

(43) International Publication Date
23 August 2012 (23.08.2012)

(51) International Patent Classification:

G01B 21/00 (2006.01) A61B 19/00 (2006.01)
 A61B 17/15 (2006.01) B23Q 16/00 (2006.01)
 A61B 17/17 (2006.01) B23Q 17/00 (2006.01)
 A61B 17/72 (2006.01) G01B 7/00 (2006.01)
 A61B 17/90 (2006.01) G12B 11/00 (2006.01)

(21) International Application Number:

PCT/CA2012/050098

(22) International Filing Date:

17 February 2012 (17.02.2012)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/444,535 18 February 2011 (18.02.2011) US
 61/444,558 18 February 2011 (18.02.2011) US
 61/444,600 18 February 2011 (18.02.2011) US
 61/476,709 18 April 2011 (18.04.2011) US
 61/553,499 31 October 2011 (31.10.2011) US

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(81) Designated States (unless otherwise indicated, for every
 kind of national protection available): AE, AG, AL, AM,
 AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,
 CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,
 DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
 HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR,
 KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
 MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
 OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD,
 SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR,
 TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
 kind of regional protection available): ARIPO (BW, GH,
 GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
 UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU,
 TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,
 DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,
 LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

[Continued on next page]

(54) Title: TOOL WITH INTEGRATED NAVIGATION AND GUIDANCE SYSTEM AND RELATED APPARATUS AND METHODS

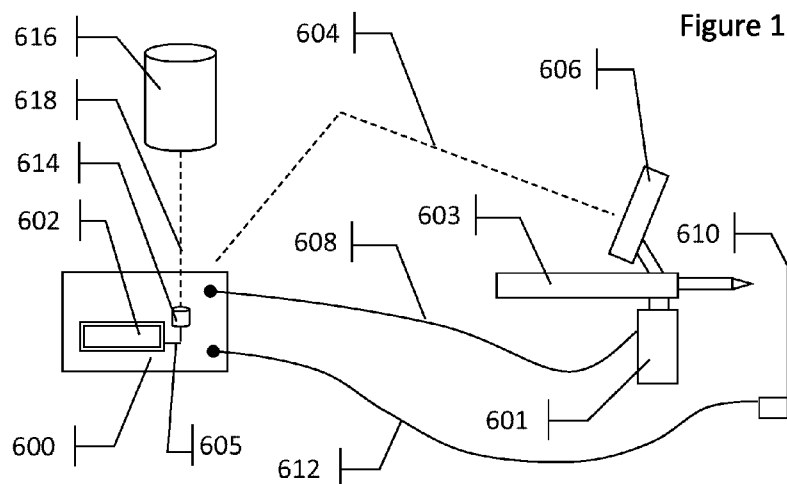


Figure 1

(57) Abstract: Methods and apparatus for integrating an electromagnetic navigation system and a tool and aligning the tool with a target are presented, including a sensor tool, a tool, a field generator, a display, and a computer. The sensor tool attaches to a target component in a unique position relative to target features. The field generator is fixed relative to the tool except in rotation about a tool axis. The display is adjustably mounted to the tool and automatically adjusts image parameters. Target registration and error compensation methods are provided. The system detects magnetic field and signal disturbances that may lead to inaccurate navigation, filters navigation data, and adjusts filtering parameters based on detected conditions. Apparatus for proximally locking an IM nail such that a clear passage through the cannulation of the nail is maintained are provided.



SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:**Declarations under Rule 4.17:**

— *of inventorship (Rule 4.17(iv))*

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

TOOL WITH INTEGRATED NAVIGATION AND GUIDANCE SYSTEM AND
RELATED APPARATUS AND METHODS

Reference to Related Application

[0001] This application claims priority from United States patent application Nos.
5 61/444,535 filed February 18, 2011, 61/444,558 filed February 18, 2011, 61/444,600
filed February 18, 2011, 61/476,709 filed April 18, 2011, and 61/553,499 filed
October 31, 2011. For purposes of the United States of America, this application
claims the benefit under 35 U.S.C. §119 of from United States patent application Nos.
61/444,535 filed February 18, 2011, 61/444,558 filed February 18, 2011, 61/444,600
10 filed February 18, 2011, 61/476,709 filed April 18, 2011, and 61/553,499 filed
October 31, 2011 all of which are hereby incorporated herein by reference.

Technical Field

[0002] This invention relates to guidance and navigation of tools. Drills and saws are
non-limiting examples of tools. The invention has application to positioning tools
15 relative to features that may be hidden from view. The invention may be applied in
positioning surgical tools but also has non-surgical applications.

Background

[0003] There are procedures in many fields including manufacturing, assembly,
repair, and surgery in which it is useful to align a tool with a target path, feature, or
20 other target location that may be hidden from view or not sufficiently visible to the
user. For example in airframe assembly and repair it may be necessary to drill a hole
through a layer of material in line with an existing hole in an inaccessible component
positioned behind the material. For another example many surgical procedures
require a surgeon to align a tool, such as a drill, a guide wire driver, a bone saw, or an
25 ultrasound probe with a target path that cannot be sufficiently marked or seen. The
target path may be an ideal plane or trajectory through tissue as determined in
preoperative planning or determined using intraoperative techniques, for example an
estimated centerline of an anatomical feature such as a femoral neck as described by
Hodgson in international patent publication WO/2006/133573. The target path may

also be related to features of an implant, such as a fixation screw hole in a bone plate or IM ("IM") nail, wherein the objective is to align a drill, guide wire driver, or other tool relative to the hole when the hole or the direction of the hole is hidden from view.

[0004] Some examples of surgical procedures which can be facilitated by guidance to establish a desired tool alignment are:

- femoral head resurfacing. This procedure involves inserting a guide wire through the femoral neck along a target path at a planned angle and location.
- pedicle screw fixation in spine surgery where a drill, drill-guide, guide wire or screw must be inserted along a target path, within a known structure (a pedicle) and for a limited depth to avoid injury to surrounding structures outside the bone.
- placement of ilio-sacral screws in pelvic bone surgery, where a drill, drill-guide, guide wire or screw must be inserted along a target path (thru the iliac bone, within the sacral ala and vertebral body) and for a limited depth to avoid injury to surrounding structures outside the bone.
- osteotomy (cutting of a bone), where orientation of a surgical saw to be used to cut a bone in a specific planned orientation would be critical to the next steps of the procedure: realignment of bones, placement of implants (e.g. knee arthroplasty)
- placement of hip or knee arthroplasty implants in a planned orientation (e.g. placement of an acetabular component in hip arthroplasty)
- locating fixed solid organs (e.g. liver, pancreas, kidney, or other) or mobile hollow organs (e.g. bowel, bladder) for percutaneous placement of a stent or device or for establishing access to a planned location which is hidden from view. (e.g. nephrostomy tube, percutaneous endoscopic gastrostomy tube, hepatic, biliary or pancreatic diverting stent.) or for sampling a mass or tissue at a location hidden from view but known relative to a probe, for the purpose of biopsy.

[0005] Furthermore in many procedures such as drilling or cutting with a tool, the user may find it useful to know how far a tool has progressed along a target path from

a starting point, for example to know how deep a hole has been drilled or in order to select the correct length of screw, pin, or the like to install. For example in various surgical procedures, surgeons may want an estimate of the correct length of a screw to be installed in a drilled hole such that the screw spans the bone at the hole location but does not protrude excessively from the bone into the surrounding tissue.

[0006] Also in many tool alignment procedures, the user may need to use the tool in various orientations relative to the user's point of view. The user may also prefer to hold the tool in their right or left hand, which may affect the orientation of the tool and the visibility of the tool and the alignment target area. For example in many surgical procedures the surgeon may need to use a tool in various orientations to gain access to working space and a clear tool path, for example to have the tool pass by the non-involved limb of the patient, the operating table, and the various limb holders, bolsters and the like that are used in surgery.

[0007] Generally, tool guidance and navigation procedures require some form of user interface and feedback, such as a visual display, to provide targeting information to the user.

[0008] Intramedullary nailing ("IM nailing") is one example of a surgical application in which it is necessary to align a tool with hidden features . In the following detailed description IM nailing is provided as a non-limiting example to illustrate application of various aspects of the invention.

[0009] To stabilize a fractured long bone, surgeons usually insert an IM nail ("IM nail") along the medullary canal of the bone. To hold the distal section of the fractured bone, distal locking screws are installed transverse to the axis of the bone and passing through holes in the distal end of the IM nail. Installing the distal locking screws creates a challenge for the surgeon because the locking screw holes are inside the bone and cannot be seen. An IM nail may also distort unpredictably as it is pushed distally down through the bone and as the bone fragments are aligned, therefore the position of the distal locking holes may be difficult to determine using guides attached to the proximal end of the nail.

[0010] Surgeons commonly locate the distal locking holes by trial and error using hand-held guide wires or a drill and a series of x-ray images taken during the operation. The main tool for acquiring these images is a C-arm fluoroscope, which is typically moved incrementally until the holes appear as circles in the image, thus indicating that the fluoroscope is aligned with the distal locking holes. Then the drill bit or drill guide is typically positioned on the skin surface over the area of the hole and adjusted, using more images, until it is centered and aligned with the hole. This method is time-consuming and exposes the surgical team and patient to radiation.

[0011] Although the radiation dose a surgeon receives from a C-arm fluoroscope has generally been considered safe, there is some disagreement about this. Hafez (2005) estimates that radiation doses recorded at the fingertips are as much as seventy five times higher than doses recorded at the base of the fingers. Cumulative exposure to radiation may be a concern particularly for trauma surgery teams.

[0012] Computer assisted techniques, making use of electromagnetic position tracking technology to assist with IM nailing surgery, are described in Krause, US6074394 and US6503249; Govari, US7060075; and Ritchey, US published application 20100274121. A navigation system (Trigen Sureshot™ Distal Targeting System, Smith & Nephew, Memphis TN, USA) is commercially available. These systems use electromagnetic navigation systems (comprising a field generator that emits a controlled magnetic field, at least one sensor that responds to the magnetic field by generating a signal indicative of the sensor's position relative to the field generator, a computer, and associated software), a drill guide, and a targeting display to show the user the relative locations of the drill guide and the sensor such that the user can align the drill guide to a predetermined position relative to the sensor. Some systems described in the prior art include an electromagnetic sensor located in the implant at a known location relative to the features to be targeted (in the case of IM nailing, the distal locking holes) throughout the targeting procedure. Ritchey, WO2010/129141 describes various methods and apparatus for estimating the travel of a drill bit through a drill guide.

[0013] Most modern, widely used, IM nails are cannulated along their length, the cannulation having a circular cross-section and a diameter related to the overall size

of the nail. Typical IM nails have various holes and slots, in addition to the locking holes, located along the length of the nail. Typically the nail is implanted by attaching an insertion tool to the proximal end of the nail and passing the nail cannulation over a guide wire. The guide wire is then withdrawn and the nail may be
5 hammered in further, rotated, withdrawn, or otherwise positioned as required using a variety of fittings attached to the insertion tool. In some systems an electromagnetic sensor tool is inserted into the cannulation at a position that is known relative to the locking screw holes.

[0014] The systems described by Krause and Govari, and the Sureshot™ system,
10 include a separate drill guide which would typically be held by the surgeon with one hand, while he or she holds a drill in their other hand.

[0015] In such systems using a separate drill guide, the drill bit slides through the guide in a direction along the drill bit axis. In prior art systems having a field generator separate from the drill and the drill guide, the drill, drill guide, and drill bit
15 all may move in and out of, and move about within, the measurement range of the field generator. When the field generator is integrated with or attached to the drill guide in a fixed position, as shown in some prior art systems, the drill bit slides in and out of the measurement range of the field generator during drilling.

[0016] In many surgical procedures, including IM nailing, it is desirable to position
20 tools with sub-millimetric and sub-degree accuracy (Beadon 2007). Electromagnetic navigation systems can be affected by the presence of certain metals (particularly ferromagnetic and electrically conductive materials) and magnetic fields located in and nearby the measurement range of the field generator (Kirsch 2005; Beadon 2007). Many drills, including commonly used surgical drills, contain ferromagnetic and
25 conductive parts, and may also contain electric motors which may contain magnets and which may generate magnetic fields during operation. Drill bits commonly used in surgery are made of ferromagnetic materials such as hardened stainless steel, which, when moved within the range of the electromagnetic tracking equipment, may cause distortion of the electromagnetic fields and may cause inaccurate tracking
30 measurements. There may also be variations in the particular field generator and environment that affect the accuracy of tracking.

[0017] In typical electromagnetic position tracking systems, the sensor coordinate system in which the system reports the position and orientation of a sensor is defined by the relative location and the characteristics of components inside the sensor tool. These are variable in manufacture. For example in a cylindrical sensor tool, the sensor coordinate system as manufactured may have an axis only approximately coaxial with the cylindrical axis. To achieve an accurate known relationship of the coordinate system to the physical shape of the sensor tool, a set of correction factors may be determined by calibrating each individual sensor tool in a calibration fixture at manufacture, and writing the correction factor to a memory device built in to the sensor (AuroraTM Tool Design Guide Rev. 3 Dec 2005 Northern Digital Inc. Waterloo, Ontario, Canada). This individual calibration and programming process, along with a suitable memory device, generally increases the manufacturing cost of the sensor tool.

[0018] When attaching a sensor tool to an implant in order to target features in the implant, the accuracy to which the relative position of the sensor coordinate system and the features is known directly affects the accuracy of targeting. This relative position may be included in a database stored in memory, and recalled if the user correctly indicates the type of sensor and implant being used, provided the database of implant dimensions includes that particular implant. In this case, the manufacturing tolerances of the implant, the sensor tool, and any other component used to position the sensor tool all become direct factors in targeting accuracy. For example with an IM nail, if the sensor tool attaches to the insertion tool which is in turn attached to the proximal end of the nail, as shown in certain embodiments described by Ritchey in patent application WO2010/129141, the manufacturing tolerances of the handle, the distance from the proximal end of the nail to the locking holes, and the sensor tool length may all contribute to targeting variance.

[0019] With electromagnetic position tracking systems, measurement errors may occur if external magnetic fields are present or objects made of certain metals are brought into the range of the field generator (Kirsch 2005). Such distortions can be unpredictable and may not be apparent to the user during navigation. For example measurements may appear steady, but be biased several millimeters in a particular

direction by the presence of a ferromagnetic tool, such as a surgical hammer, located close to the field generator.

5 [0020] Outputs of typical electromagnetic position tracking systems can include low frequency, high amplitude measurement noise. Such noise can cause measurement values to vary. It is also typical for these systems to occasionally fail to return a valid reading for a sensor which can cause the user display to freeze momentarily until good data is received again. Small, lightweight field generators and small sensors are especially prone to produce orientation data having occasional outlying values.

10 [0021] Finally, in certain cases and with certain types of IM nailing procedures, the preferred practice is to drill through the proximal holes and lock the proximal bone fragment to the nail prior to drilling and locking the distal holes (e.g. see TFNTM Titanium Trochanteric Fixation Nail System; Technique Guide. Synthes GmbH, Oberdorf, Switzerland). In these cases the proximal locking screws block the nail cannulation and make it impossible to install a sensor tool that passes through the
15 cannulation past the proximal locking screws, for example for the purpose of targeting distal locking holes.

[0022] The foregoing examples of the related art and limitations related thereto are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a
20 study of the drawings.

Summary

[0023] The invention has several aspects. These aspects may be applied in combination but also have application individually and in sub-combinations. These aspects include without limitation:

- 25
- sensor tools;
 - tools having integrated field generators;
 - methods for measuring distances traversed by tools having integrated field generators;

- tools configured to measure distances traversed and other parameters of position and motion of the tools;
- tools having integrated user interfaces and visual display devices;
- methods for displaying alignment of tools to targets;
- 5 • tools configured to display alignment of the tools to targets;
- attachments for calibrating tools having integrated field generators;
- attachments for registering tools having integrated field generators to targets;
- methods for calibrating tools having integrated field generators;
- tools configured with calibration functions;
- 10 • methods for registering tools having integrated field generators to targets;
- tools configured with functions for registering the tools to targets;
- methods and apparatus for monitoring the measurement conditions affecting field generators integrated with tools;
- methods and apparatus for filtering measurement data from field generators integrated with tools and interacting with sensors;
- 15 • methods and apparatus for determining and optimizing filtering parameters used to filter measurement data from field generators integrated with tools and interacting with sensors;
- tangible media storing computer software which, when executed, causes a processor to perform any of the methods listed above, and;
- 20 • methods and apparatus for fixing surgical implants, the apparatus having provisions for installation of electromagnetic sensor tools.

The invention includes, without limitation, the aspects claimed in the appended claims. The invention also includes all other aspects that may be made the subject of additional claims that may be properly presented in future as supported by the present specifications, drawings and claims.

25

[0024] In an example application, the tool is a drill, the feature is a hole in a component which is positioned behind an opaque material, and the objective may be to align the drill with the hole so that the user can drill a hole through the material in line with the hole. For another example the tool may be a driver and the objective may be to align the driver with the feature in order to install a pin or screw through

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the feature. For another example the tool may be a tool and the feature may be an anatomical feature of a patient. For another example the tool may be a drill and the feature may be a hole in an implant. Some embodiments of the invention are particularly adapted for computer-assisted locking of IM nails, including location of the locking holes in the nail, computer-assisted drill positioning, and real-time intra-operative positioning feedback to the user.

[0025] Some embodiments of the invention provide a sensor tool adapted for attachment to a target component having a target feature. Sensor tools according to some embodiments have one or more of the following features:

- fits a range of existing components of a variety of sizes and shapes,
- as required, fits a variety of existing tools or fixtures that may be used with the component for positioning or holding the component;
- is able to be installed quickly and precisely to a unique position relative to the target feature;
- indicates to the user when the sensor is installed in the unique position, and;
- remains in the position throughout the entire drilling procedure, without blocking or otherwise interfering with the target feature.

[0026] One example aspect of the invention provides a sensor tool incorporating a tip portion at a distal end, a handle portion at a proximal end and a shaft portion connecting the tip portion and the handle portion. Electromagnetic sensor coils are provided at a fixed position inside the tool near the distal end. The shaft portion may be flexible. The tip portion is adapted to fit and center itself within a cannulation in a component such as an IM nail or other implant. A single sensor tool may have a tip that is self-centering within cannulations having various diameters within a range of diameters.

[0027] In some embodiments the handle portion is adapted to engage features of existing insertion tools that are normally used to insert IM nails or other implants. Such engagement may hold the sensor tool in a predetermined fixed position relative to the nail or other implant in all 6 degrees of freedom until it is removed. The handle portion may be further adapted to create an audible sound (such as a click) when the

sensor tool is fully engaged to the insertion tool. The handle portion may further be adapted to create a different indication to the user that it is fully engaged, such as a vibration, or a change in shape or position of a part of the handle portion.

[0028] In some embodiments the shaft portion has selected flexibility sufficient to allow the sensor tool to be inserted into IM nails or other components that are not straight. The shaft portion has a selected length to match a predetermined range of IM nail lengths, such that the distal end of the tool does not block a distal locking hole of the shortest nail in the range, and such that the sensor element is within a predetermined distance (related to the range of the electromagnetic navigation system) of the locking holes when used in the longest nail in the range.

[0029] Another aspect of the invention provides a navigation unit incorporating a field generator. The navigation unit may be integrated with a tool or adapted for attachment to a tool. Navigation units according to some embodiments have one or more of the following features:

- work with a variety of existing tools, including those having electric motors and containing parts made of ferromagnetic material,
- can be easily attached, removed from, and reattached to the tool such that an axis of the tool and a point on that axis have the same position and orientation relative to the field generator each time the unit is attached, and in the case of the tool being a drill, is able to hold the field generator static relative to the drill axis and the drill tip point, such that the only freely allowed relative motion between the field generator and the drill bit is rotation about the drill axis.
- can be attached in positions offset from the tool axis, to give the user a clear view of the working area and to provide space around the tool to allow the user to work with the tool without removing the field generator,
- is light and small enough so as not to interfere with handling and positioning of the tool, and;

- has the capability to record, store, and use a correction map to correct for tracking measurement distortions produced by the tool being mounted close to the field generator.

5 [0030] An example embodiment provides a drill-mounted electromagnetic field generator and mounting structure unit adapted to attach to a drill quickly, easily, temporarily, and precisely in a known position relative to a drill axis before or during use. The mounting structure is designed such that the field generator is temporarily fixed relative to a drill axis about which a drill bit rotates and a point on the axis at the drill tip. In an example embodiment the mounting structure comprises a drill chuck, a
10 housing portion enclosing the drill chuck, a rigid extension arm extending away from the housing portion and having a distal end at a predetermined distance from the axis, and a field generator mounting portion attached to the distal end of the extension arm. The drill chuck is adapted to attach to a drill in at least one rotational position about the drill axis, and to hold a drill bit.

15 [0031] In accordance with another aspect of the invention, the mounting structure is adapted such that the field generator component may be removed and replaced precisely to the same location in the structure as described above. In some embodiments the structure also encloses and isolates the field generator, for example to isolate a non-sterile field generator in a sterile surgical field.

20 [0032] In accordance with another aspect of the invention, the mounting structure includes a drill bushing rigidly connected to the field generator mounting portion and having a close running fit to the shank of the drill bit, thereby limiting the possible relative movement between the field generator and the drill axis.

25 [0033] In accordance with another aspect of the invention, there is provided a method of determining the position of a tool axis and a point on the tool axis relative to a field generator, the method comprises:

- connecting the field generator unit to an electromagnetic navigation system, such that the position of the field generator may be recorded relative to a fixed reference frame,

- holding the tool axis in a fixed position relative to the fixed reference frame,
- rotating the field generator about the tool axis and recording the field generator position at a number of rotational positions;
- calculating the position of the tool axis relative to the field generator by determining the least variant axis of rotation of the field generator, and;
- defining a point on the axis at a predetermined position relative to the field generator, or if the tip of the tool lies on the axis, by using a pivot calibration method to define the point coincident with the tip of the tool.

[0034] In accordance with another aspect of the invention, selected motions and parameters of motion of a point on the tool axis relative to a target component are recorded and analysed and used advantageously, optionally in conjunction with other recorded parameters, to advise the user and trigger selected actions related to the movement and state of the tool.

[0035] In accordance with another aspect of the invention, there is provided a method of calibrating the navigation system to correct for measurement errors caused by the presence of portions of a tool within the measurement volume of the navigation system, and portions of a tool positioned close to the field generator, the method comprising the steps of:

- attaching the tool to the field generator and recording the position of a sensor as it is moved through a series of known positions,
- calculating the difference between the known position and the recorded position for each known position in the series, thereby creating a lookup table of measurement correction values,
- interpolating between correction values in the lookup table to create a continuous function of correction value versus sensor position, and
- reading the current position of the sensor during navigation, finding the closest corresponding measurement correction factors from the lookup table, or alternately calculating the correction values from the continuous function, and applying the correction values to the current position of the sensor to create a corrected current position of the sensor for use in navigation.

5 **[0036]** In an embodiment of the invention the lookup table is generated by mounting a drill, drill chuck, drill bit, and field generator assembly in a fixture on a coordinate measuring machine, moving a sensor through the series of known positions programmed into the coordinate measuring machine, and storing the lookup table in a memory device integrated with the field generator.

10 **[0037]** In another embodiment of the invention, the lookup table is generated during use with the specific sensor and target component being used by installing a registration tool onto a drill, drill chuck, drill bit, and field generator assembly, inserting a sensor into an IM nail, inserting the registration tool into a distal locking
15 hole in the nail such that the drill bit axis and the hole axis are coincident, rotating the assembly about the coincident axes, recording a hole axis definition for each location recorded around the drill axis, interpolating between the locations to increase the resolution of the lookup table or to create a continuous function of hole axis definition versus position about the drill axis, and storing the lookup table or function in the
20 navigation system memory for use during navigation. Alternately any device that can be calibrated from measurement data and produce corrected sensor readings can replace the function of a lookup table used in the exemplary embodiment. The correction can with equal effect be applied to the calibrated position of the drill hole or the sensor readings.

25 **[0038]** To allow a user to navigate and align a tool with one hand, and not have to look away from the work area to view navigation and alignment information and feedback or reach away from the work area to send operational commands to the navigation system, a visual display and user interface unit may be advantageously mounted on or near the tool and generally move with the tool.

30 **[0039]** For use in the sterile field, surgical drills are typically designed to be steam sterilized (autoclaved). However electronic display and touchscreen devices most suitable for the exemplary surgical application and available at reasonable cost generally cannot withstand steam sterilization. It is possible to use lower temperature sterilization processes such as ethylene oxide sterilization for items containing
35 sensitive electronic components, but this still generally increases the cost of the electronic components, and in the case of ethylene oxide sterilization the process

takes longer and may present occupational health and safety concerns due to residual chemicals. For these reasons steam sterilization is the preferred method in most hospitals, and accordingly a display and user interface unit containing electronic components and located on or near a tool in the sterile field is advantageously detachable from the tool so that it can be sterilized separately by an alternate method, or isolated in a sterile drape or bag, and then reattached to the tool in the sterile field.

[0040] When the user interface unit is integrated with the tool as described above, the different orientations of the tool that may be used may require adjustability of the user interface unit relative to the tool to allow adjustment to a position where the display screen is easily visible to the user. As the display is moved relative to the drill, and the drill is used in various orientations relative to the target, it is an advantage if the image shown on the display can automatically change field of view, magnification, and/or orientation to best represent the target area.

[0041] To align a tool with a selected target, the user typically needs to first find the target within the general target area and possibly locate the desired target from among a group of possible targets, in which case a large field of view is advantageous. Then when close to the desired target the user typically makes fine adjustments of the tool position to within a suitable tolerance, in which case a smaller field of view that is aligned with, magnified and centered on the chosen target is advantageous.

[0042] Accordingly, some embodiments of the invention provide a user interface unit attached to a tool and having one or more of the following features:

- mounted on or near the tool, such that it is generally within the user's field of view while looking towards the working area of the tool;
- adapted to fit and work with a variety of existing tools;
- attachable and detachable by hand without the use of tools;
- visible, or may be adjusted to be visible, to the user in various tool orientations;
- can receive input from the user and relay information and commands to and from the navigation system;

- automatically adjusts the image orientation, field of view, and/or magnification using information on the display orientation, patient position, and/or tool movement relative to the target, and;
- displays to the user the current position and orientation of the tool relative to the target, and indicates to the user when alignment to the target is within selected limits based on selected parameters, where the limit of any parameter may be a function of other parameters.

[0043] Another aspect of the invention provides an electronic display and user interface unit with mounting apparatus adapted for installation on a tool, wherein the user interface unit may be removed for separate sterilization or draping, and reinstalled easily in the sterile surgical field.

[0044] Another aspect of the invention provides an electronic display and user interface unit with an adjustable mounting mechanism allowing the unit to be moved relative to the tool to be visible in various tool positions relative to the user's point of view.

[0045] In one embodiment the mounting mechanism comprises a swivel joint with an axis about which the user interface unit can rotate, a second swivel joint having a second axis about which the user interface unit can rotate, and a releasable joint between the user interface unit and the mounting mechanism designed to accommodate a flexible film material or drape material between joining surfaces of the releasable joint.

[0046] Some embodiments comprise at least one sensor that generates a signal indicative of the position of the user interface unit relative to the direction of gravity.

[0047] Some embodiments comprise sensing apparatus that generates a signal indicative of the position of the user interface unit relative to a field generator.

[0048] Another aspect of the invention provides a method of comparing and indicating to the user the current relative position of a tool axis and a target axis having a fixed position relative to a sensor, comprising the steps of:

- Monitoring the current position and orientation of the tool axis and a point on the tool axis relative to the sensor;
- Calculating the normal distance from the target axis to the point and determining if the distance is within a selected limit, and if so displaying a first indicator, and;
- Calculating the intersection point of the tool axis and a plane normal to the target axis and passing through a selected point along the target axis,
- Calculating the normal distance from the target axis to the intersection point and determining if the distance is within a selected limit and if so, and the first indicator is displayed, displaying a second indicator.

[0049] The distance measure between the point and the target axis may be any that consistently reflects tip-axis distance. In some embodiments the point is coincident with the tool axis and the tip of the tool.

[0050] Another aspect of the invention provides an alternate method of comparing the current relative position of a tool axis and a target axis having a fixed position relative to a sensor, comprising the steps of:

- Monitoring the current position and orientation of the tool axis relative to the sensor,
- Calculating a first intersection point of the drill axis and a first plane normal to the target axis and passing through a first selected point along the target axis,
- Determining if the first intersection point is within a selected first tolerance zone around the target axis, and if so displaying a first indicator,
- Calculating a second intersection point between the tool axis and a second plane normal to the target axis and passing through a second selected point along the target axis, and
- Determining if the second intersection point is within a selected second tolerance zone around the target axis and if so, and the first indicator is displayed, displaying a second indicator.

[0051] In order to minimize cost, risk of error, reliance on accurate manufacturing tolerances, accurate stored dimensions, individual sensor tool calibration, and

consistent sensor, field generator, and environment characteristics, it is advantageous to directly register a target feature to a sensor using the particular tool and field generator assembly, sensor, target component, and any component insertion or holding tool being used. Some embodiments of the invention provide a registration
5 tool having one or more of the following features:

- fits target features within a range of sizes;
- fits the tool and navigation unit as assembled for use, and;
- holds the navigation unit accurately at a known relative position to the target feature in selected degrees of freedom during the registration measurement.

10 **[0052]** Another aspect of the invention provides a registration tool comprising a body portion adapted to slide over a portion of a tool, for example a saw or drill, and a tip portion adapted to fit within a target feature in a target component, thereby fixing the position of the registration tool relative to the feature in selected degrees of freedom.

15 **[0053]** In one embodiment, the registration tool has a sliding fit over a drill bit such that when installed on the drill bit the tip portion has an axis coincident with the longitudinal axis of the drill bit, the target feature is a cylindrical hole having a diameter within a predetermined range and a centerline of the cylinder, and the tip portion is adapted to closely fit the hole such that when the tip portion is installed in the hole the tip portion axis and target hole axis are coincident, thereby fixing the
20 relative position between the hole and the registration tool in all six degrees of freedom except rotation about and translation along the coincident axes. The tip portion may include at least one resilient element adapted to provide a tight fit in different holes having diameters within a predetermined range of diameters. In some
25 embodiments the fit is an interference fit and the interference is selected in conjunction with the stiffness of the resilient element and the friction between the resilient element and the hole or other feature to allow the registration tool to be installed in and removed from the feature by hand.

30 **[0054]** In another embodiment, the registration tool has a sliding fit over a drill bit and engages a target hole having a revolved surface about a hole axis within predetermined size and shape limits, such that drill bit axis and the hole axis are

coincident, thereby fixing the relative position between the hole and the registration tool in all six degrees of freedom except rotation about and translation along the coincident axes.

[0055] In another embodiment, the registration tool has a sliding fit over a drill bit and engages a target hole having a revolved surface about a hole axis within predetermined size and shape limits, such that drill bit axis and the hole axis are coincident and the registration tool further engages a second feature fixed relative to the target hole such that the relative position between the hole, the second feature, and the registration tool is fixed in all six degrees of freedom.

[0056] Another aspect of the invention provides a method of registering the navigation system to at least one target feature of a target component by measuring the target feature position relative to a sensor. In one embodiment, the method comprises the steps of:

- attaching a sensor component of a navigation system to a target component such that the sensor is fixed in all six degrees of freedom at a position relative to a target feature of the target component, but wherein the relative position is not previously known to a sufficient degree of accuracy,
- attaching a registration tool to a tool and field generator assembly such that an axis of the registration tool is at a known location relative to the field generator,
- temporarily fixing the registration tool and assembly to the target feature of the target component such that the registration tool axis is at a known spatial relationship to the target feature,
- recording the position of the sensor relative to the field generator,
- calculating the relative position of the feature to the sensor, and
- storing the relative position of the feature to the sensor into the memory of the navigation system.

[0057] In one embodiment of the invention the relative position of the feature to the sensor is defined as a line expressed in the coordinate system of the sensor and

representing a target axis, and is recorded by averaging a selected number of position measurements.

[0058] Some embodiments of the invention provide controlling and signal processing methods, apparatus, and software having one or more of the following features. The
5 controlling and signal processing methods, apparatus, and software may advantageously:

- Detect measurement distortions during navigation;
- Detect externally generated magnetic fields during navigation;
- Monitor overall measurement noise and detect outlying data;
- 10 • Filter the measurement data to minimize signal noise to create a smooth display;
- Filter the data to exclude low frequency high amplitude outlying data;
- Present the remaining valid measurement data to the user;
- Warn the user of potentially inaccurate data and high rates of outlying data,
15 and;
- Use detected information about the measurement data, measurement distortions, and externally generated magnetic fields to optimize filtering parameters.

[0059] Another aspect of the invention provides a method of detecting tracking
20 measurement distortions and externally generated magnetic fields during navigation, the method comprising the steps of:

- Tracking the position of a first sensor and simultaneously monitoring the position of a reference sensor, wherein the first sensor may move relative to the field generator and the reference sensor is mounted in a fixed position in
25 selected degrees of freedom with respect to a field generator,
- Comparing selected parameters of the deviation in position and/or orientation of the reference sensor (which may include position, orientation, and their time derivatives, or any function thereof) to predetermined threshold values,
- Activating warning functions, modifying selected characteristics of the
30 navigation system and the filtering and processing of navigation data,

including the display of navigation information to the user, when the selected parameters or combinations of the parameters fall within a range of predetermined values or exceed threshold values.

[0060] In an embodiment data from the reference sensor is compared to its known, calibrated position and orientation. The sum of the absolute values of the difference between the reference sensor position reading and the calibrated position is compared to a threshold. The same procedure is applied to the orientation expressed as a vector of quaternions with a separate threshold. An interference condition is recognized if either the position or orientation derived quantity exceeds its associated threshold value. The reference sensor may additionally self-calibrate automatically upon startup of the navigation system and/or upon a user-issued command. Data from the reference sensor may additionally be used to help determine certain states of a tool, such as motor on or off, and certain conditions of use of the tool, such as motor speed range and engaged or not engaged with the target.

[0061] Another aspect of the invention provides a method of filtering measurement data generated by the navigation system to detect and exclude or correct data that is altered by interference or measurement errors, the method comprising the steps of:

- Monitoring the current position and orientation of a first sensor which may move relative to the field generator, calculating their time derivatives, and calculating selected characteristics of the position and orientation data from the first sensor over a selected time period,
- Comparing selected characteristics to predetermined threshold values,
- Deleting the current position and orientation reading if certain selected characteristics or combinations of characteristics exceed predetermined threshold values,
- Monitoring the frequency of deleted position and orientation readings over a selected time period preceding the current reading, and if this frequency exceeds a selected threshold, displaying to the user an indication that current data is unreliable, and, optionally, displaying to the user an estimate of current position and orientation that is calculated from position and orientation data gathered over a selected time period.

[0062] In an embodiment of the invention, outlying sensor readings are determined from the sum of the absolute values of the time derivative of the position vector and the time derivative of the orientation vector expressed as quaternions. Each value is compared with an associated threshold and when either threshold is exceeded the sensor reading is identified as an outlier. Once a certain number of consecutive outliers or missing readings have been identified an appropriate indicator is shown on the user interface.

[0063] In another embodiment of the method, the reference sensor is used to provide a correlated measure of interference noise and used to remove interference noise in the first sensor. Noise cancellation may be performed with a linear adaptive noise cancellation technique, or any other cancellation method that uses a noise reference source as input.

[0064] In yet another embodiment of the method, a Kalman filter is applied to the sensor readings. Any other adaptive method that uses the statistics of the input signal to adjust its filter behavior, such as recursive Bayesian estimation methods, may also be applied.

[0065] In certain variations of the exemplary surgical procedure, there may be a need to proximally lock an IM nail before distal locking is complete. In these cases it is an advantage if a sensor tool may pass through the length of the nail cannulation when a proximal locking apparatus is in place. Accordingly in another aspect of the invention, there is provided an apparatus and method to lock a bone fragment to an IM nail in such a way as to maintain, temporarily or permanently, an open passage through the cannulation along the longitudinal centerline of the nail. In an embodiment of the invention the locking apparatus is a fenestrated drill bit also adapted to drill through the bone. In another embodiment the locking element is a fenestrated stud inserted temporarily after drilling, engaging the bone and passing through the nail, before installation of the permanent locking element. In another embodiment the permanent locking element is fenestrated. In another embodiment of the invention the locking element is a stud with an expanding element at one end adapted to engage one cortex of a bone and the inner bore of a locking hole in an IM nail implanted in the bone.

[0066] One example embodiment is particularly adapted for computer assisted IM nailing, with particular focus on the step of drilling through the bone in line with selected cross holes in the nail (known as locking holes) to allow installation of locking screws. In this exemplary embodiment the apparatus comprises:

- 5 • a surgical drill with a ferromagnetic drill bit;
- a small, lightweight field generator mounted to the drill, and with a portion of the drill bit lying within the measurement range of the field generator; and;
- 10 • a sensor tool that generates a response indicative of its position relative to the field generator and adapted for precise insertion into an implant during surgery to a predetermined location fixed in all 6 degrees of freedom relative to selected features of the implant.

[0067] A display screen is provided to display alignment information to a user. In some embodiments the display screen is mounted to or in close proximity to the drill. In some embodiments the display screen is mounted on the drill in a position relative to the drill that is fixed in 4 degrees of freedom and adjustable to various positions in two degrees of freedom relative to the drill.

[0068] The embodiments shown are particularly adapted for use, along with an electromagnetic navigation system, in computer assisted IM nailing, in particular the step of drilling through the bone and selected cross holes in the nail (known as locking holes) to allow installation of the locking screws.

[0069] In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to the drawings and by study of the following detailed descriptions.

Brief Description of the Drawings

[0070] The included drawings illustrate non-limiting example embodiments of the invention.

[0071] **Figure 1** is a block diagram illustrating a system according to an example embodiment of the invention.

[0072] **Figure 1a** shows an example sensor tool according to one embodiment of the invention and a set of IM nails with which the sensor tool may be used.

5 [0073] **Figure 2** and **Figure 2a** show detail of the tip portion of the exemplary sensor tool.

[0074] **Figure 3** is an exploded view showing an insertion tool, cannulated bolt, IM nail, and the exemplary sensor tool.

10 [0075] **Figure 4** shows the components of **Figure 3**, assembled for use in the exemplary embodiment of the invention.

[0076] **Figure 5** is a section view through the assembly of **Figure 4** showing the engagement of the sensor tool to the cannulated bolt according to the exemplary embodiment.

15 [0077] **Figure 6** is a section view through the exploded view of **Figure 3**, looking at the approach of the sensor tool to the insertion tool during installation according to the exemplary embodiment.

[0078] **Figure 6a** is a section view through the assembly of **Figure 4**, looking at the engagement of the exemplary sensor tool to the insertion tool according to the exemplary embodiment.

20 [0079] **Figure 6b** shows another example of a snap-fit arrangement for a sensor tool.

[0080] **Figure 6c** is a section view taken from **Figure 6b** showing a snap-fit sensor handle engaged with a cannulated bolt having a groove.

[0081] **Figure 6d** is a section view taken from **Figure 6b** showing a rotational constraint arrangement for a sensor tool to an implant and insertion handle assembly.

25 [0082] **Figure 6e** is a detail view showing the proximal portion of a cannulated bolt with an extended cap, a groove, and a countersink.

[0083] **Figure 6f** shows another example of an attachment of a sensor tool to an implant using a hand-tightened fastener.

[0084] **Figure 6g** is a section view taken from **Figure 6f**.

5 [0085] **Figure 7** shows an example navigation unit integrated with a drill, according to one embodiment of the invention, along with an IM nail having a locking hole, and a sensor tool, and also showing an exemplary set of coordinate systems.

10 [0086] **Figure 7a** shows the exemplary coordinate systems of the field generator and sensor looking along the drill axis from the drill user's point of view, and the parameters of the subset of sensor positions that are critical in the exemplary embodiment and application.

[0087] **Figure 8** is a section taken from **Figure 7**, through the drill axis, showing the exemplary navigation unit attached to the drill.

15 [0088] **Figure 8a** shows an alternate embodiment of the invention, in which a navigation unit is integrated with a drill via structure above rather than below the drill chuck.

[0089] **Figure 8b** shows another embodiment of the invention in which the field generator may be removed and replaced repeatably to the same location within the navigation unit.

20 [0090] **Figure 9** shows an example of a trace of drill bit distance along a drilling path versus time for drilling through a bone.

[0091] **Figure 9a** shows a flowchart of the targeting and user interface method described in **Figure 9**.

25 [0092] **Figure 10** shows an example of a user interface unit mounted to a drill according to one embodiment of the invention, with a display screen in position for drilling with the drill upright and pointing forward and away from the user's body, with the user holding the drill in their right hand.

[0093] **Figure 10a** is similar to **Figure 10**, but with the screen adjusted to a position for a user holding the drill in their left hand.

5 [0094] **Figure 11** shows the exemplary user interface unit mounted to a drill with the screen in position for drilling with the drill turned to a horizontal position and pointing forward and away from the user's body.

[0095] **Figure 11a** is similar to **Figure 11**, but with the screen adjusted to a position for a user holding the drill in the opposite horizontal orientation.

10 [0096] **Figure 12** shows the exemplary user interface unit mounted to a drill with the screen in position for drilling with the drill turned to a horizontal position and pointing to the user's left.

[0097] **Figure 12a** is similar to **Figure 12**, but with the screen adjusted to a position for drilling with the drill turned to a horizontal position and pointing to the user's right.

15 [0098] **Figure 13** shows an exploded view of the exemplary embodiment of the invention, showing a detachable user interface unit, a mounting unit, and a movable joint between the display and mounting units.

[0099] **Figure 14** is a section showing the exemplary mounting unit installed on a drill chuck.

20 [0100] **Figure 15** is a section view taken from **Figure 14**, normal to the drill axis, looking towards the drill user.

[0101] **Figure 16** is a section view taken from **Figure 14**, normal to the drill axis, looking towards the drill bit.

[0102] **Figure 17** shows an alternate embodiment of the invention having multiple display screens rather than a movable joint between a user interface unit and the drill.

25 [0103] **Figure 17a** shows the alternate embodiment of **Figure 17**, in a second drilling position.

[0104] **Figure 18** shows an example user interface according to one embodiment of the invention during use in the exemplary application, with the drill approaching alignment with a locking hole.

5 [0105] **Figure 18a** shows the exemplary user interface of **Figure 18**, but with the drill within alignment tolerance to a locking hole and with a depth indicator displayed.

[0106] **Figure 18b** shows a flowchart of a method for controlling field of view and magnification parameters of the user interface display.

10 [0107] **Figure 19** shows a section view through a bone and implant during use of the exemplary embodiment in the exemplary application, with the drill aligned with a locking hole within predetermined limits.

[0108] **Figure 19a** shows a flowchart of the targeting and user interface method described in **Figure 19**.

[0109] **Figure 20** is similar to **Figure 19** but shows an alternate method of defining the drill alignment limits.

15 [0110] **Figure 20a** shows a flowchart of the alternate targeting and user interface method described in **Figure 20**.

20 [0111] **Figure 21** shows an exploded view of an example field generator component of a navigation system, a drill, a drill bit, an IM nail with a distal locking hole, a sensor inserted in the nail, a registration tool, and a drill bushing integrated with the field generator according to one embodiment of the invention.

[0112] **Figure 22** shows the components of **Figure 21** assembled according to the exemplary embodiment and exemplary application, with the registration tool inserted in the distal locking hole and in position for registering the system to the hole.

[0113] **Figure 23** shows a section through the exemplary registration tool.

25 [0114] **Figure 23a** shows a section through the tip portion of the exemplary registration tool.

[0115] **Figure 24** shows a section through the exemplary registration tool and IM nail when in position for registering the system to the hole.

[0116] **Figure 24a** shows a section through a first additional example embodiment of a registration apparatus.

5 [0117] **Figure 24b** shows a section through a second additional example embodiment of a registration apparatus.

[0118] **Figure 24c** shows a section through a third additional example embodiment of a registration apparatus.

10 [0119] **Figure 24d** shows an exploded view of a fourth additional example embodiment of a registration apparatus.

[0120] **Figure 24e** shows a section through the fourth additional example embodiment of a registration apparatus.

[0121] **Figure 24f** shows a section through a fifth additional example embodiment of a registration apparatus, in which an additional degree of freedom is controlled.

15 [0122] **Figure 25** shows an example plot of typical measurement error versus field generator position about the drill axis at various distances from the field generator, with the field generator mounted to a typical drill.

[0123] **Figure 26** shows an example flowchart of the registration and operation steps of the system according to one embodiment of the invention.

20 [0124] **Figure 26a** shows a flowchart of intraoperative calibration of a navigation system which also generates a lookup table of correction values, according to an alternate embodiment of the invention.

25 [0125] **Figure 27** shows an example plot of reference sensor readings when a ferromagnetic tool is passed in and out of the measurement range of a field generator and causing measurement error.

[0126] **Figure 28** shows an example plot of reference sensor readings when a drill motor of an attached drill is started and stopped, creating external magnetic fields that affect navigation system measurements.

5 [0127] **Figure 29** shows an example plot of sensor orientation readings versus field generator position about the drill axis, with a field generator mounted to a typical drill.

[0128] **Figure 30** shows a flowchart of an example filtering method for smoothing and correcting sensor position and orientation data during navigation, and modifying filtering parameters based on selected conditions detected by the system, according to
10 one embodiment of the invention.

[0129] **Figure 31** shows an IM nail implanted in a femur, with the femur shown in section, with a fenestrated drill bit passing through the femoral neck and into the femoral head, and a sensor tool, in accordance with one embodiment of an aspect of the invention.

15 [0130] **Figure 32** shows the fenestrated drill bit, looking along the axis of the slotted hole.

[0131] **Figure 32a** shows the fenestrated drill bit, looking normal to the axis of the slotted hole.

[0132] **Figure 33** shows a section view through the femur and the IM nail with the fenestrated drill bit in place and a sensor tool installed.
20

[0133] **Figure 34** shows a top view of a cannulated and fenestrated stud, according to an alternate embodiment of an aspect of the invention.

[0134] **Figure 35** is a front view on the alternate embodiment of the invention shown in **Figure 34**.

25 [0135] **Figure 36** shows a section view through a femur and IM nail showing the cannulated and fenestrated stud of **Figure 34** and a guide wire in place, before retraction of the guide wire.

[0136] **Figure 37** shows an expanding stud which engages only one cortex of the bone and one wall of the nail, in accordance with yet another embodiment of an aspect of the invention.

5 [0137] **Figure 37a** is a section view taken from **Figure 37** through the expanding stud.

[0138] **Figure 38** is a section view of the expanding stud of **Figure 37** in use in a patient's limb.

Description

10 [0139] Throughout the following description specific details are set forth in order to provide a more thorough understanding to persons skilled in the art. However, well known elements may not have been shown or described in detail to avoid unnecessarily obscuring the disclosure. Accordingly, the description and drawings are to be regarded in an illustrative, rather than a restrictive, sense.

15 [0140] Different aspects of the invention and their presently preferred embodiments will be better understood by reference to the detailed disclosure below and/or the accompanying drawings. Where the same reference numbers are used in different drawings, the reference numbers refer to the same or similar parts.

20 [0141] As used herein "distal", when referring to a drill and attached components, refers to the direction leading further away from the user and towards the drill bit tip, and proximal as used herein is the opposite direction to distal. As used herein "distal", when referring to an IM nail and components attached to it, refers to the direction leading further away from the insertion tool, and proximal as used herein is the opposite direction to distal.

25 [0142] As used herein, 'navigation system' is a combination of an electromagnetic field generator, at least one electromagnetic sensor, and a controller, which may comprise a computer, connected to the field generator and sensor. The controller is configured to determine the position and orientation of the sensor element relative to the field generator. An example of a suitable navigation system is an AuroraTM system

made by Northern Digital Inc. (Waterloo, Ontario, Canada), which can be suitably modified and controlled by customized software for use in applications as described herein. Other suitable navigation systems are available from Ascension Technology Corporation, 107 Catamount Drive, Milton, VT 05468 USA.

5 [0143] **Figure 1** is a block diagram illustrating a system according to an example embodiment of the invention. Console **600** includes processor and power supply components of an electromagnetic navigation system. Console **600** may provide additional processing and communication components particular to an application, such as IM nailing. Charging dock **602** receives and charges user interface unit **606**
10 when not in use. When in use, user interface unit **606** and navigation unit **601** are attached to tool **603**. Unit **601** includes a field generator and at least one reference sensor that communicates with console **600** via cable **608**. User interface unit **606** communicates with console **600** via wireless communication link **604**. Sensor tool **610** communicates with console **600** via sensor cable **612**. Memory **614** accessible to
15 console **600** includes dimensions, features and graphic data models of components, and also measurement correction maps, lookup tables, parameters sets, software, firmware, and the like.

[0144] Database **616** contains dimensions, features and graphic data models of components, and also measurement correction maps, lookup tables, parameters sets,
20 software, firmware, and the like and is stored in an external memory device. Database **616** may be linked via communication link **618** to memory **614** to update the contents of memory **614**. Communication link **618** may comprise, for example, a wired, internet or wireless link or some combination thereof.

[0145] Software, firmware, and data stored in user interface unit **606** may be updated
25 via communication link **604** and via connection **605** from charging dock **602** to memory **614**. Software, firmware, and data stored in unit **601** may be updated via cable **608**. In various other embodiments in which tool **603** includes an electrical power source, such as a battery, cable **608** may be replaced with a wireless communication link for control signals between console **600** and unit **601**, and a wire
30 supplying power from tool **603** to unit **601**. In various other embodiments sensor cable **612** may be replaced with a power source, signal amplifier, and wireless

communication unit included in sensor tool **610**, and a wireless communication link from sensor tool **610** to console **600**. Non-limiting examples of suitable wireless links are Bluetooth™ and WiFi local area wireless communication systems.

[0146] One aspect of the invention provides a sensor tool for use with a navigation system. The sensor tool comprises an elongated member having a self-centering tip portion containing a sensor element. A snap fit mechanism is provided to hold the sensor tool in place in a component (e.g. an IM nail) so that the sensor element has a known geometrical relationship to a feature on the component (e.g. a locking hole).

[0147] **Figures 1a** through **6**, show an example sensor tool **10**. The illustrated sensor tool **10** may be used in IM nailing procedures, for example. Example sensor tool **10** includes several desirable features as described below. Each feature may be advantageous individually or in combination with some or all of the other features described. Other embodiments within the scope of the invention may include a subset of the advantageous features described in the example embodiment.

[0148] One desirable feature of sensor tool **10** is that the distal tip portion is self-centering in a range of different cannulation diameters. The self-centering characteristic may be provided by resiliently flexible members incorporated in the tip portion that are biased radially outwards to a maximum diameter, but may be resiliently compressed radially inwards to a range of smaller diameters all concentric with the maximum diameter. For example the self-centering characteristic may be provided by flexible members **186** (shown in **Figures 2** and **2a**) that are arch-shaped when viewed in a plane passing through the longitudinal centerline of sensor tool **10** and that are spaced angularly about a centerline of the tip portion.

[0149] Another desirable feature of sensor tool **10** is that sensory feedback is provided to the user when sensor tool **10** is properly installed in a component, such as an implant. The sensory feedback may be provided by a snap-fit mechanism. The snap-fit mechanism may provide tactile and/or audible feedback to the user upon engagement exclusively in the properly installed position. A snap-fit mechanism may be provided between the sensor tool **10** and a component, such as an implant, or between the sensor tool **10** and an insertion tool affixed to the component. A snap fit

mechanism may be provided by way of a suitable detent mechanism. For example a snap-fit mechanism may be provided by flexible tabs **192** shown in **Figures 6** and **6a** engaging grooves **195**.

[0150] Another desirable feature of sensor tool **10** is its fixed length and single-piece finished construction which allows the user to install sensor tool **10** with precision to a unique, predetermined position relative to a component in a single motion without adjustment or reference to graduation markings or the like to select the correct installation position. For example sensor tool length **176** shown in **Figure 1a** determines the position of tip portion **154** relative to the assembly of nail **37** and insertion tool **39** (depicted in **Figure 3**) along the centerline of nail **37**.

[0151] Figure 1a, shows a sensor tool **10** and a set of IM nails **37** and **165** (collectively or generally set **164** or IM nails **164**) with which the sensor tool may be used. One nail in set **164** may have different characteristics from another, for example a different length, cannulation diameter, or a different arrangement of features such as slots and holes. Each IM nail in set **164** has at least one distal locking hole **38** which may vary in size and location from one nail to another in set **164**, and may be the only distal feature of interest, or may be part of a group of distal locking holes **189** as shown. For the purposes of this description, if group **189** includes more than one hole or feature that will be drilled through, hole **38** is defined as the most proximal hole of group **189**.

[0152] Sensor tool **10** has tip portion **154** at its distal end, shaft portion **156**, and handle portion **158** at its proximal end. The shaft diameter **160** of shaft portion **156** is less than or equal to the minimum cannulation diameter **162** (visible in **Figure 5**) present in set **164**. For example, shaft diameter **160** in some cases is in the range of three to four millimeters. Tip diameter **166** is selected to be equal to or slightly greater than the maximum cannulation diameter **168** present in set **164**. Shoulder **170** has shoulder diameter **172** which is greater than bolt cannulation diameter **174** of cannulated bolt **173** (both shown in **Figure 5**). Length **176** from shoulder **170** to the distal end of sensor tool **10** is selected to be less than the minimum locking hole distance **178** (shown in **Figure 4**) present among the nails in set **164**, so that hole **38** remains clear for drilling through.

[0153] Referring to **Figures 1** and **Figure 2** together, sensor wire **180** extends from sensor element **182** embedded inside sensor tool **10** and connects to the navigation system (not shown) via connector **184** (visible in **Figure 3**). Sensor tool **10** may be injection moulded from medical grade plastic, for example ABS or PEEK, and may be assembled and bonded together from two or more parts to form a solid unit in which sensor element **182** is embedded and held in a fixed position within sensor tool **10** with the longitudinal axis of sensor element **182** lying approximately collinear with the common longitudinal axis of tip portion **154** and shaft portion **156**.

[0154] An example of a suitable sensor element **182** is a Mini 6 DOF sensor from Northern Digital Inc., Waterloo, Ontario, Canada, part number 610029. This sensor is approximately 1.8 millimeters in diameter by nine millimeters long. In an alternate embodiment sensor **10** may incorporate a battery, amplifier, analog to digital converter, and wireless transmitter to send signals wirelessly to the navigation system. Some or all of these components may be housed in handle portion **158**.

[0155] **Figures 2** and **2a** show tip portion **154** of sensor tool **10** in detail. As best seen in **Figure 2a**, flexible segments **186** all have the same cross section and shape and are evenly spaced about the common longitudinal axis of tip portion **154** and shaft portion **156**. Flexible segments **186** are designed to flex within the elastic range of their material such that tip diameter **166** may be compressed down to minimum cannulation diameter **162** without breaking or permanently deforming, so that sensor tool **10** may be removed, cleaned and re-sterilized, and reused if desired. Sensor element **182** is embedded in sensor tool **10** near tip portion **154**. Since flexible segments **186** compress radially inwards evenly when tip portion **154** is in a cylindrical bore having a diameter less than tip diameter **166**, sensor element **182** is centered within the cannulation of any nail in set **164** when tip portion **154** is inserted into the nail. Shaft diameter **160** is also shown.

[0156] One of ordinary skill in the art will recognize that a variety of other constructions may be chosen to provide the self-centering characteristic of tip portion **154**, for example flexible segments **186** may be replaced with a series of flexible vanes or tip portion **154** may be a cylinder having at least one relief slot allowing the cylinder to be compressed down to a smaller diameter.

[0157] With reference to **Figure 3**, in accordance with an embodiment of the invention, nail **37** which is selected from set **164** (See **Figure 1a**) is shown in an exploded view with insertion tool **39** and cannulated bolt **173**, which may be used with all nails in set **164** to insert and position the nail in a patient's bone. Selected nail **37** is attached to insertion tool **39** using cannulated bolt **173** which threads into nail **37**. Tang **187** of insertion tool **39** engages slot **188** at the proximal end of nail **37**, thereby fixing nail **37** in all six degrees of freedom relative to insertion tool **39**, and sensor tool **10** may be inserted through cannulated bolt **173** and into the cannulation of nail **37**. Connector **184** is also shown.

[0158] With reference to **Figure 4**, the exploded view of **Figure 3** is shown assembled with sensor tool **10** installed and showing nail **37**, insertion tool **39**, and cannulated bolt **173**. Minimum locking hole distance **178** extends from the contact point of shoulder **170** and cannulated bolt **173** (as seen in **Figure 5**) to the proximal edge of distal locking hole **38**, which is the most proximal feature that will be drilled through.

[0159] **Figure 5** is a partial section view taken from **Figure 4** on a plane through the longitudinal centerline of cannulated bolt **173**. When sensor tool **10** is fully inserted into the assembly of nail **37**, insertion tool **39**, and cannulated bolt **173**, shoulder **170** contacts countersunk surface **175** of cannulated bolt **173**. When full contact is maintained between the circular edge of shoulder **170** and the conical surface of countersunk surface **175**, sensor tool **10** is fixed in translation along the axis of nail **37**. Bolt cannulation diameter **174**, shaft portion **156** and sensor wire **180** are also shown.

[0160] Shaft portion **156** may be flexible with a flexibility sufficient to allow the sensor tool to be inserted into IM nails or other components that are not straight.

[0161] **Figures 6 and 6a** illustrate engagement of sensor tool **10** to insertion tool **39**. **Figure 6** is a section view through handle portion **158** of sensor tool **10** and also through insertion tool **39**, taken from **Figure 3** in the area of grips **197**, with sensor tool **10** approaching but not yet engaged with insertion tool **39**. **Figure 6a** is a section view taken from **Figure 4**, similar to **Figure 6** but with sensor tool **10** in its installed

position, engaged with insertion tool **39**. Referring to **Figure 6**, gap **198** is less than tool width **191** so that as sensor tool **10** is pushed distally into position, flexible tabs **192** are forced to spread outward to pass over insertion tool **39**. When surface **193** of sensor tool **10** contacts top surface **194** of insertion tool **39**, flexible tabs **192** snap into groove **195** as shown in **Figure 6a**, creating an audible snap sound and a vibration that can be felt by the user through grips **197** when sensor tool **10** reaches its fully installed position.

[0162] Referring to **Figure 6a**, flexible tabs **192** are designed to have an interference fit with edge **196** of groove **195** so that in the installed position, deflected gap **199** is greater than gap **198** and flexible tabs **192** are flexed outwards a predetermined amount within the elastic range of the material, and thereby create a distally directed seating force on sensor tool **10** against insertion tool **39** which is reacted at top surface **194** and at the contact of shoulder **170** to countersink surface **175** of cannulated bolt **173** (seen in **Figure 5**). The interference fit of flexible tabs **192** against edge **196** also creates a centering force preventing rotation of sensor tool **10** about the longitudinal axis of cannulated bolt **173** (see **Figure 5**). Sensor tool **10** is thereby held fixed in all six degrees of freedom relative to insertion tool **39**, which in turn is fixed in all six degrees of freedom relative to nail **37**. Referring also to **Figure 1a** and **Figure 2**, since sensor element **182** is fixed within sensor tool **10** at a known location relative to shoulder **170** and is centered within the nail cannulation having a diameter within the range of diameter **162** to diameter **168**, sensor element **182** is thereby held in a known fixed position and orientation relative to nail **37**, and by referring to registration measurements (described elsewhere in this description) and/or predetermined geometry of nail **37**, selected features of nail **37** such as the distal locking hole **38** or group of holes **189** can be located by the navigation system to which sensor element **182** is connected without specifying the cannulation diameter.

[0163] To remove sensor tool **10**, the user squeezes the handle portion **158** of sensor tool **10** at grips **197** towards the midplane of sensor tool **10**, causing flexible tabs **192** to spread apart and clear edge **196**, allowing the user to withdraw sensor tool **10** in a proximal direction.

[0164] One of ordinary skill in the art will recognize that there are a variety of constructions of sensor tool **10** that may also be used to provide the characteristic of sensor tool **10** engaging and indicating engagement at a unique position relative to nail **37**. For example various connection methods may be used to attach sensor tool **10** to one or any combination of insertion tool **39**, cannulated bolt **173**, or nail **37** for example by clamping, bolting, or friction fit.

[0165] **Figures 6b** through **6e** show another example of a snap-fit arrangement for a sensor tool adapted to engage a feature (such as a cannulated bolt **178**). Such an arrangement is adaptable to a wide variety of insertion tools. **Figures 6b** shows sensor tool **10** with sensor wire **180** and an alternate handle portion **676**. Sensor tool **10** is shown installed in insertion tool **39** which is assembled to nail **37** with cannulated bolt **673**. **Figure 6c** is a section view taken from **Figure 6b** showing a snap-fit sensor handle engaged with groove **671** in bolt **673**. **Figure 6d** is a section view taken from **Figure 6b** showing boss **684** engaged in bore **670** of insertion tool **39**. **Figure 6e** is a detail view showing the proximal portion of a cannulated bolt **673** having a proximally extended cap portion with a groove **671** and countersink surface **672**.

[0166] In this example embodiment sensor tool **10** includes handle portion **676** having conical surface **682**. Groove **671** has a constant rotated section of a complete rotation about the bolt centerline forming edge **674**. Countersunk surface **672** may be a complete rotated section but may also be evenly spaced segments of a rotated section about the bolt centerline. Handle portion **676** also includes flexible tabs **678** that engage edge **674** and create a seating force holding conical surface **682** against countersunk surface **672** of bolt **673** in a similar manner to flexible tab **192** and groove **195** shown in **Figure 6** and **Figure 6a**, and thereby constraining sensor tool **10** relative to bolt **673** in all degrees of freedom except rotation about the centerline of bolt **673**.

[0167] A wide variety of features in the insertion tool may be engaged by a portion of the sensor tool to fix The rotational position of sensor tool **10** may be fixed by providing a portion of the sensor tool adapted to engage any of a wide variety of features in the insertion tool. In the example embodiment shown, insertion handle **39**

has bore **670** parallel to the bolt centerline. Cylindrical boss **684** is a push fit with bore **670**. Boss **684** has slit **686** to enable a push fit to eliminate rotational play between sensor tool **10** and nail **37** under expected torque loads that may be applied to sensor tool **10** during use. Handle portion **676** also includes angled surfaces **688** which engage a countersink in a different type of insertion tool (not shown).

[0168] To remove sensor tool **10** the user squeezes grips **680** towards the bolt centerline to flex tabs **678** outwards to clear groove **671** and then pulls sensor tool **10** out proximally.

[0169] Because the engagement features in bolt **673** are revolved sections about the bolt centerline, which is coaxial with the nail centerline, sensor tool **10** can be installed at the same position regardless of the rotational position of the bolt about the centerline. Thus bolt **673** may be tightened and retightened to different rotational positions without substantially affecting the installed location of sensor tool **10** relative to nail **37** when sensor tool **10** is reinstalled. Conical surface **682** may alternately be a shoulder similar to shoulder **170** shown in **Figure 5**. Conical surface **682** and countersunk surface **672** may alternately be any mating surfaces or features that fix the location of handle portion **676** in translation along the centerline of bolt **673** regardless of the rotational position of bolt **673** about its centerline.

[0170] Various other mechanical arrangements could be used in place of boss **684** or surfaces **688** depending on common features of a group of different style insertion tools intended for use with sensor tool **10**, for example referring also to **Figures 6** and **6a**, in a set of tools with a common width **191** but not sharing a common geometry of grooves **195** or bore **670** relative to the cannulated bolt, a set of flexible tabs similar to tabs **192** having an interference fit to the outer surfaces of tool **39** may be used to constrain rotation and, in combination with the attachment arrangement of bolt **673** and tabs **678**, fix the location of sensor tool **10** relative to nail **37**.

[0171] **Figure 6f** shows an example of an attachment of a sensor tool to an implant using a hand-tightened fastener rather than a snap-fit attachment of sensor tool **10** to an insertion handle, cannulated bolt, and intramedullary nail assembly. **Figure 6g** is a section through the sensor tool, insertion handle, and nail showing the threaded hand-

tightened fastener attachment arrangement. In certain embodiments, a set of insertion tools including tool **702** may have a common threaded hole **690** relative to the centerline of cannulated bolt **173**, and a surface **704** to which a surface **692** of the handle portion **696** sensor tool **10** may mate when hand-tightened fastener **698** is tightened. In this embodiment sensor tool **10** has fixed length **694** from mating surface **692** to the sensor tip (not shown, see **Figure 1a**) and the translational position along the centerline of nail **37** of sensor tool **10** is determined by surface **704** and surface **692**. Sensor handle portion **696** and fastener **698** have countersink **700**. Fastener **698** is threaded to match hole **690**.

[0172] In this embodiment sensor tool **10** has shaft diameter **706** at least over the proximal region where the sensor shaft lies inside bolt **173** when sensor tool **10** is installed. Diameter **706** of shaft portion **156** of sensor tool **10** is a sliding fit to cannulation diameter **174** of bolt **173** (visible in **Figure 5**). When fastener **698** is tightened sensor tool **10** may rotate about the centerline of hole **690** only to the extent of the difference of diameters **706** and **174**, and shaft portion **156** and will bear against the inner surface of cannulated bolt **173** as fastener **698** is tightened. Thus when fastener **698** is tight sensor tool **10** is fixed in all six degrees of freedom relative to nail **37** in a precise position. Fastener **698** may be made of sterilizable plastic material similar to that of sensor tool **10** and supplied with sensor tool **10**, for example, or may be made of metal or another reusable and sterilizable material. One ordinarily skilled in the art will recognize that to be compatible with various insertion handles, handle portion **698** may have an array of holes at different locations and may have several different mating surfaces similar to surface **692** to match the selected insertion handles.

[0173] Another aspect of the invention provides a tool comprising a field generator that is configured to remain fixed relative to an axis of the tool and a point along the axis during use of the tool, where the portion of the tool may move relative to the axis and/or the point. For example the tool may comprise a drill and the moving portion may be a drill bit that rotates about the axis with the tip of the drill bit at the point on the axis. For another example the tool may comprise a saw and the moving portion may be a saw blade that rotates about the axis in a plane passing through the point.

For another example the tool may be an oscillating saw and the moving portion may be a saw blade that rotates back and forth through a small range of rotation, in a plane passing through the point. This arrangement is an advantage because, particularly when the moving portion of the tool is made of ferromagnetic and/or electrically
5 conductive materials, the tool may affect the performance of the field generator and cause measurement errors. Therefore limiting the position, pattern of motion, and range of motion of the tool and any movable portion of the tool to known and predictable values may allow various measurement correction and error compensation to be used to improve the performance of the field generator.

10 **[0174]** In some embodiments the axis may be offset from field generator, which may improve access to portions of the tool located on the axis and improve the user's view of the tool and the work area. For example a drill bit located along the axis and passing outside, rather than through, the field generator may be easier to change and easier to aim as the user can see along the drill bit length.

15 **[0175]** The field generator may be mounted or mountable directly to the tool. In other embodiments the field generator is mounted or mountable and detachable to an attachment for the tool. In other embodiments the field generator and/or attachment unit may be attachable to a variety of tools. In other embodiments the field generator and/or attachment unit may be attachable at various rotational positions about the axis
20 without changing the relationship of the field generator to the axis or the point on the axis. For example the tool may be a drill and the field generator may be mounted to a unit comprising a drill chuck that may fit several different types of drill, and may attach to a drill at various angles about the drill bit axis relative to a drill handle, allowing the user to select a position of the field generator that does not block the
25 view of the work area or interfere with obstacles in the work area.

[0176] In other embodiments the field generator is mountable and detachable to an attachment for the tool, wherein the attachment is adapted to hold the field generator at a selected location relative to an axis and a point on the axis. Some embodiments may additionally comprise a housing that encloses and isolates the field generator.

30 For example in embodiments adapted for surgery the attachment may comprise an autoclavable housing and the field generator may be non-autoclavable, and in use in a

sterile field a non-sterile user drops the field generator into the sterile attachment held by a sterile user, who then closes the housing thereby fixing the field generator in position and isolating it from the sterile field. This arrangement has the advantage of reducing the cost and increasing the service life of the field generator.

5 [0177] Each feature of a tool comprising a field generator described above may be advantageous individually or in combination with some or all of the other features described. Other embodiments within the scope of the invention may include a subset of the advantageous features described above and in example embodiments.

10 [0178] **Figure 7** shows an example navigation unit **1** with drill bit **2** installed. The navigation unit is mounted to drill **3**. Sensor tool **10**, and IM nail **37** having locking hole **38** are also shown. Unit **1** includes electromagnetic field generator **7**.

[0179] We have observed that when a commonly used type of drill bit **2** (Part #03.010.104 SynthesTM, Monument, CO 80132) is moved in front of a typical field generator, measurement distortions are:

- 15
- Much greater than one millimeter when drill bit **2** is moved about in front of the field generator,
 - Greater than one millimeter when drill bit **2** is moved in and out of the area in front of the field generator along a fixed axis, and
 - Less than one millimeter when drill bit **2** is spinning about a fixed axis relative
- 20 to a field generator.

[0180] Advantageously, in the embodiment of the invention depicted in **Figure 7** drill bit **2** rotates about drill axis **5** and unit **1** holds drill bit **2** in a fixed location relative to field generator **7** via housing **9**. Point **98** is coincident with axis **5** and with the tip of drill bit **2**, and along with axis **5** is fixed relative to housing **9** and field generator **7**

25 while unit **1** is in use. This arrangement limits electromagnetic distortion effects on the navigation system due to the presence of drill bit **2** in the measurement range of field generator **7** to a predictable and manageable level, thereby allowing drill bit **2** to be made of typical ferromagnetic materials. In various embodiments of the invention

drill bit **2** may be replaced with various items such as reamers, milling cutters, burrs, guide wires, and the like.

[0181] Advantageously, drill **3** and unit **1** including field generator **7** may be assembled into a single unit that can be operated with one hand. In such an integrated unit, it may be a further advantage to minimize the size and weight of field generator **7**, and to position field generator **7** relative to drill **3** in such a way as to minimize interference with handling of drill **3**, the patient and operating table, and the user's view of the work area. In particular it may be an advantage if the user has a clear view of the drill bit **2**. Accordingly in certain embodiments unit **1** may be attached to drill **3** at a variety of rotational positions about drill axis **5** and may be removed and reattached at a different rotational position during use without requiring recalibration.

[0182] A further advantage of unit **1** having field generator **7** and chuck **4** integrated may be that the distal tip of drill bit **2** is at a fixed position relative field generator **7**, and with sensor tool **10** in a fixed position relative to the region being drilled, the distance traveled by drill bit **2** along drill axis **5** through the region can be tracked directly by the navigation system as described below in **Figure 9**. By identifying an entry or starting point, the drilling progress along the drill axis can be reported to the user. By identifying an entry point and an exit point through a bone, for example, the length of the drilled hole through the bone can be reported to the user and used to help select the correct screw length to install.

[0183] In general, electromagnetic measurement distortions may be limited to manageable levels by limiting and predicting the introduction, removal, and movement of ferromagnetic and conductive material mass within the range of field generator **7** and to a lesser extent near field generator **7**. Accordingly in another example embodiment, unit **1** is adapted to attach to a tool such as an oscillating saw, and is further adapted to hold a cutting tool, such that the cutting tool moves in a limited range and in a predetermined pattern, the pattern being in a fixed location relative to field generator **7**. For example an example embodiment is like the drill shown in **Figure 7** except that drill bit **2** is replaced with an oscillating saw blade, drill **3** is replaced with an oscillating saw, and chuck **4** is replaced with an oscillating saw blade chuck having an axis about which the blade oscillates within a

predetermined limit of angular travel, such that the blade oscillates about the axis in a plane normal to the axis, both the plane and the axis being in fixed positions relative to field generator 7.

[0184] Looking now in detail at the exemplary embodiment depicted in **Figure 7**, unit 1 includes chuck 4 as an integral component of housing 9, reference sensor 8 (visible in **Figure 8**), and drill bushing 46, all of which are mounted in fixed locations relative to field generator 7. Axis 5 is defined by chuck 4 and bushing 46, and is therefore also in a fixed location relative to field generator 7 during use. User interface unit 6 is also mounted to unit 1 and may be adjusted to different positions relative to unit 1 as described in more detail later in the description. One of ordinary skill in the art will recognize embodiments that do not include user interface unit 6 on unit 1, for example a display screen may alternately be located outside the surgical field.

[0185] Referring also to **Figure 8**, in which field generator 7 emits an electromagnetic field which causes reference sensor 8 and sensor tool 10 to emit signals indicative of their positions relative to field generator 7. Field generator 7, sensor 8, and sensor 10 are part of, and are connected to, a navigation system (not shown). Reference sensor 8 returns a constant predetermined location relative to field generator 7 to the navigation system and if this location varies beyond predetermined limits an error warning may be issued to the user. Reference sensor 8 is shown in the embodiment embedded in the structure connecting field generator 7 and bushing 46, however one skilled in the art will recognize that reference sensor 8 may alternately be integrated into field generator 7 (as shown in **Figure 8a**, **Figure 8b**, and **Figure 8c**) for example mounted rigidly or moulded in to the front face of field generator 7, or otherwise mounted in a fixed position relative to field generator 7 and within the measurement range of field generator 7. For increased reliability and redundancy a group of several reference sensors 8 may be used. When installed (see **Figures 1** through **6b**), sensor tool 10 is located in IM nail 37 at a fixed, predetermined location relative to locking hole 38, but does not block or protrude into hole 38. Nail 37 is shown as a straight nail having a straight longitudinal centerline 40, however nail 37 may also be curved over selected regions of its length. In the embodiments shown, unless otherwise noted, nail 37 is straight from a point proximal to the most proximal

locking hole **38** to the distal end of nail **37**, and centerline **40** refers to the longitudinal centerline of this straight portion.

[0186] In typical use, nail **37** is implanted inside a bone (not shown). The navigation system uses the position data from sensor **10** and the predetermined location to generate guidance information displayed to the user on display **6** to help the user align axis **5** with locking hole **38**. A suitable navigation system, including field generator **7** and suitable sensors **8** and **10** is an AuroraTM system made by Northern Digital Inc., Waterloo, Ontario, Canada. A suitable model of field generator for this application is the Compact Field GeneratorTM, being of a small enough size and low enough weight so as to not hamper operation of drill **3**, yet having enough measurement range to encompass sensor tool **10** during aiming of drill **3** with drill bit **2** attached. Field generator **7** has an integrated erasable and rewritable memory **620**, visible in **Figure 8**, which can be used to store information such as calibration factors and serial numbers. Memory **620** may be, for example, a flash-type memory device.

[0187] Drill **3** may be a typical electric or air powered surgical drill that optionally contains ferromagnetic parts and may generate and emit magnetic fields. In the exemplary embodiment drill **3** is a Synthes Small Battery Drive (Synthes USA, West Chester, PA) with a brush-type DC electric motor powered by a battery mounted in the drill handle area. Drill bit **2** may be made of ferromagnetic material, such as hardened stainless steel. Chuck **4** is adapted to couple to drill **3** at several rotational positions about axis **5**. The interface between chuck **4** and drill **3** may be adapted as desired to fit selected types of drill **3**, for example drills from various different manufacturers, air-powered drills, or other types of tool. Chuck **4** is mounted so that its axis of rotation is fixed relative to field generator **7**. For example, chuck **4** may be mounted to rotate using suitable bushings, bearings or the like.

[0188] Although unit **1** is depicted as being separate from drill **3**, in other embodiments, features of unit **1** such as field generator **7** and/or a display and/or chuck **4** may be integrated directly with a tool such as drill **3**.

[0189] Chuck **4** may be replaced or adapted for tools other than drills and drill bits, for example K-wire drivers, screwdrivers, pin inserters, or for other procedures

requiring alignment of a tool having an axis that can be defined relative to field generator 7. Chuck 4 may also contain or be made of hardened stainless steel or other ferromagnetic materials.

[0190] Referring also to **Figure 8**, field generator 7 is both connected to a navigation system console (not shown, typically located outside the sterile surgical field) via cable 73. Reference sensor wire 79 also joins cable 73 and is also connected to the navigation system. The navigation console communicates wirelessly to display screen 6. Cover 24 is also shown. One of ordinary skill in the art will recognize that various combinations of wired and wireless communication may be used in alternate embodiments of the invention, for example field generator 7 may be powered from an electrical power source also powering drill 3, such as a battery, and field generator 7 control communication and reference sensor 8 signals may be transmitted wirelessly to and from the navigation system console, thereby eliminating cable 73. In the embodiment shown in **Figure 8**, field generator 7 is adapted to be sterilized with unit 1 and is rigidly connected to housing 9 by countersunk screws 85.

[0191] Also shown in **Figure 7** are the coordinate frames are defined for calibration and navigation. Various arrangements of coordinate frames may be used to relate a target axis such as the axis of hole 38 to sensor 10 and drill axis 5. All coordinate frames described below for the embodiment shown are not necessarily required in other embodiments of the invention. The configuration shown in is a lateral approach, and arrow 44 shows the direction of a medial approach. Field generator coordinate system 130 (subscripted 'w' for 'world'), drill coordinate system 132 (subscripted 'd'), sensor coordinate system 134 (subscripted 's'), and locking hole coordinate system 136 (subscripted 'h') are all three dimensional right hand Cartesian coordinate systems with orthogonal X, Y, and Z axes. Field generator coordinate system 130 is predetermined at field generator manufacture, is fixed in all six degrees of freedom relative to the structure of field generator 7, and is the coordinate system in which the navigation system reports the position of sensors such as sensor 8 and sensor 10 within the measurement range of field generator 7 (hence the subscript 'w' for 'world' since this is the how the navigation system sees the world). Describing the relative positions in the components in terms of homogeneous transforms, a

constant transform T_{wd} is defined from field generator coordinate system **130** of the field generator **7** to drill coordinate system **132** aligned with drill axis **5**. Drill coordinate system **132** has its origin at a selected point on drill axis **5**, a suitable point being the tip of drill bit **2** which may be preprogrammed into the system, determined by the user entering the drill bit length, or by a typical pivot calibration method as described in the spatial tracking literature (also available as software routines from navigation system manufacturers such as Northern Digital Inc., Waterloo Ontario Canada). The Z_d axis of drill coordinate system **132** is defined as collinear with drill axis **5** and having the positive Z_d direction extending distally from the drill user. The X_d axis of drill coordinate system **132** is defined as normal to the Z_d axis of drill coordinate system **132** and lying in the plane passing through drill axis **5** and the origin of field generator coordinate system **130**, with the positive X_d direction of drill coordinate system **132** extending away from field generator **7**. The Y_d axis of drill coordinate system **132** is then defined by the cross product of the X_d and Z_d axes to form a right hand three dimensional Cartesian coordinate system. Sensor coordinate system **134** is predetermined at sensor manufacture and is fixed in all six degrees of freedom relative to the structure of sensor **10**, with the Z_s axis of sensor coordinate system **134** being approximately collinear with the longitudinal centerline **40** of nail **37** when sensor **10** is installed in nail **37**. During operation the navigation system reports the transform T_{ws} from field generator coordinate system **130** to sensor coordinate system **134** at a rate of twenty to forty times per second. Locking hole coordinate system **136** may be defined by the predetermined dimensions of sensor tool **10**, nail **37**, and insertion tool **39**. Alternately locking hole coordinate system **136** may be defined by aligning drill axis **5** with the centerline of hole **38** (for example by using a registration tool as shown below in **Figure 22**) and making a direct measurement as follows:

- The Z_h axis of locking hole coordinate system **136** lies on the line normal to drill axis **5** and passing through the origin of sensor coordinate system **134**, with the positive Z_h direction towards the distal end of nail **37**
- The origin of locking hole coordinate system **136** is at the intersection of the Z_h axis and drill axis **5**.

- The Xh axis of locking hole coordinate system **136** is collinear with drill axis **5** with the positive Xh direction pointing away from the drill.
- The Yh axis of locking hole coordinate system **136** is the cross product of the Zh axis and drill axis **5**.

5 [0192] Also shown is reference sensor coordinate system **137** which is at a fixed location relative to field generator coordinate system **130**. Reference sensor coordinate system **137** may be positioned at any fixed location and orientation within the measurement volume of the navigation system. Distance **141** is defined as the distance from the origin of field generator coordinate system **130** to the YsZs plane of
10 sensor coordinate system **137** along the Zw axis of field generator coordinate system **130**. The approach direction of navigation unit **1** with respect to the assembly of handle **39** (seen in **Figure 3**), nail **37**, and sensor **10** can be determined as lateral or medial as follows:

- If the dot product of Zw and Xs is negative, it is a lateral approach, and
- 15 • If the dot product of Zw and Xs is positive, it is a medial approach.

[0193] With reference to **Figure 7a**, in accordance with an embodiment of the invention, a view is shown looking along drill axis **5** from the drill user's point of view and a set of parameters defining critical sensor positions for the exemplary embodiment are described. It is advantageous to define a subset of sensor positions and orientations that are critical to the targeting objective for a particular application
20 and embodiment in order to simplify various calibration and error compensation methods described elsewhere in this specification. In other embodiments of the invention, different sets of parameters may be critical and may be defined differently. For clarity nail **37**, drill **3**, navigation unit **1** and the proximal portion of sensor **10**
25 (seen in **Figure 7**) are not shown in **Figure 7a**, and only the outer perimeter of field generator **7** is shown. The outer perimeter of field generator **7** is located distance **14** from drill axis **5** to allow access to the distal portion chuck **4** for ease of installation and removal of a drill bit or other drill-mounted tool (see **Figure 8**), and to give the user a clear view of the drill bit. For example distance **14** may be twenty-five
30 millimeters. Rotated field generator position **138** is a dashed outline of field generator **7** shown rotated about drill axis **5** to heading **139**. Heading **139** is defined as zero

when the Yw axis of field generator coordinate system **130** is parallel with, and in the opposite direction to, the projection of the Zs axis of sensor coordinate system **134** into the XwYw plane of field generator coordinate system **130**; the solid outline of field generator **7** shown is the position at which heading **139** equals zero. Heading **139** is defined as positive as the field generator is rotated about drill axis **5** in the direction of arrow **140**. Heading **139** is expressed as an angle greater than or equal to zero degrees and less than three hundred and sixty degrees.

[0194] When drill axis **5** is held coaxial with the centerline of hole **38** (for example by using a registration tool as shown below in **Figure 22**) and field generator **7** is rotated about drill axis **5** through various headings **139** from zero to three hundred and sixty degrees, the origin of sensor coordinate system **134** describes a nominal circle **142** having radius **144**, and in the exemplary embodiment since drill axis **5** is nominally parallel to the Zw axis of field generator coordinate system **130**, nominal circle **142** lies in a plane normal to the Zw axis of field generator coordinate system **130**. Radius **144** is constant for a particular combination of nail **37** and sensor tool **10**.

[0195] The exemplary embodiment shown is designed to be used with a predetermined range of different nails, having known lengths and locking hole positions along the length, and sensor tools are provided in a variety of lengths and one or two particular lengths are recommended for use with each type of nail, and the origin of sensor coordinate system **134** is always proximal to hole **38** due to the relationship (shown in **Figure 1a** and **Figure 4**) of length **176** to minimum distance **178**, therefore radius **144** has a predetermined range. Similarly, referring also to **Figure 7**, there is a known range of distances **141**, which is a function of the length of drill bit **2** and the range of bone diameters expected to be encountered. Thus when drill axis **5** is aligned with locking hole **38** and in a position to begin drilling, with field generator **7** at any heading **139**, it is critical to maximize measurement accuracy and there is a subset of possible positions of sensor **10** relative to field generator **7** defined by three parameters: radius **144**, heading **139**, and distance **141**.

[0196] **Figure 8** is a section taken from **Figure 7** through drill axis **5** with drill **3** and user interface unit **6** deleted for clarity. In the exemplary embodiment it is advantageous to permanently fix chuck assembly **4** to housing **9** in such a way as to

deter users from attempting to reposition or remove and reinstall chuck assembly **4** and thereby possibly alter the position or orientation of chuck assembly **4** relative to field generator **7** which would require recalibration of drill coordinate system **132** (shown in **Figure 7**) and may also affect various error compensation methods

described in subsequent parts of this specification. Housing **9** has inner bore **43**. Chuck assembly **4** is permanently fixed within bore **43** at a selected rotational position relative to housing **9**, with sufficient strength to withstand weight and inertial loads generated as the user moves drill **3** or picks up and holds unit **1** and drill **3** by grasping a part of unit **1** such as field generator **7**. In the exemplary embodiment chuck assembly **4** is fixed to housing **9** by driving spring pin **22** against divot **12** in chuck assembly **4**. One of ordinary skill in the art will recognize that a variety of attachment methods may be used that will sufficiently hold unit **1** in place on chuck assembly **4**, for example chuck assembly **4** may be bonded into inner bore **43** using a suitable adhesive, interference fit, or the like.

[0197] An advantageous feature of unit **1** is that field generator **7** is located at an offset from drill axis **5**, which allows for sufficient space around chuck **4** for the user to operate chuck **4** and to install and remove drill bits, and also provides the user with a better view of drill bit **2** and the target area. Distance **14** is selected to allow a typical user's index finger to grasp collar portion **36** and pull it back in a proximal direction to release the drill bit. Arm portion **30** of unit **1** connects the field generator mounting portion **32** of unit **1** to housing **9** of unit **1** and has thickness **67** and width (not shown) selected to allow arm portion to fit between the user's index and middle finger so the user can hold the drill while changing the drill bit. For arm portion **30** a suitable thickness **67** is ten millimeters and width (not shown) is twenty millimeters.

Housing **9** also includes cover **24** and bushing **46** which are both rigidly attached to chuck **4** via housing **9** and field generator mounting portion **32**. The material of housing **9**, including arm portion **30**, field generator mounting portion **32**, bushing **46**, and cover **24**, is preferably non-ferrous and of low conductivity so as to minimize effects on the electromagnetic navigation system, lightweight so as not to hamper the user in operating drill **3**, but of sufficient rigidity to maintain the position of field generator **7** relative to drill axis **5** within one millimeter and one degree under normal inertial and handling loads during use. For the exemplary embodiment the material

preferably withstands autoclave or other high temperature sterilization processes without deforming. Some examples of suitable materials are titanium, PEEK, or UltemTM. A wide variety of other suitable materials may be used. Memory device **620** which is a part of field generator **7** and is connected to the navigation system via cable **73** is also shown.

[0198] **Figure 8a** shows an alternate embodiment of the invention in which navigation unit **1** has an alternate structure that maintains open access to drill chuck **4** from below drill axis **5** thereby allowing use of drill chucks with attachments below the drill axis, such as a K-wire driver. In this alternate embodiment two rigid arm portions **81** and **82** connect housing portion **80** to field generator mounting portion **83**.

[0199] **Figure 8b**, **Figure 8c**, and **Figure 8d** show another embodiment of the invention in which the field generator may be removed and replaced to the same location within the navigation unit relative to drill axis **5** and tip point **98**, and is housed and isolated within navigation unit **1**. This arrangement allows field generator and reference sensor unit **640** to be separated from navigation unit **1** before cleaning and sterilizing unit **1**. Unit **640** may then be cleaned (but not necessarily sterilized) using different methods which may be more compatible with the field generator, sensor and associated electronic components in unit **640**. Unit **640** may then be reinstalled in a sterile environment with no contact between unit **640** and any surface of unit **1** that is exposed after installation of unit **640** is complete. Housing and isolation of unit **640** is designed to prevent direct contact by a user and direct communication of fluids with unit **640** when unit **640** is installed in housing **9**. The embodiment shown may also be adapted to non-surgical applications in which it is an advantage to protect unit **640** from the environment, for example from fluids or dust, while unit **1** is in use.

[0200] **Figure 8b** is an exploded view showing unit **640** outside housing **9**. In this example embodiment field generator **7** is shown adapted for mounting in housing **9** via chassis **622** and is rigidly fixed to chassis **622** by countersunk screws **624**. Sensor interface circuit board **626**, accelerometer **62**, docking connector jack **628**, and reference sensor **8** are all mounted to chassis **622** to form one rigid field generator unit **640**. Reference sensor **8** (visible in **Figure 8d**) is rigidly mounted, for example by

bonding, to chassis **622** at distance **642** in front of the front face of field generator **7** as shown, within the measurement range of field generator **7**.

[0201] **Figure 8b** is a view looking inside housing **9** with unit **640** removed. In this example embodiment housing **9** is adapted to receive field generator **7**, and includes docking connector plug **630**, seal **632**, door **634**, elastic bumper **636**, and latch **638**. Cable **73** is mounted to housing **9**, wired to plug **630**, and connects to the navigation system console **600** (visible in **Figure 1**).

[0202] In the example embodiment shown, a minimum constraint design is used to position unit **640** at a precise position in housing **9**. When installed, chassis **622** contacts housing **9** at six points as follows: Three convex contact surfaces **648** each make a point contact with planar surface **650**, convex contact surface **652** makes two point contact with v-groove **654**, and convex contact surface **656** makes point contact with planar surface **658**. When seating force **644** is applied in a direction that creates a reaction force from housing **9** towards unit **640** at all six contact points, unit **240** is held in all six degrees of freedom relative to housing **9**. Seating force **644** is directed approximately through the middle of the group of contact points in order to produce approximately equal reaction forces at each point. Seating force **644** is designed to be sufficient to maintain contact at all six points as unit **1** is used, for example force **644** must be sufficient to resist inertial loads on unit **640** created as unit **1** is moved about by the user. Seating force **644** is created by elastic bumper **636** which is compressed a selected amount against contact surface **646** of unit **240** when door **634** is closed and latch **638** is engaged.

[0203] Reference sensor **8** is wired to circuit board **626**. Circuit board **626** converts signals from reference sensor **8** to digital signals which are then sent to the navigation system console via jack **628**, plug **630** and cable **660**. Sensor readings from reference sensor **8** may be more reliable when transmitted as digital signals, rather than the original sensor signals, along the length of cable **660** in conductors running alongside the power supply conductors for field generator **7** included in cable **660**. However in some embodiments wiring from reference sensor **8** may connect to docking connector **628** and continue on to console **600** via jack **630** and shielded conductors in cable **660**, thereby eliminating the need for board **626** in unit **640**. Accelerometer **62** and

field generator **7** are wired to docking connector jack **628** and in turn communicate with the navigation system via plug **630** and cable **660**. Field generator cable **73** (visible in **Figure 8b**) is wired to jack **628**. Memory device **620** which is a part of field generator **7** is also shown and communicates with the navigation system via cable **73**.

[0204] An example of a suitable field generator **7** is an Aurora Compact Field GeneratorTM and an example of a suitable sensor interface circuit board **626** is part number 7000420, both available from Northern Digital Inc, Waterloo, Ontario, Canada. An example of a suitable distance **642** is five millimeters. Chassis **622**, screws **624**, door **634**, and latch **638** may all be made of a lightweight, rigid, non-ferromagnetic and low electrical conductivity material, for example PEEK or titanium. Seal **632** and elastic bumper **636** may be made of a high temperature tolerant elastomer, for example silicone. For another example elastic bumper **636** may be a spring. The remaining components comprising unit **640** may be selected and designed to minimize mass of included ferromagnetic and conductive materials.

[0205] In some embodiments a plurality of reference sensors may be used at various locations in front of field generator **7** and at various distances approximately equal to or greater than distance **642**. In some embodiments accelerometer **62** may be integrated with circuit board **626**. One ordinarily skilled in the art will recognize that many alternate mechanical arrangements may be used to enclose and seal unit **640** within housing **9** after installation and to apply seating force **644**, and that many alternate mechanical arrangements may be used to hold unit **640** at a precise position within housing **9**. For example a threaded clamp, over center clamp, or a cam mechanism may be used. For another example unit **644** may alternately be isolated in a sealable sterile isolation bag before installation into housing **9**, in which case the contact pins of jack **628** pierce the isolation bag upon installation. In some embodiments, for example where operation in a sterile field is not required or when an isolation bag is used as described above, seal **632** and/or door **634** may not be required and a wide variety of alternate securing arrangement may be used to hold unit **640** in position. One ordinarily skilled in the art will recognize that unit **640** is shown as an example arrangement incorporating an existing and available field

generator and that all or some of the components of unit **640** may be integrated into the structure of a custom field generator to form a single unit.

[0206] **Figure 9** is sample trace **57** of drill travel along a drilling path versus time. Referring also to **Figure 7**, a feature of unit **1** having drill axis **5** and a tool tip point **98** on axis **5** in a fixed position relative to field generator **7** is that the motion of tip point **98** relative to sensor **10** (and thereby any structure at a known position relative to sensor **10**), may be recorded and analysed. In various embodiments the data may be processed and used advantageously to advise the user of tool travel, tool performance, to optimize parameters related to tool travel such as cutting speed and feed rate, to warn the user of possibly unsafe or damaging conditions such as rapid plunge-through of the tool, and to initiate or advise of corrective actions such as stopping a tool motor.

[0207] In some embodiments this data may be used in conjunction with other recorded parameters such as a state of the tool (for example if the tool motor is on or off), tool power draw, tool torque, vibration, tool motor speed, mode of tool operation (for example, forward, reverse, or oscillating drill rotation), and the like, some of which may be detectable using reference sensor **8** and sensor **10** and some of which may additionally require a data monitoring link from the tool to the navigation system. Certain states of the tool may be determined using the navigation system by processing data from sensor **10**. In embodiments including a reference sensor such as reference sensor **8**, certain states of the tool may be determined using the navigation system by processing data from the reference sensor as described in more detail in **Figure 28**, either in conjunction with or instead of data from sensor **10**.

[0208] In addition to being able to monitor the length of the drilled hole (as described below), knowledge of the distance versus time relationship may be used in conjunction with other sensed information to optimize the drilling process. For example, if it is desired to progress at a desired rate (for example to avoid bone necrosis due to excessive heating), the current cutting rate may be estimated by applying any of the many known filter designs for estimating the derivative of a position signal (for example, a simple finite difference differentiator, a differentiator in combination with a low-pass filter, or a state-estimator design). The current

estimated cutting rate may then be compared with a desired cutting rate and a signal provided to the user (for example a visual indicator on the screen with arrows or numbers, an aural indicator using pitch or loudness variations, or a tactile indicator using vibration or pressure to indicate the magnitude of the difference). Similarly, since plunge-through can be detected by a sudden increase in the tool velocity in the direction of drilling, such an event can be used, in certain embodiments which may include a control communication link to the tool, to reduce or shut off power to the drill to prevent inadvertent damage to underlying structures or to generate some other indication (for example visual, auditory or tactile) to alert the user to this event. For example in particular, in an embodiment as described elsewhere in this description in which navigation unit **1** is powered from the drill battery, a control connection to the drill may be included.

[0209] In the exemplary embodiment, the data recorded is time versus the distance travelled by unit **1** relative to sensor **10** along drill axis **5** while the coaxiality of drill axis **5** and hole **38** is within predetermined limits and the drill motor is on, where the drill has an electric motor and the state of the drill motor may be determined using data from reference sensor **8** as described in **Figure 28**. These conditions indicate that the user is likely drilling along the target drilling path. The time versus the distance data is used to estimate the length of a drilled hole traversing a bone so that the correct locking screw length may be quickly determined.

[0210] An example of such data is shown in time versus distance trace **57**. When drilling through a femur or other long bone, for example, we have observed that there may be several characteristic points and regions in trace **57** that may be recognized by analysing location and time data of drill tip relative to the sensor, including entry point **59** which indicates where the drill tip enters the bone at the start of drilling and exit point **61** where the drill tip exits the bone between which is the estimated depth of drilling **63** which can be reported to the user. Both points have the characteristic of a period of slow advancement along the drilling path as the drill cuts through cortical bone before or after the point, followed by a sudden increase in advancement speed as the drill bit exits the cortex, and may therefore be detected automatically by searching trace **57** for areas falling within a range of predetermined motion parameters.

[0211] Going through trace **57** in more detail, during the pre-drilling phase of initial aiming (before active drilling begins), there will likely be a positioning phase where the drill tip may advance and retreat, as well as be adjusted parallel to the bone surface, before settling down. When this motion settles to the drill tip being static and close to the axis, with drill angle likely varying and the drill motor likely off, trace **57** is flat at region **336**. Region **337** of relatively steady progress along the target axis, combined with drill angle being close to alignment (and optionally detecting a motor-on state), indicates the drilling rate through the near cortex. After plunging through the near cortex as indicated by a sudden increase in speed at region **338**, there is a region of higher speed progress through the cancellous bone and nail hole at region **339**. Progress slows again at region **340** of drill feed rate through cortical bone. Finally rate will likely increase again suddenly at region **341** after which the user should stop advancing the drill at flat region **342**. The start of region **337** of steady slope within a range of expected drill feed rates indicates entry point **59**, and similarly the end of region **340** indicates exit point **61**. Entry point **59** may be recognized after a small amount of travel from region **336** as shown. One ordinarily skilled in the art will recognize that different applications will produce different characteristic traces **57**, and that various thresholds, ranges, and estimation factors may need to be determined by experimentation for various materials, tools, cutting tool types, and the like in order to detect or estimate the desired regions and points of trace **57**.

[0212] **Figure 9a** shows a flowchart of a drill-travel-detection and drilling depth estimation method. At step **592**, a positioning phase is detected by recognizing the drill point to be near the target axis but not progressing along it. In step **593** a drilling phase is detected by the start of progress along the target axis within an alignment tolerance zone, optionally coupled with a drill motor on state. In step **594** the rate of progress along the axis is monitored and compared to selected thresholds, and reported to the user in step **595**. A rapid increase in rate exceeding selected thresholds is detected at step **596** and related warnings and actions may be applied at step **597**.

[0213] Another aspect of the invention provides a tool comprising a user interface unit. For example the tool may comprise a drill and the interface unit may comprise a touchscreen display. The user interface unit may be mounted or mountable directly to

the tool and may also be detachable from the tool. In other embodiments the user interface unit is mounted or mountable to an attachment for the tool and may also be detachable from the attachment. In other embodiments the user interface unit is adjustable relative to the tool such that the user may move the interface unit to a suitable position when the tool orientation is changed. For example the user interface unit may be a visual display screen attached via a swivel joint to a drill. For another example the user interface unit may be a visual display screen attached via a swivel joint to a drill chuck, which in turn attaches to a drill.

[0214] In other embodiments the user interface unit may detect the direction of gravity and adjust the orientation of an image displayed on the unit to a predetermined relationship to gravity. In other embodiments the user interface unit may detect the relative orientation of the unit to a reference direction defined by a navigation system and adjust the orientation of an image displayed on the unit to a predetermined relationship to the reference direction. For example the user interface unit may comprise a visual display screen and an accelerometer, which in some embodiments may communicate with a second accelerometer attached to a field generator or a sensor of a navigation system.

[0215] Each feature of a tool comprising a user interface and display described above may be advantageous individually or in combination with some or all of the other features described. Other embodiments within the scope of the invention may include a subset of the advantageous features described above, and described in more detail in example embodiments below.

[0216] **Figure 10** shows navigation unit **1** including user interface unit **6** is shown mounted to drill **3**. A feature of user interface unit **6** is that it is integrated with unit **1**, and in turn drill **3** when unit **1** is attached to drill **3**, so that the display and user interface functions are easily accessible to the drill user during use and the user's attention may remain directed towards the working area of unit **1** and/or drill **3** during use. In various embodiments this integration may be provided by mechanical arrangements such as making unit **6** an integral part of unit **1** or by a bracket, fastener, snap-fit mechanism, or friction fit. In the exemplary embodiment shown unit **6**

mounts to unit **1** via rotating ring **13**, stud **49**, and accompanying elements depicted in detail in **Figure 13** and **Figure 14**.

[0217] Another feature of user interface unit **6** is that it may be attached and detached as required by the user during use manually and without the use of separate tools. In various embodiments unit **6** may be detachably integrated with unit **1** using various mechanical arrangements such as hand-operated fasteners, snap-fit mechanisms, threaded connections, detent mechanisms, quarter-turn style quick release joints or fasteners, and the like. In the exemplary embodiment shown unit **6** removably attaches to unit **1** via stud **49**, clasp **69**, and accompanying elements depicted in detail in **Figure 14**.

[0218] Another feature of user interface unit **6** as integrated with navigation unit **1** is that user interface unit **6** may be adjustable to various positions and orientations relative to the rest of unit **1** and in turn drill **3**, so that the user may select a suitable viewing and access position of user interface unit **6** as unit **1** and/or drill **3** are moved to different positions and orientations. In various embodiments the integration of unit **6** may be made adjustable by use of various mechanical arrangements such as adjustable arms or brackets, linkage mechanisms, sliding fit mechanisms, swivel joints, spherical joints, and the like. In the exemplary embodiment shown unit **6** is adjustable relative to unit **1** via two separate swivel joints incorporating rotating ring **13**, stud **49**, and accompanying elements as depicted in detail in **Figure 13** and **Figure 14**.

[0219] Another feature of user interface unit **6** is that it remains at its current position during normal use until subsequent adjustment to a new position, without requiring the user to unlock, lock, remove, replace, tighten, loosen, use an additional tool, or take any other action other than moving user interface unit **6** to the desired position. In various embodiments this feature may be provided by linkage arrangements with friction joints and/or springs, detent mechanisms, and the like. In the exemplary embodiment shown unit **6** maintains the selected position relative to unit **1** via detent mechanisms including ball plungers **71** and **27** and accompanying elements depicted in detail in **Figure 14**, **Figure 15**, and **Figure 16**.

[0220] Another feature of user interface unit **6** is that it may have predetermined ranges of adjustability relative to unit **1** that prevent the user from moving unit **6** to various disadvantageous positions, for example positions where unit **6** may interfere with the function and performance of field generator **7** or drill **3**. In various
5 embodiments this feature may be provided by various mechanical stop or link arrangements. In the exemplary embodiment shown the rotation of unit **6** about one axis of adjustment is limited by boss **31** and groove **33** depicted in detail in **Figure 15** and **Figure 16**.

[0221] For embodiments in which unit **6** includes a visual display and unit **6** is
10 integrated with a tool that may be used in various positions relative to a target, it is advantageous to determine the direction of gravity in real time so that the image displayed by unit **6** may be oriented in a selected way relative to gravity regardless of the orientation of the tool. Orientation data may be provided by incorporating an accelerometer into unit **6**.

[0222] It is advantageous for embodiments in which the orientation of the field
15 generator may change during use (for example when the field generator is integrated with a tool that may be used in various positions) to determine the orientation of unit **6** relative to the field generator so that the image displayed by unit **6** may be oriented in a selected way relative to the field generator or in turn relative to any sensor having
20 a known location relative to the field generator. Relative orientation data may be provided by sensors that generate a signal indicative of the orientation of the user interface unit relative to the field generator, such as proximity sensors, electrical contacts, optical encoders, and the like. Alternately the relative orientation data may be provided by incorporating accelerometers in both unit **6** and at a fixed location
25 relative to field generator **7**, both producing signals indicative of the direction of gravity, and comparing the two gravity directions to determine the relative orientation.

[0223] Now looking at the exemplary embodiment in more detail, navigation unit **1**
30 has axis **5**. User interface unit **6** comprises an electronic touchscreen display in a housing, and may additionally include user interface devices such as buttons, switches, touchpads, and the like that may be operated through an isolation bag or

surgical drape. Navigation unit **1** comprises housing **9**, rotating ring **13** onto which user interface unit **6** mounts, and retainer **15**. In the embodiment shown field generator **7** is included in surgical navigation unit **1**. One ordinarily skilled in the art will recognize other possible embodiments that do not include field generator **7** or other navigation system components, wherein the targeting information displayed on user interface unit **6** is obtained by methods that do not require a field generator, such as optical tracking. User interface unit **6** is shown adjusted to a position suitable for a right-handed user drilling with drill **3** upright, pointing forward and away from the user's body.

[0224] With reference to **Figure 10a**, user interface unit **6** is shown adjusted from the position shown in **Figure 10** by approximately one hundred and eighty degrees about drill axis **5** in direction **19** and tilted in direction **17** about axis **18**, to obtain a viewable position of display **6** for a left-handed user drilling with drill **3** upright, pointing forward and away from the user's body.

[0225] With reference to **Figure 11**, in accordance with an embodiment of the invention, navigation unit **1** is mounted to drill **3** with screen surface positioned for drilling with drill **3** turned to a horizontal position and pointing forward from the user's body. From the position shown in **Figure 10a**, user interface unit **6** has been rotated counterclockwise, in direction **19** about axis **5** approximately ninety degrees, and may be adjusted in direction **17** about axis **18** to a suitable viewing angle.

[0226] With reference to **Figure 11a**, if the user needs to hold the drill **3** in the opposite horizontal orientation from that shown in **Figure 11**, user interface unit **6** may be rotated about axis **18** in direction **17** to a suitable viewing angle.

[0227] Referring to **Figures 10, 10a, 11, and 11a**, the adjustability of the position of user interface unit **6** relative to drill **3** allows the user to maintain a clear line of sight along drill axis **5** to the area being drilled in a variety of drilling positions.

[0228] With reference to **Figure 12**, in accordance with an embodiment of the invention, user interface unit **6** is mounted to drill **3** and adjusted to a position suitable for drilling with drill **3** turned to a horizontal position and pointing to the user's left. From the position shown in **Figure 11a**, user interface unit **6** has been rotated

approximately ninety degrees in direction **17**, and forty-five degrees in direction **19**. Referring also to **Figure 12a**, opposite adjustments may be made to obtain a suitable position and angle of display **6** when drill **3** is used in a horizontal position and pointing to the user's right.

5 **[0229]** Referring to **Figures 10** through **12a**, one skilled in the art will recognize that various degrees of freedom and ranges of adjustability of user interface unit **6** relative to navigation unit **1** may be selected depending on the range of drilling positions expected in the particular application and the desired allowable positions of unit **6**. For example in certain embodiments, adjustability in either direction **17** or direction
10 **19** may not be required. For another example it may be advantageous to restrict unit **6** from being positioned in the region directly between field generator **7** and drill **3** due to clearance required for operating drill **3** and/or to limit the effects of measurement distortion from unit **6**. For another example it may be advantageous to restrict unit **6** from being rotated to a position where the display screen faces distally towards the tip
15 of drill bit **2**. Certain other embodiments may require additional degrees of freedom.

[0230] With reference to **Figure 13**, in accordance with an embodiment of the invention, an exploded view of navigation unit **1** is shown illustrating one example of a structure that allows two degrees of freedom between unit **6** and chuck **4**, one being rotation about drill axis **5** and the other being rotation about an axis of unit **6** that is
20 normal to and intersecting axis **5**. Housing **9** has outer cylindrical surface **21**. Housing **9** is fixed to drill chuck **4** (see **Figure 8**) which in turn mounts to drill **3**. Rotating ring **13** slides over cylindrical surface **21**. Retainer **15** has pins **23** (not shown, see **Figure 14**) extending radially inwards and slides over cylindrical surface **21** such that pins **23** engage slots **25** in housing **9**, and when fully engaged, retainer **15**
25 is fixed to housing **9** in a position that pushes ball plungers **27** (not shown, see **Figure 14**) of rotating ring **13** against face **29** of housing **9**. Rotating ring **13** can then rotate about cylindrical surface **21** and axis **5**. This arrangement allows quick and easy disassembly of retainer **15** and rotating ring **13**, without requiring tools, for cleaning and sterilization. Drill **3**, field generator **7** and cover **24** (seen in **Figure 8**) are not
30 shown for clarity. Rotating ring **13** also includes stud **49** and collar **50**, to which user interface unit **6** is removably attached as described below.

[0231] With reference to **Figure 14**, **Figure 15**, and **Figure 16**, in accordance with an embodiment of the invention, a section through drill axis **5** is shown with navigation unit **1** assembled and user interface unit **6** in place. Chuck **4** is fixed within housing **9** as described in **Figure 8**. Housing **9** also has three proximity sensors **47** (visible in **Figure 16**) installed flush with face **29** and wiring **48** leading from proximity sensors **47** to the navigation system console. Rotating ring **13** includes three ball plungers **27** (one shown, all three visible in **Figure 15**) and three permanent magnets **28** (visible in **Figure 15**). Retainer **15** has pins **23** that engage slots in housing **9** to lock retainer **15** in position relative to housing **9**, such that ball plunger **27** installed in rotating ring **13** rolls along face **29** as rotating ring **13** is rotated by the user about axis **5**. Face **29** has radial grooves **45** spaced at intervals such that ball plunger **27** engages a groove **45** at selected intervals of the rotation of ring **13**. The releasable joint between user interface unit **6** and stud **49** of rotating ring **13** is also shown. User interface unit **6** comprises housing **34**, electronic touchscreen **65**, clasp **69** which pivots in housing **34** on pin **35** and is spring biased in a counterclockwise direction, and ball plunger **71** which engages divot **41**, which is one of a set of twelve divots circumferentially spaced around the outer cylindrical surface of stud **49** at thirty degree intervals. To install user interface unit **6** onto mounting unit **2**, the user slides user interface unit **6** onto stud **49** until clasp **37** engages shoulder **42** of stud **49** with an audible 'click' sound. As user interface unit **6** is rotated about stud **49**, ball plunger **39** engages a divot **41** and stops with an audible 'click' sound. User interface unit **6** remains in that position until it is rotated by the user by thirty degrees and ball plunger **39** engages the next divot **41**. Collar **50** is a clearance fit over stud **49** and circumferential groove **52** in collar **50** engages ball plunger **56** in stud **49** with a clearance fit, such that collar **50** is free to rotate about stud **49** but will not slide off stud **49** unless pulled off by the user for cleaning and sterilizing. Collar **50** allows user interface unit **6** to be enclosed in a sterile plastic drape **58** before installation onto stud **49**, allowing user interface unit **6** to be used in the sterile field without having to be sterilized. Drape **58** is made of thin clear plastic material which is pierced as the user slides user interface unit **6** over stud **49**, and when user interface unit **6** is in position as shown, the edge of the resulting pierced hole in drape **58** is compressed between housing **34** and collar **50** thereby preventing the user from having direct contact with any surface of user

interface unit **6**. As user interface unit **6** is rotated on stud **49** collar **50** is free to rotate with housing **34** thereby preventing twisting or tearing of drape **58**. Electronic touchscreen **65** is a touch screen unit comprising a battery power source, a computer, and a wireless communication device **20** to receive and transmit information to the navigation system. A suitable electronic display screen is an EMX-270 Embedded Mobile Device unit from Compulab™ (Haifa, IL). Wireless communication device **20** eliminates the need for a wired connection between user interface unit **6** and the navigation system console, (or, referring also to **Figure 7**, to field generator **7** and then on to the navigation system via cable **73**) which is important due to the degrees of freedom between user interface unit **1**, field generator **7**, and the navigation system console located outside the sterile surgical field.

[0232] Referring to **Figure 15**, a section through chuck **4** and housing **9** taken from **Figure 14** and looking proximally on retaining ring **13** is shown. Rotating ring **13** has three ball plungers **27** and three permanent magnets **28** installed at forty five degree intervals, with magnets bonded in place. Rotating ring **13** also has groove **33** into which boss **31** of housing **9** fits with a clearance fit.

[0233] Referring to **Figure 16**, a section through chuck **4** and housing **9** taken from **Figure 14** and looking distally on face **29** of housing **9** is shown. Face **29** has radial grooves **45** evenly spaced at forty-five degree intervals about axis **5** (not shown, visible in **Figure 14**), so that rotating ring **13** (not shown, visible in **Figures 13** and **14**) stops with an audible 'click' at each interval in its travel and remains in that position until it is moved by the user to the next forty-five degree interval position. Housing **9** also has boss **31** which fits in groove **33** of rotating ring **13** (see **Figure 15**), and proximity sensors **47** bonded in place flush with face **29** and located at forty five degree intervals as shown.

[0234] Referring to **Figures 15** and **16** together, groove **33** and boss **31** limit the rotation of rotating ring **13** to one hundred and eighty degrees, and in combination with radial grooves **45** defines five possible rotational positions of ring **13** relative to clamp portion **9**. At each forty-five degree interval in the rotation of rotating ring **13**, at least one of the three magnets **28** is aligned with at least one of the three proximity sensors **47**, and at each of the five possible forty five degree interval positions of

rotating ring **13** relative to housing **9**, a unique combination of proximity sensors **47** senses the presence of a magnet **28**. Referring to **Figure 14**, via wiring **48** to the navigation system console, the unique combination of activated proximity sensors is sent as a signal to the navigation system to indicate the user interface unit **6** position relative to housing **9**, and allowing the orientation of the image on touchscreen **65** to be rotated as desired.

[0235] Referring to **Figure 16a**, an embodiment of the invention without proximity sensors **47**, magnets **28** and wiring **48** is shown in a section view through navigation unit **1**, similar to **Figure 14**. In this embodiment electronic touchscreen **65** additionally includes accelerometer unit **60** which senses the direction of gravity relative to user interface unit **6** and communicates this information to touchscreen **65**, and in turn to the navigation system via wireless communication device **20**. Field generator **7** includes an embedded accelerometer **62** which generates a signal indicative of the direction of gravity which is sent to the navigation system via field generator cable **73**. By comparing the gravity direction vectors of accelerometers **60** and **62** the relative orientation of user interface unit **6** to field generator **7** can be determined and the image displayed on unit **6** can be aligned relative to a selected sensor being tracked by the navigation system. In another embodiment of the invention, for example for applications where the orientation of the target sensor is known relative to gravity or in which aligning the image shown on unit **6** relative to gravity is sufficient, accelerometer **62** is not required, accelerometer **60** is used alone (in place of proximity sensors **47** magnets **28** and wiring **48**), and the image on touchscreen **65** is aligned to the direction of gravity using the signal from accelerometer **60**.

[0236] With reference to **Figures 17** and **17a**, in another embodiment a plurality of display screens are mounted to the drill at selected locations, eliminating the need for degrees of freedom between user interface unit **6** and housing **9**. Auxiliary display screen **74** is powered and supplied with signals from touchscreen **65** by wiring **75** (but may alternately be similar to touchscreen **65** having a wireless communication device, internal battery, and an accelerometer, and may be a different size or shape). The horizontal drilling position shown in **Figure 17** is detected by accelerometer **60** (seen

in **Figure 16a**), and auxiliary screen **74** which is visible to the user in this drilling configuration is activated and the image on screen **74** is adjusted to the appropriate orientation and moved in direction **76** to optimize visibility. When drill **3** is operated in the position shown in **Figure 17a**, based on signals from accelerometer **60** (seen in **Figure 16a**) the image on screen **74** is rotated one hundred and eighty degrees relative to screen **74** and also moved in direction **78** to optimize visibility to the user.

[0237] Another aspect of the invention provides a user interface indicating the relationship of a tool to a target and also indicate tolerance limits of alignment of the tool to the target. For example the interface may comprise a display screen showing a drill icon representing a drill relative to a graphic of a target hole, and may also comprise indicators of coaxiality of the drill to the hole within specified parameters.

[0238] In some embodiments the user interface may indicate to the user where the tool is in real time relative to the target. The indication may have various forms depending on the particular targeting task, for example the task could be aligning two planes to be coplanar, aligning a tool tip with a point without indicating the angle of the tool, or aligning a tool axis to be coaxial with a target axis as described in the exemplary embodiment. The representation of the tool and the target may also be done various ways, for example the target may be shown in a fixed location on the display screen with the representation of the tool moving on the display, or vice versa, or the indication may be a hybrid in which the tool representation moves on the display in translation but the target moves on the screen in rotation, or vice versa. We have observed that users are successful at targeting in the exemplary drill alignment embodiment when a drill icon moves in both translation and rotation on the display screen while the target remains at a fixed position on screen. We have also observed that many users understand the interface well when the drill is represented by a graphic icon that looks like a drill bit and chuck.

[0239] In some embodiments the interface may automatically adjust field of view and magnification based on detected conditions of alignment. This enables optimization of view parameters without additional input from the user, such as a requirement to press a zoom in or zoom out command or to have a separate selection dialog to specify a target to zoom in on, and the like. For example in an embodiment the

display shows a large field of view showing all potential targets, and then centers
aligns with and zooms in on a particular target axis when the user has been within
selected limits of alignment to the particular target for a selected minimum continuous
time period, in order to allow fine adjustment of alignment. Similarly the
5 embodiment infers when the user has backed away from a particular target and zooms
out to a global view to allow the user to locate and select a different target. Different
parameters and thresholds may be applied for zooming in and zooming out.

[0240] In some embodiments indication of one parameter of alignment being within
tolerance may only be given if selected other parameters are also within tolerance.

10 For example, we have observed better user response to the interface when acceptable
angular alignment of a drill axis to a target hole axis is only indicated at times when
the drill tip is simultaneously within an acceptable distance from the target axis. We
have also observed that the preferred technique of many users is to align the drill tip
within the acceptable tolerance range, establish a pivot point in the material being
15 drilled if possible, and then rotate the drill into the acceptable angular tolerance range.

[0241] In some other embodiments the tolerance limit for one parameter of alignment
may depend on at least one other parameter. We have observed better targeting
results with many users when targeting limits of position and angle are related to each
other rather than treated separately. For example if a tool tip point is located a certain
20 distance from a target axis that is within the specified distance tolerance, and the
angle between the tool axis and the target axis is also within a specified magnitude of
angle tolerance, the direction of the angular error may lead the tip point closer or
farther from the target axis as the tool advances along the tool axis. Therefore it may
be an advantage to restrict the acceptable angular difference to those magnitudes and
25 directions that maintain the tip point within its distance tolerance, or lead the tip point
to a target region at a specified point along the target axis as the tool advances. It may
also be an advantage to select a region of the target axis where distance from the tool
tip to the target axis is most important, for example at the entrance to a target hole,
and project the current tool path to this region to calculate the distance parameter of
30 alignment rather than calculating distance to the target axis at the current tool tip point
location. This method makes the angular tolerance limit a function of how far the tool

tip is from the critical target region; the farther away, the closer the angle must be held to be aiming at the target. For example alignment between a drill axis and a target axis may have a magnitude of angle tolerance and a distance tolerance from the drill tip to the target axis, wherein the angle tolerance is reduced for certain directions depending on the location of the drill tip such that the projected drill axis passes through a selected tolerance zone. In an embodiment a positional alignment parameter may be the normal distance from a drill tip to a target axis and an angular alignment parameter may be the normal distance from the target axis to the intersection point of the projected drill axis and a selected plane near the target hole.

[0242] In another embodiment a positional alignment parameter may be the normal distance from the target axis to the intersection point of the projected drill axis and a first selected plane near the target hole, and an angular alignment parameter may be the normal distance from the target axis to the intersection point of the projected drill axis and a second selected plane near the target hole, the first and second planes defining a region of the target axis over which the coaxiality tolerance of the drill axis to the target axis is applied.

[0243] Each feature of a visual user interface described above may be advantageous individually or in combination with some or all of the other features described. Other embodiments within the scope of the invention may include a subset of the advantageous features described above, and described in more detail in example embodiments below.

[0244] **Figure 18** shows user interface unit **6** during targeting, with the drill approaching alignment with a locking hole. User interface unit **6** indicates to the user where the tool is in real time relative to the target. Drill icon **392** moves in both translation and rotation on screen **390** while the target, nail **37**, remains at a fixed position on screen **390**.

[0245] Drill icon **392** comprises a shank portion **393** connecting two separate indicators of successful alignment within a tolerance zone, one being tip indicator **394** indicating the position of the tip of drill bit **2**, and the other being alignment indicator

396 representing a point on drill axis 5 closer to drill 3 and thus indicating orientation of drill axis 5.

[0246] Referring also to **Figure 7**, during targeting display screen 390 shows a graphic representation 387 of nail 37 with hole 38 shown graphically by hole graphic 388 comprising the perimeter edge of hole 38 and crosshairs intersecting at the centre of hole 38. **Figure 18** shows the display zoomed in and centered on one target hole, the navigation system having detected that the drill tip has been within a selected distance from the hole axis continuously for at least a selected amount of elapsed time, as described in more detail in **Figure 18b**. Tip indicator 394 is semi-transparent in its non-activated state, such that nail graphic 387 and hole graphic 388 are visible through tip indicator 394 when tip indicator 394 is in its non-activated state.

Similarly alignment indicator 396 is also semi-transparent in its non-activated state, such that tip indicator 394, nail graphic 387, and hole graphic 388 are visible through alignment indicator 396 when alignment indicator 396 is in its non-activated state.

Drill icon 392 is semi-transparent such that tip indicator 394, nail graphic 387, and hole graphic 388 are visible through drill icon 392 at all times. For example in the exemplary embodiment, tip indicator 394 and alignment indicator 396 are rendered in a semi-transparent gray colour when in their non-activated states, and turn to an opaque green colour when in their activated states. One ordinarily skilled in the art will recognize that many alternate graphic shapes may be used and many other differences between activated and non-activated states are possible such as visible and invisible, filled and outline, flashing and steady display, changing shapes, or changing fill pattern.

[0247] **Figure 18a** shows user display 6 with display screen 390 during targeting, with the drill within alignment tolerance with locking hole graphic 388 of nail graphic 387. In this view shank portion 393 (see **Figure 18**) of drill icon 392 is not visible, and tip indicator 394 and alignment indicator 396 and depth indicator 398 are all shown in their activated states. Display 390 includes depth indicator 398 which indicates to the user that the tip of drill bit 2 as represented by tip indicator 394 is approaching the surface of nail 37, so the user has an indication of when drill bit 2 is about to enter locking hole 38. Depth indicator 398 is active and appears on display

390 only when tip indicator 394 is located within a predetermined range of distances from the plane through the Yh and Zh axes of locking hole coordinate system 136 (seen in **Figure 7**), and also within a minimum normal distance to the Xh axis of locking hole coordinate system 136. Since the objective is only to indicate to the user approximately when to expect the drill tip to enter the target hole, depth indicator 398 may be a qualitative indicator and as such has three fill-bar style graphic segments which are displayed as filled progressively to qualitatively represent the approach of drill bit 2 to nail 37. Alternately depth indicator 398 may be a side view showing a real time representation of the drill tip approaching the target hole. One ordinarily skilled in the art will recognize that depth indicator 398 may be implemented in many different ways using different graphic elements, sound, text, quantitative information, or a combination of these indicators, and that depth indicator 398 may be active at all times, or activated by different or additional parameters such as the drill motor detected as being on (refer to **Figure 27** and **Figure 32**).

[0248] **Figure 18b** shows a flowchart of a method for controlling field of view and magnification parameters of the user interface display. At step 530 targeting mode is active which may occur when the targets are defined and the navigation system is tracking the tool relative to the targets. Initially a global view showing all targets is displayed in step 532, and a distance parameter from the drill tip to each target is calculated, for example the normal distance to each target hole axis. The minimum of these distances is found and compared to a selected threshold D_{close} in step 534, and if the tool is within distance D_{close} to any target, the state of a timer T_{close} is checked in step 536. If T_{close} is not already running, it is started from zero in step 538 and the system returns to step 532 remaining in a global view. If timer T_{close} is already running, meaning that the tool has been near a particular target for some time, the value of that elapsed time near the target is checked against a selected threshold T_{zoomin} in step 540. Once T_{close} exceeds the zoom in threshold, timer T_{close} is stopped in step 552 and the system changes the display to a zoomed in view centered on the target the tool has been near for the selected continuous amount of time T_{zoomin} in step 542. Once zoomed in on a particular target the system checks for tool distance to the target to exceed a selected threshold D_{far} in step 544, and if the tool has moved away timer T_{far} is checked in step 546 and if not already running, started at zero in step 548.

If timer T_{far} is already running, meaning that the tool has been moved away from the current target for some time, the value of that elapsed time far from the target is checked against a selected threshold T_{zoomout} in step **550**. Once T_{far} exceeds the zoom out threshold, timer T_{far} is stopped in step **554** and the system returns to the global view in step **532**.

[0249] One ordinarily skilled in the art will recognize that other parameters, for example speed and acceleration of the tool towards or away from a target, may be used in place of or in addition to time and distance. For example a characteristic motion of the tool such as a flicking motion or a rapid tilt in a particular direction may be defined, detected and used to change view parameters.

[0250] With reference to **Figure 19**, in accordance with an embodiment of the invention, a section view through a bone and implant with a drill bit approaching alignment with a locking hole in the implant is shown to illustrate an exemplary method of determining when the tool has reached an acceptable alignment with the target according to selected limits. One example of this method is described in detail as follows: Drill bit **2** has tip **402** and is shown passing through skin and underlying soft tissues **400** with tip **402** contacting bone **401**. Drill axis **5** is coincident with the longitudinal centerline of drill bit **2**. Drill bit **2** rotates about drill axis **5** during drilling. Locking hole **38** in nail **37** has hole axis **404** which is collinear with the Xh axis of locking hole coordinate system **136** (shown in **Figure 7**). Drill axis **5** is shown at alignment angle **406** relative to the direction of hole axis **404**. Plane **408** passes through the Yh and Zh axes of locking hole coordinate system **136** (shown in **Figure 7**) and is therefore normal to hole axis **404** and also passes through the longitudinal axis of nail **37**. Drill axis **5** intersects plane **408** at intersection point **410**. Angle **406** is calculated as the acute angle between drill axis **5** and a vector normal to plane **408** passing through intersection point **410**. During targeting, the position of drill tip **402** and the position and orientation of drill axis **5** relative to hole coordinate system **136** is monitored constantly, for example at a rate of twenty to forty hertz, as described in the previous figures. Therefore during targeting distance **412** from drill tip **402** normal to hole axis **404** is calculated, and at any time angle **406** does not equal ninety degrees, intersection point **410** and distance **414** from intersection point **410** normal to

hole axis **404** is calculated. Referring also to **Figure 18** and **Figure 18a**, to indicate to the user when position and alignment of drill bit **2** to hole axis **404** is within predetermined limit, tip indicator **394** is switched to its activated state whenever distance **412** is within a preselected limit, for example one millimeter. Then to

5 indicate that the angular alignment is adequate, alignment indicator **396** is switched to its activated state whenever tip indicator **394** is in its activated state and simultaneously distance **414** is within a preselected limit. Note that the location of plane **408** along hole axis **404** may be selected to be a different point than the origin of hole coordinate system **136**, for example plane **408** may be located near the surface

10 of the nail **37** that is closest to drill tip **402**. Projecting drill axis **5** to a point near or within hole **38** while also monitoring the distance of drill tip **402** to hole axis **404** creates an interaction between position and orientation limits that ensures that the user does not only have the drill tip **402** within an acceptable distance of hole axis **404**, but also has drill bit **2** oriented such that for the current position of drill tip **402**, drill bit **2**

15 is oriented to a path that passes within a preselected tolerance zone relative to the center of hole **38**. This method has the effect of reducing the allowable angular error as the distance from plane **408** to drill tip **402** is increased.

[0251] **Figure 19a** shows a flowchart of an example targeting and user interface method described in **Figure 19**. Referring also to **Figure 19**, at step **560** targeting

20 mode is active which may occur when the targets are defined and the navigation system is tracking the tool relative to the targets. At step **562** a distance parameter D_{tip} is calculated as the normal distance **412** from the drill tip **402** to drill axis **5**. At step **564** if distance **412** is less than a selected maximum D_{tipmax} , the systems activates a position indicator such as tip indicator **394** at step **566**. If the distance parameter is

25 outside of the selected limit, both tip indicator **394** and angle indicator **396** are turned off at step **576**, if they are active from a previous measurement sample. At step **568** an angular alignment parameter D_{hole} is calculated as the normal distance **414** from intersection point of drill axis **5** and selected plane **408**. At step **570** distance **414** is compared to a threshold $D_{holemax}$ and if distance **414** is greater than $D_{holemax}$ angle

30 indicator **396** is turned off at step **578** if it is still active from a previous measurement sample. If distance **414** is less than $D_{holemax}$ the state of tip indicator **394** is checked at step **572** and if tip indicator **394** is still active, angle indicator **396** is activated, and

acceptable alignment is indicated by both tip indicator **394** and angle indicator **396** being simultaneously activated.

[0252] With reference to **Figure 20**, in accordance with an alternate embodiment of the invention, a section view through a bone and implant with a drill bit approaching alignment with a locking hole in the implant is shown to illustrate an alternate method of determining when the tool has reached an acceptable alignment with the target according to selected limits. In some applications it may be advantageous to define a segment of the target axis over which the alignment tolerances apply, and to potentially specify different tolerance limits at each end of the segment. For example an allowable angular tolerance for a shaft passing through a hole may be greater for a short hole than a long hole for a given radial clearance between the shaft and the hole. For another example in the case of a countersunk screw it may be desired to specify a tight positional tolerance at the point on the target axis in plane with the countersunk edge of the hole, so that the countersink aligns well, while the positional tolerance at the other end of the hole may be allowed to be larger. One example of this method is described in detail as follows: Nail **37**, locking hole **38**, skin and soft tissue **400**, bone **401**, hole axis **404** and plane **408** are shown and are defined in **Figure 14**. The alternate targeting method shown differs from the exemplary embodiment described in **Figure 19** in that proximal plane **450** is defined normal to hole axis **404** at a selected distance **452** along hole axis **404** from plane **408**, and distal plane **454** is defined normal to hole axis **404** at a selected distance **456** along hole axis **404** from plane **408**, and proximal plane **450** is closer to drill bit **2** than distal plane **454**. During targeting, the position and orientation of drill axis **5** relative to hole coordinate system **136** (shown in **Figure 7**) is monitored constantly as described above. Therefore during targeting at any time that drill axis **5** is not normal to hole axis **404**, proximal intersection point **458** between drill axis **5** and proximal plane **450** is defined and proximal distance **460** is calculated as the normal distance from point **458** to axis **404**. Similarly distal intersection point **462** between drill axis **5** and distal plane **454** is defined and distal distance **464** is calculated as the normal distance from point **462** to axis **404**. Referring also to **Figure 18** and **Figure 18a**, to indicate to the user when position and alignment of drill bit **2** to hole axis **404** is within predetermined limit, tip indicator **394** is switched to its activated state whenever proximal distance **460** is

within a preselected limit. Then to indicate that the angular alignment is adequate, alignment indicator **396** is switched to its activated state whenever tip indicator **394** is in its activated state and simultaneously distal distance **464** is within a preselected limit. This targeting method ensures that the drilled hole axis lies within a cylindrical or frustum-shaped tolerance zone about hole axis **404**, over only a selected segment of axis **404** as defined by distance **452** and distance **456**. For example, for a cylindrical screw shank having a diameter one millimeter less than the diameter of hole **38**, the limit for distance **460** and distance **464** may be selected to be less than one-half of a millimeter, and both proximal plane distance **452** and distal plane distance **456** may be selected to be equal to the radius of nail **37**, as shown in the figure, thus ensuring that if the screw is installed coaxial with drill axis **5** the screw shank will not foul hole **38** (assuming angles are small). Alternately different limits may be applied to distance **460** and distance **464**, for example to accommodate a tapered screw shank while maximizing the tolerance limits.

[0253] **Figure 20a** shows a flowchart of an example targeting and user interface method described in **Figure 20**. Referring also to **Figure 20**, at step **560** targeting mode is active which may occur when the targets are defined and the navigation system is tracking the tool relative to the targets. At step **582** a distance parameter D1 is calculated as the normal distance from hole axis **404** to the intersection point of drill axis **5** and a selected proximal plane **450**. At step **584** if distance D1 is less than a selected maximum $D1_{max}$, the systems activates a position indicator such as tip indicator **394** at step **566**. If the distance parameter D1 is outside of the selected limit, both tip indicator **394** and angle indicator **396** are turned off at step **576**, if they are active from a previous measurement sample. At step **586** an angular alignment parameter D2 is calculated as the normal distance from hole axis **404** to the intersection point of drill axis **5** and selected distal plane **454**. At step **588** D2 is compared to a threshold $D2_{max}$ and if D2 is greater than $D2_{max}$ angle indicator **396** is turned off at step **578** if it is still active from a previous measurement sample. D2 is within the selected limit $D2_{max}$ the state of tip indicator **394** is checked at step **590** and if tip indicator **394** is still active, angle indicator **396** is activated, and acceptable alignment is indicated by both tip indicator **394** and angle indicator **396** being simultaneously activated.

[0254] Another aspect of the invention provides registration apparatus configured to temporarily align a tool and field generator with selected target features, thereby allowing the invention to be used without prior knowledge of the relationship of a sensor to the target features of interest. For example some embodiments do not require a database of target component dimensions and can infer targeting information from registration data.

[0255] Target features may be measured directly in a variety of different ways, for example by digitizing the surfaces or edges of the target or by temporarily aligning the tool with the target and recording the ideal targeted position of the tool.

Registration measurements may also have selected degrees of freedom, for example in registering a hole to be drilled through, it may be sufficient to measure only the hole centerline and disregard orientation about or location along the centerline, for example if it is only important that the navigated tool aligns with the hole.

[0256] In other cases it may be useful to additionally register a point on the centerline (for example to measure tool proximity to the hole) and/or a rotational position about the centerline (for example to be able to infer the location of other features relative to the hole in a single registration measurement).

[0257] With particular relevance to electromagnetic navigation systems, registration is advantageously done with all components that may affect navigation measurements present and in place as they will be used during targeting, and in the relative positions that will be most critical during targeting. The registration apparatus may alternately approximate the effects of any components that may be not be present during registration.

[0258] In some embodiments the registration apparatus is a registration tool that may be mountable directly to the tool, for example the registration tool may slide over a drill bit portion of the tool, and be made of selected materials that do not affect the navigation system.

[0259] In some embodiments the registration apparatus is a registration tool that temporarily replaces part of the tool and approximates the effect of the replaced part

on the navigation system. For example the registration tool may replace a drill bit and have similar material, form and mass to the drill bit.

[0260] In some embodiments the registration apparatus is a feature or adaptation of the tool. For example the tool may include a shoulder adapted to fit the target feature to be registered and incorporated into the structure of the tool. For another example a drill bit may include a series of shoulders adapted to fit a selected range of target features.

[0261] Each feature of a registration apparatus described above may be advantageous individually or in combination with some or all of the other features described. Other embodiments within the scope of the invention may include a subset of the advantageous features described above and in example embodiments.

[0262] With reference to **Figure 21**, in accordance with an embodiment of the invention, an exploded view of the apparatus is shown similar to **Figure 7** and additionally illustrates an example of a registration tool included to allow direct measurement of the target holes relative to sensor **10**. Navigation unit **1** has bushing **46** and chuck **4**, drill bit **2** which rotates about drill axis **5**, drill **3** coupled to navigation unit **1**, IM nail **37** having distal locking hole **38**, sensor **10**, cannulated screw **173**, and insertion tool **39** are shown, and also including registration tool **110** for temporarily aligning drill axis **5** with hole **38** for the purpose of directly measuring and recording the relative position of sensor tool **10** to hole **38**. Registration tool **110** has body portion **112** and tip portion **114** and longitudinal axis **111**.

[0263] With reference to **Figure 22**, the components of **Figure 21** are shown assembled with registration tool **110** inserted in the distal locking hole **38** of nail **37**, in position for calibrating the system to hole **38**. IM nail **37**, insertion tool **39**, cannulated screw **173** and sensor **10** are assembled (as described above in **Figure 7**) such that sensor **10** is held in a fixed, predetermined location relative to a target location on the object being drilled, in this embodiment locking hole **38**. Registration tool **110** slides on to drill bit **2** and abuts against drill bushing **46**. Body portion **112** of registration tool **110** fits drill bit **2** with a close sliding fit (referring also to **Figure 24**), causing the longitudinal axis **111** of registration tool **110** to be coincident with

drill axis **5**. Tip portion **114** fits locking hole **38** with an interference push fit. Thus when assembled for hole registration as shown, locking hole **38** and drill bit **2** are coaxial and their axes are coincident with drill axis **5** which is fixed relative to navigation unit **1**, and sensor **10** is fixed in all degrees of freedom except rotation about drill axis **5** with respect to navigation unit **1**. Distance **141** from unit **1** to sensor **10** as defined above in **Figure 7** is shown.

[0264] With reference to **Figure 23**, a section through registration tool **110** taken from **Figure 21** is shown. Registration tool **110** comprises body portion **112** and tip portion **114** connected by threads **115** so that tip portion **114** may be replaced with an alternate tip portion having a different diameter or shape. Longitudinal axis **111** is common to tip portion **114** and body portion **112**. Body portion **112** has hole **116** along axis **111**. Hole **116** has diameter **118** selected to be a close sliding fit over the shank of drill bit **2** (seen in **Figure 21**) such that registration tool **110** may be slid on and off drill bit **2** by hand with a friction fit, and bending of drill bit **2** and play between drill bit **2** and registration tool **110** is minimized when registration tool **110** is installed over drill bit **2** as shown in **Figure 24**. Also referring to **Figure 24**, registration tool **110** has length **113** a selected amount greater than the length of drill bit **2** extending distally from drill bushing **46** so that when assembled for calibrating a locking hole (as shown in **Figure 22**), the distal tip of drill bit **2** is positioned in approximately the same position relative to sensor **10** as it will be during surgery as the drill bit **2** enters bone and approaches hole **38**. The materials used for registration tool **110** are ideally non-ferromagnetic, and preferably of low electrical conductivity, to minimize effects on the electromagnetic navigation system. Body portion **112** may be made of a rigid material and tip portion **114** may be made of a material with an elastic range and modulus sufficient to provide a suitable push fit in a hole having a selected diameter range. For example body portion **112** may be made of round acetal rod having a one inch outside diameter, and tip portion **114** may be made of 300 series stainless steel. Many other materials may be suitable for both parts, for example titanium, and high modulus sterilizable plastics such as PEEK or UltemTM.

[0265] With reference to **Figure 23a**, a section through the tip portion **114** of registration tool **110** is shown. Referring to **Figure 23** and **Figure 23a** together, tip

portion **114** has hole **121** along axis **5**, and four slots **123** extending radially outwards from axis **111**, thus forming four flexible segments **120** all having the same cross section and shape defined by hole diameter **122** and slot width **124** and all being evenly distributed about axis **111**. Hole diameter **122** and slot width **124** are selected
5 along with the material properties of the material selected for tip portion **114** such that flexible segments **120** flex within the elastic range of their material such that free diameter **128** may be compressed down to tip fixed diameter **126** without breaking or permanently deforming. Since flexible segments **120** compress radially inwards evenly when tip portion **114** is in a cylindrical bore having a diameter less than free
10 diameter **128**, tip portion **114** is centered within any cylindrical bore within a predetermined diameter range between tip fixed diameter **126** and free diameter **128**. Flexible segments **120** are furthermore designed to flex within a subrange of the elastic range of the material such that registration tool **110** may be inserted and removed by hand with a push fit, yet provide resistance to forces tending to make axis
15 **111** non-colinear with the cylindrical axis of hole **38** (seen in **Figure 21**). A suitable non-colinearity limit is one degree when subjected to a moment in any plane passing through axis **111** of up to 5 N-m. For example, for a locking hole having a tolerance range of 5.1 millimeters to 5.2 millimeters and a tip portion **114** made of 303 stainless steel, suitable values for hole diameter **122**, slot width **124**, tip fixed diameter **126**,
20 and free diameter **128** are 2.8, 1.0, 4.9 and 5.3 millimeters respectively. One skilled in the art will recognize that the apparatus shown in **Figures 23** and **23a** may be adapted to various shapes such as slotted hole by way of suitable detail design of slots **124** and flexible segments **120**.

[0266] Referring to **Figure 24**, a section through registration tool **110** taken from
25 **Figure 22** is shown, with registration tool **110** installed. Referring also to **Figure 23**, longitudinal axis **111** and is coincident with drill axis **5** when registration tool **110** is installed over drill bit **2**. Countersink **117** has diameter **119**, depth **125**, and angle **127** selected to fit over boss **85** of drill bushing **46**, boss **85** having length **87** and sharing diameter **119** and angle **127** with countersink **117**. Length **87** is less than depth **125**.
30 Boss **85** and countersink **117** thereby together provide a positive stop defining the position of registration tool **110** along axis **5** and coaxiality of axis **111** to axis **5**.

[0267] Referring to **Figure 24a**, a section through a first additional example embodiment of a registration apparatus is shown similar to **Figure 24**, but wherein registration tool **110** is not used and instead bushing **46** includes boss **85** adapted as shown with diameter **90** chosen to fit the target feature. Drill bit **2** and drill axis **5** are also shown.

[0268] Referring to **Figure 24b**, a section through a second additional example embodiment of a registration apparatus is shown, similar to **Figure 24**, but wherein registration tool **110** is not used and instead drill bit **2** has shoulder portions **92** and **94** adapted to fit target features having diameters **90** and **96**. Bushing **46** and drill axis **5** are also shown.

[0269] Referring to **Figure 24c**, a section through a third additional example embodiment of a registration apparatus is shown similar to **Figure 24**, but wherein registration tool **110** is not used and instead drill bit **2** is removed and replaced with registration tool **100** having a series of shoulders **102**, **104**, and **106** having diameters selected to fit three different target features. In this embodiment the design and material of registration tool **100** are selected to have similar effect on electromagnetic position tracking as drill bit **2**. Referring also to **Figure 22**, in this embodiment the diameter of the target feature may be determined from among the three possible diameters by recording the distance **141** along drill axis **5** from navigation unit **1** to a sensor fixed relative to the target feature.

[0270] Referring to **Figure 24d** and **Figure 24e**, a fourth additional example embodiment of a registration apparatus is shown which is suitable for a target hole having a revolved section portion that makes a complete revolution about the hole axis at each end of the hole, for example a sharp edge, or a chamfered edge of a minimum depth. This embodiment has the advantage of being adaptable to a wider range of target hole diameters than the previous examples. In the example embodiment shown in **Figure 24d** and **Figure 24e**, locking hole **38** has a ninety degree countersink having a minimum depth at both ends of the hole. Locking registration tool **250** slides over drill bit **2** and further includes conical surface **251**, threaded portion **252** and cylindrical portion **257**, and lock nut **253** has conical surface **254** and threaded hole **255**. In use registration tool **250** is passed through the hole **38**

and lock nut **253** is threaded on to registration tool **250** and tightened to create a seating force along direction **256** which compresses conical surfaces **251** and **254** against the countersunk edges of hole **38**, thereby making axis **5** coaxial with hole **38**.

In this embodiment cylindrical portion **257** of registration tool **250** need only be smaller than the diameter of hole **38** and therefore locking registration tool **250** may be used with a range of hole diameters, and the user does not have to operate an interference fit as described in some other example embodiments. One skilled in the art will recognize that a variety of mechanical arrangements may be used in place of the threaded connection between lock nut **253** and registration tool **250**; any mechanism which can maintain conical surfaces **251** and **254** coaxial and apply a seating force acting to compress conical surfaces **251** and **254** towards each other along common axis **5** may be used.

[0271] Referring to **Figure 24f**, **Figure 24g** and **Figure 24h**, a fifth additional example embodiment of a registration apparatus is shown, in which an additional degree of freedom is controlled. In addition to temporarily fixing drill axis **5** coaxial with hole **38** as in the previously described embodiments, registration tool **470** can additionally fix the rotational position of navigation unit **1** relative to nail **37** about axis **5**, thereby providing the definition of a plane through nail longitudinal centerline **40** and the axis of hole **38** relative to sensor coordinate system **134** (seen in **Figure 7**) as additional registration information. This additional constraint may be achieved in a variety of ways depending on the specific form of nail **37** and hole **38**, for example referring also to **Figure 1a**, if every nail **37** in a set of IM nails **164** has some common geometric element, the example registration tools described above may easily be adapted to constrain the nail in rotation about axis **5**. For example if the common geometric element is at least two holes in group **189**, the registration tool could have a variety of structural elements added to engage the second hole and also be adapted as shown in **Figure 24h** to have a fixed rotational position relative to navigation unit **1**. In the example embodiment shown, nail **37** has a constant cross section with a cylindrical outer envelope within a selected diameter range in the area of hole **38**. The centerline of hole **38** is perpendicular to and passes through nail centerline **40**, and hole **38** has a countersink at each end. Registration tool **470** includes body portion **471** having multi-faceted surface **476**. Threaded collar **488** engages clamp

portion **478** and bears on shoulder **473** such that when tightened, clamp portion **478** is drawn towards surface **476** in direction **486** and creates a seating force holding nail **37** against surface **476**. Surface **476** has at least two planar facets at angle **490** symmetrical about a plane through axis **5** and nail centerline **40**, therefore when nail **37** is seated against surface **476** by a seating force in direction **486**, nail **37** is held in line contact with surface **476** at two lines, both parallel to nail centerline **40** and passing through contact points **492** and **494**, thereby constraining nail **37** in rotation about axis **5** relative to registration tool **470**. Clamp portion **478** has conical surface **480** having an axis of revolution coincident with axis **5** and engaging hole **38**, therefore when nail **37** is compressed between surface **476** and surface **480** by a seating force in direction **486**, hole **38** is constrained to be coaxial with axis **5**. Plunger **472** has conical surface **474** having an axis of revolution coincident with axis **5** and spring **482** pushes plunger **472** against nail **37**, thereby constraining rotation of nail **37** about centerline **40**. Plunger **472** is stopped from sliding out of body portion **471** by set screw **498** which engages slot **499** in plunger **472**. Clamp portion **478** is stopped from sliding off of and rotating relative to body portion **471** by set screw **489** which engages slot **491** in body portion **471**. Threaded collar **488** is held from sliding off body portion **471** by snap ring **496**. As long as at least one of the line contacts passing through point **492** and point **494** can be maintained and conical surfaces **474** and **480** remain seated in the edges of hole **38**, nail **37** is constrained in all six degrees of freedom relative to body portion **471**. One skilled in the art will recognize that there may be other mechanical arrangements that may be used to apply the constraints described above, and that various adaptations may be made to accommodate variations in the shape of nail **37** and hole **38**, for example for non-cylindrical cross sections of nail **37**, surface **476** may be modified to have asymmetrical facets, non-planar facets, or a specific form to match the nail. Similarly surface **476** may be replaced with a variety of mechanical clamping arrangements. Referring to **Figure 24h**, body portion **471** has vee-shaped groove **493**, and bushing **46** is adapted to include convex boss **495**. Groove **493** engages boss **495** and constrains rotation of registration tool body portion **471** about axis **5** relative to unit **1** when the user inserts unit **1** and drill bit **2** into registration tool **470**.

[0272] Referring to the exemplary registration tools described above, one ordinarily skilled in the art will recognize that the target feature to be registered may be of other forms such as a recess, slot, conical hole, or non-cylindrical hole, with corresponding adaptation of the registration tool shape, and that a variety of mechanical
5 arrangements may be used to temporarily align the registration tool to the feature such as clamping, bolting, using an expanding shaft or collet, and the like.

[0273] With reference to **Figure 25**, a plot is shown of typical measurement error versus field generator heading **139** (referring also to **Figure 7** and **Figure 7a**) about drill axis **5** at selected distances **141**, with navigation unit **1** and drill bit **2** mounted to
10 a typical drill **3**. When ferromagnetic and/or conductive metals are within or near the measurement volume of the navigation system, the magnetic fields generated by the navigation system may be distorted, causing the measurements to become inaccurate. These effects may be exaggerated with field generators such as field generator **7** which are small and light enough to be directly mounting on a handheld tool; smaller,
15 lighter field generators generally have smaller drive coils and generate weaker magnetic fields. Large masses of ferromagnetic and/or conductive materials, such as those found in a typical electric drill such as drill **3**, can distort measurements even if they are placed near, but not necessarily within, the measurement volume of the navigation system. For example placing a steel plate of sufficient mass behind unit **1**
20 will distort the measurement field enough to cause large errors throughout the measurement volume in front of unit **1**. We have observed that when drill **3** is positioned close behind field generator **7** included in unit **1**, measurement errors become larger as the measured sensor is brought closer to unit **1**, as illustrated in **Figure 25**. Therefore to integrate tools such as drill **3** and ferromagnetic drill bit **2**
25 with field generator **7** and maintain sufficiently accurate navigation for the application, detection of and compensation for magnetic field distortion due to the presence of tools is advantageous. In **Figure 25** the horizontal axis of the plot is heading **139**. The vertical axis of the plot shows the deviation in millimeters of the origin of sensor coordinate system **134** from nominal circle **142** as field generator **7** is
30 rotated about drill axis **5**. Curve **146** shows errors when nominal circle **142** described by sensor **10** lies in a plane intersecting the Zw axis of field generator coordinate system **130** at a distance **141** of one hundred and thirty millimeters. Similarly curves

148, 150, and 152 are generated at values of distance 141 of one hundred and ten, one hundred, and eighty millimeters respectively. **Figure 25** illustrates that measurement error varies with heading 139 of field generator 7 about drill axis 5 when drill axis 5 is aligned with the axis of hole 38, and measurement error increases as sensor 10 is brought closer to field generator 7 and drill 3.

[0274] Another aspect of the invention provides a registration method for measuring a target feature position relative to a sensor. In one embodiment, the method comprises the steps of temporarily fixing a tool and field generator assembly to the target feature of the target component at a known position in selected degrees of freedom, recording the position of the sensor relative to the field generator, calculating the relative position of the feature to the sensor, and storing the relative position of the feature to the sensor into the memory of the navigation system. For example in an embodiment the target feature may be a hole, the tool and field generator may be a drill, the drill axis and the hole axis may be held coaxial during registration, and the hole may be defined as a target axis expressed in the coordinate system of the sensor and representing a target axis which is calculated from an average of a selected number of position measurements.

[0275] The method may additionally comprise a step producing a lookup table of hole locations at a number of different locations of the sensor relative to the tool and field generator assembly. For example in another embodiment the registration measurement may be made as described above, with registration data being recorded as the user rotates the tool and field generator assembly about the common tool and hole axis. Target location relative to the sensor may then be stored for a selection of different rotational positions, and the appropriate location recalled during targeting when the tool and field generator assembly is at a similar position. In another embodiment the lookup table of target positions may be interpolated and/or a continuous function of target position versus field generator position may be created.

[0276] Each feature of a registration method described above may be advantageous individually or in combination with some or all of the other features described. Other embodiments within the scope of the invention may include a subset of the advantageous features described above and in example embodiments.

[0277] With reference to **Figure 26**, in accordance with an exemplary embodiment of the invention, a flowchart of the method of intraoperative registration and operation of the navigation system is shown, in which factory calibration has been performed and lookup table **143** is stored in system memory. The exemplary method illustrated generally includes the steps of registering the target features and determining the current measured location of a sensor and applying a predetermined correction to the measured location to estimate a more accurate location. The method may also advantageously include defining a subset of critical sensor locations and determining corrective maps or functions for these locations only.

[0278] Referring also to **Figure 7a** and **Figure 22**, measurement errors as shown in **Figure 25** which are a function of radius **144**, heading **139**, and distance **141** are measured at manufacture and lookup table **143** of correction values is stored in a memory device embedded in field generator **7**. Lookup table **143** includes corrections to translations and rotations in the transform T_{ws} from field generator coordinate system **130** to sensor coordinate system **134** which is measured by the navigation system during targeting. For example, navigation unit **1** with drill bit **2** is attached to drill **3** and mounted in a coordinate measuring machine, which may be programmed to move a nail **37** and sensor **10** through a series of nominal circles **142** (having known accuracy and precision limits), in planes normal to the Z_w axis of field generator coordinate system **130** and having a range of radii **144**, a range of distances **141**, and a number of headings **139**. A suitable range of radii **144** is ten to ninety millimeters in increments of twenty millimeters, a suitable range of distances **141** is eighty to one hundred and forty millimeters in increments of twenty millimeters, and a suitable number of headings **139** is thirty six, evenly distributed into increments of ten degrees. Thus lookup table **143** is generated from seven hundred and twenty pair of nominal $T_{ws(nom)}$ and measured ($T_{ws(measured)}$) transforms, and contains seven hundred and twenty corrective transforms $T_{ws(corr)}$ such that for each set of parameters i of radius **144**, heading **139**, and distance **141**:

$$T_{ws(nom)(i)} = T_{ws(measured)(i)} * T_{(corr)(i)}$$

[0279] To begin the registration procedure, the system is assembled as shown in **Figure 22** including drill bit **2** installed into navigation unit **1** and registration tool **110**

is slid over drill bit **2** and pushed proximally until it abuts bushing **46**, and the selected nail **37** is assembled to insertion tool **39** by tightening cannulated screw **22**. In step **200** the user powers on the system and in step **202** the transform T_{wd} from field generator coordinate system **130** to drill coordinate system **132** (see **Figure 7**) is
5 retrieved from the system memory. In step **203** the user selects right limb or left limb, and antegrade or retrograde approach, so that the correct image orientation may be determined. In step **204** the user inputs either the selected nail being used by selecting it from a preprogrammed list, or a skip command to bypass the specific nail selection and use a generic nail graphic. If the user selects a nail from the list in step **204**, the
10 system proceeds to step **208** in which the user is advised of the best length sensor tool **10** to use. In certain cases there may additionally be alternate sensor tool lengths recommended for use with the selected nail and indicated in step **208**. Sensors may additionally be colour coded and step **208** may have colour and graphic advisory messages in addition to or in place of text. Step **208** also begins a sensor detection
15 routine **210** in which the navigation system checks to determine if a sensor is plugged in. If the system does not detect a sensor, the process returns to step **208** and cycles through step **208** and step **210** constantly until a sensor is detected.

[0280] When a suitable sensor is detected, the system proceeds to step **212** which prompts the user to begin calibrating locking holes. In the exemplary embodiment the
20 criterion for a suitable sensor is a functioning sensor returning complete position and orientation data. In another embodiment sensor tool **10** has sensor identification information stored in a memory device which is read by the navigation system, and the system proceeds to step **212** only if the sensor is one of the recommended types displayed in step **208**. Referring back to step **204**, if the user elected to skip the
25 specification of the particular nail being used then the system bypasses step **208** advising the user of which sensor to use and proceeds directly to step **210**.

[0281] In step **212** the user selects 'Start Registration' when the system is assembled as shown in **Figure 22**, which starts the locking hole axis measurement process of step **214**. In step **214** (referring also to **Figure 7** and **Figure 7a**), locking hole
30 coordinate system **136** is defined relative to sensor coordinate frame **134** by calculating the constant transform T_{sh} for the current locking hole as follows, with

drill axis **5** is held coincident with the axis of locking hole **38**. Field generator to sensor transform $T_{WS(measured)}$ is recorded from the navigation system, and heading **139**, distance **141**, and radius **144** are calculated. $T_{WS(measured)}$ is then corrected to $T_{WS(corrected)}$ using lookup table **143** by retrieving the corrective transform $T_{(corr)}$ corresponding to heading **139**, radius **144** and distance **141** at the current position:

$$T_{WS(corrected)} = T_{WS(measured)} * T_{(corr)}$$

[0282] Then T_{sw} , the inverse of $T_{WS(corrected)}$, is calculated. The transform T_{sd} from sensor coordinate frame **134** to drill coordinate system **132** is then calculated as:

$$T_{sd} = T_{sw} * T_{wd},$$

where T_{wd} is the constant field generator to drill transform retrieved in step **206**. The Z_d axis of drill coordinate system **132**, which is collinear with drill axis **5**, can then be expressed as a line in the coordinates of sensor coordinate frame **134** using the transform T_{sd} . Locking hole coordinate system **136** for the current locking hole may then be defined relative to sensor coordinate frame **134** as described above in the detailed description of **Figure 7** and expressed as the transform T_{sh} . Accuracy is increased by recording a number of samples of $T_{WS(corrected)}$, calculating T_{sh} for each sample, and averaging the resulting group of transforms T_{sh} . A suitable number of samples of $T_{WS(corrected)}$ is thirty. The resulting transform $T_{sh(i)}$ is stored as a constant for the current hole i .

[0283] After registration of a hole the system returns to step **212** and when at least one hole has been calibrated the user may select 'Done' to advance the system to step **216** in which it is determined if the user selected a specific nail being used in step **204**, or elected to skip nail selection. If a specific nail type was selected in step **204**, the system advances to step **218** and retrieves the graphic model of the selected nail from memory. If only one locking hole was calibrated at step **212**, the graphic model of the specified nail is aligned with the calibrated hole and rotated about the hole axis such that the nail longitudinal centerline **40** (seen in **Figure 7**) is coincident with the projection of the sensor Z_s axis onto the plane through the Y_h and Z_h axes, with the distal tip of the nail at a positive Z_s value. If the specified nail graphic model has more than one locking hole, the hole that was calibrated is determined by comparing

the distance along Zs from the origin of sensor coordinate frame **134** to the origin of hole coordinate system **136** (seen in **Figure 7**) to the expected values for the specified nail and the recommended sensor tool lengths of step **208**. If more than one locking hole was calibrated at step **212** the system fits the graphic model to the calibrated hole axes such that the mismatch between the calibrated hole axes and the graphic model hole axes is minimized, and the maximum mismatch among the calibrated holes is reported as two mismatch parameters:

- Angular difference between a calibrated hole axis and the corresponding graphic model hole axis, and
- Distance between the intersection points of a calibrated hole axis and the corresponding graphic model hole axis with a plane passing through the longitudinal centerline of the graphic model of the nail.

[0284] One skilled in the art will recognize that other fitting algorithms such as least-squares or other methods to fit selected points or vectors in locking hole frames to graphic model frames may alternately be used.

[0285] The system proceeds to step **222** to determine if the calibrated holes match the nominal hole positions in the graphic model for the selected nail. If the mismatch parameters are greater than the predetermined limits the system returns the user to step **212** to recalibrate the holes. If all calibrated hole axes are coincident with the corresponding nominal axes in the graphic model within predetermined limits of the mismatch parameters, the system proceeds to step **224** to draw the targeting view and prompt the user to check registration by confirming that the target graphic shows good alignment with the correct holes. If the user accepts the registration the system proceeds to step **226** in which the navigation system changes from registration to targeting mode and begins constantly reading TwS. If the registration is not correct, the user rejects the registration and returns to step **212**. If the user has selected the wrong nail setup in step **203** or nail type in step **204**, they may power the system off and on again to return to step **203**.

[0286] Referring back to step **216**, if the user had elected not to select a specific nail in step **204** then the system proceeds to step **220** in which a generic nail graphic

model is drawn showing the calibrated holes at their as-calibrated positions, a typical nail shape around these holes having a distal tip at a typical +Zs location. In step **220** if a single hole was calibrated, the graphic is aligned such that the longitudinal axis of the generic nail graphic model is coincident with the projection of the sensor Zs axis onto the plane through the Yh and Zh axes, with the distal tip of the nail at a positive value along the Zs axis of sensor coordinate system **134** (seen in **Figure 7**). If two or more holes were calibrated, the longitudinal axis of the generic nail graphic model is aligned with the least squares best fit line to the group of Zh axes of the hole coordinate systems **136** of all the calibrated holes (seen in **Figure 7**). The system may then proceed to step **224** and registration can be confirmed as described above.

[0287] In step **226** the set of parameters of the current sensor position, heading **139**, radius **144**, and distance **141**, is calculated and the corresponding correction transform $T_{(corr)}$ is retrieved from lookup table **143**. A corrected value of Tws for the current reading is calculated by:

$$TWS_{(corrected)} = TWS_{(measured)} * T_{(corr)}$$

and the system proceeds to step **228** to update the targeting display for final alignment using the corrected value.

[0288] With reference to **Figure 26a**, in accordance with an alternate embodiment of the invention, a flowchart of an alternate method of intraoperative calibration of the navigation system which generates a lookup table of correction values and registers a target feature intraoperatively is shown. The alternate method illustrated generally includes the steps of registering a target feature, recording a correction map for a subset of critical sensor locations, determining correction functions, determining the current measured location of a sensor, and applying a correction if available for the measured location to estimate a more accurate location. Referring also to **Figure 7**, **Figure 7a**, and **Figure 22**, the alternate method is identical to that shown in **Figure 26** except that step **214** of **Figure 26** is replaced by alternate hole axis measurement steps **230**, **234**, **236**, **238**, and **240**, and the resulting lookup tables **242** and **243** are used in step **246** to compensate for measurement distortions related to the position of field generator **7** about drill axis **5** during targeting.

[0289] In contrast to recording transform T_{ws} with navigation unit **1** a randomly selected heading **139** about drill axis **5** as described in step **214** of **Figure 26**, the user is instead prompted to begin rotating navigation unit **1** about drill axis **5** through a range of headings **139** in either the positive direction **140** or the negative direction opposite to direction **140**, with drill axis **5** held coincident with the axis of locking hole **38** by registration tool **110**. The user may rotate all the way around drill axis **5** in either direction, or back and forth. In step **230**, the position of sensor **10** relative to field generator **7** (expressed as transform T_{ws}) is measured, the sensor to hole transform T_{sh} is calculated (as described above for **Figure 26**), the corresponding heading **139** is calculated, and the T_{sh} and corresponding angle are stored in lookup table **242**. Also in step **230**, continuous measurement of T_{ws} and calculation of heading **139** begins, and the difference between the current measured heading **139** and the last recorded value of heading **139** in lookup table **242** is calculated. In step **234** the difference between the current measured heading **139** and the last recorded heading in lookup table **242** is compared to a predetermined angular movement threshold. If the difference exceeds the threshold the current measured T_{ws} and heading **139** pair is recorded and stored in lookup table **242**. In step **236**, the number of entries in lookup table **242** is compared to a predetermined minimum number of readings. In step **238** headings **139** in lookup table **242** are sorted into numerical order and the maximum difference between consecutive ordered headings in lookup table **242** is compared to a maximum angular gap. Recording continues until both the minimum number of readings in lookup table **242** and the maximum allowable angular gap between adjacent headings have been reached. A suitable angular movement threshold is three point five degrees, a suitable number of readings is two hundred, and a suitable maximum angular gap is two degrees.

[0290] In step **240**, the completed lookup table **242** is interpolated by fitting a quadratic polynomial to position data and quaternions to data in the lookup table segments neighbouring the point of interest, to create a smooth transition between transforms T_{sh} at adjacent field generator headings **139**. Alternately in step **240**, a smooth function may be determined by curve fitting to the T_{sh} values recorded in steps **230** through **240**, the resulting function producing corrected T_{sh} values as a function of heading **139**. The system returns to step **212** giving the user the option to

calibrate a second locking hole and generate a corresponding lookup table **243** for that hole, and so on until all desired holes are calibrated and each has an associated lookup table. After at least one hole is calibrated, at step **212** the user may proceed to steps **216** through **224** which are as described in **Figure 26**.

5 **[0291]** In step **246**, during tracking to target a locking hole, the position of sensor **10** relative to field generator **7** measured by the navigation system and expressed as transform T_{ws} , and the current field generator heading **139** is calculated and the calibrated hole currently closest to drill axis **5** is determined. The lookup table corresponding to the closest calibrated hole is retrieved, the heading in the lookup
10 table closest to the current heading is found, and the corresponding transform T_{sh} is retrieved from the lookup table and used to generate the display of relative position between locking hole coordinate system **136** and drill coordinate system **132** in step **248**, thereby correcting for tracking errors that are a function of heading **139**. The definition of drill axis **5** to field generator coordinate system **130** transform T_{wd} may
15 then be checked using the data from the hole registration procedure described above, by fitting a plane through the data points recorded from the origin of sensor coordinate system **134** as it rotates about drill axis **5** relative to field generator coordinate system **130**, fitting a circle to the data points, and comparing the plane normal passing through the circle center to the Z_d axis of drill coordinate system **132**.
20 Transform T_{wd} may also be optimized by finding the Z_d axis of drill coordinate system **132** relative to sensor coordinate system **134** at each of the data points recorded during rotation of field generator **7** about drill axis **5** in steps **230** to **240** above (using the current T_{wd} and the recorded transform T_{ws} at each data point), producing a group of axes, and modifying T_{wd} until the variation in this group of
25 axes is minimized. For example an optimization method such as a Nelder-Mead simplex method may be used to minimize the range of angles found between each Z_d axis and the mean axis of the group.

[0292] Another aspect of the invention provides methods and apparatus for monitoring the measurement conditions affecting field generators integrated with
30 tools. In an embodiment, the tool and field generator assembly may include a reference sensor in a fixed position relative to the field generator, and the location of

the reference sensor is constantly monitored by the navigation system, and the nominally constant reading of reference sensor position may be analysed for unusual variations which may indicate measurement distortion, interference, signal noise, and the like.

5 **[0293]** In some embodiments the reference sensor may self-calibrate upon startup of the navigation system, during use, and/or upon a user-issued command. To calibrate the reference sensor the system may average a number of reference sensor readings at a time when there is unlikely to be unusual interference or distortion conditions present. For example reference sensor calibration may automatically carry out during
10 the registration step described above. For another example the user may be prompted to run a reference sensor calibration with no known interference conditions present.

[0294] In some embodiments the reference sensor location may be compared to previous values stored in system memory to indicate a possible system error or change in the characteristics of the tool and field generator assembly. For example
15 upon system startup, the last known calibrated location of the reference sensor may be retrieved from memory and compared to the current value, and if the difference is greater than a selected threshold, the user may be prompted to check for interference or distortion causing conditions, run a reference sensor calibration routine, or carry out a service procedure.

20 **[0295]** In some embodiments data from the reference sensor may also be used to help determine certain states of a tool, such as motor on or off, and certain conditions of use of the tool, such as motor speed range and engaged or not engaged with the target. For example the tool may have an electric motor, and the reference sensor data may be searched for characteristic variation corresponding to the motor running or not
25 running.

[0296] An example of a method of using reference sensor data to monitor measurement conditions and modify navigation system function accordingly may comprise the steps of comparing selected parameters of the deviation in position and/or orientation of the reference sensor to predetermined threshold values, and then
30 activating warning functions, modifying selected characteristics of the navigation

system, and/or modifying the filtering and processing of navigation data including the display of navigation information to the user when the selected parameters or combinations of the parameters fall within a range of predetermined values or exceed threshold values. Parameters may include position and orientation of the reference sensor, or their time derivatives, or any other function thereof. Warning functions may be visual warning on the user interface, suspension of navigation, an alarm, and the like. Characteristics of the navigation system may include filtering parameters to smooth navigation data, for example applying selected filters when an electric motor in the tool is running.

[0297] Each feature of a method and apparatus for monitoring measurement conditions described above may be advantageous individually or in combination with some or all of the other features described. Other embodiments within the scope of the invention may include a subset of the advantageous features described above, and described in more detail in example embodiments below.

[0298] With reference to **Figure 27**, in accordance with an embodiment of the invention, and referring also to **Figure 7**, a plot of readings from reference sensor **8** is shown when a ferromagnetic tool is passed in and out of the measurement range of the field generator, creating a distorted field and causing measurement error. Vertical axis **260** is the Z_w component of the transform T_{wr} from the field generator coordinate system **130** to reference sensor coordinate system **137** in millimeters. Horizontal axis **262** is number of readings of T_{wr} and the plot shown includes thirty seconds of continuous consecutive readings of T_{wr} at a rate of forty hertz, the plot therefore showing about one thousand two hundred readings. Curve **264** is the Z_w component of T_{wr} when a ferromagnetic tool is passed in and out of the measurement range seven times during the thirty second recording, producing measurement distortion peaks **266**.

[0299] With reference to **Figure 28**, in accordance with an embodiment of the invention, and referring also to **Figure 7**, a plot is shown of readings from reference sensor **8** when the electric motor of the attached drill **3** is started and stopped, creating external magnetic fields that affect the navigation system measurements. We have observed that drills such as drill **3** may produce magnetic field distortions when the

drill motor is spinning, which in turn can cause high frequency signal noise affecting electromagnetic navigation systems. This signal noise can cause the targeting display to become erratic and show unrealistic movement of the graphic drill icon **392** shown in (**Figures 18** and **18a**) when the drill motor of drill **3** is running. This erratic display
5 behaviour makes it difficult for the user to maintain and check alignment while drilling. In **Figure 28**, vertical axis **270** is the Zw component of the transform Twr from the field generator coordinate system **130** to reference sensor coordinate system **137**. Horizontal axis **272** is number of readings of Twr and the plot shown includes thirty seconds of continuous consecutive readings of Twr at a rate of forty hertz, the
10 plot therefore showing about one thousand two hundred readings. Curve **274** is the Zw component of Twr when the motor of drill **3** is started and stopped eight times during the thirty second recording, producing measurement distortions **276** during the time the drill motor is running.

[0300] Another aspect of the invention provides methods and apparatus for filtering
15 measurement data from field generators integrated with tools, which may include detection, exclusion, correction or estimation of data that is altered by interference or measurement errors. An embodiment the method may comprise the steps of reading the current sensor position and motion data, calculating selected characteristics of the data over a selected time period, comparing the characteristics to predetermined
20 threshold values, deleting the current data if selected characteristics exceed selected thresholds, and monitoring the frequency of deleted position and orientation readings over a selected time period preceding the current reading, and if this frequency exceeds a selected threshold, displaying to the user a warning, and optionally displaying an estimate of current position and orientation calculated from previous
25 data.

[0301] In another embodiment, a reference sensor in a fixed location relative to the field generator is used to provide a correlated measure of interference noise and used to remove interference noise in other sensors. Noise cancellation may be performed with a linear adaptive noise cancellation technique, or any other cancellation method
30 that uses a noise reference source as input. For example a Kalman filter may be applied to the sensor readings. One ordinarily skilled in the art will recognize that any

other adaptive method that uses the statistics of the input signal to adjust its filter behavior, such as recursive Bayesian estimation methods, may also be applied.

[0302] Each feature of a method and apparatus for filtering measurement data from field generators integrated with tools described above may be advantageous individually or in combination with some or all of the other features described. Other embodiments within the scope of the invention may include a subset of the advantageous features described above, and described in more detail in example embodiments below.

[0303] With reference to **Figure 29**, in accordance with an embodiment of the invention, a plot of orientation errors versus field generator heading is shown. Referring also to **Figure 7** and **Figure 7a**, the plot shows data taken from a complete rotation of navigation unit **1** and drill **3** about drill axis **5**, with the motor of drill **3** off, and no substantial magnetic interference present. Vertical axis **290** is the angular error in degrees of the tracked transform **T_{ws}** from field generator coordinate frame **130** to sensor coordinate frame **134**. Horizontal axis **292** is heading **139** of navigation unit **1** and drill **3** about drill axis **5**. Curve **294** is the angular error in varus-valgus, which is defined as rotation about the **Y_h** axis of locking hole coordinate system **136**. Curve **296** is the angular error in version, which is defined as rotation about the longitudinal centerline **40** of nail **37**. Curve **294** shows a generally smooth function of error in the range of plus or minus one half of a degree which is within the normal capabilities of typical electromagnetic tracking systems having a small enough field generator to be mounted on a hand-held tool, and a small enough sensor element for the exemplary application. Curve **296** shows a smooth pattern of errors of up to two degrees in version, which is expected because version error is rotation about the **Z_s** axis of sensor coordinate system **134**, which is typically two to four times less precise than rotation measurements about the remaining two axes **X_s** and **Y_s**. This is a typical characteristic of electromagnetic tracking systems and is due to the physical arrangement of the sensing coils within sensor **10** being restricted to fit within a small radius about the **Z_s** axis in order to make sensor **10** small enough to fit within the cannulation of nail **37** along longitudinal centerline **40**. However outliers **298** of version error having magnitudes up to four degrees error have been observed and

cause noticeable inconsistencies in tracking accuracy at various headings **139** and can lead to drill axis **5** being substantially misaligned with locking hole **38** when the targeting display indicates correct alignment.

[0304] With reference to **Figure 30**, in accordance with an embodiment of the invention, a flowchart of the filtering method for smoothing and correcting sensor position and orientation data during navigation is shown. The method generally includes the use of tracked sensor location and motion data, optionally in combination with reference sensor data, to determine signal processing parameters and inform the user of measurement conditions.

[0305] Referring also to **Figure 7**, in step **300**, the current reading of data is received from the navigation system. Typical navigation systems return parameters along with the spatial position data indicating if the data is present, and if so if it is valid or likely to be unreliable. In step **302**, the parameters supplied by the navigation system are assessed, and if the current reading is usable the system proceeds to step **304** in which the data from the reference sensor is assessed. If in step **302** it is determined that the current reading is missing or invalid, the system indexes a missing sample counter by one and compares the missing data counter to a preselected limit in step **316**.

Alternately the limit for missing data in step **316** may be a percentage of missing readings over a selected time period, or a selected time period since the last usable reading. If the limit of missing data has been reached, the system moves to step **318** and an unreadable data state or warning is activated. Step **318** most commonly will be activated by sensor **10** being out of range, however other conditions may be detectable from the parameters supplied by the navigation system, and this information is passed to step **318** to activate a more specific warning (for example sensor unplugged, field generator unplugged, and unrecognized sensor type).

[0306] If in step **302** the reading is successful, the transforms T_{ws} from field generator coordinate system **130** to sensor coordinate system **134** and T_{wr} from field generator coordinate system **130** to reference sensor coordinate system **137** are received and in step **304** the current transform $T_{wr}(i)$ is compared to the constant T_{wr} stored in system memory. If the current $T_{wr}(i)$ differs from the stored constant T_{wr} by more than a predetermined limit, some form of interference or distortion of

tracking is indicated and the system moves to interference assessment and classification step **320**.

[0307] Referring also to **Figure 27** and **Figure 28**, distortion **266** due to ferromagnetic object interference and distortion **276** due to drill motor interference are distinguishable from each other and from the referenced sensor location tracked during normal aiming motions as shown in curve **284**. Therefore by monitoring reference sensor **8** continuously during targeting a warning message can be activated when distortions similar to distortion **266** having parameters above predetermined thresholds are detected. Suitable parameters for magnetic object interference detection are a threshold of three millimeters for position and a threshold of 0.01 for orientation expressed as quaternions. Similarly activation of the drill motor in drill **3** may be detected by monitoring for distortions similar to distortion **276** having parameters above predetermined thresholds, and signal processing parameters such as noise filtering parameters may be changed accordingly. Similarly cyclic interference from nearby equipment also typically have distinct patterns of variation in $Twr(i)$. Interference may also create distinct variations in $Tws(i)$ that may also be used to detect and classify the type of interference. Interference may also create distinct variations in $Tws(i)$ that may also be used to detect and classify the type of interference. In step **320** the type of interference is identified and classified into classes **322**, **324**, or **326**.

[0308] Depending on the type of interference detected, filtering and data smoothing parameters may be selected in step **328** to make the data usable, or if the data is inaccurate (such as in the case of a constant field distortion due to a ferromagnetic object being too close to field generator **7** or sensor **10**), filtering cannot make the data usable then the system proceeds to step **330** in which a warning is activated. If in step **304** the current $Twr(i)$ matches the stored constant Twr within the predetermined limit, the system proceeds to step **306** to determine what region of the measurement range sensor **10** is in.

[0309] Typically, navigation systems have worse response, accuracy, and precision in the far range which can lead to greater measurement noise levels and in turn a jumpy or erratic targeting display. In the exemplary embodiment, the measurement range of

field generator **7** is divided into two ranges, close range and far range. Close range is defined as sensor **10** being within the cylindrical volume about the Zw axis of field generator coordinate system **130** extending from Zw of negative five millimeters to negative one-hundred and eighty millimeters and having a radius of one hundred and ten millimeters. Far range is defined as sensor **10** being within the cylindrical volume about the Zw axis of field generator coordinate system **130** extending from Zw of negative five millimeters to negative two-hundred and seventy-five millimeters and having a radius of two hundred millimeters, but excluding the close range volume defined above. If the current reading Tws(i) is in the far range, the system proceeds to step **332** and applies filtering parameters suitable for the far range. In the exemplary embodiment a moving average filter is used with default averaging over ten samples while in the close range, increasing to twenty samples while in the far range. In step **308** either a default low pass filter or the filtering parameters determined in the preceding steps is applied to Tws. In step **310** the current filtered Tws(i) is compared to previous values and it is determined if Tws(i) is an outlier **298** (as shown in **Figure 29**).

[0310] In the exemplary embodiment, outliers **298** are detected by comparing the change of Tws over a selected time period to a threshold. If the change is substantially higher than that normally recorded during targeting, an outlier **298** is indicated. A suitable time period is fifty milliseconds and a suitable change threshold is ten millimeters for translation and 0.25 for orientation expressed as quaternions, with both thresholds applied to the sum of the absolute values. If an outlier **298** is detected, the system proceeds to step **334** and the current reading is discarded, the missing reading counter is indexed, and the system returns to step **316**. If it is determined in step **310** that Tws(i) is not an outlier, the system proceeds to step **312**, where the targeting display is updated using filtered data, and then to step **314** where the next data sample is retrieved from the navigation system.

[0311] **Figure 31** through **Figure 38** show several examples of embodiments of an aspect of the invention providing apparatus and method to lock a bone fragment to an IM nail in such a way as to maintain, temporarily or permanently, an open passage through the cannulation along the longitudinal centerline of the nail.

[0312] With reference to **Figure 31**, in accordance with the exemplary embodiment of the invention, sensor tool **10** having shaft portion **156** and tip portion **154** fits inside IM nail **37** which is implanted in femur **354**. Insertion tool **39** is temporarily bolted to nail **37** during the insertion and positioning of nail **37** in femur **354**.

5 Insertion tool **39** also has a guide hole to align proximal locking drill bit **344** with proximal locking hole **346**. Proximal locking drill bit **344** passes through proximal locking hole **346** of nail **37** and extends up into femoral head **348** over guide wire **374** to prepare a hole for a permanent locking element (not shown) to be installed at a later stage in the procedure. Tip portion **154** contains a sensor element as described above
10 in **Figure 1a** through **Figure 6** and is used as described above to locate distal locking hole **38** of nail **37**, in particular to guide a drill in drilling through femur **354** in line with distal locking hole **38** for installation of distal locking screw **352**.

[0313] With reference to **Figure 32**, in accordance with the exemplary embodiment of the invention, proximal locking drill bit **344** is shown having cannulation **376**,
15 slotted hole **356** having width **366** and length **368**, and marking **358** aligned with slotted hole **356**. Marking **358** is the same size and shape as slotted hole **356**, located a selected distance **370** along drill bit **344** to be visible outside of the patient's body when drill bit **344** is passed to the desired maximum depth into femur **354** (seen in **Figure 31**) and is duplicated on the opposite side of drill bit **344** so that the user can
20 see the orientation of slotted hole **356** at one hundred and eighty degree intervals in the rotation of drill bit **344**. One ordinarily skilled in the art will recognize that marking **358** may alternately be any suitable indicator indicating the rotational orientation of slotted hole **356** (for example an arrow, hole, groove, or slot) located at a known fixed rotational orientation about the longitudinal axis of drill bit **344** relative
25 to slotted hole **356**, and that a single marking **358** may be used.

[0314] Referring to **Figure 31**, **Figure 32** and **Figure 33**, diameter **360** of drill bit **344** is selected to suit the permanent locking element that will be installed through proximal locking hole **346**, slotted hole width **366** is selected to be similar to nail cannulation diameter **372** and large enough for tip portion **154** of sensor tool **10** to
30 pass through, and slotted hole length **368** is selected to encompass the range of distances between nail **37** and femoral head **348** encountered among patients of

different sizes. A suitable diameter **360** for drill bit **344** is eleven millimeters, a suitable width **366** of slotted hole **356** is six millimeters, and a suitable length **368** of slotted hole **356** is twenty millimeters. Cannulation **376** has a diameter selected to slide over guide wire **374**. Examples of suitable diameters are 3.2 millimeters for guide wire **374** and 3.4 millimeters for cannulation **376**. One ordinarily skilled in the art will recognize that slotted hole **356** may alternately be a variety of shapes, for example an oval, elliptical, or a cylindrical hole may be used. One ordinarily skilled in the art will also recognize that depending on the size and flexibility of sensor tool **10**, slotted hole **356** could be offset from the centerline of nail **37**, need not be symmetrical about the centerline of nail **37**, and could have the form of a notch or recess instead of a fenestration.

[0315] With reference to **Figure 32a**, in accordance with the exemplary embodiment of the invention, a side view of proximal locking drill bit **344** is shown with cannulation **376** and with markings **358** visible.

[0316] With reference to **Figure 3**, in accordance with the exemplary embodiment of the invention, a section view taken in a frontal plane through the midline of femur **354** is shown, in the area of the proximal femur only. Shaft portion **156** of sensor tool **10** has shaft diameter **160**, suitable diameters being in the range of three to four millimeters, and nail **37** has a cannulation along its axis having diameter **372**, typically in the range of four to five millimeters. Drill bit **344** is shown having been drilled to the appropriate depth into femoral head **348** as determined by the surgeon over guide wire **374**, and guide wire **374** has been pulled out laterally enough to clear the cannulation diameter **372** in nail **37**, and could optionally be withdrawn completely. Slotted hole **356** in bit **344** is approximately aligned with the cannulation in nail **37** by visually aligning markings **358** with the patient's limb, such that the tip portion **154** (seen in **Figure 31**) and shaft portion **156** of sensor tool **10** may pass through slotted hole **356** as sensor tool **10** is installed in nail **37**.

[0317] With reference to **Figure 31**, **Figure 32**, and **Figure 33**, an exemplary method of use of an aspect of the invention is as follows: IM nail **37** is inserted in femur **354** with insertion tool **39** attached. The fragments of femur **354** are positioned and the position of nail **37** in femur **354** is set, and drill bit **344** is passed through proximal

locking hole **346** and into femoral head **348** over guide wire **374** to the appropriate depth. Drill bit **344** is then rotated to a position where markings **358** are in proximal and distal facing positions relative to femur **354**. Guide wire **374** is then drawn back out of the femur with drill bit **344** left in place to hold the proximal fragments of femur **354** in place. Sensor tool **10** is then inserted into nail **37** to facilitate installation of distal locking screw **352**. When distal locking is complete sensor tool **10** is removed, guide wire **374** may be reinserted if desired, drill bit **344** is withdrawn, and the permanent proximal locking element (not shown) is installed through proximal locking hole **346** and into femoral head **348**.

[0318] Referring to **Figures 31** through **33**, one skilled in the art will recognize that other embodiments are possible in which, in place of drill bit **344**, a temporary stud or guide wire having a slotted hole similar to slotted hole **356** may be used (one such exemplary alternate embodiment is shown in **Figures 34, 35, and 36** below). One skilled in the art will also recognize that a slotted hole similar to slotted hole **356** may be placed directly in the permanent locking element.

[0319] With reference to **Figure 34**, in accordance with an alternate embodiment of the invention, a top view of temporary locking stud **420** is shown. One end of stud **420** is screwed into the femoral head during use, with threads **422** engaging the femoral head fragment. Outer diameter **424** in this area may be, for example, 5.4 millimeters. Stud **420** is cannulated along its entire length, the cannulation having diameter **426** selected to be suitable to slide over a guide wire (see **Figure 36**). Slotted hole **428** has width **430** approximately equal to, or greater than, the cannulation diameter **372** of IM nail **37** (seen in **Figure 33**), and has length **432**. Length **432** is chosen to allow for a range of distances along the axis of stud **420** from the centerline of nail **37** up into the femoral head **348** to the tip of stud **420**, such that the centerline of nail **37** lies within length **432** when stud **420** is installed. To accommodate the range of femoral neck lengths encountered across the patient population, a set of studs **420** having different slotted hole lengths **432** and overall lengths **434** may be provided. Indicator hole **436** is aligned with slotted hole **428**, and also has a diameter suitable for insertion of a pin wrench or a rod to allow easier turning of stud **420**, for

insertion and removal. For example a suitable diameter for indicator hole **436** is 4.4 millimeters.

[0320] With reference to **Figure 35**, a front view of the alternate embodiment of the invention shown in **Figure 34** is shown. Temporary locking stud **420** of the alternate
5 embodiment is shown. Stud **420** has longitudinal axis **438**. Slotted hole **428** is oriented at angle **440** which is chosen to match typical femoral neck to shaft angles. A suitable value for angle **440** is one hundred and thirty degrees. Indicator hole **436** is also shown.

[0321] With reference to **Figure 36**, in accordance with the alternate embodiment of
10 the invention shown in **Figure 34**, a section view taken in a frontal plane through the midline of femur **354** is shown, in the area of the proximal femur only. Guide wire **442** having threads **444** at one end is shown inserted into femoral head **348** with threads **444** engaged in the cortical bone near the outer surface of femoral head **348**. Stud **420** is shown in position over guide wire **442** with threads **422** engaging femoral
15 head **348** lateral to guide wire threads **444**. Slotted hole **428** in stud **420** is approximately aligned with the cannulation in nail **37** by visually aligning indicator hole **436** with the patient's limb, such that guide wire **442** may be temporarily withdrawn without losing stabilization of femoral head **348**, and then sensor tool **10**
(see also **Figure 31**) may pass through slotted hole **428** as sensor tool **10** is installed in
20 direction **446** into the cannulation of nail **37**. After distal locking is completed and sensor tool **10** is removed, guide wire **442** may be re-inserted and threaded back into femoral head **348**, stud **420** removed, and the permanent locking element installed over guide wire **442**.

[0322] With reference to **Figure 31** and **Figures 34** through **36**, the method of use of
25 the alternate embodiments of the invention is similar to that of the exemplary embodiment, except that only the lateral cortex of femur **354** is drilled using a drill bit, and stud **420** is used in place of drill bit **344**. This method may be used when it is preferable not to drill through the femoral neck and into femoral head **348** and instead use the guide wire **442** only to stabilize femoral head **348** and to guide the installation
30 of the permanent locking element.

[0323] With reference to **Figure 37**, **Figure 37a**, and **Figure 38**, a second alternate embodiment of the invention is shown for applications where the locking hole diameter is similar to the cannulation diameter, in which case the drill bit used to drill the locking hole is too small to accommodate a slotted hole as shown in the exemplary embodiment. **Figure 37** shows stud **504** having an outer portion **506** and a plunger **508**. Outer diameter **502** is selected to be a sliding fit in drill hole **522** (see **Figure 38**) made in the bone for a locking screw. Expanding tip portion **510** has two slits **500** dividing expanding tip portion **510** into four quadrants.

[0324] **Figure 37a** is a section through stud **504** showing plunger **508** which is a sliding fit inside outer portion **506**. Stud **504** may be made of, for example, stainless steel, titanium, or of a high modulus autoclavable plastic such as PEEK or of any other material which provides sufficient resistance to deflection and shear.

[0325] **Figure 38** is a section view through bone **512** with IM nail **514** implanted and stud **504** shown engaged in only one cortex of bone **512** and one wall of nail **514**.

Nail **514** has cannulation of diameter **520** which is similar to locking hole diameter **518**. Locking hole drill diameter **522** is slightly smaller than locking hole diameter **518**. In use the locking hole drill (not shown) is passed through soft tissues **516**, one cortex of bone **512**, nail **514**, and the opposite cortex of bone **512**. Stud **504** is slid through the resulting drill hole far enough to engage one wall of nail **514** and plunger **508** is pushed down relative to outer portion **506**, expanding tip portion **510** (see **Figures 37** and **37a**) out to an interference fit with locking hole **518**. Sensor tool shaft portion **156** may be passed through the cannulation in nail **514** after drilling, and either before or after installation of stud **504**. Stud **504** thereby holds nail **514** in place relative to bone **512** while sensor tool **10** (see **Figure 31**) is in use. When sensor tool **10** is no longer required it is removed, stud **504** is removed, and the permanent locking element (such as a locking screw, not shown) is installed through bone **512** and nail **514**.

[0326] Some embodiments of the invention comprise kits made up of one or more of the tools and devices described herein. For example, a kit may comprise one or more sensor tools as described herein and one or more implants or other components with which those sensor tools may be used. Such a kit may further comprise one or more

insertion tools attachable to the implants or other components. The sensor tools and insertion tools may be configured with features permitting the sensor tools to be detachably coupled to the insertion tools. Such a kit may also comprise a registration tool for registering a tool with an implant or other component. Another example of a kit comprises a tool and one or more of a field generator attachable to the tool, a display attachable to the tool and a navigation unit attachable to the tool. In some embodiment the kit comprises multiple different tools and the field generator and tools are configured to allow the field generator to be coupled to any of the different tools. The navigation unit may comprise a field generator and display (which may be fixed to or detachable from the navigation unit). Such a kit may also comprise a registration tool for registering the tool with an implant or other component. Such a kit may also comprise one or more tool members such as one or more drill bits, saws, pins, milling cutters, or the like.

[0327] All publications, patents and patent applications are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

INTERPRETATION OF TERMS

[0328] Unless the context clearly requires otherwise, throughout the description and the claims:

- "comprise," "comprising," and the like are to be construed in an inclusive sense, as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to" .
- "connected," "coupled," or any variant thereof, means any connection or coupling, either direct or indirect, between two or more elements; the coupling or connection between the elements can be physical, logical, or a combination thereof.
- "herein," "above," "below," and words of similar import, when used to describe this specification shall refer to this specification as a whole and not to any particular portions of this specification.

- "or," in reference to a list of two or more items, covers all of the following interpretations of the word: any of the items in the list, all of the items in the list, and any combination of the items in the list.
- the singular forms "a", "an" and "the" also include the meaning of any appropriate plural forms.

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[0329] Words that indicate directions such as "vertical", "transverse", "horizontal", "upward", "downward", "forward", "backward", "inward", "outward", "vertical", "transverse", "left", "right", "front", "back", "top", "bottom", "below", "above", "under", and the like, used in this description and any accompanying claims (where present) depend on the specific orientation of the apparatus described and illustrated. The subject matter described herein may assume various alternative orientations. Accordingly, these directional terms are not strictly defined and should not be interpreted narrowly.

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[0330] Data processing features of embodiments of the invention may be implemented using specifically designed hardware, configurable hardware, programmable data processors configured by the provision of software (which may optionally comprise 'firmware') capable of executing on the data processors, special purpose computers or data processors that are specifically programmed, configured, or constructed to perform one or more steps in a method as explained in detail herein and/or combinations of two or more of these. Examples of specifically designed hardware are: logic circuits, application-specific integrated circuits ("ASICs"), large scale integrated circuits ("LSIs"), very large scale integrated circuits ("VLSIs") and the like. Examples of configurable hardware are: one or more programmable logic devices such as programmable array logic ("PALs"), programmable logic arrays ("PLAs") and field programmable gate arrays ("FPGAs"). Examples of programmable data processors are: microprocessors, digital signal processors ("DSPs"), embedded processors, graphics processors, math co-processors, general purpose computers, server computers, cloud computers, mainframe computers, computer workstations, and the like. For example, one or more data processors in a control circuit for a device may implement methods as described herein by executing software instructions in a program memory accessible to the processors. Any of the

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methods as described above may be implemented in any of these ways. A system according to certain embodiments of the invention may be configured to perform one or more of the methods described herein. Where a system is configured to perform more than one function or method as described herein different methods or functions may be implemented using the same or different hardware. For example, a computer processor may serve to provide computation for a position sensing system and also to coordinate and/or implement one or more methods as described herein. In other embodiments different methods and/or different functions may be implemented using different hardware.

[0331] Processing may be centralized or distributed. Where processing is distributed, information including software and/or data may be kept centrally or distributed. Such information may be exchanged between different functional units by way of a communications network, such as a Local Area Network (LAN), Wide Area Network (WAN), or the Internet, wired or wireless data links, electromagnetic signals, or other data communication channel.

[0332] Software and other modules may reside on servers, workstations, personal computers, tablet computers, database servers, and other devices suitable for the purposes described herein.

[0333] Some embodiments of the invention may also be provided in the form of a program product. The program product may comprise any non-transitory medium which carries a set of computer-readable instructions which, when executed by a data processor, cause the data processor to execute a method of the invention. Program products according to the invention may be in any of a wide variety of forms. The program product may comprise, for example, non-transitory media such as magnetic data storage media including floppy diskettes, hard disk drives, optical data storage media including CD ROMs, DVDs, electronic data storage media including ROMs, flash RAM, EPROMs, hardwired or preprogrammed chips (e.g., EEPROM semiconductor chips), nanotechnology memory, or the like. The computer-readable signals on the program product may optionally be compressed or encrypted.

[0334] Where a component (e.g. a coupling, sensor, field generator, display, tool, software module, processor, assembly, device, circuit, etc.) is referred to above, unless otherwise indicated, reference to that component (including a reference to a "means") should be interpreted as including as equivalents of that component any component which performs the function of the described component (i.e., that is functionally equivalent), including components which are not structurally equivalent to the disclosed structure which performs the function in the illustrated exemplary embodiments of the invention.

[0335] Specific examples of systems, methods and apparatus have been described herein for purposes of illustration. These are only examples. The technology provided herein can be applied to systems other than the example systems described above. Many alterations, modifications, additions, omissions and permutations are possible within the practice of this invention. This invention includes variations on described embodiments that would be apparent to the skilled addressee, including variations obtained by: replacing features, elements and/or acts with equivalent features, elements and/or acts; mixing and matching of features, elements and/or acts from different embodiments; combining features, elements and/or acts from embodiments as described herein with features, elements and/or acts of other technology; and/or omitting combining features, elements and/or acts from described embodiments.

[0336] Another example application of apparatus as described herein is a tool-mounted display. Such a display may be used with milling tools to monitor the cutting process, on saws to control alignment and/or depth of cut, on reamers to control acetabular cup placement, on pin insertion guides to control insertion of K-wires and the like.

[0337] Described methods may be varied. For example, while processes or blocks are presented in a given order, alternative examples may perform routines having steps, or employ systems having blocks, in a different order, and some processes or blocks may be deleted, moved, added, subdivided, combined, and/or modified to provide alternative or subcombinations. Each of these processes or blocks may be implemented in a variety of different ways. Also, while processes or blocks are at times shown as being performed in series, these processes or blocks may instead be

performed in parallel, or may be performed at different times. In addition, while elements are at times shown as being performed sequentially, they may instead be performed simultaneously or in different sequences.

5 **[0338]** While a number of exemplary aspects and embodiments have been discussed above, those of skill in the art will recognize certain modifications, permutations, additions and sub-combinations thereof. It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions and sub-combinations.

WHAT IS CLAIMED IS:

1. A hand tool comprising:
 - a hand-holdable body;
 - a tool member coupled to the body;
 - 5 a field generator coupled to the body, the field generator operable to emit a field for detection by a sensor of a position-sensing system, the field permitting determination of the position of the sensor relative to the field generator.
- 10 2. A hand tool according to claim 1 wherein the field generator is supported at a position that is fixed relative to an axis of the tool member and a point on the tool member.
- 15 3. A hand tool according to claim 1 or claim 2 wherein the field generator is configured to emit an electromagnetic field.
4. A hand tool according to any of claims 1 to 3 comprising a motor coupled to actuate movement of the tool member.
- 20 5. A hand tool according to claim 4 wherein the tool member comprises a rotary cutter.
- 25 6. A hand tool according to claim 5 wherein the field generator is fixed relative to the rotary cutter in 5 degrees of freedom such that the only significant permitted relative motion between the rotary cutter and the field generator is relative rotation of the rotary cutter about a fixed axis of rotation of the rotary cutter.
- 30 7. A hand tool according to claim 5 or 6 wherein the tool member comprises a drill bit.

8. A hand tool according to any of claims 1 to 4 wherein the tool member comprises a saw blade.
- 5 9. A hand tool according to any of claims 1 to 4 wherein the tool member comprises a tool bit selected from the group consisting of: a milling cutter; a reamer; a drill bit; and a saw blade.
- 10 10. A hand tool according to any of claims 1 to 9 wherein the tool member comprises a ferromagnetic material.
- 11 11. A hand tool according to claim 4 wherein the motor is coupled to rotate or pivot the tool member about an axis of rotation and the field generator is located off of the axis of rotation.
- 15 12. A hand tool according to claim 11 wherein the field generator is movable among two more different positions relative to the body wherein each of the different positions is equidistant from the axis of rotation and each of the different positions is equidistant from a point in the tool member on the axis of rotation.
- 20 13. A hand tool according to claim 4 wherein the motor is coupled to rotate or pivot the tool member about an axis of rotation and the field generator is located on the axis of rotation.
- 25 14. A hand tool according to claim 13 wherein the tool member extends through a passage through the field generator.
- 30 15. A hand tool according to any of claims 1 to 14 wherein the field generator is coupled to the body by an adjustable coupling permitting the field generator to be moved relative to the body.

16. A hand tool according to any of claims 1 to 15 wherein the field generator is detachably coupled to the body.
- 5 17. A hand tool according to claim 15 wherein the tool member has an axis of rotation and the coupling is configured to permit rotation of the field generator about the axis of rotation of the tool member.
- 10 18. A hand tool according to claim 17 wherein the coupling is configured to maintain a fixed radial spacing of the field generator to the axis of rotation of the tool member.
- 15 19. A hand tool according to any of claims 1 to 14 wherein the tool comprises a plurality of mounting couplings and the field generator is detachably affixable to each of the plurality of mounting couplings.
- 20 20. A hand tool according to claim 19 wherein the tool member has an axis of rotation and the plurality of mounting couplings are angularly spaced apart around the axis of rotation.
- 25 21. A hand tool according to claim 20 wherein the mounting locations are on a circle centered on the axis of rotation.
22. A hand tool according to any of claims 1 to 21 wherein the tool member is movable relative to the body in a predetermined pattern within a limited range of motion.
- 30 23. A hand tool according to claim 22 wherein the tool member is movable relative to the body only about an axis of symmetry of the tool member.
24. A hand tool according to any one of claims 1 to 23 further comprising a sterile enclosure enclosing the field generator.

25. A hand tool according to any one of claims 1 to 24 further comprising a clip coupled to the body for holding a surgical drape to the hand tool.
- 5 26. A hand tool according to claim 1 wherein the field generator is supported on a navigation unit that is detachably coupled to the body, the navigation unit comprises a bushing, and the tool member passes through the bushing.
- 10 27. A hand tool according to any of claims 1 to 14 wherein the field generator is supported on a navigation unit that is detachably coupled to the body, the navigation unit comprises a rotatable shaft coupled to be turned by the motor, and the tool member is coupled to the rotatable shaft.
- 15 28. A hand tool according to claim 27 comprising a drill chuck mounted to a distal end of the rotatable shaft.
- 20 29. A hand tool according to claim 28 wherein the tool member comprises a drill bit engaged with the drill chuck.
- 30 30. A hand tool according to any of claims 1 to 14 wherein the field generator is supported on a navigation unit that is detachably coupled to the body the navigation unit comprises a drill chuck and the body comprises a drill motor attachable to drive the drill chuck.
- 25 31. A hand tool according to claim 30 to comprising a display configured to display targeting information from a navigation system, the display coupled to the body.
- 30 32. A hand tool according to claim 31 wherein the display is coupled to the body by way of a coupling permitting the orientation of the display relative to the body to be changed.

33. A hand tool according to claim 31 or 32 wherein the display is coupled for pivotal motion relative to an axis of the tool.
- 5 34. A hand tool according to any of claims 31 to 33 comprising an inclinometer coupled to the display, the inclinometer providing an output signal indicating an inclination of the display.
35. A hand tool according to claim 34 wherein the inclinometer comprises an accelerometer.
- 10 36. A hand tool according to claim 34 or 35 wherein an orientation of content displayed on the display is controlled based on the on the output signal from the inclinometer.
- 15 37. A hand tool according to any of claims 31 to 33 comprising an encoder configured provide an output signal indicative of an angular position of the display relative to the body.
- 20 38. A hand tool according to claim 37 wherein an orientation of content displayed on the display is controlled based on the on the output signal from the encoder.
- 25 39. A hand tool according to any one of claims 1 to 39 comprising a reference sensor, the reference sensor operable to receive the field emitted by the field generator and to output a signal indicative of a position of the reference sensor relative to the field generator.
40. A hand tool according to claim 39 wherein the reference sensor is affixed to or within a housing of the field generator.
- 30 41. A hand tool according to claim 39 or 40 comprising a plurality of reference sensors affixed to the tool.

42. A hand tool according to claim 41 wherein the plurality of reference sensors are affixed to or within a housing of the field generator.
- 5 43. A hand tool according to any one of claims 1 to 42 in combination with a registration tool having a member projecting along a registration axis wherein the registration tool is adapted to be temporarily coupled to the tool member such that the registration axis is held in a predetermined spatial relationship relative to an axis of the tool member.
- 10 44. The hand tool according to claim 43 wherein the member is configured to be temporarily coupled to a target feature of a component such that the registration axis is held in the first predetermined spatial relationship relative to an axis of the target feature.
- 15 45. The hand tool according to claim 43 wherein the member of the registration tool comprises a tip portion that is compressible to fit snugly into target features of a plurality of different sizes.
- 20 46. The hand tool of claim 43 wherein the member of the registration tool comprises at least one resiliently elastic element.
- 25 47. The hand tool of any of claims 43 to 46 wherein the member of the registration tool is coaxial with the tool member when the registration tool is coupled to the tool member.
- 30 48. A system comprising a hand tool according to any one of claims 1 to 47 in combination with a position-sensing system comprising at least one sensor that is operable to receive the field emitted by the field generator and to output a signal indicative of a position of the sensor relative to the field generator.
49. A system according to claim 48 wherein the sensor has a sensor origin point at a fixed location relative to the sensor, and a sensor axis at a fixed orientation

relative to the sensor and passing through the origin point, and wherein the field generator further comprises a memory device, and a set of correction factors stored in the memory device, wherein each correction factor corresponds to one of a predetermined set of positions of the sensor relative to the hand tool.

5

50. A system according to claim 49 wherein at each position in the set of sensor positions the sensor axis is normal to an axis of the tool axis and intersects the axis of the tool at a selected distance from a tip point on the tool.

10

51. A system according to any one of claims 48 to 50 comprising a filter connected to filter the signal from the at least one sensor.

52. A system according to claim 51 wherein the filter comprises one or more variable parameters, the hand tool comprises one or more reference sensors and the system is configured to set the one or more variable parameters of the filter based at least in part on signals from the one or more reference sensors.

15

53. A system according to any one of claims 49 to 52 comprising a processor coupled to receive the signal from the sensor and configured to, from the signal, determine a difference between a current position and orientation of the hand tool relative to the sensor and to display on the display information indicative of the determined difference.

20

54. A system according to claim 53 wherein the processor is configured to display on the display a first indicator of a first difference between a current position of the hand tool and a desired position and a second indicator of a second difference between a current alignment of the hand tool and a desired alignment wherein the system is configured to display the second indicator only if the first difference is less than a threshold difference.

25

30

55. A system according to any one of claims 49 to 54 wherein the system comprises a correction unit configured to correct a position of the sensor determined from the signal based at least in part on the determined position of the sensor relative to an axis of the tool member and a fixed point on the tool member to which the field generator has a known spatial relationship.
56. A system according to claim 55 wherein the correction unit comprises one or more of: a lookup table, a predetermined correction function such as a polynomial function, a spline interpolation, a parametric map optimized to reduce field generator output error, and a neural network.
57. A system according to any one of claims 49 to 56 wherein the navigation system is configured to track motion of the sensor relative to the field generator and, based at least in part on the tracked motion to determine a cutting depth of the tool member.
58. A system according to claim 57 wherein the navigation system is further configured to:
- monitor one or more additional parameters including one or more of:
 - whether a motor of the hand tool is on and a speed of a motor of the hand tool and
 - generate a warning when the tracked motion of the sensor and the one or more additional parameters correspond to predetermined criteria for a dangerous condition.
59. A system according to any one of claims 49 to 58 comprising a visual user interface adapted to display a position of the hand tool relative to a target, the visual user interface comprising:
- a target graphic element representing the target;
 - a tool graphic element representing the tool; and
 - at least one relative position parameter representing the relative position of the tool to the target.

60. A system according to claim 59 wherein the visual user interface comprises a variable magnification factor determining the displayed sizes of the target graphic element and the tool graphic element.
- 5 61. A system according to claim 60 configured to change the magnification factor in response to the relative position parameter being within a preselected range of values for a first preselected time interval.
- 10 62. A system according to claim 61 configured to set the magnification factor to a default value in response to the relative position parameter being outside of the preselected range of values for a second preselected time interval.
- 15 63. A system according to any one of claims 49 to 62 comprising a database comprising geometry data for a plurality of components, the geometry data including data indicating orientation and location of one or more target features of each of the components relative to one or more reference locations on the components.
- 20 64. A tool with integrated navigation apparatus, comprising:
a tool having a tool axis, and a tip point located on the tool axis;
a magnetic field generator component of an electromagnetic position measurement system;
wherein the tool and the field generator are coupled together such that the tip point is located in a fixed position relative to the field generator, and
25 the tool axis is located in a fixed orientation relative to the field generator.
- 30 65. A tool navigation apparatus adapted for aligning a tool with a target feature in a field, the apparatus comprising:
a tool having a tool axis;
a field generator component of an electromagnetic navigation system;
a first sensor fixed relative to a target and adapted to produce a first signal indicative of a location of the first sensor relative to the field generator;

a second sensor fixed relative to the field generator and adapted to produce a second signal indicative of a location of the second sensor relative to the field generator, and;

an indicator configured to indicate a distorted field condition to a user based at least in part on the second signal.

66. A tool navigation apparatus according to claim 65 wherein the navigation system is configured to monitor a first parameter set comprising at least one parameter of the second signal and to signal a distorted magnetic field condition when the first parameter set exceeds a first preselected set of threshold values.

67. A tool navigation apparatus according to claim 66 wherein the navigation system is configured to monitor a second parameter set comprising at least one parameter of the second signal, the apparatus further comprising a filter adapted to smooth the first signal, the filter having at least one selectable filtering parameter, wherein the filtering parameter is selected based on one or more parameter values of the second parameter set.

68. A tool navigation apparatus according to any one of claims 65 to 67 wherein the target feature comprises a hole in an orthopaedic implant.

69. A tool navigation apparatus according to any one of claims 65 to 67 wherein the target feature comprises an anatomical feature of a patient.

70. A hand tool comprising:
a tool comprising a tool body;
a display screen coupled to the tool body by a coupling that allows movement of the display screen relative to the tool body in at least one degree of freedom.

71. A tool according to claim 70 wherein the tool comprises a tool member defining a longitudinal axis and the at least one degree of freedom comprises rotation about the longitudinal axis.
- 5 72. A tool according to claim 71 wherein the tool comprises a tool bit rotatable relative to a body of the tool and the longitudinal axis is an axis of rotation of the tool bit.
- 10 73. A tool according to claim 72 wherein the display screen is independently rotatable relative to a body of the tool about two axes of rotation.
74. A tool according to any one of claims 70 to 73 wherein the coupling comprises a locking mechanism for holding the display screen in a selected orientation related to the tool body.
- 15 75. A method for calibrating a system comprising a hand tool and a position sensing system for determining a position and orientation of the hand tool relative to a target feature of a component, the method comprising:
providing on the hand tool a probe member having a fixed position and
20 orientation on the hand tool;
fully inserting the probe member into the target feature of the component, the probe member configured to closely fit the target feature;
with the position sensing system determining relative position and
25 orientation of the hand tool and the component.
76. A method according to claim 75 wherein the hand tool comprises a tool member and the probe member is provided on the hand tool by sliding the tool member into an opening in the probe member.
- 30 77. A method according to claim 75 wherein the probe member comprises a cutting tool.

78. A method according to claim 75 wherein the probe member comprises a drill bit.

79. A method according to claim 78 wherein the drill bit comprises a shoulder.

5

80. A method according to claim 76 wherein the tool member comprises a drill bit, the opening in the probe member comprises a hole dimensioned to receive the drill bit and the probe member comprises an elongated projection coaxial with the hole.

10

81. A method according to claim 80 wherein the elongated projection comprises a resilient material and inserting the probe member into the target feature of the component comprises compressing the resilient material of the elongated projection.

15

82. A method according to any one of claims 75 to 81 comprising recording the relative position and orientation of the hand tool and the component.

83. A method according to claim 82 comprising calibrating the position sensing system based upon the relative position and orientation of the hand tool and the component and a known geometry of the probe member.

20

84. A registration apparatus for use in calibrating a system comprising a hand tool and a position sensing system for determining a position and orientation of the hand tool relative to a target feature of a component, the hand tool comprising a tool member, the registration apparatus comprising a member having a projection for closely fitting engagement with the target feature and a recess for receiving the tool member and holding the tool member in a predetermined fixed orientation and position relative to the projection.

25

30

85. A registration apparatus according to claim 84 wherein the target feature comprises a hole, the tool member comprises a drill bit, the recess comprises a

hole dimensioned to provide a sliding fit on the drill bit, and the projection comprises an elongated member coaxial with the recess.

5 86. A registration apparatus according to claim 84 or 85 comprising an abutting surface adjacent a proximal end of the projecting member, the abutting surface configured to limit insertion of the projecting member into the target feature to a predetermined depth by engagement with a surface of the component adjacent to the target feature.

10 87. A tool comprising:
a tool member having a tool axis;
a field generator component of an electromagnetic navigation system,
the field generator supported at a fixed location relative to the tool axis and a
point on the tool axis;
15 an orthopaedic implant having a feature, the feature having a feature axis, and;
a sensor tool adapted to produce a signal indicative of the sensor tool location relative to the field generator,
wherein;
20 the sensor tool is coupled to the orthopaedic implant in a predetermined fixed location relative to the feature;
the tool is adapted to be temporarily coupled to the feature such that the tool axis is held in a first predetermined spatial relationship relative to the feature axis; and
25 the navigation system is adapted to record the position of the feature axis relative to the sensor tool.

88. A sensor tool adapted for attachment to a component, the sensor tool comprising:
30 a shaft portion having a length, a distal end, and a proximal end;
a handle portion attached to the proximal end,

a tip portion at the distal end, wherein the tip portion includes at least one flexible elastic member and;

a position indicating element attached at a fixed location near the distal end.

5

89. A sensor tool according to claim 88 wherein the tip portion comprises a plurality of radially-extending elastic members.

10

90. A sensor tool according to claim 89 wherein the elastic members are arcuate and have proximal and distal ends attached to the tip portion.

15

91. A sensor tool according to any one of claims 88 to 90 wherein the handle portion further comprises a connecting element adapted to temporarily attach the handle portion to an insertion tool such that the sensor tool is held in a unique and predetermined fixed position relative to the component.

92. A sensor tool according to any of claims 88 to 91 adapted for attachment to an implantable medical device.

20

93. A sensor tool according to claim 92 wherein the implantable medical device comprises an IM nail.

94. A sensor tool according to any of claims 88 to 93 wherein the shaft portion is flexible.

25

95. A sensor tool according to claim 91 wherein the shaft portion has a length sufficient to place the tip portion proximal of a target feature to within a desired distance of the target feature.

30

96. A sensor tool according to claim 91 wherein the connecting element comprises a screw adapted to engage a threaded hole in the handle.

97. A sensor tool according to any of claims 88 to 95 wherein the connecting element comprises a clamp adapted to engage a portion of the handle.
- 5 98. A sensor tool according to claim 91 wherein the connecting element comprises at least one flexible elastic element of the body portion, and wherein the elastic element is adapted to engage at least one selected feature of the insertion tool.
- 10 99. A sensor tool according to any of claims 88 to 98 to wherein the tip portion is self-centering in bores having diameters lying in a range.
100. A sensor tool according to any of claims 88 to 99 wherein the handle portion comprises a snap-fit mechanism for engaging the sensor tool with a component.
- 15 101. A sensor tool adapted for insertion into a first feature of an orthopaedic implant having a target feature, the sensor tool comprising a tip portion for insertion into the first feature to a location proximal relative to the target feature, a position indicating element mounted at a fixed location on the sensor tool at or near the tip portion and a retaining portion for directly or indirectly coupling the sensor tool to the orthopaedic implant wherein the tip portion is compressible to fit into first features having sizes within a range of sizes.
- 20 102. A sensor tool according to claim 101 wherein the first feature comprises a cannulation.
- 25 103. A sensor tool according to claim 101 or 102 wherein the sensor tool is configured to hold the tip portion at a predetermined minimum distance from the target feature.
- 30

104. A sensor tool according to any of claims 101 to 103 wherein the position indicating element is configured to generate a response indicative of its position relative to an element of a navigation system.
- 5 105. A sensor tool according to any of claims 101 to 104 wherein the tip portion is self-centering in the first feature.
106. A sensor tool adapted for attachment to an insertion tool rigidly connected to an orthopaedic implant, the sensor tool comprising:
- 10 a body portion having a length;
a position indicating element embedded at a fixed location within the body portion, and;
a connecting element,
wherein the connecting element is adapted to temporarily attach the
15 body portion to the insertion tool such that the body portion is fixed in a unique predetermined position relative to the implant.
107. A method for providing visual feedback regarding the position and orientation of a tool relative to a target, the method comprising:
- 20 displaying a target graphic element representing the target
displaying a tool graphic element representing the tool;
determining at least one relative position parameter representing the relative position of the tool to the target; and
setting a value of a magnification factor that determines displayed sizes
25 of the target graphic element and the tool graphic element based at least in part on the relative position parameter.
108. A method according to claim 107 comprising setting the value of the magnification factor to an alternate value in response to the relative position
30 parameter being within a preselected range of values for a first preselected time interval.

109. A method according to claim 108 comprising setting the magnification factor to a default value in response to the relative position parameter being outside of the preselected range of values for a second preselected time interval.
- 5 110. A method for providing visual feedback regarding the position and orientation of a tool relative to a target feature wherein the tool has a tool axis and the target feature has a target axis, the method comprising:
- monitoring relative positions and orientations of the tool and target feature;
- 10 determining a first relative position parameter representing the relative position of the tool axis to a first selected point on the target axis;
- determining a second relative position parameter indicative of a relative orientation of the tool axis to the target axis;
- 15 displaying a position indicator indicating a relative position of the tool and the target feature and an alignment indicator indicating a relative alignment of the tool and the target feature; and
- suppressing display of the alignment indicator whenever the first relative position parameter has a value outside of a predetermined range.
- 20 111. A method according to claim 110 wherein the first relative position parameter comprises a distance from a first selected point on the target axis to the tool axis measured normal to the target axis.
112. A method according to claim 110 or 111 wherein the second relative position parameter comprises an orthogonal distance from the tip point to the target axis.
- 25 113. A method according to claim 110 wherein the first relative position parameter comprises a distance measured normal to the target axis from a first selected point on the target axis to the tool axis.
- 30

114. A method according to claim 110 or 113 wherein the second relative position parameter comprises a distance measured normal to the target axis from a second selected point on the target axis to the tool axis.

5 115. A visual user interface for indicating the position and orientation of a tool relative to a target feature wherein the tool has a tool axis and the target has a target axis, the interface comprising:

10 means for determining a first relative position parameter representing the relative position of the tool axis to a first selected point on the target axis and a second relative position parameter, which together with the first relative position parameter represents the relative orientation of the tool axis to the target axis;

a display;

15 an interface controller configured to display first indicia on the display indicating an acceptable position of the tool when the first relative position parameter is within a first preselected range, and to display second indicia on the display indicating an acceptable orientation of the tool when the first relative position parameter is within the first preselected range and the second relative position parameter is simultaneously within a second preselected range wherein display of the second indicia is suppressed when the first relative position parameter is not within the first preselected range.

20 116. A visual user interface according to claim 115 wherein the first relative position parameter comprises a distance from a first selected point on the target axis to the tool axis measured normal to the target axis.

25 117. A visual user interface according to claim 115 or 116 wherein the second relative position parameter comprises an orthogonal distance from a tip point on the tool axis at a tip of the tool to the target axis.

30

118. A visual user interface according to claim 115 wherein the first relative position parameter comprises a distance measured normal to the target axis from the first selected point on the target axis to the tool axis.
- 5 119. A visual user interface according to claim 118 wherein the second relative position parameter comprises a distance measured normal to the target axis from a second selected point on the target axis to the tool axis.
- 10 120. A fixation element adapted for fixation of a bone fragment relative to an intramedullary nail, the nail having a cannulation along a longitudinal axis and a cross hole having a hole axis, wherein the hole axis intersects the longitudinal axis,
- the fixation element comprising: a shank portion, a fenestration passing through the shank portion, and a tip portion adapted to engage the fragment,
- 15 the fixation element dimensioned to slide through the cross hole to at least one position relative to the nail in which the tip portion engages the fragment
- wherein, in the at least one position, the fenestration aligns with the cannulation such that a selected minimum cross sectional area of the cannulation is unobstructed.
- 20 121. The fixation element of claim 120 wherein the element comprises a drill bit and the tip portion is further adapted to drill through bone.
- 25 122. The fixation element of claim 121 wherein the element comprises a stud and the tip portion comprises an external threaded portion.
123. Temporary fixation apparatus adapted for fixation of a bone fragment relative to an orthopaedic implant having a hole having a diameter,
- 30 the fixation apparatus comprising a member having a shank portion and a tip portion, the shank portion is adapted to engage a bone fragment, the tip portion is adapted to engage the hole, the tip portion is expandable in

diameter from a first diameter smaller than the diameter of the hole to a second diameter larger than the diameter of the hole.

- 5 124. The temporary fixation apparatus of claim 123 wherein the implant comprises an intramedullary nail having a longitudinal axis and the hole has a hole axis, and wherein the hole axis is skew to, or intersects, the longitudinal axis.
- 10 125. Use of a fixation element or temporary fixation apparatus according to any one of claims 120 to 124 for holding an implant in place without blocking a cannulation of the implant.
126. A method for communicating information to a user of a hand held tool, the method comprising:
- 15 monitoring a relative position of a tool and a component;
detecting a start of cutting;
monitoring a rate of cutting;
and one or more of:
displaying indicia indicating deviations from a desired rate of cutting;
and,
20 detecting plunge through of a cutter.
127. Apparatus configured to perform a method as described herein or a portion thereof.
- 25 128. A method as illustrated in any one or more of Figures 9A, 18B, 19A, 20A, 26, 26A, or 30 or a portion thereof.
- 30 129. A program product comprising tangible media storing computer-readable computer software which, when executed by a processor, causes the processor to implement a method as described herein.

130. A method comprising any new and inventive step, act, combination of, steps and/or acts or sub-combination of steps and/or acts as described herein.
131. Apparatus comprising any new and inventive element, combination of elements or subcombination of elements as described herein.
- 5

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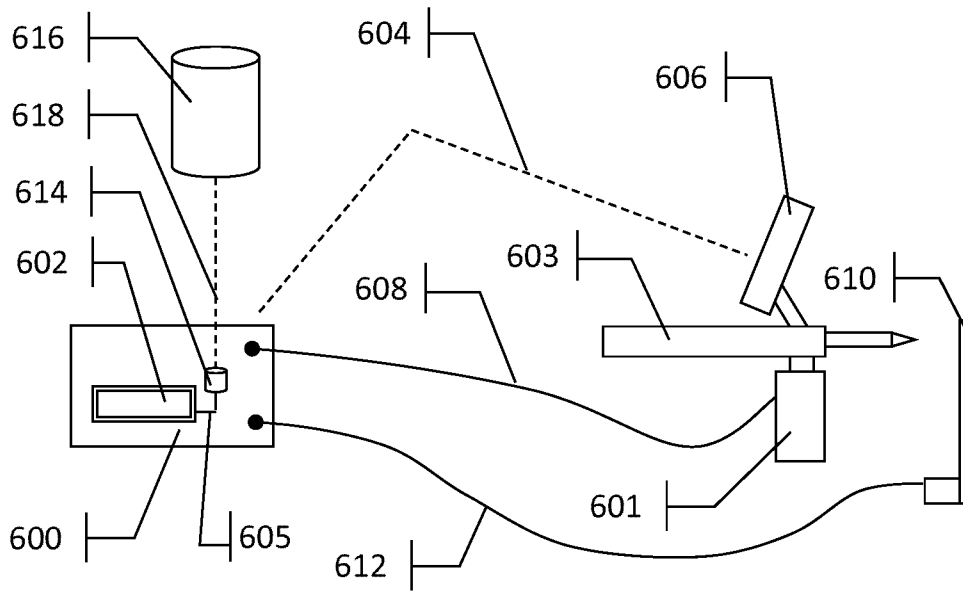


Figure 1

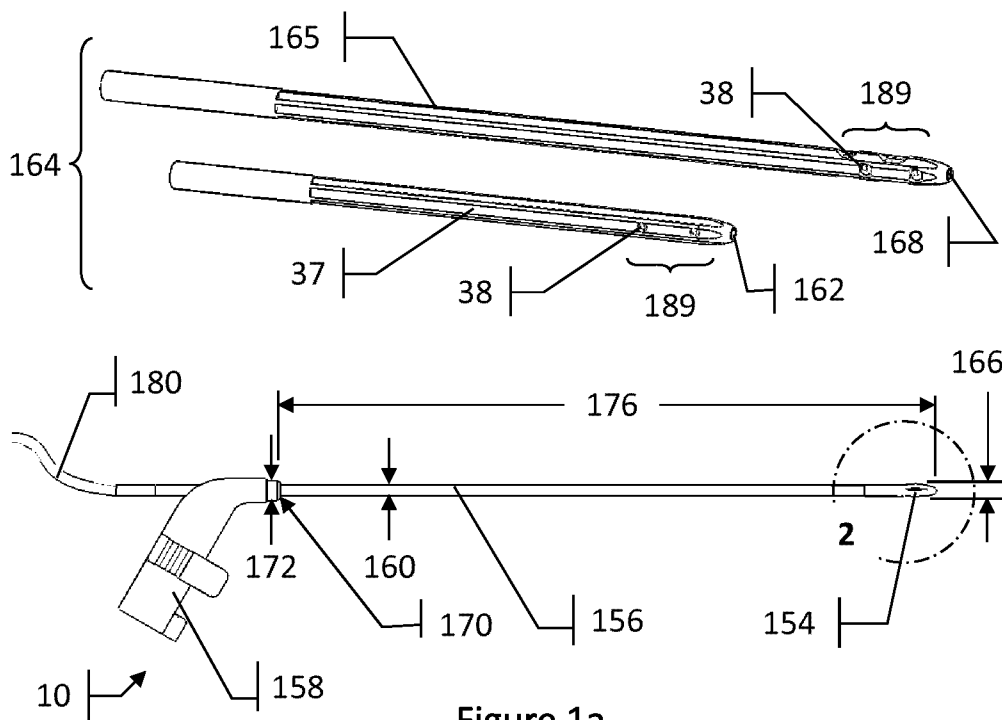


Figure 1a

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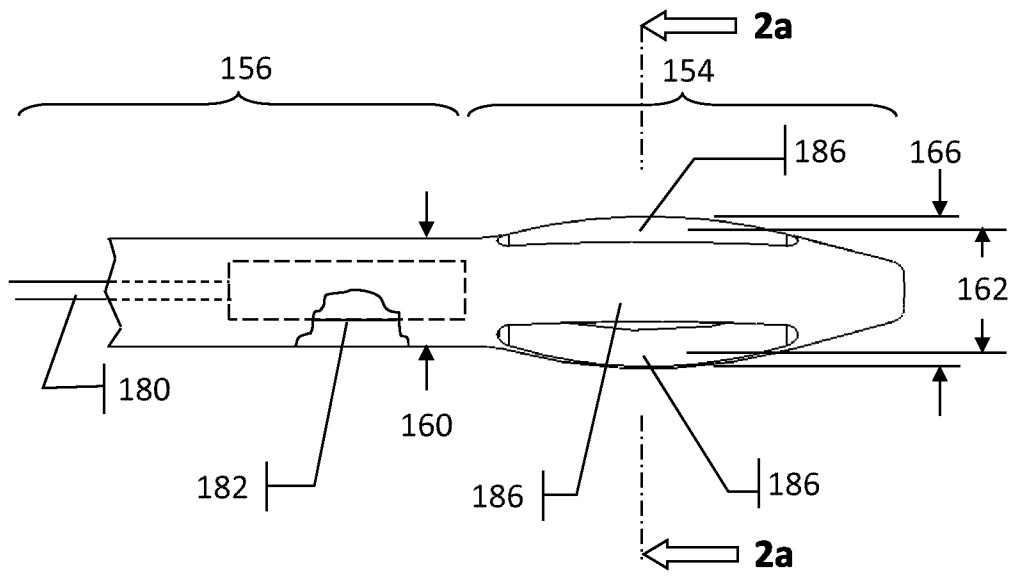


Figure 2

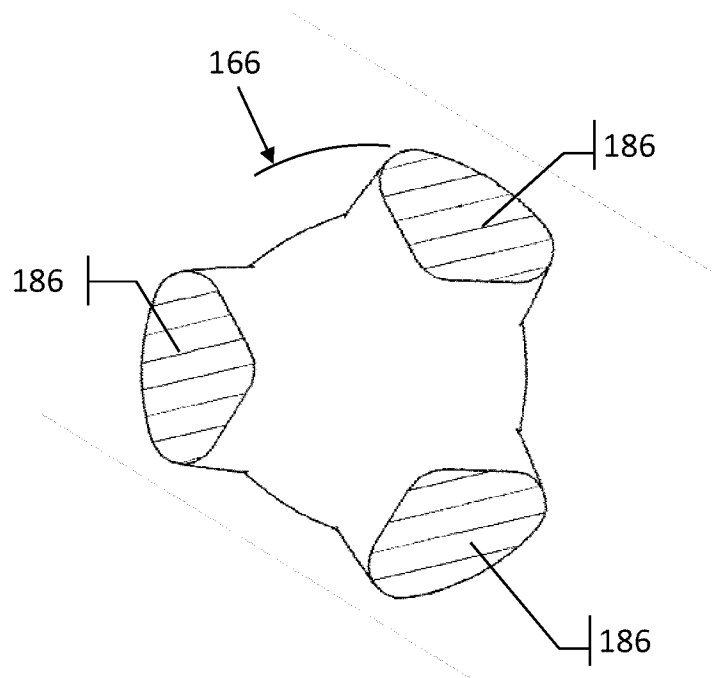


Figure 2a

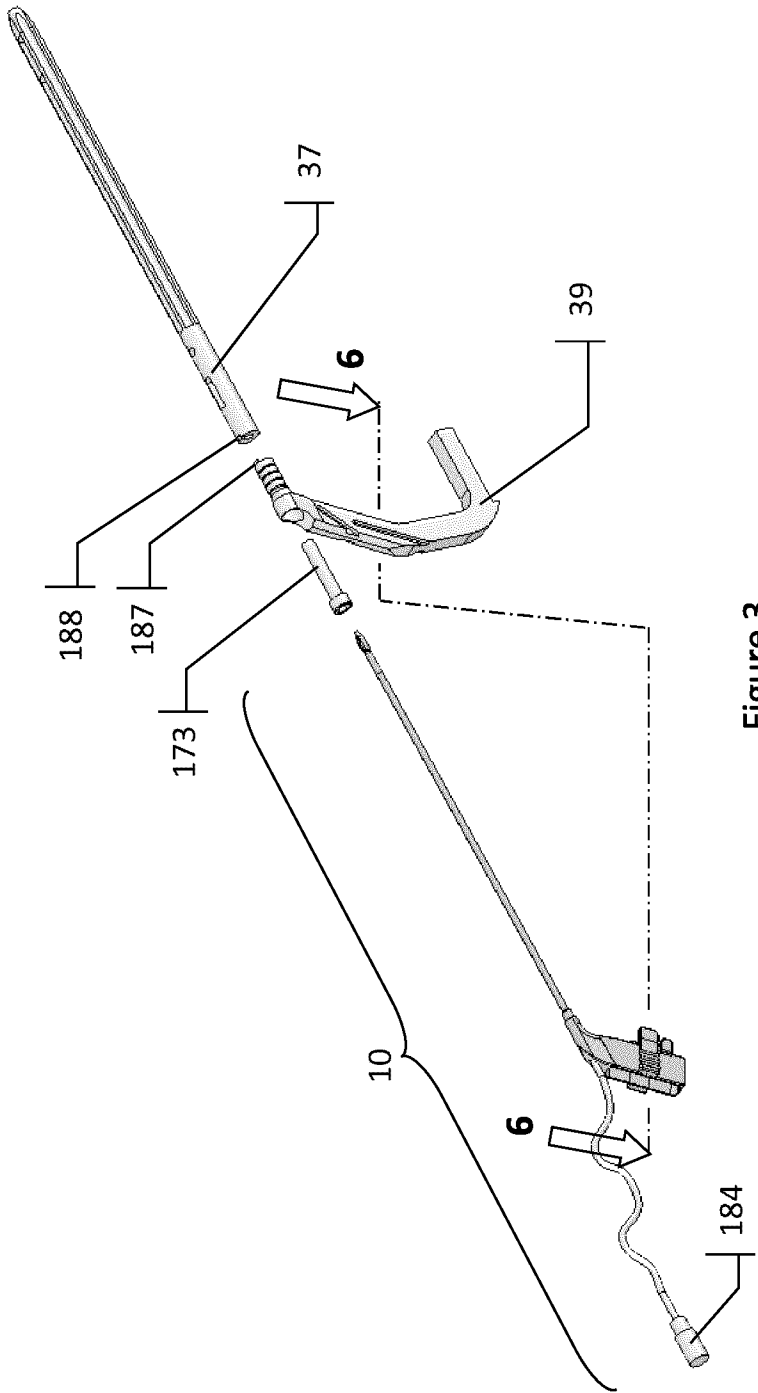


Figure 3

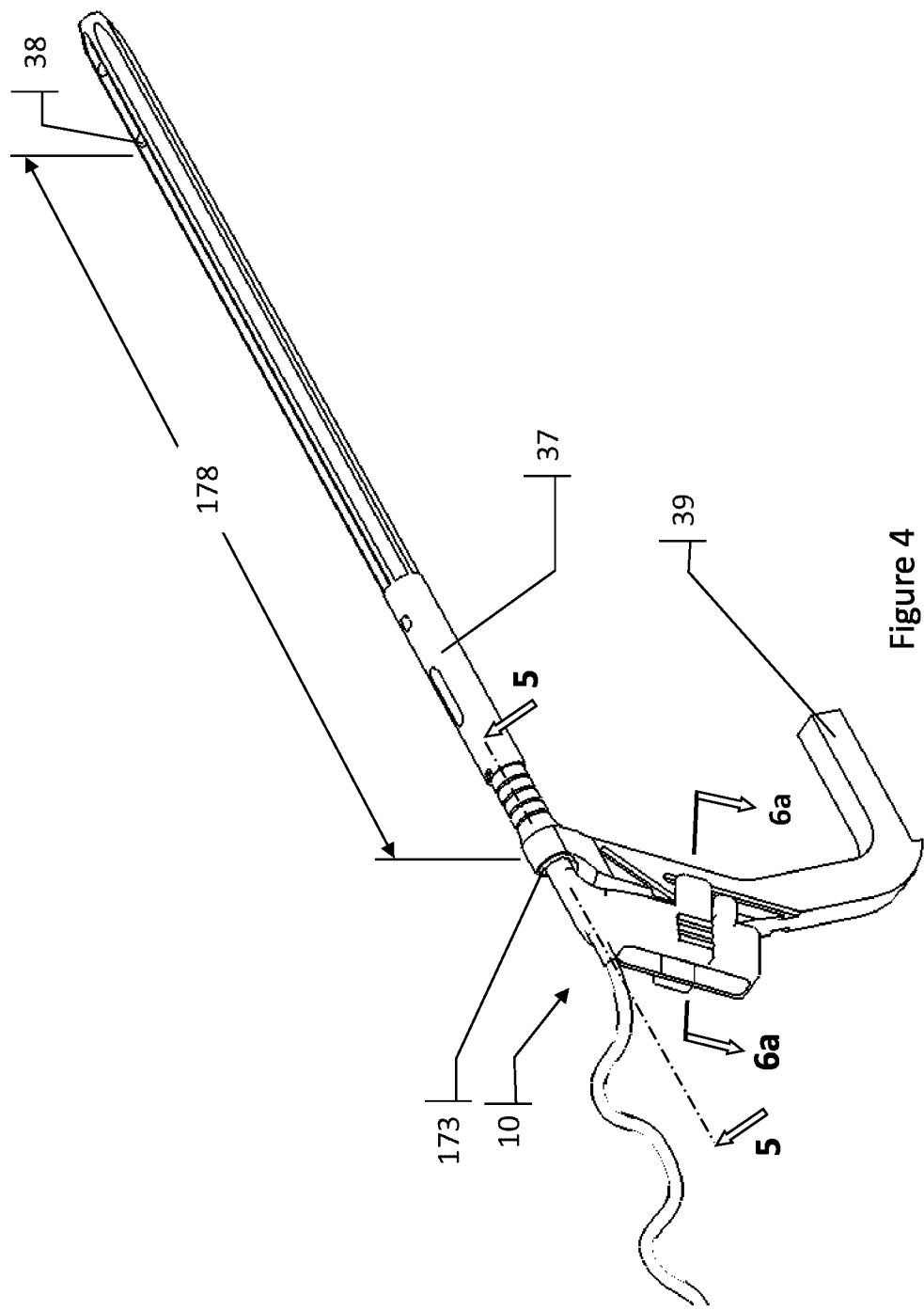


Figure 4

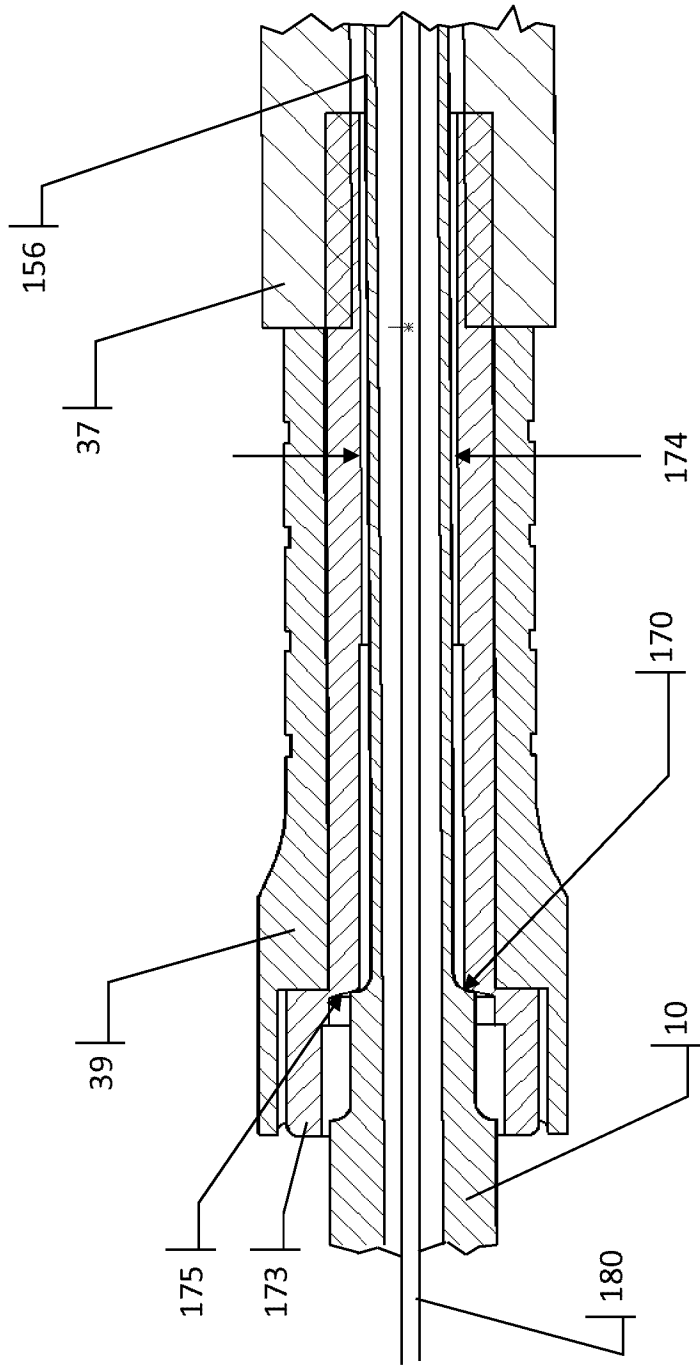


Figure 5

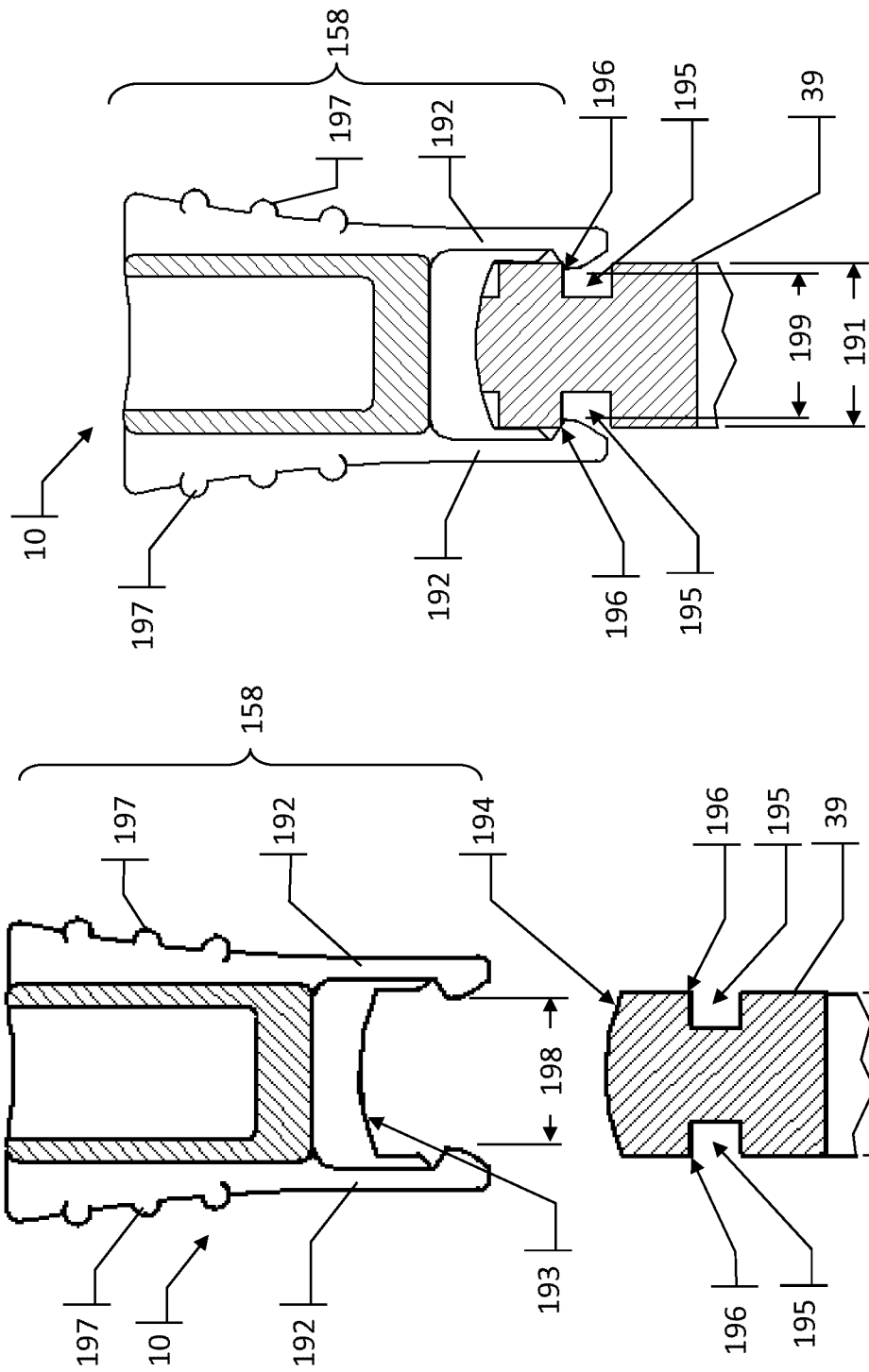


Figure 6a

Figure 6

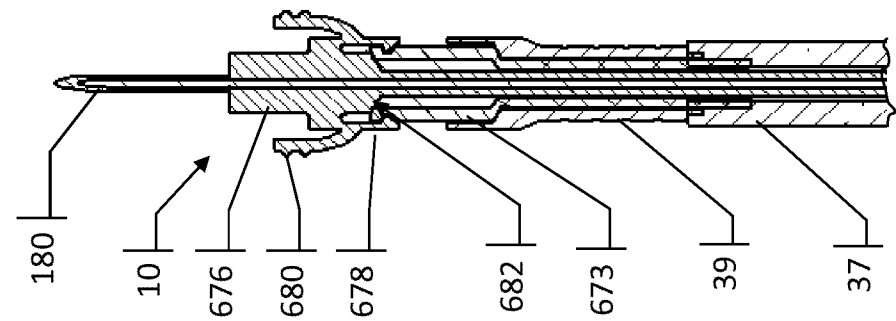


Figure 6c

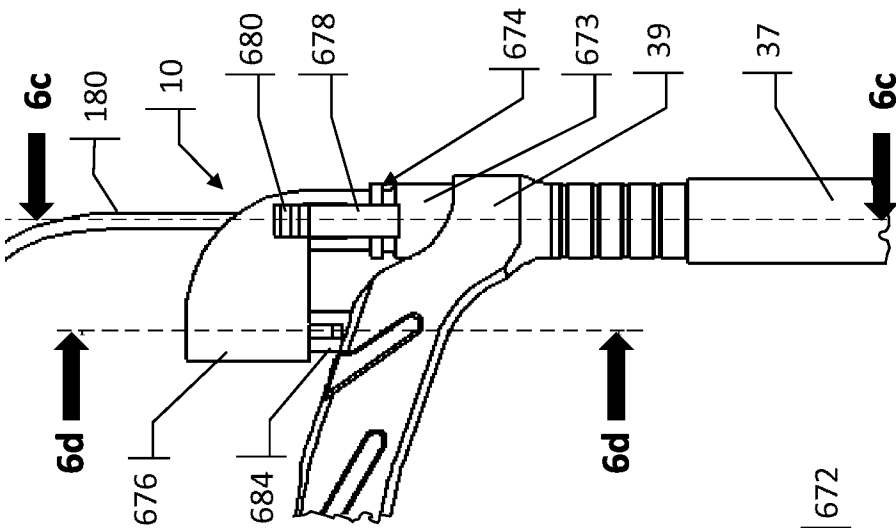


Figure 6b

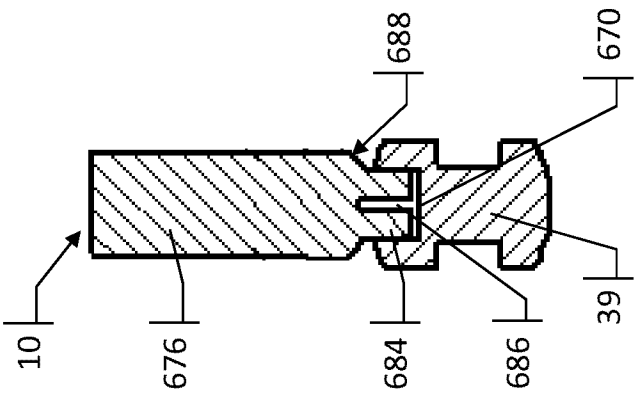


Figure 6d

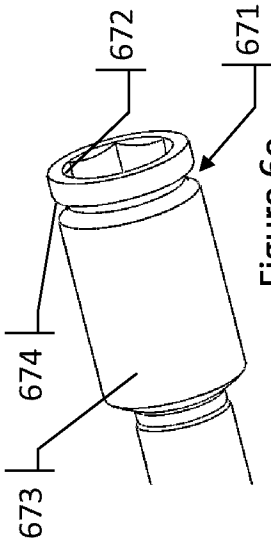
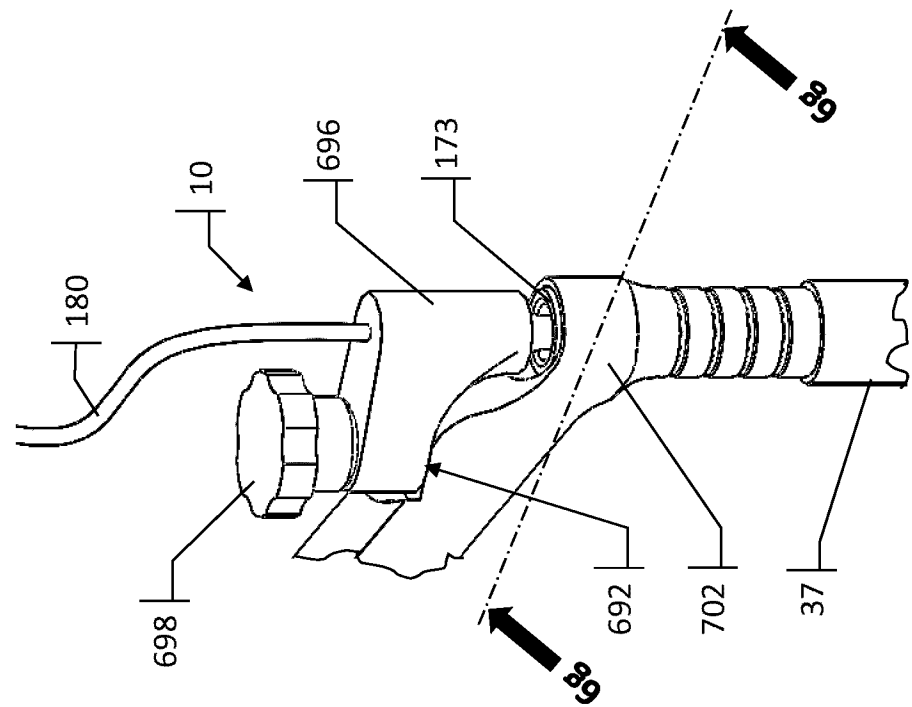
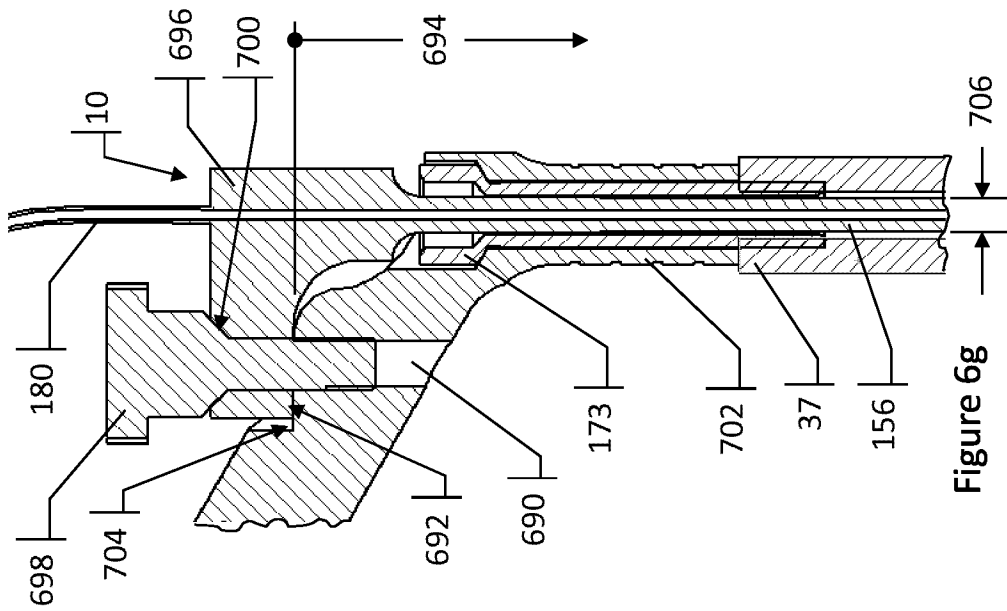


Figure 6e



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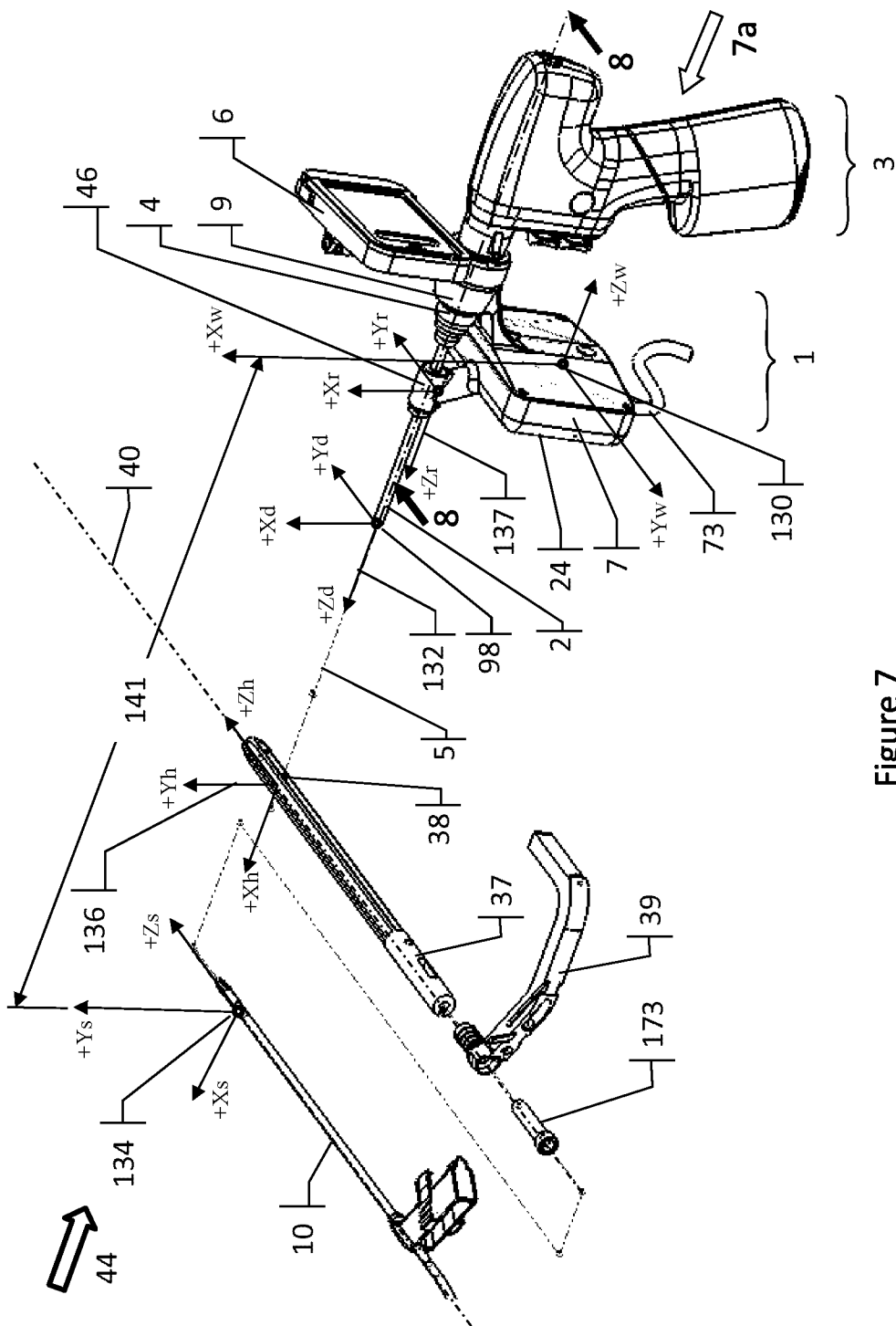


Figure 7

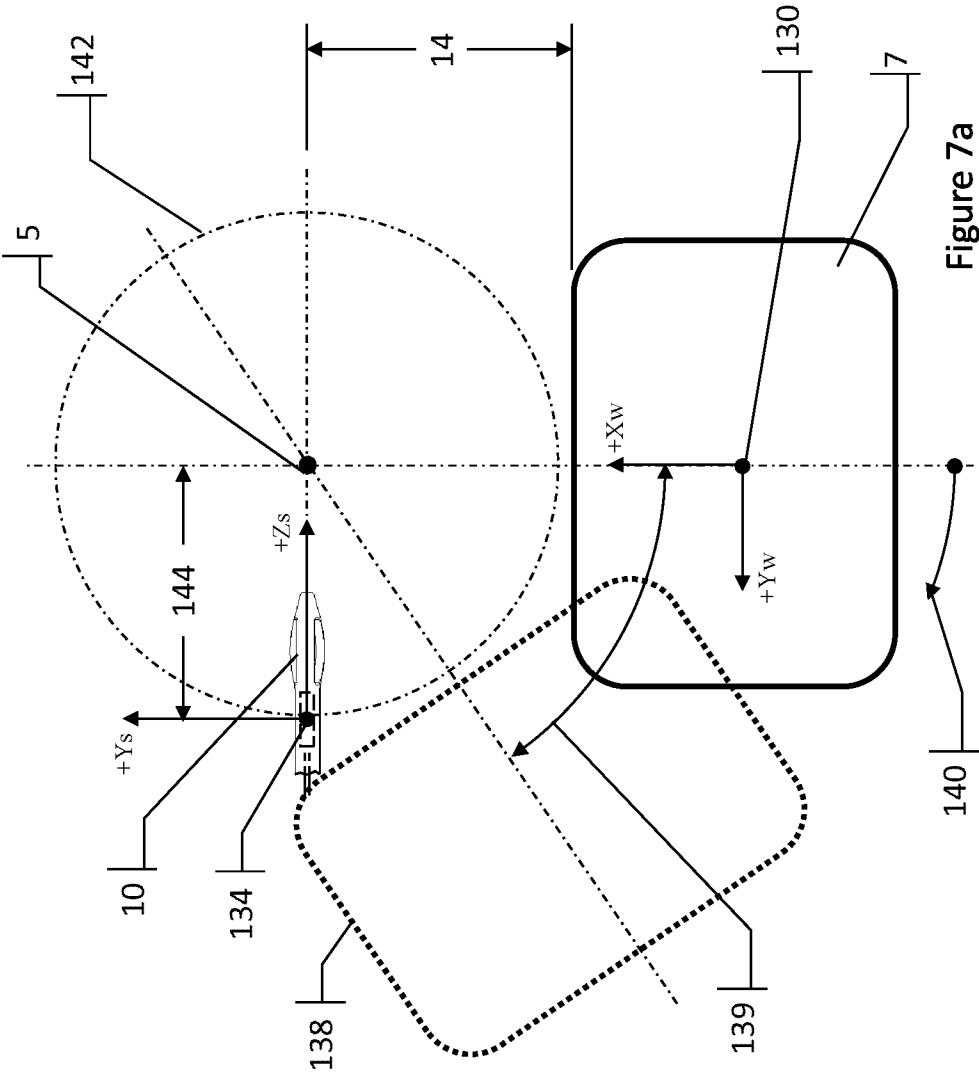


Figure 7a

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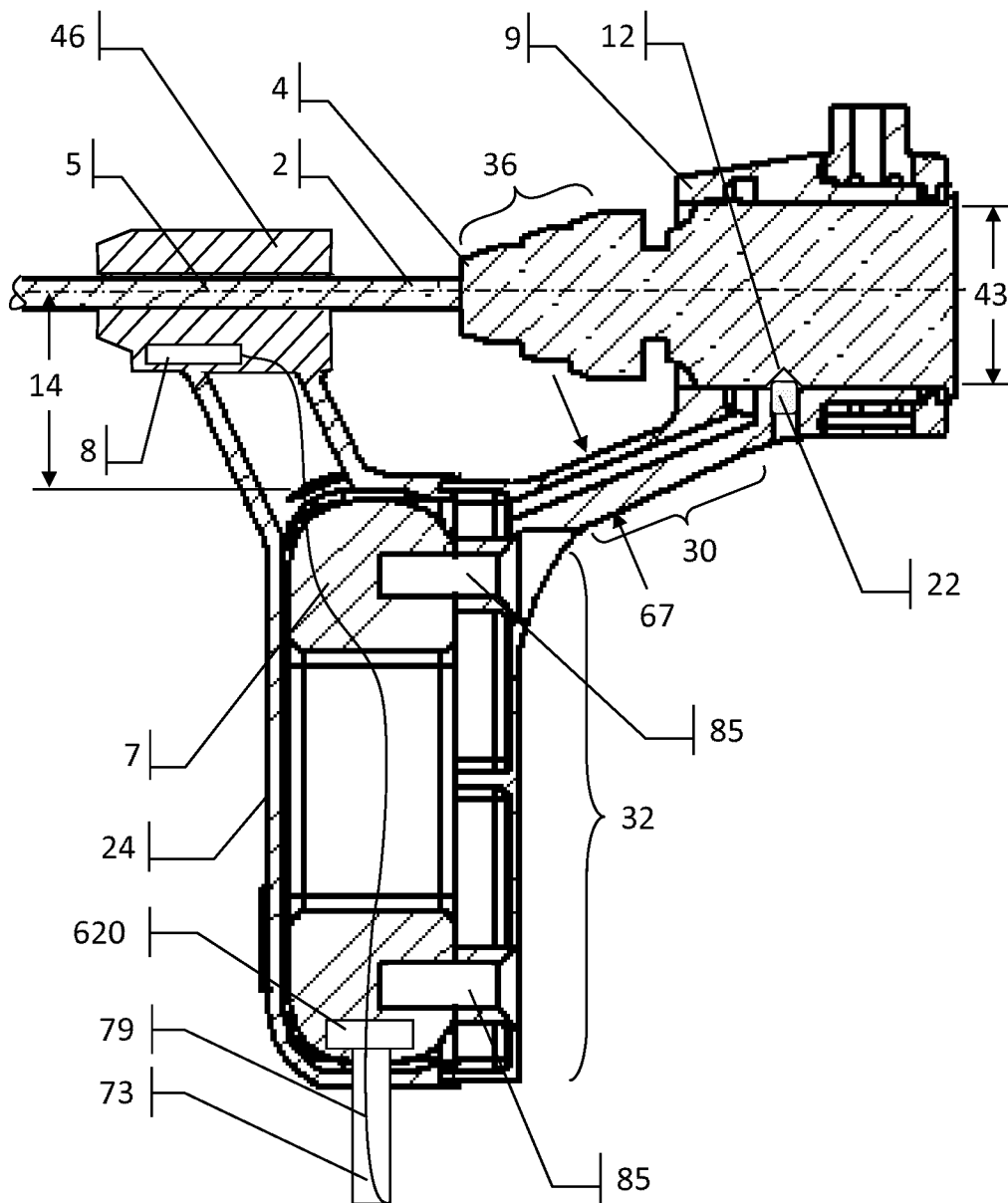


Figure 8

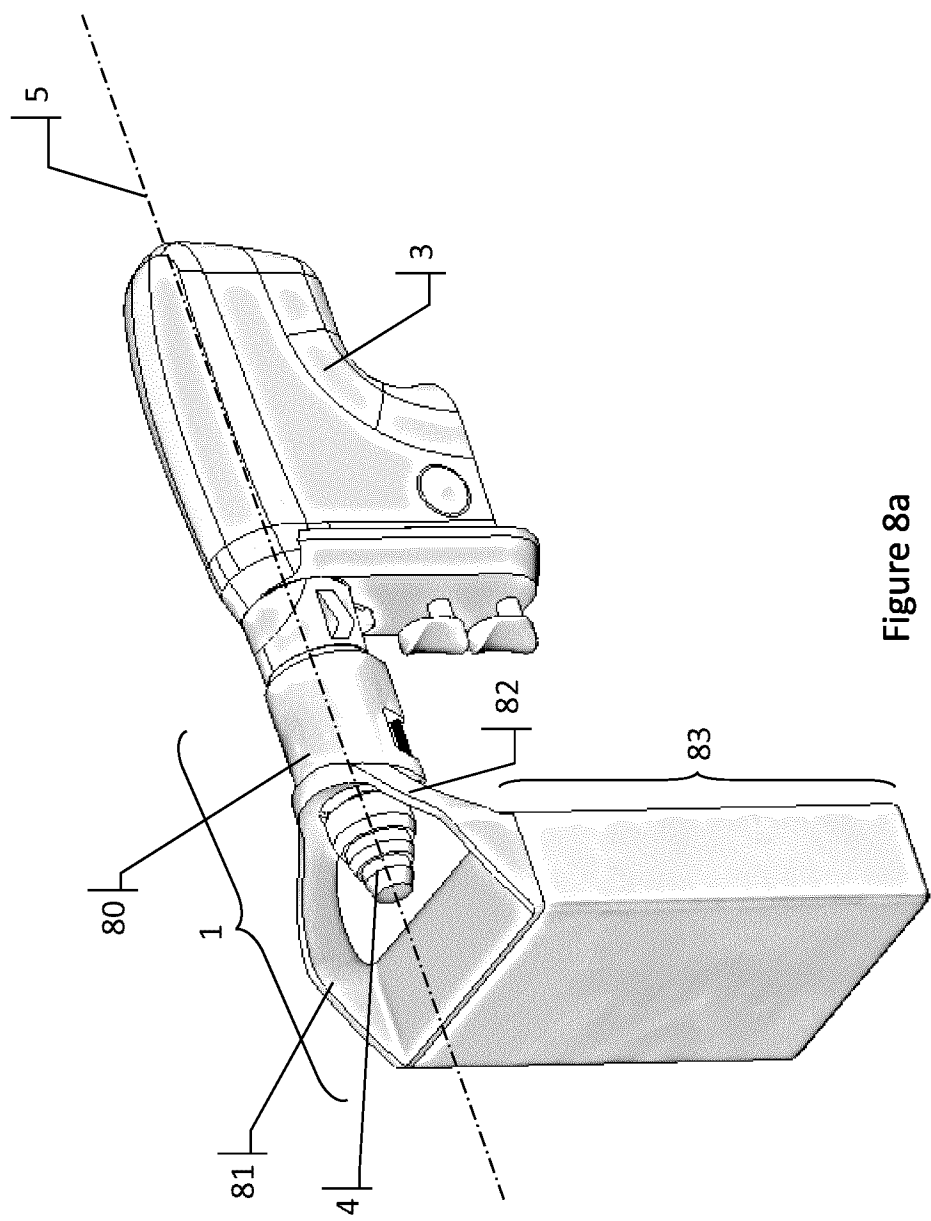


Figure 8a

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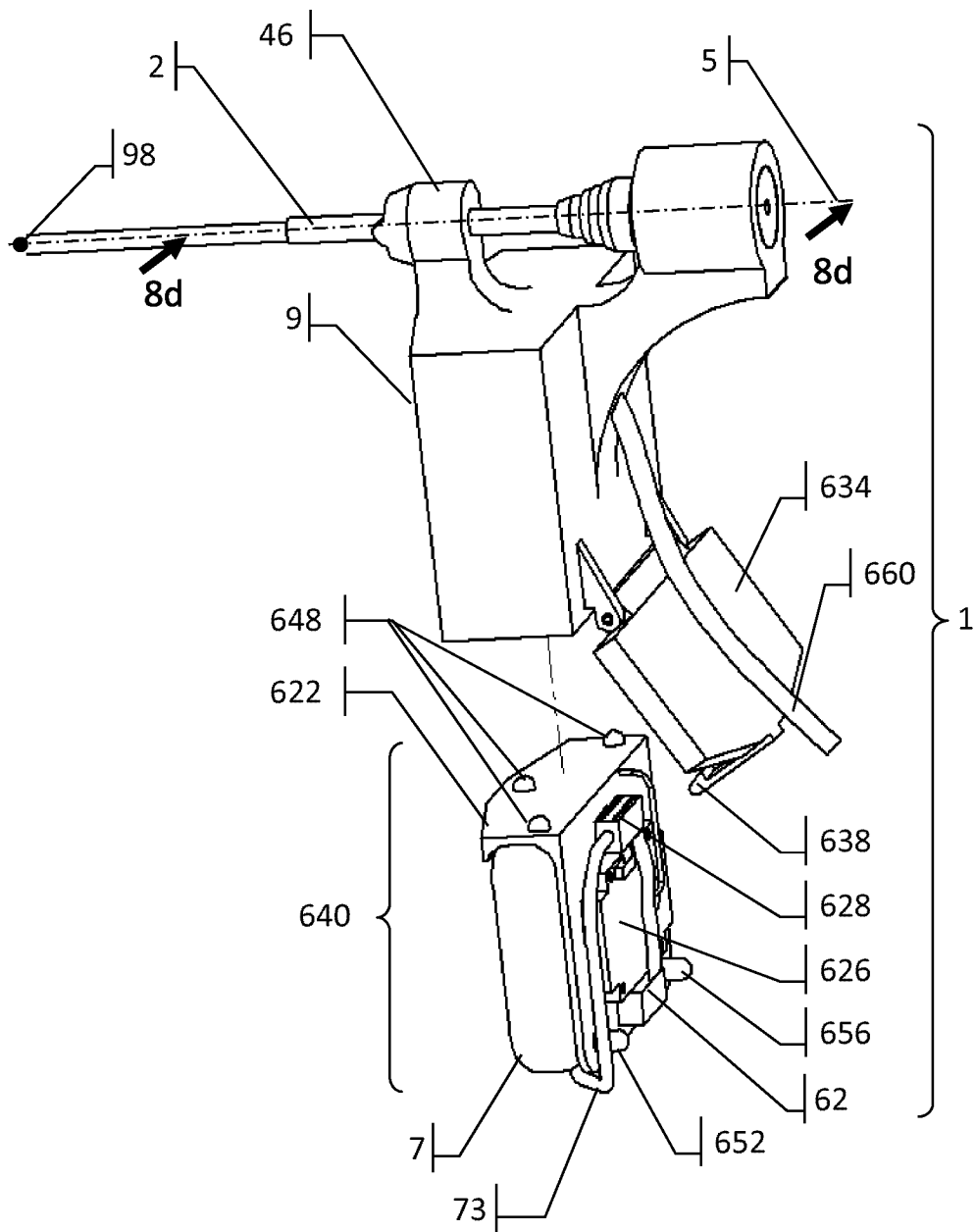


Figure 8b

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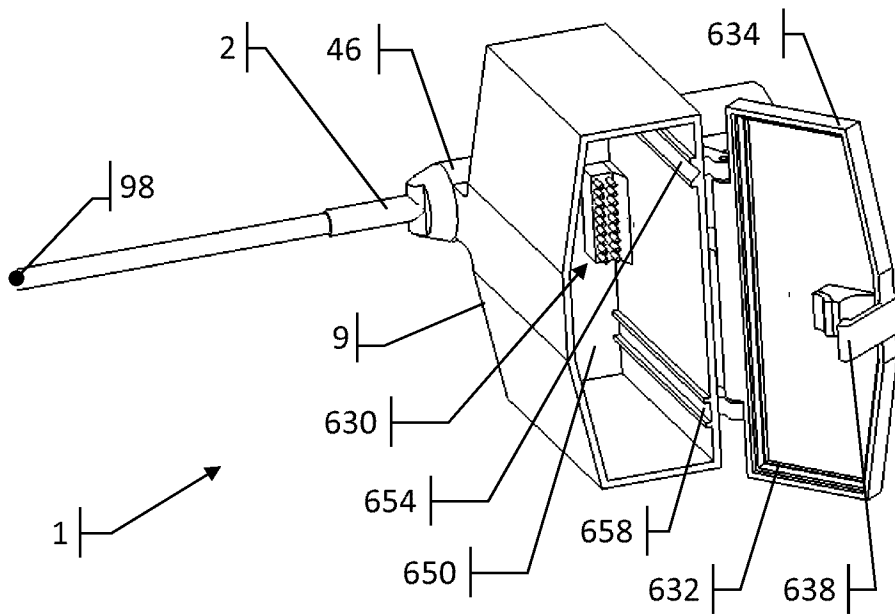


Figure 8c

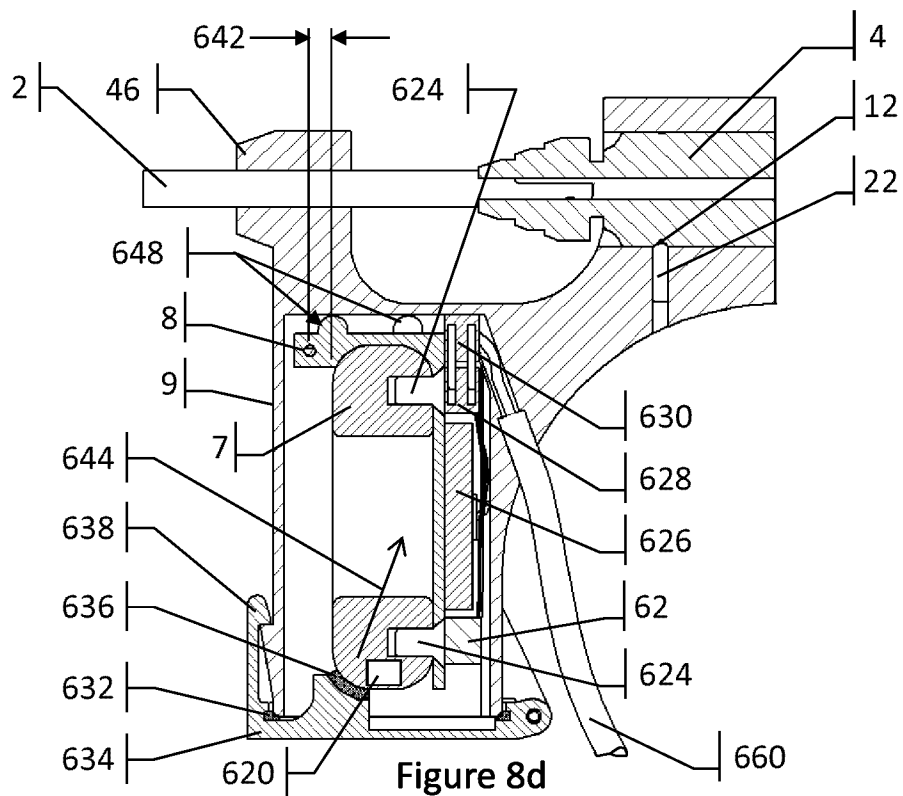


Figure 8d

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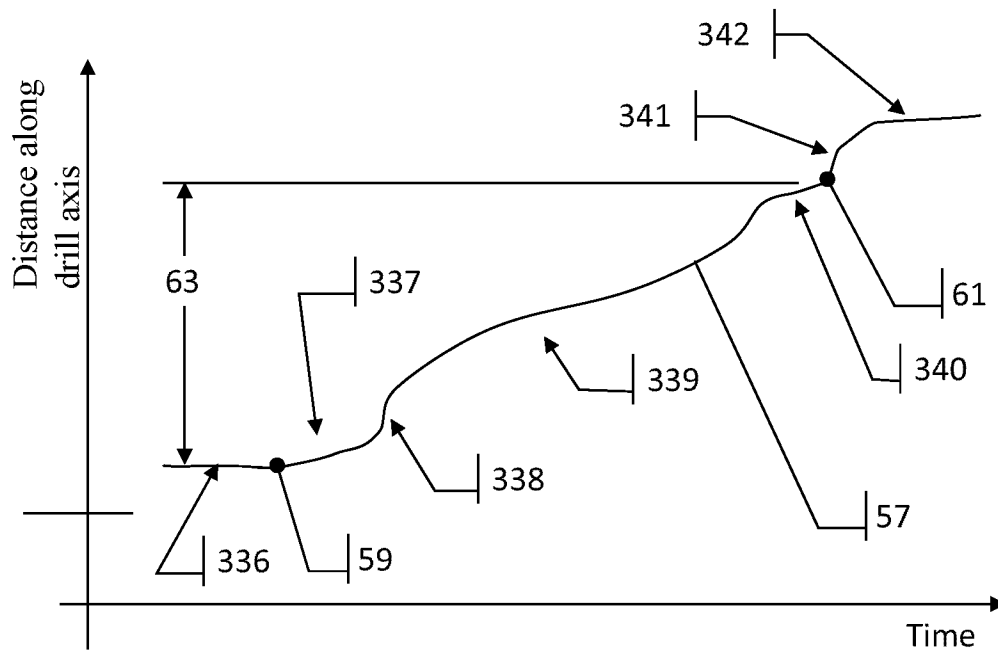


Figure 9

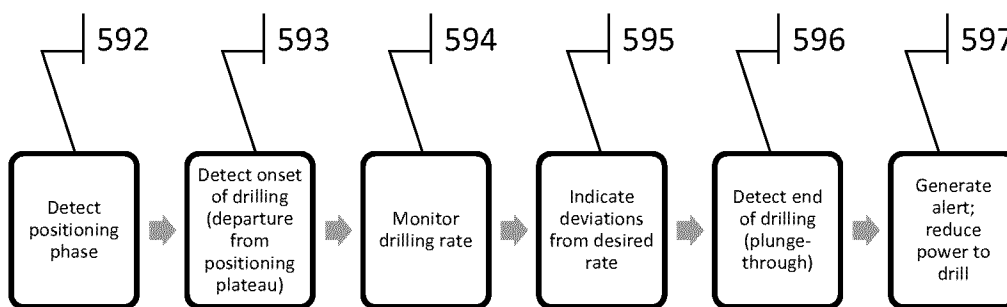


Figure 9a

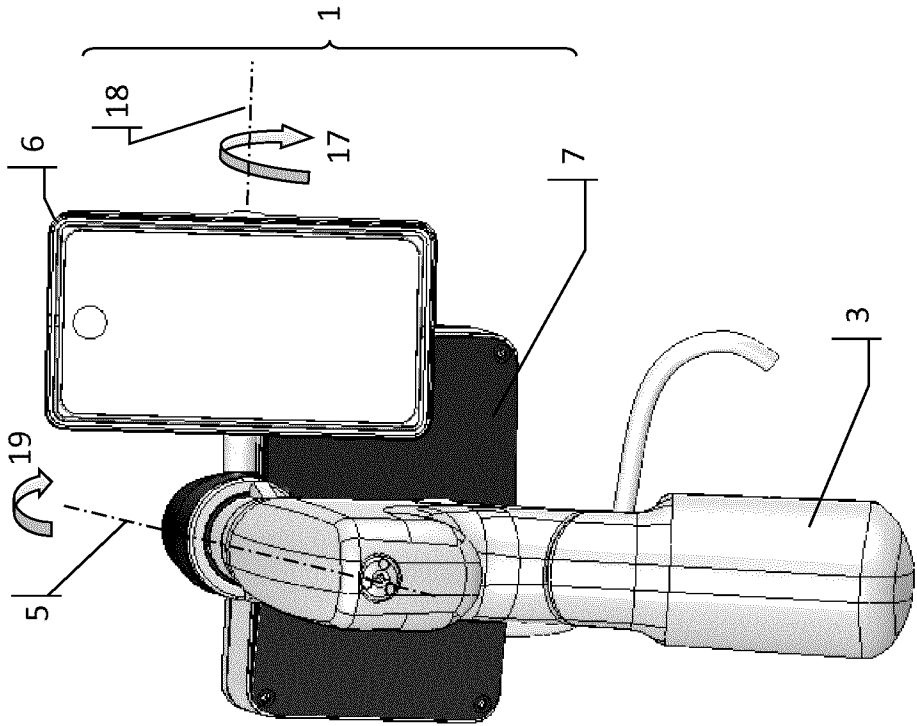


Figure 10a

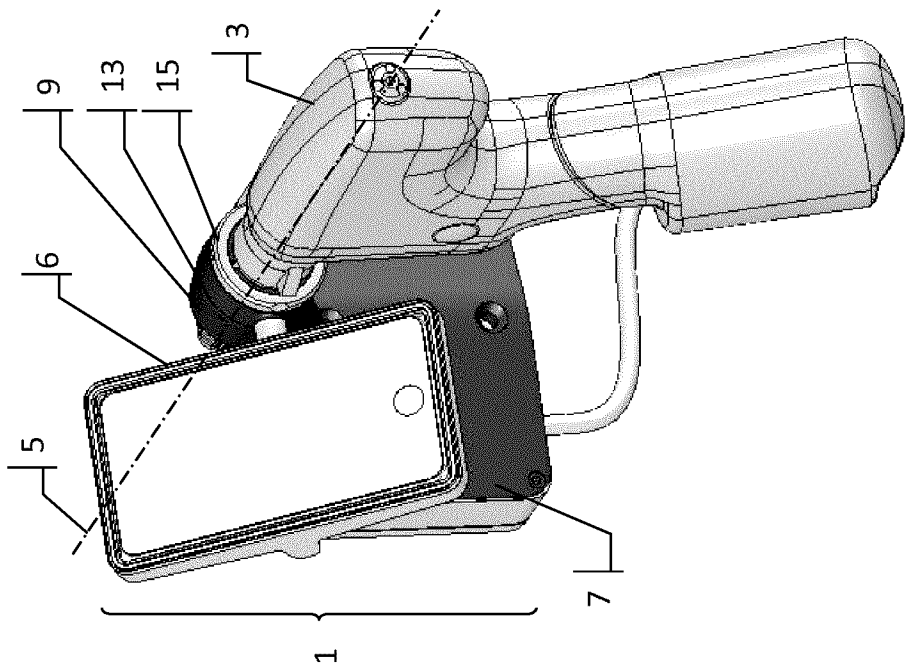


Figure 10

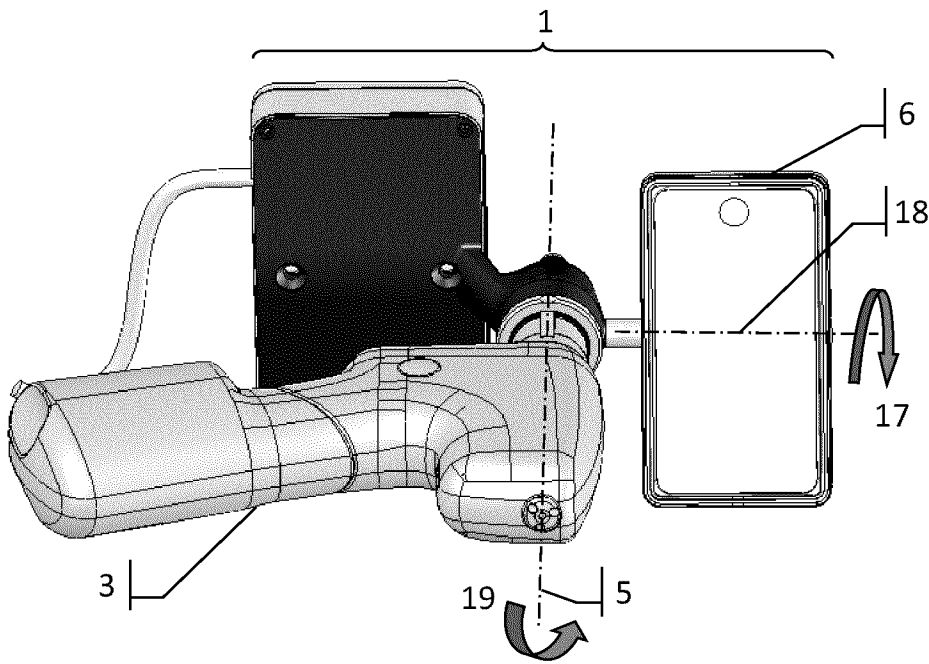


Figure 11

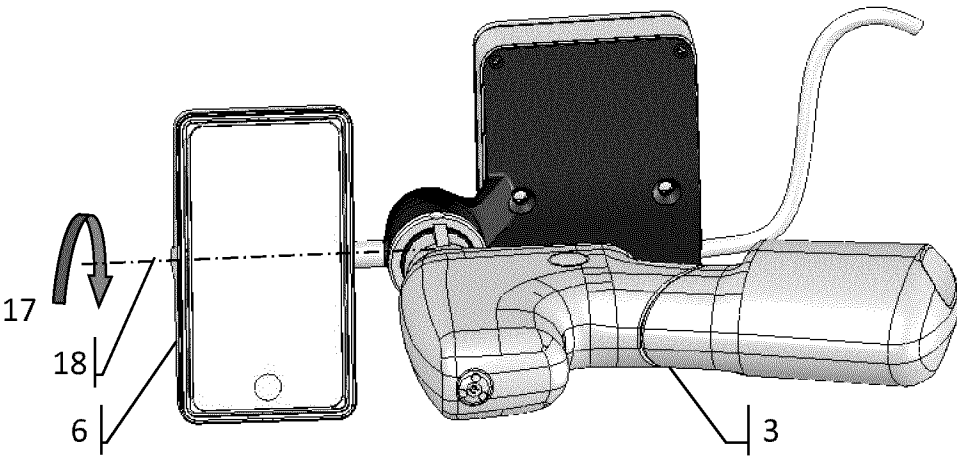


Figure 11a

18/50

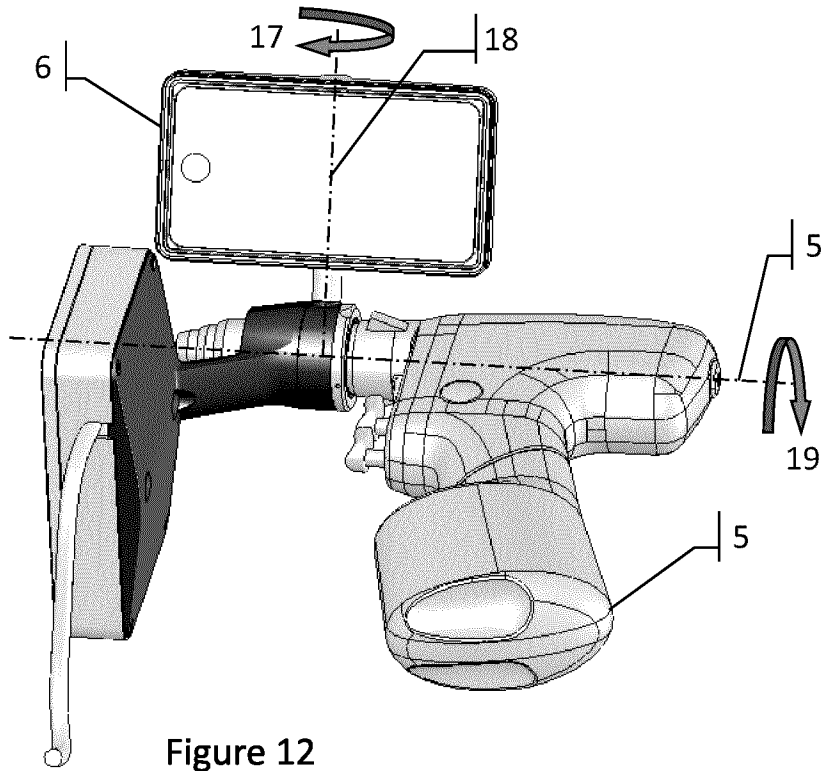


Figure 12

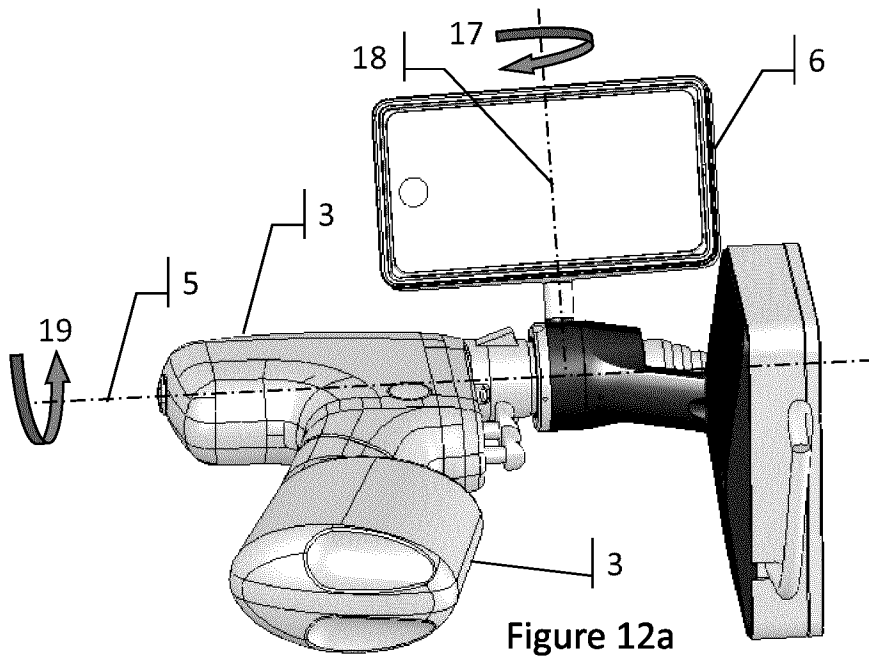


Figure 12a

19/50

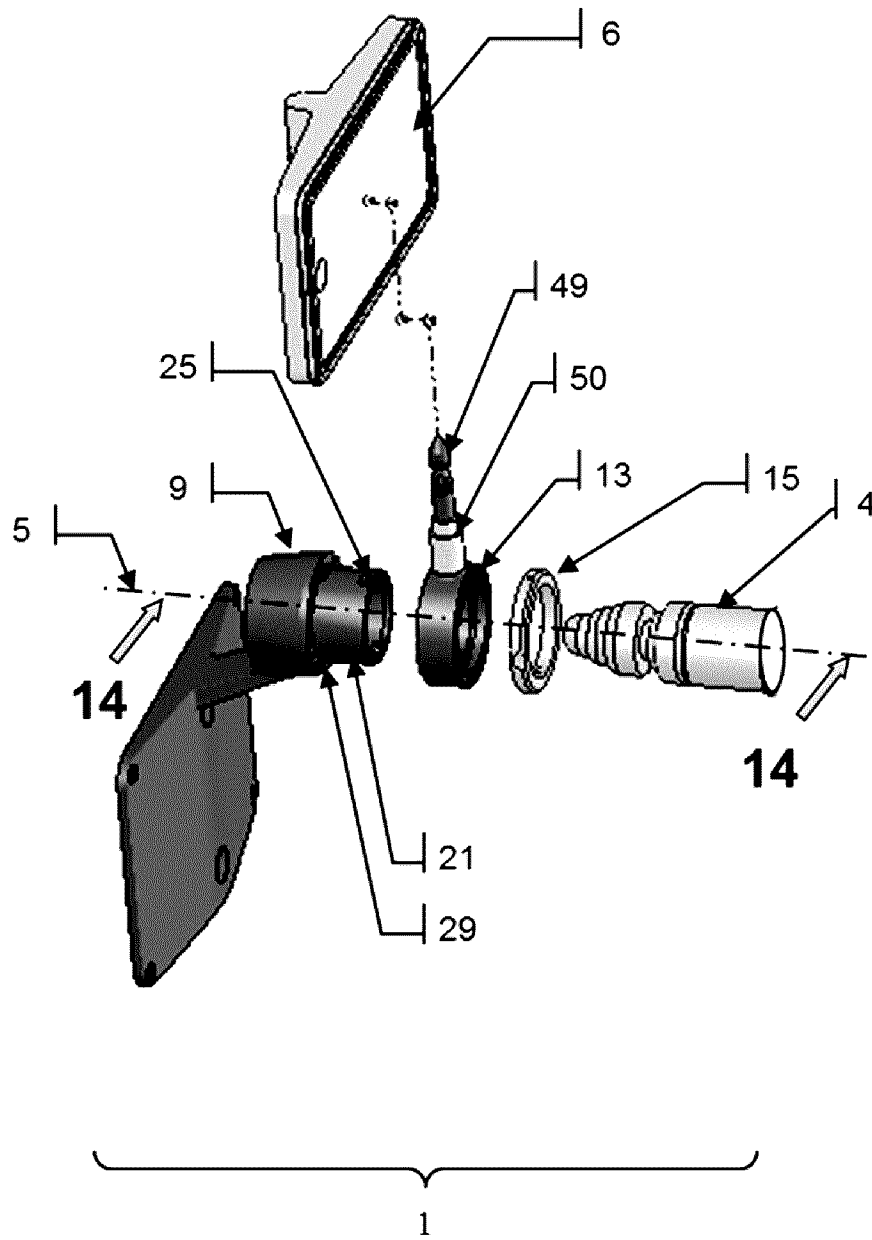


Figure 13

20/50

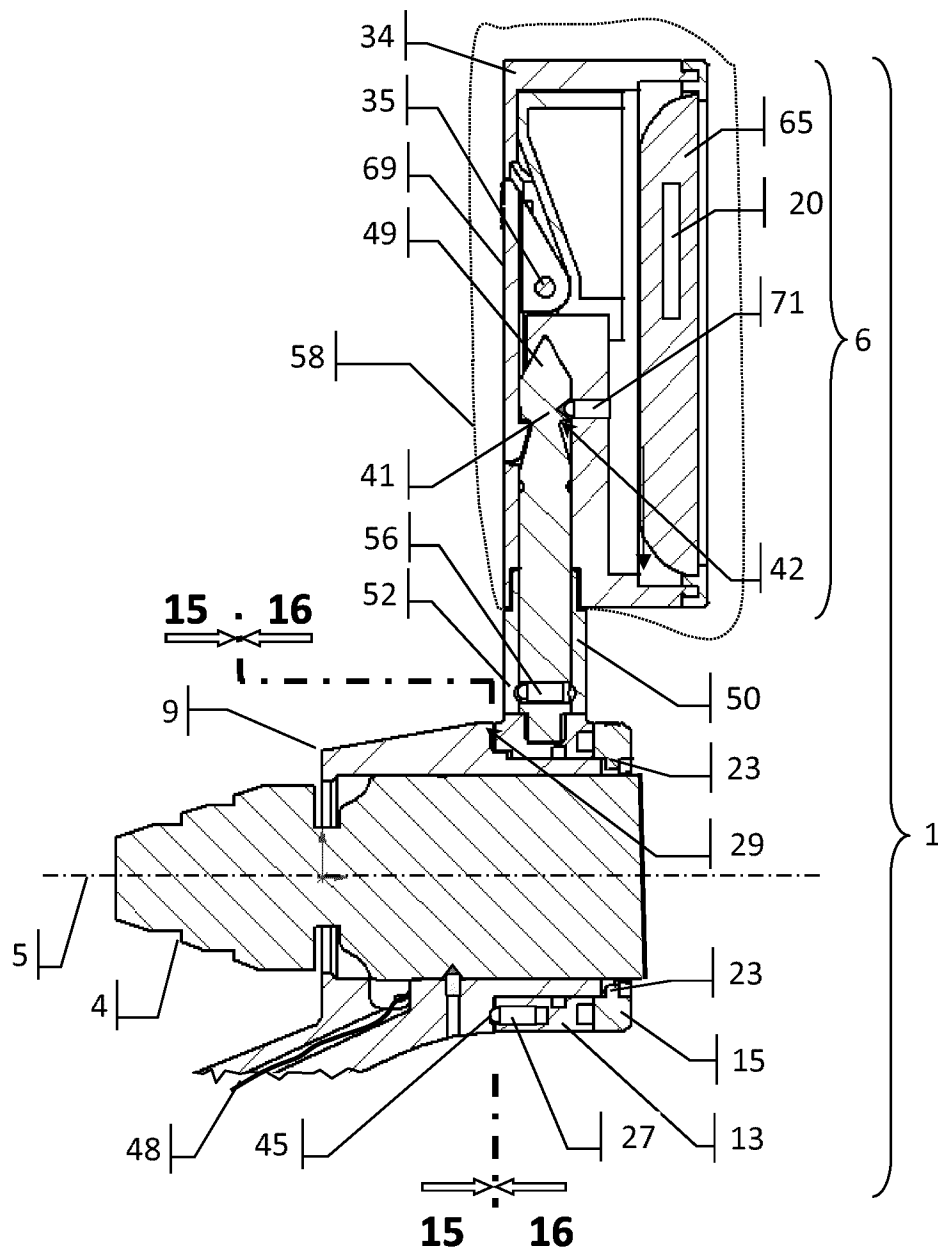


Figure 14

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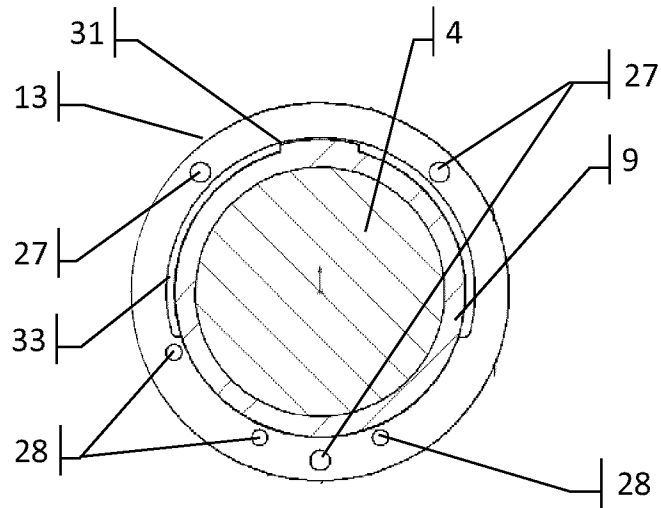


Figure 15

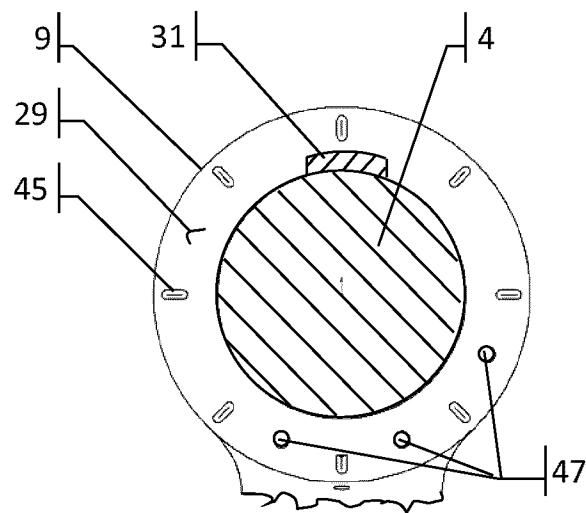


Figure 16

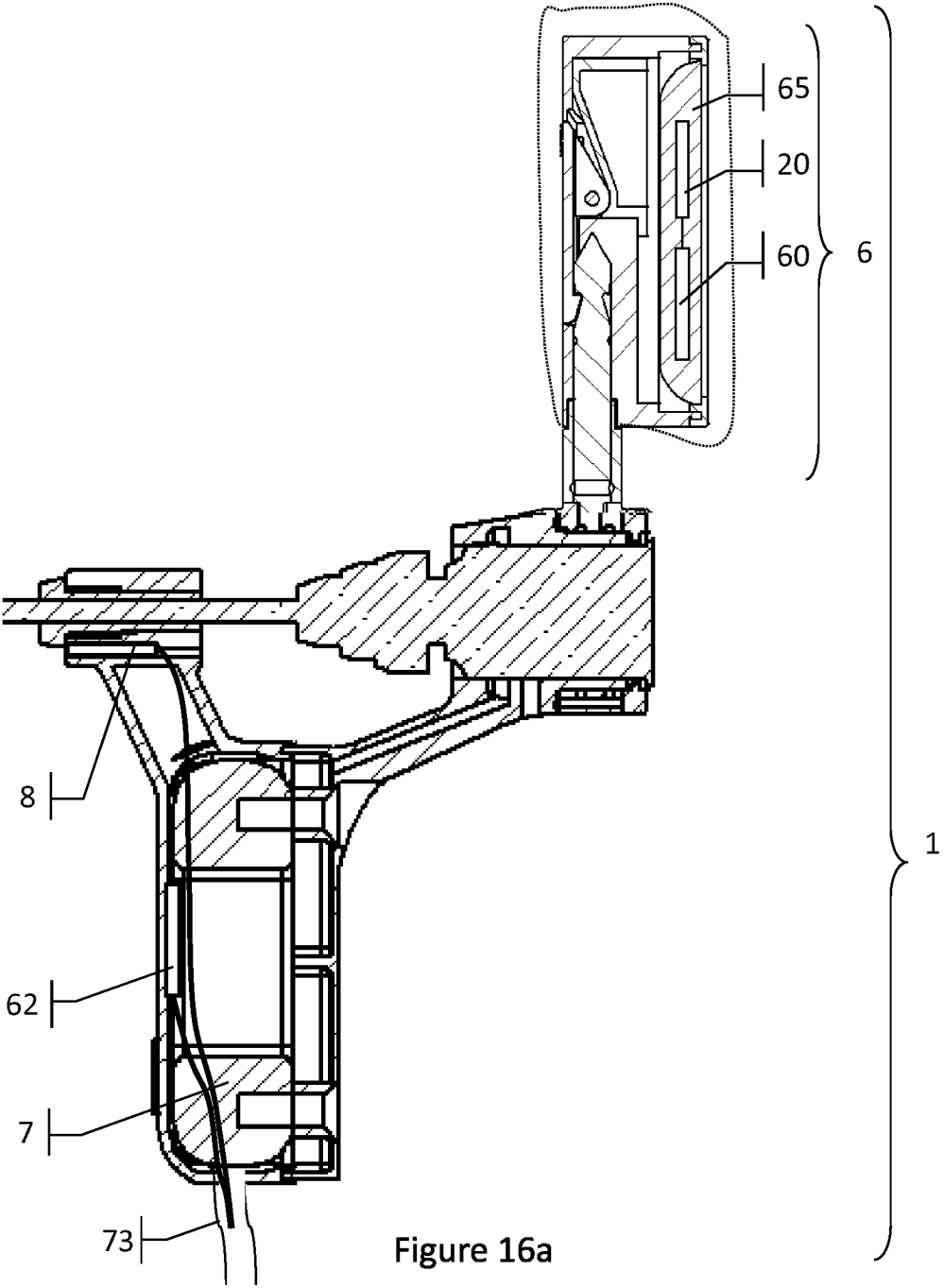


Figure 16a

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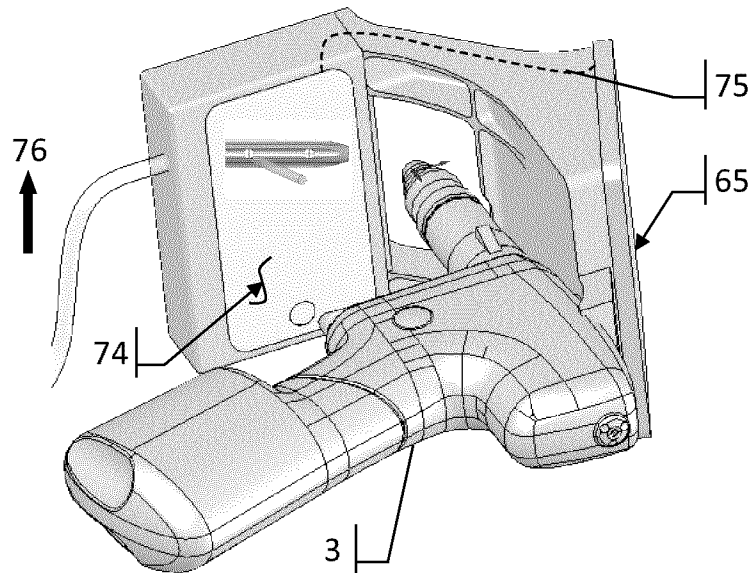


Figure 17

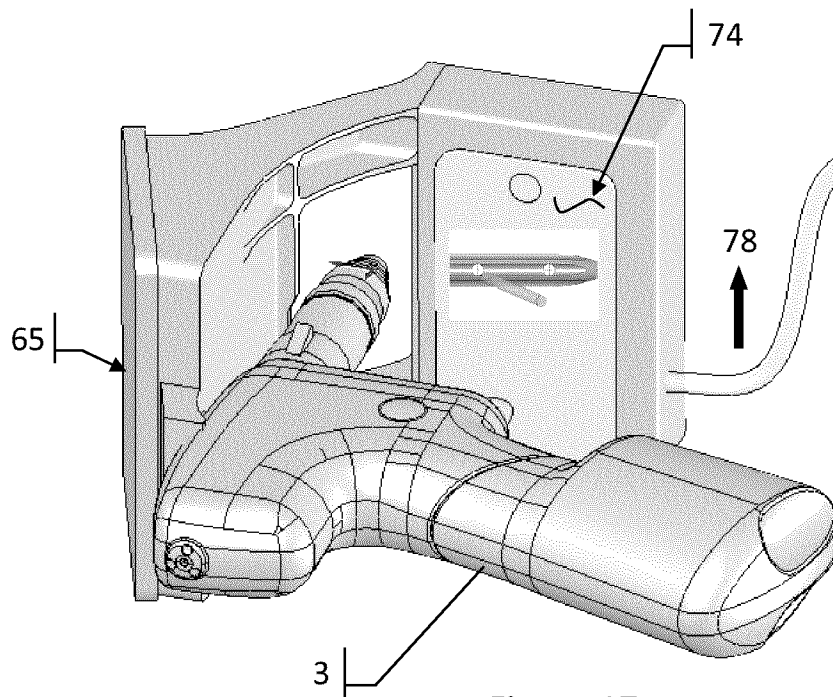


Figure 17a

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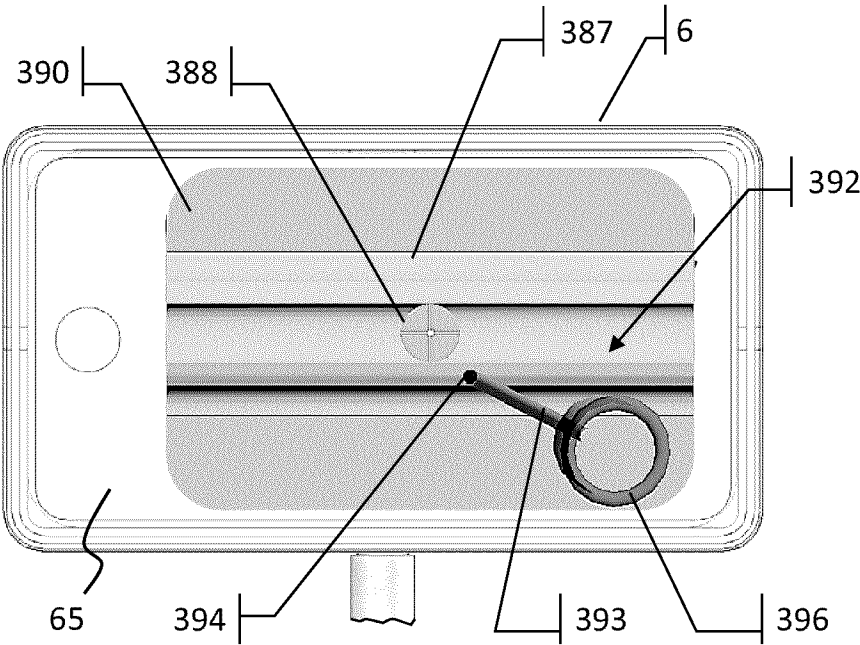


Figure 18

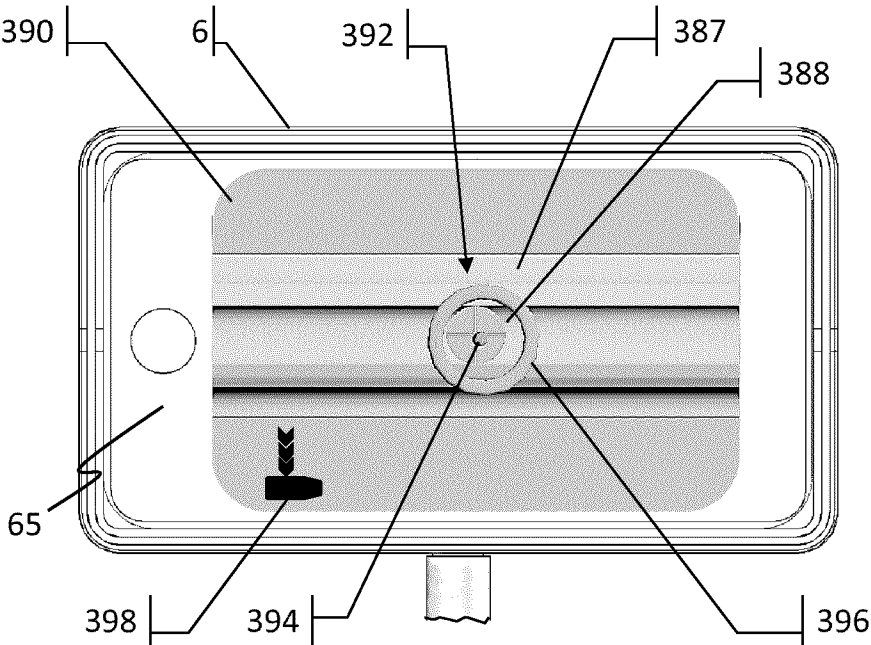


Figure 18a

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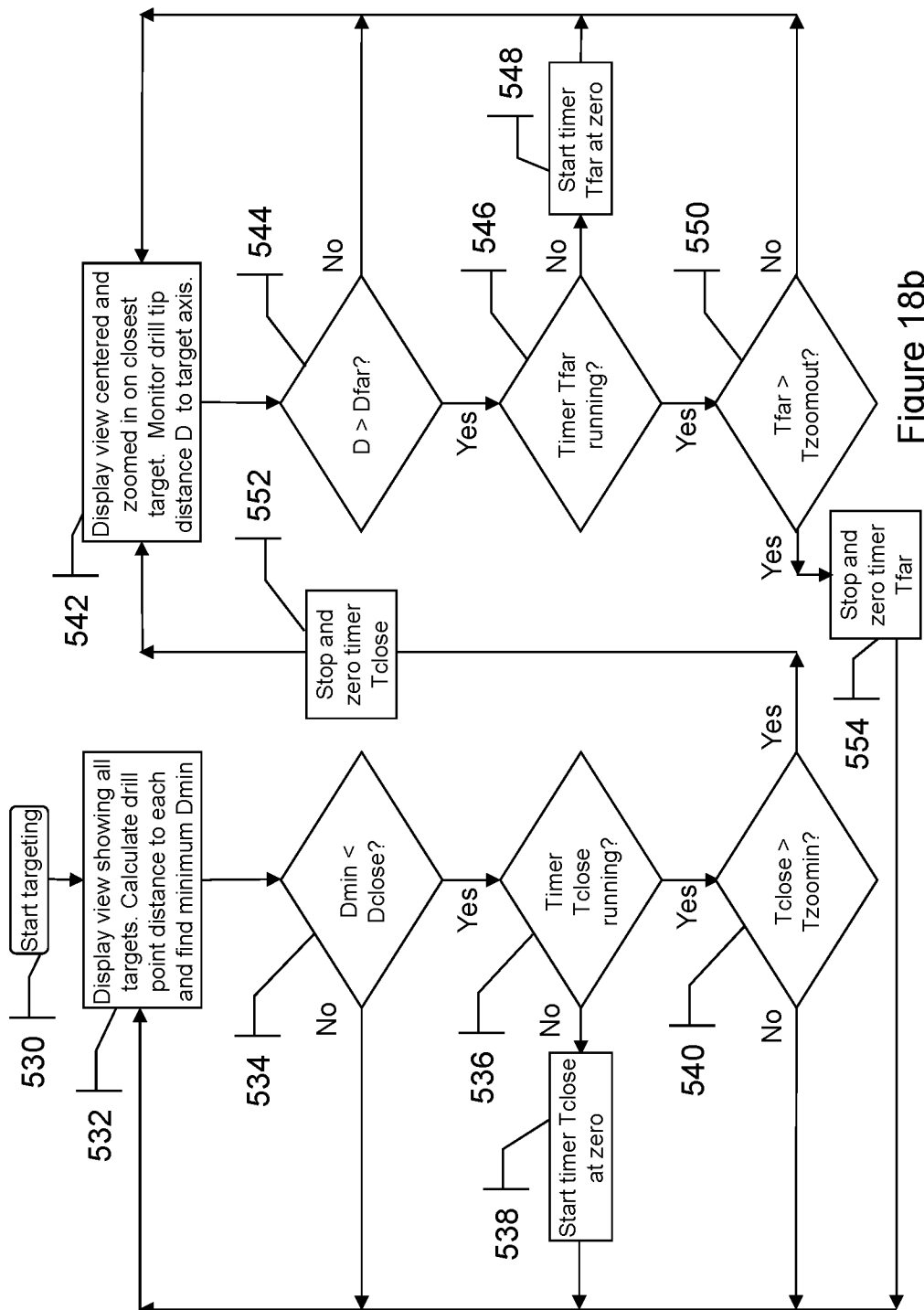


Figure 18b

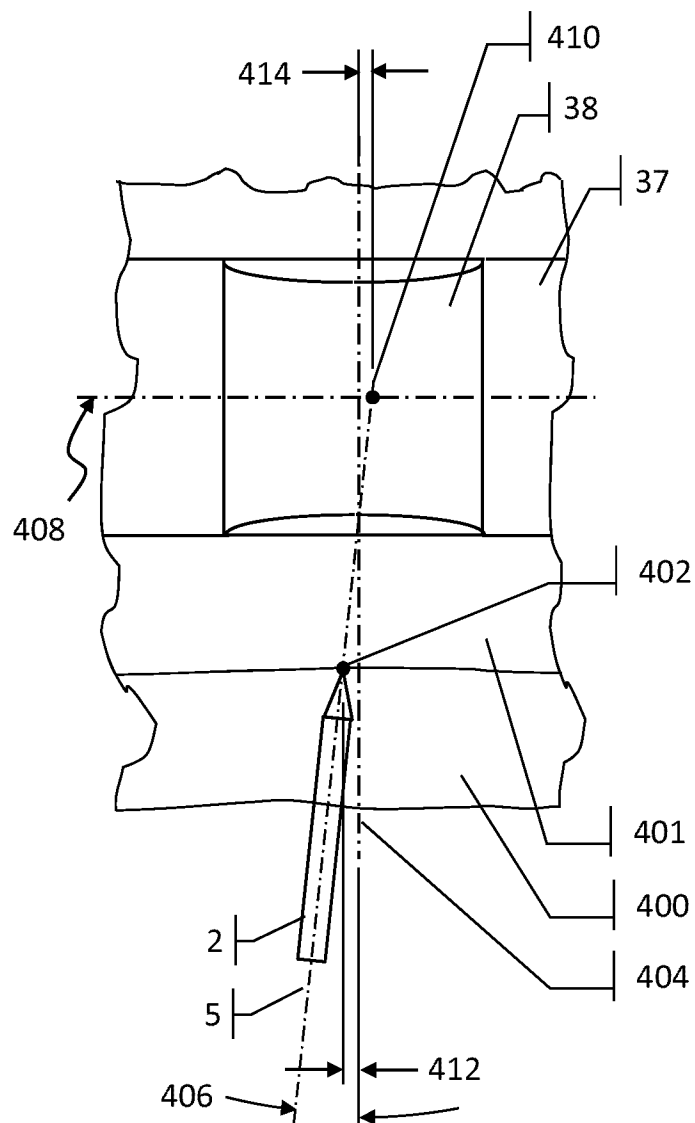


Figure 19

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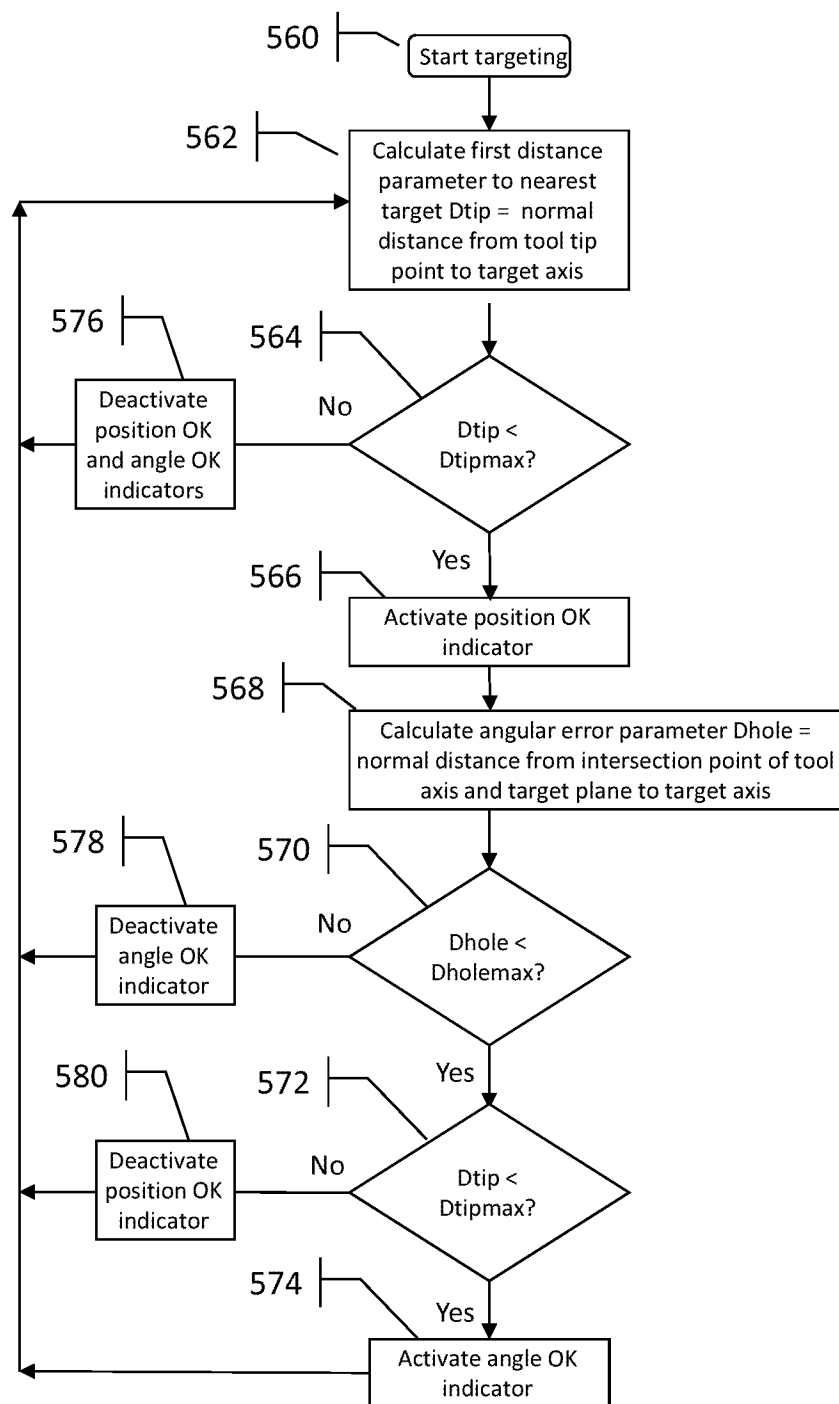


Figure 19a

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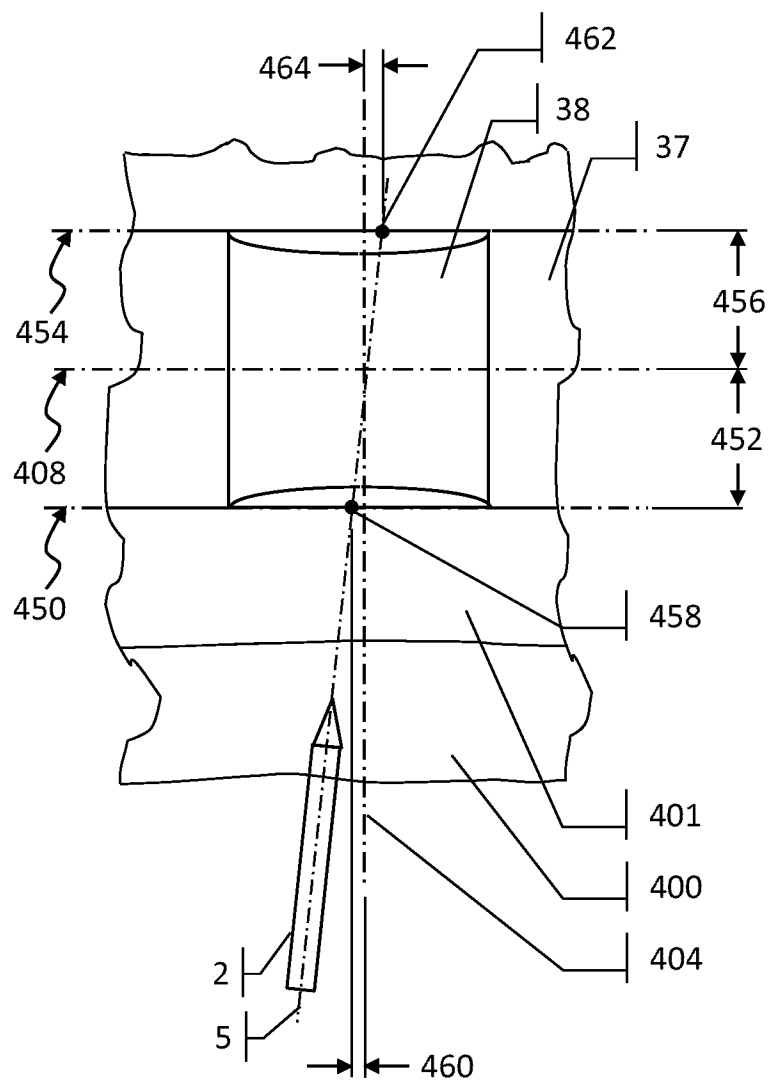


Figure 20

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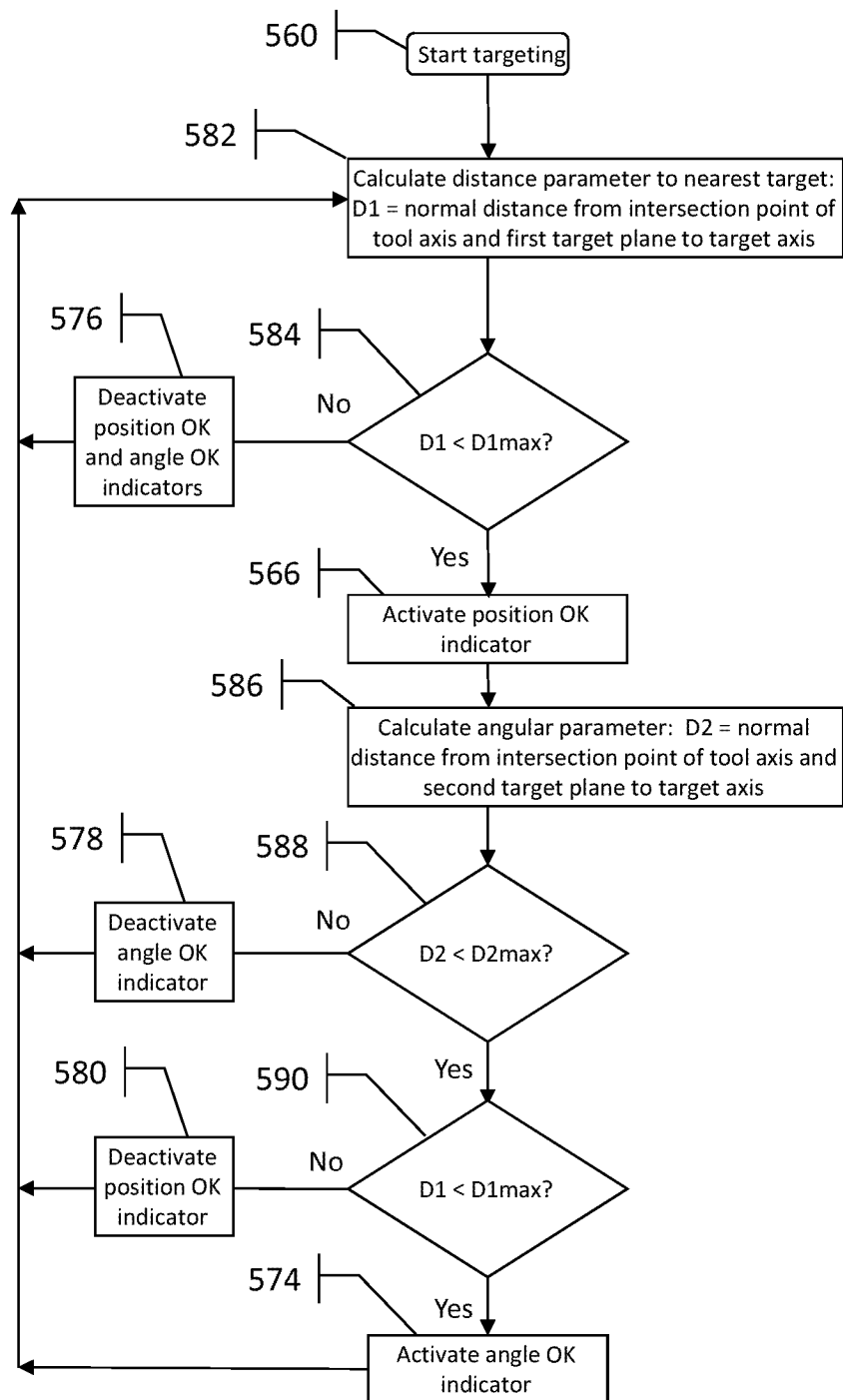


Figure 20a

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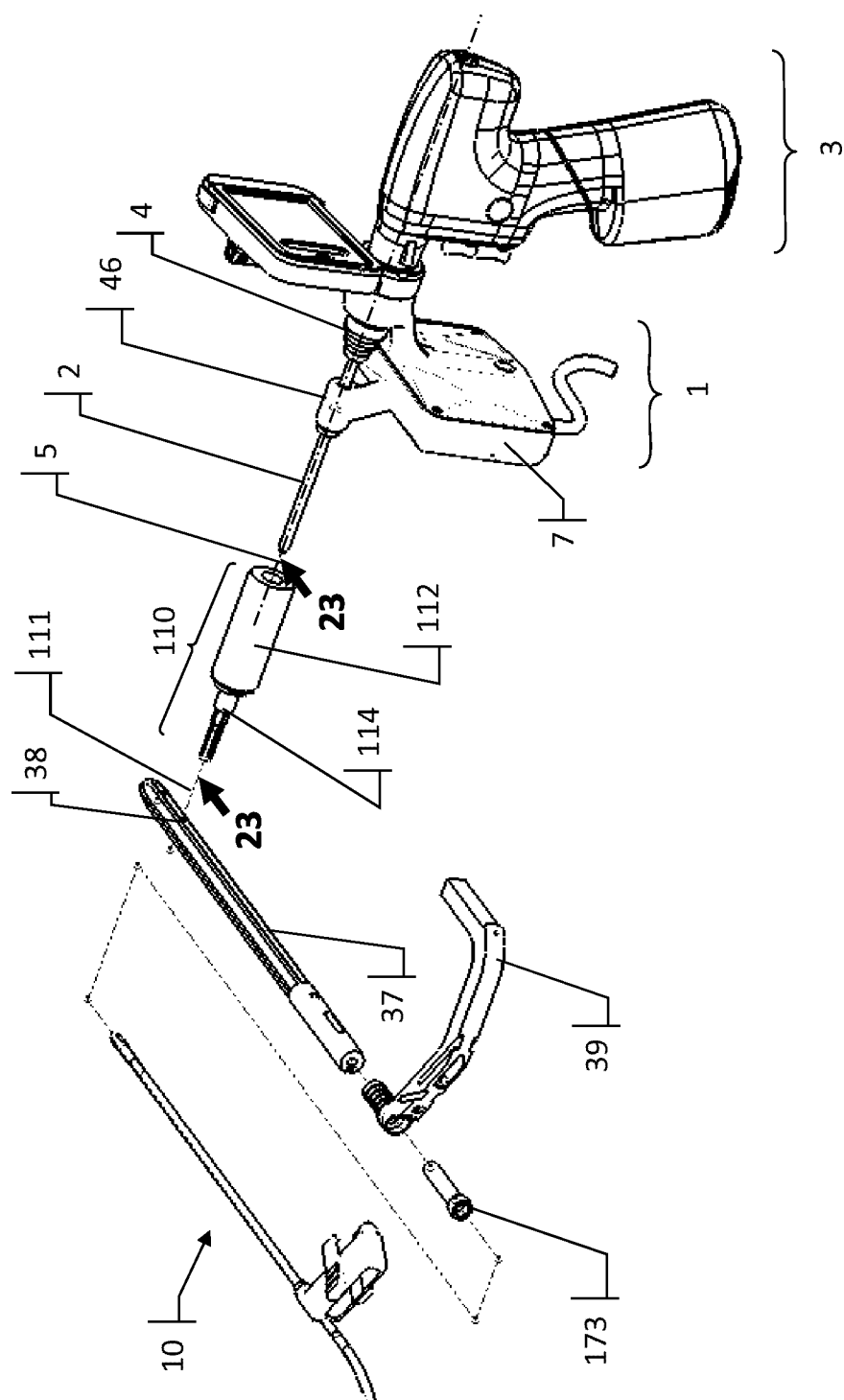


Figure 21

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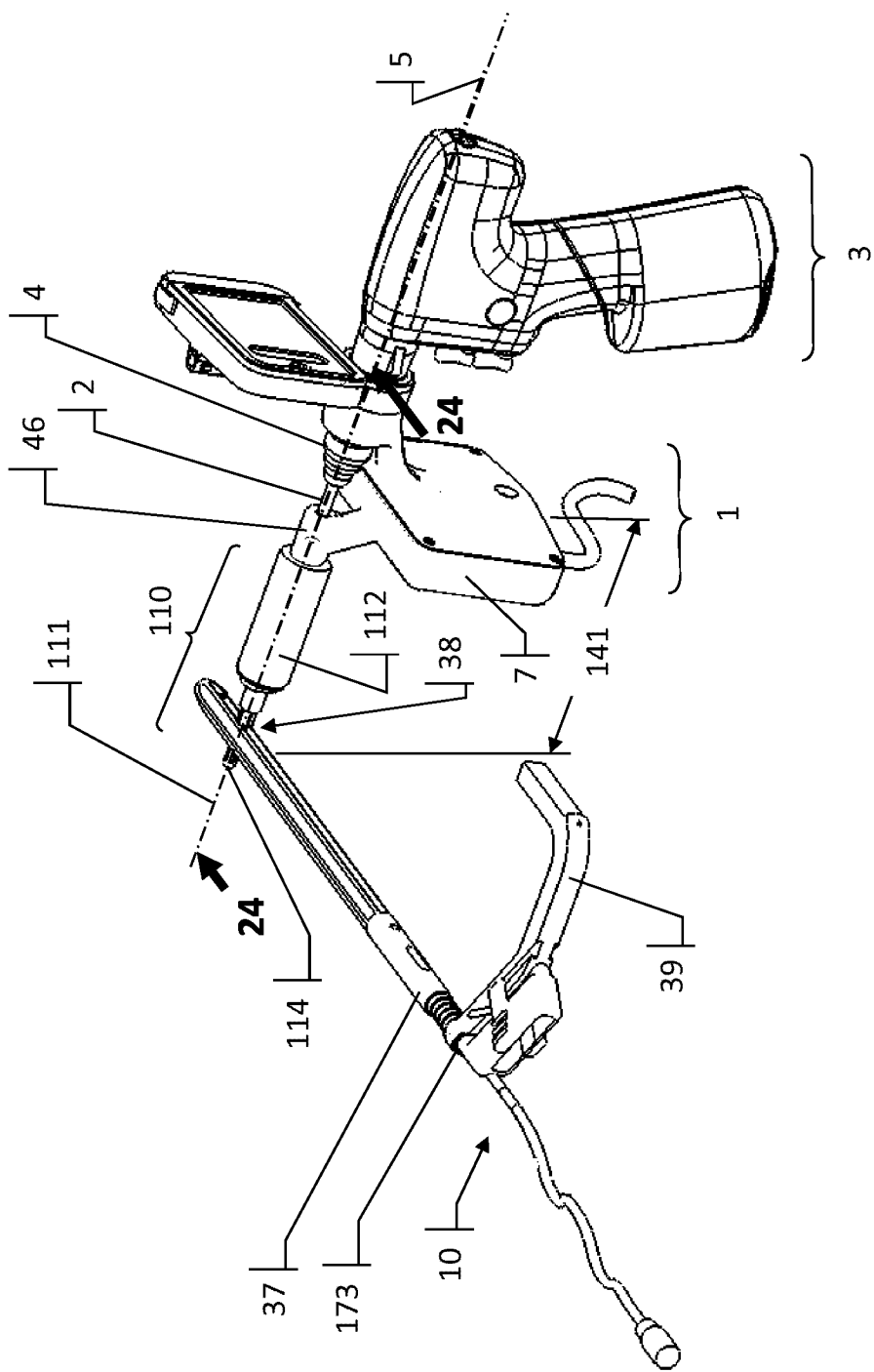


Figure 22

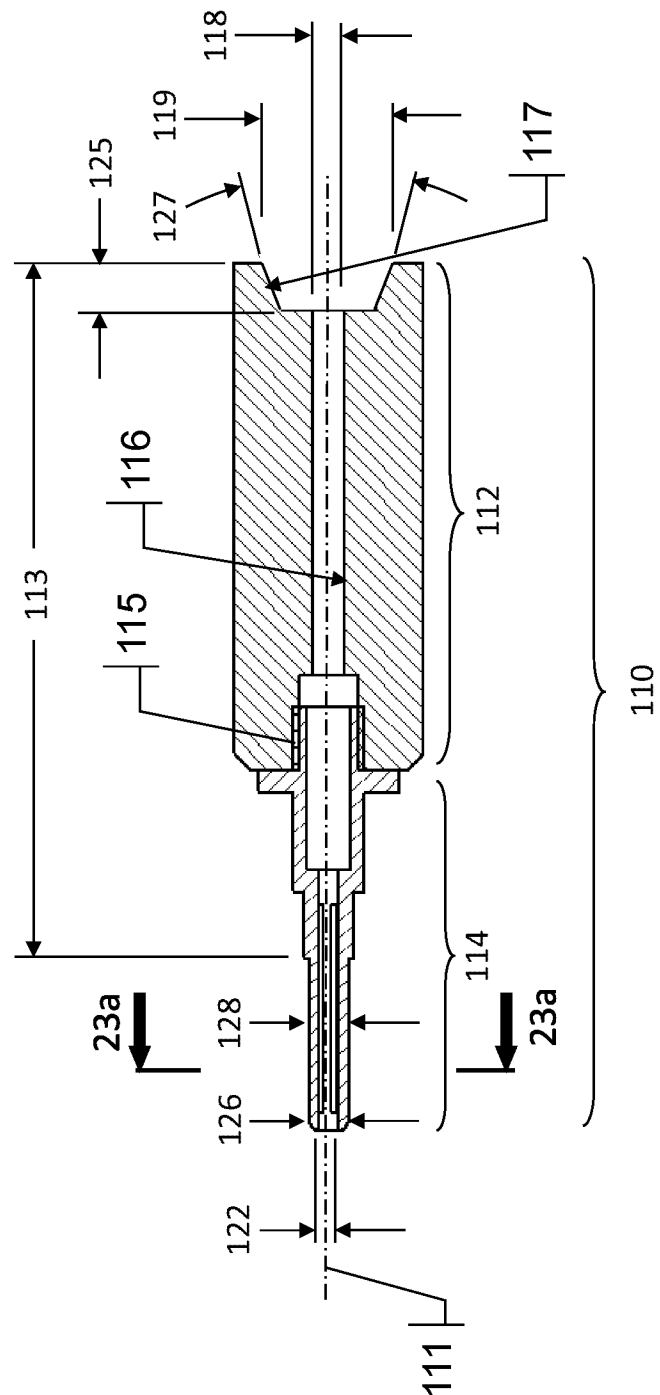


Figure 23

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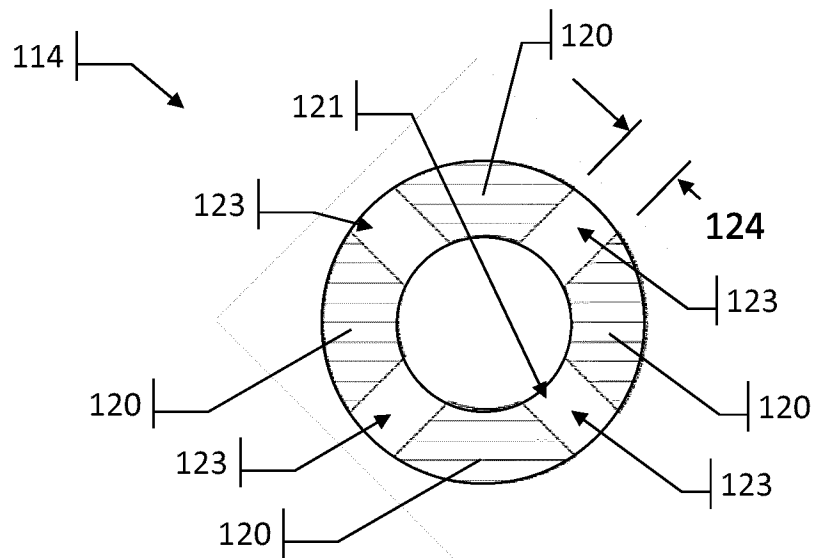


Figure 23a

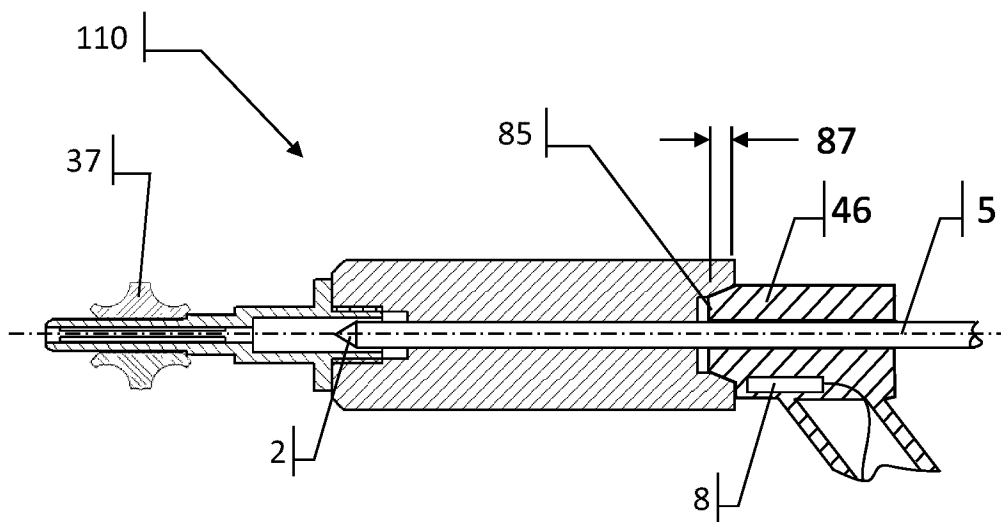


Figure 24

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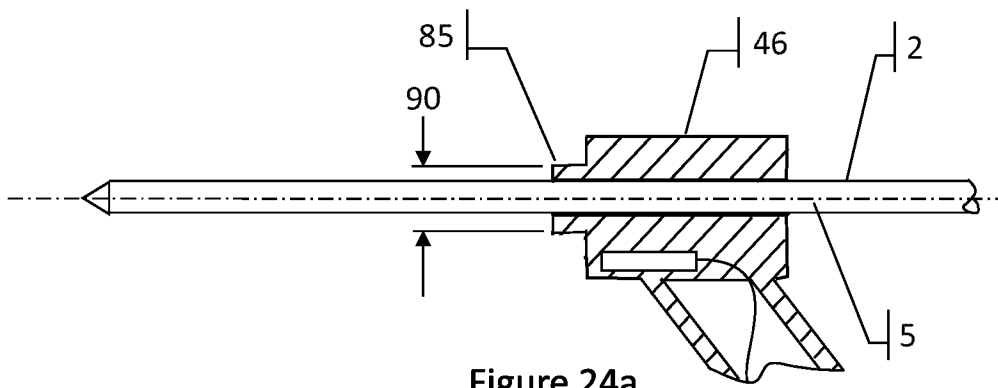


Figure 24a

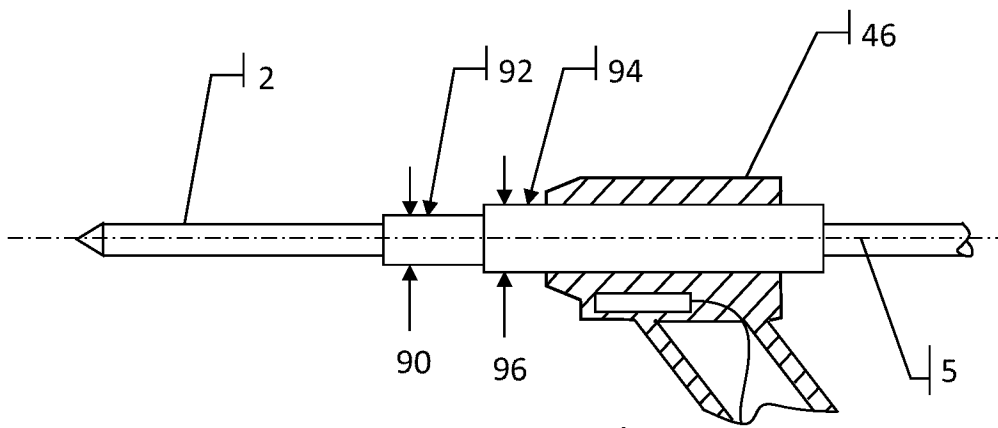


Figure 24b

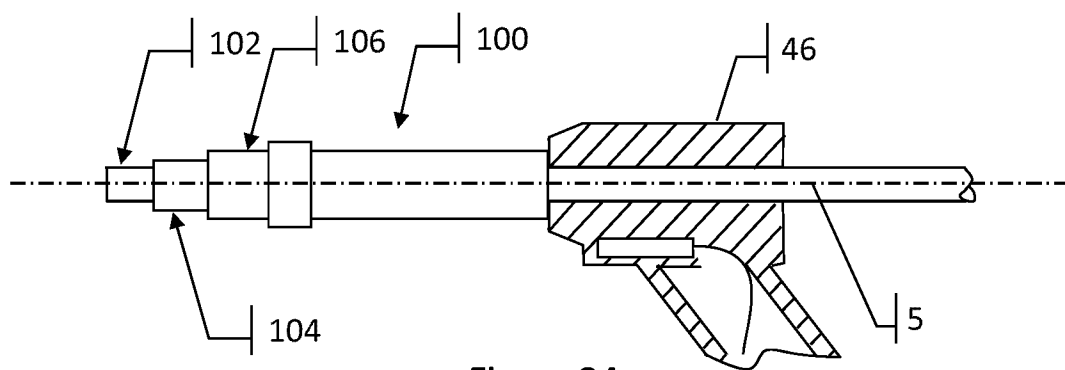


Figure 24c

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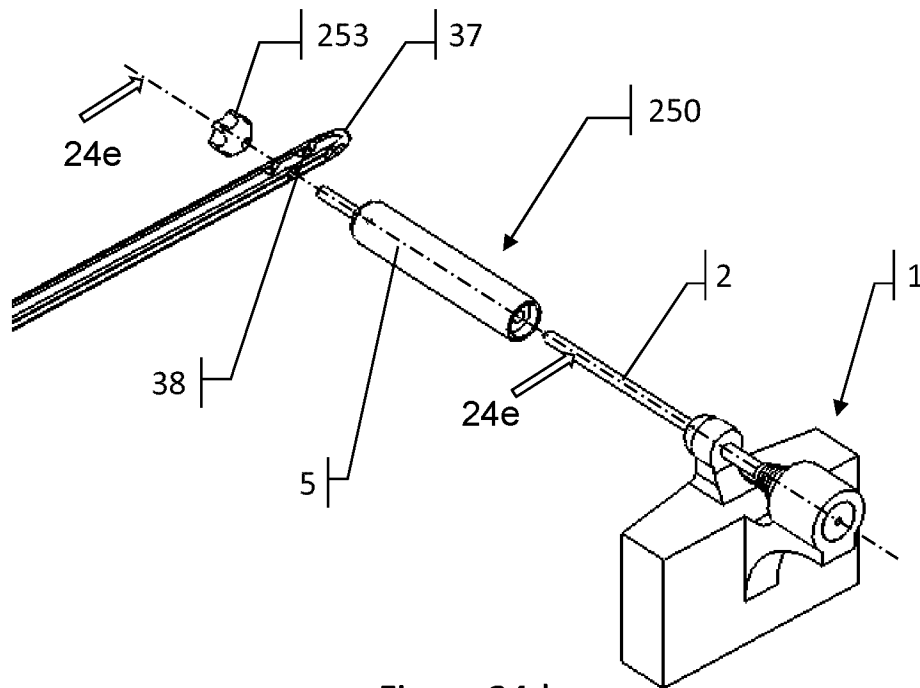


Figure 24d

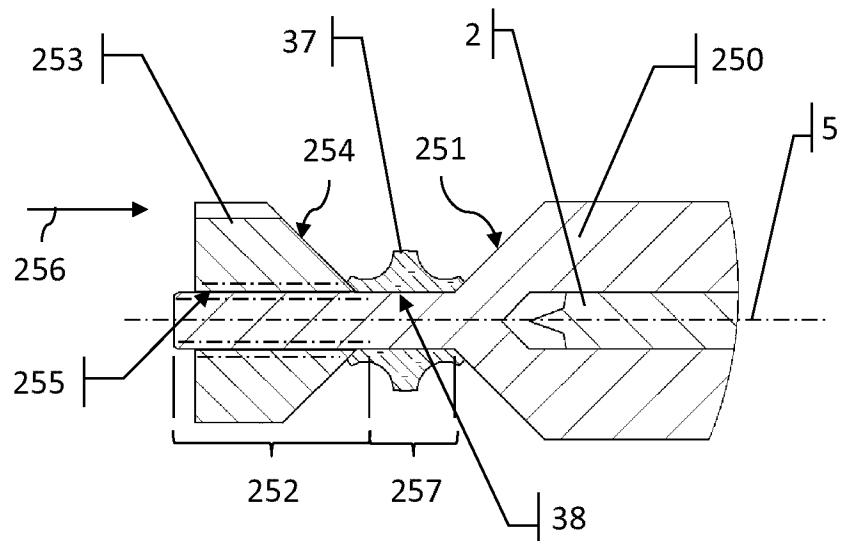


Figure 24e

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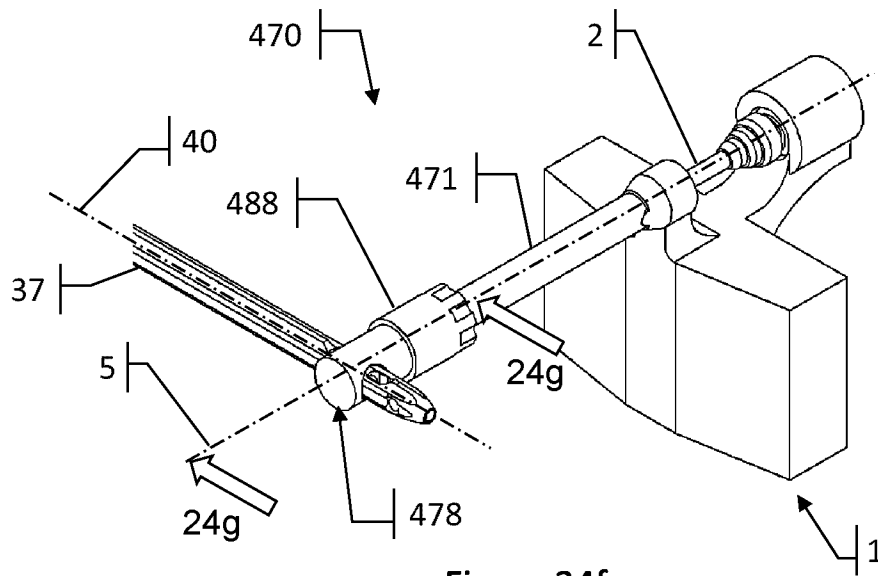


Figure 24f

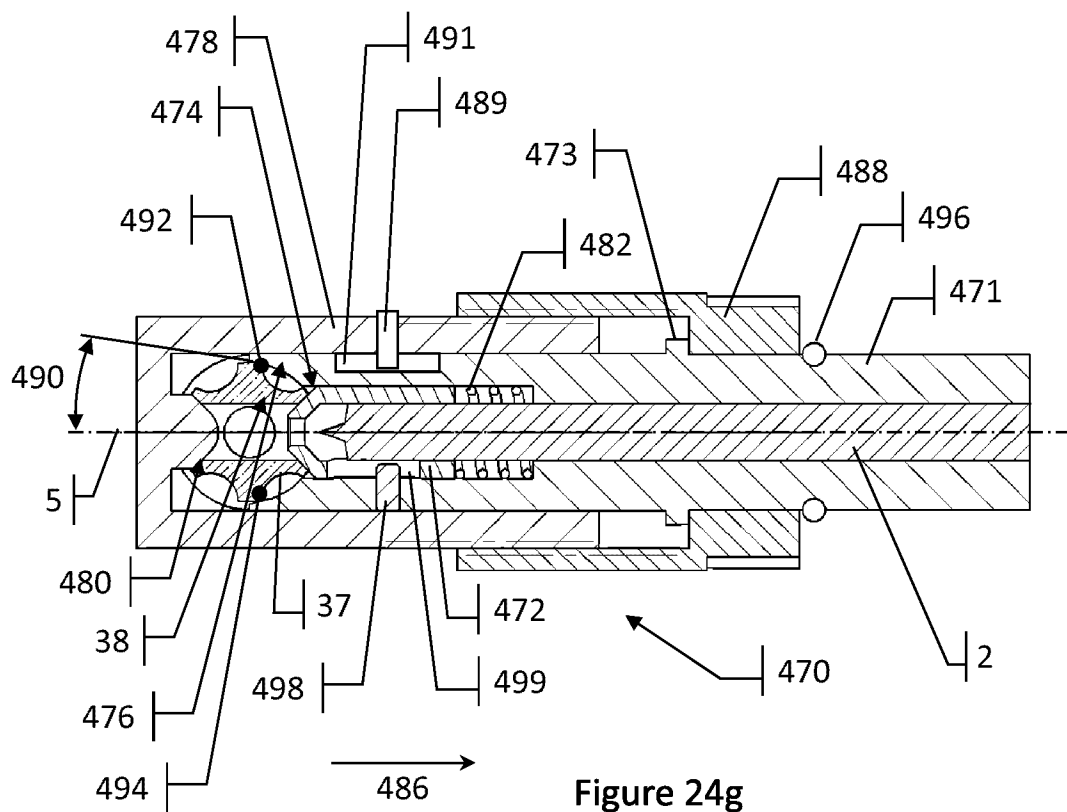


Figure 24g

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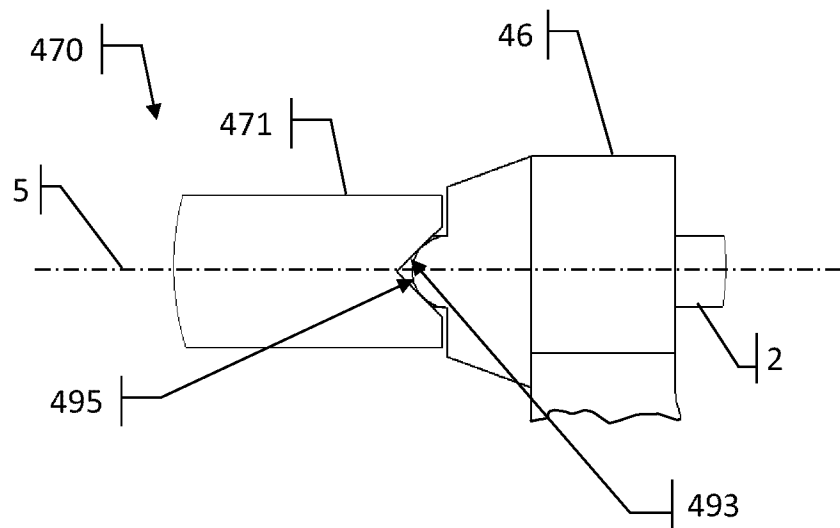


Figure 24h

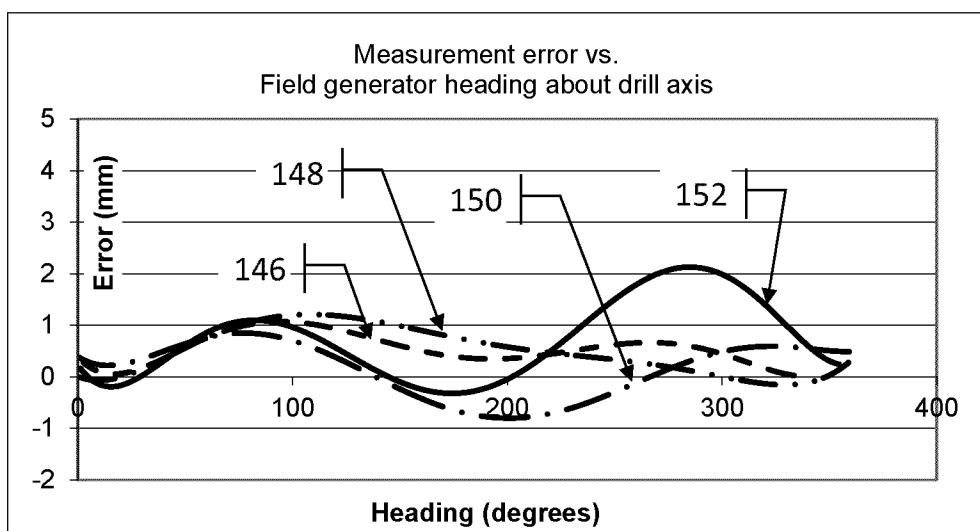


Figure 25

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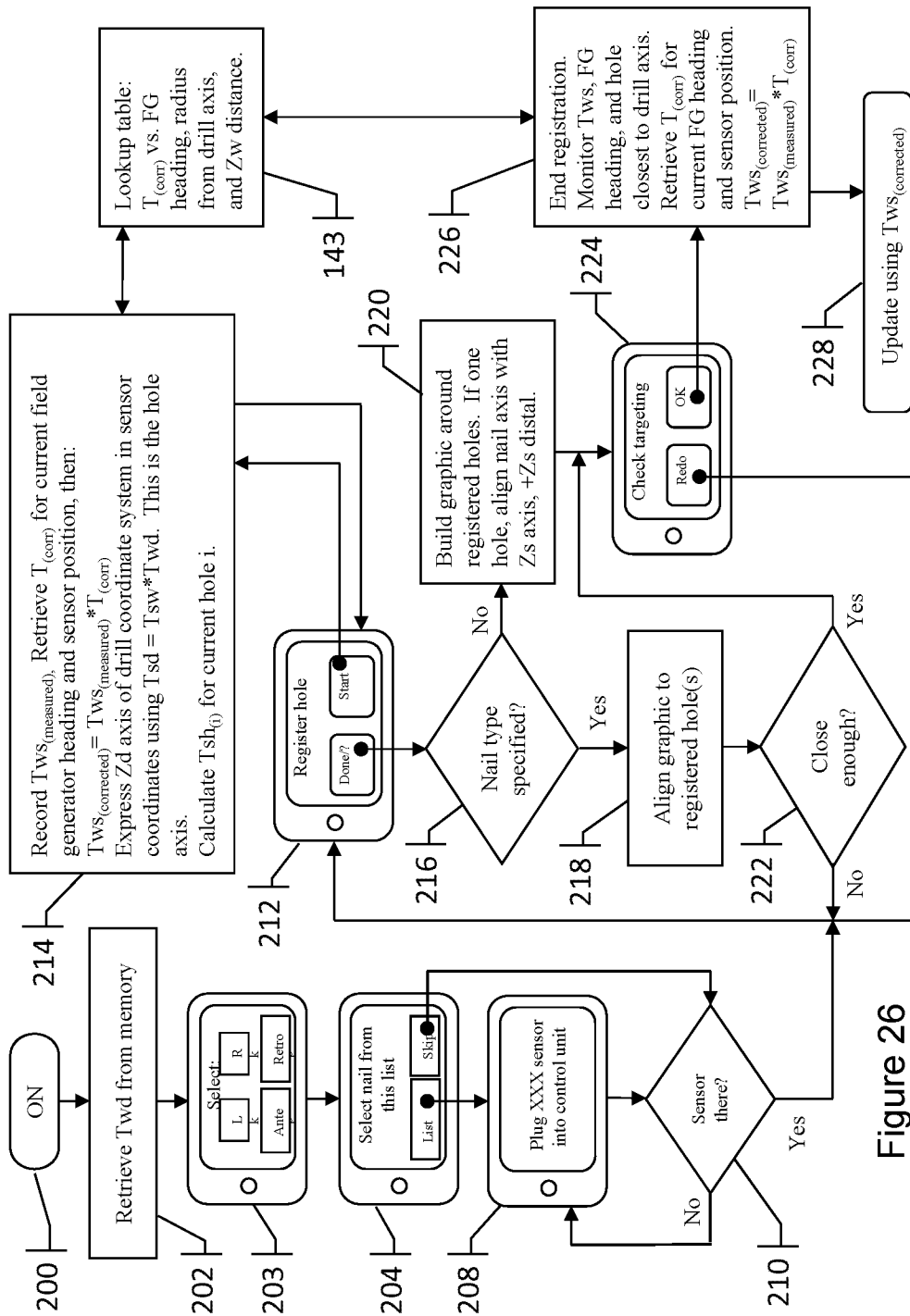


Figure 26

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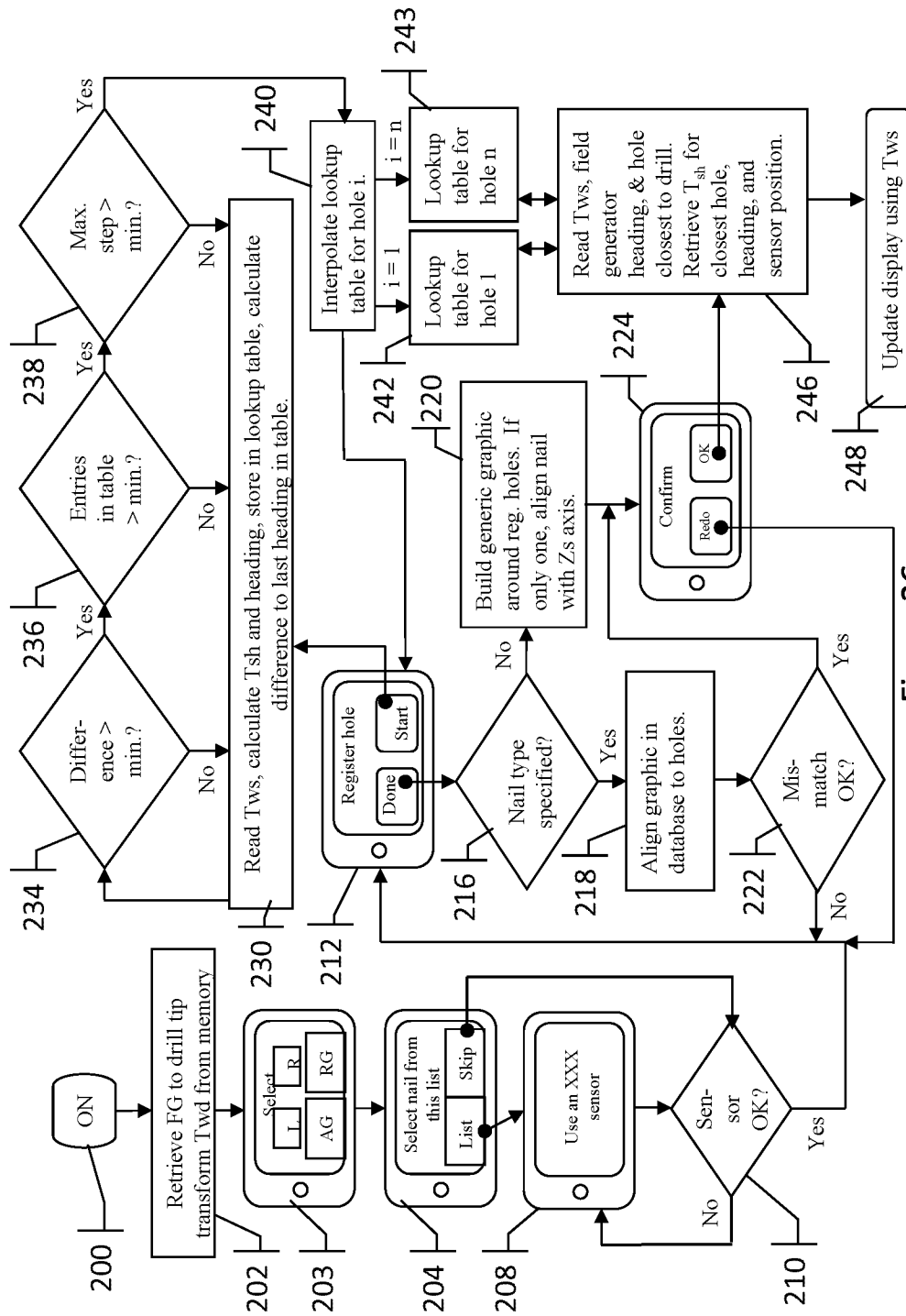


Figure 26a

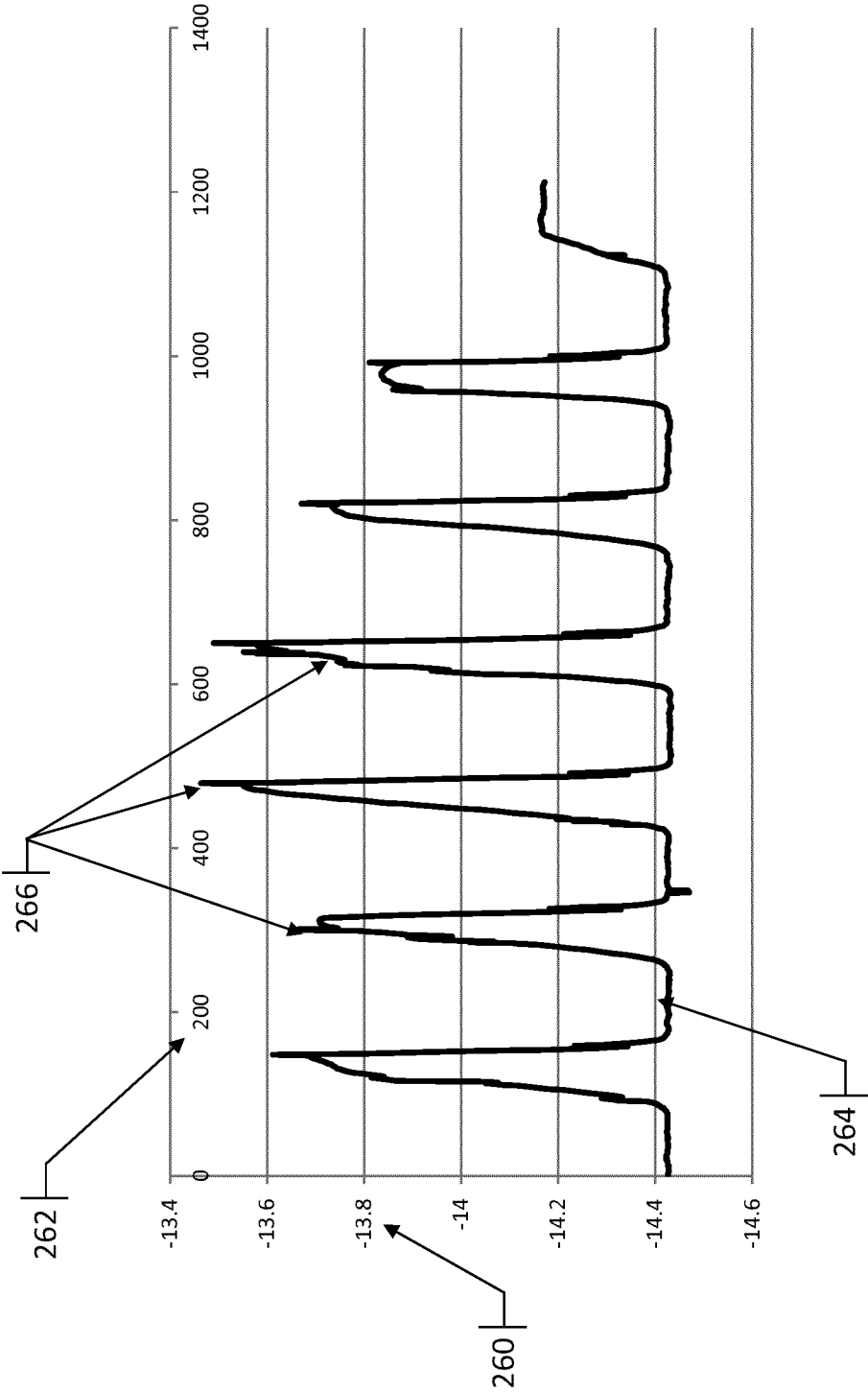


Figure 27

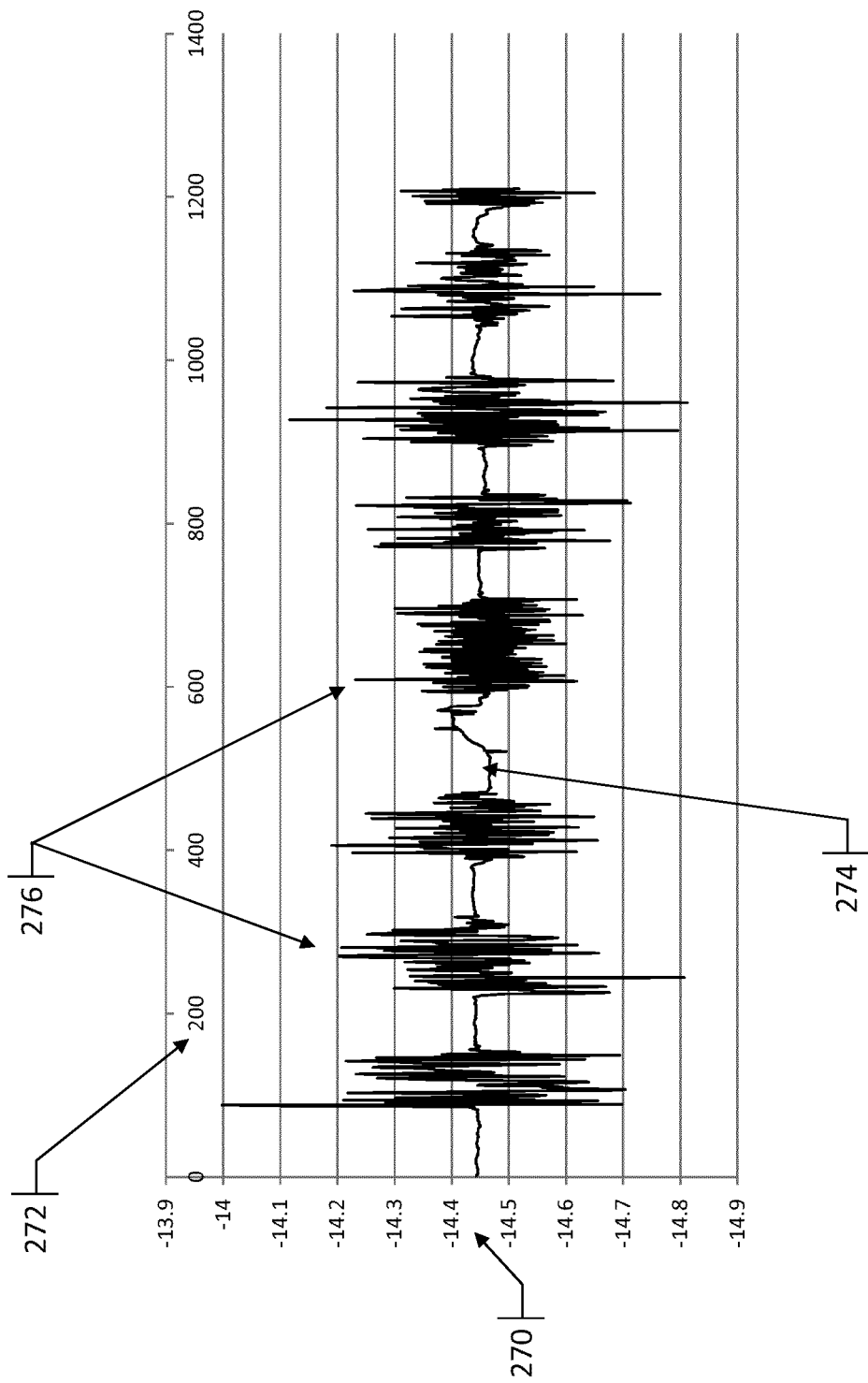


Figure 28

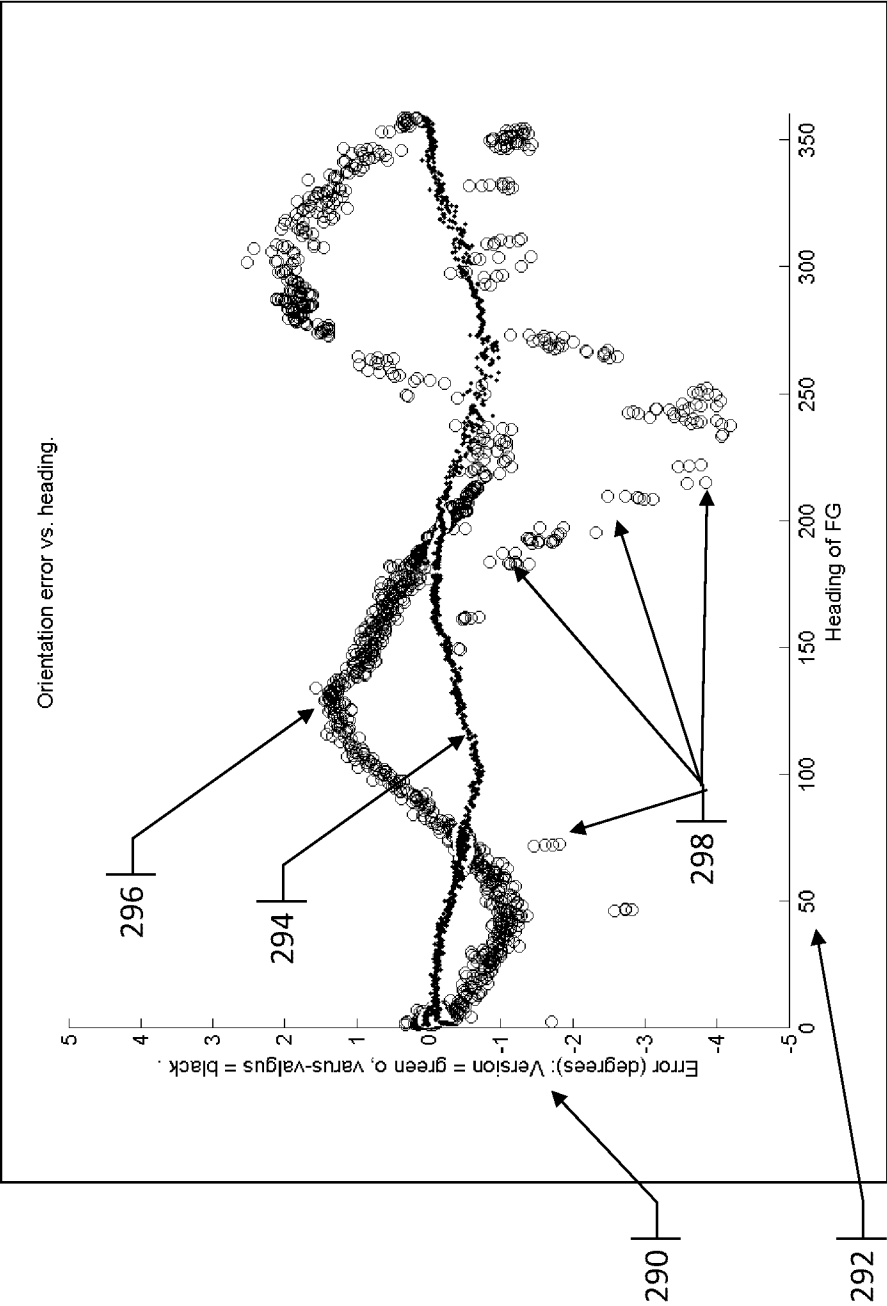


Figure 29

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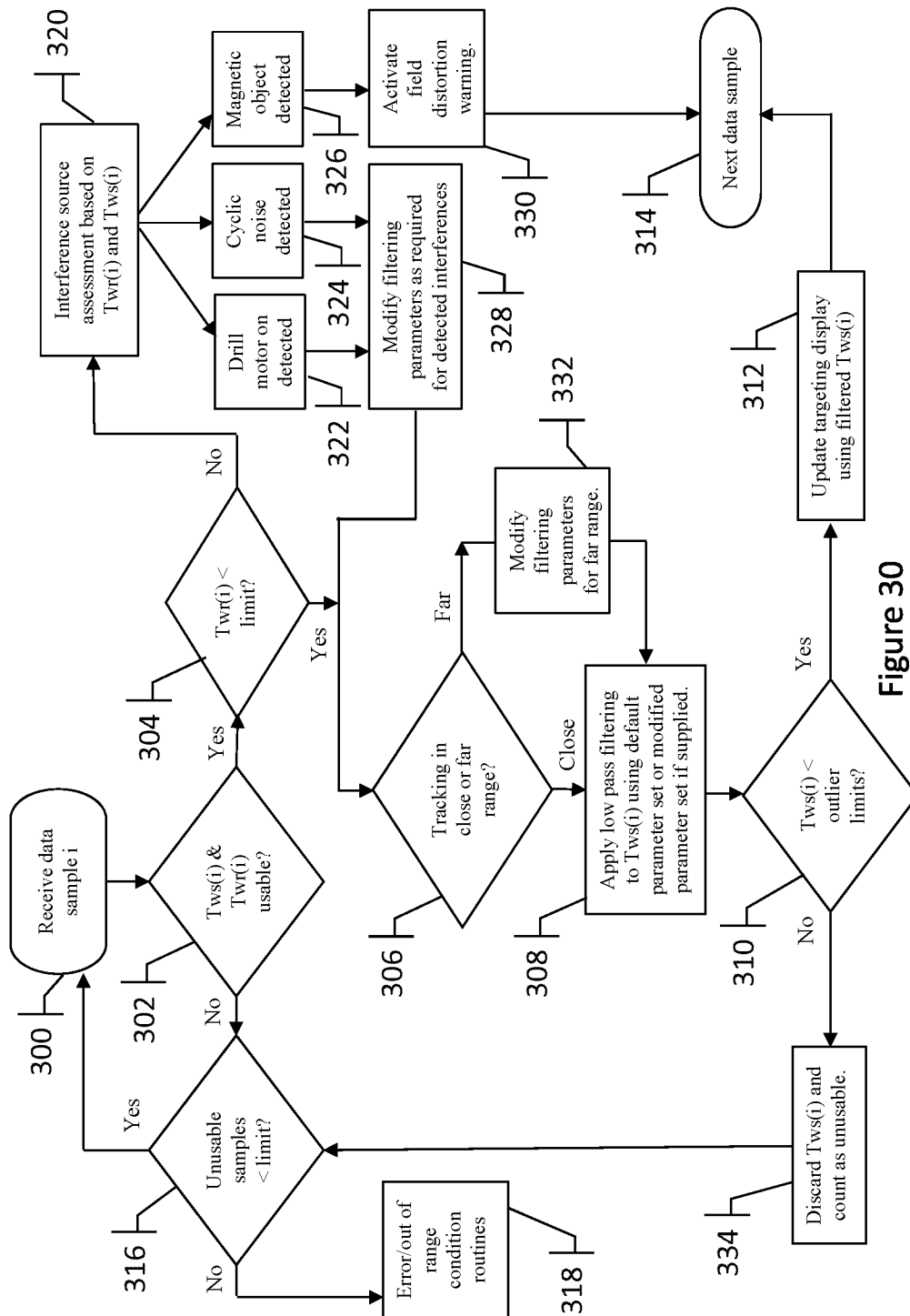


Figure 30

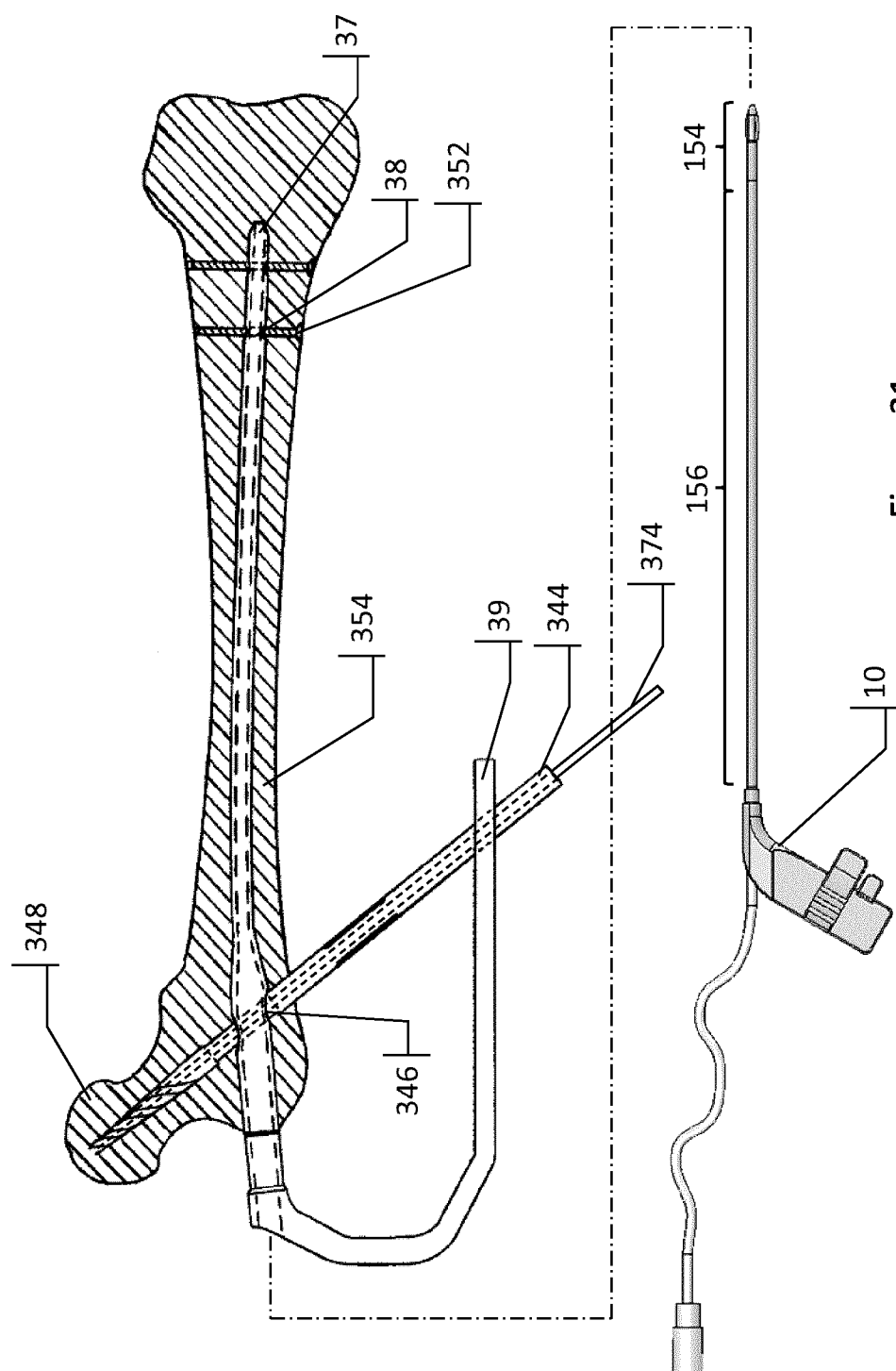


Figure 31

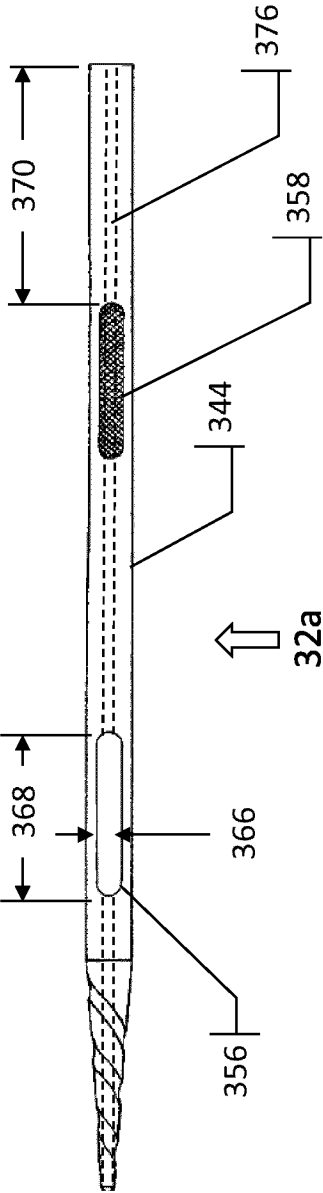


Figure 32

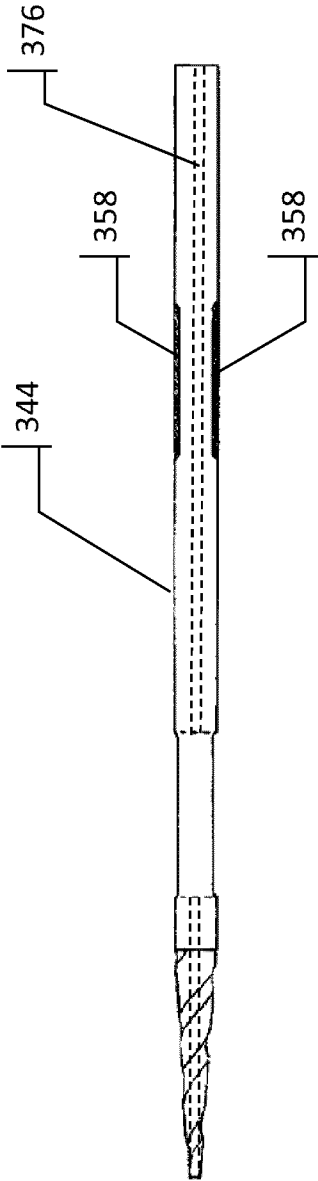


Figure 32a

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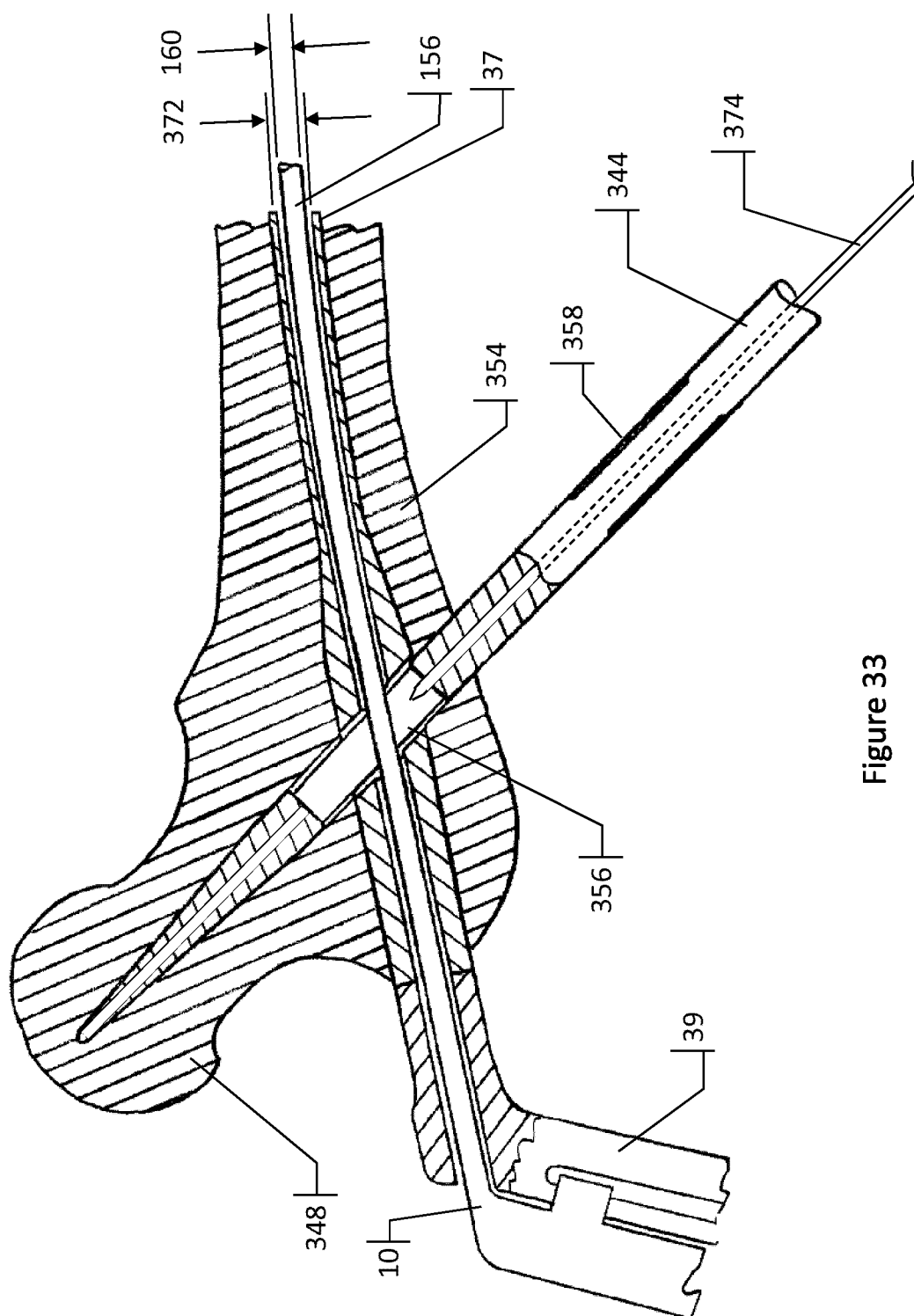
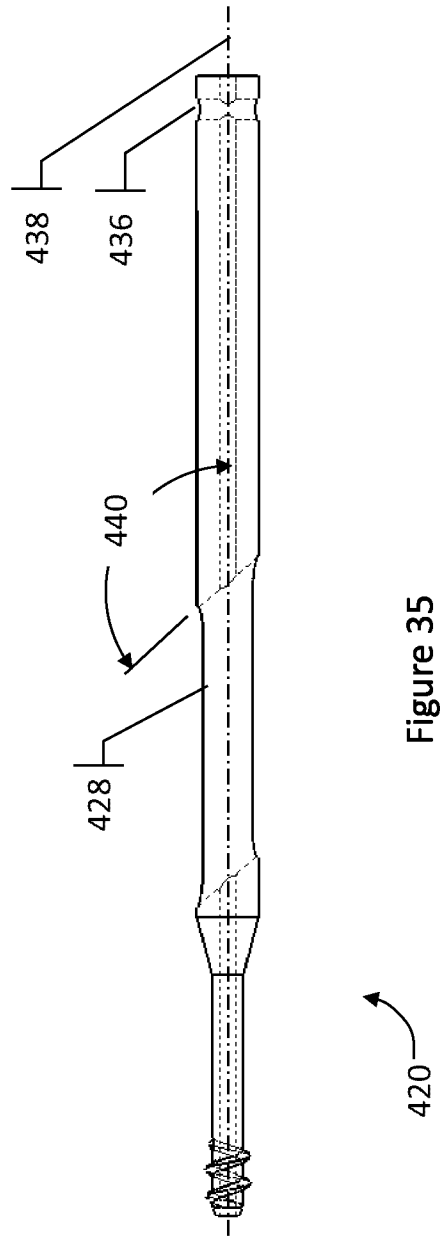
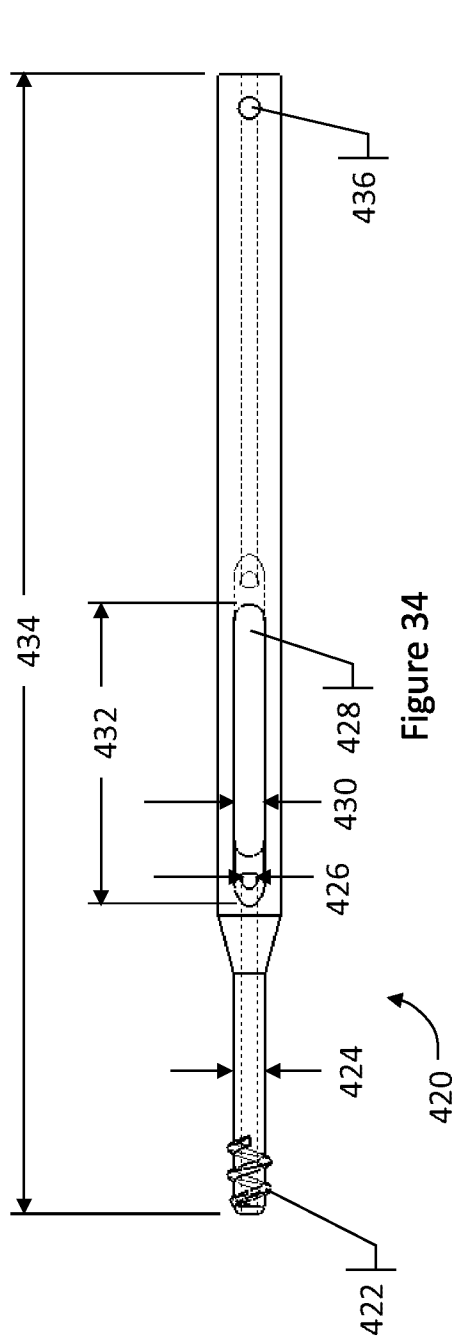


Figure 33



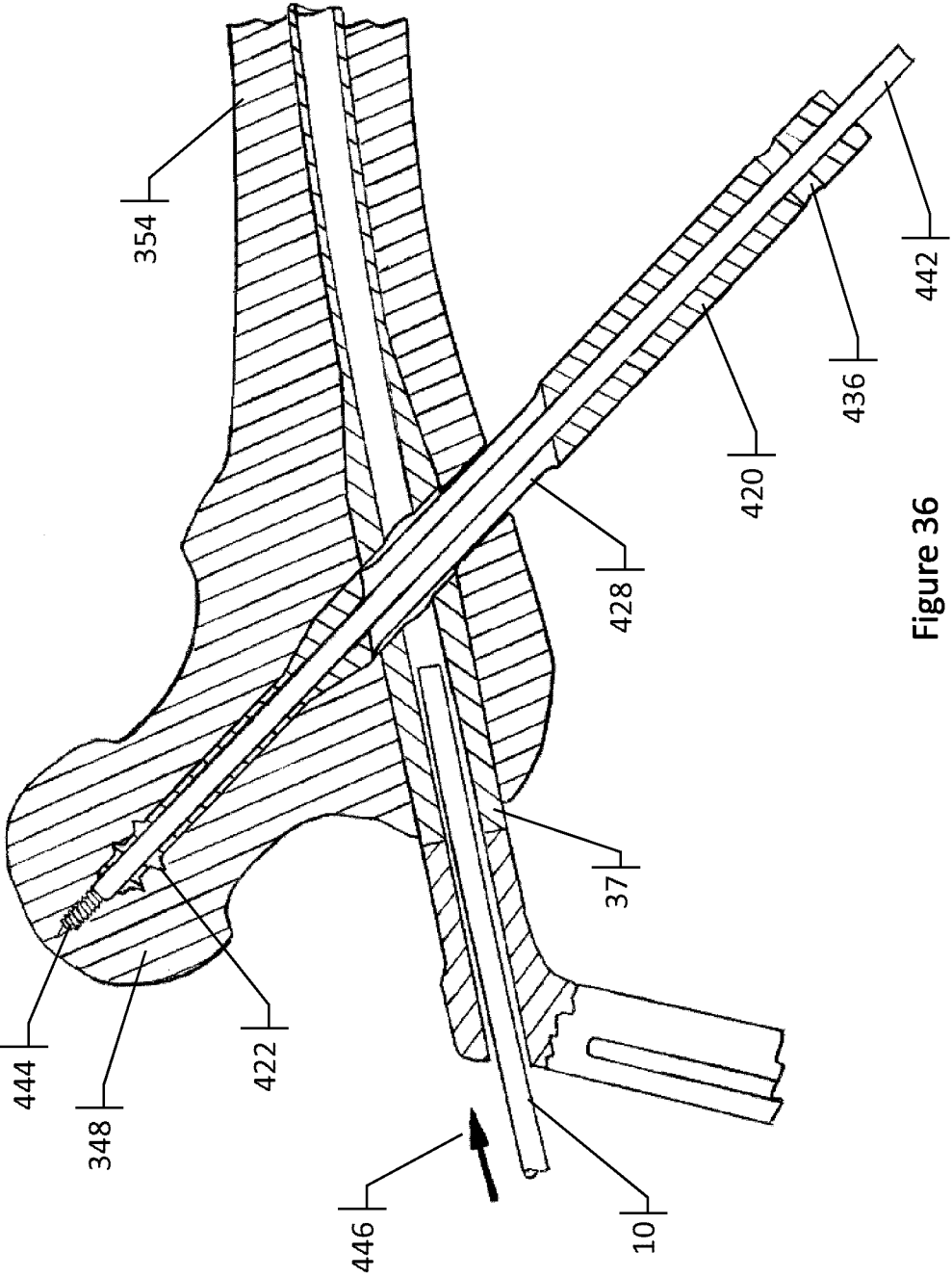


Figure 36

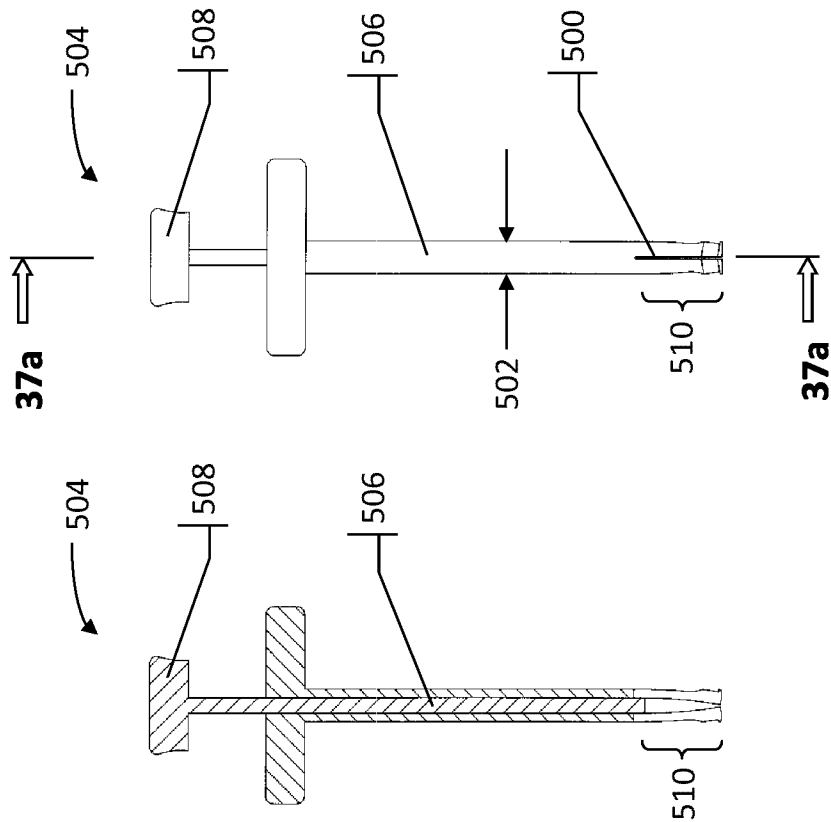


Figure 37

Figure 37a

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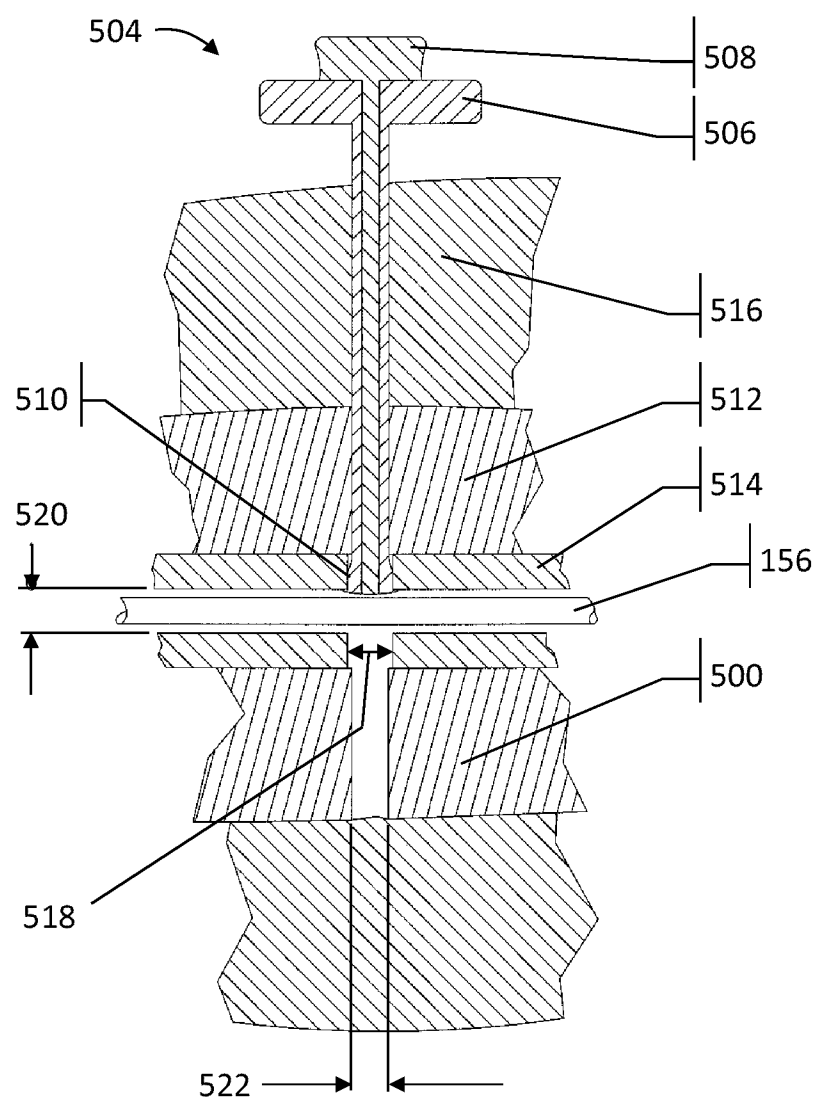


Figure 38

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2012/050098

A. CLASSIFICATION OF SUBJECT MATTER

IPC: **G01B 21/00** (2006.01) , **A61B 17/15** (2006.01) , **A61B 17/17** (2006.01) , **A61B 17/72** (2006.01) , **A61B 17/90** (2006.01) , **A61B 19/00** (2006.01) (more IPCs on the last page)

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)

IPC (2006.01): G01B; A61B; B23Q; G12B

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

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

Canadian Patent Database, Epoque, Total Patent

keywords: hand, tool, field generator, sensor, position, electro-magnet, display, cutter drill saw, motor, correction, navigation, filter, signal, target , indicator, shaft, handle, tip, flex elastic, position

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US2010/0274121 A1 (Ritchey N.S. et al.) 28 October 2010 (28-10-2010) *par. 0085, 0087, Fig. 39*	1-14, 16-19, 23-25, 39-42, 48, 65, 68, 69
X	US2003/0184285 A1 (Anderson P. T. et al.) 02 October 2003 (02-10-2003) *par. 0089, 0096, claims 14, 15 *	1-3, 15, 22, 39, 48, 65, 69
X	US7060075 B2 (Govari A. et al.) 13 June 2006 (13-06-2006) *col. 9, lines 7-12, Fig. 1*	1-3, 9, 10, 19-21, 48
X	WO2010/027109 A1 (Torii Y. et al.) 11 March 2010 (11-03-2010) *Fig. 1, 2; page 14, line 8 - page 18, line 4*	88-92, 94, 95, 100

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

☒ See patent family annex.

* Special categories of cited documents :	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search

14 May 2012 (14-05-212)

Date of mailing of the international search report

14 June 2012 (14-06-2012)

Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, C114 - 1st Floor, Box PCT
50 Victoria Street
Gatineau, Quebec K1A 0C9
Facsimile No.: 001-819-953-2476

Authorized officer

Goran Basic (819) 953-2098

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/CA2012/050098**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the 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. ☐ Claim Nos. :
because they relate to subject matter not required to be searched by this Authority, namely :

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

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

This International Searching Authority found multiple inventions in this international application, as follows :
(see extra sheet)

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying 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 claim Nos. : 1-63, 65-69, 88-100
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 claim 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.

The claims are directed to a plurality of inventive concepts as follows:

Group A - Claims 1-63 are directed to a hand tool comprising a hand-holdable body, a tool member coupled to the body and a field generator coupled to the body.

Group B - Claims 64 and 87 are directed to a tool with integrated navigation apparatus comprising a tool having a tool axis and a tip located on the tool axis, a magnetic field generator wherein the tip point is located in a fixed position relative to the field generator.

Group C - Claims 65-69 are directed to a tool navigation apparatus adapted for aligning a tool with a target feature in a field comprising a first sensor fixed relative to a target and a second sensor fixed relative to the field generator.

Group D - Claims 70-74 are directed to a hand tool comprising a display screen coupled to the tool body.

Group E - Claims 75-83 are directed to a method for calibrating a system comprising a hand tool and a position sensing system comprising the step of providing on the hand tool a probe member having a fixed position and orientation on the hand tool.

Group F - Claims 84-86 are directed to a registration apparatus for use in calibrating a system comprising a hand tool and a position sensing system.

Group G - Claim 88-100 is directed to a sensor tool comprising a shaft and a tip portion at the distal end of the shaft including at least one flexible elastic member.

Group H - Claims 101-105 are directed to a sensor tool adapted for insertion into a first feature of an orthopaedic implant having a target feature, the sensor tool comprises a tip portion compressible to fit into first features having sizes within a range of sizes.

Group I - Claim 106 is directed to a sensor tool adapted for an attachment to an insertion tool rigidly connected to an orthopaedic implant.

Group J - Claims 107-109 are directed to a method for providing a visual feedback regarding the position and orientation of a tool relative to a target comprising the step of setting a value of a magnification factor that determines displayed sizes of the target graphic element and the tool graphic element.

Group K - Claims 110-114 are directed to a method for providing a visual feedback regarding the position and orientation of a tool relative to a target feature comprising the step of suppressing display of the alignment indicator whenever the first relative position parameter has a value outside of the predetermined range.

Group L - Claims 115-119 are directed to a visual user interface comprising a display and an interface controller.

Group M - Claims 120-125 are directed to a fixation element and apparatus adapted for fixation of a bone fragment.

Group N - Claim 126 is directed to a method for communicating information to a user of a hand held tool comprising the steps of monitoring a relative position of a tool and a component, monitoring a rate of cutting and displaying indicia indicating deviations from a desired rate of cutting.

Group O - Claims 127-131 are omnibus type claims.

The claims must be limited to one inventive concept as set out in Rule 13 of the PCT.

Additional IPC classes:

B23Q 16/00 (2006.01) , **B23Q 17/00** (2006.01) , **G01B 7/00** (2006.01) , **G12B 11/00** (2006.01)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2012/050098

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US2010274121A1	28 October 2010 (28-10-2010)	AU2008221332A1 AU2010245015A1 AU2010245179A1 CA2678369A1 CA2716836A1 CA2759694A1 CN101621966A CN102014771A EP2424455A2 EP2424459A2 JP2010519971A JP2011528917A KR20120013392A US2010145337A1 US2010152566A1 US2010152573A1 US2010274256A1 US2011208037A1 US2011288600A1 US2012035468A1 US2012101361A1 WO2010129141A2 WO2010129141A3 WO2010129308A2 WO2010129308A3	04 September 2008 (04-09-2008) 10 November 2011 (10-11-2011) 10 November 2011 (10-11-2011) 04 September 2008 (04-09-2008) 03 September 2009 (03-09-2009) 11 November 2010 (11-11-2010) 06 January 2010 (06-01-2010) 13 April 2011 (13-04-2011) 07 March 2012 (07-03-2012) 07 March 2012 (07-03-2012) 10 June 2010 (10-06-2010) 01 December 2011 (01-12-2011) 14 February 2012 (14-02-2012) 10 June 2010 (10-06-2010) 17 June 2010 (17-06-2010) 17 June 2010 (17-06-2010) 28 October 2010 (28-10-2010) 25 August 2011 (25-08-2011) 24 November 2011 (24-11-2011) 09 February 2012 (09-02-2012) 26 April 2012 (26-04-2012) 11 November 2010 (11-11-2010) 20 January 2011 (20-01-2011) 11 November 2010 (11-11-2010) 24 March 2011 (24-03-2011)
US2003184285A1	02 October 2003 (02-10-2003)	US2003184285A1 US6774624B2 US2004107070A1 US6980921B2 US2005165297A1 US7096148B2 US2007055125A1 US7835779B2	02 October 2003 (02-10-2003) 10 August 2004 (10-08-2004) 03 June 2004 (03-06-2004) 27 December 2005 (27-12-2005) 28 July 2005 (28-07-2005) 22 August 2006 (22-08-2006) 08 March 2007 (08-03-2007) 16 November 2010 (16-11-2010)
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WO2010027109A1	11 March 2010 (11-03-2010)	CN102149312A EP2339950A1 JP2010063483A JP2010063484A JP2010075319A JP2010075320A KR20110066137A	10 August 2011 (10-08-2011) 06 July 2011 (06-07-2011) 25 March 2010 (25-03-2010) 25 March 2010 (25-03-2010) 08 April 2010 (08-04-2010) 08 April 2010 (08-04-2010) 16 June 2011 (16-06-2011)