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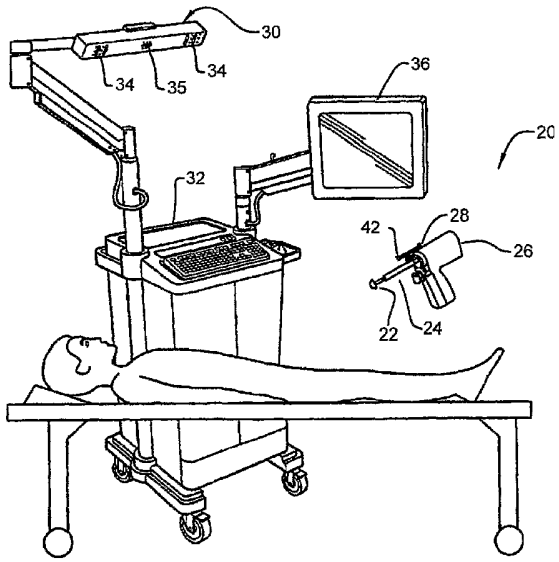
(54) Title: WIRELESS SYSTEM FOR PROVIDING INSTRUMENT AND IMPLANT DATA TO A SURGICAL NAVIGATION UNIT




(57) Abstract: A system for wirelessly providing data regarding surgical implements such as surgical tools, trial and inserts themselves to a surgical navigation unit. Each implement includes an RFID (74) in which data regarding the implement are stored. The tool used to fit the implement has a first coil (96) positioned to exchange signals with a complementary coil (80) integral with the RFID.The tool also has a prism (46) for receiving a navigation tracker (28). A second tool coil, in the prism, is connected to the first coil. The second coil is also connected to an RFID integral with the tool. The tracker, through the tool coils, reads the data in the implement RFID and the tool RFID. A transmitter (194) in the tracker wirelessly forwards the data to the surgical navigation system (20). The data are used to facilitate reactive workflow guidance of the procedure and monitor the position of the implement.

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# WIRELESS SYSTEM FOR PROVIDING INSTRUMENT AND IMPLANT DATA TO A SURGICAL NAVIGATION UNIT

## FIELD OF THE INVENTION

**[0001]** This invention is generally directed to a surgical navigation system. More particularly, this invention is directed to a system for providing a surgical navigation system with information about the surgical instruments, surgical devices and implants tracked by the system without wired connections to the instruments, devices and implants.

## BACKGROUND OF THE INVENTION

**[0002]** Surgical navigation systems have become extremely useful tools in operating rooms. Generally, a surgical navigation system consists of one or more trackers. Each tracker is attached to a specific surgical instrument, device or implant. The system also includes a localizer. Each tracker generates one or more specific signals. These signals may be radio signals, other EM signals, light signals or ultrasonic signals. The localizer monitors from where the signals are broadcast. The tracker location-identifying signals obtained by the localizer are forwarded to a processor. Based on the data contained in these signals, including their signal strength and relative phases, the processor generates data indicating the position of the tracker and the attached component. Either prior to or at the start of the procedure, the processor is provided with data identifying the relative positions of tissue landmarks at the surgical site. The processor also has data that indicates the location of the surgical site relative to

the localizer. Based on the above data, the processor provides information about the location of the surgical component attached to the tracker relative to the surgical site. Often this information is presented on a display that shows the position of the surgical component at a location within the patient. A surgical navigation system thus provides a view of the location of a surgical component at surgical site that, due to the presence of surrounding tissue, otherwise cannot be seen.

**[0003]** During the performance of a surgical procedure, a number of different instruments and other components are typically positioned at a surgical site. For example, during a procedure to implant an orthopedic implant, a first set of tissue cutting devices are used to gain access to the surgical site. A second set of devices are used to remove the bone and surrounding soft tissue that are to be replaced. A third set of devices shape the remaining tissue, typically the bone, so it can accept the implant. Often, trial implants are positioned at the surgical site to determine the appropriately sized implant components that should be permanently fitted to the patient. Then, the positions of the implant components themselves are tracked. Once an implant is fitted, the position of the instruments used to close the surgical site are tracked. Each of these of these instruments, implants and other components has a set of unique physical dimensions. For the surgical navigation system to accurately generate data indicating the location of a component relative to the surgical site, the system processor must have data describing component's dimensions.

**[0004]** The Applicant's U.S. Patent Application No. 10/214,937, filed August 8, 2002, U.S. Patent

Publication No. US 2003/0093103 A1, now U.S. Patent No. _____, and incorporated herein by reference, discloses one system for providing a surgical navigation unit with data regarding the individual components applied to a surgical site. In the invention of this system, a radio frequency identification device (RFID) is attached to each component. Internal to the RFID is a memory in which data regarding the component are stored. These data identify the component and/or the physical dimensions of the component. The component also includes a coil through which the RFID is capable of exchanging signals. Prior to use, the component is attached to a handpiece. The handpiece is attached to some sort of control console. Internal to the handpiece is a coil. The handpiece coil and component coil are in sufficient proximity to allow inductive signal transfer. The control console, through the handpiece, reads the data from the component RFID. These data are transferred from the console to the surgical navigation system. Based on these data, the surgical navigation system processor generates data indicating the position of the component at the surgical site.

**[0005]** The above system is an efficient means for providing a surgical navigation system with information regarding the physical characteristics of surgical components. By repeatedly sending interrogation signals through the handpiece, the system is always provided with data identifying the specific component attached to the handpiece. However, this system requires a corded connection between the handpiece and a control console capable of reading the component RFID. For many components such as burs, shavers and saw blades, this is not drawback. These components are attached to and

driven by powered handpieces. The power to such a handpiece is typically supplied through cable that extends from the control console. It is a simple task to build into the cable the conductors required for signal exchange with the component RFID.

**[0006]** Nevertheless, there are times where it is difficult to provide a corded connection to the instruments, implants and other components applied to a surgical site. For example, some surgeons employ battery-powered instruments. A surgeon uses this type of instrument because he/she does not want to introduce a cable into the vicinity of the surgical site. Some components, when applied to a surgical site, are not driven by powered handpieces. These surgical components include, implants, trial implants and hand powered tissue cutting and shaping tools. Attaching a cord to each of these components as part of surgical procedure to read their RFIDs can complicate and increase the time it takes to perform the procedure.

**[0007]** Several solutions have been proposed to the problem associated with providing component data to the surgical navigation system in the above situations. One solution is to provide a stand alone box that contains a coil for inductively exchanging signals with the component RFID. Prior to a new component being applied to the surgical site, the component is passed by the box. The RFID data are read by the box and forwarded to the surgical navigation unit. A second proposed solution involves providing a corded hand held pointer with a coil in its tip. Prior to the surgical component being applied to the surgical site, the operating room personnel place the pointer in close to the component RFID. The data in the component RFID are read by the

pointer and transmitted to the surgical navigation system.

**[0008]** Both of the above solutions require extra components to be introduced into the operating room. To perform surgery as efficiently as possible, one tries to minimize the number of pieces of surgical equipment used to perform a procedure. Moreover, both solutions require the surgical personnel to perform an additional step, namely, to have the RFID of the new component read, as part of the procedure. Requiring the personnel to take this step increases the complexity of the procedure and overall time it takes for the procedure to be performed.

**[0009]** Moreover, in the event the steps are not taken to properly perform the identification procedure, the navigation system may provide incorrect information about the location or shape of the surgical component. This type of error may occur, for example, when a surgeon is using a number of different trial implants to determine the proper size or type of implant that should properly be fitted to the patient. Typically, a common handle is used to place the different implants at the surgical site. If, after the switching of the attached trial implant, the component identification step is not performed, the surgical navigation system may generate information that gives an inaccurate impression of the implant. Thus, it is desirable to automate as fully as possible the identification of components used in a procedure that are tracked by a surgical navigation system.

## SUMMARY AND INVENTION

**[00010]** This invention is related to a new and useful surgical navigation system. The system of this invention

includes a tracker and surgical components that are integrated together. The tracker and complementary components are integrated so that the tracker, upon attachment to a component, reads the data in a memory integral with the component. The data in the memory include information that describes the characteristics of the component. The tracker broadcasts the read data wirelessly to the static components of the system. The system, based on these data, the location of the tracker and the previously stored data, provides information that accurately describes the location of the component at the surgical site.

**[00011]** The system of this invention provides information about components that, when applied to the surgical site, are static relative to the handles used to position them at the site. These components, sometimes referred to as implements, include implants, bone anchors and trial implants. The system also provides information about components that are moving when applied to a surgical site. These components include reamers and other surgical instruments used to remove and/or selectively shape tissue.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[00012]** The invention is pointed out with particularity in the claims. The above and further objects, features and benefits of this invention are discussed in the detailed description below taken in conjunction with the accompanying drawings in which:

**[00013]** Figure 1 depicts the surgical navigation system of this invention;

**[00014]** Figure 2 is a side view of a tracker base and the surgical components to which it is connected according to this invention;

**[00015]** Figure 3 is an exploded view of the tracker base and components to which it is connected;

**[00016]** Figure 4 is an exploded view of the tracker base and handle prism and the components internal to these components;

**[00017]** Figure 5 is a top elevational view of a core;

**[00018]** Figure 6 is a top view of the handle of the handle assembly;

**[00019]** Figure 7 is a side view of the handle;

**[00020]** Figure 8 is a perspective view of the outer sleeve of the handle assembly;

**[00021]** Figure 9 is a side view of the bearing and coil fitted to the bearing;

**[00022]** Figure 10 is a perspective view of the bearing;

**[00023]** Figure 11 is a side view of the handle assembly shaft and the coil mounted to the shaft;

**[00024]** Figure 12 is a cross sectional view of the shaft taken along line 12-12 of Figure 11 wherein the components mounted internal to the shaft are shown in an exploded view;

**[00025]** Figure 13 is an exploded view illustrating the components integral with the reamer and the shaft head unit;

**[00026]** Figure 14 is a cross sectional and exploded view of the reamer and shaft head unit;

**[00027]** Figure 15 is schematic and block diagram of the electrical components of this invention;

**[00028]** Figure 16 is a diagram the different types of data stored in the memory of an RFID integral to a surgical component of this invention;

**[00029]** Figure 17A, 17B and 17C collectively form a flow chart of the process steps executed by the system of this invention;

**[00030]** Figure 18 is a perspective view of an positioner, sometime called an impactor, of this invention,

**[00031]** Figure 19 is a cross sectional view of the positioner of Figure 18,

**[00032]** Figure 20 is a cross sectional exploded view of the positioner of Figure 18 of a acetabular shell that is fitted in place with the positioner;

**[00033]** Figure 21A and 21B collectively form a flow chart of the how the cup of Figure 18 is fitted with the positioner in the surgical navigation and reactive workflow process of this invention;

**[00034]** Figure 22 is a plan view of a broach handle of this invention;

**[00035]** Figure 23 is a cross sectional view of the broach handle of Figure 22;

**[00036]** Figure 24 is a perspective view of a stem inserter of this invention;

**[00037]** Figure 25 is an exploded view of the stem inserter of Figure 24;

**[00038]** Figure 26A is a plan view of how the stem inserter of Figure 24 is coupled to an asymmetric surgical implement, here an implantable femoral stem;

**[00039]** Figure 26B is a cross sectional view of the stem inserter of Figure 24;

**[00040]** Figure 26C is a perspective view of the alignment yoke of the stem inserter of Figure 24;

**[00041]** Figure 27 is a schematic of the electrical components of the stem inserter of Figure 24;

**[00042]** Figure 28 is a diagrammatic view of a surgical component, here an implant, of this invention to which plural RFIDs are mounted;

**[00043]** Figure 29 is a diagrammatic illustration of a bone in a fractured state;

**[00044]** Figure 30 is a diagrammatic illustration of a pin of this invention used to mark the position of a body component and the handle used to fit the pin; and

**[00045]** Figure 31 is a flow chart of the process steps executed when using the system of this invention to track the removal of body tissue and then return the tissue to the location from which the tissue was removed; and

**[00046]** Figure 32 is a depiction about how markers are presented on the display according to this invention to facilitate the precise positioning of tissue

## DETAILED DESCRIPTION

**[00047]** Figure 1 depicts a surgical navigation system 20 of this invention that obtains data about surgical components 22 and 24 without wire connections to the components. In Figure 1, surgical component 22 is a reamer. Surgical component 24 is a handle assembly. The proximal end of the handle assembly 24 is attached to a battery operated driver 26 that actuates the reamer 22. ("Proximal", it is understood, means away from the surgical site. "Distal" means towards the surgical site.) Not shown and not part of the invention is the battery attached to the base of the handgrip of the driver 26 that supplies the energization current for the driver. It should also be understood, and as will be discussed below "surgical component" may be any other instrument used to cut, form or shape tissue, a trial implant or an actual implant. Sometimes, the surgical

component is alternatively referred to as a "surgical implement."

**[00048]** System 20 of this invention includes a tracker 28 attached to handle assembly 24. Tracker 28 broadcasts a specific form of energy from one or more emitters. Some trackers, for example, emit infra-red light or visible light. Other trackers emit RF energy, electromagnetic energy or sonic energy. Still other trackers emit sonic energy. A localizer 30, also part of system 20, monitors the position of the tracker 28. Specifically, the localizer 30 contains one or more receivers capable of receiving the energy emitted by the tracker 28. The receivers may determine the direction from which the energy is transmitted or the strengthen o the received energy.

**[00049]** The localizer receivers send signals representative of the measurements made thereby to a processor 32, also part of system 20. The processor Based on the determination of the different locations from which the individual tracker transmitters emit energy or the strength of the received energy, the localizer 30 determines where, in three-dimension space, the tracker 28 is positioned and the orientation of the tracker. The data representative of the location and orientation of the tracker 28, or the signals used to determine this information, are forwarded by the localizer 30 to a processor 32 also part of the system 20. Processor 32, based on the signals from the localizer procedure, then generates signals representative of the position and orientation of the tracker 28. A more detailed explanation of how a surgical navigation system operates is contained in the Applicant's U.S. Patent Application No. 10/677,874, filed

October 2, 2003, U.S. Patent Publication No. US 2004/0073279 A1, now U.S. Patent No. _____ and incorporated herein by reference.

**[00050]** As will be discussed in detail below, internal to the reamer 20 and handle assembly 24 are separate data storage devices. Each of these devices stores data that identifies the associated surgical component. These data include data that identify the physical characteristics of the component. When the reamer-handle-tracker sub-assembly is assembled, the tracker 28 reads the data in the storage devices. Tracker 28 transmits signals containing these data. A receiver 34, typically positioned in the localizer 30, reads these data. These data are transmitted by the receiver 34 to the system processor 32.

**[00051]** Prior to the commencement of the procedure in which system 20 is employed, the processor 32 is loaded with data that identifies the location of individual body tissues and organs at the surgical site. During the procedure, the processor 32 is provided with data indicating the location of the surgical site. Based on these data, the data indicating the position and orientation of the tracker 28 and the data identifying the physical characteristics of the surgical components 22 and 24, processor 32 generates information indicating the position of the surgical components relative to the surgical site. More particularly, the processor generates information indicating the position of the surgical components relative to the body tissue at the surgical site. Typically, this information is presented visually on a display 36. The surgeon is thus able to view the position of the surgical components that otherwise cannot readily be seen.

**[00052]** Figure 2 and 3 illustrate a tracker base 40 and the surgical components to which the base is connected, reamer 22 and handle assembly 24. The tracker base 40, is the bottommost component of the tracker 28. Located above base 40, tracker has a shell unit 42 (Figure 1). The shell unit 42 contains the components that transmit location and data signals to the static components of the system 20. Base 40 is fixedly attached to the shell unit 42 by an convention fastening means such as threaded fasteners or welding.

**[00053]** The tracker base 40 is removably coupled to a generally tube-shaped handle 44 that is part of the handle assembly 24. A solid metal prism 46 is fixedly mounted to an outer surface of the handle 44 immediately forward of the proximal end of the handle. Tracker base 40 is formed to have a slot 48 along the bottom that extends the length of the base. Slot 48 is dimensioned to facilitate the tight slip fit of prism 46 into the slot. A locking mechanism, not shown, releasably tightly couples the tracker base 40 and prism 46 together.

**[00054]** A shaft 50, also part of handle assembly 24, is rotatably mounted in the handle 44. Shaft 50 has a proximal end tail 52 that extends rearwardly out of the proximal end of the handle 44. Shaft tail 52 is formed with geometric features 54 that facilitate the coupling of the shaft 52 to a complementary shaft internal to the driver 26. More particularly, the handle assembly shaft 50 engages the driver shaft so that the two shafts rotate in unison.

**[00055]** Shaft 50 also has a distal end 56 that is located forward of the distal end of the handle 44. A ring shaped bearing 58 is statically mounted in the open

distal end of the handle 44. Bearing 58 functions as an interface between handle 44 and shaft 50.

**[00056]** A head unit 60 is attached to and extends forward from the shaft distal end 56. The head unit 60 contains a cylindrical stem 62 that is most proximal section of the head unit and is the portion of the head unit attached to the shaft 50. A crown 63, with a diameter wider than the stem 62, is formed integrally with stem 62 and is the most distal portion of the handle assembly 24. Crown 63 is formed with geometric features designed to couple the reamer 22 to the head unit 60. While not illustrated, it should be understood some type of locking device is attached to the head unit 60. The locking device, which is typically moveable along the length of the stem 62, includes locking member that, when selectively positioned, engage members integral with the reamer 22. These locking members releasably hold the reamer 22 to the handle assembly 24. One locking device is described in U.S. Patent No. 6,540,739 B2, SURGICAL INSTRUMENTATION SYSTEM, issued April 1, 2003 and incorporated herein by reference.

**[00057]** A more detailed description of the interface between the tracker base 40 and handle prism 46 is now set forth by reference to Figures 3 and 4. Prism 46 is in form of a solid elongated block. The bottom portion, the base 64 of the prism 46, has a generally rectangular cross sectional profile. Integral with the base 64, prism 66 is formed to have a head 66 that tapers outwardly from the base. A crown 67, integral with and located on top of the head 66 forms the top most section of the prism 46. Prism 46 is further formed to have a notch 69 that extends laterally across the prism. The

notch 69 cuts fully across the crown 67 and extends a short distance into the head.

**[00058]** Prism 46 is further formed with two longitudinally spaced apart bores 70 and 71, both shown in phantom. Bores 70 and 71 each extend upwardly through the prism base 64 are partially through the prism head 66. Bores 70 and 71 are dimensioned to receive positioning pins, not illustrated, that precisely hold the prism 46 to the handle 44. During the assembly process, the pins hold the prism 46 to the handle 44 so the two components, when welded together, are in a precise spatial relationship.

**[00059]** The tracker base 40 is formed so that slot 48 opens downwardly and is formed to extend forward from the proximal end of the base. (In Figure 4, the base of slot 48 is shown in phantom.) Slot 48 is dimensioned to allow the close slip fitting of the handle prism 46 into the slot. While not illustrated, it should be understood that internal to the tracker base is a moveable tongue positioned to tightly fit in prism notch 69. This tongue is part of the locking mechanism that holds the prism 46 to the tracker base 40. The tongue-and-groove fitting of prism 46 into slot 48 and of the tracker base tongue into prism notch 69 result in the tracker base 40 and prism 46 being tightly locked together.

**[00060]** An RFID 74 specific to handle 44 is mounted in the prism 46. The RFID 74 is seated in a downwardly extending bore 76 (shown in phantom) formed in the prism 46. The bore is located immediately rearward of the distal end of the prism 46 and extends through the prism crown 67 and a short distance into the prism head 66. The RFID 74 is located in the base of bore 76. Also located in base of the prism bore 76 is a

capacitor 78. While not illustrated in Figure 4, the RFID 74 and capacitor 78 are connected together.

**[00061]** A coil 80 connected to RFID 74 and capacitor 78 is disposed in the prism bore 76 above the RFID and capacitor. The coil 80 is seated in a magnetic core 82 also seated in bore 76. The core 82 is formed from highly magnetic material such as ferrite. A ferrite core can be a ceramic formed from iron oxide mixed with an oxide or carbonate of manganese, zinc, nickel or magnesium. Core 82, as seen in Figures 4 and 5, includes a circular base 84. A boss 88 extends upwardly from the center of the base 84. The boss 88 is formed with an axially extending through hole 90. The core 82 is also formed with two arcuately shaped and spaced apart flanges 92. The flanges 92 extend upwardly from the perimeter of the base 84. Core 82 is also shaped so that in the interstitial gaps between the flanges 92, the base 84 is formed with notches 93

**[00062]** The coil 80 is seated in the annular space between the center located core boss 88 and the outwardly located flanges 92. The ends of the wire forming the coil 80, while not illustrated, extend downwardly through the base notches 93. A potting material (not illustrated) encapsulates the RFID 74, capacitor 78, coil 80 and core 82 in the prism bore 76. An epoxy may be used as the potting material. It should be understood that the potting material is able to withstand the rigors of autoclave sterilization.

**[00063]** Signals are inductively exchanged between the handle coil 80 and a coil 96 disposed in the tracker base 40. Specifically, the tracker base 40 is formed with a closed end bore 98 (shown in phantom) in which coil 96 is held. Bore 98 is formed in the tracker

base 40 to extend upwardly from the distal end of the downwardly directed surface that defines the base of slot 48. In the depicted version of the invention, the tracker base 40 has a nose 102 that extends forward from the portion of the base that defines slot 48. The bottom surface of nose 102 is flush with the surface of the tracker base 40 that defines the tracker slot 48. The nose 102 is further formed so that a distal end section of the tracker base bore 98 is formed in the nose 102. Collectively, the tracker base 40 and prism 46 are formed so that, when the base is mounted to the prism, the tracker base bore 98 is in registration with the prism bore 76.

**[00064]** The tracker base coil 96 is seated in a core 99 similar to core 82. Potting material encapsulates the core 82 and coil 96 in the tracker base bore 98. Not illustrated is a bore formed through the tracker base that opens into the base of bore 98. This bore serves as the conduit wherein the wires to the coil 96 are connected to the other electrical components integral with the tracker 28. These components are disposed in the tracker shell unit 42.

**[00065]** The handle coil 80 is also connected to a coil 104 disposed around the handle assembly bearing 58 (Figure 9). Conductors 106, seen best in Figures 4 and 6, connect coils 80 and 104 together. The conductors 106 extend from capacitor 78 through a through hole 108 (shown in phantom) formed in the base of prism bore 76. Hole 108 opens into the most distal of the bores, bore 70 that receives a positioning pin. The conductors 106 extend out of notch 109 (shown in phantom) formed in the bottom of the prism base 64. Notch 109 extends from bore 70 distally forward to the front end of the base 64.

**[00066]** The conductors 106 extend over an undercut face 110 formed on the outer surface of the handle 44 as depicted in Figures 6 and 7. Specifically, handle 44 is formed so that face 110 starts at a location forward of the proximal end of the handle and terminates at a location rearward of the distal end. Two through holes 112 are formed in the handle 44 to open into the proximal end of face 110. Through holes 112 receive the positioning pins that hold the prism 46 to the handle 44 during the fastening process. A third through hole, hole 114, extends from face 110 into the center of the handle 44 adjacent the distal end of the face. Through hole 114 functions as the opening through which conductors 106 are feed into the center void of the handle 44.

**[00067]** A generally tubular outer sleeve 118, now described by reference to Figures 3 and 8, extends over the handle 44. Sleeve 118 is open at both ends and is dimensioned to closely slip fit over the handle 44. The sleeve 118 is formed with a slot 120 that extends forward from the proximal end of the sleeve 118. Slot 120 has a width equal to the width of the prism base 64. When the handle assembly 24 is assembled, the prism base 64 is seated in the sleeve slot 120. In the illustrated version of the invention, sleeve 118 extends from the distal end of handle 44 to the proximal end of prism 46. The handle 44 extends proximally a short distance beyond prism 46. Therefore, the proximal end of the handle 44 is not encased within the sleeve 118.

**[00068]** Bearing 58, now described by reference to Figures 9 and 10, is formed from a single piece of low friction material such as PEEK plastic. The bearing 58, as seen by reference to Figures 9 and 10, is formed to

have an axially extending through bore 124. Bore 124 is dimensioned to allow the shaft 50 rotate freely in the bore. The bearing 58 is shaped on the outside to have a circular head 126. Bearing head 126 has an outer diameter equal to the outer diameter of handle 44. Extending proximally from the head 126, the bearing 58 has a stem 128. Stem 128 generally has a diameter that allows the close slip fit of the stem into the distal end opening of the handle 44.

**[00069]** The bearing 58 is further formed to have an inwardly directed undercut 130. Specifically, the undercut extends circularly around the stem 128 and is located forward of the proximal end of the stem. Coil 104 is disposed in the annular space located above undercut 130. The proximal end of the stem 128, the end rearward of the undercut 130, is formed to have a planar face 132. Face 132 extends across an arcuate section of the stem 128. Undercut 130 defines a space between the inner surface of handle 44 and bearing 58 through which conductors 106 extended to coil 104.

**[00070]** Handle assembly shaft 50 is now described by reference to Figures 11 and 12. The shaft 50 is the form of a generally rigid rod. The shaft 50 includes the proximal end tail 52 with features 54 that facilitate the coupling of the tail to a shaft assembly integral with the driver 26 so that two shafts rotate in unison. Forward of tail 52, the shaft 50 has a trunk section 134 with a diameter slightly larger than the diameter of the body of the shaft. A bearing, not illustrated, is disposed in the proximal end of the handle 44. The bearing extends to the trunk section 134 to provide a second low friction interface between the handle 44 and the shaft 50.

**[00071]** At distal end 56, shaft 50 is formed to have a head 136 that has an outer diameter less than that of the main body of the shaft. Extending proximally from the head 136, the shaft 50 has a neck 138 with a diameter equal to that of the main body of the shaft. The neck 138 extends from a collar 140. The collar 140 has a diameter greater than that of main body of the shaft. More particularly, collar 140 has an outer diameter greater than the diameter of bearing through bore 124. Thus, when handle assembly 24 is assembled, the shaft 50 is positioned so that collar 140 is located immediately forward of the bearing head 126.

**[00072]** Located immediately proximally rearward from collar 140, shaft 50 has a shoulder 142. The shoulder 142 has a distal section 144 with a constant diameter outer surface. The outer diameter of the shoulder distal section 144 is selected to allow a close rotating fit between the shoulder and the adjacent inner surface bore-defining wall of the bearing 58. Shoulder 142 has a proximal section 146 that is longitudinally spaced from the distal section 144. The shoulder proximal section 146 is shaped so as to taper outwardly along the length of the section 146 such that the diameter increases from the shaft main body towards the shaft head 136. The most distal portion of the shoulder proximal section 146 has a diameter equal to that of the distal section 144. Between the shaft distal and proximal sections 144 and 146, respectively, there is an intermediate section 148. Intermediate section 148 has an outer diameter substantially equal to that of the main body of the shaft 50.

**[00073]** A coil 150 is wound in the annular space immediately above the shoulder intermediate

section 148 and between the distal and proximal sections 146 and 148, respectively. Coil 150 is wound over a counterbore 152 that extends laterally towards the longitudinal center axis of the shaft from the shoulder intermediate section. An RFID 156 that contains data specific to the shaft 50 is disposed in the counterbore 152 below coil 150. A capacitor 158, also connected to the coil 150, is also located in the counterbore 152.

**[00074]** Conductors 160, shown schematically in Figure 15, extend forward from the coil 150, the RFID 156 and capacitor 156 through the shaft 50. Specifically, the shaft 50 is formed with a bore 159 that opens from the base of counterbore 152 into the longitudinal center axis of the shaft 50. Shaft 50 also has a bore 161 that extends from the shaft head 136 proximal to bore 162. Conductors 160 extend through bores 159 and 161. Potting compound encapsulates coil 150 over shaft shoulder intermediate and RFID 156 and capacitor 158 in counterbore 152.

**[00075]** The shaft head unit 60, now described by reference to Figures 13 and 14, is secured to the shaft head 136. Specifically, the head unit 60 is formed with a threaded bore 162 that extends forward from the unit stem 62. The shaft head 136 is formed with complementary threading to facilitate the attachment of the head unit 60 to the shaft 50. (Bore and head threading not illustrated.)

**[00076]** Shaft head unit 60 is further formed to have a bore 164 that extends axially through the unit stem 62 from the base of bore 162 towards the unit crown 63. Bore 164 opens into first and second counterbores 166 and 168. The first counterbore 166, the bore into which

bore 164 opens, is located in the unit stem 62. The second, outer counterbore, counterbore 168, is formed in a circular plate that is part of the unit crown 63. Second counterbore 168 has a diameter greater than that of the first counterbore 166.

**[00077]** Conductors 160 are connected to a coil 170 seated in the first counterbore 166 of the shaft head unit 60. Coil 170 is seated in a core 172 similar to core 82. Potting compound encapsulates the coil 170 and core 172 in the first counterbore 166. The second counterbore 168 is open to the environment.

**[00078]** Reamer 22 includes head 176. In the depicted version of the invention, head 176 is semi-spherical. It is appreciated by those familiar with the design of reamers that this shape is exemplary, not limiting. The head 176 is formed with cutting surfaces. In Figure 13, a plurality of scalloped edges 177 represent the cutting surfaces. The exact geometry of the cutting surfaces is not relevant to this invention. Two perpendicularly aligned cross bars 178 extend across the inner surfaces of the head. The cross bars 178 are the reamer structural members that engage the components of crown 63 of the shaft head unit 60.

**[00079]** The reamer 22 also has a cup 180 that is welded or otherwise secured to the cross bars 178 at the point the cross bars intersect. Cup 180 is generally ring shaped. The distal end of the cup 180 is formed with four equiangularly spaced apart concave surfaces 182. When cup 180 is fitted to the reamer 22, cross bars 178 seat in the circular spaces defined by surfaces 182. Typically, the cup 182 is laser welded to the cross bars 178.

**[00080]** An RFID 184 that contains data specific to the reamer 22 is disposed in the center space internal to the cap 180. A capacitor 186 and coil 188 are connected in parallel across the RFID 184. The coil 188 is seated in a proximally-directed core 190 disposed in the cup 180. The RFID 184 and capacitor 186 are seated in the cup 180 between the cross bars 178 and the base of the core 190. Potting compound encapsulates the RFID 184, the capacitor 186 the coil 188 and the core 190 in the cup 180.

**[00081]** Cup 180 is shaped to have an outer diameter that is slightly less than the diameter of the shaft head unit second counterbore 168. The cup 180 is dimensioned so that, when the reamer 22 is coupled to the shaft head unit 60, the proximal end of the cup 180, the end containing coil 188, seats in the head unit second counterbore 168.

**[00082]** Figure 15 is a block and schematic drawing of the electrical components integral with the reamer 22, the handle 24 and tracker 28. The tracker 28 has a primary microcontroller 190. Microcontroller 190 regulates the overall operation of the electrical components internal to the tracker 28. One suitable unit that can be employed as the microcontroller 190 is from the C51 family manufactured by Philips Semiconductor. Integral with the microcontroller 190, though not illustrated, is a memory that stores program instructions executed by the microcontroller and data received by and transmitted from the tracker 28.

**[00083]** The tracker 28 includes a set of one or more energy transmitting devices that transmit signals used to identify the location of the tracker. In Figure 15 these devices are infra-red light transmitting LEDs 192. The

actuation of the LEDs 192 is regulated by a tracker transmitter 194. The actual pattern in which the LEDs 192 are switched on and off is regulated by command signals generated by microcontroller 190.

**[00084]** Tracker 28 also contains a set of devices that exchange data signals with the static components of the surgical navigation system 20. In the tracker of Figure 15, these devices are a second set of infra red light transmitting LEDs 196 and a photosensor 197. In Figure 1 a rectangular phantom box 35 in the localizer represents the complementary transceiver.

**[00085]** The on/off sequences of the individual LEDs 196 are set by a data transceiver 198. Data transceiver 198 causes the LEDs 196 to be actuated in order to send a specific data stream based on instructions from the microcontroller 190. Transceiver 198 also receives signals generated by photosensor 197 in response to the receipt of infra-signals generated by a transmitter integral, (not illustrated). In response to the signals generated by photosensor 197, data transceiver 198 generates data containing signals that can be read by microcontroller 190.

**[00086]** It should be understood that in alternative versions of the invention, transceiver 198 is capable of exchanging RF signals with the complementary external transceiver 35. In these versions of the invention LEDs 196 and photosensor 197 are replaced by an antenna, (not illustrated).

**[00087]** The tracker coil 96 is connected to a decoder/encoder 202 also internal to the tracker. One suitable decoder/encoder is the HTC110 manufactured by Philips Semiconductor. More particularly, the $Tx_1$ pin of the decoder/encoder 202 is connected to through a series

connected inductor 204 and resistor 206 to one end of coil 96. The $Tx_2$. pin of the decoder/encoder 202 is directly connected to the opposed end of coil 96. A resistor 208 extends from the Rx pin of encoder/decoder 202 to the junction between the inductor 204 and resistor 206. A capacitor 210 extends from the inductor 204-resistor 206 junction to the $Tx_2$ pin.

**[00088]** The above circuit is constructed so that each inductor-capacitor sub-circuit is tuned to a specific and identical resonant frequency. The specific frequency is the frequency at which the RFIDs 74, 156 and 186 exchange signals. In one particular version of the invention, this frequency is 125 K Hz. Thus, inductor 204 and capacitor 210 are tuned to this frequency. Coils 80 and 104 and capacitor 76 of the prism-handle-bearing sub-assembly are similarly tuned to this frequency. Coils 150 and 170 and capacitor 158 of the shaft 50 and head unit 60 are tuned to this frequency. The circuit integral with the reamer 22, capacitor 186 and coil 188 are likewise tuned to this frequency.

**[00089]** Each RFID 74, 156, 184 has a memory in which data describing the surgical component or the surgical component subsassembly with which the RFID is integral are stored. The RFID 74 integral with the handle, as represented by the data fields depicted in Figure 16, stores data identifying the type of handle, component identity field 216. These data may be alphanumeric data. If the data are in this form, the data is simply presented in the appropriate location on the display 36. Alternatively, these data may be a code. The memory integral with the system processor 32 contains a look up table with these codes and data indicating which code

corresponds to a particular instrument. The component identity data stored in the RFID 74 also includes serial number, manufacturer, manufacturing lot number and manufacturing date data. While not shown in Figure 16, it should be appreciated these data are separate data fields.

**[00090]** The memory internal to RFID 74 also has data describing the physical characteristics of the prism-handle-bearing sub-assembly, represented by physical definition field 218. These data describe the physical structure of the sub-assembly. These data, for example, may include the length and diameter of the sub-assembly. In surgical components having complex geometry, for example implants and trial implants, there may be significant amounts of data that collectively describe the physical structure of the component.

**[00091]** The memory of the RFID 74 also includes data indicating the components with which the handle sub-assembly can be used, companion component field 220. For example, there may only be certain shafts that should be fitted to the handle-subassembly. In this situation, companion component field 220 contains data that identifies the specific shafts that can be used with the handle assembly.

**[00092]** RFIDs 156 and 184 integral with, respectively, shaft 50 and reamer 22, contain data similar to that within RFID 74. RFIDs 156 and 184, also contain, in operating parameters fields 222, data that describes how these components should be actuated. These data include a general preferred and maximum operating speed at which these components should be actuated and a maximum torque the component should be allowed to develop.

**[00093]** Each RFID 74, 156 and 158 also contains one or more data fields to which the tracker 28 is able to both read and write data. These fields include a use count field 224. Field 224 is used to store data indicating the number of times the particular component is used. There is a sterilization state field 225. Field 225 contains data indicating whether or not a particular component has been sterilized. Typically, after a component has been sterilized, a data decoder/encoder at the sterilization facility sets the data in field 225 to indicate that the component has been sterilized. There is a sterilization date field 226. The sterilization facility data decoder/encoder is used to write into field 226 the data the component was last sterilized. The RFIDs also include a use history field 227. Each time the component is used, the tracker writes the data of use into field 227. Thus, field 227 contains a record of the dates the component was used. Field 227 in some versions of the invention contains one or more subfields in which data identify the surgeon using the component, the name of the patient on which the component was used or the type of procedure in which the component is used are stored.

**[00094]** While not shown, the RFID memory also contains fields indicating one or more of the following types of data: the total amount of time the component has been used; and the amount of time of use remaining before the component should be subjected to a maintenance overall. The use data are written to the component RFID by the tracker 28 as a consequence of the use of the component. The use remaining data are initially written into the memory at the maintenance facility. The data are then

updated by the system processor 32 and tracker 28 as a result of the use of the component.

**[00095]** In some versions of the invention, one or more of the above types of data may be encoded. The data may be encoded under a public key. The RFID 74, 156, and 184 each contains, in a private key field 228, a private key to decode the companion data. The private key field 228 is one of the data fields in the RFID that can be overwritten. Thus, after the associated component has reached its use limit, the tracker 28 overwrites the data in the private key field 228. This makes it impossible to decode the encoded data.

**[00096]** While not illustrated, it should also be recognized that the RFID memory contains fields with error correction data.

**[00097]** System 20 of this invention is prepared for use by fitting reamer 22 to the handle assembly 24, attaching the handle assembly to the power driver 26 and attaching the tracker 28 to handle assembly. Once the tracker 28 is actuated, the tracker microcontroller 190 continually instructs the decoder/encoder 202 to send out a interrogation signal through coil 96, step 230 in Figure 17.

**[00098]** It should be appreciated that the decoder/encoder 202 generates output signals in the form of square waves. Inductor 204 and capacitor 210, not coil 96, convert the square wave signals into sinusoidal signals for the inductive signal transfer. Since coil 96 is not part of the sub-circuit that generates the sinusoidal signals, changes in the load downline from the tracker 28 neither results in significant attenuation nor significant phase shift in the signals applied across the coil 96.

**[00099]** If, in response to a basic interrogation signal, the tracker 28 does not receive a response, the microcontroller 190 recognizes the tracker 28 as being in a state wherein no surgical component is attached, step 232. The tracker then continues to reexcute step 230.

**[000100]** When the reamer and handle assembly is attached to the tracker 28, in response to the basic interrogation signal, each RFID 74, 156 and 184 initially, and near simultaneously, respond by sending back a component identification signal, step 234. This signal based on data stored in the component identity field 216 and provides a basic identification to the tracker of the component.

**[000101]** The tracker decoder/encoder 202 only reads and decodes the strongest of these signals, step 236. Typically, this is the signal of the closest RFID. In the described configuration, this is the RFID 74 integral with the handle 44. As part of step 236, the decoded identification data are sent to the tracker microcontroller 190.

**[000102]** In response to a receipt of this specific basic identification, the tracker microcontroller 190 and the decoder/encoder 202, in step 238, generate a component specific integration signal to the handle RFID 74 directing it to affirmatively acknowledge its present. The handle RFID 74 responds to this inquiry in step 239.

**[000103]** As a result of the handle RFID 74 acknowledging its presence, the tracker 28, in step 240, reads out the data from the handle RFID 74. Once these data are read, the microcontroller 190, in step 242 transmits the data through transmitter 198 and LEDs 196 to the static receiver 34. Once the data read is complete, in

step 244, the tracker microcontroller 190, instructs the handle RFID 74 to not respond to the next basic interrogation query.

**[000104]** Tracker 28 again performs a basic interrogation step, step 246. Given the prior instructions received by the handle RFID 74, in response to this inquiry, the RFID 74 does not respond. Instead only the shaft RFID 156 and reamer RFID 184 respond, step 248. Since the shaft RFID 156 signal is the stronger of the two signals, this is the RFID that is next read by the tracker 28. In other words, steps 236-244 are reexecuted. Only during this sequence of the execution of these steps, the data from the shaft RFID are read. These steps are shown collectively as step 250.

**[000105]** A third basic interrogation signal is then generated. In other words, step 246 is reexecuted. At this time, both the handle RFID 74 and shaft RFID 170 are instructed not to respond. Therefore, in response to the second execution of step 246, only the reamer RFID 184 responds. Then, in the second reexecution of steps 236-244, the data stored in the reamer RFID 184 are read and forwarded to processor 32.

**[000106]** Basic interrogation step 246, is then reexecuted. At this time, each of the RFIDs 74, 156 and 184 is operating under an instruction not to respond. Therefore, since no response is received to the interrogation, in step 248 the tracker microprocessor 190 recognizes the system as being in a state in which the data stored in each component RFID has been read. The microprocessor 190 causes a message informing the system processor 32 of this fact in step 252.

**[000107]** Based on the data received from the RFIDs 74, 170 and 184, the system processor 32 first determines

whether or not the system is appropriately configured. For example, the system determines whether or not the reamer 22 is appropriate for the shaft 60. This step is performed by reference to the companion component data from field 220 for the shaft 60 and the component identity data from field 216 for the reamer 22. If the data indicate that the reamer is not appropriate, the processor 32 causes an appropriate warning to be presented on the display 36, steps 254 and 256.

**[000108]** System processor 32, in step 258, also determines whether or not the components are actually useable. This step is determined by making sure, based on data in the use count fields 224, sterilization state fields 225 and sterilization data fields 226, the useful life time of each component has not been exceeded, the component is sterilized, based on the date of sterilization, can still be considered sterilized, and the component is not in need of service. If there is an indication the component cannot be used, an appropriate warning message is presented, step 256 is executed

**[000109]** If the surgical components are appropriately assembled, the processor 32 assembles a virtual image of the surgical component assembly, step 260. This image is based on the received data describing the physical characteristics of the components from the physical definition fields 218.

**[000110]** During the actual performance of the procedure, the system monitors the position of the tracker 28, step 262. Based on the position of the tracker 28, the stored data describing the position of the surgical site and adjacent body tissue and the virtual image of the surgical components, processor 32, in step 264, generates information indicating the position of the surgical

components relative to the surrounding site and body tissue. Typically, this information is presented visually on display 36.

**[000111]** Throughout the time the tracker 28 is actuated, microcontroller 190 repetitively causes interrogation signals to be resent. In other words, basic interrogation signals are sent to cause a series of component specific interrogation signals to be sent. If, in response to the signals, the same component identification data are received, microcontroller 190 recognizes the assembly as being one in which no components have been switched.

**[000112]** However, if, for example, a different sized reamer 22 is attached, the received component identification data will be different. Based on the receipt of these data, the tracker reads out all of the data from the RFID 184 of the new reamer. Based on these data, the processor 32 generates a new virtual image that reflects the size and shape of the new reamer.

**[000113]** System 20 of this invention continually generates information indicating the location of the surgical components 22 and 24 relative to the surgical site. Should, during the surgical procedure, the components change, the system 20 remains able to generate this information. System 20 does this by without requiring a wired connection between the components and the static equipment. Thus, the system 20 of this invention does require the use of corded equipment in order to obtain data that describes the new surgical components that are being introduced into the surgical site.

**[000114]** Moreover, system 20 automatically reads the data from the new surgical components as soon as they are

attached to the tracker 28. Surgical personnel are not required to take any active steps to ensure that the data describing these components are read. The possibility that system 20 will generate information based on the assumption that a removed component is still in use is essentially eliminated.

**[000115]** Another feature of system 20 of this invention is that the coils 80, 96, 104, 150, 170 and 188 that perform the inductive signal transfer are not the sole components responsible for generating the sinusoidal signals that are so exchanged. In the tracker 28, this function is performed by capacitor 204 and inductor 210. In the downline components, this function is performed by the coils and associated capacitors. A benefit of this arrangement is that a change in circuit load as a result of the change of the downline components does not cause the significant attenuation or phase shift of the signals from those components.

**[000116]** System 20 of this invention also has a means to prevent the unauthorized reading of the data in the RFIDs. Specifically, if it is determined that the data in an RFID for a particular component should not be read, the tracker 28 only has to destroy the data in the private key field 228 for the RFID. This prevents the decryption software in the tracker 28 or processor 32 from being able to decode the encrypted data.

**[000117]** It should be recognized that the system 20 of this invention can be used to provide data about surgical components other than those that are actively driven such as reamers and other cutting devices. System 20 provides information about other surgical implements such as manually actuated tools such as rasps. Still other surgical implements system can be used to provide

information about include trial implants and implants themselves. A manually actuated tool may be provided with an RFID that is attached to the mounting member to which the associated tracker 28 is attached. The instrument data are read from the tracker 28 and broadcast by the tracker to the system processor 32.

**[000118]** If the tool has moving parts, a sensor or sensors monitor the positions of these parts. For example, a potentiometer is used to monitor the extent to which the arms of forceps are open and closed. The signal across the potentiometer is digitized by a circuit internal to the forceps and transmitted to the tracker over the coils used to perform the inductive data transfer. The tracker then broadcasts a signal containing the data indicating the open/closed position of the forceps arms. In this way, the system processor 32 generates a near instantaneous virtual image of the forceps in their current open/closed state.

**[000119]** Typically, a handle is used to fit an implant or a trial implant to a patient. An RFID and coil are contained inside the implant or trial implant. Information similar to that carried in the reamer RFID 184 are stored in these components.

**[000120]** One such embodiment of the above described version of the invention is now described by reference to Figures 18-20. These Figures illustrate an acetabular shell 290 and the positioner 292, sometimes called an impactor, used to fit the shell. Shell 290 is the outer part of an artificial acetabular cup that is fit to the hip bone as part of the joint replacement process. Positioner 292 is a manually actuated tool used to drive, compression fit, shell 290 into the bone.

**[000121]** Shell 290 has a generally has a generally semi-spherical shape and is hollow. Shown as outwardly extending spikes 296 are surface features that facilitate the locking of the shell 290 to the bone. An open ended sleeve 298 extends outwardly from the inner surface of the shell 290. Sleeve 298 is centered along the longitudinal axis of the shell. The inner wall of sleeve 298 is provided with threading to facilitate the releaseable coupling of the shell 290 to positioner 292.

**[000122]** An RFID 302 is disposed in the base of sleeve 298. RFID 302 stores data similar to that in reamer RFID 184 (Figure 13). A coil 304 is connected to and disposed above RFID 302 in the sleeve 298. An encapsulating material 306 both holds the RFID 302 and coil 304 in position and protects these components from boy fluids.

**[000123]** Positioner 292 has an elongated shaft 310. At the proximal end, positioner 292 is formed with a rounded knob 312. A stem 314 having a diameter less than that of shaft 310 and the adjacent section of the knob 312 holds the knob away from the adjacent proximal end of the shaft. Collectively the knob 312, the stem 314 and the adjacent proximal end of the shaft 310 are dimensioned to removably receive a grip, sometimes called a handle, (not illustrated). The surgeon strikes the grip with a mallet so that positioner 292 drives the attached shell 290 into the bone.

**[000124]** A cylindrical boss 316 extends forward from the distal end of the positioner shaft 310. The outer circumferential surface of boss 316 is formed with threading, (not identified) dimensioned to engage the complementary threading integral with shell sleeve 298. Positioner boss 316 is also formed to have closed end

bore 318 that opens proximally rearward from the front face of the boss. A coil 320 is disposed in bore 318. Coil 320 is positioned so that when the positioner boss 316 is screw secured in shaft sleeve 298 inductive signal exchange between coils 304 and 320 is possible. An encapsulating material 322 capable of withstanding the rigors of autoclave sterilization holds coil 320 in bore 318.

**[000125]** Conductors 324, shown as a single line in Figure 20, extend proximally from the opposed ends of the coil 320. The conductors 324 are disposed in a bore 326 that leads proximally from the base of boss bore 318 and into a bore 328 that extends through shaft 310. (Bores 326 and 328 seen best in Figure 20.)

**[000126]** Two prisms 332 and 334 are attached to the proximal end of positioner shaft 310. Prisms 332 and 334 are each like the reamer handle prism 46 (Figure 4.) Thus each prism 332 and 334 includes both an RFID that contains data describing the positioner 292 and a coil for inductively exchanging signals with the complementary tracker coil 96 (Figure 4). The RFIDs integral with each prism 332 and 334 also contain data fields in which data identifying the location at which the associated prism is attached to the positioner shaft 310. Conductors 324 that extend from coil 320 are connected to the RFIDs and coils of both prisms 332 and 334.

**[000127]** When, in the course of the surgical procedure it is time to mount the cup 290 to the hip, in a step 340 of Figures 21A and 21B, the cup is screw secured to positioner boss 316. In a step 342, the tracker 28 (Figure 1) is fitted to one of the prisms 332 or 334. Two prisms 332 and 334. are provided so the tracker can be placed in a location to best ensure that, during the

procedure, the tracker is positioned so that the requisite line of sight path is established between the tracker 28 and localizer 30 (Figure 1). The providing of the two prisms 332 or 334 also facilitates optimal placing of the tracker for reasons of ergonomics.

**[000128]** In step 344, the tracker microcontroller 190 (Figure 15) reads the data from both the RFID of the prism to which the tracker 28 is attached and the cup RFID 302. As part of this process the data are forward through transceivers 198 (Figure 15) and 35 (Figure 1) to the system processor 32. The same general process described with respect to Figures 17A and 17B is used to ensure the data from each RFID are read and transmitted to the system processor 32 (Figure 1). System processor 32 then enters a reactive workflow protocol to further facilitate the performance of the surgical procedure. As part of this process the processor 32 reviews the data from the cup RFID 302 to determine the type of cup, step not illustrated. Then, based on the data previously acquired during the procedure, in a step 348, system processor 32 determines if the cup is appropriate for the procedure. For example, earlier in the procedure, a reamer 22 with a 48 mm diameter may have been used to form an opening in the bone for receiving the cup. In step 348, processor 32 determines if a complementary cup 290, a cup with the same diameter is now fitted to the positioner 292. If, in step 348 it is determined the cup is of a different size than the reamer, processor, in a step 350 causes an appropriate warning notice to be presented on display 36.

**[000129]** Thus, another feature of this invention is that the surgeon is provided with information if it appears a particular surgical instrument or implant appears

inappropriate for use in a particular part of the procedure.

**[000130]** In step 348 it may be determined that the cup 290 is appropriate for fitting to the patient. If this determination is made, as part of the reactive workflow process, in step 352, processor 32 presents on the display 36 an image of the position of the cup 290 and positioner 292 relative to the surgical site. This image is based on: the data obtained from the localizer 40 regarding the position and orientation of the tracker 28; the data regarding the physical characteristics of the positioner from the RFID integral with one of the prisms 332 or 334; and the data from the cup RFID 302 describing the cup 290.

**[000131]** Also as part of step 352, additional information may be presented on display 36. These data include text messages that offer guidance for positioning the cup 290.

**[000132]** During the procedure, in step 354 of Figure 21B, positioner 292 is used to fit the cup 292. The real time monitoring of the changes in position and orientation of the tracker 28 is then used to determine by extension the exact position of the cup in the hip, step 356.

**[000133]** Once the cup 290 is properly positioned, step 357, the positioner 292 is decoupled from the cup, step 358. This action is accomplished by unscrewing the positioner boss 316 from the cup sleeve 298.

**[000134]** Figures 22 and 23 illustrate a broach handle 370 of this invention. The broach handle 370 is used to hold a broach (not illustrated). The broach, sometimes called a rasp, is used to create a void space in the bone for insertion of a stem portion of an

artificial joint. Broach handle 370 has an elongated flat body 372. A cap 374 is disposed over the proximal end of the body 372 to facilitate the holding of the handle 370 and the application of the force needed to press the broach against bone. A locking assembly 376, the exact structure and operation of which is not relevant to this invention, is fitted in the body 372. The locking assembly 376 contains the structural components of the handle 370 that releasably hold the broach to the handle. Locking assembly 376 includes a release lever 377 that is pivotally attached to the handle body 372. The release lever 377 is then manually actuated member of the locking assembly 376 that holds the broach in/releases the broach from the locked state.

**[000135]** Two prisms 379 and 380 are mounted to handle body 372. Each prism 379 and 380 includes its own RFID and coil as described above with respect to prisms 46, 332 and 334. Prisms 379 and 380, though, it will be observed are not symmetrically mounted to the handle body 372. Instead one prism, prism 379 is mounted to the body for receiving the tracker 28 when broach handle 370 is used in a procedure where the patient is placed in the lateral decubitus position. Examples of such procedures include, and are not limited to, posterior-lateral total hip arthroplasty (THA) and a mini-posterior-lateral THA. The second prism, prism 380, is mounted to the body 372 for receiving a tracker when the broach handle 370 is used in a procedure. Examples of such procedures include, and are not limited to an anterior-lateral THA or a direct anterior THA. Thus, regardless of the type of procedure the broach handle is used to perform, the attached tracker is able to transmit data signals to the static transmitter.

**[000136]** While not illustrated, it should further be understood that the broaches used with handle 370 may be provided with their own RFIDs. These RFIDs are encapsulated in a manner similar to which reamer RFID 184 (Figure 15) or cup RFID 302 (Figure 20) is sealed. In these versions of the invention a sealed coil (not illustrated) is mounted to the distal end of the handle body 372. The coil serves as the antenna through which signals are exchanged with the RFID in the broach. Conductors that extend through handle body 372 connect the coil to the complementary coils disposed in the prisms 340 and 342.

**[000137]** In these versions of the invention, system processor 32 performs a reactive workflow process by first determining the geometry of the broach attached to the handle. Then in a step similar to step 348 (Figure 21A), the processor determines if the surgical site is set to accept the broach. Thus, if previous data indicates that a pilot bore of a specific size was formed in the bone, the system processor determines whether or not the broach attached to the handle is to large to be received in the pilot bore. Also as part of the evaluation step, system processor may evaluate if based on measurements of bone shape and dimensions, the expanded bore the broach is shaped to cut will too big for the surrounding bone.

**[000138]** Figures 24-25 illustrate another surgical instrument, a stem inserter 390 constructed in accordance with this invention. Stem inserter 390 is used to insert a stem 391 (Figure 26A), another artificial joint component in position. Stem 391 includes a body 381. Stem body 381 is the portion of the stem inserted in the bone. A neck 382 extends upwardly and tapers inwardly

from the body. A prism 383, which has circular cross sectional profile and an inward taper, extends upwardly from stem neck 382. Prism 383, which forms the head of the stem is the member to which a ball (not illustrated) complementary to the acetabular cup is fit. Stem 391, like numerous other implants, trial implants and surgical instruments, it will be observed, is asymmetrically shaped.

**[000139]** Returning to Figures 24 and 25 it can be seen that stem inserter 390 has a cylindrical shaft 392. A cylindrical boss 394 projects forward from the distal end of shaft 392. Boss 394, like positioner boss 316 (Figure 20), is provided with threading to facilitate the releasable coupling of a stem to the inserter 390. A coil 395 mounted in the distal of boss 396 provides for inductive signal exchange with a complementary coil 389 in the stem that is attached to the stem identifying RFID 388. Conductors 393 (Figure 27) extend through the shaft 392 and boss 394 to coil 395 or the conduits in which the conductors are seated. Not illustrated are the shaft and boss bores through which conductors 393 extend.

**[000140]** A knob 396 extends away from the proximal end of shaft 392. Knob 396, like positioner knob 312 (Figure 18), is designed to receive a grip or a handle 397. Distal to knob 396, shaft 392 is formed with a wide diameter circular flange 398. Distal to flange 398, shaft 392 has a head 402. Shaft head 402 has a diameter less than that of flange 398. Distal to head 402 the shaft has a neck 404 with a diameter less than that of the head. Neck 404 is located proximal to a shaft collar section 406. Collar section 406 has a diameter approximately equal to that of the head 402.

**[000141]** A generally sleeve shaped cannula 410 is rotating fitted over the shaft 392. Cannula 410 extends from a position proximal to the distal end of the shaft 392 to a position distal to shaft collar 406. While the inner and outer diameters of the cannula 410 are generally constant along the length, there is a proximal end base 412 that is outwardly flared. Cannula 410 is further formed so at the distal end there are two parallel, spaced apart, outwardly extending tabs 384. Two pins 385 extend between tabs 384.

**[000142]** Two prongs 414 and 415 extend proximally rearward from the proximal end of cannula base 412. Prongs 414 and 415 are symmetrically located around the center longitudinal axis of the cannula 410. Prong 414 is longer than prong 415. The outer surface of both prongs 414 and 415 is provided with threading (not identified).

**[000143]** A barrel 417 is fitted to the cannula 410 and positioned over shaft head 402, neck 404 and collar 406. Barrel 417 is generally circular in shape. Barrel 417 is formed with a through bore 422 that allows the rotation movement of the barrel over the stem head 402, neck 404 and collar 406 sections. A lock assembly with a reverse biased release button 424 holds the barrel 417 in a fixed angular position relative to the longitudinal axis of the stem 392. More specifically, the lock assembly includes a plate 419 (partially seen in Figure 26B) disposed over the stem neck section 404. A spring, (not illustrated) holds plate 419 against the stem to, by extension, hold the barrel 417 in position. Depression of release button moves the lock plate 419 away from the stem so barrel 417 can be rotated.

**[000144]** While not illustrated, barrel 417 is also formed with two supplemental bores. The supplemental bores are parallel to bore 422 and symmetric to each other around the longitudinal axis of bore 422. Each of the supplemental bores is sized to slidably receive a separate one of the prongs 414 and 415. The supplemental bores are of unequal length such that only a single one of the bores can receive the longer of the two prongs, prong 415.

**[000145]** A ring 420 is rotatably mounted to the distal end of barrel 417. Ring 420 is formed with a threaded through bore 423. More particular the threading defining the ring bore 423 is positioned such that threading engages the outer surface threading of prongs 414 and 415.

**[000146]** Two prisms 428 and 430 are symmetrically disposed over barrel 417. Prisms 428 and 430 contain RFIDS 432 and 436, respectively and coils 434 and 438, respectively, seen in Figure 27. The capacitors connected across the coils are illustrated but not identified. The conductors that extend to stem coil 395 are electrically connected to the prisms integral with coils by two coils 442 and 444, best seen in Figures 26B and 27. Coil 442 is disposed in a recess in shaft collar 406. Coil 442 is the component to which the conductors 393 that extend to boss coil 395 are connected. Not shown is the protective ring disposed around coil 442 that protects the coil from the rigors of autoclave sterilization.

**[000147]** Coil 444 is disposed in barrel 417. More particularly, coil 444 is positioned to extend around the inner wall of the barrel 417 and positioned so as to subtend coil 442. Coil 444 is connected to coils 434 and

438 of, respectively, prisms 428 and 430. Again, a protective ring, not illustrated is disposed around the inner surface of coil 444 to protect the coil from the rigors of autoclave sterilization.

**[000148]** Stem inserter 390 also has an alignment yoke 448 best seen in Figures 26A and 26C. The alignment yoke is formed of plastic and has a J-shaped base 450. More particularly, the yoke base 450 is dimensioned to be releasably snap fit to pins 385 integral with cannula 410. The hook portion of the yoke base 385 extends over the proximal of the two pins. Two legs 452 extend outwardly from the yoke base 450. Legs 452 are symmetric with respect to longitudinal axis of the base 450. The legs 452 are spaced apart to define a space therebetween in which a portion of the complementary surgical implement can be received. In the depicted version of the invention, the legs are spaced apart a sufficient distance to receive a section of the stem neck 382.

**[000149]** Thus, inserter 390 is designed so that the barrel 417 can be rotated relative to the shaft 392 while still maintaining an electrical connection between prism coils 442 and 444 and shaft coil 395.

**[000150]** Also, inserter 390 is designed to be set in fixed spatial relationship, here an angular orientation, relative to the surgical implement, stem 391. More particularly, inserter 390 is configured for use by first fitting the barrel and ring sub assembly over the shaft 392 so that the proximal end of the barrel 417 seats against flange 398. Cannula 410 is fitted over the shaft 392 so that each prong 414 and 415 seats in the appropriate supplemental bore of the barrel. This step is accomplished by placing aligning prongs 414 and 415

with the supplemental bores and then rotating ring 420. The threading on the inside of ring bore 423 engages the prongs 414 and 415 to draw the cannula 410 proximally to the barrel 417.

**[000151]** Then, stem 391 is screw secured onto shaft boss 394. At this time the distal end of cannula 410 is spaced from the stem. Thus, the barrel and cannula sub assembly can freely rotate relative to the stem. This sub assembly is rotated to align yoke 448 with the stem neck 382. Ring 382 is then rotated. The rotation of ring 382 urges the cannula distally forward. Eventually this longitudinal displacement of the cannula results in the yoke legs 452 seating over the stem neck 382. As a consequence of the yoke seating around the stem neck 382, the cannula 410 and by extension barrel 417 and prisms 428 and 430 are in a specific known spatial (angular) relationship with the stem.

**[000152]** Thus this invention provides a means to ensure that a tracked component, here the inserter 390 and a component attached to the tracked component are in a defined spatial relationship. This, in turn, ensures that the surgical navigation system is able to generate data that accurately indicates the position and orientation of the down lone attached component. Further, given the above example, this ensures such spatial position locking can be provided even if the attached component is, like stem 391, asymmetrically shaped.

**[000153]** It should be recognized that the implants of this invention are not just the actual implants permanently fitted to the patient. They include trial implants.

**[000154]** An advantage of this feature of the invention is that when the surgeon switches trial implants, processor 32 is automatically provided with data indicating the trial implant with which the surgeon is presently working. Based on these data, the system automatically generates information indicating the location of the trial implant.

**[000155]** There may also be versions of this invention wherein it may be desirable to provide the cutting accessory or implant with plural RFIDs located at different locations. Such an assembly is represented diagrammatically in Figure 28. Here an implant 460 has two spaced apart bores 462 and 464. Each bore 462 and 464 serves as an opening wherein a handle can be positioned to manipulate the implant. Two bores 462 and 464 that are spaced apart from each other are provided to give the surgeon a choice of locations regarding where the handle is to be attached. This choice is desirable to accommodate individual surgeon preferences for manipulating the implant or viewing the implant 460 upon implementation. Coupling members, not illustrated, are disposed insider the bores 282 for holding the implant 460 to the handle.

**[000156]** In the above version of the invention, a separate RFID 466 and 468 is associated with each bore 462 and 464, respectively. The memory internal to each RFID 466 and 468 also contains an orientation field 470 (Figure 16). The data in the orientation field 470 indicates the orientation of the handle relative to the implant when the handle is fitted in the specific associated bore 462 or 464.

**[000157]** These orientation data are part of the data that are read by the tracker 28 and forwarded to the

processor 32. Based on the orientation data, the processor 32 generates a virtual image of the handle and implant assembly that accurately indicates the relative orientation of the handle and the implant. Cutting devices and other surgical components can similarly be provided with multiple coupling members and RFIDs that contain orientation data for specific to the complementary coupling members.

**[000158]** System 20 of this invention is also used to provide an inventory of bone and other tissue that may be temporarily removed and reinserted at the surgical site during the course of an operation. For example, as illustrated in Figure 29, as a result of a trauma, a bone 490 may fracture into different sections 492-500. In Figure 29, for reasons that will become apparent, sections 492 and 500 are sections that are not removed from the site of the trauma. Sections 494, 496 and 498 are bone sections, fragments, that, as part of the procedure to repair the bone 490, it is necessary to remove and then reattach. As long as the fragments 494, 496 and 498 are at least loosely together at the surgical site, the relative positions of the sections can be easily determined. However, once the bone fragments 494, 496 and 498 are removed from the surgical site, it may be difficult to determine the exact order in which they should be properly arranged.

**[000159]** System 20 includes a set of pins 502a-f that mark the positions of the individual bone segments 492-500. For reasons discussed below, two pins, 502b and 502c, mark segment 294. As seen in Figure 30, each pin 502 consists of a generally cylindrical head 506. Extending downwardly from the head is a conically shaped shaft 508. The outer surface of

shaft 508 is threaded, (threading not identified) to facilitate the screw securement of the pin 502 into a bone section. Alternatively, instead of being provided with a shaft, an exposed layer of adhesive material may be attached to the distal end of the pin head 506. The adhesive is of a type that adheres to bone and that upon application of a release force can be removed. Alternative methods of attaching the pin head 506 to a bone include simply providing shaft 508 with a pointed distal end that, upon the application of pressure can penetrate and lock into bone.

**[000160]** Internal to the pin head is an RFID 510 that is connected to a coil 512. While not illustrated, it should be understood that a tuning capacitor may be connected in parallel across the RFID 510. The memory in RFID 510 contains a data field in which data are stored that identifies that associated pin 502 with specificity.

**[000161]** A handle 514 secures the pins 502 into the bone sections 492-500 before the removal of the bone fragments 494, 496 and 498 from the surgical site. Handle 514 includes an elongated shaft 515. A collet assembly extends out from the proximal end of the shaft 515. The collet assembly includes a plurality of legs 518 (two legs shown partially in solid and partially in phantom). Each leg 518 has a foot 320 that extends inwardly. Each collet foot 520 seats in a complementary indentation 522 formed in pin head 306. A lock and latch mechanism, also part of the collet assembly and not illustrated, urges the collet feet 520 towards the longitudinal center axis of the handle shaft 515. When the collet assembly is in this state, the collet feet 520 hold the pin 502 fast to the distal end of the handle 514.

**[000162]** A tracker 524 is integrally attached to the proximal end of the handle shaft 515. Illustrated are the location identifying LEDs 526, the data transmitting LEDs 328 and the data receiving photosensor 529. Tracker 524, while attached to shaft 515, is able to rotate relative to the shaft. A coil 530 is disposed in the distal end of the shaft 515. Coil 530 is positioned to inductively exchange signals with coil 512 integral with the pin 502.

**[000163]** When system 20 of this invention is used to keep track of bone sections 492-500, handle 514 is used to attach the individual pins 502a-e, step 540 in Figure 31. Under the protocol, the handle 514 is used to drive the pin shaft secure the pin shaft into the bone section. The pins 502a-e are driven into the individual sections prior to the removal of the bone fragments 494, 496 and 498. Once each pin 502 is sufficient secured, as part of step 540, the tracker 524 is rotated relative to the handle shaft 515 so the LEDs 526 and 328 are directed to the localizer 30. The LEDs 526 provide the localizer data from which the position of the pin 30 is determined. As part of step 540, for each pin the data in the RFID 510 are transmitted through coils 312 and 330 to the tracker 524. The tracker 524 broadcasts these data through LEDs 328 to the localizer transceiver 35.

**[000164]** The localizer transceiver 35 forwards the data from LEDs 526 and 328 to the system processor 32. Based on these data, the system processor 32 assigns each pin 502 and the respective bone section 492-500 a specific location at the surgical site. Based on the data regarding the location of the pins 502a and 502f in the bone sections 492 and 500, respectively, that are not removed, the processor determines the locations where the

pins 502b, c, d and e are to be returned, step 542. These are the pins attached to the bone fragments 494, 496 and 498 that, as part of the procedure, are removed from the surgical site. As part of step 542, this location identifying data are stored in a look-up table internal to the memory integral with the processor 32.

**[000165]** The bone sections to be removed, fragments 494, 496 and 498 are then removed, step 544. Handle 514 or other surgical instrument is employed to remove the fragments. The bone fragments 494, 496 and 498 are removed with the pins 502b, c, d and e still attached.

**[000166]** At the point in a procedure in which it is necessary to reattach a specific bone fragment 494, 496, or 498, the handle 514 is reattached to the pin 502b, 502d or 502e integral with the fragment. The data in the pin RFID 510 are read back into the system processor 32, step 546.

**[000167]** The processor 32 references the table established in memory of pin locations. Based on these data and the identity of the specific pin 502b, d, or e the processor provides information regarding the location at the surgical site at which the bone fragment attached to the surgical site should be reattached, step 548.

**[000168]** During the reattachment procedure, step 550, handle 514 is used to grasp the pin 502 so the pin-and-bone fragment is returned to the appropriate position. Based on the data indicating from where the pin 502 was when the bone fragment was removed, and the data regarding the location of the fixed points, the system processor 32 provides information regarding the exact location at the surgical site at which the bone fragment should be placed, step 352. As depicted in Figure 32, this information is often presented on the display 36 as

in image indicating the target location for the pin, blue dot 560 (the location at which the pin should be located) and the actual location of the pin, red dot 564.

**[000169]** Thus, system 20 of this invention, without wires, provides a means to both maintain a record of where, relative to each other removed body tissue is located and where, at the surgical site, the tissue is to be reattached.

**[000170]** In an alternative version of the above system, two or more pins 502 are attached to each bone fragment to be removed. This is depicted in Figure 29 wherein two pins 502b and 502c are attached to bone fragment 494. In step 542, the location of both pins 502b and 502c is determined and stored in the system processor. During the fragment reattachment process, steps 550 and 552, the location of both pins is tracked. Processor 32 causes display 36 to present images of both the target return and actual locations of each pin integral with fragment 494. Thus, in Figure 22, blue dots 560 and 562 may be the target return locations for pins, 502b and 30c, respectively. Red dots 564 and 566 are the actual locations of the pins.

**[000171]** This information allows the surgeon to determine both the correct location at which the fragment should be positioned and the proper orientation of the fragment.

**[000172]** In the above version of the invention, a handle with plural movable legs may be simultaneously locked to both pins 502b and 502c. Each leg contains a coil for reading the data associated with the complementary pin. Sensor provide data regarding the orientation of the legs relative to each other. Both the data read from the pin RFIDs and the data indicating the orientation of the legs

is supplied through the associated tracker to the system processor 32. Based on the data describing the leg positions, using geometric formulas, the processor 32 is able to determine the relative positions of the pins to each other.

**[000173]** The foregoing description is directed to specific versions of the invention. It should be appreciated that other versions of the invention may have features different what has been described

**[000174]** For example, there is no requirement that in all versions of the invention, the transmitting/receiving heads used to exchange signals with the tracker be integral with the localizer. In some versions of the invention, these heads may be positioned at different locations.

**[000175]** In the described version of the invention, the tracker 28 emits energy and the source of the transmissions is monitored by the localizer 30. These functions may be reversed in some surgical navigation systems. For example, in a magnetic system, the tracker contains sensor that monitor the strength of magnetic fields that emanate from fixed sources. Based on the differences in the strengths of the measured fields, processors integral with the tracker or system processor determine tracker location and orientation. Thus, it should be understood that this invention is not limited to integration with one specific type of navigation system.

**[000176]** Similarly, there is no requirement that in all versions of the invention, RFIDs be employed as the devices with memories in which data describing the associated surgical component are stored. In some versions of the invention, the memory may be a bar code

placed on the device. In these versions of the invention, readers integral with the tracker scan the bar code data. Other circuitry internal to the tracker converts the data into a form in which it can be broadcast to by the tracker to the associated static receiver. Alternatively, the data may be stored in other forms of memories that are read by optical scanning or other reading methods.

**[000177]** Electrical connectors in the tracker and complementary surgical components that require physical connection may be used as the signal transmitting/receiving heads. However, given the presence of conductive fluids at surgical sites, this is not a preferred means of connection.

**[000178]** Also, while it is preferred that the tracker only have a single transmitting/receiving head for exchanging signals with the multiple downline components, coil 96 in the described embodiment, this is exemplary, not limiting. In some versions of the invention, the tracker may have multiple signal transmitting/receiving heads.

**[000179]** Also, in versions of the invention wherein the tracker is able to, through a single signal transmitting/receiving head obtain signals from multiple attached components, different protocols may be used to ensure that the data from the multiple memories are read. For example, in some versions of the invention, the RFID or other storage device associated with each class of component may be set to, in response to read request, be configured to write out the data after a specific delay period. Thus, in response to the tracker sending a basic identity interrogation signal, each component, at a different time, responds with a signal containing the

identifying data. In this manner, the tracker microcontroller receives in a sequence, data that identifies each of the attached components.

**[000180]** Furthermore, it should be appreciated that the method set forth in the main description regarding how the decoder/encoder 202 responds to the receipt of simultaneous responses to the basic interrogation signal may change. The above method is employed only if the decoder/encoder, through other protocols, cannot respond to data collisions. In one alternative protocol, the decoder/encldoer, when collisions occur, may respond by repeatedly sending out basic interrogation signals. In response to the multiple sets of collided responses, the decoder/encoder may be able to determine the identity of the individual responding components.

**[000181]** In a variation of the primary described method for dealing with data collisions, resistors are series connected to the RFIDs associated with some surgical components. For example, it may be desirable to attach resistors with a high resistance to the RFIDs of the components that would be most distal to the decoder/encoder. Resistors with a lower resistance are attached to the RFIDs of the components intended for connection at an intermediate distance to the decoder/encoder. No resistors are attached to the RFIDs of the components normally located proximal to the decoder/encoder.

**[000182]** As a consequence of the above circuit arrangement, when the first basic interrogation signal is sent, the strengths of the signals associated with the RFIDs distal to the decoder/encoder are significantly attenuated. Consequently, there is essentially no likelihood these signals are read by the decoder/encoder

during the time the reply signals to the first basic interrogation signal is received. Therefore, the decoder/encoder since it would initially only receive the basic identify reply from the RFID of the closest component, would immediately read the data from that RFID. Steps 238 and 239 could thus potentially be eliminated. Again, after the data from the closest RFID are read, the RFID is instructed to respond to the next basic interrogation. This would allow the data in the more distal RFIDs to be read.

**[000183]** Similar changes may be made in the mechanical structure of the features of the invention. For instance, in some versions of the invention, a secondary conduit may be formed in handle 44 to extend the length of the conduit. Conductors 106 may be disposed in this conduit. This conduit would thus eliminate the need to provide the outer sleeve. Also, a highly magnetically permeable sleeve may be fitted around a portion of bearing 58. Coil 104 may is then wound around this sleeve.

**[000184]** In the described version of the invention, the tracker is described as being attached to non-motorized components. This should not be considered limiting. For example, in some versions of the invention, the tracker may be removably attached to or integrally built into a power tool such as the power driver 26. In this version of the invention, a coil located in the power driver 26 is used to read the data in the surgical components attached to the power driver.

**[000185]** In these versions of the invention, sensors integral with the power tool provide data regarding the operating state of the tool. During the time periods the tool is actuated, the sensor data are transmitted through

the tracker to the surgical navigation unit. The system processor 32 based on these data and the operational data read from the component RFID determines whether or not, for the specific attached component, the tool is being operated appropriately.

**[000186]** For example, the RFID integral with a specific reamer 22 in the operating parameter field 222 stores data indicating the maximum speed at which the reamer should be rotated. During the procedure, the power driver 26, through the attached tracker, provides system processor 32 with data indicating the speed at which the driver is being operated. If this speed is above the maximum reamer speed, processor 32 displays a warning message. Processor 32 may also, in a log, record that the reamer was driven at the excessive speed.

**[000187]** Also, there is no requirement that in all versions of the invention wherein RFID pins are used to track body fragments, the devices used to mount the pins also be used to provide the pin RFID data to the system processor 32. In some versions of the invention a first surgical tool may be used to mount the RFID pin. Then once a pin is mounted, a second pointer-with-tracker is locked to the pin. Once this component is so locked, the pointer-with-tracker is used to read and transmit the pin RFID data to the system processor 32 and generate data indicating the position of the pin.

**[000188]** It should be appreciated from the description of handle 514, that, in some versions of the invention, the tracker is integrally assembled into a first surgical component that both reads the data from the RFID integral with a second component and that manipulates the second component.

**[000189]** Alternative means to hold pins 502 to a handle may be employed. For example, the pin head 306 may be formed with geometric features such as threading. The distal end of the handle 514 may have a bore dimensioned to receive the pin head 306. The handle is formed with structural or geometric features in the bore that serve to securely and releasably hold the pin head in the bore.

**[000190]** Also, while the disclosed method of tracking body tissue describes how hard tissue, bone, can be tracked and then guided for proper return, this is only an example. This system and method of this invention may employ tags that are attached to other types of tissue, such as soft tissue to ensure that they are appropriately returned. In these versions of the invention, the tracking pins may be provided small spring feet. These feet are used to clamp around a section of tissue to be removed. Thus, if a tendon is removed and then reinstalled, by attaching these pins, the surgeon will have markers regarding where, upon reinstallation, certain sections of the tendon should be positioned.

**[000191]** Moreover, the type of data stored in the memory integral with the component is clearly a function of component type. For example, if the component is an RF ablation electrode, the RFID would store therein data describing the operating temperature of the electrode, the amount of current the electrode should draw and the type of cannula in which the electrode can be inserted.

**[000192]** It should likewise be appreciated that the means for encapsulating the data storage devices, the RFIDs, may be different from what has been described. In some versions of the invention a cap formed from a polymer may be fitted over the RFID in the reamer or the handle prism. In some versions of the invention, this

cap may be formed from metal. In these versions of the invention, laser welding may be employed to seal the cap. This cap can also be formed from a ceramic. In still other versions of the invention, this cap, which may be three dimensional or in the form of a planar disk, is formed from combinations of two or more of the above materials.

**[000193]** Some processing functions performed by the system processor 32 may alternatively be performed by the tracker microcontroller 190. For example, based on the data received from the component RFIDs, the microcontroller may determine whether or not the associated surgical components can be used together and whether or not sterilization service or run time data indicates a particular component is ready for use. If the microprocessor 190 detects a fault state, it forwards an appropriate message to the system processor 32. Processor 32, in turn, causes an appropriate warning message to be presented on display 36.

**[000194]** Also, it should be appreciated that there is no limit to the types of surgical components, surgical implements, that can be provided with an RFID and employed in the reactive surgical and surgical navigation system of this invention. Other components that can be provided with RFIDs include: acetabular window trials; femoral reamers; femoral neck trials; femoral heads, including trial heads; and femoral implants. Surgical implements, including trial inserts and the actual implants themselves used for other joint replacement procedures may likewise be fitted with RFIDs so they can be used in the wireless reactive surgical and surgical navigation system of this invention.

**[000195]** Similarly, the information stored in the RFIDs integral with the components may be different from what has been described. Each RFID memory, in addition to storing data that identifies the component also has space in which a surgical log can be maintained. Each time the component is used in a surgery, the data in the log are updated to reflect the date of the surgery. A code identifying the patient on which the surgery was performed may also be written into the log. These data would make it possible to after the surgery, if necessary, locate the patient on whom the component was used.

**[000196]** Further, means other than inductive signal transfer may be used to transfer data through from the implement, the implant, the tissue forming instrument, through the surgical instrument to the tracker. In some versions of the invention, fiber optic cables are disposed in the instrument to facilitate the transmission of optical signals to the tracker. The tracker includes a complementary receiver able to receive these signals and forward them to the data transceiver 198.

**[000197]** Therefore, it is an object of the appended claims to cover all such variations and modifications that come within the true spirit and scope of the invention.

What is claimed is:

1. A surgical instrument, said instrument including:

a handle (24);

a drive shaft (50) mounted to said handle to rotate, said drive shaft having a distal end;

a coupling assembly attached to the drive shaft distal end, said coupling assembly configured to releasably lock a surgical implement to said drive shaft so that the implement moves with said drive shaft;

a first receiver located in said coupling head for receiving signals from a memory unit in the surgical implement.

a first transmitter connected to said coupling assembly and that connected to receive the signals from said first receiver and to wireless broadcast the signals;

a second receiver attached to said handle positioned and configured to receive the signals transmitted by said first transmitter; and

a tracker attached to said handle, a navigation unit that wirelessly exchanges signals with a remote navigation unit to facilitate the generation of data regarding the position or orientation of said tracker; and a transmitter connected to said second receiver for receiving the signals received by said second receiver and that wireless transmits the signals to a remote receiver.

2. The surgical instrument of Claim 1, wherein:

said tracker is removably attached to said handle;

a second transmitter is attached to said handle, said second transmitter being connected to said second

receiver and being configured to wireless transmit signals received from said second receiver to said tracker;

a third receiver is attached to said tracker, said second receiver being positioned to a configured for receiving signals transmitted by said second transmitter; and

said tracker transmitter is connected to said third receiver for receiving the signals received by said third receiver.

3. A surgical reamer, said reamer including;

a body, said body shaped to having cutting surfaces;

a structural member integral with said body, said structural member dimensioned to be received in a coupling unit that releasably holds said structural member to a drive shaft; and

a memory unit attached to said structural member, said memory unit containing data that identifies said reamer; and a transmitter integral with said memory unit for wirelessly transmitting data from said memory unit to the drive shaft.

4. The surgical reamer of Claim 3, wherein said structural member is an elongated bar that extends between opposed ends of said body.

5. The surgical reamer of Claim 3, wherein:

said structural member is elongated bar; and

said memory unit and said transmitter are contained in a cap mounted to said structural member.

6. A surgical instrument for fitting a surgical implement, said instrument including:

a body having opposed proximal and distal ends;

a coupling assembly attached to the distal end of said body configured to removably hold a surgical implement to said body;

a first head disposed in the distal end of said body for contactlessly receiving signals from a memory integral with the surgical implement;

a mounting block attached to said body, said mounting block configured to removably receive a surgical navigation tracker; and

a second head disposed in said mounting block, said second head connected to said first head for receiving signals from the first head and configured to contactlessly transmit the signals to the tracker.

7. The surgical instrument of Claim 6, wherein:

said first head is configured to inductively exchange signals with a head integral with the surgical implement memory; and

said second head is configured to inductively exchange signals with a head integral with the tracker.

8. The surgical instrument of Claims 6 or 7, wherein a plurality of said mounting blocks are attached to said body at spaced apart locations along said body and each said mounting block has a separate said second head, each said second head being attached to said first head.

9. The surgical instrument of Claim 6, 7 or 8, wherein:

said mounting block is rotatingly attached to said body; and

an alignment unit extends distally from said mounting block to releasably abut the surgical implement to position the surgical implement and said mounting block in a spatial relationship.

10. A surgical instrument including:

a body, for positioning a surgical implement, said body having a distal end;

a coupling member attached to the distal end of said body, said coupling member configured to releasably hold the surgical implement to said body;

a mounting block movably attached to said body, said mounting block shaped to removably receive a surgical navigation tracker;

an alignment unit that extend from said mounting block to releasably abut the surgical implement to position the surgical implement and said mounting block in a select spatial relationship;

a memory integral with said body of said mounting block that stores data describing said surgical instrument; and

a transmitter in said mounting block attached to said memory, said transmitter connected to said memory for contactlessly transmitting signals containing the data in said memory to a receiver in the tracker.

11. A tracker for surgical navigation system, said tracker including:

a body (42);

at least one transducer (192) for transmitting signals to or receiving signals from a localizer (30) so that the position of the tracker can be determined; and

a coupling unit (42) attached to the body for releasably securing the body to a surgical component,

characterized in that:

a receiver (96) is attached to the body or the coupling unit for receiving signals from the surgical component to which the coupling unit is attached; and

a transmitter assembly (196, 198) is attached to the body and is connected to the receiver, said transmitter assembly configured to receive the signals from said receiver and transmit the signals wireless to a remote receiver (35).

12. The tracker of Claim 11, wherein said receiver (95) is configured to be inductively coupled to a complementary transmitter integral with the surgical component.

13. The tracker of Claim 11, wherein said receiver is configured to receive light signals from the surgical component.

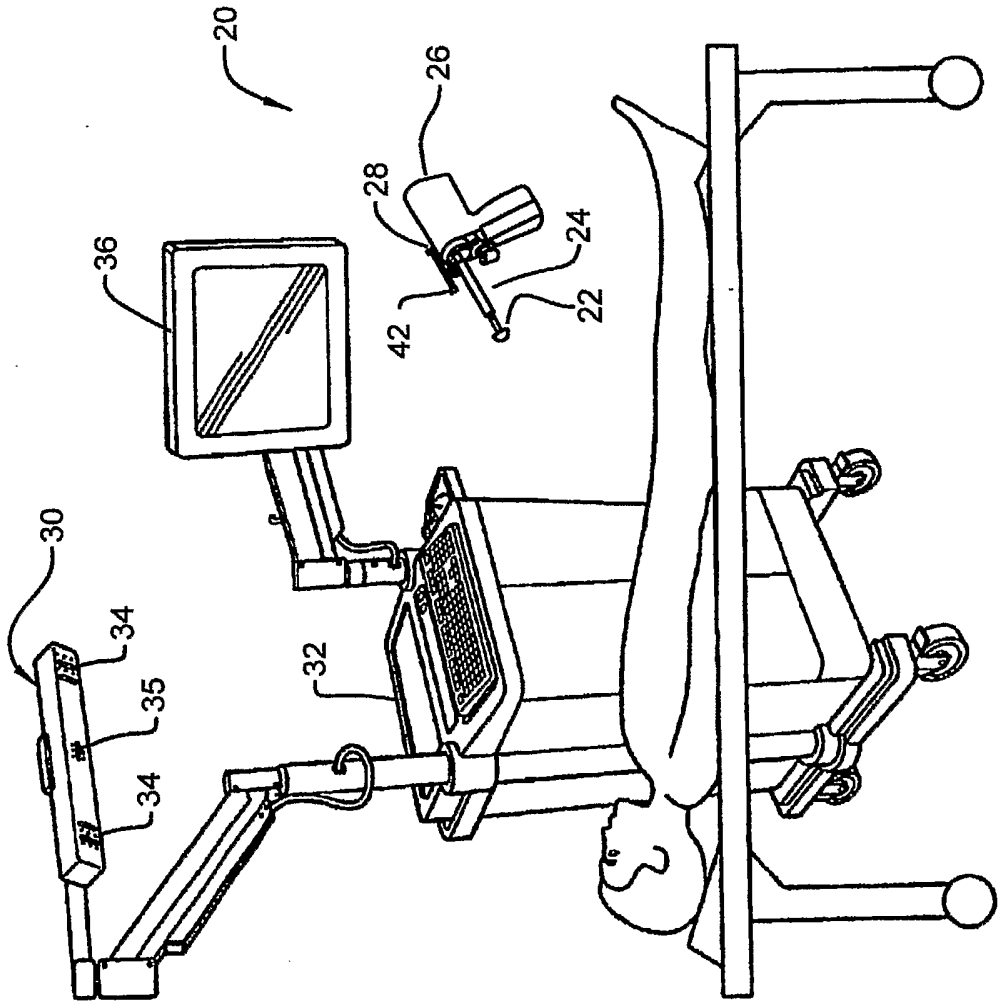
14. The tracker of Claim 11, 12 or 13 wherein said transmitter assembly is configured to transmit light signals to the remote receiver.

15. The tracker of Claims 11, 12 or 13, wherein said transmitter assembly is configured to transmit RF signals to the remote receiver.

16. The tracker of Claims 11, 12, 13, 14 or 15, wherein the at least one transducer transmits or receives light energy.

17. The tracker of Claims 11, 12, 13, 14 or 15, wherein the at least one transducer transmits or receives RF energy or EM energy or sonic energy.

FIG. 1



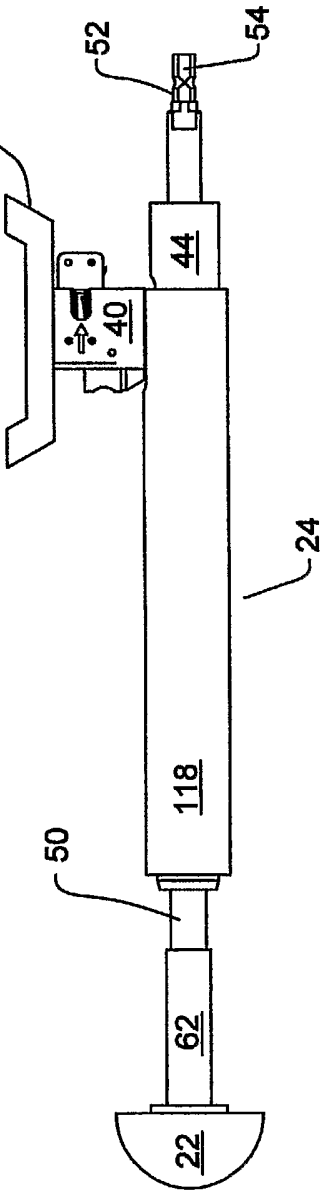



FIG. 2

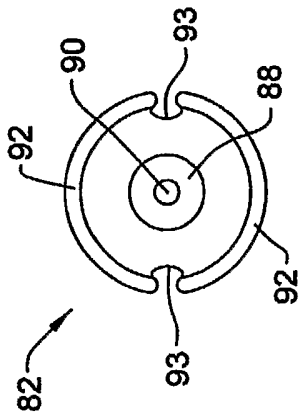



FIG. 5

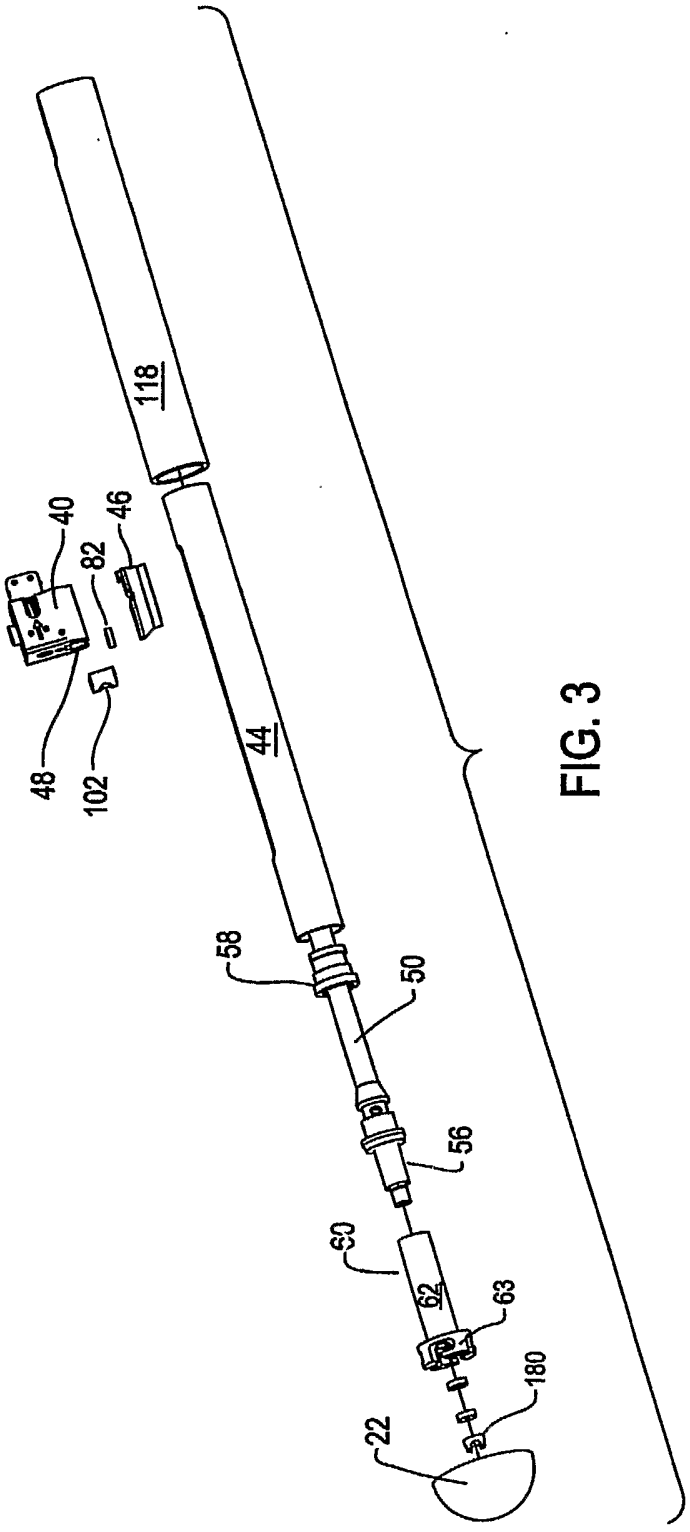
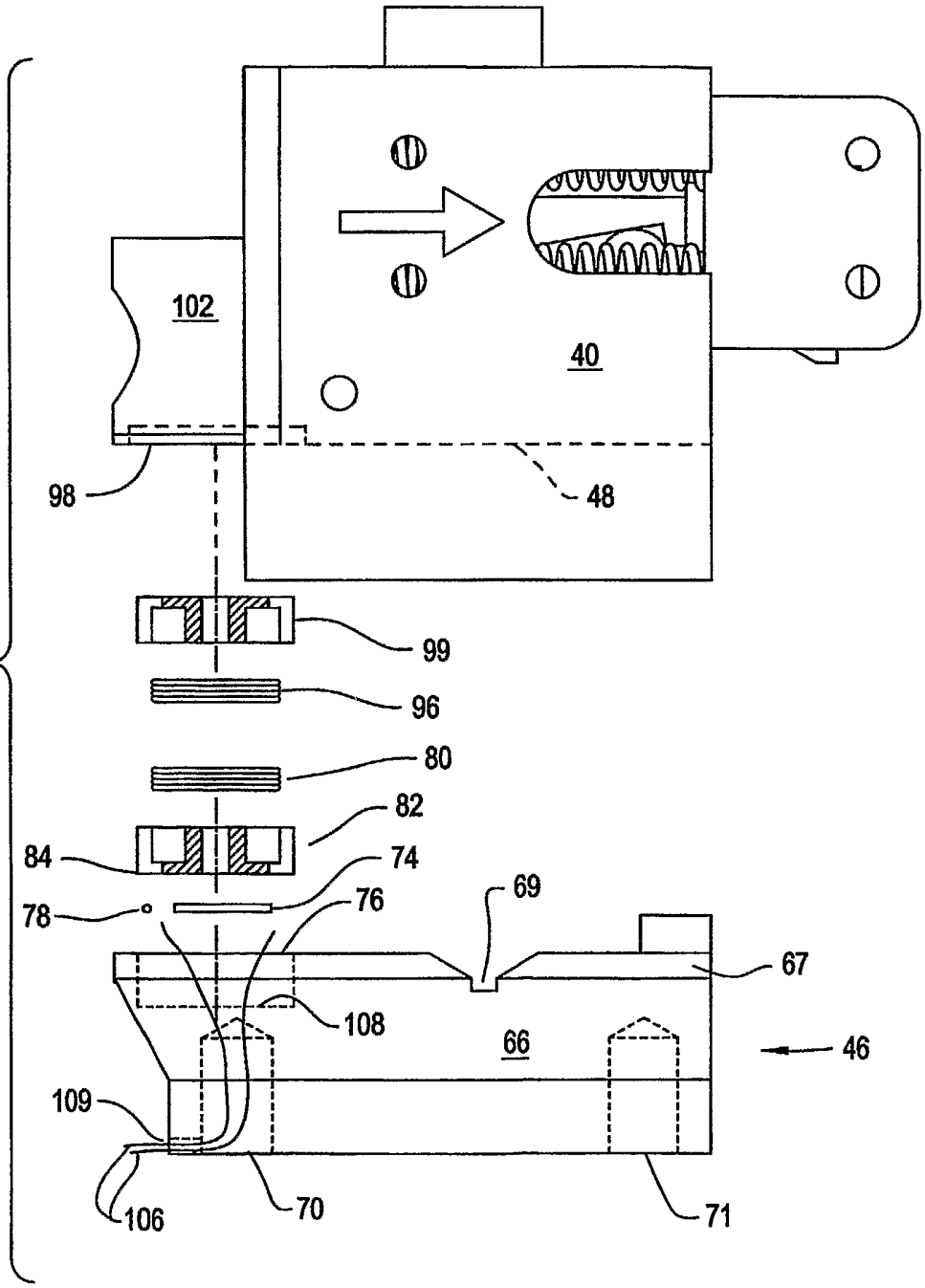



FIG. 3

FIG. 4



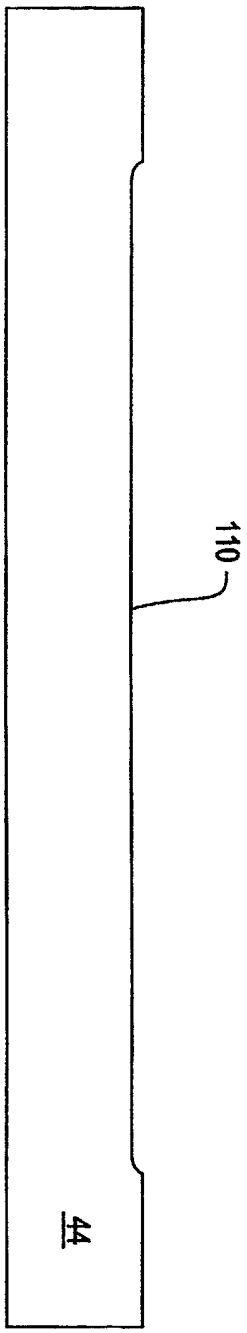



FIG. 7

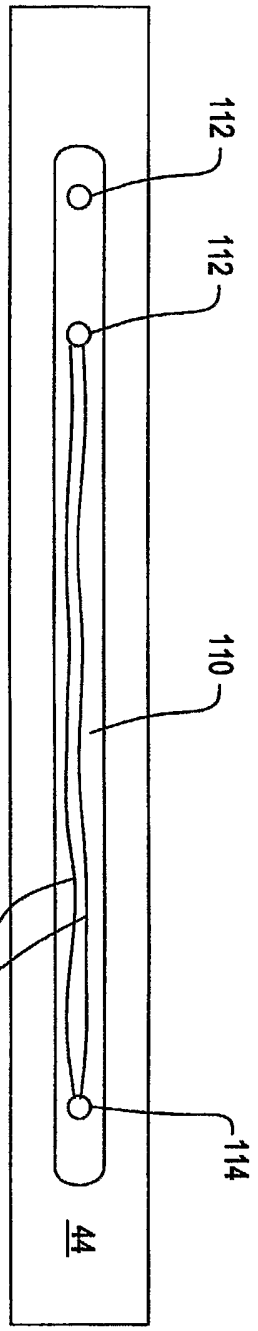



FIG. 6

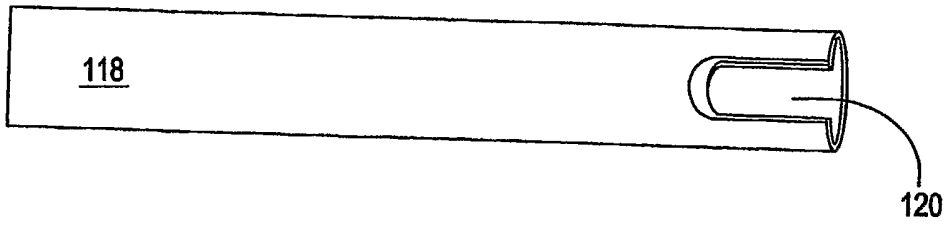



FIG. 8

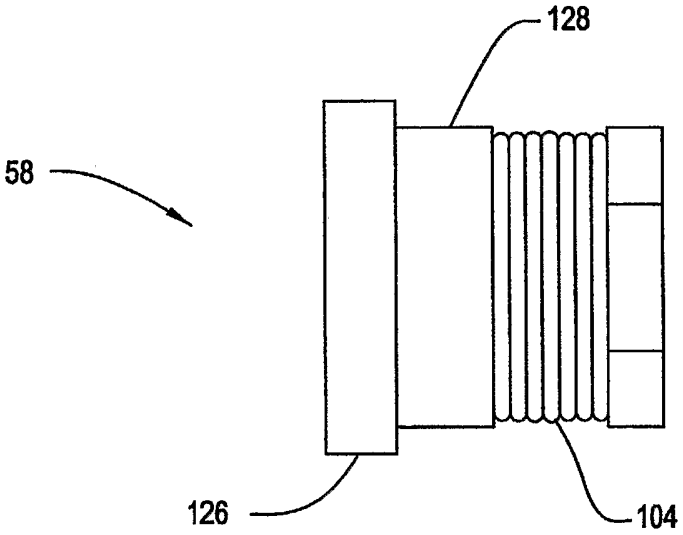



FIG. 9

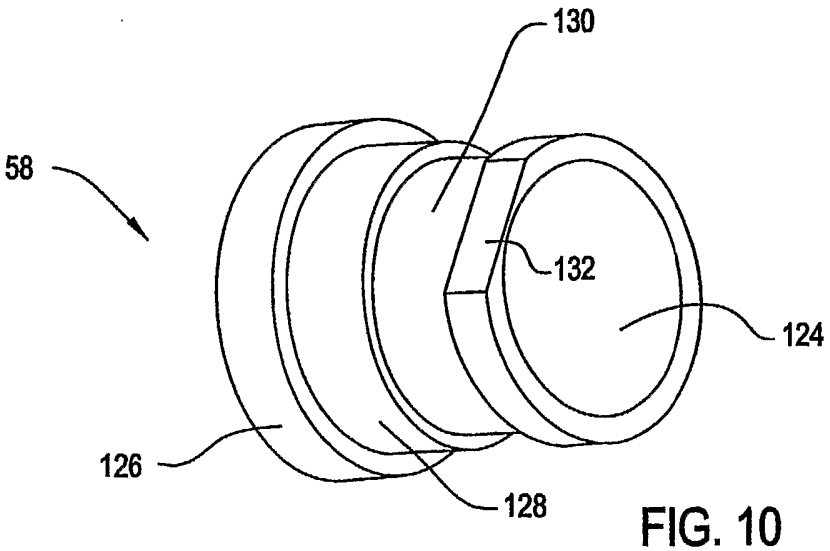



FIG. 10

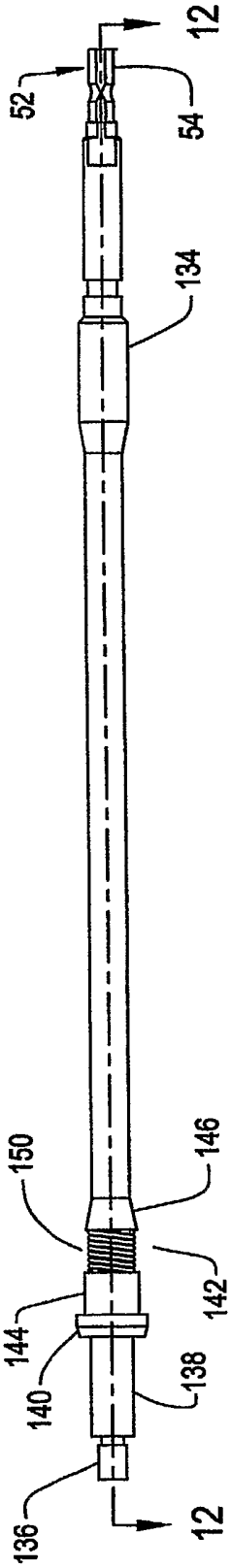
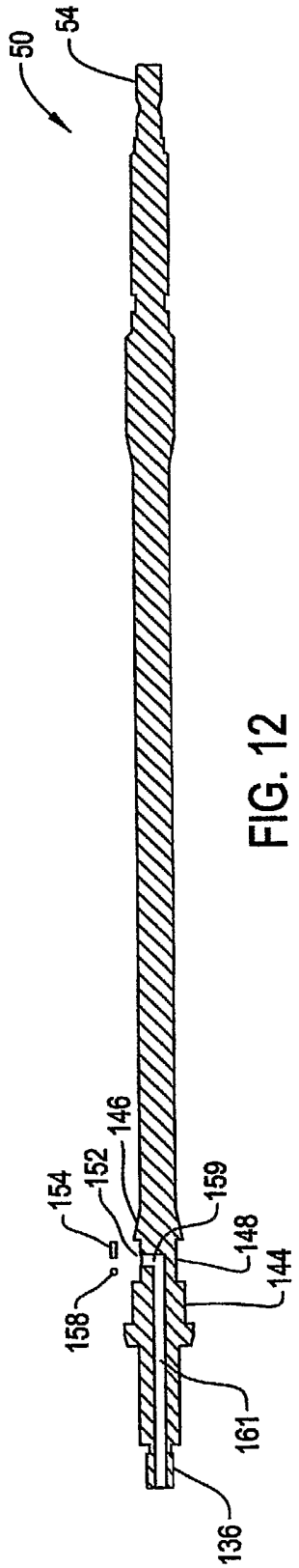

12
52
54
134
150
146
142
144
140
138
136
12

FIG. 11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54
146
154
152
159
148
144
158
161
136

FIG. 12

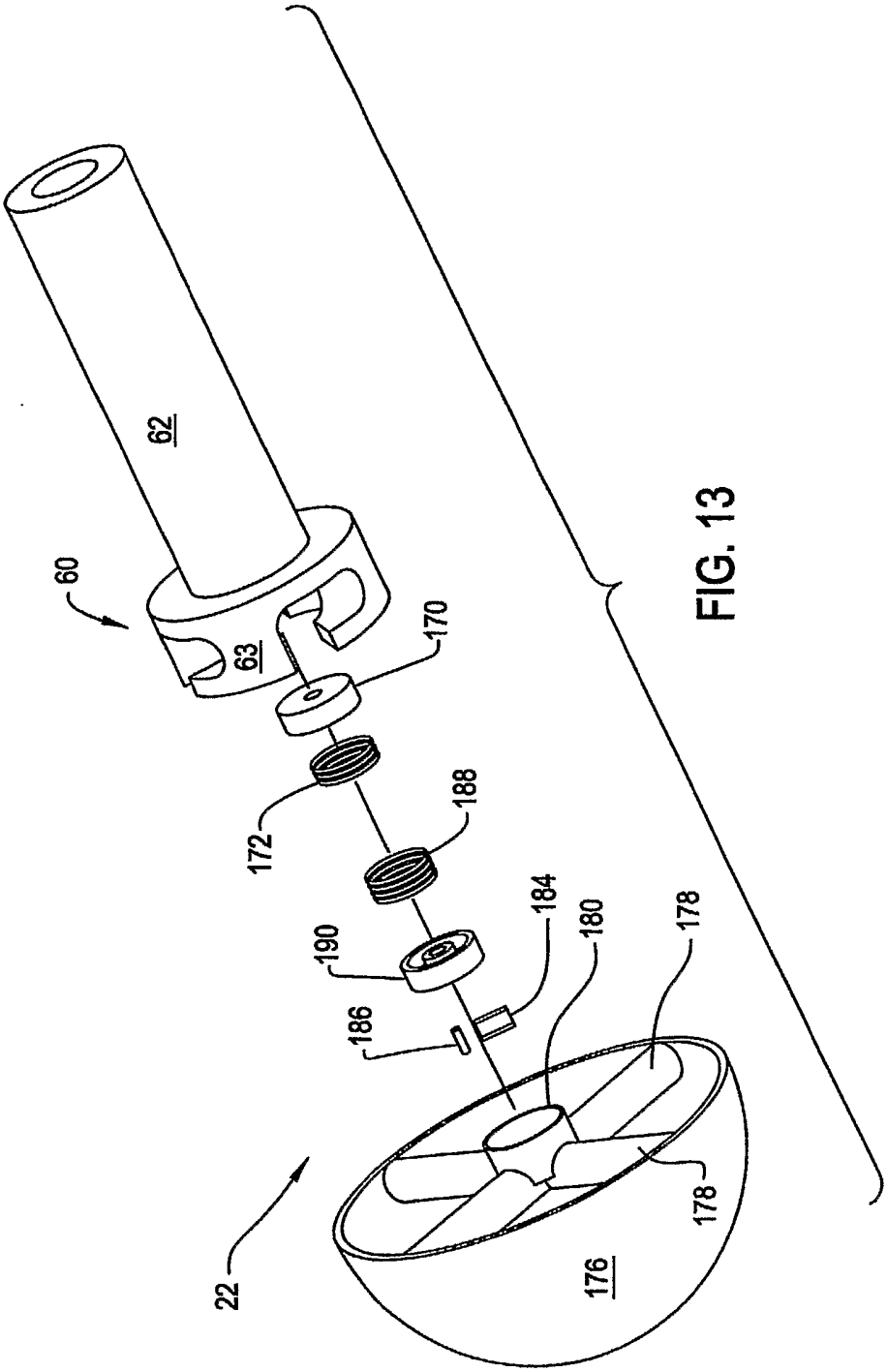


FIG. 13

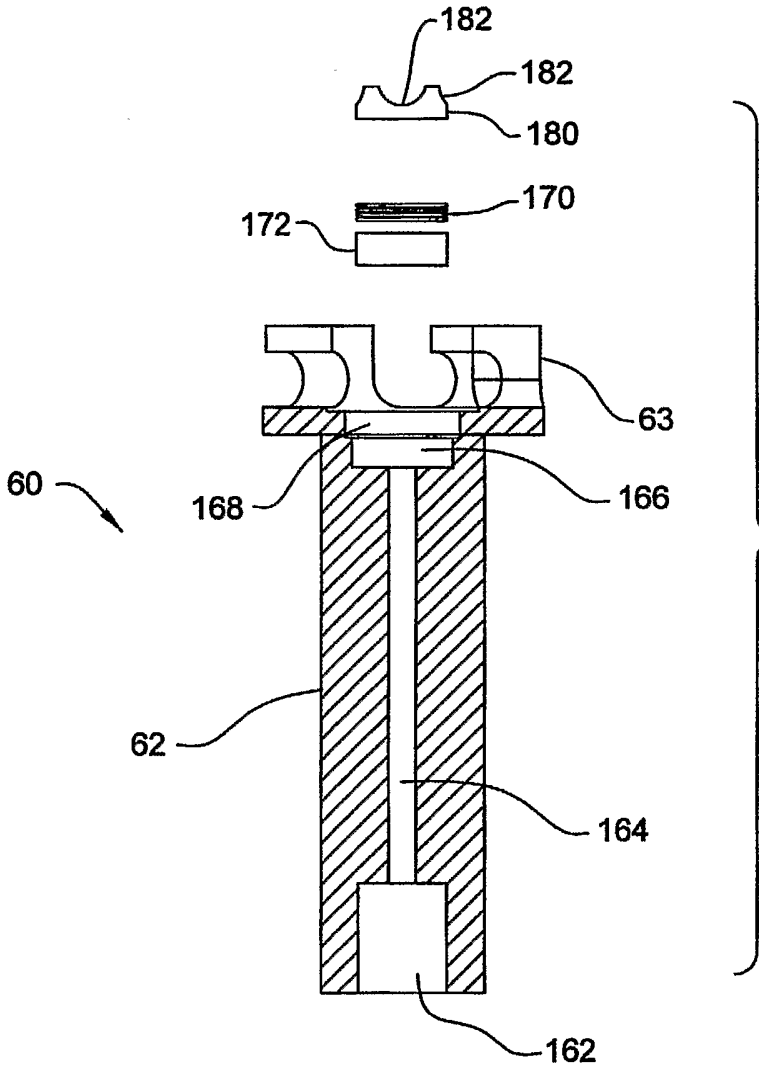


FIG. 14

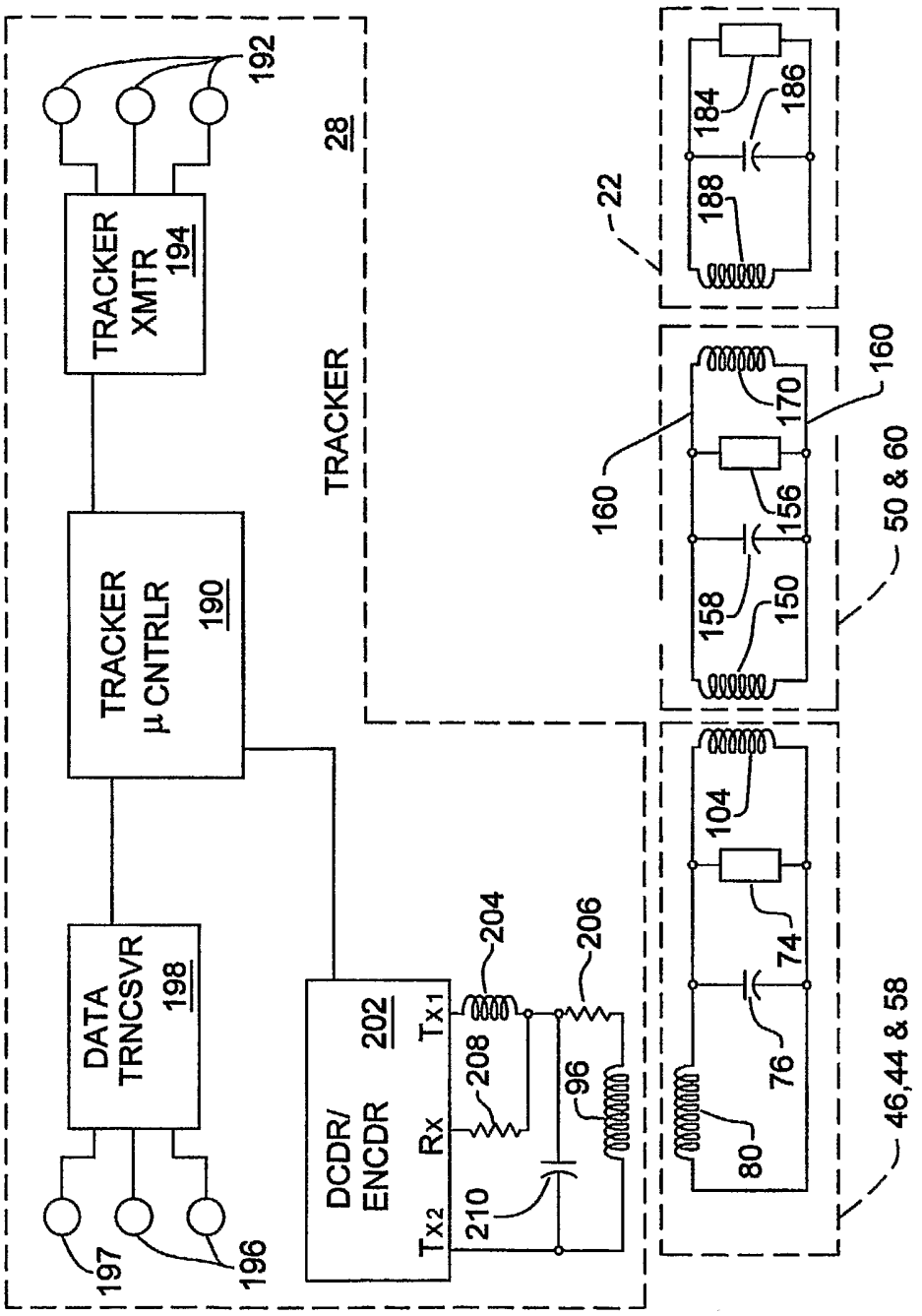
TRACKER
28
TRACKER XMTR 194
TRACKER μ CNTRLR 190
DATA TRNCSVR 198
DCDR/ ENCDR 202
Tx1
Rx
Tx2
192
197
196
204
206
208
96
210
22
184
186
188
160
170
156
158
150
50 & 60
104
74
76
80
46,44 & 58

FIG. 15

| | |
|---|---|
| COMPONENT IDENTITY | 216 |
| COMPONENT PHYSICAL DEF. | 218 |
| COMPANION COMPONENTS | 220 |
| OPERATING PARAMETERS | 222 |
| USE COUNT | 224 |
| STERILIZATION STATE | 225 |
| STERILIZATION DATE | 226 |
| USE DATES | 227 |
| PRIVATE KEY | 228 |
| COMPONENT ORIENTATION | 470 |

FIG. 16

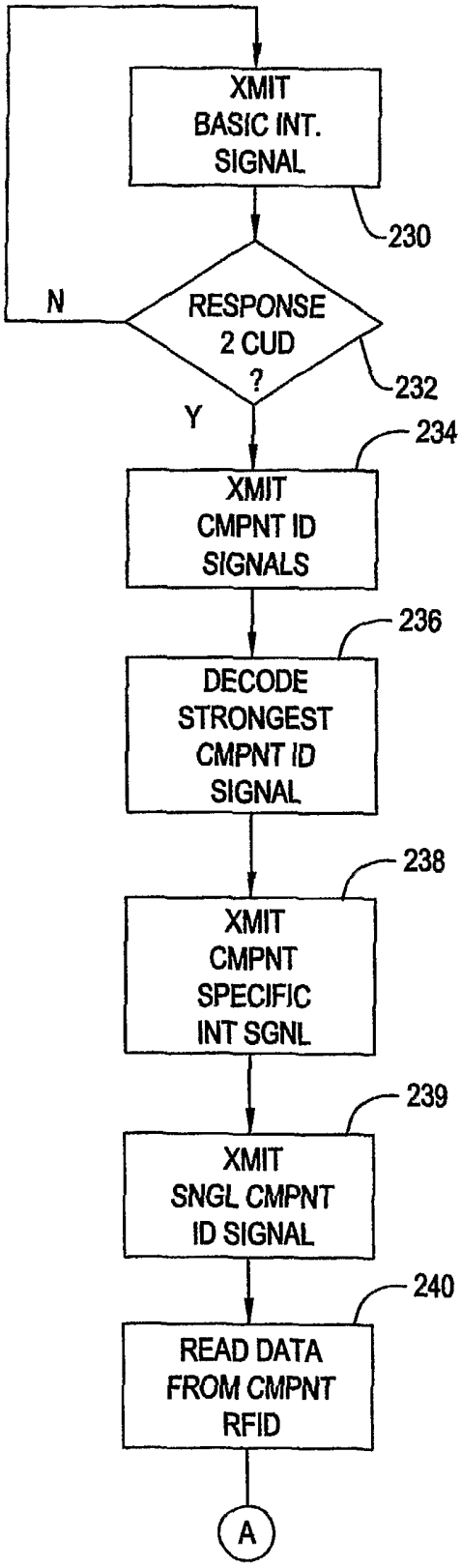
XMIT BASIC INT. SIGNAL
230
RESPONSE 2 CUD ?
232
N
Y
234
XMIT CMPNT ID SIGNALS
236
DECODE STRONGEST CMPNT ID SIGNAL
238
XMIT CMPNT SPECIFIC INT SGNL
239
XMIT SNGL CMPNT ID SIGNAL
240
READ DATA FROM CMPNT RFID
A

FIG. 17A

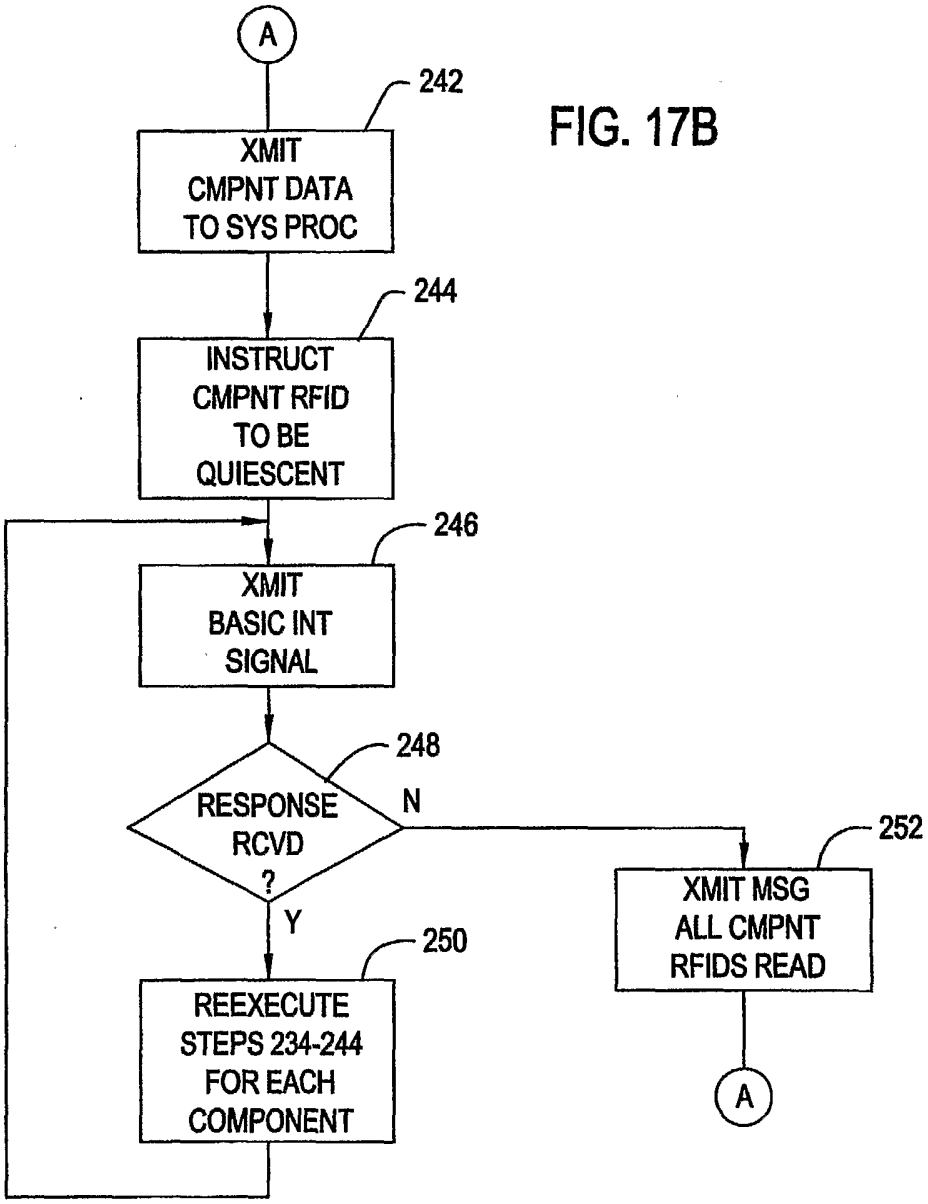
A
242
XMIT CMPNT DATA TO SYS PROC
244
INSTRUCT CMPNT RFID TO BE QUIESCENT
246
XMIT BASIC INT SIGNAL
248
RESPONSE RCVD ?
N
Y
252
XMIT MSG ALL CMPNT RFIDS READ
250
REEXECUTE STEPS 234-244 FOR EACH COMPONENT
A

FIG. 17B

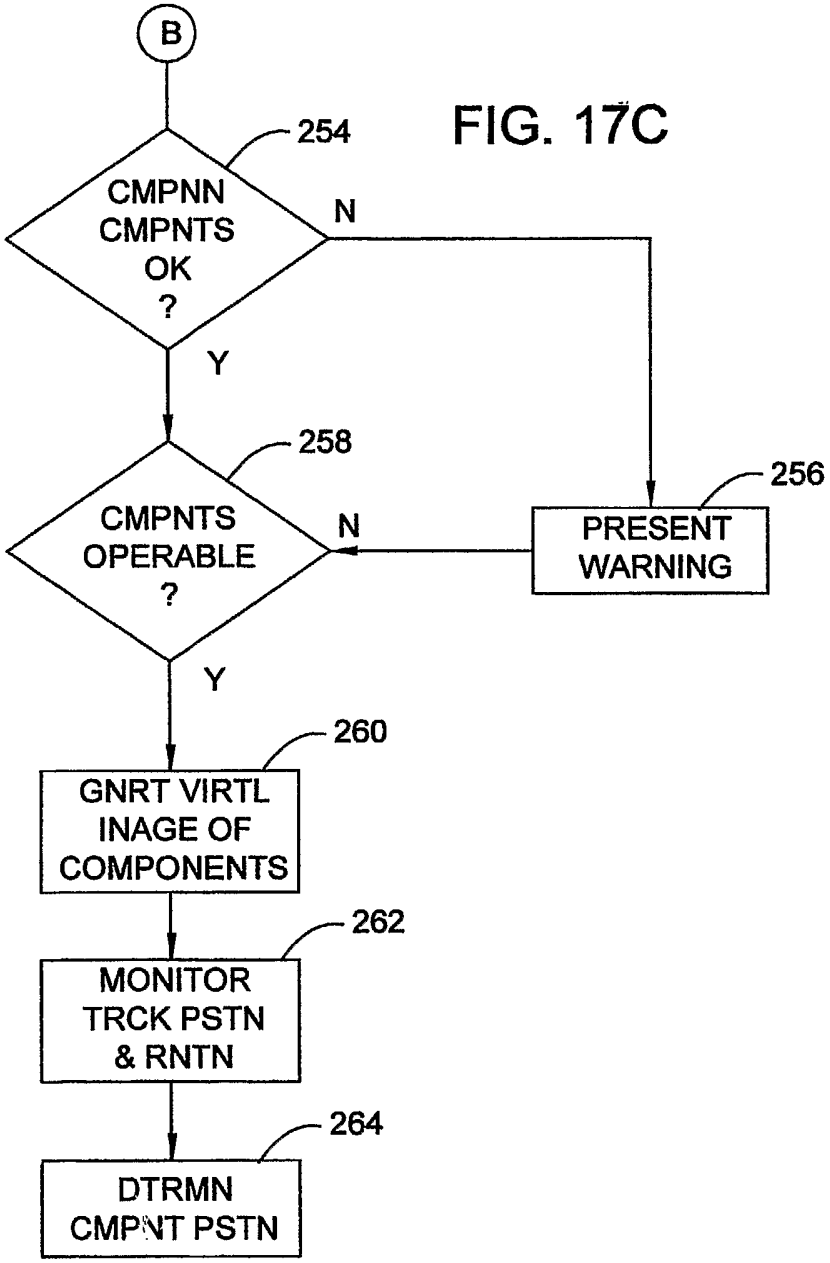
B
254
CMPNN CMPNTS OK ?
N
Y
258
CMPNTS OPERABLE ?
N
256
PRESENT WARNING
Y
260
GNRT VIRTL INAGE OF COMPONENTS
262
MONITOR TRCK PSTN & RNTN
264
DTRMN CMPNT PSTN

FIG. 17C

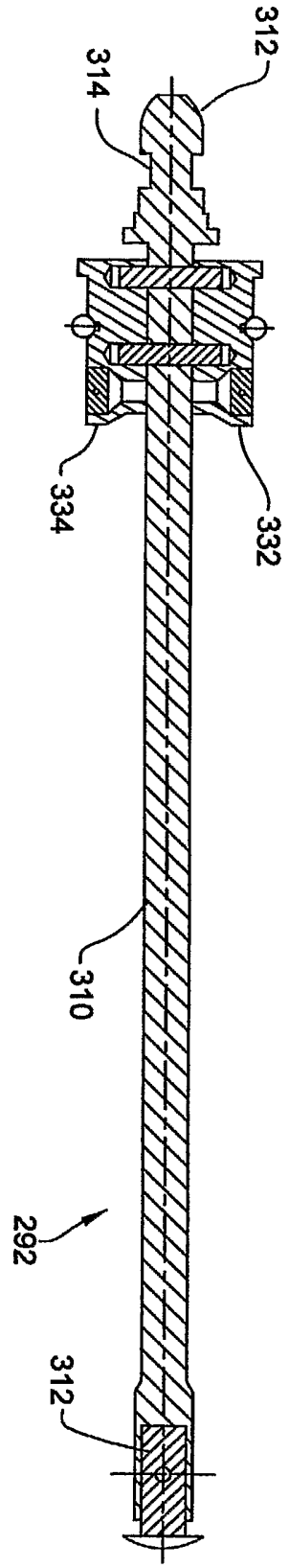


FIG. 19

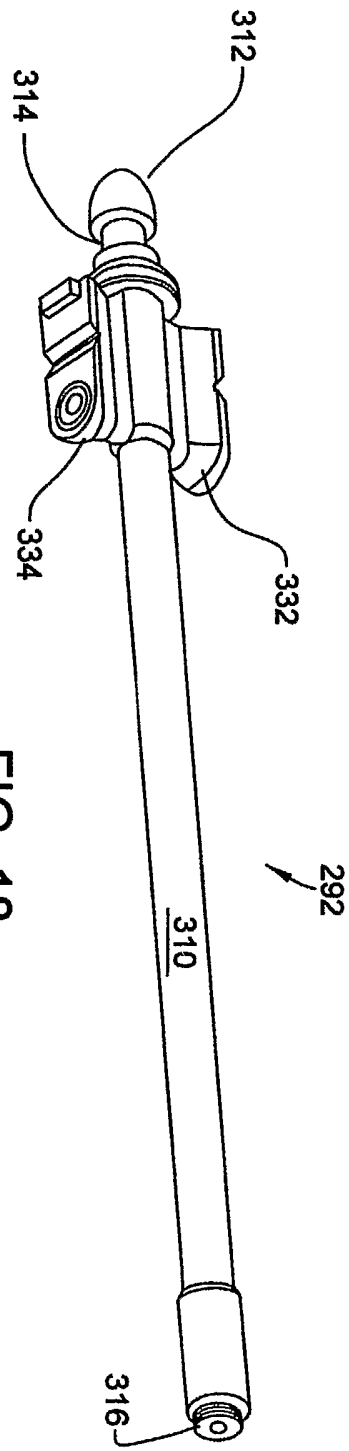


FIG. 18

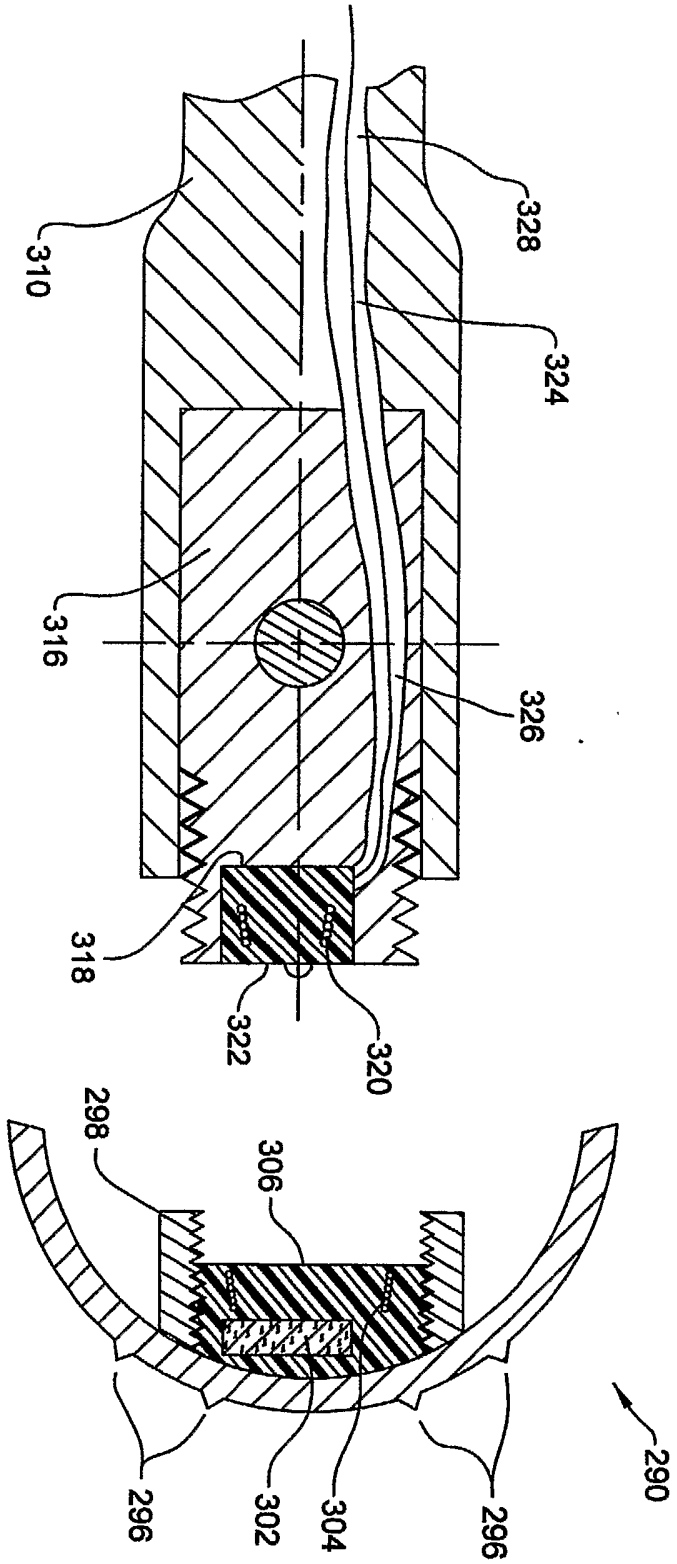


FIG. 20

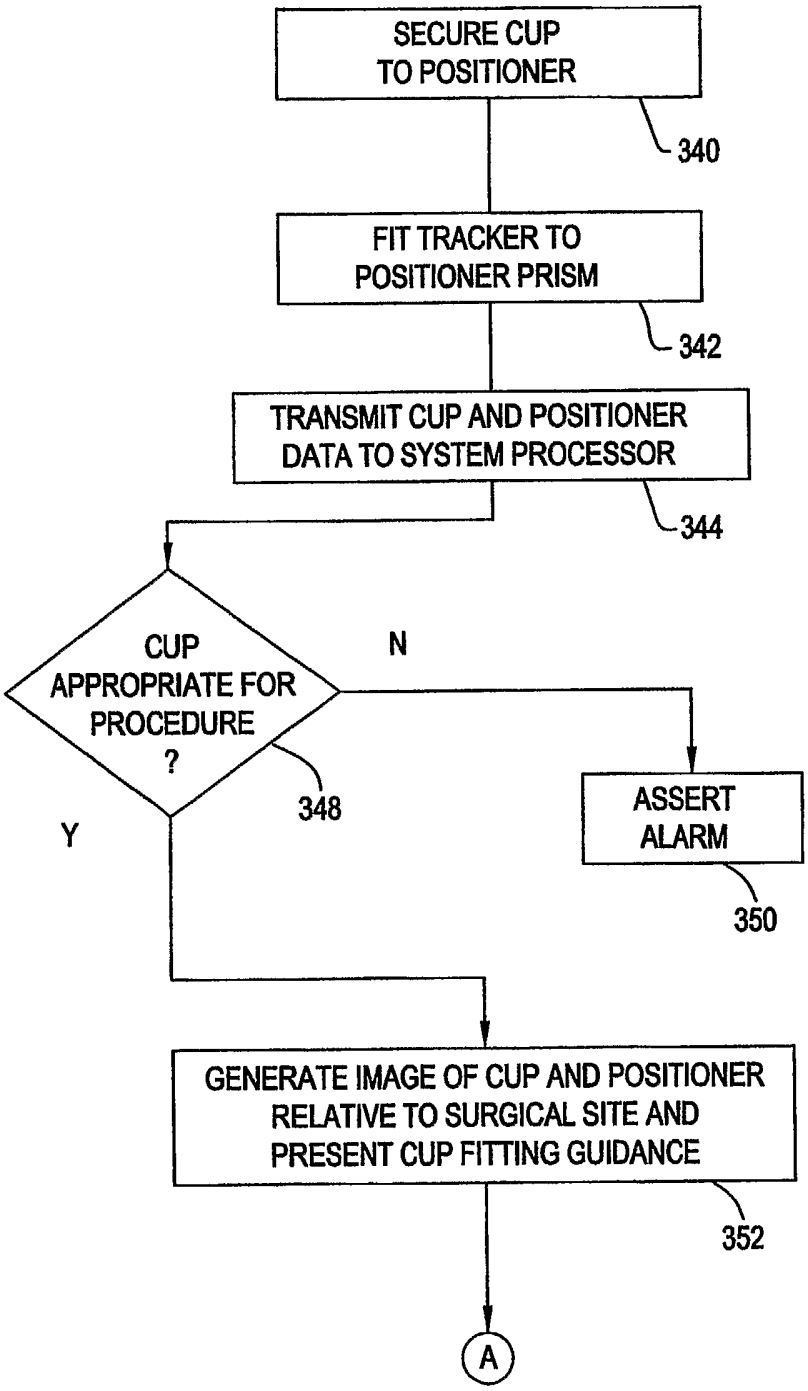
SECURE CUP TO POSITIONER
340
FIT TRACKER TO POSITIONER PRISM
342
TRANSMIT CUP AND POSITIONER DATA TO SYSTEM PROCESSOR
344
CUP APPROPRIATE FOR PROCEDURE ?
348
N
Y
ASSERT ALARM
350
GENERATE IMAGE OF CUP AND POSITIONER RELATIVE TO SURGICAL SITE AND PRESENT CUP FITTING GUIDANCE
352
A

FIG. 21A

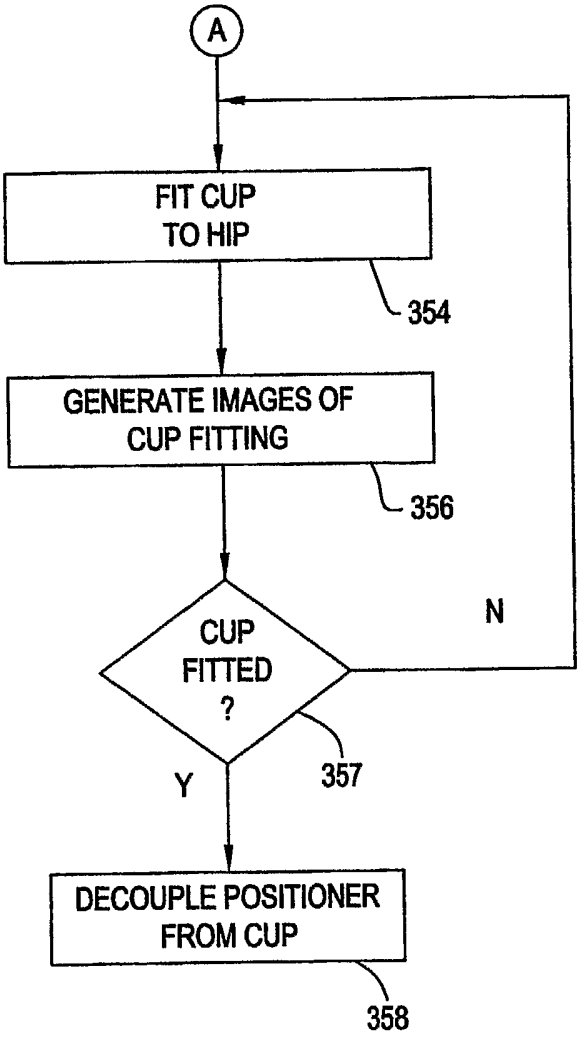
A
FIT CUP TO HIP
354
GENERATE IMAGES OF CUP FITTING
356
CUP FITTED ?
N
357
Y
DECOUPLE POSITIONER FROM CUP
358

FIG. 21B

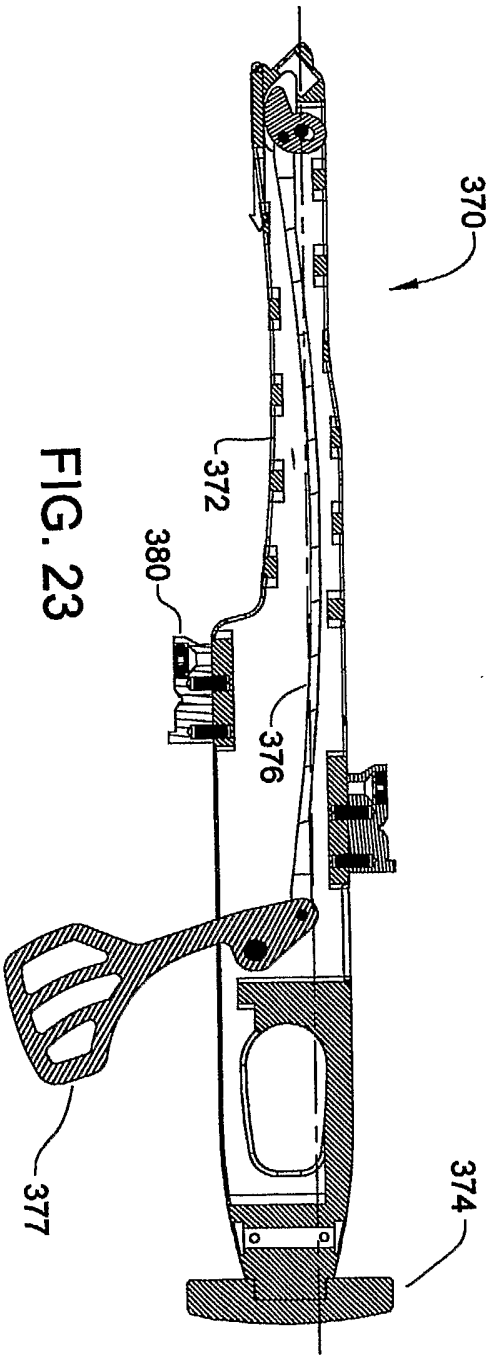


FIG. 23

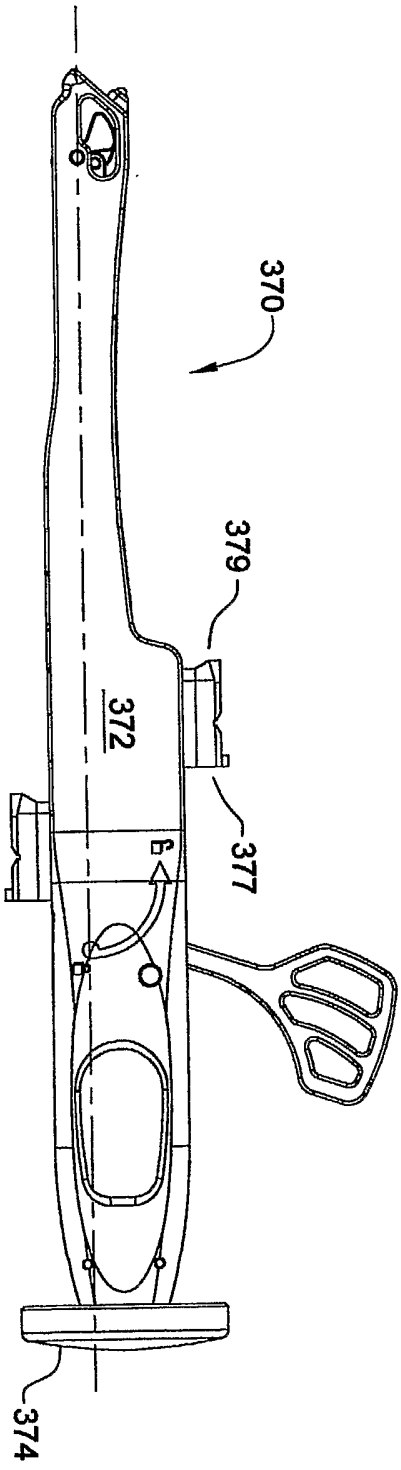


FIG. 22

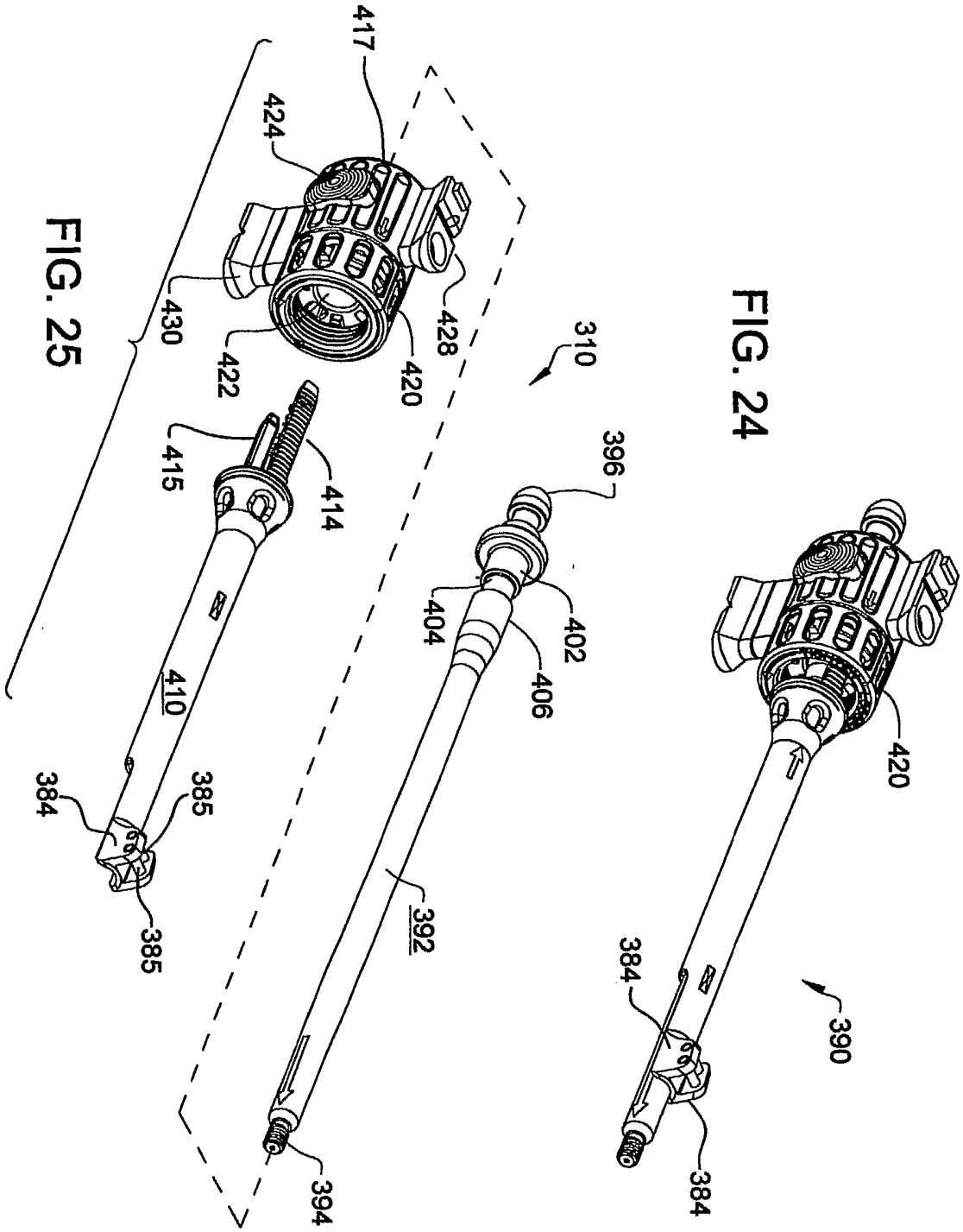
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FIG. 25

FIG. 24

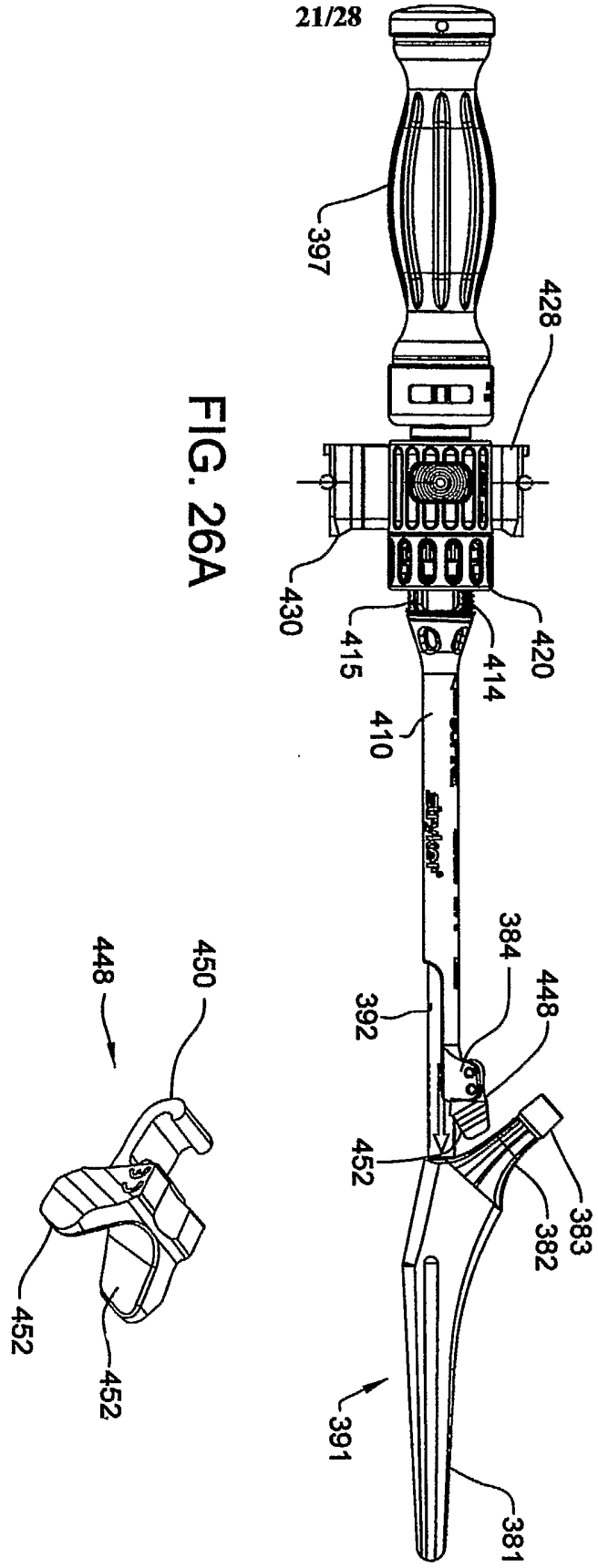


FIG. 26A




FIG. 26C

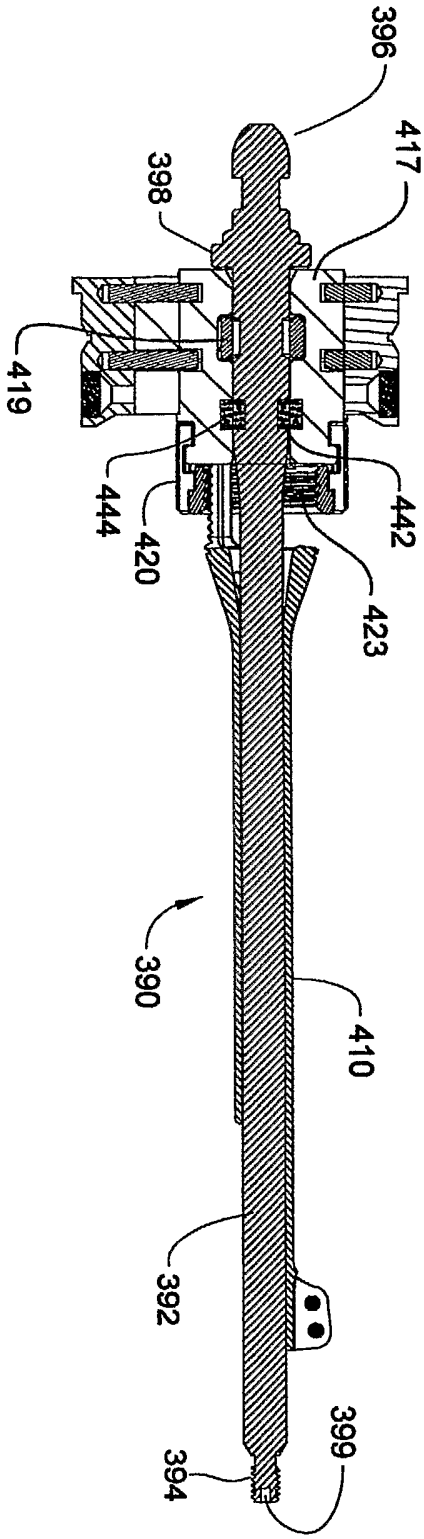


FIG. 26B

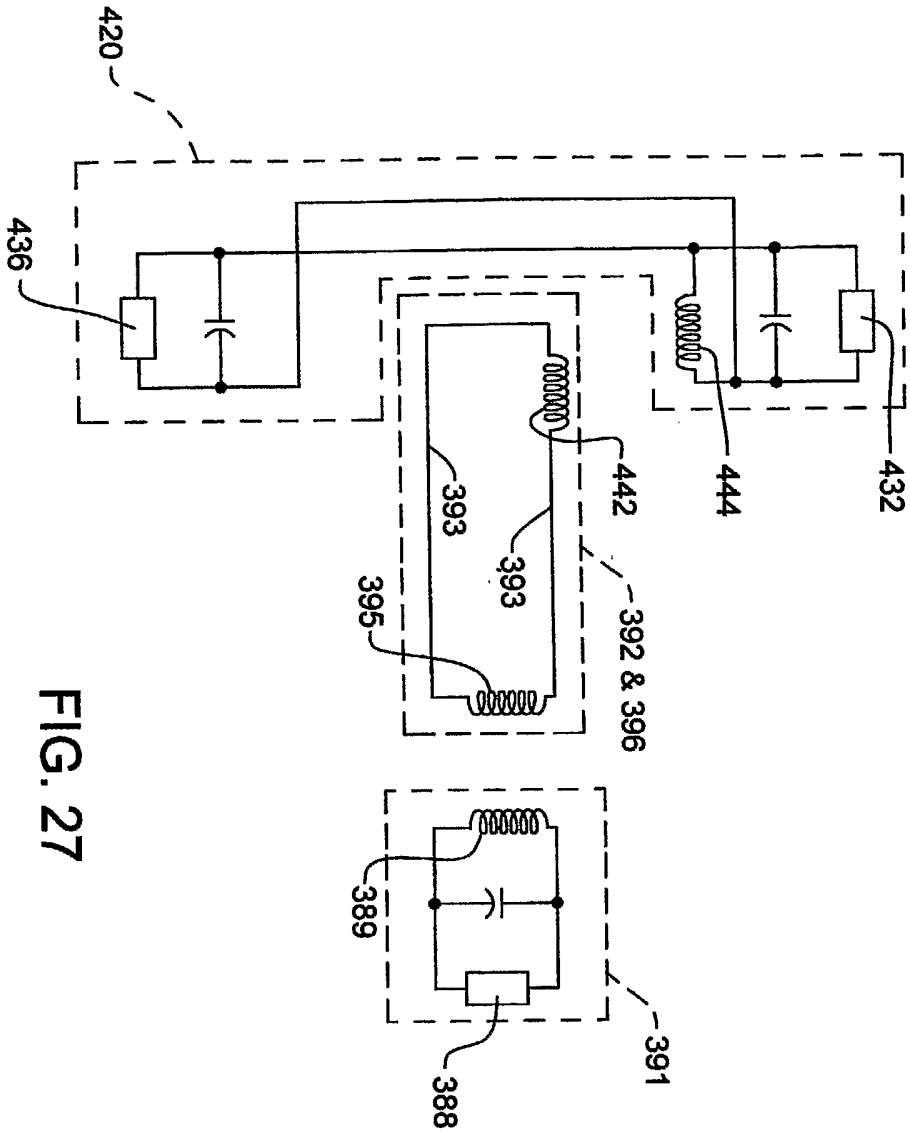


FIG. 27

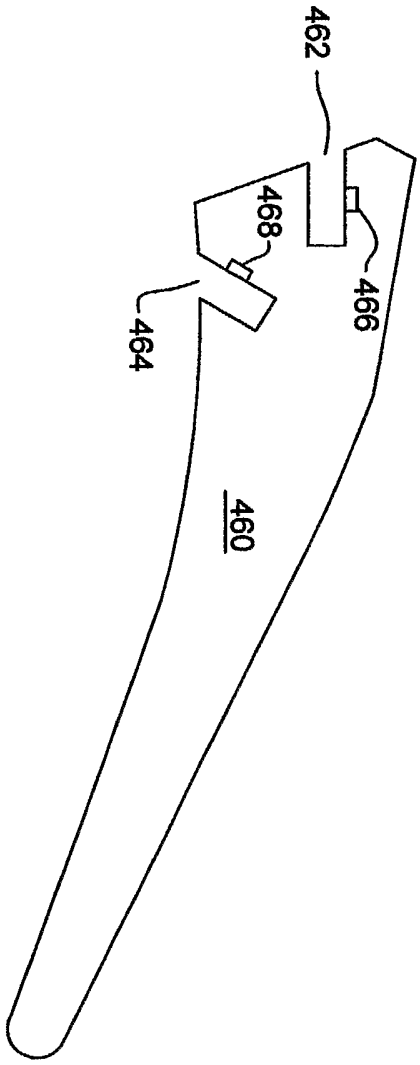


FIG. 28

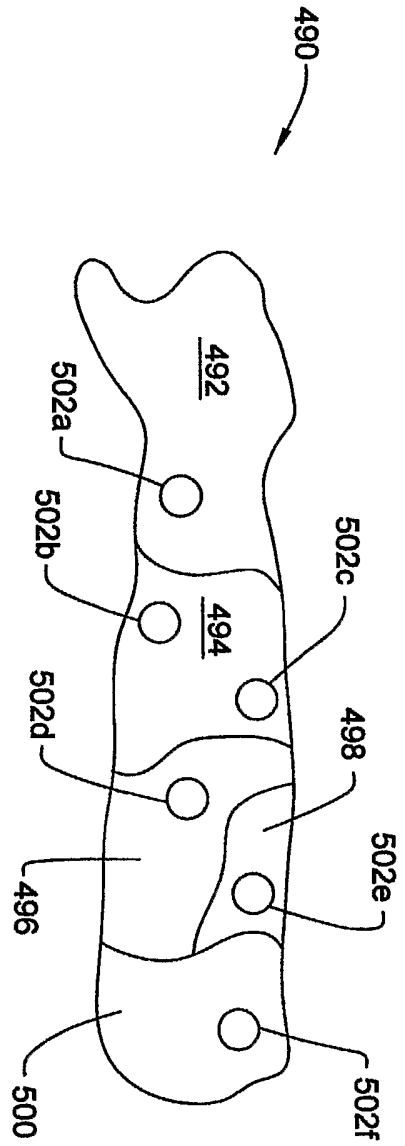


FIG. 29

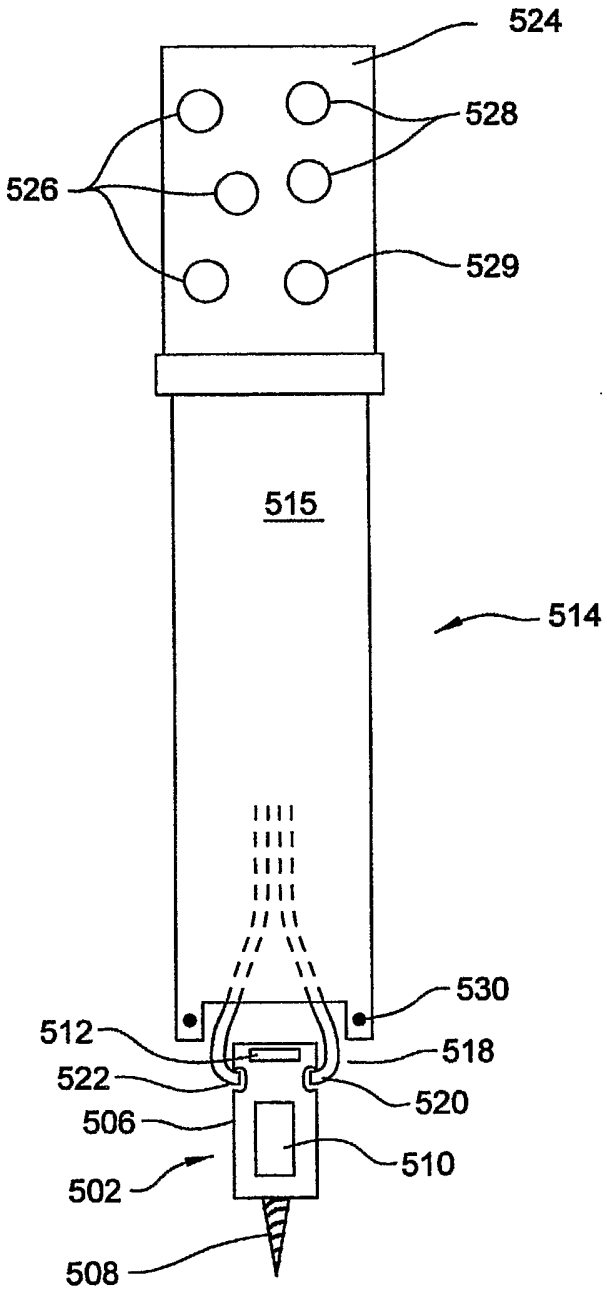


FIG. 30

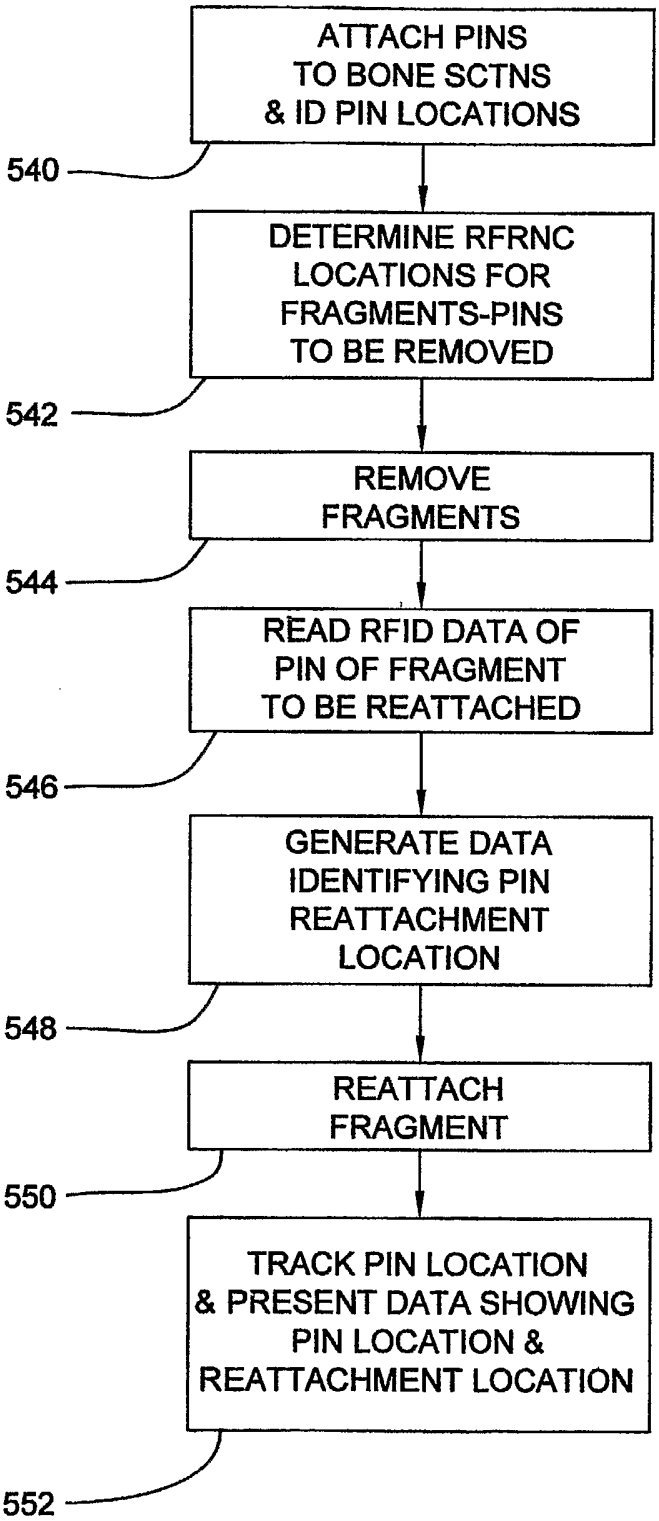
ATTACH PINS TO BONE SCTNS & ID PIN LOCATIONS
540
DETERMINE RFRNC LOCATIONS FOR FRAGMENTS-PINS TO BE REMOVED
542
REMOVE FRAGMENTS
544
READ RFID DATA OF PIN OF FRAGMENT TO BE REATTACHED
546
GENERATE DATA IDENTIFYING PIN REATTACHMENT LOCATION
548
REATTACH FRAGMENT
550
TRACK PIN LOCATION & PRESENT DATA SHOWING PIN LOCATION & REATTACHMENT LOCATION
552

FIG. 31

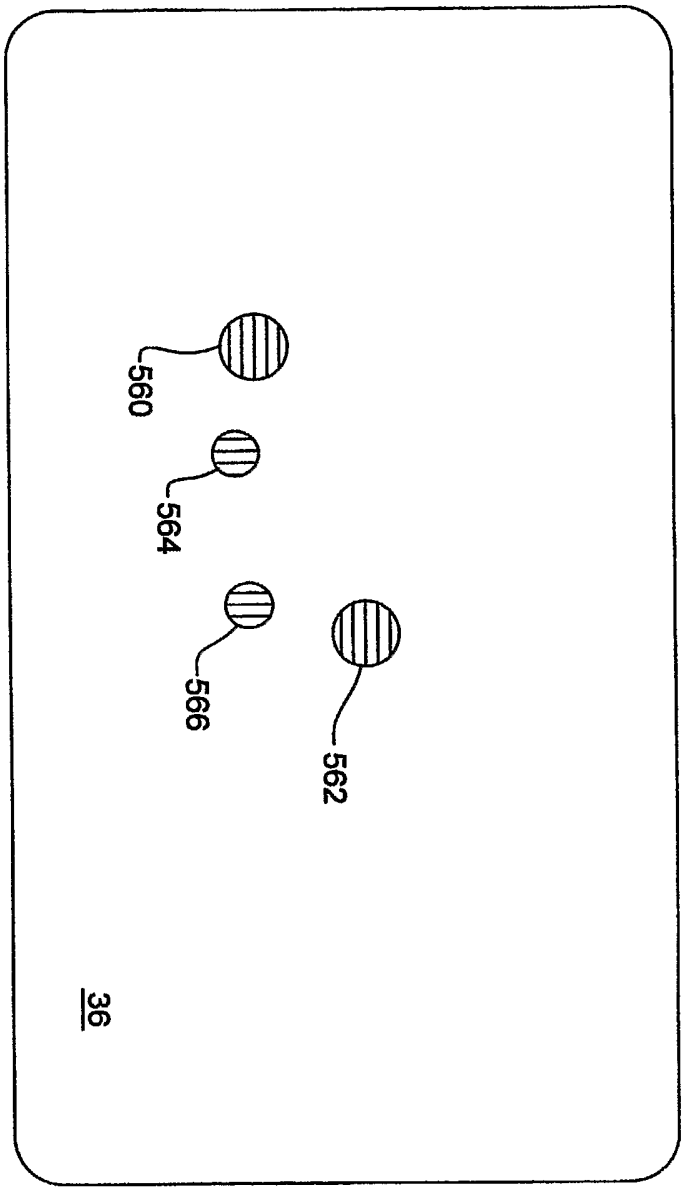


FIG. 32

# INTERNATIONAL SEARCH REPORT

International application No
US2005/044457

A. CLASSIFICATION OF SUBJECT MATTER
A61B17/32 A61B17/16

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | DE 102 39 673 A1 (SCHWARZ, MARKUS; POTT, PETER) 11 March 2004 (2004-03-11) abstract; figures paragraphs [0007] - [0041] | 1-17 |
| Y | DE 102 41 070 A1 (AESCULAP AG & CO. KG) 18 March 2004 (2004-03-18) abstract; figures paragraphs [0004] - [0031] | 1-17 |
| Y | US 6 434 507 B1 (CLAYTON JOHN B ET AL) 13 August 2002 (2002-08-13) abstract; figures column 1, lines 15-25 column 2, line 38 - column 4, line 65 column 5, line 48 - column 8, line 46 | 1-17 |

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 31 March 2006 | 10/04/2006 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Lager, J |

# INTERNATIONAL SEARCH REPORT

International application No
US2005/044457

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US 2004/092991 A1 (DENG WENJIE)<br>13 May 2004 (2004-05-13)<br>abstract; figures<br>paragraphs [0002], [0009], [0010],<br>[0025] - [0080] | 1-17 |
| A | EP 1 110 504 A (GENERAL ELECTRIC COMPANY)<br>27 June 2001 (2001-06-27)<br>the whole document | 1-17 |
| A | US 2003/093103 A1 (MALACKOWSKI DON ET AL)<br>15 May 2003 (2003-05-15)<br>cited in the application<br>abstract; figures | 1-17 |
| A | WO 03/013372 A (STRYKER CORPORATION)<br>20 February 2003 (2003-02-20)<br>cited in the application<br>abstract; figures | 1-17 |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
US2005/044457

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| DE 10239673 A1 | 11-03-2004 | AU 2003266186 A1 | 19-03-2004 |
| | | CN 1688258 A | 26-10-2005 |
| | | WO 2004019785 A2 | 11-03-2004 |
| | | EP 1531744 A2 | 25-05-2005 |
| DE 10241070 A1 | 18-03-2004 | NONE | |
| US 6434507 B1 | 13-08-2002 | NONE | |
| US 2004092991 A1 | 13-05-2004 | NONE | |
| EP 1110504 A | 27-06-2001 | JP 2001245868 A | 11-09-2001 |
| | | US 6356780 B1 | 12-03-2002 |
| US 2003093103 A1 | 15-05-2003 | US 2004267297 A1 | 30-12-2004 |
| WO 03013372 A | 20-02-2003 | CA 2456424 A1 | 20-02-2003 |
| | | EP 1424944 A2 | 09-06-2004 |
| | | JP 2004537367 T | 16-12-2004 |
| | | JP 2005324060 A | 24-11-2005 |