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(54) **PERCUTANEOUS REGISTRATION APPARATUS AND METHOD FOR USE IN COMPUTER-ASSISTED SURGICAL NAVIGATION**

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See application file for complete search history.

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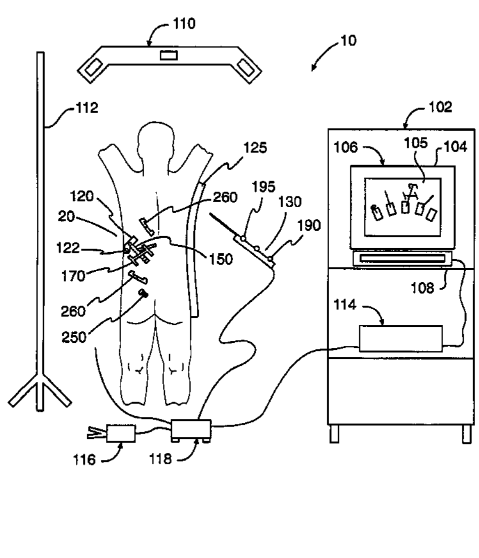
(57) **ABSTRACT**

An apparatus and procedures for percutaneous placement of surgical implants and instruments such as, for example, screws, rods, wires and plates into various body parts using image guided surgery. The invention includes an apparatus for use with a surgical navigation system, an attaching device rigidly connected to a body part, such as the spinous process of a vertebrae, with an identification superstructure rigidly but removably connected to the attaching device. This identification superstructure, for example, is a reference arc and fiducial array which accomplishes the function of identifying the location of the superstructure, and, therefore, the body part to which it is fixed, during imaging by CAT scan or MRI, and later during medical procedures.

53 Claims, 19 Drawing Sheets



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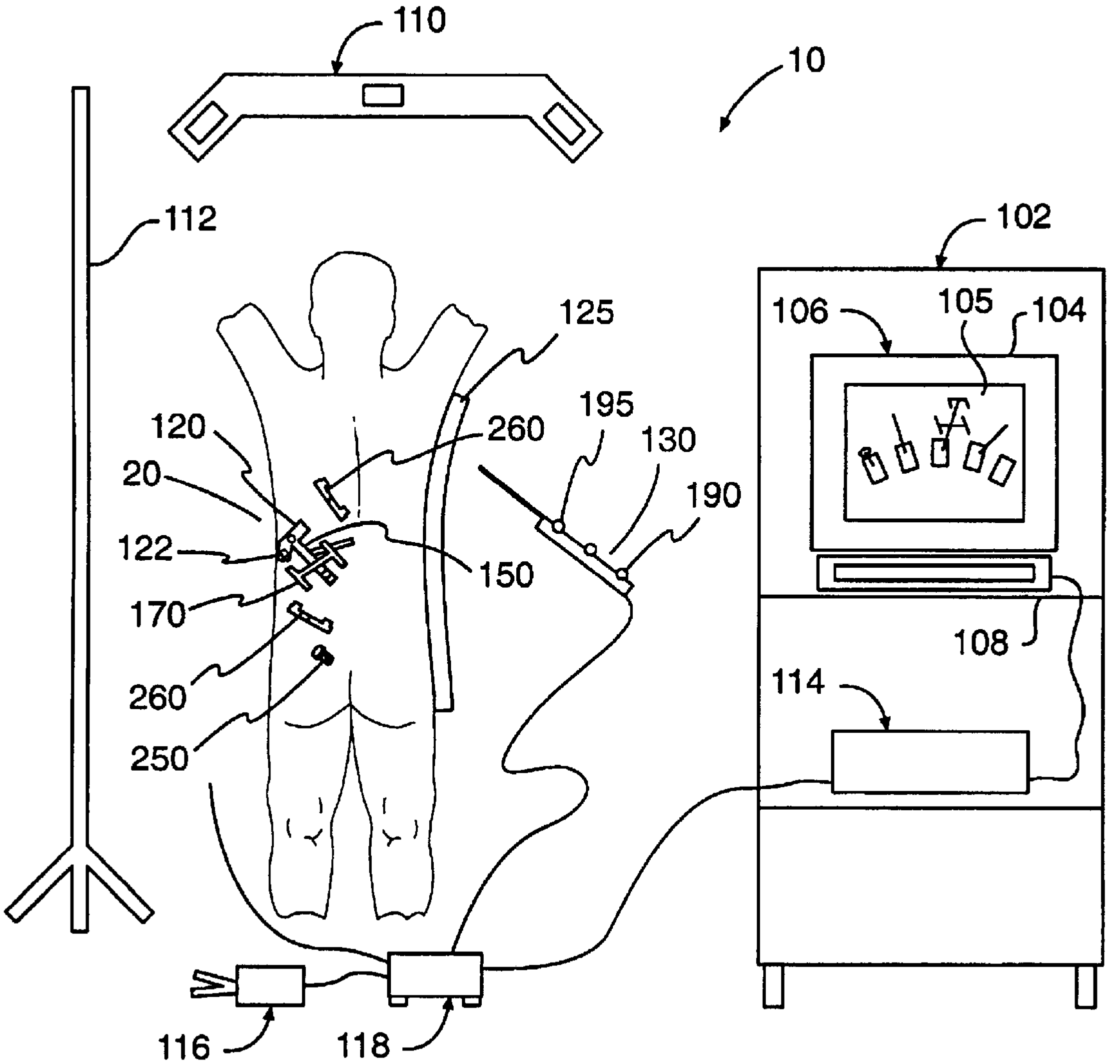
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FIG. 1

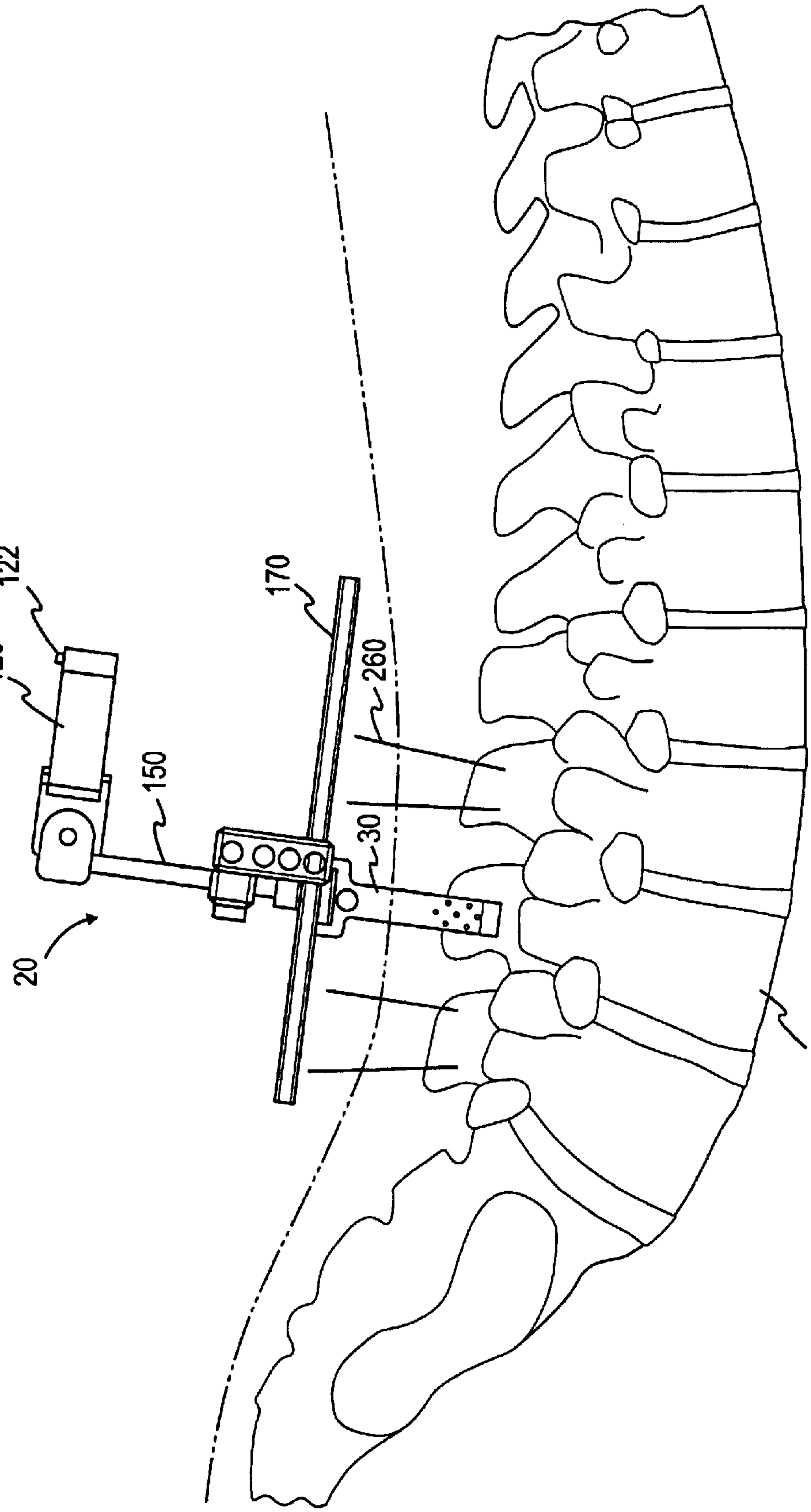

FIG. 1A

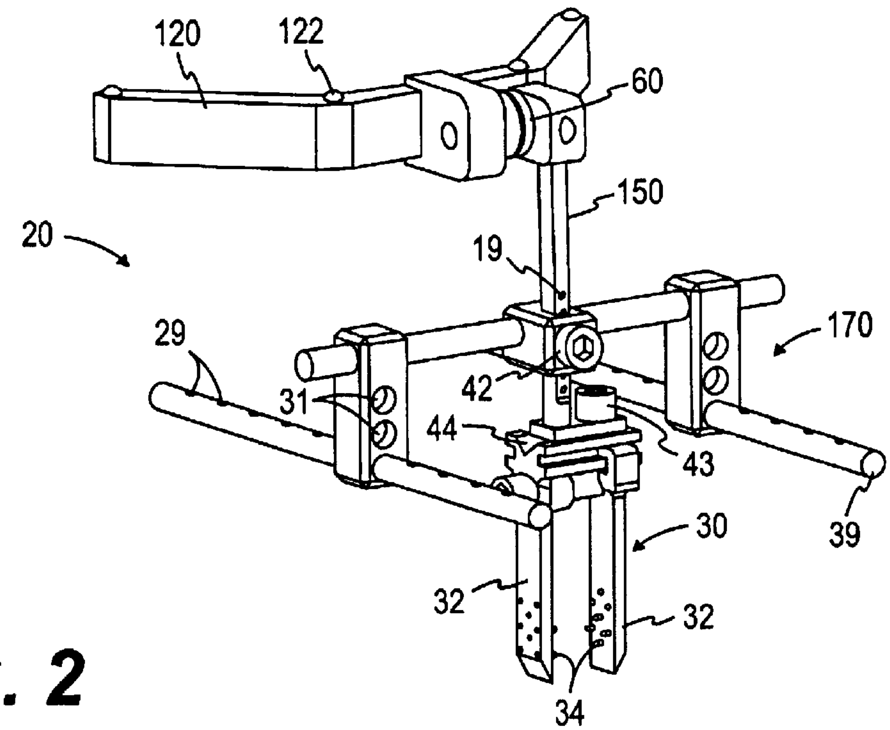
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FIG. 2

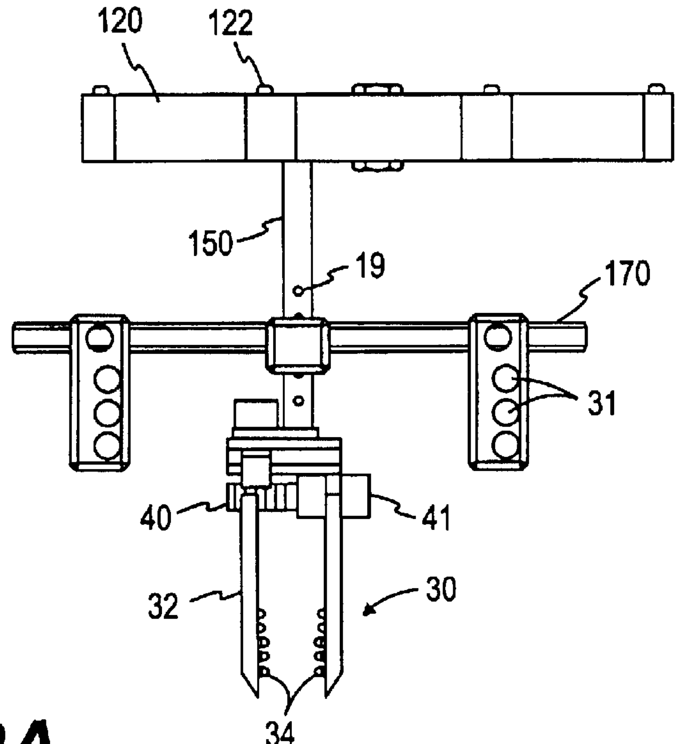
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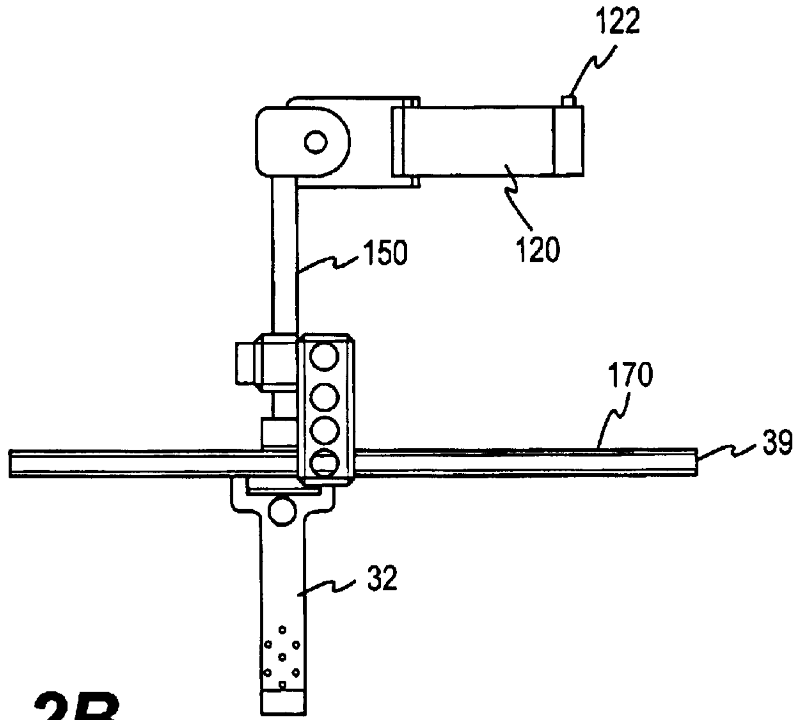
FIG. 2A



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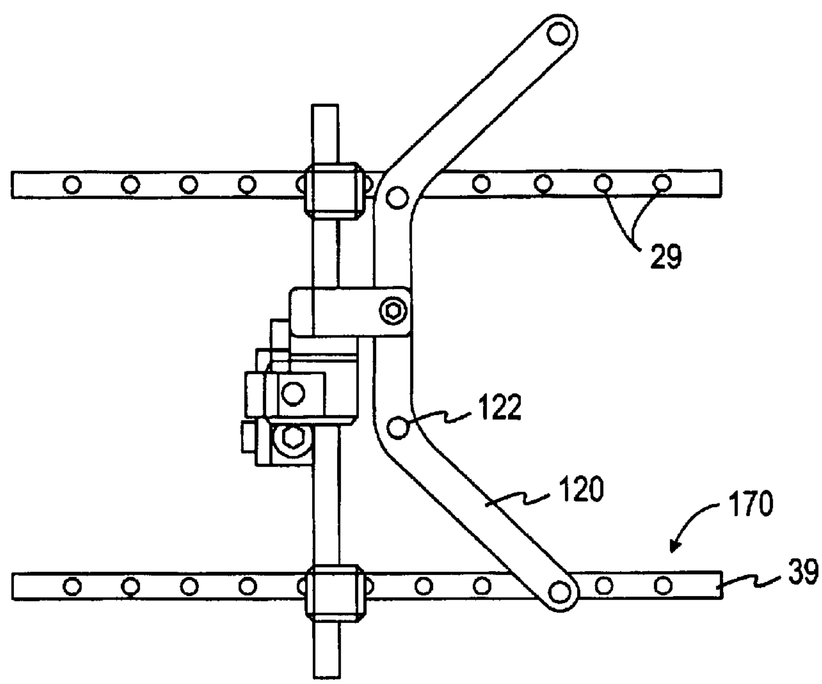


FIG. 2C

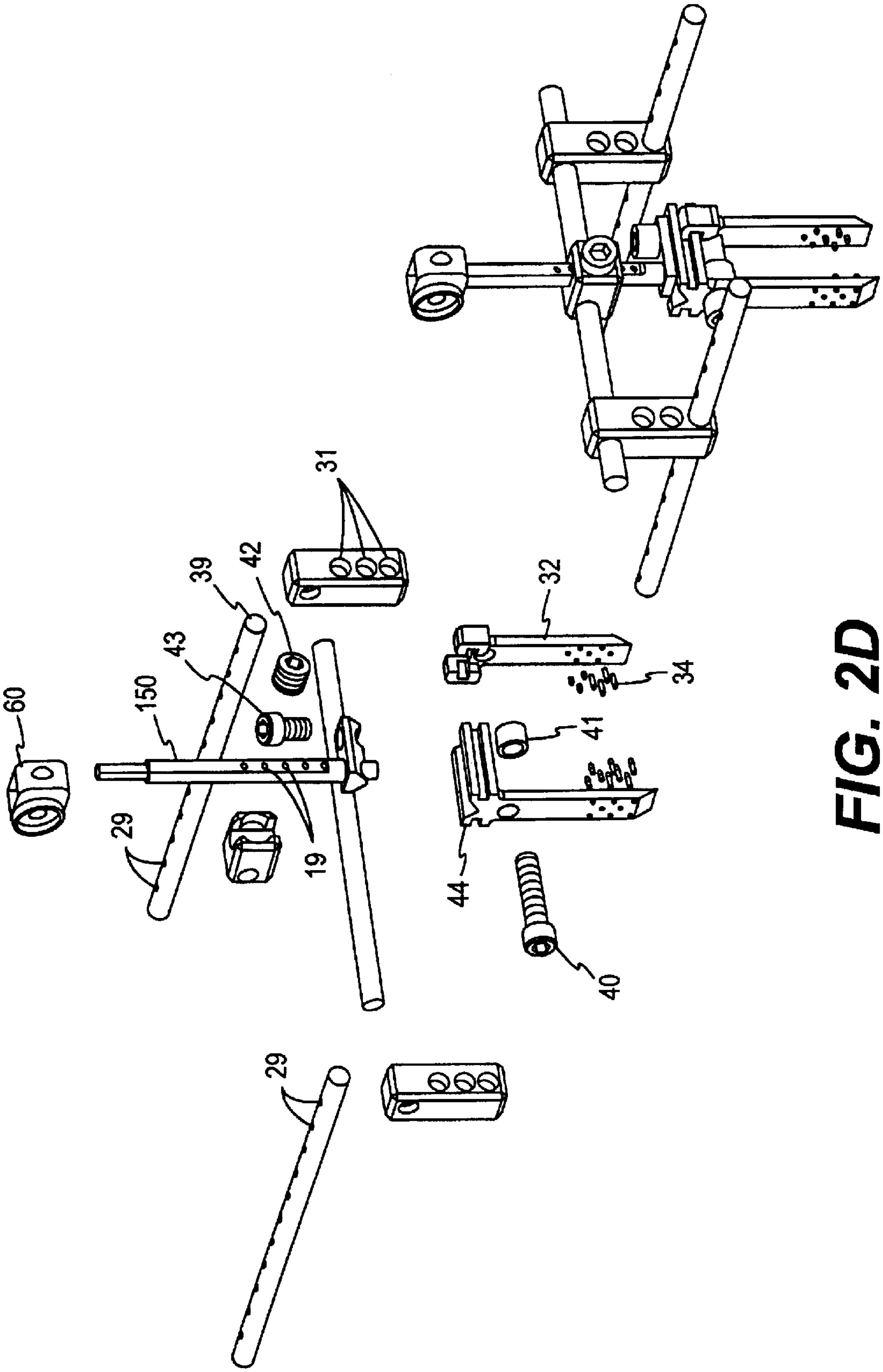


FIG. 2D

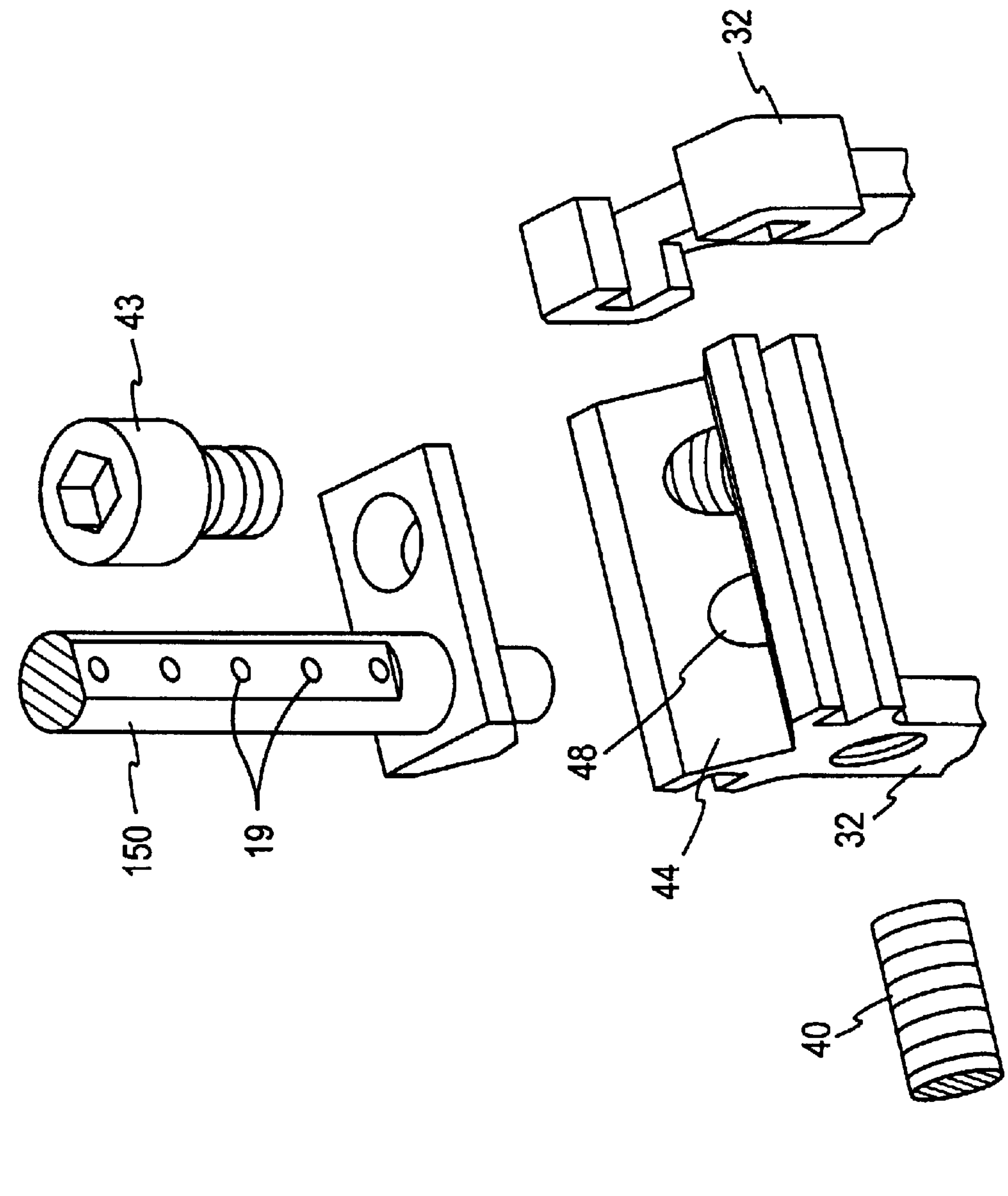
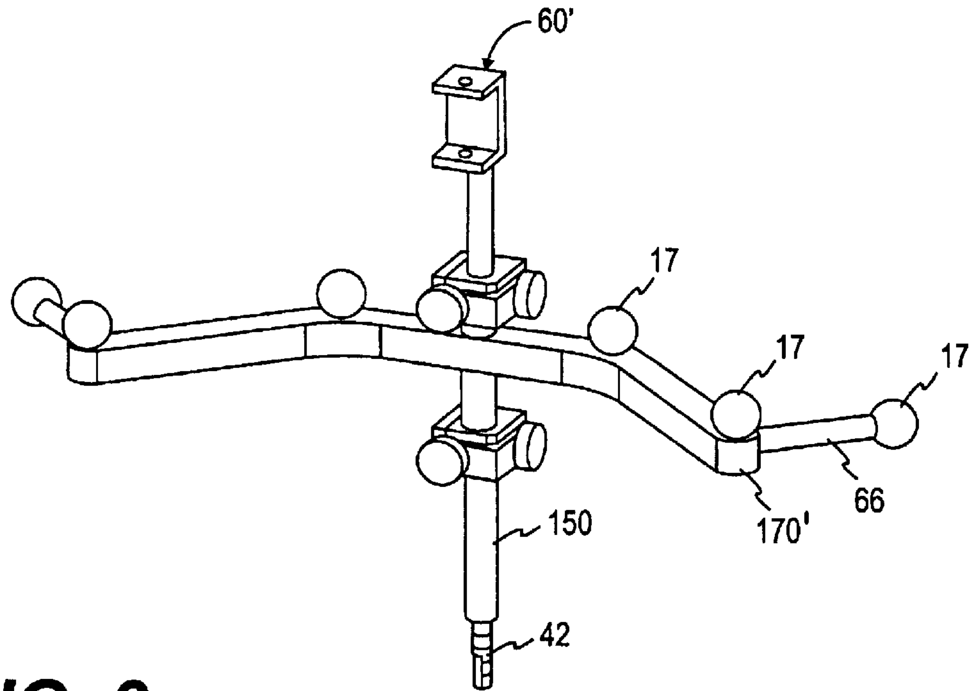


FIG. 2E



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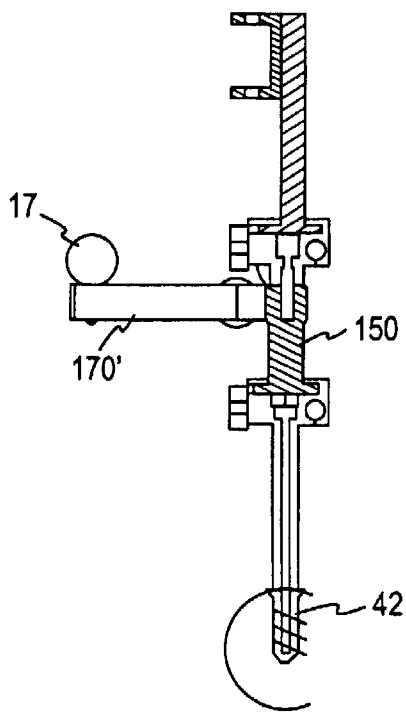

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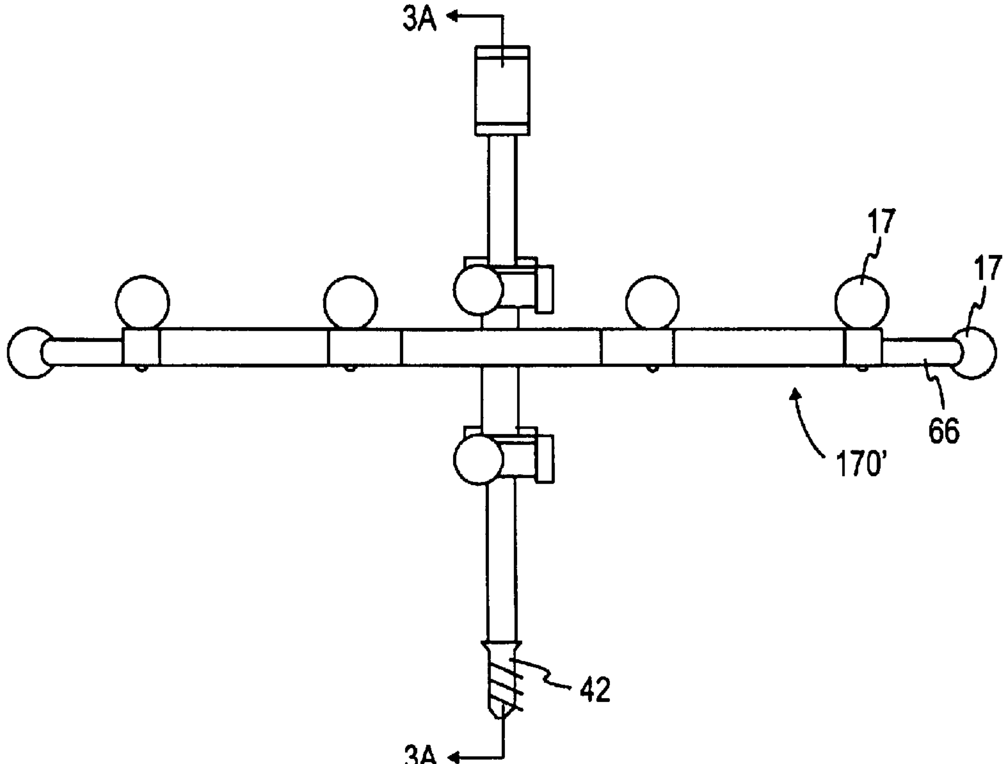

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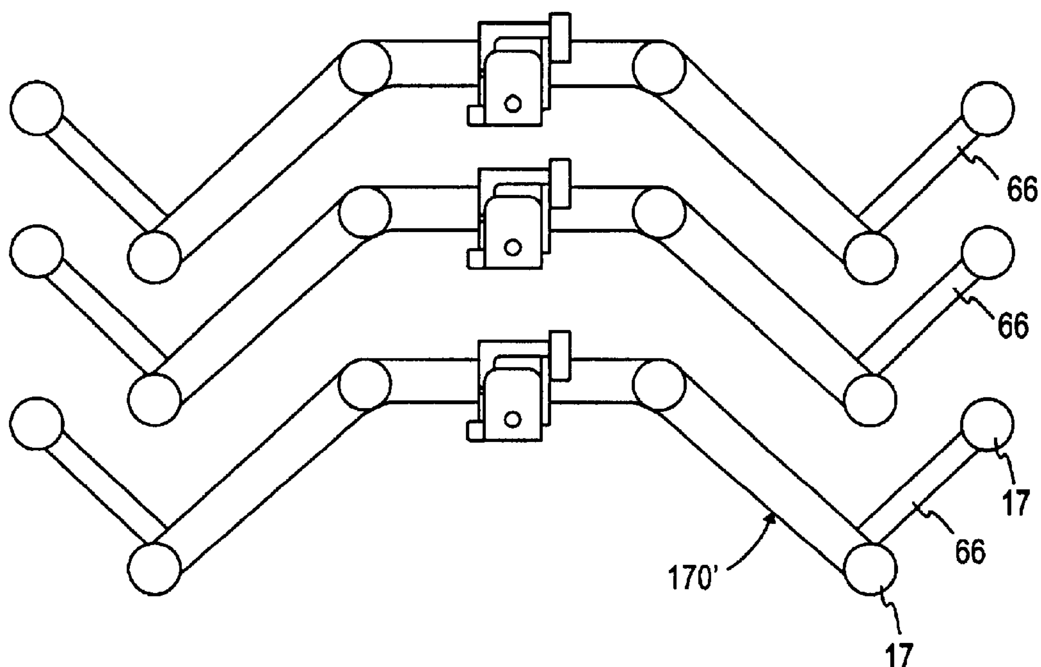


FIG. 3C

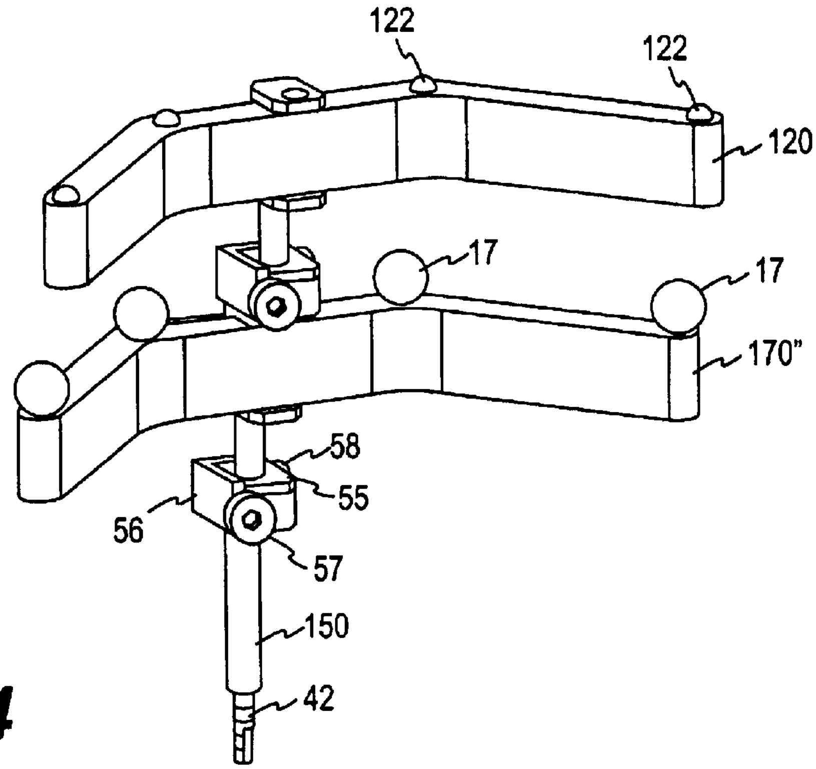


FIG. 4

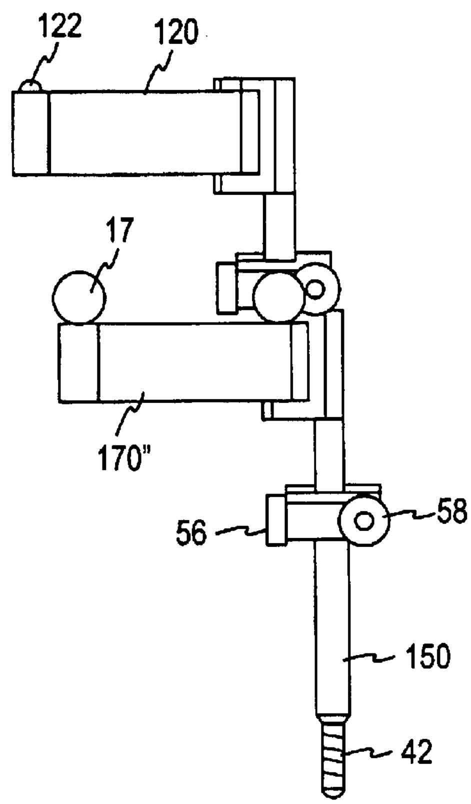
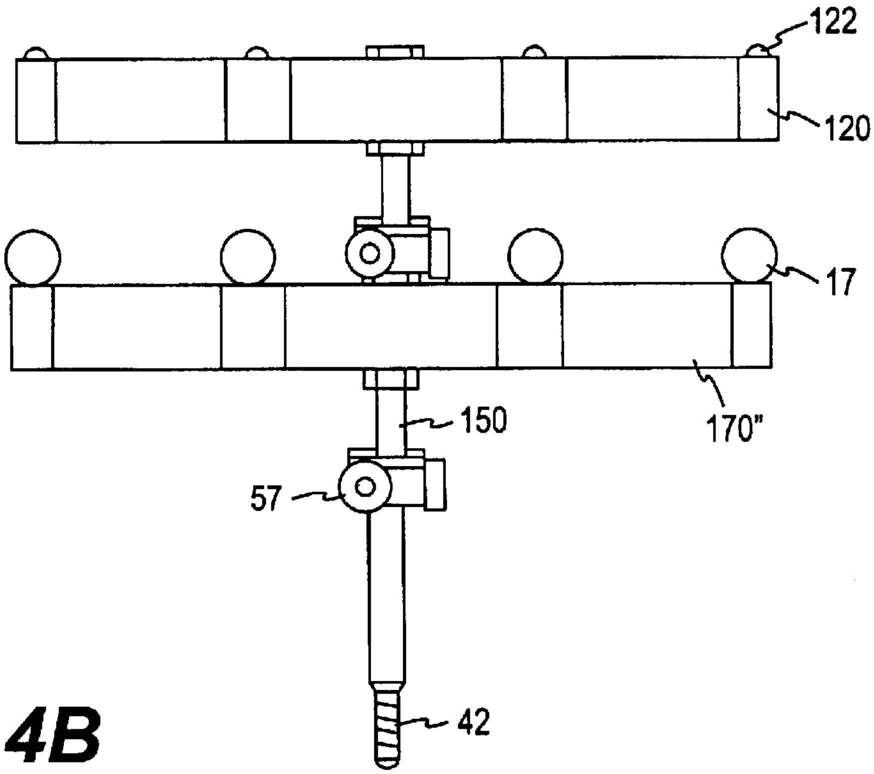


FIG. 4A



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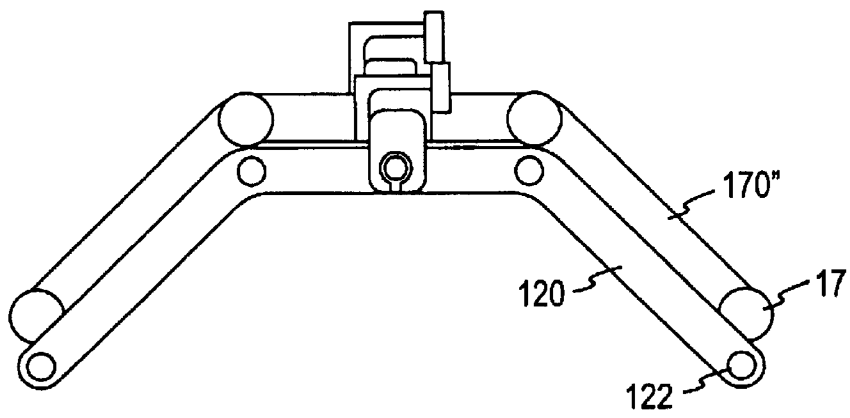
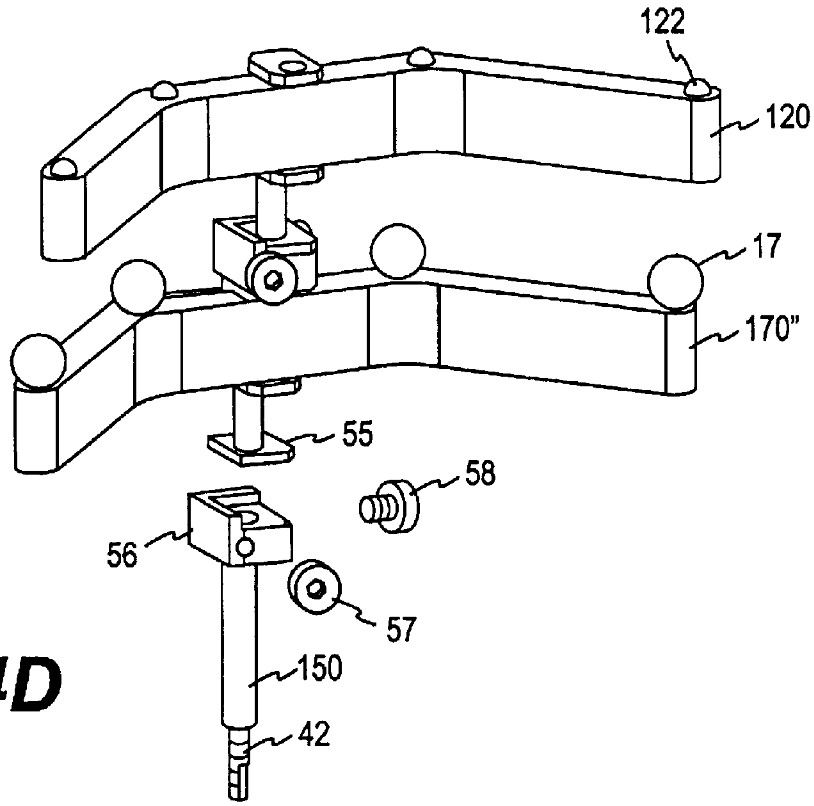


FIG. 4C



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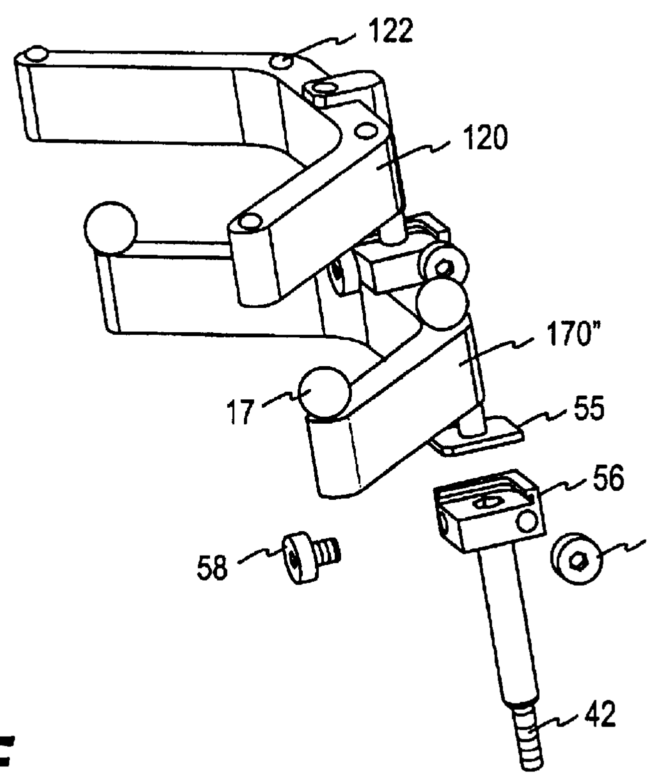

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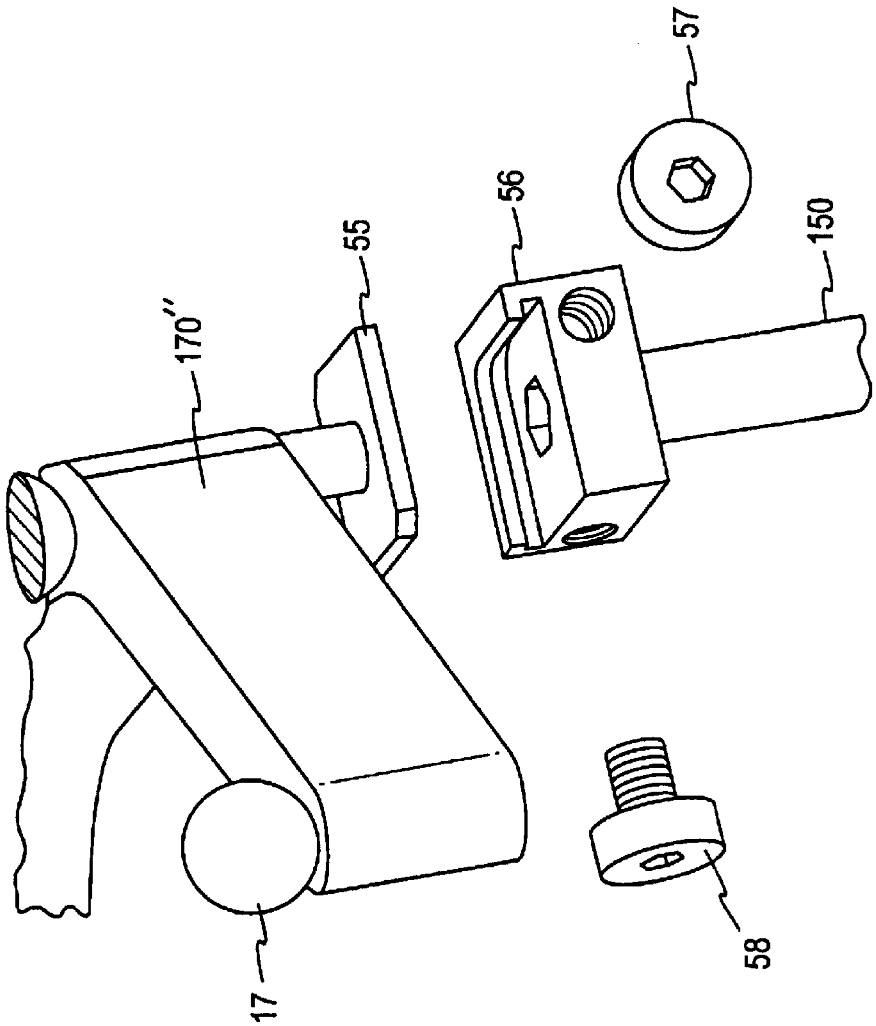

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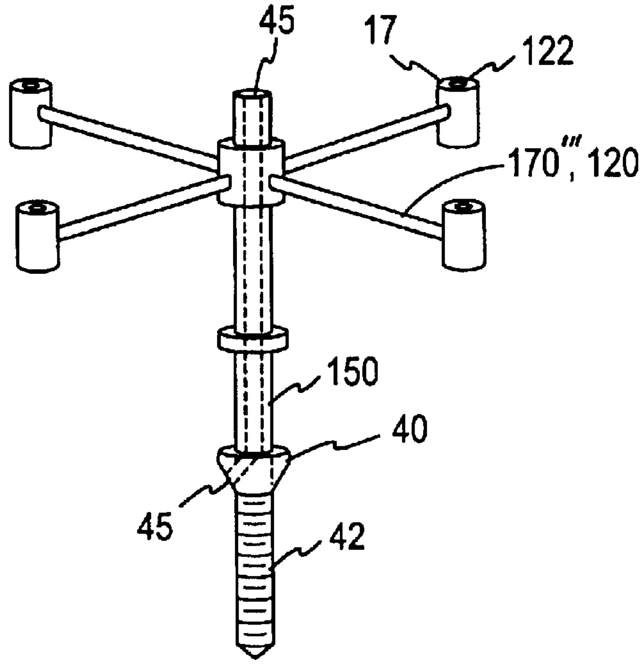

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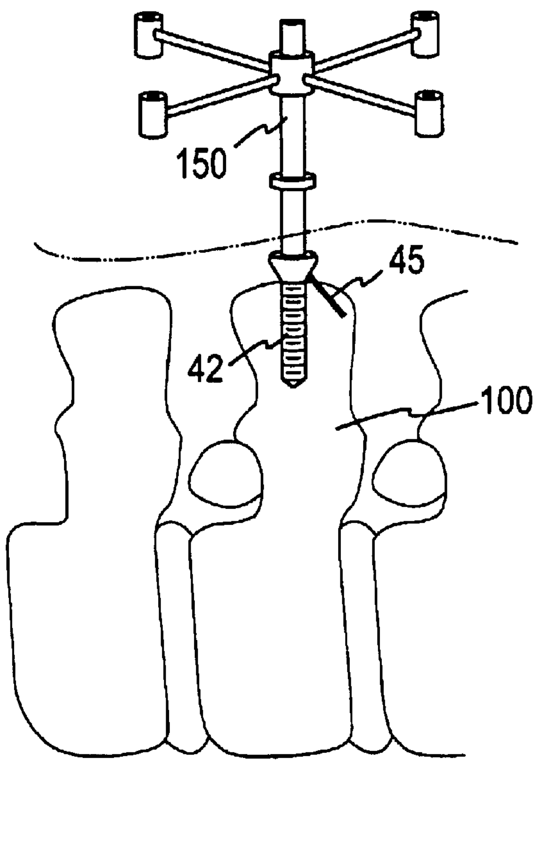


FIG. 6

FIG. 7

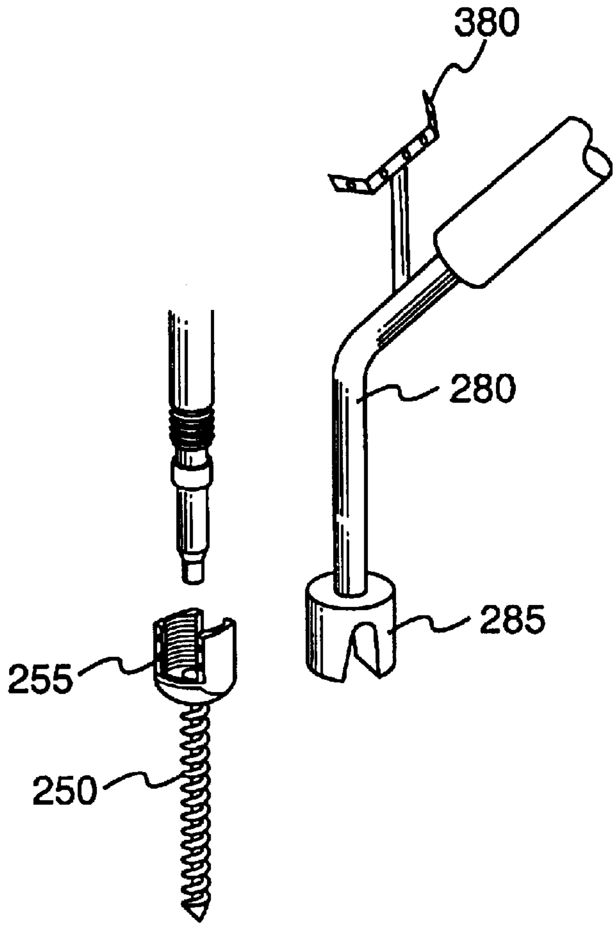
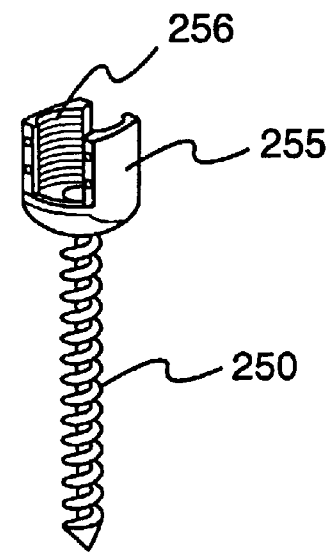


FIG. 7A



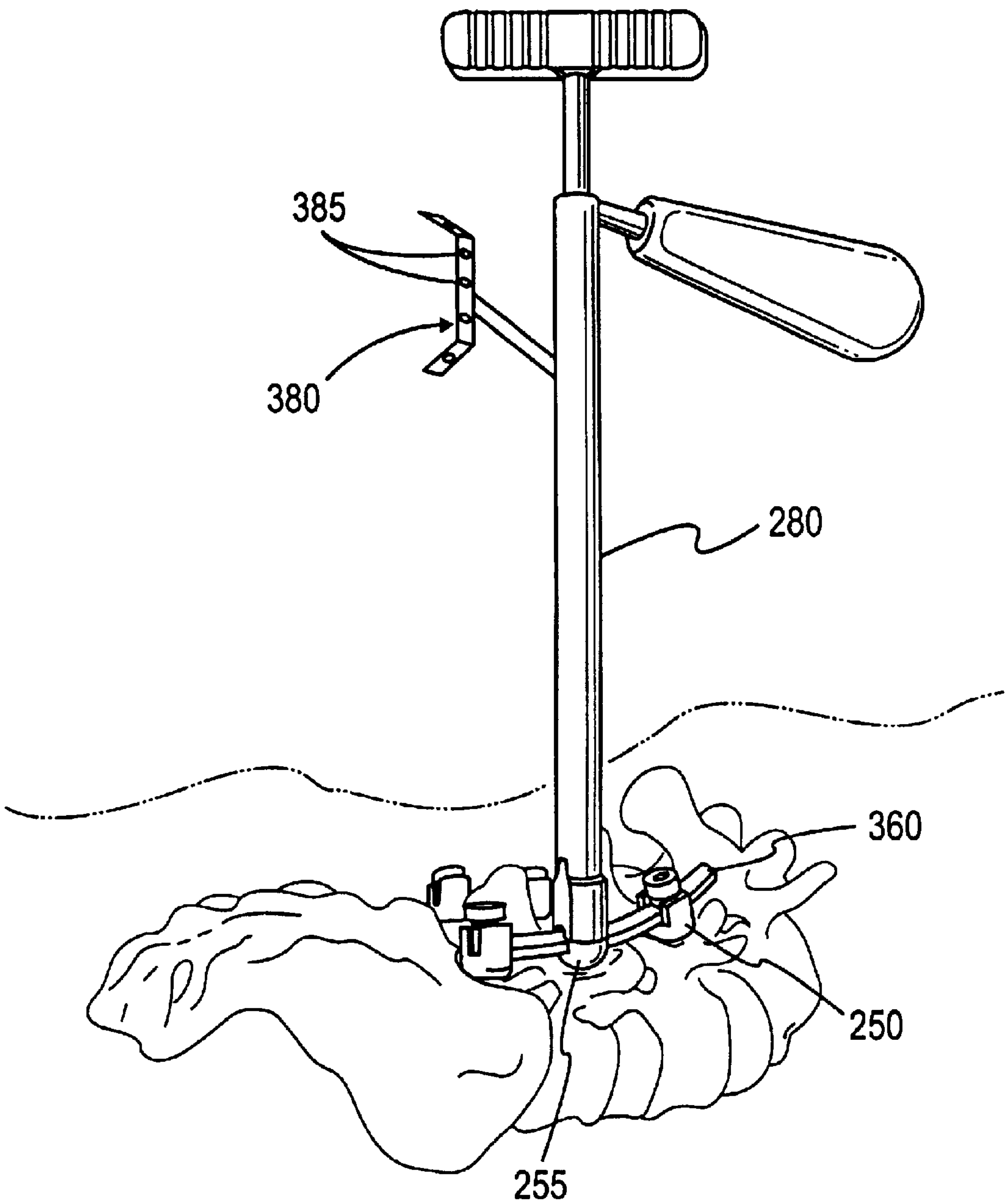


FIG. 8

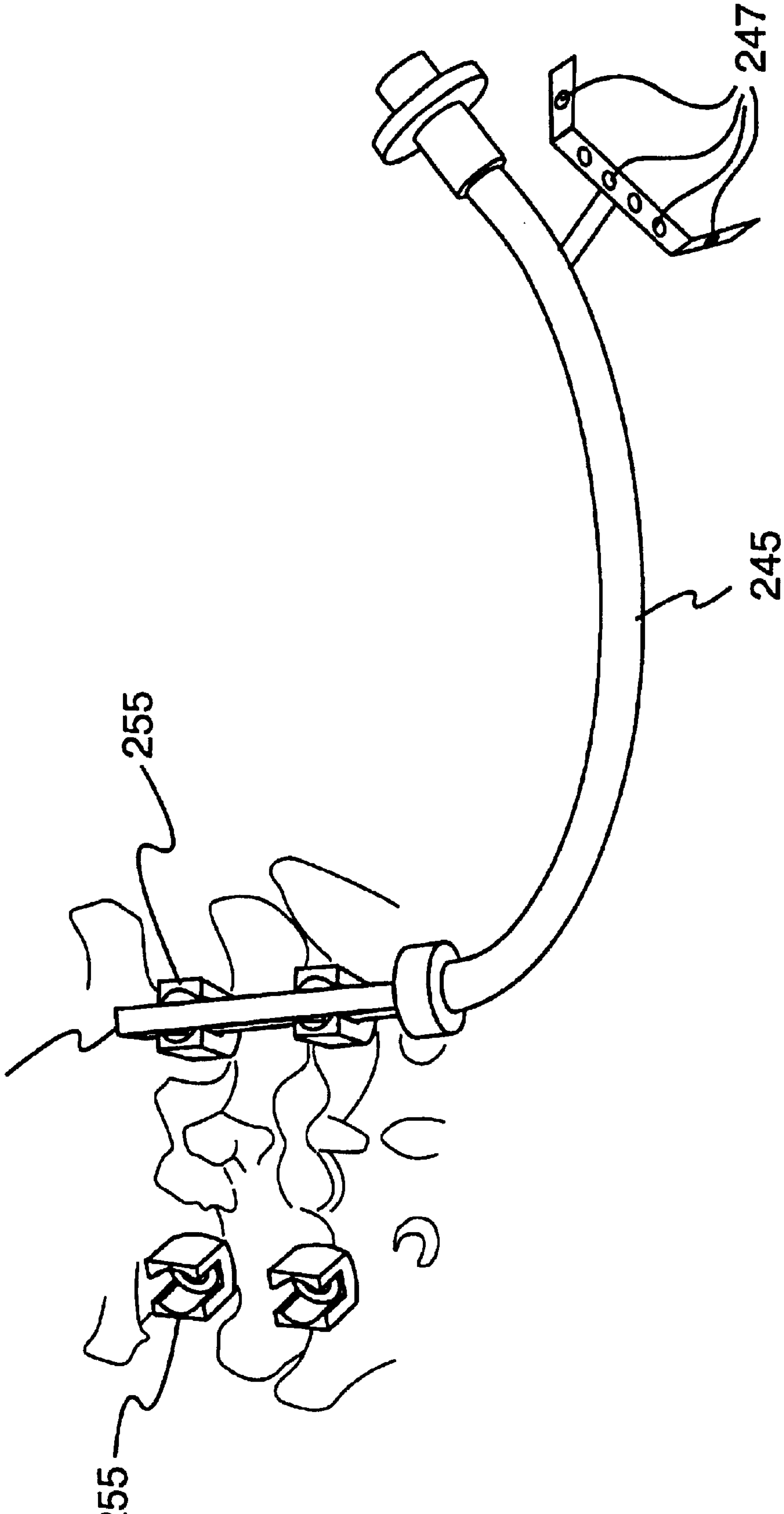


FIG. 9

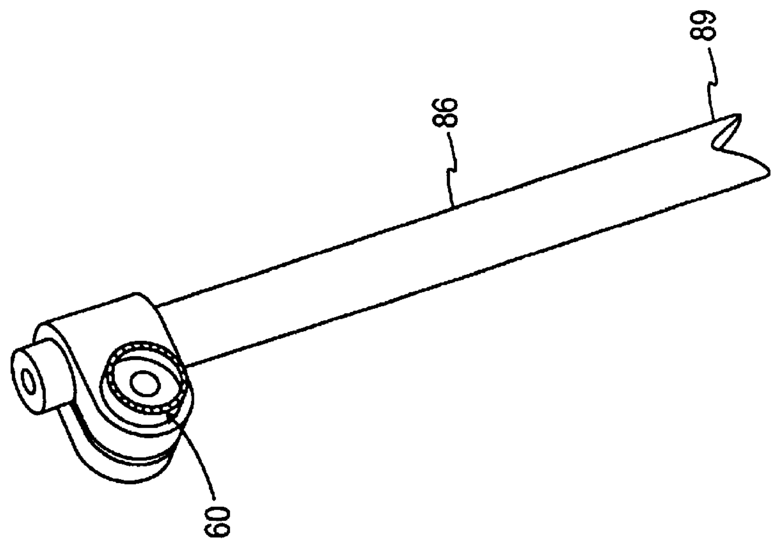


FIG. 10

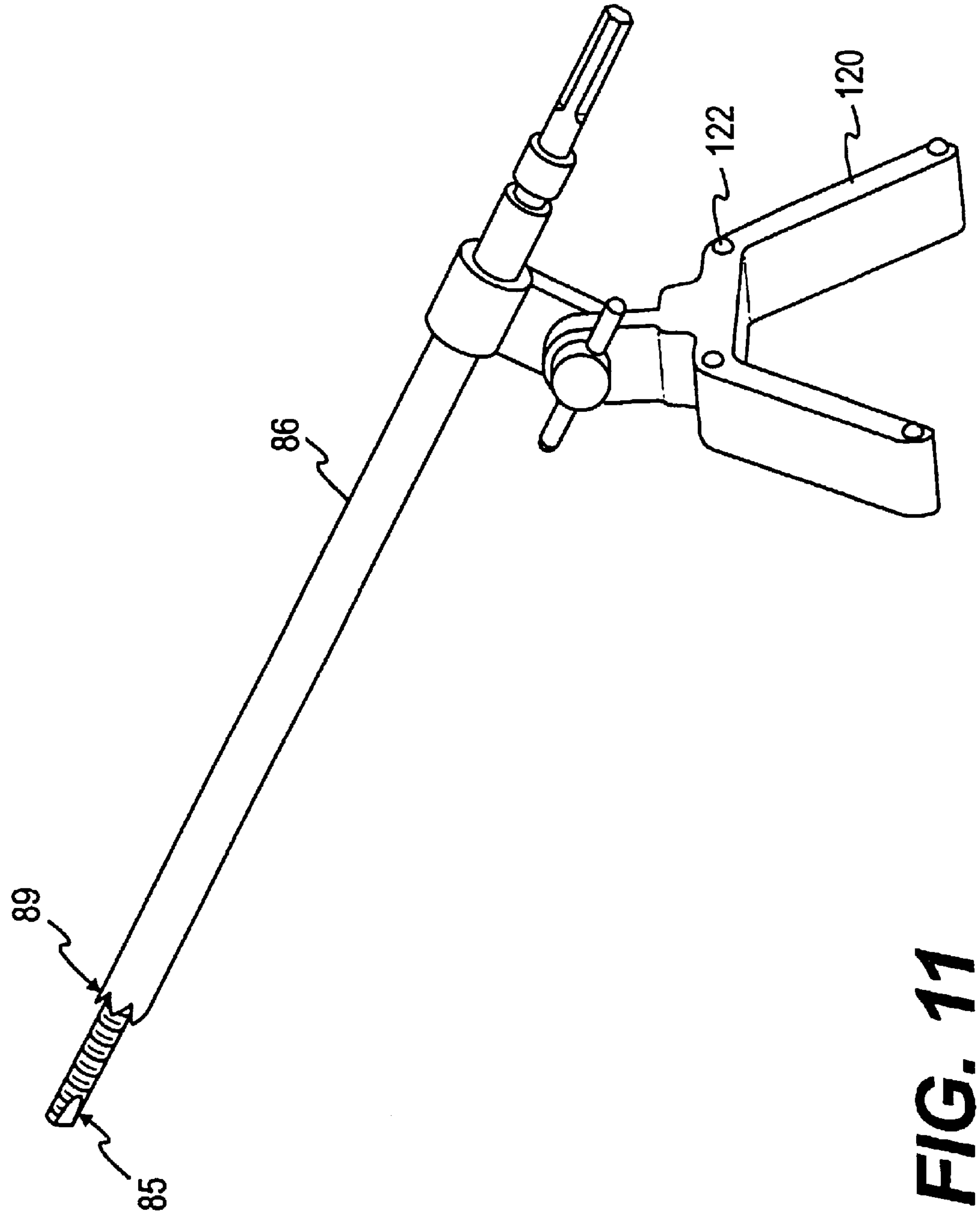


FIG. 11

FIG. 12

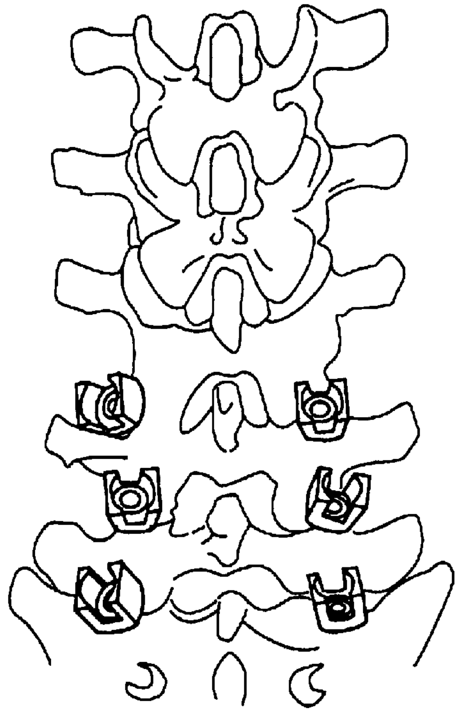
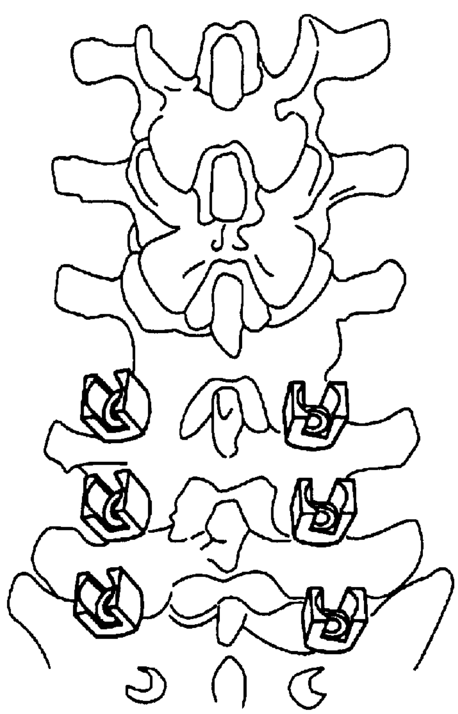


FIG. 13



PERCUTANEOUS REGISTRATION APPARATUS AND METHOD FOR USE IN COMPUTER-ASSISTED SURGICAL NAVIGATION

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

This application is a reissue of U.S. Pat. No. 6,226,548 issued on May 1, 2001 and also claims benefit under 35 U.S.C. §120 as a continuation of U.S. patent application Ser. No. 10/423,332 filed on Apr. 24, 2003 now RE39,133; which is a reissue of U.S. Pat. No. 6,226,548 issued on May 1, 2001; which claims rights under 35 U.S.C. §119 on provisional application Ser. No. 60/059,915, filed on Sep. 24, 1997. Notice is also given that concurrently filed is United States Patent Application No. filed on; which is also is a reissue of U.S. Pat. No. 6,226,548 issued on May 1, 2001 and also claims benefit under 35 U.S.C. §120 as a continuation of U.S. patent application Ser. No. 10/423,332 filed on Apr. 24, 2003; which is a reissue of U.S. Pat. No. 6,226,548 issued on May 1, 2001; which claims rights under 35 U.S.C. §119 on provisional application Ser. No. 60/059,915, filed on Sep. 24, 1997. The disclosures of the above applications are incorporated herein by reference.

The present invention claims rights under 35 U.S.C. § 119 on provisional application No. 60/059,915, filed on Sep. 24, 1997, and entitled "Percutaneous Registration Apparatus and Method for Use in Computer-Assisted Surgical Navigation."

FIELD OF THE INVENTION

The present invention relates generally to guiding, directing, or navigating instruments or implants in a body percutaneously, in conjunction with systems that use and generate images during medical and surgical procedures, which images assist in executing the procedures and indicate the relative position of various body parts, surgical implants, and instruments. In particular the invention relates to apparatus and minimally invasive procedures for navigating instruments and providing surgical implants percutaneously in the spine, for example, to stabilize the spine, correct deformity, or enhance fusion in conjunction with a surgical navigation system for generating images during medical and surgical procedures.

BACKGROUND OF THE INVENTION

Typically, spinal surgical procedures used, for example, to provide stabilization, fusion, or to correct deformities, require large incisions and substantial exposure of the spinal areas to permit the placement of surgical implants such as, for example, various forms of screws or hooks linked by rods, wires, or plates into portions of the spine. This standard procedure is invasive and can result in trauma, blood loss, and post operative pain. Alternatively, fluoroscopes have been used to assist in placing screws beneath the skin. In this alternative procedure at least four incisions must be made in the patient's back for inserting rods or wires through previously inserted screws. However, this technique can be difficult in that fluoroscopes only provide two-dimensional images and require the surgeon to rotate the fluoroscope frequently in order to get a mental image of the anatomy in three dimensions. Fluoroscopes also generate radiation to which the patient and surgical staff may become over exposed over time. Additionally, the subcutaneous implants

required for this procedure may irritate the patient. A lever arm effect can also occur with the screws that are not connected by the rods or wires at the spine. Fluoroscopic screw placement techniques have traditionally used rods or plates that are subcutaneous to connect screws from vertebra to vertebra. This is due in part to the fact that there is no fluoroscopic technique that has been designed which can always adequately place rods or plates at the submuscular region (or adjacent to the vertebrae). These subcutaneous rods or plates may not be well tolerated by the patient. They also may not provide the optimal mechanical support to the spine because the moment arm of the construct can be increased, thereby translating higher loads and stresses through the construct.

A number of different types of surgical navigation systems have been described that include indications of the positions of medical instruments and patient anatomy used in medical or surgical procedures. For example, U.S. Pat. No. 5,383,454 to Bucholz; PCT Application No. PCT/US94/04530 (Publication No. WO 94/24933) to Bucholz; and PCT Application No. PCT/US95/12894 (Publication No. WO 96/11624) to Bucholz et al., the entire disclosures of which are incorporated herein by reference, disclose systems for use during a medical or surgical procedure using scans generated by a scanner prior to the procedure. Surgical navigation systems typically include tracking means such as, for example, an LED array on the body part, LED emitters on the medical instruments, a digitizer to track the positions of the body part and the instruments, and a display for the position of an instrument used in a medical procedure relative to an image of a body part.

Bucholz et al. WO 96/11624 is of particular interest, in that it identifies special issues associated with surgical navigation in the spine, where there are multiple vertebral bodies that can move with respect to each other. Bucholz et al. describes a procedure for operating on the spine during an open process where, after imaging, the spinous process reference points may move with respect to each other. It also discloses a procedure for modifying and repositioning the image data set to match the actual position of the anatomical elements. When there is an opportunity for anatomical movement, such movement degrades the fidelity of the pre-procedural images in depicting the intra-procedural anatomy. Therefore, additional innovations are desirable to bring image guidance to the parts of the body experiencing anatomical movement.

Furthermore, spinal surgical procedures are typically highly invasive. There is, thus, a need for more minimally invasive techniques for performing these spinal procedures, such as biopsy, spinal fixation, endoscopy, spinal implant insertion, fusion, and insertion of drug delivery systems, by reducing incision size and amount. One such way is to use surgical navigation equipment to perform procedures percutaneously, that is beneath the skin. To do so by means of surgical navigation also requires apparatus that can indicate the position of the spinal elements, such as, for example the vertebrae, involved in the procedure relative to the instruments and implants being inserted beneath the patient's skin and into the patient's spine. Additionally, because the spinal elements naturally move relative to each other, the user requires the ability to reorient these spinal elements to align with earlier scanned images stored in the surgical navigation system computer, to assure the correct location of those elements relative to the instruments and implants being applied or inserted percutaneously.

In light of the foregoing, there is a need in the art for apparatus and minimally invasive procedures for percutaneous placement of surgical implants and instruments in the spine, reducing the size and amount of incisions and utilizing surgical navigation techniques.

SUMMARY OF THE INVENTION

Accordingly, the present invention is directed to apparatus and procedures for percutaneous placement of surgical implants and instruments such as, for example, screws, rods, wires and plates into various body parts using image guided surgery. More specifically, one object of the present invention is directed to apparatus and procedures for the percutaneous placement of surgical implants and instruments into various elements of the spine using image guided surgery.

To achieve these objects and other advantages and in accordance with the purpose of the invention, as embodied and broadly described herein, the invention includes an apparatus for use with a surgical navigation system and comprises an attaching device rigidly connected to a body part, such as the spinous process of a vertebrae, with an identification superstructure rigidly but removably connected to the attaching device. This identification superstructure is a reference arc and fiducial array, which accomplishes the function of identifying the location of the superstructure, and, therefore, the body part to which it is fixed, during imaging by CAT scan or MRI, and later during medical procedures.

In one aspect, the attaching device is a clamp with jaws and sharp teeth for biting into the spinous process.

In another aspect, the fixture is a screw, having a head, wherein the screw is implanted into the spinous process and a relatively rigid wire is attached to the head of the screw and also implanted into the spinous process at an angle to the axis of the screw to prevent the screw from rotating in either direction.

In another aspect, the superstructure includes a central post, and a fiducial array and a reference arc rigidly but removably attached to the central post. The fiducial array is composed of image-compatible materials, and includes fiducials for providing a reference point, indicating the position of the array, which are rigidly attached to the fiducial array, composed of, for example titanium or aluminum spheres. The reference arc includes emitters, such as, for example Light Emitting Diodes ("LEDs"), passive reflective spheres, or other tracking means such as acoustic, magnetic, electromagnetic, radiologic, or micropulsed radar, for indicating the location of the reference arc and, thus, the body part it is attached to, during medical procedures.

In addition, the invention further comprises a method for monitoring the location of an instrument, surgical implants and the various portions of the body, for example, vertebrae, to be operated on in a surgical navigation system comprising the steps of: attaching a fixture to the spinous process; attaching a superstructure including a fiducial array with fiducials and a reference arc to the fixture; scanning the patient using CT, MRI or some other three-dimensional method, with fiducial array rigidly fixed to patient to identify it on the scanned image; and thereafter, in an operating room, using image-guided technology, touching an image-guided surgical pointer or other instrument to one or more of the fiducials on the fiducial array to register the location of the spinal element fixed to the array and emitting an audio, visual, radiologic, magnetic or other detectable signal from the reference arc to an instrument such as, for example, a digitizer or other position-sensing unit, to indicate changes in position of the spinal element during a surgical procedure, and performing a surgical or medical procedure percutaneously on the patient using instruments and implants locatable relative to spinal elements in a known position in the surgical navigation system.

In another aspect, the method includes inserting screws or rigid wires in spinal elements in the area involved in the anticipated surgical procedure before scanning the patient, and after scanning the patient and bringing the patient to the operating area, touching an image-guided or tracked surgical pointer to these screws and wires attached to the vertebrae to positively register their location in the surgical navigation computer, and manipulating either the patient's spine or the image to align the actual position of the spinal elements with the scanned image.

In another aspect, the method includes percutaneously implanting screws into spinal elements, which screws are located using image guided surgical navigation techniques, and further manipulating the orientation of the screw heads percutaneously using a head-positioning probe containing an emitter, that can communicate to the surgical navigation computer the orientation of the screw heads and position them, by use of a specially designed head-positioning tool with an end portion that mates with the heads of the screws and can rotate those screw heads to receive a rod, wire, plate, or other connecting implant. If a rod is being inserted into the screw heads for example, the method further includes tracking the location and position of the rod, percutaneously using a rod inserter having one or more emitters communicating the location and orientation of the rod to the surgical navigation computer.

The objects of the invention are to provide a user, such as a surgeon, with the system and method to track an instrument and surgical implants used in conjunction with a surgical navigation system in such a manner to operate percutaneously on a patient's body parts, such as spinal vertebrae which can move relative to each other.

It is a further object of this invention to provide a system and method to simply and yet positively indicate to the user a change in position of body parts, such as spinal vertebrae segments, from that identified in a stored image scan, such as from an MRI or CAT scan, and provide a method to realign those body parts to correspond with a previously stored image or the image to correspond with the actual current position of the body parts.

It is a further object of this invention to provide a system or method for allowing a fiducial array or reference arc that is removable from a location rigidly fixed to a body part and replaceable back in that precise location.

It is another object of this invention to provide a system and method for positively generating a display of instruments and surgical implants, such as, for example screws and rods, placed percutaneously in a patient using image-guided surgical methods and techniques.

It is another object of this invention for a percutaneous reference array and fiducial array, as described in this appplication, to be used to register and track the position of the vertebrae for the purposes of targeting a radiation dose to a diseased portion of said vertebrae using a traditional radiosurgical technique.

Additional objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in this description.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate one embodiment of the invention and together with the description, serve to explain the principles of the invention.

FIG. **1** is a schematic diagram of one preferred embodiment of a superstructure for use in the current invention, including a reference arc, center post and fiducial array and rigid Kirschner wires ("K wires") and screws placed in the spine for use with a surgical navigation system for percutaneous spinal surgical procedures.

FIG. **1**A is an enlarged view of the superstructure depicted in FIG. **1** engaging a vertebra by a clamp and also K wires implanted in adjacent vertebrae in the superior and inferior positions of the spinous process.

FIG. **2** is a diagram of the preferred embodiment of a clamp fixture for rigid connection to the spinous process of a single vertebrae with an H-shaped fiducial array attached to a center post rigidly attached to the clamp and a mating connector at the tip of the post for mating with a reference array, and a reference array for use in the current invention.

FIG. **2**A is a side view of FIG. **2** FIG. **2**B is another side view of FIG. **2**.

FIG. **2**C is a top view of FIG. **2**.

FIG. **2**D is an exploded view of FIG. **2** without the reference arc.

FIG. **2**E is an exploded view of the interface of the center post and clamp of FIG. **2**.

FIG. **3** is a diagram of a W-Shaped fiducial array mounted to a central post with generally spherical fiducials attached to the array, for mounting to a single vertebrae.

FIG. **3**A is a side view of FIG. **3**.

FIG. **3**B is another side view of FIG. **3**.

FIG. **3**C is a top view of FIG. **3**.

FIG. **4** is a diagram of a reference arc and fiducial attached to a center post for use in the current invention in mounting to a single vertebrae.

FIG. **4**A is a side view of FIG. **4**.

FIG. **4**B is a back view of FIG. **4**.

FIG. **4**C is a top view of FIG. **4**.

FIG. **4**D is an expanded view of FIG. **4**.

FIG. **4**E is an expanded side view of FIG. **4**.

FIG. **4**F is an expanded view of the array foot and shoe of FIG. **4**E.

FIG. **5** is a diagram of an alternative embodiment of a fixture for use in the current invention using a cannulated screw for insertion into a vertebrae, with Kirschner wire mounted on a central post and including an alternate embodiment of a fiduciary array and reference arc combined on a single structure.

FIG. **6** is a side view of the screw and Kirschner wire fixture of FIG. **5** implanted in a spinous process of a vertebrae.

FIG. **7** is a diagram of a screw-head positioning probe and multiaxial screw for insertion into a single vertebrae.

FIG. **7**A is a diagram of the screw of FIG. **7**.

FIG. **8** is a diagram of a head positioning probe, multiaxial screw and spinal segment.

FIG. **9** is a diagram of a rod inserter with an LED.

FIG. **10** is a diagram of an alternative embodiment of the invention depicting a cannulated tube and attachment for holding a reference arc.

FIG. **11** is a diagram of the cannulated tube of FIG. **10** with a reference arc and screw for attachment to a spinal process.

FIG. **12** is a posterior view of spinal segment and implanted screws before alignment.

FIG. **13** is a posterior view of spinal segment and implanted screws after alignment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Reference will now be made in detail to the present preferred embodiment of the invention, an example of which is illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts. The following example is intended to be purely exemplary of the invention.

As generally described in PCT/US95/12894, the entire disclosure of which is incorporated herein by reference, a typical surgical navigation system is shown in FIG. **1** adopted to be used in the present invention. A computer assisted image-guided surgery system, indicated generally at **10**, generates an image for display on a monitor **106** representing the position of one or more body elements, such as spinal elements fixedly held in a stabilizing frame or device such as a spinal surgery frame **125** commonly used for spinal surgery. A reference arc **120** bearing tracking means or emitters, such as for example LED emitters **122**, is mounted to the spinous process by a central post **150**. The structures **20** and K wires **260** of FIG. **1** are depicted in more detail in FIG. **1**A. The image **105** is generated from an image data set, usually generated preoperatively by a CAT scanner or by MRI for example, which image **105** has reference points for at least one body element, such as a spinal element or vertebrae. The reference points of the particular body element have a fixed spatial relation to the particular body element.

The system includes an apparatus such as a digitizer or other Position Sensing Unit (PSU), such as for example sensor array **110** on support **112** for identifying, during the procedure, the relative position of each of the reference points to be displayed by tracking the position of emitters **122** on arc **120**. The system also includes a processor **114** such as a PC or other suitable workstation processor associated with controller **108** for modifying the image data set according to the identified relative position of each of the reference points during the procedure, as identified by digitizer **110**. The processor **114** can then, for example, generate an image data set representing the position of the body elements during the procedure for display on monitor **106**. A surgical instrument **130**, such as a probe or drill or other tool, may be included in the system, which is positioned relative to a body part and similarly tracked by sensor array **110**.

In summary, the general operation of a surgical navigating system is well known in the art and need not further be described here.

In accordance with the preferred embodiment of the present invention, with further reference to FIGS. **1** through **6**, a registration device **20** is rigidly fixed to a spinal element by, for example, a device such as a bone clamp **30** depicted in FIG. **2**. Alternatively, a screw retention device **40**, such as the cannulated screw **42** depicted in FIG. **5**, and described in more detail below, can be used.

With reference now to FIG. **2**, bone clamp **30** is fixedly attached to the spinous process. The clamp **30** includes at least two blades (or jaws) **32** with tips or teeth **34**, which are preferably sharp, for driving together and penetrating soft tissue or more dense bone for rigid fixation to the spinous process. The teeth **34** are also preferably sized to accommodate the bulb shape of the spinous process. The driving mechanism **40** is, for example, a screw driven into a sleeve **41** and is also preferably located such that it will be accessible in a percutaneous manner. Attached to the clamp **30** is a superstructure **20**. The superstructure **20** includes a central post **150** which is relocatable, that is, it fixes to the clamp **30** in a rigid fashion, for example, as depicted in FIGS. **2**D and **2**E, by being inserted into a V-shaped wedge **44** orienting the post **150** front to back and providing a mating hole **48** along the wedge **44** for insertion of post **150** in a single orientation and also providing fasteners such as screw **43** for tightning to lock the post **150** in place. The post **150** can be removed and reapplied by loosening and tightening screw **43**, such that the original geometry and orientation is maintained. The central post **150** has at its apex a connector **60** with unique geometrical configuration, such as, for example, a starburst, onto which a spinal reference arc **120** of the superstructure **20** attaches. Any such standard reference arc **120** can be used, such as depicted in FIGS. **1**A, **4**, and **11**, preferably including emitters **122**, such as for example LEDs or reflective spheres for providing a positive indication of movement to the surgical navigation system during a procedure.

Also rigidly attached to the central post **150**, as part of the superstructure **20** preferably at a location closer to the skin, or possibly collocated with or also performing the function of the reference arc **120**, is a fiducial array **170**, which can be of various different shapes, such as, for example the H-shaped frame **170** depicted in FIG. **2**, the W-shaped frame **170'** as depicted in FIG. **3**, the U-shaped frame **170"** as depicted in FIG. **4** or the X-shaped frame **120'**, **170'"** depicted in FIG. **5** (depicting a structure that is both a fiducial array and a reference arc). As depicted in FIGS. **2** and **3**, this array can include fiducial points **29** or spheres **17**, rigidly attached to fiducial array **170**, **170'** and is, for example, as depicted in FIG. **3**, substantially in the shape of spheres **17** and of a material detectable by the CAT scan or MRI, preferably titanium or aluminum. This fiducial array such as **170** indicates to the surgical navigation system the location of the bone structure to which the clamp **30** and central post **150** are attached by touching a pointed surgical tracker to fiducial points **29** or a cup-shaped probe to fiducial spheres **17**, thereby indicating the center of the fiducial to the surgical navigation controller **114**. The array **170** and central post **150** are also attached to the clamp **30**, as described above, in such a way that they can be removed and replaced in the same geometric orientation and location, for example, by means of a uniquely shaped interface, for example, a triangle, or a single unique shape or a combination of unique angles or pins with the clamp **30** such that the post **150** can only be reinserted the same way it was removed.

Additionally, the fiducial array **170**, can be located at various heights on the post **150** to accomodate variations in patient tissue depth and size, preferably as close to the patient's body as possible, and then fixed at that specific height by the use of pins or indents matched to holes **19** (shown in FIG. **2**) in the central post **150** or by placing the rods **39** of H-shaped array **170** in different holes **31**. The fiducial array **170** also has, for example, divots **29** (shown in FIG. **2**) shaped to interface with an instrument such as a surgical pointer **130** which can touch that divot **29** to register the location of the divot **29** and, thus, the location of the fiducial array **170** and likewise the spinal element in the surgical navigation system. Multiple divots can be registered to further increase accuracy of the registration system. In one preferred embodiment of the array, the fiducials **17** or **29** can be mounted in a manner such that they can be adjusted, for example by mounting them on a rotatable or collapsible arm **66** (as depicted in FIG. **3**) that pivots and folds together, to get the maximum distance between fiducials while not dramatically increasing the field of view required at the time of scanning.

Alternatively, rather than using clamp **30**, a screw **42** and rigid wire **45** attachment, as depicted in FIGS. **5** and **6**, may be used to rigidly attach the central post of the superstructure **20** to a body element, such as, for example, a vertebrae. As depicted in FIG. **6**, screw **42** is screwed into the spinal process of spinal element **100**. A rigid wire **45**, post, or other sufficiently rigid fastener such as for example a Kirschner wire (K-wire), is inserted through the cannulation in the center of post **150** and the screw **42** or is otherwise fixed to the screw **42**, and exits the tip of the screw **42** at some angle, and is also implanted into the spinal element **100** to prevent the screw **42** from rotating in either direction.

Another embodiment for preventing the superstructure **20** from rotating as depicted in FIGS. **10** and **11** includes the insertion of a screw **85** through a cannulated tube **86** which has teeth **89** in the end (or V-shaped end) that would bite into the tip of the spinous process, preventing rotation.

Having described the preferred embodiment of this apparatus of the present system, the method of using this apparatus to practice the invention of registering a single vertebrae will now be discussed. The operation of a surgical navigating system is generally well known and is described in PCT/US95/12894. In the preferred method of operation, clamp **30** of FIG. **2** or screw **42** and K-Wire **45** of FIG. **5** are implanted percutaneously through a small incision in the skin and rigidly attached to the spinal process. This attachment occurs with the clamp **30**, by driving the blades **32** of the clamp **30** together to hold the spinous process rigidly. The central post **150** is then rigidly fixed to the clamp **30** or screw **42** and the fiducial array **170** is rigidly fixed to the central post **150**. The patient is then scanned and imaged with a CAT scan or MRI with a field of view sufficiently large to display the spinal anatomy and the clamp **30** or screw **42** and the fiducial array **170**. This scan is loaded into the surgical navigation system processor **104**.

After scanning the patient, the array **120** and post **150** can be removed from the patient, while leaving in place the rigidly connected clamp **30** or screw **42**. For example, as depicted in FIGS. **4**D and **4**E, a foot **55** located below array **170"** engages with shoe **56** and rigidly connected by screws **57** and **58**. Before the surgical procedure, the post **150**, array **120** and other remaining portions of the superstructure **20**, once removed, may be sterilized. The patient is then moved to the operating room or similar facility from, for example, the scanning room.

Once in the operating room, the patient may be positioned in an apparatus, such as, for example, a spinal surgery frame **125** to help keep the spinal elements in a particular position and relatively motionless. The superstructure **20** is then replaced on the clamp **30** or screw **42** in a precise manner to the same relative position to the spinal elements as it was in the earlier CAT scan or MRI imaging. The reference arc **120** is fixed to the starburst or other interface connector **60** on the central post **150** which is fixed to the clamp **30** or screw **42**. The operator, for example a surgeon, then touches an instrument with a tracking emitter such as a surgical pointer **130** with emitters **195** to the divots **29** on the fiducial array **170** to register the location of the array **170** and, thus, because the spinal process is fixed to the fiducial array **170**, the location of the spinal element is also registered in the surgical navigation system.

Once the superstructure **20** is placed back on the patient, any instrument **130** fitted with tracking emitters thereon such as, for example, a drill or screw driver, can be tracked in space relative to the spine in the surgical navigation system without further surgical exposure of the spine. The position of the instrument **130** is determined by the user stepping on a foot pedal **116** to begin tracking the emitter array **190**. The emitters **195** generate infrared signals to be picked up by camera digitizer array **110** and triangulated to determine the position of the instrument **130**. Additionally, other methods may be employed to track reference arcs, pointer probes, and other tracked instruments, such as with reflective spheres, or sound or magnetic emitters, instead of LED's. For example, reflective spheres can reflect infrared light that is emitted from the camera array **110** back to the camera array **110**. The relative position of the body part, such as the spinal process is determined in a similar manner, through the use of similar emitters **122** mounted on the reference frame **120** in mechanical communication with the spinal segment. As is well known in this art and described generally in PCT/US95/12894, based upon the relative position of the spinal segment and the instrument **130** (such as by touching a known reference point) the computer would illustrate a preoperative scan—such as the proper CAT scan slice—on the screen of monitor **106** which would indicate the position of the tool **130** and the spinal segment for the area of the spine involved in the medical procedure.

For better access by the operator of various areas near the central post **150**, the fiducial array **170** can be removed from the central post **150**, by, for example, loosening screw **42** and sliding the array **170** off post **150**, leaving the reference arc **120** in place or replacing it after removal of array **170**. By leaving the reference arc **120** in place, the registration of the location of the spinal process is maintained. Additionally, the central post **150**, reference arc **120**, and fiducial array **170** can be removed after the spinal element has been registered leaving only the clamp **30** or screw **42** in place. The entire surgical field can then be sterilized and a sterile post **150** and reference arc **170** fixed to the clamp **30** or screw **42** with the registration maintained.

This surgical navigation system, with spinal element registration maintained, can then be used, for example, to place necessary and desired screws, rods, hooks, plates, wires, and other surgical instruments and implants percutaneously, using image-guided technology. Once the location of the spinal element **100** involved in the procedure is registered, by the process described above, in relation to the image data set and image **105** projected on monitor **106**, other instruments **130** and surgical implants can be placed under the patient's skin at locations indicated by the instrument **130** relative to the spinal element **100**.

Additionally, the location of other spinal elements, relative to the spinal element **100** containing the fiducial array **170**, can be registered in the surgical navigation system by, for example, inserting additional screws **250**, rigid wires **260**, or other rigid implants or imageable devices into the spinal segment.

For example, as depicted in FIG. **1**, and in more detail FIG. **1**A, additional screws **250** or rigid and pointed wires **260** are placed in the vertebrae adjacent to the vertebrae containing the clamp **30** and post **150** prior to scanning. On the image **105** provided by monitor **106**, the surgeon can see the clamp **30** or screw **42** and fiducial array **170** and also the additional screws **250**, wires **260** or other imageable devices. When screws **250** or other devices are used, these screws **250** (as depicted in FIG. **7**) may contain a divot **256** or other specially shaped interface on the head **255** so that a pointer probe **130** can be used to point to the head **255** of the screw **250** (or wire) and indicate the orientation of the screw **250** or wire **260** to the surgical navigation system by communicating to the controller **114** or by emission from LEDs **195** on probe **130** to digitizer **110**. The image of these additional screws **250** also appear in the scan. Once the patient is then moved to the operating facility, rather than the scanning area, the image of the screw **250** can be compared to the actual position of the screw **250** as indicated by the pointer probe **130** that is touched to the head **255** of the screw **250** or wire **260**. If necessary, the operator can manipulate the position of the patient to move the spinal element and thus the location of the screw **250** or wire **260** to realign the spinal elements with the earlier image of the spine. Alternatively, the operator can manipulate the image to correspond to the current position of the spinal segments.

For additional positioning information, the operator can place additional rigid wires **260** or screws **250** into the vertebrae, for example, located at the superior (toward the patient's head) and inferior (towards the patient's feet) ends of the spinal process to more accurately position those vertebrae relative to the other vertebrae and the image data. Additionally, the wires **260** and screws **250** implanted to provide positioning information can also be equipped with emitters, such as, for example, LEDs, to provide additional information to the surgical navigation system on the location of the wire **260** or screw **250**, and thus the vertebra to which they are affixed.

Alternatively, the patient can be placed in a position stabilizing device, such as a spinal surgery frame **125** or board, before a scan is taken, and then moved to the operating facility for the procedure, maintaining the spine segments in the same position from the time of scanning until the time of surgery. Alternatively, a fluoroscope can be used to reposition the spinal segments relative to the earlier image from the scan. An ultrasound probe can be used to take real-time images of the spinal segment which can be portrayed by monitor **106** overlayed or superimposed on image **105**. Then the operator can manually manipulate the spinal elements and take additional images of these elements with the fluoroscope to, in an iterative fashion, align the spinal elements with the previously scanned image **105**.

Alternatively, a clamp **30** or screw **42** and superstructure **20** can be rigidly fixed to each vertebra involved in the surgical or medical procedure to register the position of each vertebra as explained previously for a single vertebra:

After the spinal elements are registered in the spine, various medical and surgical procedures can be performed on that patient. For example, spinal implants, endoscopes, or biopsy probes can be passed into the spine and procedures such as, for example, spinal fusion, manipulation, or disc removal can be performed percutaneously and facilitated by the surgical navigation image-guiding system. Additionally, a radiation dose can be targeted to a specific region of the vertebrae.

One such procedure facilitated by the apparatus and methods described above is the percutaneous insertion of screws and rods, fixed to different vertebra in a spine to stabilize them. Once screws, for example multiaxial screws **250**, (as depicted in FIG. **12**, before manipulation) are implanted through small incisions they can be manipulated by a head-positioning probe **280**. The final position of screws **250** and heads **255** are depicted in FIG. **13**. This probe **280**, as depicted in FIG. **7**, includes a head **285** that mates in a geometrically unique fashion with the head **255** of the screw **250**. An emitter, such as for example an LED array **380** on the probe **280**, indicates the location and orientation of the screw head **255** to the computer **114** of the surgical navigation system by providing an optical signal received by digitizer **110**. The screw head **255** can then be rotatably manipulated under the patient's skin by the head positioning probe **280** to be properly oriented for the receipt of a rod **360** inserted through the rotating head **255**. The operator can then plan a path from the head **255** of each screw **250** to the other screws **250** to be connected. Then, with reference now to FIG. **9**, an optically tracked rod inserter **245** also equipped with emitters, such as, for example LEDs **247**, can be placed through another small incision to mate with and guide a rod **360** through the holes or slots in the screw heads **245**, through and beneath various tissues of the patient, with the rod inserter **245**, and, therefore, the rod **360**, fixed to the inserter **245**, being tracked in the surgical navigation system. The operator can also use the computer **114** to determine the required bending angles of the rod **360**. For greater visualization, the geometry of the screws **250** could be loaded into the computer **114** and when the position and orientation of the head **255** is given to the computer **114** via the probe **280**, the computer **114** could place this geometry onto the image data and three-dimensional model. The rod **360** geometry could also be loaded into the computer **114** and could be visible and shown in real time on monitor **106** as the operator is placing it in the screw heads **255**.

In an alternative procedure, one or more plates and/or one or more wires may be inserted instead of one or more rods **360**.

It will be apparent to those skilled in the art that various modifications and variations can be made in the present invention and in construction of this surgical navigation system without departing from the scope or spirit of the invention. Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only.

What is claimed is:

[1. An apparatus for facilitating percutaneous placement of surgical instruments into the spine, adapted for use with a surgical navigation system employing an energy-detecting array in communication with a surgical navigation computer to track positions of instruments in three dimensional space relative to a known reference point, said apparatus comprising:

a connector adapted to be rigidly attached to a portion of the spine;

at least one central post connected to said connector;

a position identification structure rigidly and removably connected to said central post at a predetermined position on said central post and adapted to be reconnected at the same said predetermined position, said identification structure being further adapted to allow a patient to be scanned with the structure connected to the central post, said structure including an assembly for communicating positioning information with respect to said assembly to the energy detecting array and surgical navigation computer; and

a connector assembly for said reconnecting of said structure substantially to said predetermined position on said central post.**]**

[2. The apparatus of claim **1**, wherein the connector is a clamp having teeth adapted for biting into a spinous process.**]**

[3. The apparatus of claim **1**, wherein the connector includes an elongated fixture with a central axis and a threaded end adapted to be inserted into the spinous process and a substantially rigid wire connected to the fixture with the central axis of the wire adapted to be implanted into the spinous process at an angle to elongated fixture to prevent the fixture from rotating.**]**

[4. The apparatus of claim **1**, wherein said assembly for communication positioning information is a substantially H-shaped frame.**]**

[5. The apparatus of claim **1**, wherein said assembly for communicating positioning information is a substantially W-shaped frame.**]**

[6. The apparatus of claim **1**, wherein said assembly for communicating positioning information is a substantially U-shaped frame.**]**

[7. The apparatus of claim **1**, wherein said assembly for communicating positioning information is a substantially X-shaped frame.**]**

[8. The apparatus of claim **1**, wherein said assembly for communicating positioning information comprises:

a fiducial array for registering the location of a spinal element with rigidly connected fiducials; and

a reference arc for signaling the position of a spinal element, said arc further comprising rigidly connected emitters.**]**

[9. The apparatus of claim **1**, wherein said reference point is on the spine.**]**

[10. A method for monitoring the location of an instrument, surgical implant and various portions of the body, to be operated on, using a surgical navigation system with a surgical navigation computer and a digitizer array for monitoring the location of instruments in three-dimensional space relative to a known reference point, said method comprising the steps of:

attaching a fixture having a central post to a portion of the spine;

removably attaching an identification structure including a fiducial array and a reference arc to said central post;

providing a scanned three-dimensional image of a patient including said fiducial array rigidly attached to said central post of said fixture, said fixture being rigidly attached to the patient to identify the position of said fixture and said fiducial array on the scanned image;

using an image-guided system, by touching an image guided surgical pointer to one or more fiducials on the fiducial array to register the location of a spinal element fixed to said array; and

emitting a signal from said reference arc to indicate changes in position of the spinal element during a surgical procedure.**]**

[11. The method of claim **10**, further comprising:

performing a surgical procedure percutaneously on a patient using an instrument and implant locatable relative to the spinal element and said structure in known positions identified in the surgical navigation system.**]**

[12. The method of claim **10**, further comprising:

inserting a threaded fixture having a substantially rigid wire into a spinal element; and

touching an image guided pointer to said threaded fixture and wire to positively register the location of said fixture and wire in a surgical navigation computer.**]**

[13. The method of claim **10**, further comprising:

implanting imageable devices into spinal elements to identify the location of the spinal elements in the surgical navigation computer.**]**

[**14**. The method of claim **10**, further comprising:

implanting imageable devices into a plurality of spinal elements; and

manipulating the patient's spine by viewing the location of the implanted devices, as communicated to the surgical navigation computer by touching an instrument with a tracking emitter to said implanted imageable devices to align the actual position of the spinal elements with the previously scanned image.]

[**15**. The method of claim **10** further comprising:

percutaneously implanting screws into spinal elements; and

locating the position of said screws using image guided surgical navigation techniques.]

[**16**. The method of claim **15** further comprising:

manipulating the orientation of the screw heads percutaneously using a head-positioning probe for communicating location containing an emitter, said probe communicating to the surgical navigation computer the orientation of the screw heads; and

using a head positioning tool for manipulating implants having an end portion that mates with the heads of the screws and rotating the screws to receive a connecting implant.]

[**17**. The method of claim **16** further comprising:

tracking the location and position of the connecting implant by means of an instrument affixed to the implant having emitters capable of communicating orientation and location to the surgical navigation computer.]

[**18**. A system for use in performing the percutaneous placement of surgical implants and instruments into the spine using image guided surgery and a surgical navigation computer and energy detecting array, said system comprising:

means for attaching a fixture to a portion of the spine;

means for communicating position information to the surgical navigation computer and energy detecting array said means rigidly and removably connected to said means for attaching a fixture;

means for providing location information of said spinal portion to the surgical navigation system adapted to be connected to spinal elements;

means for indicating screw-head position said means electrically connected to the surgical navigation system and adapted to mate with the head of a screw implanted in one or more of said spinal elements.]

[**19**. The system of claim **18** further comprising:

an elongated implant adapted to be inserted into said implanted screws;

means for indicating the position of said elongated implant electrically connected to the surgical navigation system and adapted to mate with the elongated implant.]

[**20**. The system of claim **18**, wherein said implanted screws have heads and the elongated implant is a rod adapted to be guided through holes in said implanted screw heads.]

21. A method of positioning an implant in an anatomy, including a first implant portion and a second implant portion with a surgical navigation system, comprising:

positioning the first implant portion through an opening in a soft tissue of the anatomy;

tracking a position of the first implant portion;

interconnecting an implant inserter with the second implant portion;

determining a location of the second implant portion; and

moving the second implant portion relative to the first implant portion via determining a location of the second implant portion.

22. The method of claim 21, wherein positioning a first implant portion through an opening in a soft tissue, moving the second implant portion relative to the first implant portion, or combinations thereof includes positioning the first implant portion, the second implant portion, or combinations thereof percutaneously.

23. The method of claim 22, wherein tracking a position of the first implant portion includes;

interconnecting a tracking apparatus with the first implant portion; and

tracking the tracking apparatus interconnected to the first implant portion.

24. The method of claim 23, further comprising:

determining a position of the portion of the first implant portion;

wherein moving the second implant portion relative to the first implant portion includes determining a location of a second implant portion relative to the first implant portion.

25. The method of claim 24, further comprising:

displaying the determined position of the first implant portion and the position of the second implant portion.

26. The method of claim 21, further comprising:

configuring the second implant portion based upon a tracked position of the first implant portion, a determined location of the second implant portion, or combinations thereof.

27. The method of claim 21, further comprising:

interconnecting a reference frame with the anatomy.

28. The method of claim 27, further comprising:

displaying a determined position of the second implant portion on a display relative to a registered image of the anatomy.

29. The method of claim 21, further comprising:

interconnecting a tracking apparatus with the implant inserter; and

tracking the tracking apparatus.

30. The method of claim 29, wherein the tracking apparatus includes a sensor.

31. The method of claim 30, further comprising:

selecting a sensor to include at least one of a light emitter, an infrared light emitter, an electromagnet, a magnet, a radiation emitter, an acoustic emitter, or combinations thereof.

32. The method of claim 21, wherein determining a location of the second implant further includes tracking the tracking apparatus.

33. The method of claim 21, further comprising:

imaging the anatomy while at least one of tracking the position of the first implant, tracking the tracking apparatus, determining a location of a portion of the second implant portion, or combinations thereof.

34. The method of claim 33, wherein imaging the anatomy includes imaging the anatomy with an ultrasound system.

35. The method of claim 21, further comprising:

positioning a third implant portion through an opening in a soft tissue; and

interconnecting the first implant portion and the third implant portion with the second implant portion by moving the second implant portion relative to the first implant portion and the third implant portion.

36. The method of claim 21, wherein said first implant portion is a slot in a screw head;

wherein said second implant portion is a rod;

wherein moving the second implant portion includes aligning the rod with the slot.

37. The method of claim 36, further comprising:

fixing the first implant portion to a vertebrae.

38. The method of claim 21, wherein tracking a position includes tracking with an acoustic tracking system, optical tracking system, electromagnetic tracking system, micropulsed radar, or combinations thereof.

39. A method of performing a spinal procedure in an anatomy with a surgical navigation system, comprising:

positioning a first screw implant in a vertebrae percutaneously through an opening in a soft tissue of the anatomy;

tracking a position of the first screw implant with a screw tracking apparatus;

orientating the first screw implant in a selected orientation at least in part via tracking the position of the first screw implant;

interconnecting an implant inserter with a rod;

determining a position of a portion of the rod; and

moving the rod relative to the first screw implant via determining a location of the rod to interconnect the screw with rod.

40. The method of claim 39, further comprising:

interconnecting a second tracking apparatus with the implant inserter.

41. The method of claim 39, wherein orientating said first screw implant includes orientating a slot defined by the screw.

42. The method of claim 41, wherein tracking a position of the first screw implant includes interconnecting the screw tracking apparatus with the first screw implant.

43. The method of claim 42, wherein interconnecting the screw tracking apparatus includes selecting a sensor.

44. The method of claim 43, wherein selecting the sensor includes selecting a light emitting diode, a light reflector, an infrared emitter, a magnet, an electromagnet, an acoustic emitter, an infrared reflector, or combinations thereof.

45. The method of claim 42, wherein interconnecting the screw tracking apparatus with the first screw implant includes positioning the screw tracking apparatus percutaneously.

46. The method of claim 42, wherein tracking the tracking apparatus includes at least triangulating a position of the tracking apparatus with the surgical navigational system.

47. The method of claim 46, wherein the surgical navigation system includes an acoustic tracking system, or electromagnetic tracking system, an optical tracking system, a micropulsed radar, or combinations thereof.

48. The method of claim 41, wherein orientating the first screw implant includes orientating the slot relative to the anatomy.

49. The method of claim 48, further comprising:

positioning a second screw implant in a vertebrae percutaneously; and

orientating the second screw implant;

wherein orientating the second screw implant includes orientating second screw implant relative to the first screw implant.

50. The method of claim 49, wherein moving the rod relative to the first screw implant includes moving the rod relative to both the first screw implant and the second screw implant.

51. The method of claim 50, further comprising:

manipulating the rod to achieve an interconnection of the first screw implant and the second screw implant.

52. The method of claim 48, wherein interconnecting the implant inserter with the rod includes interconnecting the implant inserter near a first end of the rod, a second end of the rod, a portion intermediate between the first end and the second end, or combinations thereof.

53. The method of claim 48, wherein interconnecting an implant inserter with a rod includes rigidly interconnecting an implant inserter with the rod.

54. The method of claim 53, further comprising:

interconnecting a tracking apparatus with the implant inserter that includes rigidly interconnecting the tracking apparatus with the implant inserter.

55. The method of claim 48, wherein interconnecting an implant inserter with a rod includes releasably interconnecting the implant inserter with the rod.

56. The method of claim 48, further comprising:

interconnecting a tracking apparatus with the implant inserter that includes positioning an emitter on the tracking apparatus.

57. The method of claim 56, wherein interconnecting a sensor with the tracking apparatus includes selecting at least one of a light emitting a diode, a light reflecting portion, an infrared light emitting portion, an infrared light reflecting portion, an acoustic emitter, an electromagnet, a magnet, or combinations thereof.

58. The method of claim 48, further comprising:

imaging a portion of the anatomy.

59. The method of claim 58, wherein imaging an portion of the anatomy includes obtaining an MRI scan, a CT scan, an x-ray image, an ultrasound image, or combinations thereof.

60. The method of claim 48, further comprising:

displaying an image of the anatomy; and

displaying a position of the portion of the screw on the display relative to the image of the anatomy, and displaying a determined position of the rod relative to the image of the anatomy.

61. The method of claim 60, wherein moving the rod relative to the screw includes displaying on the display the portion of the rod relative to the position of the head of the screw.

62. The method of claim 61, further comprising:

manipulating the rod to achieve a selected interconnection of the rod and the screw implant.

63. The method of claim 62, wherein manipulating the rod includes bending the rod.

64. The method of claim 63, further comprising:

positioning a second screw implant in a vertebrae percutaneously; and

moving the rod relative to the screw implant and the second screw implant.

65. The method of claim 48, wherein moving the rod relative to the screw includes moving the rod substantially percutaneously.

66. The method of claim 65, wherein moving the rod substantially percutaneously includes inserting the rod through a substantially single opening in a soft tissue of the anatomy and moving the rod based upon a tracked position of the rod.

67. The method of claim 66, wherein tracking a position of the portion of the screw and determining a position of a portion of the rod is substantially percutaneous.

68. The method of claim 48, wherein tracking the position of the first screw implant includes tracking a position of a slot defined by the screw.

69. The method of claim 68, wherein moving the rod relative to the first screw implant includes moving the rod percutaneously through the slot.

70. The method of claim 69, further comprising:

positioning a second screw implant in a vertebrae percutaneously through an opening in a soft tissue of the anatomy;

tracking a position of the second screw implant; and

orientating the second screw implant in a selected orientation at least in part via tracking the position of the second screw implant.

71. The method of claim 70, wherein orientating the second screw implant includes aligning a second slot defined by the second screw implant with a first slot defined by the first

screw implant at least in part by tracking the position of the first screw implant, tracking the position of the first screw implant, or combinations thereof;

wherein moving the rod includes moving the rod through the first slot and the second slot.

72. The method of claim 71, further comprising:

fixing the rod to the first screw implant and the second screw implant.

73. The method of claim 39, wherein orientating the first screw implant includes selecting an orientation of a head of the screw relative to a portion of the anatomy.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : RE42,226 E
APPLICATION NO. : 11/451595
DATED : March 15, 2011
INVENTOR(S) : Kevin T. Foley et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, line 32, above the heading, "FIELD OF THE INVENTION" insert: --Notice: More than one reissue application has been filed for the reissue of patent RE42,226. The reissue applications are RE39,133 and RE42,194.--

Signed and Sealed this
Twenty-sixth Day of February, 2013

Teresa Stanek Rea
Acting Director of the United States Patent and Trademark Office