullary nails 60 have an annular cavity 62 about 3-4 mm in diameter. The magnet 70 used in the bucking arrangement therefore are preferably sized with about 3 mm in cross-sectional width (i.e., diameter of a cylindrical-shaped magnet) and

preferably no more than about 4 mm in cross-sectional width. This provides an optimal strength while still fitting in the annular cavity **62** of the intramedullary nail **60**. However, it is within the scope of the present invention to use any size of magnet **72**, as long as the magnet **72** can fit within the annular cavity **62** of the intramedullary nail **60**.

5 Other magnet configurations for producing radially oriented magnetic fields **74** that can be used in the present invention are provided by U.S. Patent No. 5,028,902 to Leupold et al. and U.S. Patent No. 5,865,970 to Stelter.

 Another version of the magnet member **70** is shown in **FIG. 12C**. This version comprises at least three magnets **72** disposed along a longitudinal axis, for example, the x
10 axis of the intramedullary nail **60**. Two of the magnets **72**, comprising the ends of the magnet member **70**, are disposed with both the north and south poles aligned along the longitudinal axis of the magnet member **70**. These longitudinally oriented magnets are oriented with their like poles (*i.e.*, north-north or south-south) facing each other, similar to the arrangement in the bucking configuration. A third, orthogonally oriented magnet **72**
15 is interposed between the longitudinally oriented end magnets with its axis and central line of flux **75**, parallel to the axis of one of the screw openings **64,66,68**. In the preferred version of this magnet member **70**, the longitudinally oriented magnets contact the orthogonally oriented magnet. However, the magnets may be separated by a short distance as well. As with the other magnet member **70** configurations, the magnet
20 member **70** configuration shown in **FIG. 12C** can be attached co-axially along the longitudinal axis to a magnet insertion rod **73** for insertion in an annular cavity **62** of an intramedullary nail **60**. The magnets **72** are each sized to fit within the annular cavity **62**.

 The magnet member **70** in the configuration shown in **FIG. 12C** produces a magnetic field **74** substantially similar in shape to a magnet member **70** comprising an
25 orthogonally oriented magnet **72** alone (see **FIG. 11**). However, the presence of the longitudinally oriented end magnets tightens and further projects the magnetic field **74** along the axis defined by the orthogonally oriented magnet **72**. The orthogonally oriented magnet **72** captures and redirects the “bucking” field preferentially toward the sensor array **33**. The magnetic field produced by this configuration permits greater resolution in
30 targeting at distances further away from the magnet member **72**.

 Several mechanisms can be employed to increase the sensitivity of the magnetic targeting device **10** with respect to the magnetic field **74**. One mechanism includes superimposing a fluctuating magnetic field upon the static magnetic field **74** produced by

the magnet member 70. Another mechanism includes placing a ferromagnetic material within the support member 14 between the sensor array 33 and the proximal end of the support member 14 on an axis running through the center of the sensor array 33. When in the presence of the magnetic field 74, the flux lines 78 concentrate on the ferromagnetic material, which extends the magnetic field 74 in the direction of the device 10.

Any type of magnet 72 may be used in the current device 10, including permanent magnets, solenoids, and electromagnets (*i.e.*, iron core solenoids). A preferred version of the magnetic targeting device 10 includes a neodymium iron boron (NdFeB) bar magnet.

Display 18

As illustrated in FIG. 9, the display 18 is preferably graphical in nature and provides a crosshair 92 in combination with a target icon 90. The crosshair 92 and target icon 90 indicate the amount of misalignment of the sensor array 33 with respect to the magnet member 70 in or on the intramedullary nail 60. Referring to FIG. 9, when the target icon 90 is centered on the crosshair 92, the sensor array 33 is centered over the magnet member 70. Depending on the version of the invention, this may indicate that the lower opening 30 of the drill sleeve 26 is centered over a screw opening 64,66,68 for accurate drilling. An advantage of this type of display is that it has sub-millimeter resolution. In addition, visualization of the position of the sensor array 33 relative to the magnet member 70 in the display 18 permits the surgeon to ultimately decide when drilling is appropriate. It is preferred that the display 18 includes a liquid crystal display (LCD) screen.

In addition to moving the target icon 90 with respect to the crosshairs 92, more accurate information can be attained by enlarging the target icon 90 in response to the strength of the magnetic field 74 being sensed. Being able to detect the strength of the magnetic field 74 at various locations ensures that the magnetic targeting device 10 is not sensing a symmetrical set of magnetic field 74 flux lines 78 around the magnet member 70 or a flux pattern created between two or more magnet members 70 which may be embedded into the side of a solid intramedullary nail 60.

Some versions of the magnetic targeting device 10 may include other types of positional indicators in addition to or as an alternative to the display 18 with crosshairs 92 and a target icon 90. These positional indicators may indicate positional information of the magnetic targeting device 10 relative to the intramedullary nail 60 and/or the magnet member 70 via any modality, including variable LED, audio output, color change, or

vibration. In a version employing audio output, the magnetic targeting device **10** provides intermittent sounds such as beeps when the magnetic targeting device **10** detects a magnet field, with intervals between the intermittent sounds becoming shorter as the magnetic targeting device **10** becomes centered over the magnet member **70**. In version employing a vibration modality, the magnetic targeting device **10** vibrates as the magnetic targeting device **10** first detects a magnetic field **74**. The vibration grows in intensity as the magnetic targeting device **10** centers over the magnet member **70**. Any of the display modalities described herein may be combined in any combination. For example, a magnetic targeting device **10** employing a visual display **18** may beep and/or provide a short vibration pulse upon the target icon **90** being centered on the crosshairs **92**.

In other versions, the display **18** can operate in the manner described in U.S. Pub. No. 2005/0075562 to Szakelyhidi et al., which is incorporated herein by reference.

Some versions of the invention are capable of detecting positional information of the magnetic targeting device **10** relative to the intramedullary nail **60** and/or the magnet member **70** in three-dimensions, *i.e.*, by detecting the position of the magnetic targeting device **10** relative to the x, y, and z axes of the intramedullary nail **60** and/or the magnet member **70**. Such versions may provide positional indicators that reflect the three-dimensional position and orientation of the sensor array **33** relative to the magnet member **70**. In one version, the positional indicator reflects the position of the magnetic targeting device **10** using two outputs. A first output displays the position with respect to a plane orthogonal to the targeted screw opening **64,66,68** (*e.g.*, the x-y plane), and a second output displays the position with respect to a central axis defined by the screw opening **64,66,68** (*e.g.*, the z axis). An example of a first output for such a positional indicator is as shown in **FIG. 9**. The translational positioning of the magnetic targeting device **10** on the x-y plane relative to the magnet member **70** is indicated by the positioning of the target icon **90** relative to the crosshairs **92**. The rotational positioning of the magnetic targeting device **10** on the x-y plane relative to the magnet member **70** is indicated by rotation of the sides of the target icon **90** relative to the crosshairs **92**. An example of a second output for such a positional indicator includes a line with a hash mark indicating the center of the line and a target icon positioned along the length of the line. Positioning of the rotational target icon along the line either to one side or the other of the hash mark would indicate rotational misalignment of the magnetic targeting device **10** relative to the z axis of the magnet member **70**. Positioning of the rotational target icon on the hash

mark would indicate alignment. The positional information afforded by such a positional indicator permits translational and/or rotational positioning with respect to the x-y plane and rotational position with respect to the z axis. This prevents off-axis drilling of the nail.

5 **Internal Operation of Device 10**

Reference is now made to **FIGS. 7 and 8** for a description of the internal operation of the device **10**. In action, the microcontroller powers a single sensor **34** in turn, using the switch **103** to connect it to the high gain amplifier **104**. The microcontroller **102** then sets the digital voltage generator **106** to a predetermined value. The microcontroller **102**
10 waits for the sensor **34** and amplifier **104** to settle and then reads the voltage from the amplifier **104**. This voltage is proportional to the applied magnetic field **74** but also contains some environmentally generated noise and noise which is inherent in the sensors **34**. The microcontroller **102** selects the four sensors **34** in sequence, measuring their outputs and saving them for targeting computations. A complete set of measurements is
15 made typically 20 to 50 times per second. As with any high gain sensor system, small errors can be multiplied by factors of 1000 or more, resulting in problems making the required measurements. The sensors **34** are no different and have offset errors in their outputs that make measurements difficult without some adjustment. The amplifier **104** introduces errors as well. The digital voltage generator **106** is used during the calibration
20 process to null out these errors.

When the magnetic targeting device **10** is powered on by the button **20**, the magnetic targeting device **10** immediately begins a calibration sequence. This involves selecting each sensor **34** in turn and determining the value from the digital voltage generator **106** that is required to bring the amplifier **104** into its linear amplifying region
25 of operation. This operation takes only a couple seconds. Thereafter, as each sensor **34** is selected, the digital voltage generator **106** is loaded with the particular value for that sensor **34**, resulting in nullification of static errors for that sensor's measurement. The circuit also features a two-step amplifier gain selection, though the software may use only the high gain setting. Such a system allows use of the magnetic targeting device **10** for
30 various thicknesses of human bone **100** without software changes. This design uses one amplifier **104** and an inexpensive commodity solid state switch **103** to select which sensor **34** to read. Another feature not shown is that the microcontroller **102** does not leave all

sensors 34 powered continuously, but rather turns them on in sequence, saving power consumption.

The microcontroller 102 uses a vector algorithm to determine how to position the target icon 90 on the display 18. The position of each sensor 34 is assigned a vector direction depending on its position in the array 33. The amplitude of the output of each sensor 34 provides the magnitude of each vector 35. Addition of the magnitudes of the vectors 35 provide a resultant vector 71 that determines the position of the magnetic targeting device 10 relative to the magnet member 70, which is represented as a two-dimensional position of a target icon 90 on the display 18 (see FIG. 9). FIG. 10, for example, shows a center box representing the magnet member 70 and four other boxes representing the magnetic sensors 34. The vector lines 35 attached to each sensor 34, respectively, indicate the strength of the field at each sensor. The resultant vector 71 is the sum of the vector lines 35 and indicates the direction the sensor array 33 should be moved to center it over the magnet member 70. The magnet member 70 in FIG. 10 corresponds with the target icon 90 in FIG. 9.

The circuitry in the present invention compares and displays information about the magnetic field 74 in real time for rapid and accurate positioning of the targeting arm 120 while drilling.

Referring back to FIG. 8, the thermal cutoff 108 is present in case the magnetic targeting device 10 is accidentally run through a sterilizer cycle. The thermal cutoff 108 activates at 82° Celsius and disables operation of the magnetic targeting device 10 permanently. Without the thermal cutoff 108, it is likely that the magnetic targeting device 10 would work somewhat after being exposed to such heat, but reliable operation could not be guaranteed. A low battery indicator is implemented that warns the user of low batteries 32 on the display 18 and also prevents the magnetic targeting device 10 from operating.

User Operation

The button 20 is used to turn on the magnetic targeting device 10, and the magnetic targeting device 10 immediately performs a calibration cycle. If the button 20 is pressed briefly thereafter, another calibration cycle is initiated. The display 18 indicates to the user that calibration is in progress. It is not possible to turn on the magnetic targeting device 10 without initiating a calibration cycle. To turn off the magnetic targeting device 10, the button 20 is held down for a couple seconds until the display 18 goes off. The

magnetic targeting device **10** also powers off after two minutes to prevent the batteries **32** from draining.

To perform targeting, the magnetic targeting device **10** is held in the same orientation as it will be used. The magnetic targeting device **10** is raised 10-12 inches
5 above the targeting magnet member **70** and the button **20** is pressed to start a calibration cycle. It is important that the magnetic targeting device **10** be oriented approximately as it will be used in order to properly null the magnetic field of the earth. Once the magnetic targeting device **10** completes its calibration operation, it is lowered to the work area and moved to achieve an on-target indication.

10 **Nail extension 110**

In a version of the invention as shown in **FIG. 13**, the magnetic targeting device **10** is included on a nail extension **110** of an intramedullary nail, the latter of which includes a nail connector **111** and a targeting arm **120**. The nail extension **110** may be a continuous unit, or may be comprised of separate but attachable nail connector **111** and
15 targeting arm **120** members.

The nail connector **111** is capable of being connected to a proximal end of an intramedullary nail **60** in a fixed rotational orientation around the x axis of the nail. The nail connector **111** may be connected to the nail by a threaded connection or in any other manner, all of which are well-known in the art. To maintain the fixed orientation, the nail
20 connector **111** preferably includes diametrically aligned lugs **113** projecting from a surface of the nail connector **111** that interfaces with the intramedullary nail **60**. The lugs **113** are shaped and sized to fit closely in respective recesses **114** in the proximal end of the intramedullary nail **60**. Insertion of the lugs **113** within the recesses **114** during attachment of the nail connector **111** to the intramedullary nail **60** prevents rotation of the
25 nail connector **111** with respect to the intramedullary nail **60** around the x axis.

The nail connector **111** further includes an annular cavity (not shown). When the nail connector **111** is connected to the intramedullary nail, the annular cavity of the nail connector **111** is co-axial and continuous with the annular cavity **62** of the nail. The annular cavity of the nail connector **111** and the annular cavity **62** of the nail are
30 dimensioned and configured to accept a magnet insertion rod **73** therein. In a one version, a distal end of the annular cavity of the nail connector **111** and the annular cavity **62** at the proximal end of the nail are both threaded, and the magnet insertion rod **73** for insertion in these annular cavities **62** is externally threaded. The nail connector **111** is fastened to

the nail **60** by threading the magnetic insertion rod **73** through both the annular cavity of the nail connector **111** and the annular cavity **62** of the nail **60**. This threaded system permits the magnet member **70** on the end of the magnet insertion rod **73** to be placed at a known location at the distal end of the nail.

5 The nail connector **111** further includes a targeting-arm connector **116** that enables connection of the targeting arm **120** to the nail connector **111**. In a preferred version, the targeting-arm connector **116** comprises a portion extending substantially parallel to the longitudinal axis of the nail. The distance between the nail **60** and the extended targeting arm **120** is preferably greater than the amount of tissue surrounding a
10 patient's bone. This distance may be adjustable by a variety of mechanisms. In an exemplary version, the targeting-arm connector **116** is slidable along an orthogonally oriented portion **115** of the targeting arm **120** and secured thereto with a compression screw mechanism **119**. The support member **14** preferably has a length sufficient to place the sensor array an appropriate distance from the magnet member **70** (see above) given
15 the distance between the nail **60** and the extended targeting arm **120**. The targeting-arm connector **116** preferably includes one or more connector holes for attaching the targeting arm **120** to the nail connector **111**.

 In one version of the invention, the nail connector **111** and targeting-arm connector **116** comprise the systems described in U.S. Patent 7,232,433 and U.S. Patent
20 7,549,994 to Zander et al., which are incorporated herein by reference.

 The targeting arm **120** is preferably connected to the nail connector **111** via the targeting-arm connector **116** and extends substantially parallel to the longitudinal axis of the intramedullary nail **60**. In the exemplary version, the targeting arm **120** may be fastened to the targeting-arm connector **116** with bolts **121** that insert through the
25 targeting arm **120** and through the connector holes in the targeting-arm connector **116**.

 The targeting arm **120** includes a plurality of bores **123A,B**. The targeting arm **120** preferably includes a corresponding bore **123A,B** for each screw opening **64,66** in the nails **60** that are intended to be used with the targeting arm **120**. The bores **123A,B** are preferably coaxial with the corresponding screw openings when the targeting arm **120** is
30 aligned with the intramedullary nail **60**. One or more of the bores **123A,B** may be dimensioned and configured to accommodate a support member **14**, and one or more bores **123A,B** may be dimensioned and configured to accommodate a drill sleeve **125**. In the preferred version, the bores **123A,B** are grouped in pairs comprising a proximal bore

123A and a distal bore **123B**, wherein the proximal bore **123A** accommodates a support member **14** and the distal bore **123B** accommodates a drill sleeve.

The proximal bore **123A** places the sensor foot directly over the magnet member **70** in the intramedullary nail **60** when the targeting arm **120** and the intramedullary nail **60** are aligned along the y and z axes. The fit of the support member **14** in the proximal bore **123A** is snug enough to prevent lateral movement of the support member **14** in the proximal bore. This prevents misalignment of the targeting arm **120** relative to the intramedullary nail when the sensor foot **16** is aligned with the magnet member **70**.

A proximal bore **123A** with a magnetic targeting device **10** inserted therethrough may be used for magnetic targeting only or may also be used for drilling. When used for magnetic targeting and drilling, the proximal bore **123A** is positioned on the targeting arm **120** such that alignment of the sensor foot **16** with respect to the magnet member **70** in the intramedullary nail **60** places the lower opening **30** of the drill sleeve **26** of the support member **14** directly over the corresponding screw opening, such as the proximal screw opening **64**.

The distal bore **123B** is configured to place a drill sleeve **125B** directly over the corresponding screw opening, such as the distal screw opening **66**, when the targeting arm **120** is aligned with the intramedullary nail **60**. The fit of the drill sleeve **125B** in the distal bore **123B** is snug enough to prevent lateral movement of the drill sleeve **125B** in the distal bore **123B**. This permits accurate drilling through the distal bore **123B** when the targeting arm **120** is aligned with the intramedullary nail **60**.

In some versions of the invention, the targeting arm **120** has more than one proximal bore **123A** and/or distal bore **123B**. This permits targeting and drilling of each screw opening of intramedullary nails of difference sizes. A targeting arm **120** having more than one proximal bore **123A** and/or distal bore **123B** preferably has indicia along the length of the targeting arm **120** indicating the correct positions for targeting and drilling for a nail **60** of a particular size.

The support member **14** and the drill sleeve **125B** preferably have substantially the same cross-sectional shapes and dimensions in the areas where each nests in the bores **123A,B**. This permits all of the bores **123A,B** in the targeting arm **120** to have the same dimensions and to accommodate either the support member **14** or the drill sleeve **125B** therein. This allows different combinations of the bores **123A,B** to be used for targeting and/or drilling. Alternatively, the support member **14** and the drill sleeve **125B** are

differently dimensioned and fit in bores **123A,B** specifically designed to accommodate each.

It is preferable that the distal bore **123B** is located on the targeting arm **120** far enough away from the proximal bore **123A** so that the metal in the drill bit **96** while drilling through the distal bore **123B** does not interfere with the magnetic field **74** generated by the magnet member **70**. However, for purposes of drilling accuracy, it is important that the distal bore **123B** is not placed too far from the proximal bore **123A**. Because the intramedullary nail **60** and the targeting arm **120** are connected at their proximal ends, a small amount of misalignment at the position of a more proximal bore **123A** results in a larger amount of misalignment at the position of a more distal bore **123B**. Placing the proximal bore **123A** just out of the range of interference induced by the drill bit **96** in the distal bore **123B** minimizes such an amplification of misalignment.

The medullary cavity **101** of the femur is curved. Intramedullary nails **60** are therefore typically curved along their longitudinal axes for insertion in the medullary cavity **101**. The targeting arm **120** may comprise a curvature that corresponds with the curvature of the intramedullary nail **60** such that each bore **123A,B** in the targeting arm **120** is axially aligned with the screw openings in the nail **60** at approximately the same distance from the intramedullary nail.

During targeting and drilling, it is preferable to attach the magnetic targeting device **10** to the targeting arm **120** in some manner to prevent movement of the magnetic targeting device **10** with respect to the targeting arm **120**. Such attachment is minimally achieved by virtue of inserting the support member **14** through the proximal bore **123A**. Additional mechanisms of attachment may include snap-fit protrusions extending from the bottom of the nail connector **111** to fit into additional bores along the length of the targeting arm **120**, zip ties, straps with "VELCRO"-brand hook-and-loop fasteners, and/or other fasteners. The targeting arm **120** may further include indented portions to nest the body of the device therein.

The nail extension **110** is preferably comprised of carbon fiber for maximum strength and minimum weight.

Y- and Z-Axis Alignment of Bores 123A,B in Nail Extension 110 with Radial Magnetic Field 74

The nail extension arm **110** does not admit of flexure along longitudinal axis of the targeting arm **120**, *i.e.*, "stretching." Therefore, the targeting arm **120** is substantially

fixed with respect to the x axis of the nail **60**. However, the nail extension arm **110** does admit of flexure across the longitudinal axis of the targeting arm **120**. In other words, the targeting arm **120** will yield slightly to forces having a z or y vector component. Because the targeting arm **120** is anchored via the nail connector **111** to the intramedullary nail **60**, purely translational displacement of the sensor array **33** with respect to the magnet member **70** does not occur. Any flexure of the targeting arm **120** will therefore induce rotational misalignment with respect to the magnetic field **74**. The rotational misalignment is read as an imbalance by the sensor array **33**. This is true even when a symmetrical, planar array **33** of four sensors **34** and a magnet member **70** producing a radial magnetic field **74** is used. The detected imbalance can be corrected by positional adjustment of the targeting arm **120** relative to the intramedullary nail **60**.

Orthogonal Targeting Guide 130

As shown in **FIG. 14**, some versions of the invention further include an orthogonal targeting guide **130**, which is configured for use with the nail extension **110**. The magnetic targeting device **10** is used to attach two parallel, mechanically stabilized drill sleeves **125A,125B** against a lateral portion of the bone **100**. The drill sleeves **125A,125B** are stabilized at one end by the targeting arm **120** and at another end with set screws that fasten into holes drilled at the screw openings **64,66,68**. Fastening the drill sleeves **125A,125B** generates a stable, substantially rectangular construct comprising the stabilized drill sleeves **125A,125B**, the targeting arm **120**, the nail connector **111**, and the intramedullary nail **60**.

The orthogonal targeting guide **130** includes a lateral support base **131**, orthogonal support arms **132**, a mechanical targeting guide **133**, and, optionally, a straight-edge guide **134**. The lateral support base **131** attaches to the two parallel, mechanically stabilized drill sleeves **125A,125B**, preferably by clamping thereto. The orthogonal support arms **132** extend from the lateral support base **131** to either the anterior or posterior side of the intramedullary nail **60** being targeted in a manner that clears soft tissues surrounding the bone **100**. The orthogonal support arms **132** include the mechanical targeting guide **133** slidably engaged thereto, such that the mechanical targeting guide **133** is capable of sliding on the orthogonal support arms **132** along the y axis of the intramedullary nail **60**. The mechanical targeting guide **133** includes one or more orthogonal guide bores **135** that correspond to the position of the orthogonal screw openings **68** along the x axis, in addition to a locking screw **136** that restricts movement of the mechanical targeting guide

133 on the orthogonal support arms 132 along the y axis. The straight-edge guide 134 is mounted on the nail extension 110 and projects a physical or visual indicator of the midline of the intramedullary nail 60 for alignment of the orthogonal guide bores 135 on the mechanical targeting guide 133 with respect to the orthogonal screw openings 68 in the nail 60. In the exemplary version of the invention, the strait-edge guide 134 is a laser 137 that projects a visual indicator of the midline of the intramedullary nail 60. The laser 137 may be used with or without a mirror 138 also mounted on the nail extension 110. The orthogonal targeting guide 130 aligns the orthogonal guide bores 135 with the underlying orthogonal screw openings 68 in the intramedullary nail 60 for accurate drilling.

As an alternative to anterior-posterior targeting with an orthogonal targeting guide 130, the nail extension 110 may be configured to rotate to either an anterior or posterior position for targeting and drilling. In this version, the targeting arm 120 further includes bores positioned along the length of the targeting arm 120 to correspond to the position of the orthogonal screw openings 68 along the length of the intramedullary nail 60. Orthogonal recesses for accepting the lugs 113 are also included in the proximal portion of the nail 60 for maintaining the orientation of the targeting arm 120 in the xy plane.

Intramedullary Nail 60 Targeting

In a preferred version of the invention, the proximal screw opening 64 is targeted while the distal screw opening 66 is drilled. This prevents magnetic interference from the drill bit 96 from disrupting targeting. The intramedullary nail 60 is placed in the marrow of the bone 100 and urged through the bone 100 as described in Szakelyhidi et al. The proximal opening 64 in the intramedullary nail 60 to be targeted has a magnet member 70 placed at a reproducible distance therefrom. The magnet member 70 is either embedded in the surface of the intramedullary nail 60 as illustrated in FIG. 6 or is inserted in the annular cavity 62 of the intramedullary nail 60 with a magnet insertion rod 73 and locked in place. A nail extension 110 with a nail connector 111 and a targeting arm 120 is attached to the intramedullary nail 60. The indicia on the targeting arm 120 indicate the end of the intramedullary nail 60, the approximate location of the openings 64, 66 in the intramedullary nail 60 in the bone 100, and the proximal bore 123A and the distal bore 123B in the targeting arm 120 that correspond with the proximal opening 64 and distal opening 66, respectively. An incision is made in the limb in the vicinity of the openings 64,66 according to the positions of the indicia. An oval trochar can be used to make a

path for the support member **14** down to the surface of the bone **100**. The support member **14** is inserted through the proximal bore **123A**, and the sensor foot **16** is placed on the surface of the bone **100**. In addition, a drill sleeve **125B** is inserted through the distal bore **123B** and placed directly on the bone **100**. A drill bit **96** is then inserted into the drill sleeve **125B**. A star-point drill prevents the drill from “walking” on the slippery curved surface of the bone and is therefore preferred.

While the distal bore **123B** in the nail extension **110** places the drill sleeve **125B** in the general vicinity of the distal opening **66**, targeting at the magnet member **70** in the general vicinity of the proximal opening **66** corrects the final 2-3 mm misalignments resulting from the flexure of the nail extension **110**. The sensor array **33** is activated to locate the magnet member **70**, which then determines the location of the proximal opening **64**. The display **18** is activated by the action of the button **20**. A signal is sent to the sensor array **33** to zero the sensors **34**. When the sensor array **33** is moved across the surface of the bone **100**, the sensor information appears on the display **18**, generally in the form of a target icon **90** and crosshairs **92** as illustrated in **FIG. 9**. If the sensor configuration affords z axis alignment information, a target icon **90** on a z-axis line in the display **18** also appears. The positioning of the target icon **90** in the center of the targeting grid **92** and positioning of the target icon **90** in the center of the z-axis line indicates correct placement of the magnetic targeting device **10** for drilling.

As soon as the target icons **90** align at the center of the crosshairs **92** and/or the z-axis line, the drill **96** is drilled through the distal opening **66** to the opposite cortex. The drill is far enough from the magnet member **70** and sensor foot that it does not produce magnetic interference.

Once the drill has passed through the bone cortex surrounding the distal opening **66**, it is left in place. A modified drill sleeve **125B** with a set screw is pushed against the cortex of the bone. The set screw is tightened, making a stable, substantially rectangular construct comprising the stabilized drill sleeve **125B**, the targeting arm **120**, the nail connector **111**, and the intramedullary nail **60**. With the distal opening **66** successfully targeted and stabilized, all proximal holes are aligned with the targeting arm **120**. Drilling the proximal opening **64** occurs either by drilling through the drill sleeve **26** in the support member **14** of the magnetic targeting device **10** or by replacing the magnetic targeting device **10** in the proximal bore **123A** with a separate drill sleeve **125A** and

drilling therethrough. Any other openings on the proximal side of the drilled and stabilized opening **66** are similarly drilled.

The user has two options for targeting and drilling orthogonal openings **68**, if drilling of such openings is desired. In a first option, the stabilized drill sleeve **125B** at opening **66** is removed. The nail extension **110** is rotated **90** degrees about the x axis of the intramedullary nail **60**. If using a magnet member **70** with its pole aligned orthogonally to the longitudinal axis of the nail **60**, the magnet insertion rod **73** is also rotated **90** degrees about the x axis of the intramedullary nail **60**. If using a magnet member **70** in a bucking arrangement, no rotation is required. If using a magnet member **70** embedded in the surface of the nail **60**, the magnet member is pre-positioned for targeting and drilling. The orthogonal openings **68** are then targeted and drilled through orthogonal guide bores **135** corresponding with the orthogonal openings **68** in the same manner in which the lateral openings **64,66** were drilled.

In a second option, a second stabilized drill sleeve **125A** is constructed at the proximal opening **64** such that there are two parallel, mechanically stabilized drill sleeves **125A,125B** braced by the nail extension **110** and the intramedullary nail **60**. An orthogonal targeting guide **130** is attached to the stabilized drill sleeves **125A,125B** with the orthogonal support arms **132** directed to the desired side for drilling. A straight-edge guide **134**, such as a laser **137**, is mounted on the nail extension **110**, and the anterior-posterior guide bores **135** are aligned with the straight-edge guide **134** to indicate the position of the underlying orthogonal openings **68** along the y axis of the nail **60**. The orthogonal openings **68** are then drilled via mechanical targeting of the orthogonal targeting guide **130**.

In some applications it is advantageous to insert a locking screw through the drilled opening **64,66,68** directly after targeting and drilling. A calibration on the drill measures the depth of the drilled hole at the upper opening **28** of the support member **14**. Alternatively, after drill removal, the magnetic targeting device **10** can remain against the bone **100**. A depth gauge is used to measure the length of the screw to be inserted. Once measured, the screw of the appropriate length is loaded onto a screw driver and inserted across the openings **64,66,68** of the intramedullary nail **60**. Self tapping screws are used in the preferred embodiment.

An aiming device is always more accurate if it has two references in space to align it. In the present invention, a first reference to provide accuracy comes from the bores

123A,B on the targeting arm 120, which indicate the entry point on the skin directly over the opening 64,66,68 to be targeted in the intramedullary nail 60. The targeting arm 120 shows the correct entry point over each opening and stabilizes the device perpendicular to the longitudinal axis of the intramedullary nail 60. A second reference is provided by the magnetic targeting device 10, which is placed directly on the surface of the bone 100 to be targeted. The targeting of the magnetic targeting device 10 at the surface of the bone 100 corrects the final 2-3 mm misalignments resulting from the tolerances of the nail extension 110. The importance of being able to rest the magnetic targeting device 10 on the surface of the bone 100 during use cannot be over-emphasized. The accuracy needed for drilling and stabilizing intramedullary nails 60 within a broken bone is on the order of 1 mm. Use of either a magnetic targeting device 10 or mechanical targeting arm 120 alone is not as accurate as using both in combination.

Bone Plates and Bone Plate Targeting

Versions of the device described herein can be extended to subcutaneous bone plating. Bone plates are generally solid, rigid plates with holes that attach to the outer surface of a bone, particularly a broken bone, to stabilize it. Bone plates are well known in the art. Examples include those described in U.S. Patent No. 7,635,365 to Ellis et al. Bone plates used in the art are modified to include a magnet member 70 for targeting. In one version, a magnet member 70 is embedded in the surface of the plate proximal to a hole to be targeted for drilling the underlying bone 100. Preferably, the most distal drill hole of every plate has a 2 mm magnet member 70 embedded into the plate just proximal to the hole. In another version, a ring magnet is embedded around the hole. In either case, the magnet members 70 included in the bone plates are disposed on the outside of the bone 100. This enables the sensor foot to be placed in a percutaneous manner in the direct vicinity of the magnet member. Because the targeting distances are so small, a sensor foot 16 including a single sensor 34 can be used for targeting.

For targeting and drilling bone plating holes, the magnetic targeting device 10 is used either with or without an intramedullary nail 60 and nail extension 110. To target the bone plate with the device 10, a drill sleeve 26 is inserted in the support member 14, and the sensor foot 16 of the support member 14 is placed in the vicinity of the distal hole to be drilled. When the sensor foot 16 is aligned with the magnet member 70, the display is centered, and the distal hole is drilled. A modified Cleco spring fastener (Cleco Industrial Fasteners, Inc., Harvey IL, USA) is inserted in the drilled hole to provide temporary

fixation and stability. If the location of the drilled hole is correct after reduction of the fracture, the Cleco spring fastener is replaced by a screw. The Cleco spring fastener allows easy repositioning and drilling if minor adjustments in position of the plate are needed.

5 In an alternate version, drill holes in a subcutaneous bone plate are located by detecting threaded magnet members **70** that are screwed into holes pre-selected for use. The magnets **72** comprising the magnet members **70** are preferably NbFeBoron magnets for maximum strength. The magnet members **70** preferably have a hex drive. Because the most advantageous hole to locate during bone plating is the most distal subcutaneous hole
10 of the plate, a magnet member **70** is inserted in the most distal hole. The magnets members **70** are sensed through the soft tissues by a sterile magnetic compass. Once located, the skin is marked and excised. The pre-positioned magnet members **70** in the screw holes are located by a magnetic screwdriver of the opposite polarity that locks into the hex head of the magnet member. Once the targeted hole is located, a hole is drilled,
15 and a Cleco plate holder is inserted for immediate temporary fixation. If x-rays show that the reduction is satisfactory, other critical holes are located in a similar fashion. The distal Cleco plate holder is then removed and replaced by a locking screw. If the position of the plate is not ideal, the Cleco plate holder allows rapid repositioning of the distal end of the plate. The magnet-to-magnet location of the screw holes provides simplicity, low cost,
20 and reliability in locating bone plating holes.

Plates made by Synthes, Inc. (West Chester, PA, USA) have a combination of holes that are immediately adjacent to each other. In targeting such plates, one of the holes is modified to include a magnet member **70** and is used for targeting. A second hole is drilled through an adjacent parallel drill sleeve stabilized by the targeting arm **120**. For
25 single-hole plate designs, a magnet member placed in a small recess in the plate would allow a drill sleeve with a magnetic material to locate and lock into position for drilling.

Any version of any component or method step of the invention may be used with any other component or method step of the invention. The elements described herein can be used in any combination whether explicitly described or not.

30 All combinations of method steps as used herein can be performed in any order, unless otherwise specified or clearly implied to the contrary by the context in which the referenced combination is made.

As used herein, the singular forms "a," "an," and "the" include plural referents unless the content clearly dictates otherwise.

Numerical ranges as used herein are intended to include every number and subset of numbers contained within that range, whether specifically disclosed or not. Further, these numerical ranges should be construed as providing support for a claim directed to any number or subset of numbers in that range. For example, a disclosure of from 1 to 10 should be construed as supporting a range of from 2 to 8, from 3 to 7, from 5 to 6, from 1 to 9, from 3.6 to 4.6, from 3.5 to 9.9, and so forth.

All patents, patent publications, and peer-reviewed publications (*i.e.*, "references") cited herein are expressly incorporated by reference in their entirety to the same extent as if each individual reference were specifically and individually indicated as being incorporated by reference. In case of conflict between the present disclosure and the incorporated references, the present disclosure controls.

The devices and methods of the present invention can comprise, consist of, or consist essentially of the essential elements and limitations described herein, as well as any additional or optional steps, ingredients, components, or limitations described herein or otherwise useful in the art.

It is understood that the invention is not confined to the particular construction and arrangement of parts herein illustrated and described, but embraces such modified forms thereof as come within the scope of the following claims.

I claim:

1. An intramedullary nail targeting apparatus including:
a nail extension capable of being connected to an end of an intramedullary nail and including a targeting arm configured to extend along a longitudinal axis of the intramedullary nail when connected thereto, the targeting arm including one or more bores;
a magnetic targeting device capable of detecting a magnet including:
a support member having a proximal end and a distal end and being structured to fit through at least one of the one or more bores in the targeting arm;
a sensor array disposed on the distal end of the support member; and
a positional indicator; and
a magnet member disposed in fixed relation to the intramedullary nail, wherein the support member has a length sufficient to place the sensor array against a bone comprising the intramedullary nail when the nail extension is connected to the intramedullary nail and the magnetic targeting device is connected to the targeting arm.
2. The apparatus of claim 1 wherein the magnet member produces a radial magnetic field.
3. The apparatus of claim 1 wherein the magnet member includes a first magnet and a second magnet arranged coaxially with like poles oriented head-to-head.
4. The apparatus of claim 1 wherein the magnet member includes a third magnet interposed between the first and the second magnets and disposed orthogonally to the first and second magnets.
5. The apparatus of claim 1 wherein the magnet member is coaxially disposed on the end of a magnet insertion rod, wherein the magnet insertion rod is dimensioned and configured to be fixedly inserted into an annular cavity of an intramedullary nail.
6. The apparatus of claim 1 wherein the magnet member is no more than 4 mm cross-sectional width.

7. The apparatus of claim 1 wherein the magnet member is embedded in the intramedullary nail.
8. The apparatus of claim 1 wherein the sensor array comprises sensors in a planar, symmetrical arrangement.
9. The apparatus of claim 8 wherein the sensor array further comprises a first additional sensor equidistant from each of the sensors in the planar, symmetrical arrangement.
10. The apparatus of claim 9 wherein the first additional sensor is disposed outside a plane defined by the sensors in the planar, symmetrical arrangement.
11. The apparatus of claim 9 wherein the sensor array further comprises a second additional sensor equidistant from each of the sensors in the planar symmetrical arrangement.
12. The apparatus of claim 1 wherein the support member comprises a ferromagnetic material disposed within the support member between the sensor array and the proximal end of the support member on an axis running through a center of the sensor array.
13. The apparatus of claim 1 wherein the sensor array comprises polarized sensors capable of detecting and distinguishing x, y, and z vectors of a magnetic field.
14. The apparatus of claim 1 wherein the support member comprises cross-sectional width no more than about 9 mm.
15. The apparatus of claim 1 wherein the support member comprises a drill sleeve.
16. The apparatus of claim 1 wherein nail extension and/or the targeting arm is comprised of carbon fiber.
17. The apparatus of claim 1 wherein the targeting arm comprises a curvature

18. The apparatus of claim 1 further comprising an intramedullary nail that connects to the nail extension, wherein the targeting arm and intramedullary nail both comprise a curvature along their longitudinal axes and the curvature of the targeting arm corresponds to the curvature of the intramedullary nail such that the intramedullary nail is disposed a same distance from the targeting arm at each point along its longitudinal axis when the intramedullary nail is connected to the nail extension.

19. The apparatus of claim 1 further comprising an intramedullary nail that connects to the nail extension, wherein the intramedullary nail comprises a longitudinal axis and one or more screw openings along the longitudinal axis, wherein each screw opening in the one or more screw openings in the intramedullary nail has a corresponding bore in the one or more bores in the targeting arm.

20. The apparatus of claim 19 wherein each screw opening in the one or more screw openings in the intramedullary nail has a central axis coaxial with a central axis of the corresponding bore in the one or more bores in the targeting arm when the targeting arm is aligned with the intramedullary nail.

21. The apparatus of claim 1 further comprising a straight-edge guide mounted on the nail extension and defining an axis corresponding to a midline of an intramedullary nail.

22. The apparatus of claim 21, wherein the straight-edge guide is a laser.

23. The apparatus of claim 22 further comprising a mirror mounted on the nail extension to direct the laser along the axis corresponding to the midline of the intramedullary nail.

24. The apparatus of claim 1 wherein the nail extension comprises an annular cavity for insertion of a magnetic insertion rod therethrough.

25. The apparatus of claim 1 wherein the positional indicator is a display disposed on the proximal end of the support member.

26. A method of targeting screw openings in an intramedullary nail for internal fixation of a bone within a limb, wherein the intramedullary nail includes first and second screw openings, the method comprising:

a. placing the intramedullary nail in a medullary cavity of the bone, wherein the intramedullary nail includes a magnet member positioned at a known, fixed position relative to the second screw opening;

b. attaching a nail extension to a proximal end of the intramedullary nail, wherein the nail extension includes a targeting arm extending a substantially consistent distance from a longitudinal axis of the intramedullary nail, the targeting arm including a first bore and a second bore, wherein the first bore includes a central axis that is configured to be substantially coaxial with a central axis of the first screw opening when the targeting arm is aligned with the intramedullary nail, and the second bore includes a central axis that is configured to be substantially coaxial with a central axis of the second screw opening when the targeting arm is aligned with the intramedullary nail; and

c. attaching a magnetic targeting device to the targeting arm, wherein the magnetic targeting device includes:

a support member having a proximal end and a distal end and being structured to fit through the second bore in the targeting arm;

a sensor array disposed on the distal end of the support member; and

a positional indicator,

wherein the support member is inserted through the second bore with the distal end of the support member positioned against the bone;

d. aligning the magnetic targeting device with the magnet member, wherein the aligning the magnetic targeting device with the magnet member aligns the targeting arm with the intramedullary nail;

f. drilling a first hole in the bone at a position of the first screw opening;

g. stabilizing the targeting arm to the first screw opening; and

h. drilling a second hole in the bone at a position of the second screw opening.

27. The method of claim 26 wherein the second screw opening is a proximal screw opening and the first screw opening is a distal screw opening, wherein the proximal screw opening and the distal screw opening are defined with respect to the proximal end of the intramedullary nail.

28. The method of claim 26 wherein the targeting arm is stabilized to the first screw opening with a first drill guide extending from the first screw opening through the first bore.

29. The method of claim 26 further comprising after step (h):

- i. stabilizing the targeting arm to the second screw opening;
- j. attaching an orthogonal targeting guide to the stabilized targeting arm; and
- k. drilling holes in the bone through the orthogonal targeting guide.

30. The method of claim 29 wherein the targeting arm is stabilized to the second and first screw openings with a first drill guide extending from the first screw opening through the first bore and a second drill guide extending from the second screw opening through the second bore, wherein the orthogonal targeting guide is attached to the first and second drill guides.

31. The method of claim 29 further comprising between steps (j) and (k):

- l. indicating a midline of the intramedullary nail with a straight-edge guide.

32. The method of claim 26 further comprising after step (h):

- m. rotating the nail extension orthogonally;
- n. targeting orthogonal openings in the intramedullary nail with the magnetic targeting device; and
- o. drilling holes in the bone through the orthogonal openings.

33. The method of claim 26 wherein the aligning in step (d) further includes inducing a pulsed magnetic field by superimposing a fluctuating magnetic field upon a static magnetic field produced by the magnet member.

34. A bone plate targeting apparatus for targeting a bone plate including holes, the apparatus comprising:

- a magnet member disposed a defined distance from at least one of the holes; and
- a magnetic targeting device capable of detecting the magnet member including:

a support member having a proximal end and a distal end and having a drill sleeve extending therethrough;

a sensor array disposed on the distal end of the support member, wherein a distance between the sensor array and a lower opening of the drill guide corresponds with the defined distance; and

a positional indicator.

35. The apparatus of claim 34 wherein the magnet member is a ring magnet embedded around the at least one of the holes.

36. The apparatus of claim 35 wherein the magnet member threads into the at least one of the holes.

37. A method of targeting holes in a bone plate for the external fixation of a bone within a limb, the method comprising:

a. placing the bone plate against the bone, wherein the bone plate comprises a magnet member disposed a defined distance from at least one of the holes;

b. placing a magnetic targeting device against the bone plate, wherein the magnetic targeting device includes:

a support member having a proximal end and a distal end and having a drill sleeve extending therethrough;

a sensor array disposed on the distal end of the support member, wherein a distance between the sensor array and a lower opening of the drill guide corresponds with the defined distance; and

a positional indicator;

c. aligning the magnet member with the sensor array, wherein the aligning the magnet member with the sensor array aligns the lower opening of the drill guide with the at least one of the holes; and

d. drilling a hole in the bone through the at least one of the holes.

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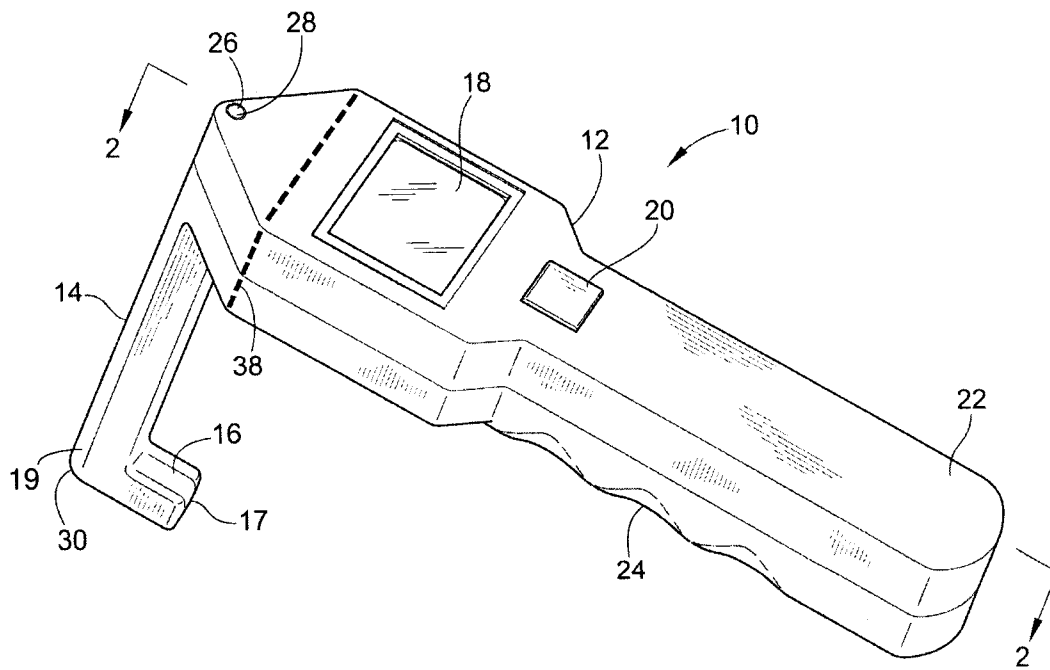


FIG. 1

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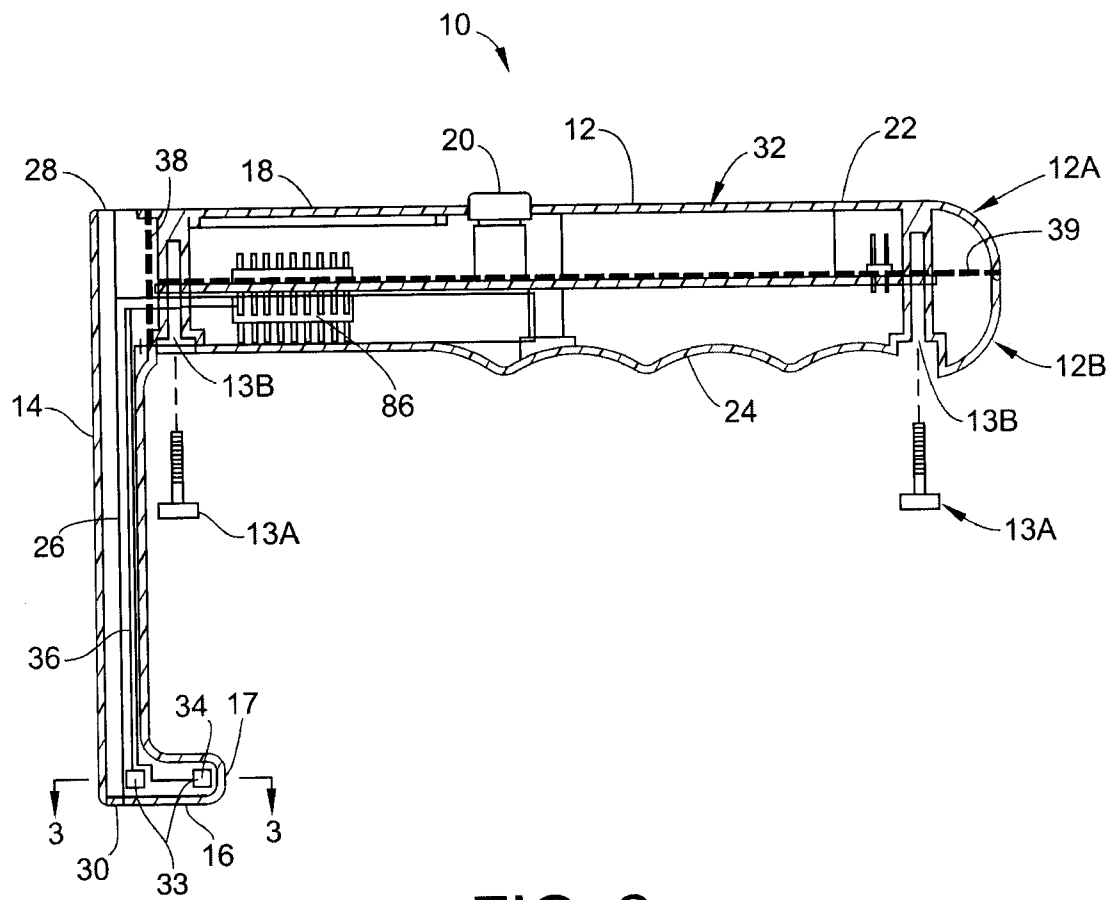


FIG. 2

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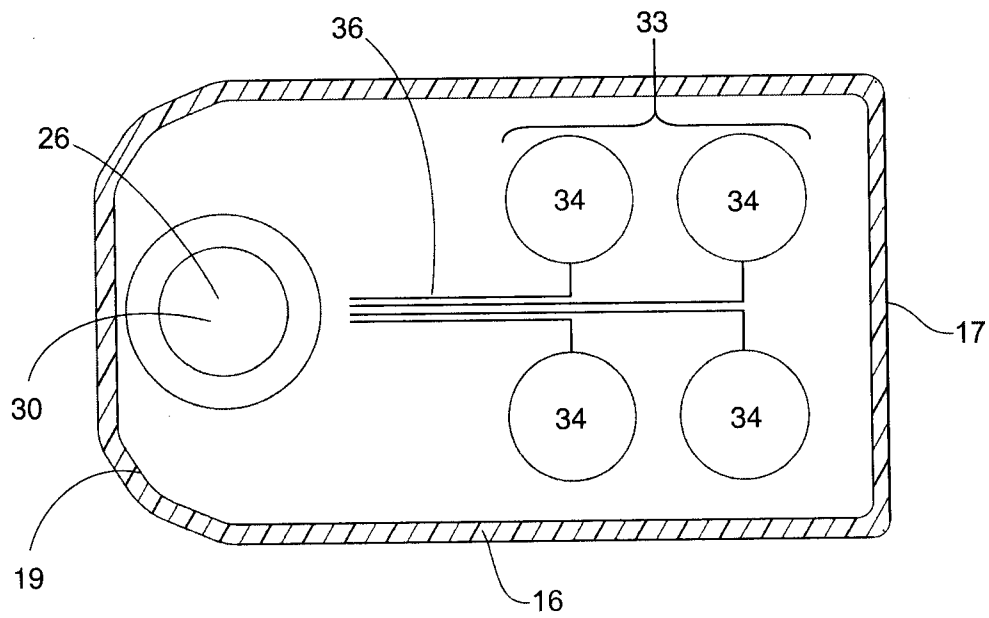


FIG. 3

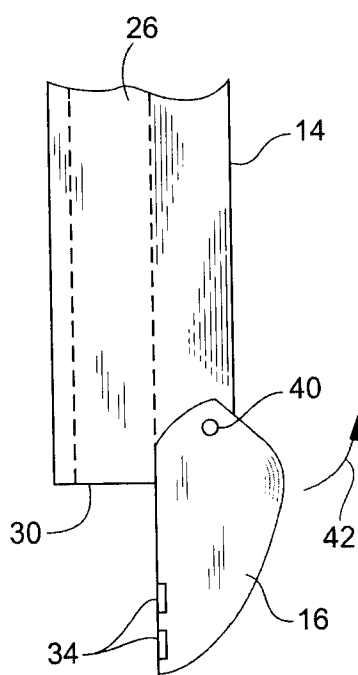


FIG. 4A

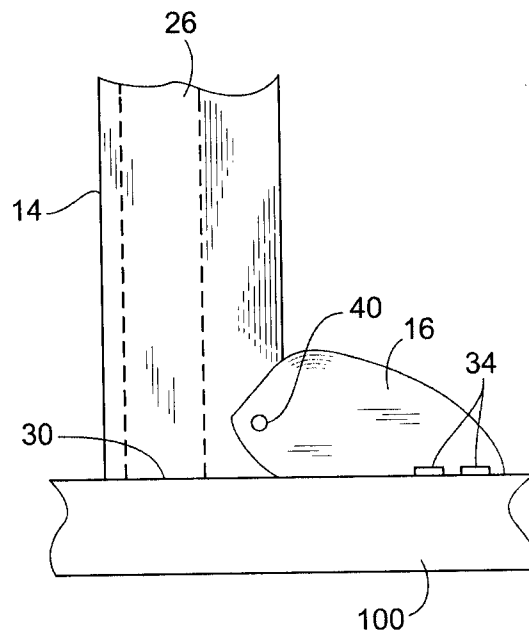


FIG. 4B

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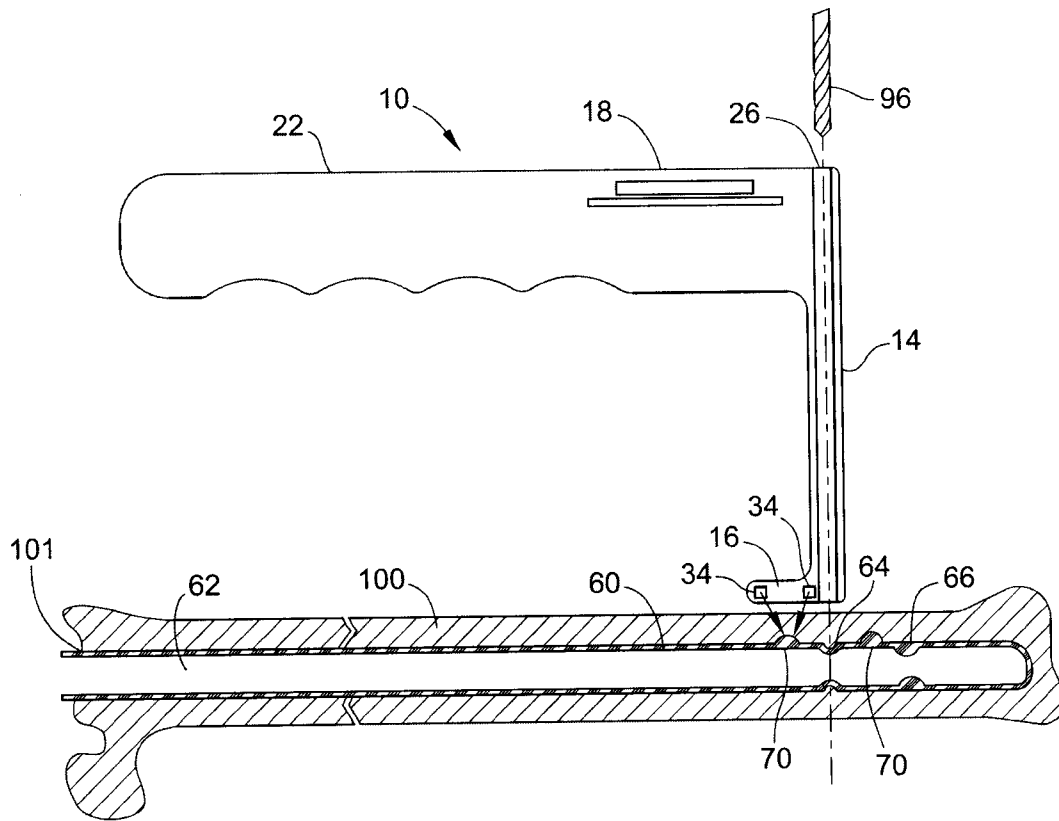


FIG. 5

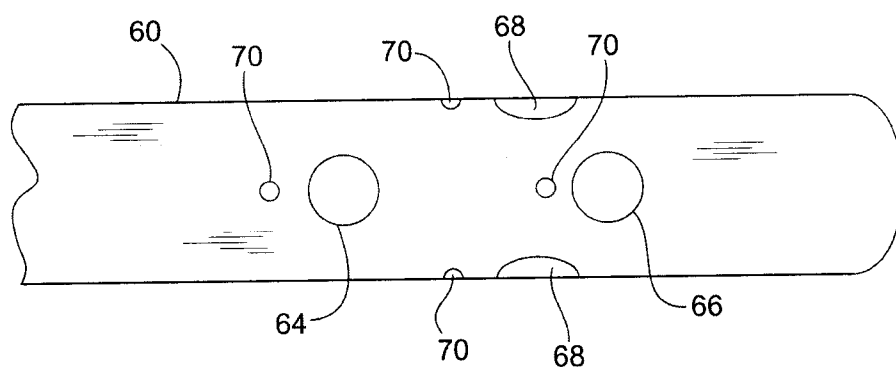


FIG. 6

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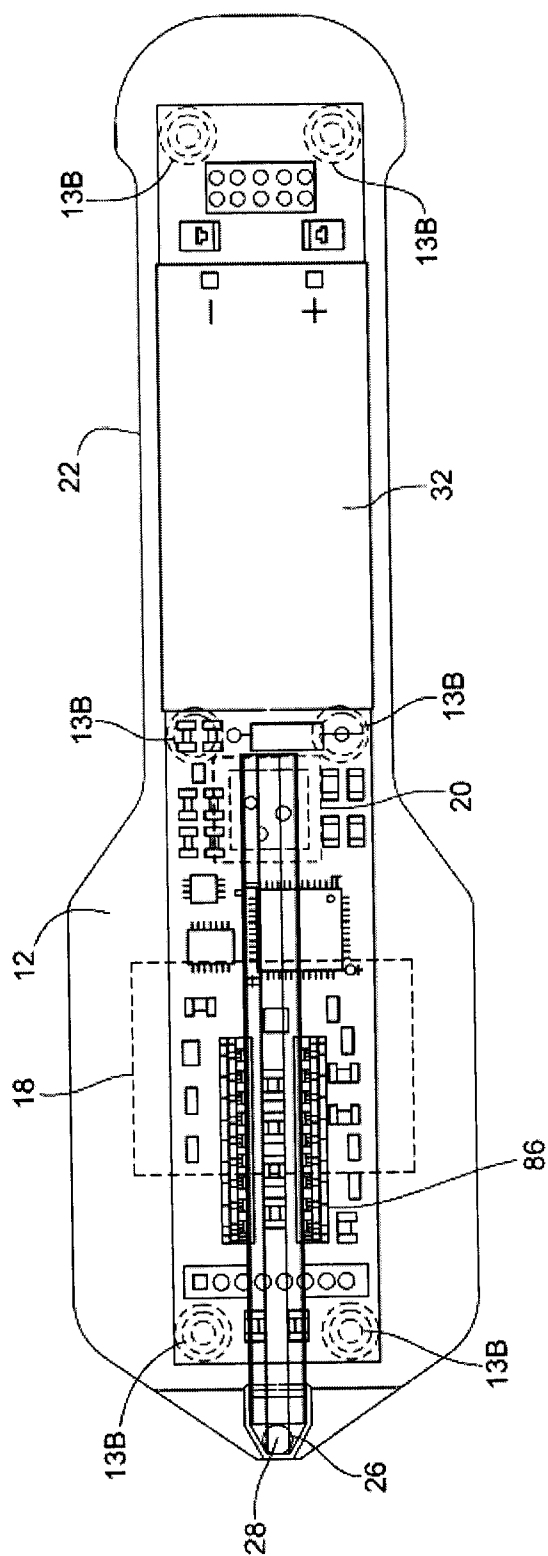


FIG. 7

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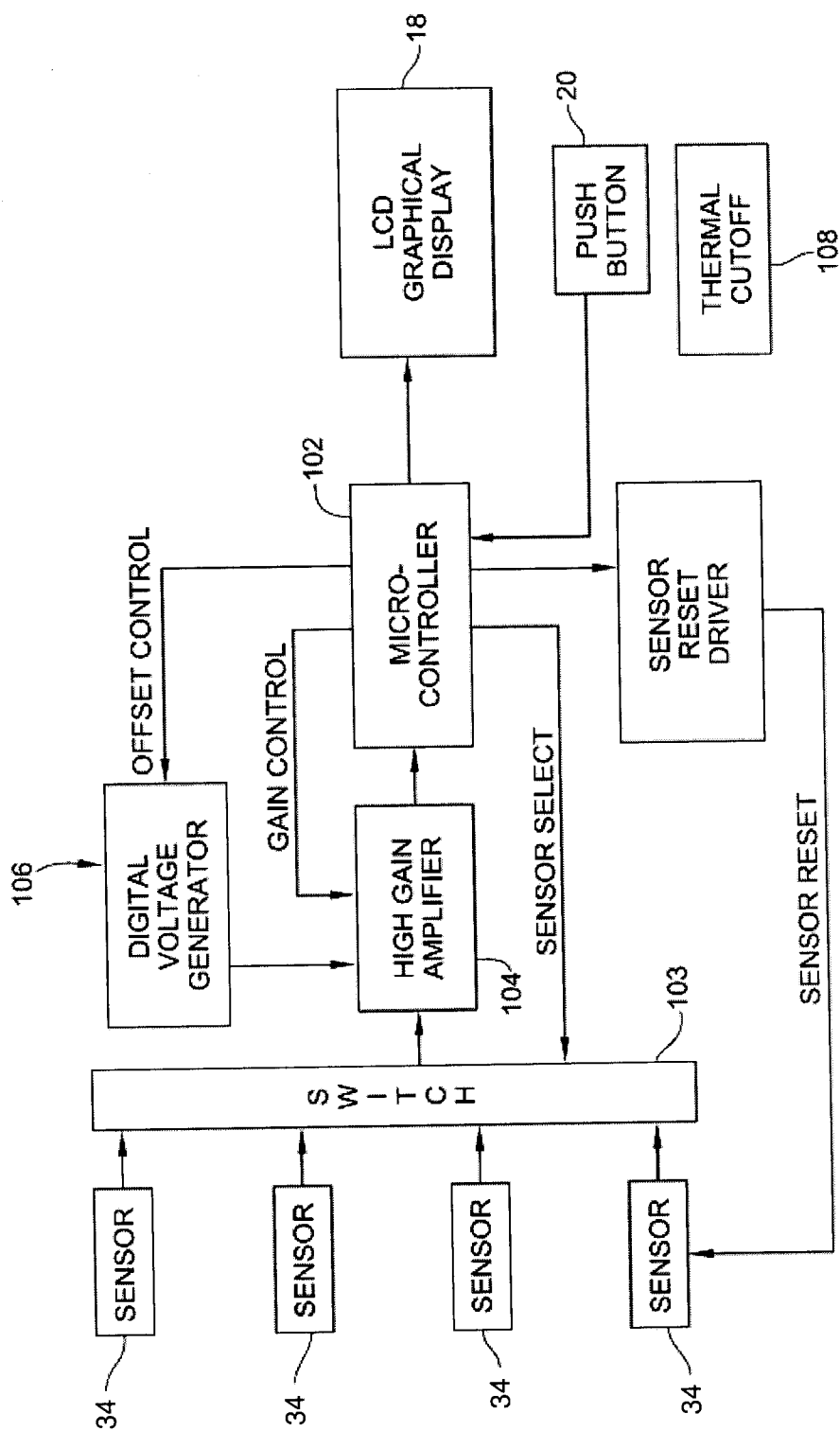


FIG. 8

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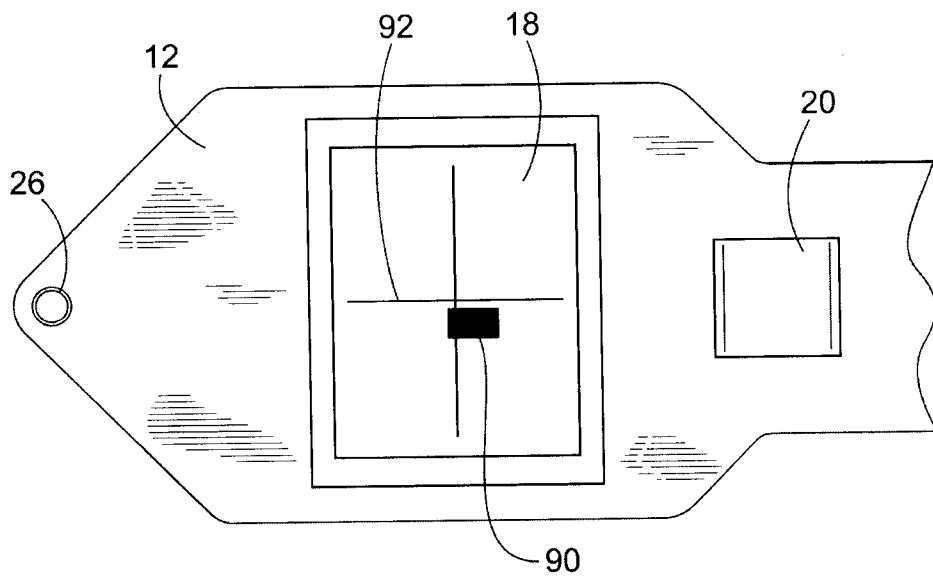


FIG. 9

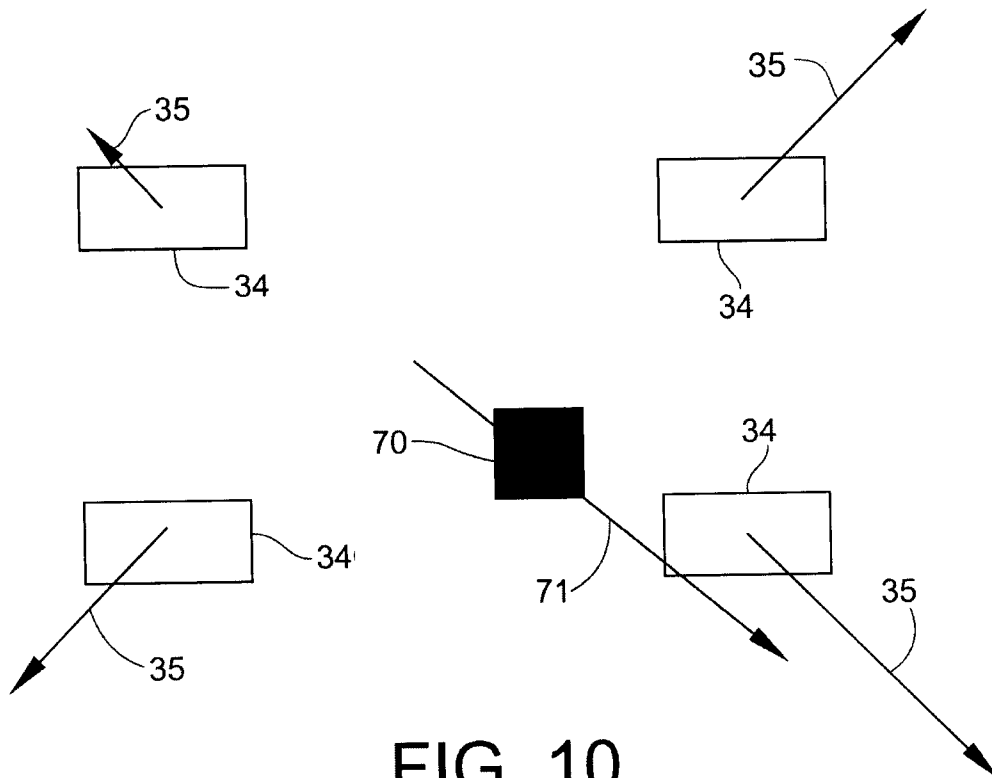


FIG. 10

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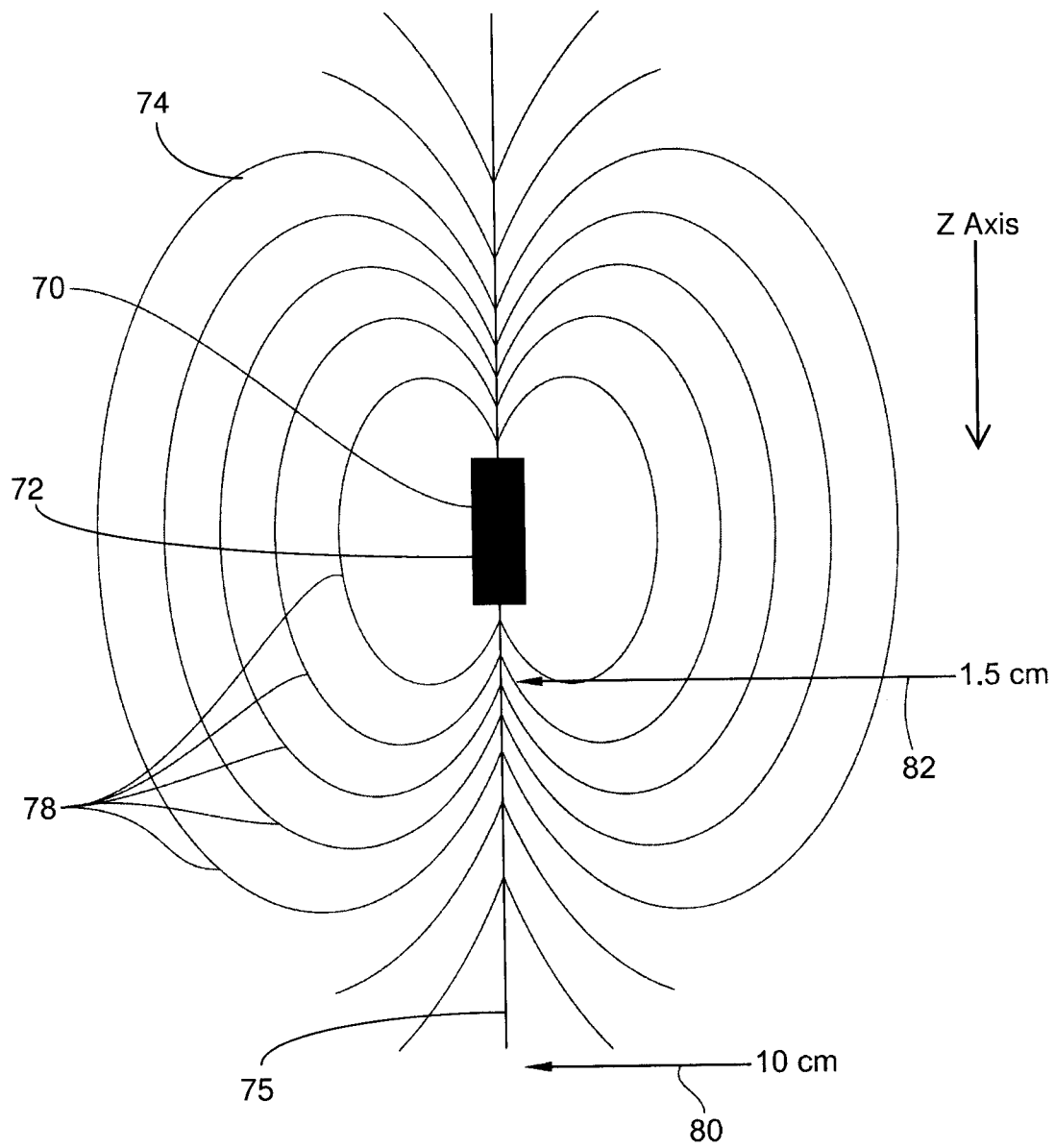


FIG. 11

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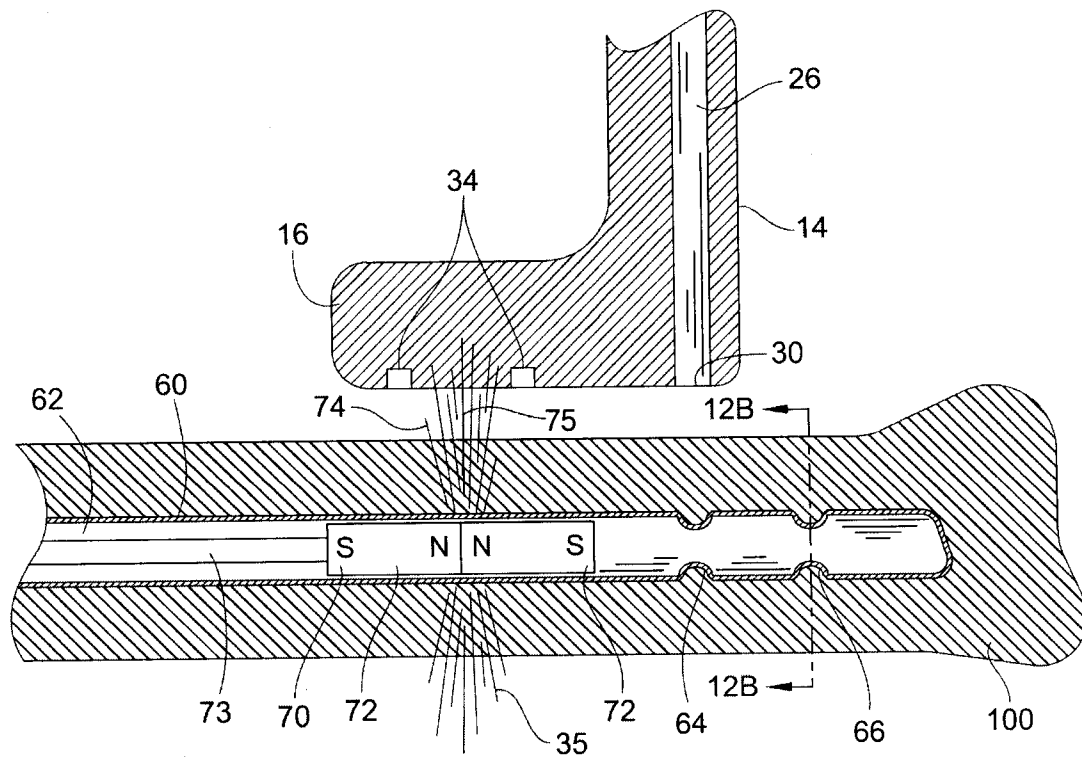


FIG. 12A

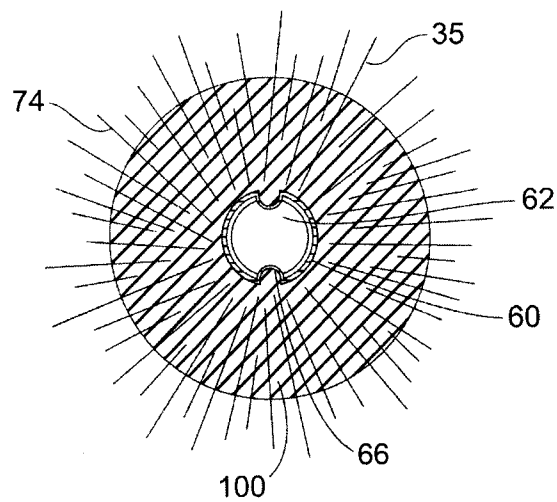


FIG. 12B

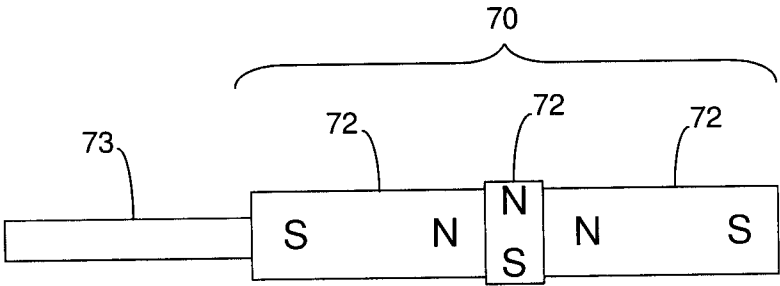


FIG. 12C

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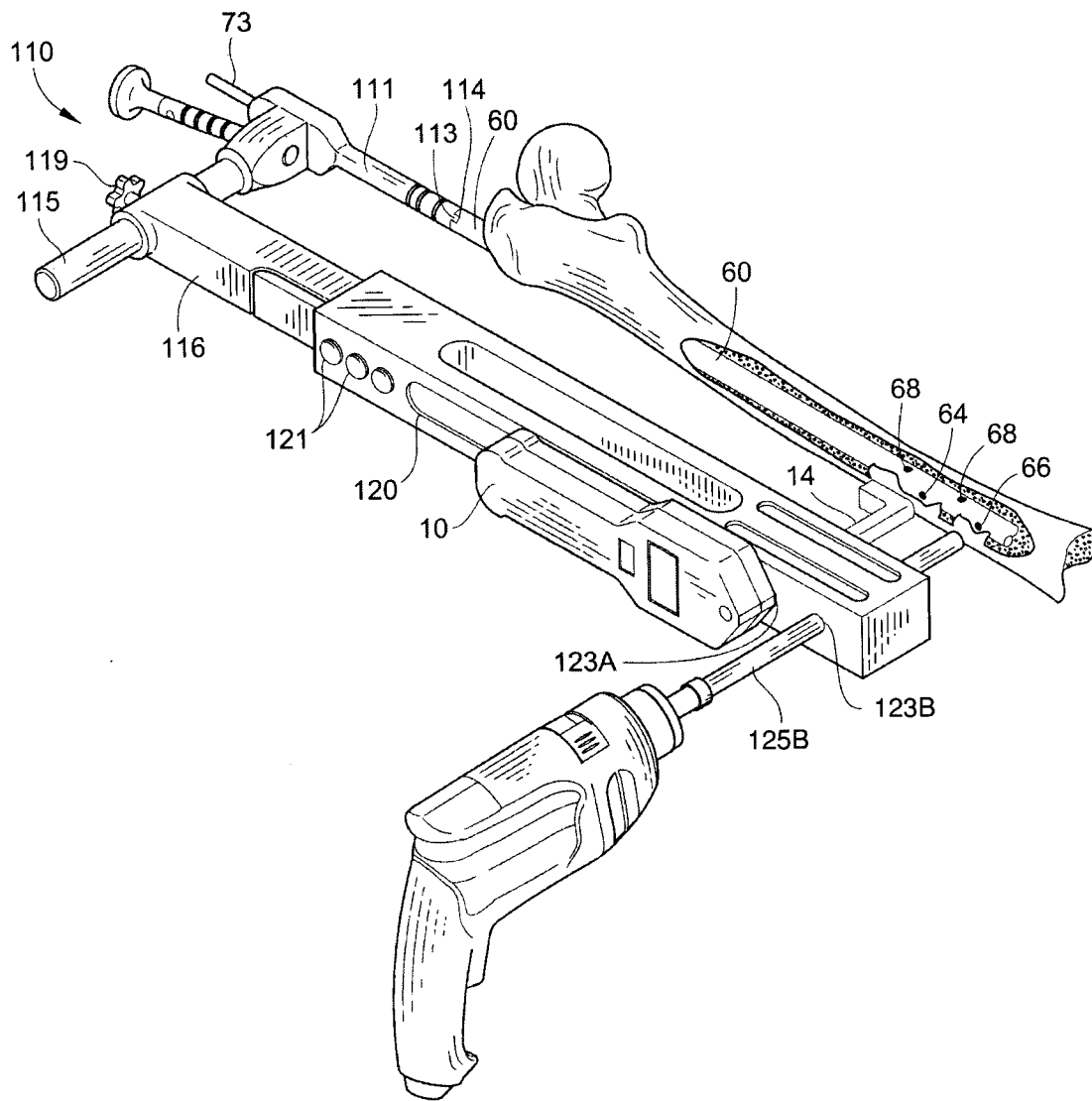


FIG. 13

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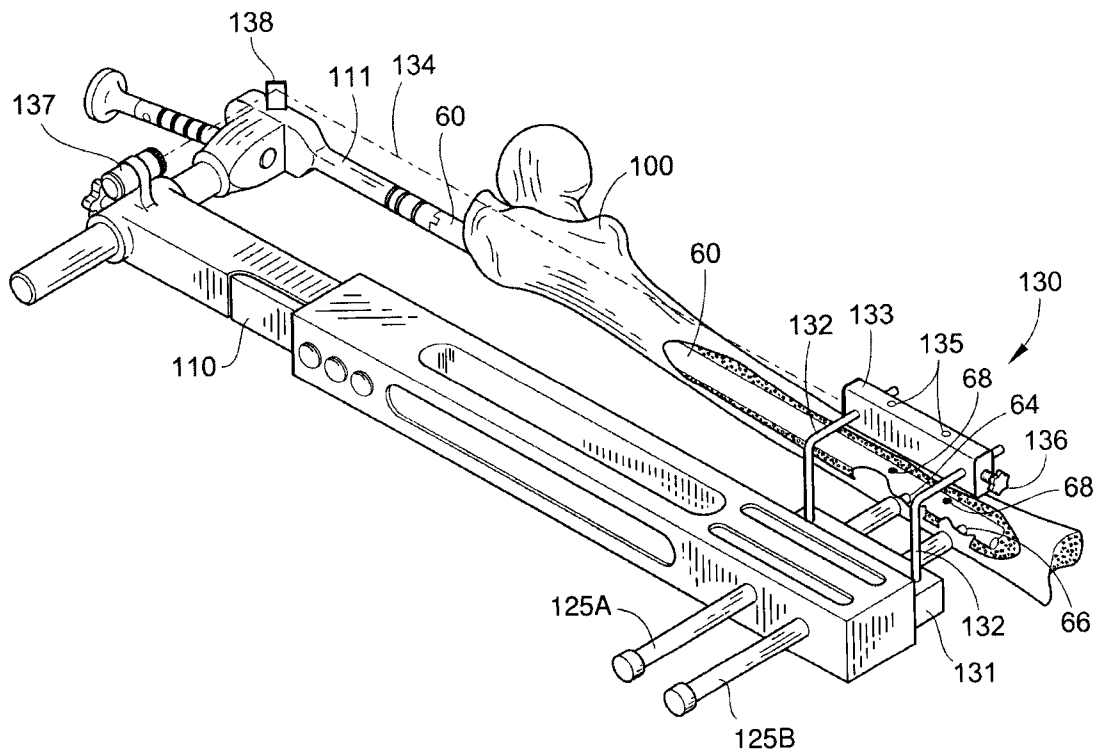


FIG. 14

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2010/031725

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/17 A61B17/80
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/34016 A2 (EEG LTD [ZA]; ELVIN ALEX [ZA]; ELVIN NIELL [US]) 17 May 2001 (2001-05-17)	1,7,15, 19-21,25
Y	figures 2,4,3b page 8, paragraph first - paragraph third page 9, paragraph first	34
Y	EP 0 468 192 A2 (SYNTHES AG [CH]) 29 January 1992 (1992-01-29) figures 1,2 * abstract	34
Y	US 6 162 228 A (DURHAM ALFRED A [US]) 19 December 2000 (2000-12-19) figure 7 column 6, line 47 - column 7, line 5 -/--	1,5,7, 15, 17-20,24



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
 "E" earlier document but published on or after the international filing date
 "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
 "O" document referring to an oral disclosure, use, exhibition or other means
 "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
 "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
 "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
 "&" document member of the same patent family

Date of the actual completion of the international search

21 September 2010

Date of mailing of the international search report

29/09/2010

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040,
 Fax: (+31-70) 340-3016

Authorized officer

Louka, Maria

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2010/031725

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 281 224 A (FACCIOLI GIOVANNI [IT] ET AL) 25 January 1994 (1994-01-25) figures 4,5 column 4, lines 25-31 -----	1,5,7, 15, 17-20,24
A	WO 99/62401 A1 (VECTOR MEDICAL INC [US]) 9 December 1999 (1999-12-09) figure 8 -----	1,34
A	US 2005/075562 A1 (SZAKELYHIDI DAVID C [US] ET AL SZAKELYHIDI JR DAVID C [US] ET AL) 7 April 2005 (2005-04-07) cited in the application the whole document -----	2-6,8-14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/031725

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

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

1. ☒ Claims Nos.: 26-33, 37
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

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Information on patent family members

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