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(71) Applicant *(for all designated States except US)*: **IMAGE-GUIDED NEUROLOGICS, INC.** [US/US]; 2290 West Eau Gallie Blvd., Melbourne, Florida 32935 (US).

(71) Applicants and
(72) Inventors: **SOLAR, Matthew, S.** [US/US]; 290 Normandy Drive, Indialantic, Florida 32903 (US). **FREAS, Mark, S.** [US/US]; 1781 Winding Ridge Circle, Palm Bay, Florida 32909 (US). **BRIDGES, Thomas, L.** [US/US]; 2999 Hwy. A1A, #12N, Melbourne Beach, Florida 32951 (US). **LEE, David, M.** [US/US]; 702 Pine Street, Melbourne Beach, Florida 32951 (US).

(74) Agents: **STEFFEY, Charles, E.** et al.; Schwegman, Lundberg, Woessner & Kluth, P.A., P.O. Box 2938, Minneapolis, Minnesota 55402 (US).

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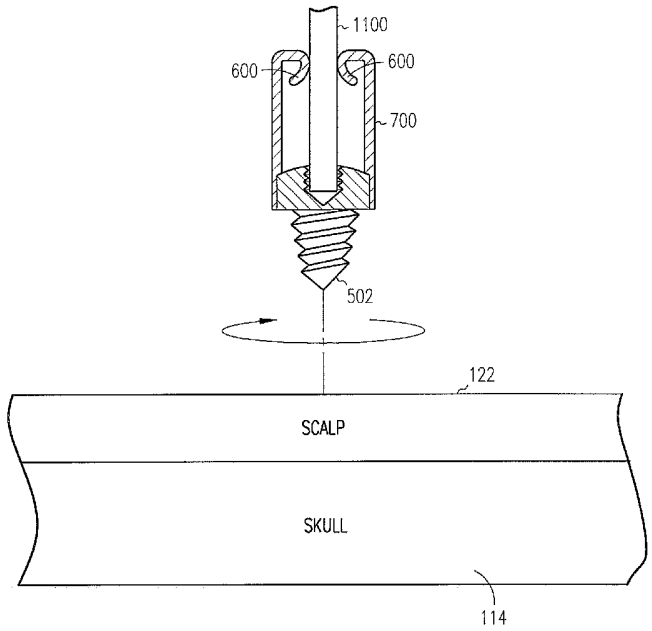
(54) **Title:** FIDUCIAL MARKER AND PROTECTIVE CAP



(57) **Abstract:** This document discusses, among other things, a fiducial marker kit. In one example, the kit includes a fiducial marker assembly that includes a bone screw base for receiving an imageable marker or locatable divot. A valved protective sleeve prevents debris from accumulating in a receptacle portion of the base, which may otherwise degrade the accuracy of patient registration in an image-guided surgical procedure. In one example, the valve automatically opens or closes upon insertion or removal of a screwdriver or other tool, or a shaft portion of the imageable marker or locatable divot. Various bone screw base and receptacle combinations are also discussed.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

FIDUCIAL MARKER AND PROTECTIVE CAP

TECHNICAL FIELD

This document relates generally to imaging and/or locating a subject, such as for performing surgical intervention, and more specifically, but not by way of limitation, to fiducial marker devices and associated devices, tools, and methods.

BACKGROUND

Fiducial markers that can be located and recognized by an imaging system or other system are useful in neurosurgery and other applications. Examples of imaging system modalities include, among other things, magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET), and single photon emission computed tomography (SPECT).

For example, in one technique, multiple fiducial markers are screwed into the patient's skull to define landmarks recognizable by an imaging system. The imaging system is used to obtain one or more preoperative images of the patient's brain. Recognizable images of the fiducial markers appear on such preoperative images. Such a bone-anchored fiducial marker typically includes an externally threaded bone-screw portion, which is driven into the skull. A threaded shaft rises up and out of the skull from the bone-screw. The threaded shaft typically receives a screwed-on imagable sphere that is visible on an MRI or CT image. The multiple fiducial markers on the patient's skull define landmarks on preoperative images that are useful to the physician for planning entry coordinates on the patient's skull and for planning a trajectory to a target location in the brain. An image-guided surgical workstation uses these preoperative images and the planning data to guide the neurosurgeon while actually performing the subsequent surgical procedure.

After the preoperative planning phase, the patient is brought into the operating room so that the planned surgical procedure can be performed. On the operating table, the patient's skull is clamped in a head-frame or otherwise immobilized. In order to use the preoperative images provided by the image-

guided workstation to guide the surgeon during the surgical procedure, the patient's skull must first be "registered" to the preoperative images. The registration creates an association between (1) the actual physical location of the fiducial markers on the patient's skull in the operating room and (2) the locations of the images of the fiducial markers visible on the preoperatively-obtained images. This allows mapping between the actual space in which the patient is located to the space defined by the preoperative images.

According to one registration technique, a "wand" is used to perform this patient registration. The wand typically includes multiple light-emitting diode (LED) locators or reflective locators, which are visible to an infrared camera or other detector of an optical positioning system in the operating room. The camera and optical positioning system are operatively connected to the image-guided workstation. The locators define the position of the wand in the operating room, including the position of a sharp tip portion of the wand, which is in a known physical relationship to the locators. To register the patient, the imagable spheres are unscrewed from the fiducial marker shafts, and replaced by respective "divots" that are sized and shaped to receive the wand tip in a recess that is shaped to mate with the wand tip. These divots are screwed or otherwise engaged onto the respective fiducial marker shafts, such that when the wand tip is received into the maximum depression point of the divot, the wand tip then corresponds to the same location as the center of the imagable sphere when the imagable sphere was screwed onto the fiducial marker shaft. A reference divot is typically also present in the operating room at a known location, such as attached to the operating table or the patient's skull-immobilizing head-frame. During the patient registration process, the surgeon touches the wand tip to the reference divot (to provide an absolute positional reference to the image-guided workstation), and then to each fiducial marker divot. This permits the image-guided workstation to correlate the actual physical location of the patient's skull to the preoperative images. The physician can then use the wand, in conjunction with the preoperative images provided by the image-guided workstation, to locate an appropriate entry point and trajectory to the target in the brain.

The present inventors have recognized an unmet need for improved fiducial marker devices, tools, and methods.

SUMMARY

In one example, this document describes, among other things, a fiducial marker assembly for an image-guided surgical procedure. The fiducial marker assembly comprises a bone screw base. The base includes a distal threaded bone screw shaft and a proximal head. The fiducial marker assembly also comprises a protective sleeve, sized and shaped to fit securely directly or indirectly about the head of the bone screw base. The protective sleeve includes a proximal valve and an internal passage between the valve and the proximal head of the bone screw base.

This document also describes variations on this or other examples. In one variation, the fiducial marker assembly comprises a tubular cylindrical spacer secured to the proximal head of the bone screw base. The spacer is located between the proximal head of the bone screw base and the protective sleeve. In another variation, the valve includes a compliant material that automatically opens upon insertion of an object therein and automatically closes upon removal of the object therefrom. In another variation, the valve includes a cap that is sized and shaped to be manually pressed onto a proximal end of the protective sleeve to prevent debris from entering the passage of the protective sleeve. In another variation, the fiducial marker assembly includes an imageable marker that is sized and shaped to be secured to the proximal head of the bone screw base. In another variation, the fiducial marker assembly comprises a locatable divot that is sized and shaped to be secured to the proximal head of the bone screw base.

In another example, this document describes a protective sleeve that is sized and shaped to fit about a portion of a fiducial marker base. The protective sleeve includes a compliant valve that automatically opens upon insertion of an object into the valve and that automatically closes upon removal of the object from within the valve.

This document also describes variations on this or other examples. In one variation, the sleeve includes a distal flange that is sized and shaped to be disposed under a scalp to retain the sleeve in place with respect to the fiducial marker base. In another variation, the sleeve includes a lip that is sized and

shaped to engage a portion of the fiducial marker head. In another variation, the sleeve includes an external coating, such as an aseptic or hydrophilic coating.

In another example, this document describes a kit. The kit comprises a bone screw base. The base includes a distal threaded bone screw shaft and a proximal head. The base also includes a protective sleeve. The protective sleeve is sized and shaped to fit securely directly or indirectly about the head of the bone screw base. The protective sleeve includes a proximal valve and an internal passage between the valve and the proximal head of the bone screw base.

This document also describes variations on this or other examples. In one variation, the kit comprises an imageable marker that is sized and shaped to be secured to the proximal head of the bone screw base. In another variation, the kit comprises a locatable divot that is sized and shaped to be secured to the proximal head of the bone screw base.

In one example, this document also describes a method. The method includes affixing a bone screw base to a skull. The base includes a valved sleeve located in association therewith. The method also includes attaching an imageable marker to the bone screw base, including inserting a portion of the imageable marker through a valve in the sleeve. The method also includes replacing the imageable marker with a locatable divot. The replacing includes removing the imageable marker and inserting the locatable divot through the valve.

This document also describes variations on this or other examples. In one variation, the method includes inserting the portion of the imageable marker through the valve such that this automatically opens the valve by compliant expansion of the valve, and such that removing the imageable marker includes automatically closing the valve by compliant relaxation of the valve.

This summary is not intended to be an exhaustive description of the described subject matter or claims, the details of which are included below.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, which are not necessarily drawn to scale, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of

substantially similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

FIG. **1** is a schematic diagram illustrating generally one example of a fiducial marker assembly.

FIG. **2** is a schematic diagram illustrating generally an example of a similar fiducial marker assembly.

FIG. **3** is a schematic diagram illustrating generally one example of a silicone or other at least somewhat compliant protective sleeve placed about a base or a spacer.

FIG. **4** is a schematic diagram illustrating a top view of a sleeve, including a valve.

FIG. **5** is a schematic diagram illustrating generally an example of a similar valved compliant protective sleeve that is coupled directly to a bone screw base, such as by a lip that extends at least partially under a head portion of the base.

FIG. **6** is a top view of the sleeve of FIG. **5**, including a valve.

FIG. **7** is a schematic diagram illustrating generally an example of a similar valved compliant protective sleeve that is snugly coupled directly about a bone screw base without using a lip.

FIG. **8** is a top view of the sleeve of FIG. **7**, including a valve.

FIG. **9** is a schematic diagram illustrating generally an example of a similar valved compliant protective sleeve that is snugly coupled directly about a bone screw base using an inner circumferential lip.

FIG. **10** is a top view of the sleeve of FIG. **9**, including a valve.

FIG. **11** is a cross-sectional schematic diagram illustrating one example of using a valved compliant protective sleeve with an object inserted through the valve to automatically open it.

FIG. **12** is a cross-sectional schematic diagram illustrating the same example of using the valved compliant protective sleeve, in which the object has been withdrawn to automatically close the valve.

FIG. **13** is a cross-sectional schematic diagram illustrating one example of a flush-mounted base and a valved compliant protective sleeve with a flange that is placed beneath the scalp to hold the sleeve in place.

FIG. **14** is a top view of the sleeve of FIG. 13, including a valve.

FIG. **15** is a cross-sectional schematic diagram illustrating the implanted bas of FIG. **13**, including the valved compliant protective sleeve with the flange in place under the scalp.

FIG. **16** illustrates an example of a valved tubular protective sleeve that includes a manually operated valve, such as a cap.

FIG. **17** illustrates an alternative example in which a manually attachable and detachable cap is integrally attached to a sleeve.

FIG. **18** is a cross-sectional schematic diagram illustrating generally one example of a fiducial marker base that includes an internal hexagonal or similar faceted orifice for being engaged by a corresponding driver or for a shaft portion of an imageable marker or locatable divot.

FIG. **19** illustrates a top view of the fiducial marker base of FIG. **18**.

FIG. **20** is a cross-sectional schematic diagram illustrating generally one example of a fiducial marker base including a head that includes an external hexagonal or similar faceted surface for being engaged by a corresponding driver, and an internal orifice for receiving a shaft portion of an imageable marker or locatable divot.

FIG. **21** illustrates a top view of the fiducial marker base of FIG. **20**.

FIG. **22** is a cross-sectional schematic diagram illustrating a bone screw base with a head that includes an orifice for receiving a shaft portion of an imageable marker or locatable divot, and which further includes screwdriver slots or other features that permit the bone screw base to be driven into the skull.

FIG. **23** illustrates a top view of the fiducial marker base of FIG. **22**.

FIG. **24** is a cross-sectional schematic diagram illustrating a bone screw base with a head that includes an internally threaded orifice for receiving an externally threaded shaft portion of an imageable marker or locatable divot, and which further includes screwdriver slots or other features that permit the bone screw base to be driven into the skull.

FIG. **25** illustrates a top view of the fiducial marker base of FIG. **24**.

DETAILED DESCRIPTION

The following detailed description includes references to the accompanying drawings, which form a part of the detailed description. The drawings show, by way of illustration, specific embodiments in which the invention may be practiced. These embodiments, which are also referred to herein as "examples," are described in enough detail to enable those skilled in the art to practice the invention. The embodiments may be combined, other embodiments may be utilized, or structural, logical and electrical changes may be made without departing from the scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents.

In this document, the terms "a" or "an" are used, as is common in patent documents, to include one or more than one. In this document, the term "or" is used to refer to a nonexclusive or, unless otherwise indicated. Furthermore, all publications, patents, and patent documents referred to in this document are incorporated by reference herein in their entirety, as though individually incorporated by reference. In the event of inconsistent usages between this document and those documents so incorporated by reference, the usage in the incorporated reference(s) should be considered supplementary to that of this document; for irreconcilable inconsistencies, the usage in this document controls.

FIG. **1** is a schematic diagram illustrating generally one example of a fiducial marker assembly **100**. In this example, the fiducial marker assembly **100** includes a bone screw base **102**. The bone screw base **102** interchangeably receives one of an imagable marker **104** or a locating divot **106**. In this example, the base **102** includes a distal self-tapping or other threaded bone screw shaft **108** and a proximal head **110**. The head **110** includes a male or female receptacle **112** for receiving a corresponding portion of the imageable marker **104** or the divot **106**. For example, FIG. **1** shows a internally threaded receptacle **112**. The base **102** is driven into the skull **114**, such as by using a threaded driver that fits into the threaded receptacle **112**, or by using another driver that engages one or

more other features of the head **110**, such as screwdriver slots, hex heads, or the like.

In the example of FIG. **1**, the imageable marker **104** and the divot **106** each have a shaft **116** and a head **118**. The head **118A** of the imageable marker **104** is imageable using the desired imaging modality. The head **118B** of the divot **106** includes a receptacle **120** for receiving a locatable wand tip of a remote optical or other positioning system. When the imageable marker **104** is removed from the receptacle **112** of the base **102** and replaced by the divot **106**, the point of maximum depression of the receptacle **120** of the divot **106** is located at the point that was previously occupied by the center of the imageable head **118A**. Although the heads **118A-B** are illustrated as generally spherical (with or without a conical recess), they could alternatively be cylindrical or various other desired shapes.

The imaging portion of an image-guided surgical procedure (e.g., using the imageable marker **104**) may be performed at a different time than the registration portion of the procedure (e.g., using the imageable marker **106**). During the intervening time, the scalp **122** may grow over or otherwise obscure the head **110** portion of the bone screw base **108**. Moreover, blood or other debris may accumulate in the receptacle **112** during such intervening time. Such accumulation typically degrades the accuracy of the registration by blocking how far the shaft **116B** of the divot **106** may be inserted into the receptacle **112**. If the shaft **116B** of the divot **106** is not inserted into the receptacle **112** as far as the shaft **116A** of the imageable marker **104**, then the point of maximum depression of the receptacle **120** will not be located at the point previously occupied by the center of the imageable head **118A**.

FIG. **2** is a schematic diagram illustrating generally an example of a similar fiducial marker assembly **200**. In this example, the fiducial marker assembly **200** includes a bone screw base **202** having an attachable, detachable, or integral tubular cylindrical spacer **203**. The spacer **203** interchangeably receives one of an imagable marker **204** or a divot **206**. The base **202** includes a self-tapping or other threaded distal bone screw shaft **208** and a proximal head **210**. In this example, the head **210** includes a slotted or Phillips receptacle **112** or the like. This permits a screwdriver or the like to drive the shaft **208** into the

skull **114**. In this example, the cylindrical spacer **203** includes an orifice **221** sized and shaped for snugly receiving a corresponding shaft portion of the imageable marker **204** or the divot **206**. In the example of FIG. **2**, the imageable marker **204** and the divot **206** each have a shaft **216** and a head **218**. The head **218A** of the imageable marker **204** is imageable using the desired imaging modality. The head **218B** of the divot **206** includes a receptacle **220** for receiving a locatable wand tip of a remote optical or other positioning system. When the imageable marker **204** is removed from the receiving cylindrical orifice **221** of the spacer **203** and replaced by the divot **206**, the point of maximum depression of the divot **206** is then located at the point previously occupied by the center of the imageable head **218A**.

In this example, the cylindrical spacer **203** is tall enough to rise above the upper surface of the scalp **102**. This makes it easier to find the fiducial marker assembly **200**, such as when the imageable marker **204** has been removed during an intervening time between imaging and a later patient registration using the divot **206**. However, the spacer **203** can still accumulate blood or other debris within the cylindrical orifice **221**. This may degrade accuracy of the subsequent patient registration, as explained above. In one example, the fiducial marker assembly **200** is included in a kit that also provides a silicone or other at least somewhat compliant cap **224** as part of the fiducial marker assembly **200**. The cap **224** is sized and shaped to be press fitted into or about the proximal end of the cylindrical spacer **203**. The cap **224** prevents debris from accumulating within the cylindrical orifice **221**. The cap **224** can be used whenever the cylindrical orifice **221** is not occupied by one of the imageable marker **204** or the divot **206**, such as during the intervening time between imaging and patient registration, for example. In an alternative example, the cap **224** is instead configured as a cork-shaped stopper having a distal end that fits within the cylindrical orifice **221**. In yet another alternative example, the spacer **208** is of a height that makes its proximal surface **226** flush with, or even recessed from, the outer surface **228** of the scalp **122**.

FIG. **3** is a schematic diagram illustrating generally one example of a silicone or other at least somewhat compliant protective sleeve **300** placed about the base **202** or the spacer **203**. FIG. **4** is a schematic diagram illustrating a top

view of the sleeve **300**, including at least one slit or other valve **400**, such as the tricuspid valve illustrated in FIG. **4**. In this example, the compliant sleeve **300** fits snugly and securely about the spacer **203**. In this example, the compliant valve **400** automatically opens when a screwdriver or other tool, or when a shaft of an imageable marker or locatable divot is inserted therein. The valve **400** automatically closes when the tool is withdrawn. In this way, the valved sleeve **300** prevents debris from accumulating within the orifice **221** of the spacer **203** or within the receptacle of the base **202**. The valve **400** includes a lumen or other passage **302** through which such tool is inserted to drive the base **202** into the skull **114**, and through which a shaft of an imageable marker or locatable divot can be inserted. The compliant sleeve **300** fits snugly enough around the spacer **203** (or alternatively, directly around the base **202**) such that it does not pull free when the driver or other tool is withdrawn from the valve **400**, thereby automatically closing the valve **400**. However, in one example, the sleeve **300** is compliant enough such that it can be removed after the base **202** is secured into the skull **114**.

In one example, the sleeve **300** is first fitted about the spacer **203** or base **202** even before the base **202** is driven into the skull **114**, and the driver is inserted into the sleeve **300**. This advantageously holds the base **202** or spacer **203** to the tip of the driver. This makes it easier to insert the base **202** into the skull **114**. For example, there is no need to separately hold the base **202** in place against the skull **114** until the driver can be inserted into the base **202** and the base **202** begins to bite into the skull **114**.

In various examples, the sleeve **300** is made from polyurethane, polyethylene, polypropylene, biomedical grade silicone rubber, Santoprene®, or any other suitable material. In various examples, the sleeve **300** is made using injection molding, extrusion, or any other suitable process. In one example, the valve **400** is then cut into the sleeve **300** after it is formed.

FIG. **5** is a schematic diagram illustrating generally an example of a similar valved compliant protective sleeve **500** that is coupled directly to a bone screw base **502**, such as by a lip **504** that extends at least partially under a head **506** portion of the base **502**. In this example, an imageable marker or locatable divot is threaded, snap-fitted, or otherwise inserted into a receptacle **508** in a

head **510** portion of the base **502**, similar to the example shown in FIG. **1**. FIG. **6** is a top view of the sleeve **500**, including a tricuspid or other compliant valve **600**.

FIG. **7** is a schematic diagram illustrating generally an example of a similar valved compliant protective sleeve **700** that is snugly coupled directly about a bone screw base **502** without using the lip **504** of FIG. **5**. In this example, an imageable marker or locatable divot is threaded, snap-fitted, or otherwise inserted into a receptacle **508** in a head **510** portion of the base **502**, similar to the example shown in FIG. **1**. FIG. **8** is a top view of the sleeve **700**, including a tricuspid or other compliant valve **600**.

FIG. **9** is a schematic diagram illustrating generally an example of a similar valved compliant protective sleeve **900** that is snugly coupled directly about a bone screw base **902** using an inner circumferential lip **904** that engages a corresponding outer circumferential groove **906** in a head **910** portion of the base **902**. Alternatively, the lip **904** and groove **906** can be exchanged such that the lip is part of the head **910** portion of the base **902** and the groove is part of the sleeve **900**. In the example of FIG. **9**, an imageable marker or locatable divot is threaded, snap-fitted, or otherwise inserted into a receptacle **908** in a head **910** portion of the base **902**, similar to the example shown in FIG. **1**. FIG. **10** is a top view of the sleeve **900**, including a tricuspid or other compliant valve **600**.

FIG. **11** is a cross-sectional schematic diagram illustrating one example of using the valved compliant protective sleeve **700**, with a screw driver tip **1100** having been inserted through the valve **600** to automatically open the valve **600**. The compliance of the valve **600** advantageously holds the sleeve **700** and base **502** onto the screw driver tip **1100**, making it easier to drive the base **502** into the skull **114**.

FIG. **12** is a cross-sectional schematic diagram illustrating the same example of using the valved compliant protective sleeve **700**, in which the base **502** has been driven into the skull **114** and the driver tip **1100** has been withdrawn to automatically close the valve **600**. In one example, one or more of the various valved compliant protective sleeves discussed in this document optionally incorporate a coating. One example includes an antiseptic or antibiotic coating to reduce infection or promote healing. Another example

includes a hydrophilic coating or other lubricant for ease of insertion or to reduce or prevent adhesion of clotting blood or other substances to the sleeve **700**. Examples include, among other things, polydimethylsiloxane (PDMS), such as Dow Corning 360 Medical Fluid, silicone oil, polyacrylomide or like hydrogels, or polyvinylpyrollidione. Other examples of lubricating coatings include, among other things, polyethylene oxide (PEO), polyhyroxyethyl methacrylate (PHEMA), or polyvinyl alcohol (PVA). FIG. **13** is a cross-sectional schematic diagram illustrating one example of a flush-mounted base **1300** that does not have a head or other flanged portion to overlay a portion of the skull about which the screw shaft of the base **1300** is driven. Examples of flush-mounted fiducial marker bases are described in Matthew S. Solar U.S. Patent Application Serial Number 10/206,884 (Attorney Docket No. 723.058US1) entitled FIDUCIAL MARKER DEVICES, TOOLS, AND METHODS, which was filed on July 29, 2002, and which is incorporated herein by reference in its entirety, including its discussion of flush-mounted fiducial marker bases. The example of FIG. **13** includes a valved compliant protective sleeve **1302** with a distal base flange **1304** that is inserted beneath the scalp **122** to hold the sleeve **1302** in place. FIG. **14** is a top view of the sleeve **1302** including a tricuspid or other valve **600**. FIG. **15** is a cross-sectional schematic diagram illustrating the implanted base **1300** including the valved compliant protective sleeve **1302** with the flange **1304** in place under the scalp **122**.

FIG. **16** illustrates an example of a valved tubular protective sleeve **1600** that includes a valve that does not automatically open and close upon insertion of a screwdriver tip or other tool through the valve. Instead, in this example, the valve takes the form of a cap **1602** that fits into or about a proximal end of the sleeve **1600**. Because the cap is manually attached to or detached from the sleeve **1600**, it typically does not require as much elasticity as the automatic valves described above. FIG. **17** illustrates an alternative example in which a manually attachable and detachable cap **1702** is integrally attached to a sleeve **1700**, such as by a compliant tie **1704**.

FIG. **18** is a cross-sectional schematic diagram illustrating generally one example of a fiducial marker base **1800** including an externally threaded distal shaft **1802** and a proximal head **1804** that includes an internal hexagonal or

similar faceted orifice **1806** for being engaged by a corresponding driver to drive the base **1800** into the skull. In one example, a shaft portion of an imageable marker or locatable divot is correspondingly shaped so that it can be press or snap fitted into the same orifice **1806**, which is also illustrated in the top view of FIG. **19**.

FIG. **20** is a cross-sectional schematic diagram illustrating generally one example of a fiducial marker base **2000** including an externally threaded distal shaft **2002** and a proximal head **2004**. In this example the proximal head **2004** includes an external hexagonal or similar faceted surface for being engaged by a corresponding driver to a drive the base **2000** into the skull. In one example, a shaft portion of an imageable marker or locatable divot is threaded into an internally threaded orifice **2006** in the head **2004**, which orifice **2006** is also illustrated in the top view of FIG. **21**.

FIG. **22** is a cross-sectional schematic diagram illustrating a bone screw base **2200** that includes an externally threaded distal shaft **2202** and a proximal head **2204**. The proximal head **2204** includes an orifice **2206** for receiving a shaft portion of an imageable marker or locatable divot that is press or snap fitted therein. The head **2204** also includes screwdriver slots **2208** or other features that permit the bone screw base **2200** to be driven into the skull, as illustrated in the top view of FIG. **23**.

FIG. **24** is a cross-sectional schematic diagram illustrating a bone screw base **2400** that includes an externally threaded distal shaft **2402** and a proximal head **2404**. The proximal head **2404** includes an internally threaded orifice **2406** for receiving an externally threaded shaft portion of an imageable marker or locatable divot that is threaded therein. The head **2404** also includes screwdriver slots **2408** or other features that permit the bone screw base **2400** to be driven into the skull, as illustrated in the top view of FIG. **25**.

The accompanying drawings that form a part hereof, show by way of illustration, and not of limitation, specific embodiments in which the subject matter may be practiced. The embodiments illustrated are described in sufficient detail to enable those skilled in the art to practice the teachings disclosed herein. Other embodiments may be utilized and derived therefrom, such that structural and logical substitutions and changes may be made without departing from the

scope of this disclosure. This Detailed Description, therefore, is not to be taken in a limiting sense, and the scope of various embodiments is defined only by the appended claims, along with the full range of equivalents to which such claims are entitled.

Such embodiments of the inventive subject matter may be referred to herein, individually and/or collectively, by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept if more than one is in fact disclosed. Thus, although specific embodiments have been illustrated and described herein, it should be appreciated that any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations, or variations, or combinations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

The Abstract of the Disclosure is provided to comply with 37 C.F.R. §1.72(b), requiring an abstract that will allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. In addition, in the foregoing Detailed Description, it can be seen that various features are grouped together in a single embodiment for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed embodiments require more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment.

It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-described embodiments (and/or aspects thereof) may be used in combination with each other. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be

determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Also, in the following claims, the terms "including" and "comprising" are open-ended, that is, a system, device, article, or process that includes elements in addition to those listed after such a term in a claim are still deemed to fall within the scope of that claim. Moreover, in the following claims, the terms "first," "second," and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

WHAT IS CLAIMED IS:

1. A protective sleeve for a fiducial marker base, the protective sleeve comprising a compliant valve that automatically opens upon insertion of an object into the valve and that automatically closes upon removal of the object from within the valve.

2. The sleeve of claim 1, wherein said sleeve is fitted about a portion of said fiducial marker base.

3. The sleeve of either of claims 1 or 2, further comprising a distal flange that is sized and shaped to be disposed under a scalp to retain the sleeve in place with respect to the fiducial marker base.

4. The sleeve of any preceding claim, further comprising a lip that is sized and shaped to engage a portion of the fiducial marker head.

5. The sleeve of any preceding claim, comprising an external coating.

6. The sleeve of claim 5, in which the coating is aseptic.

7. The sleeve of claim 5, in which the coating is hydrophilic.

8. A fiducial marker assembly for an image-guided surgical procedure, the fiducial marker assembly comprising:

a bone screw base, the base including a distal threaded bone screw shaft and a proximal head; and

the protective sleeve of any of claims 1 to 7, fitted about the head of the bone screw base.

9. The fiducial marker assembly of claim 8, further comprising a tubular cylindrical spacer secured to the proximal head of the bone screw base, the

spacer located between the proximal head of the bone screw base and the protective sleeve.

10. The fiducial marker assembly of either of claims 8 or 9, in which the valve comprises a cap that is sized and shaped to be manually pressed onto a proximal end of the protective sleeve to prevent debris from entering the passage of the protective sleeve.

11. The fiducial marker assembly of any of claims 8 to 10, further comprising an imageable marker that is sized and shaped to be secured to the proximal head of the bone screw base.

12. The fiducial marker assembly of any of claims 8 to 11, further comprising a locatable divot that is sized and shaped to be secured to the proximal head of the bone screw base.

13. The fiducial marker assembly according to any of claims 8 to 12, wherein the sleeve comprises an internal passage between the valve and the proximal head of the bone screw base.

14. A kit comprising:

a bone screw base, the base comprising a distal threaded bone screw shaft and a proximal head; and

the protective sleeve of claims 1 to 7.

15. The kit of claim 14, further comprising an imageable marker that is sized and shaped to be secured to the proximal head of the bone screw base.

16. The kit of claim 14, further comprising a locatable divot that is sized and shaped to be secured to the proximal head of the bone screw base.

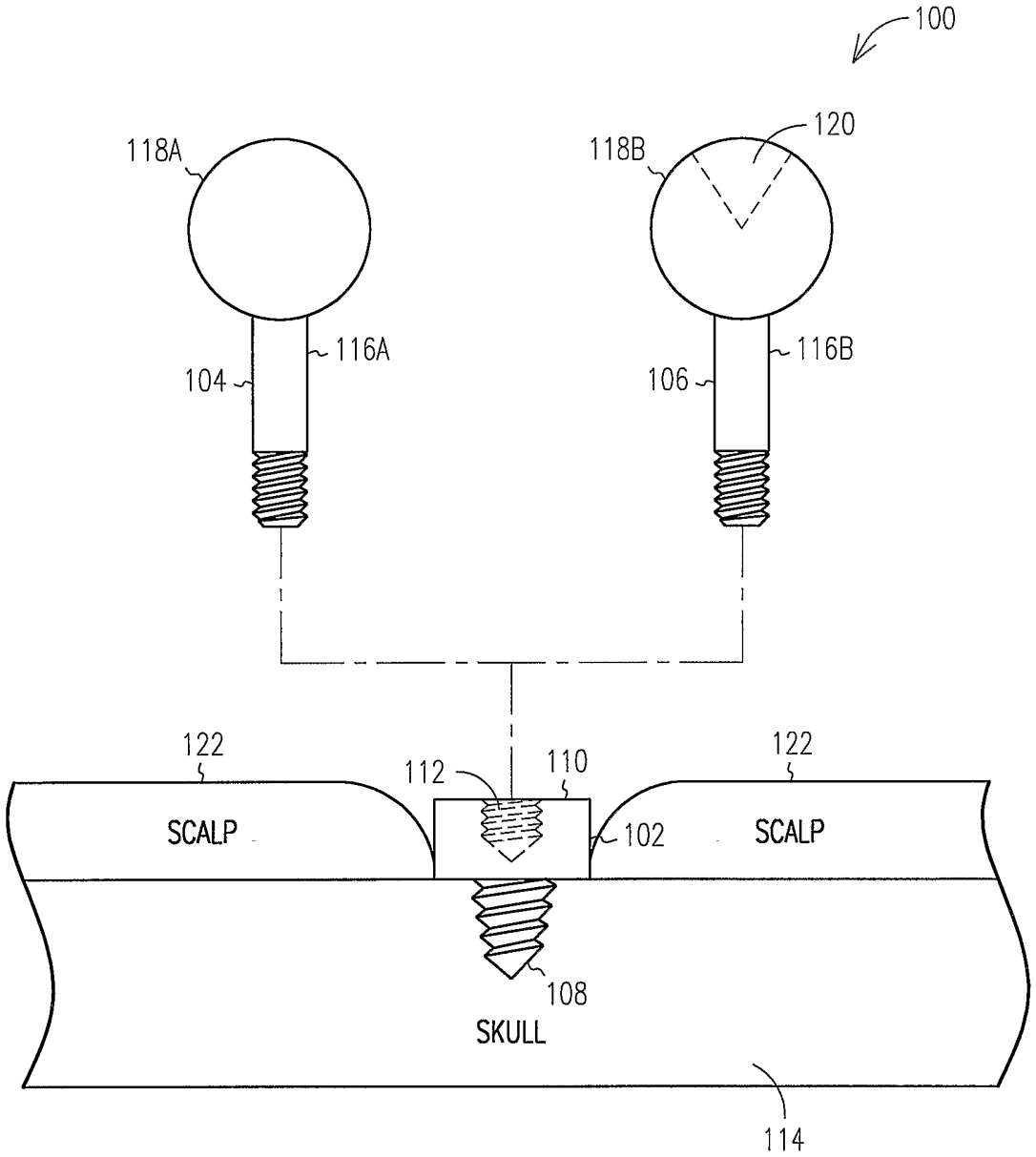
17. A method comprising:

affixing a bone screw base to a skull, the base including a valved sleeve located in association therewith;

attaching an imageable marker to the bone screw base, including inserting a portion of the imageable marker through a valve in the sleeve; and

replacing the imageable marker with a locatable divot, the replacing including removing the imageable marker and inserting the locatable divot through the valve.

18. The method of claim 17, in which the inserting the portion of the imageable marker through the valve automatically opens the valve by compliant expansion of the valve, and in which the removing the imageable marker includes automatically closing the valve by compliant relaxation of the valve.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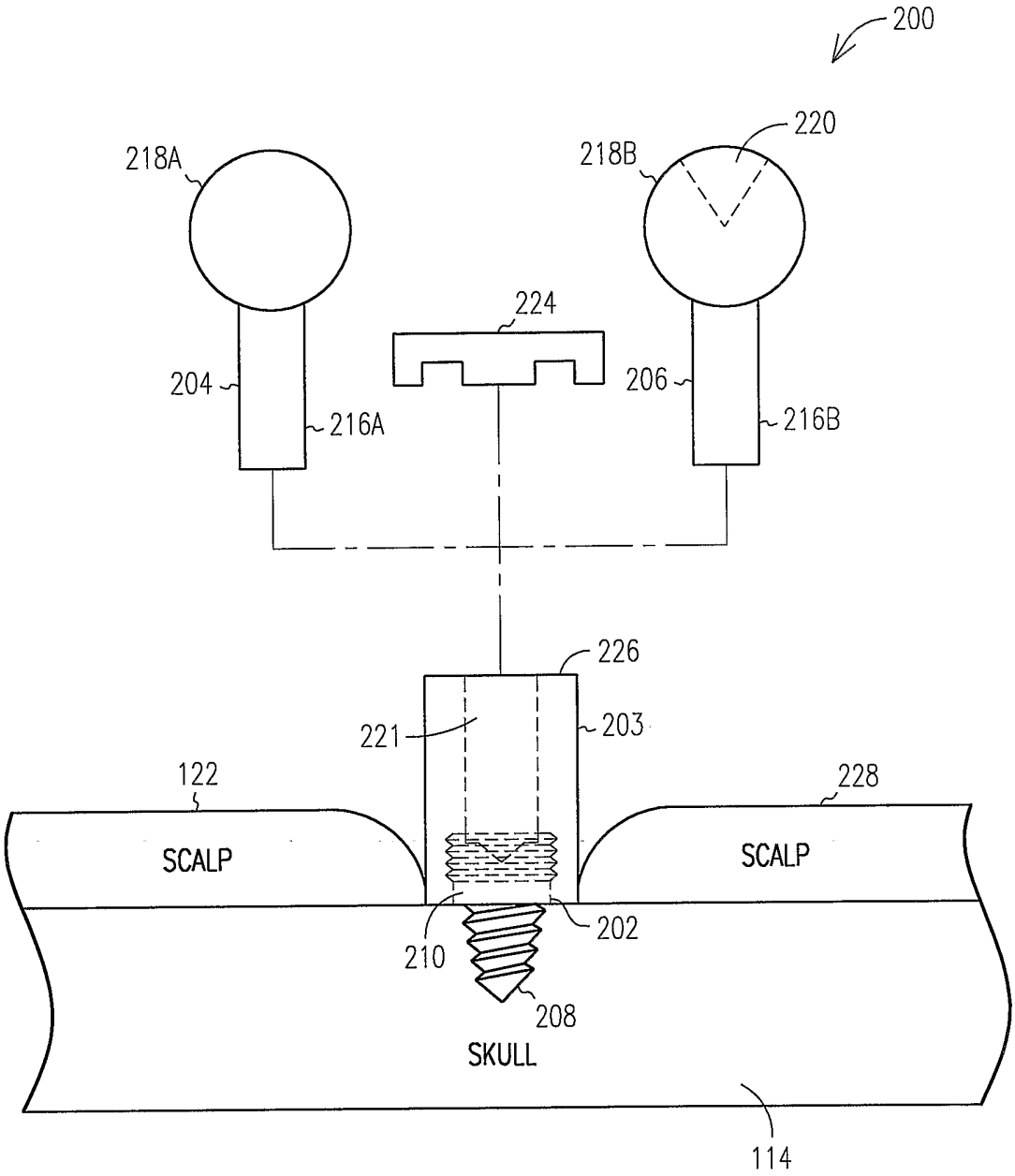
114

FIG. 1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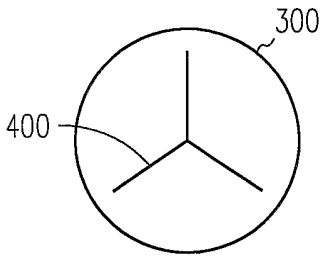
SKULL
114

FIG. 2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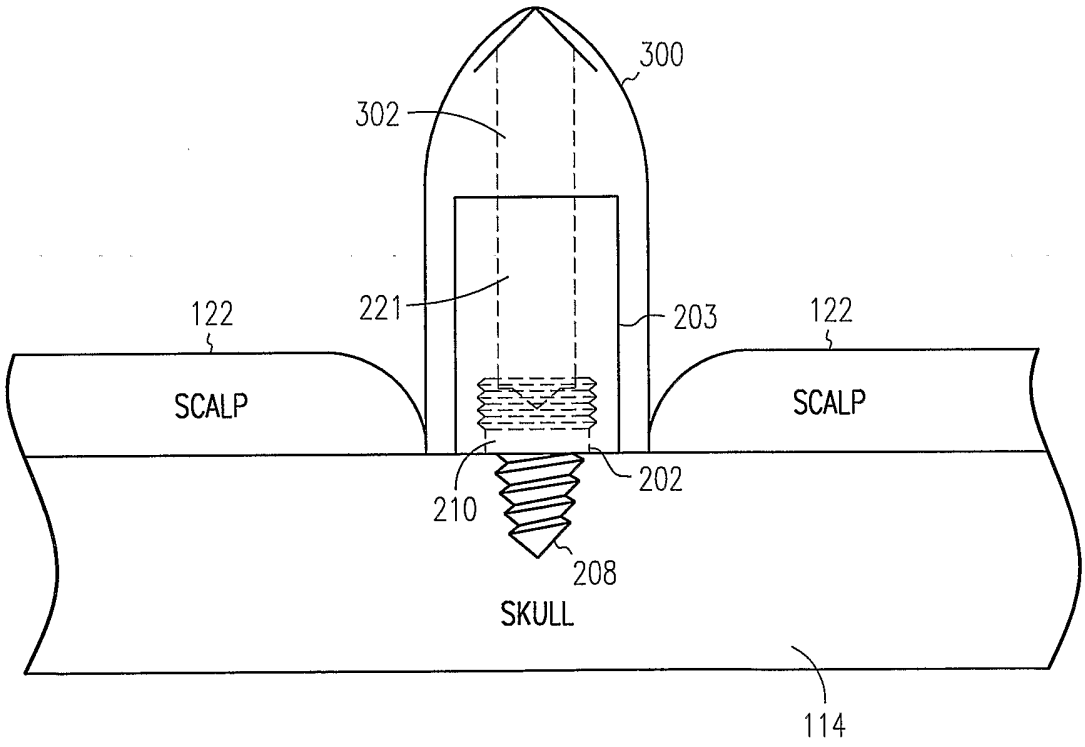
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SKULL
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FIG. 3

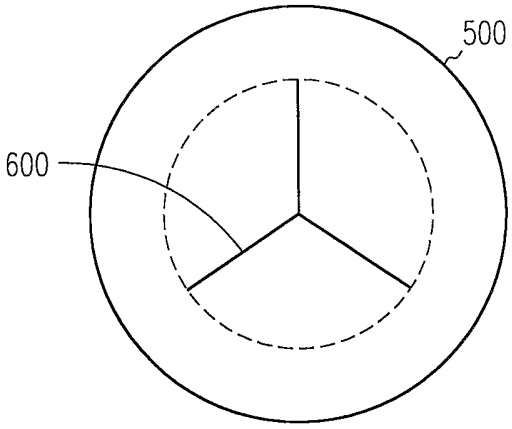


FIG. 6

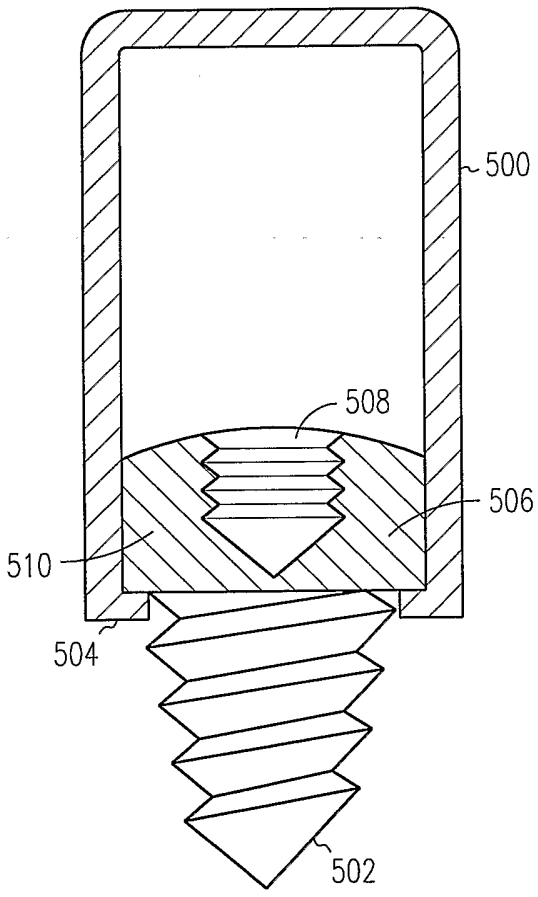


FIG. 5

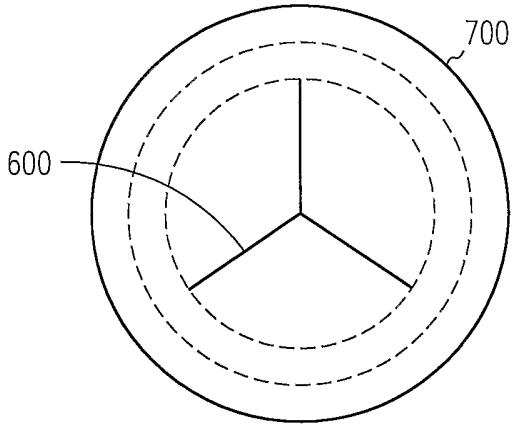


FIG. 8

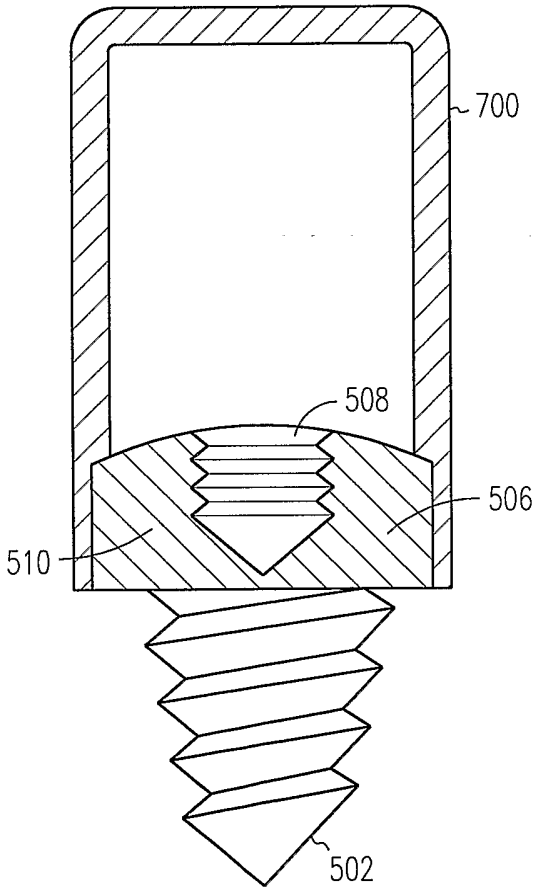
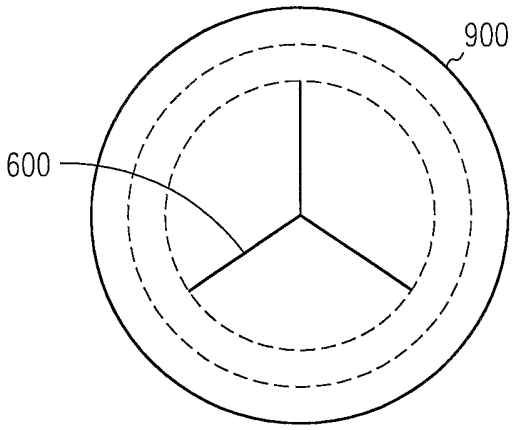


FIG. 7



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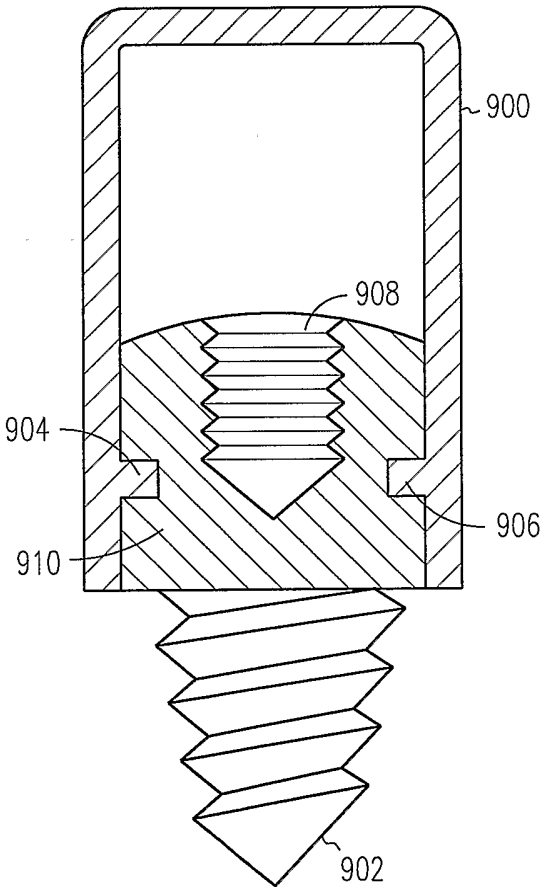
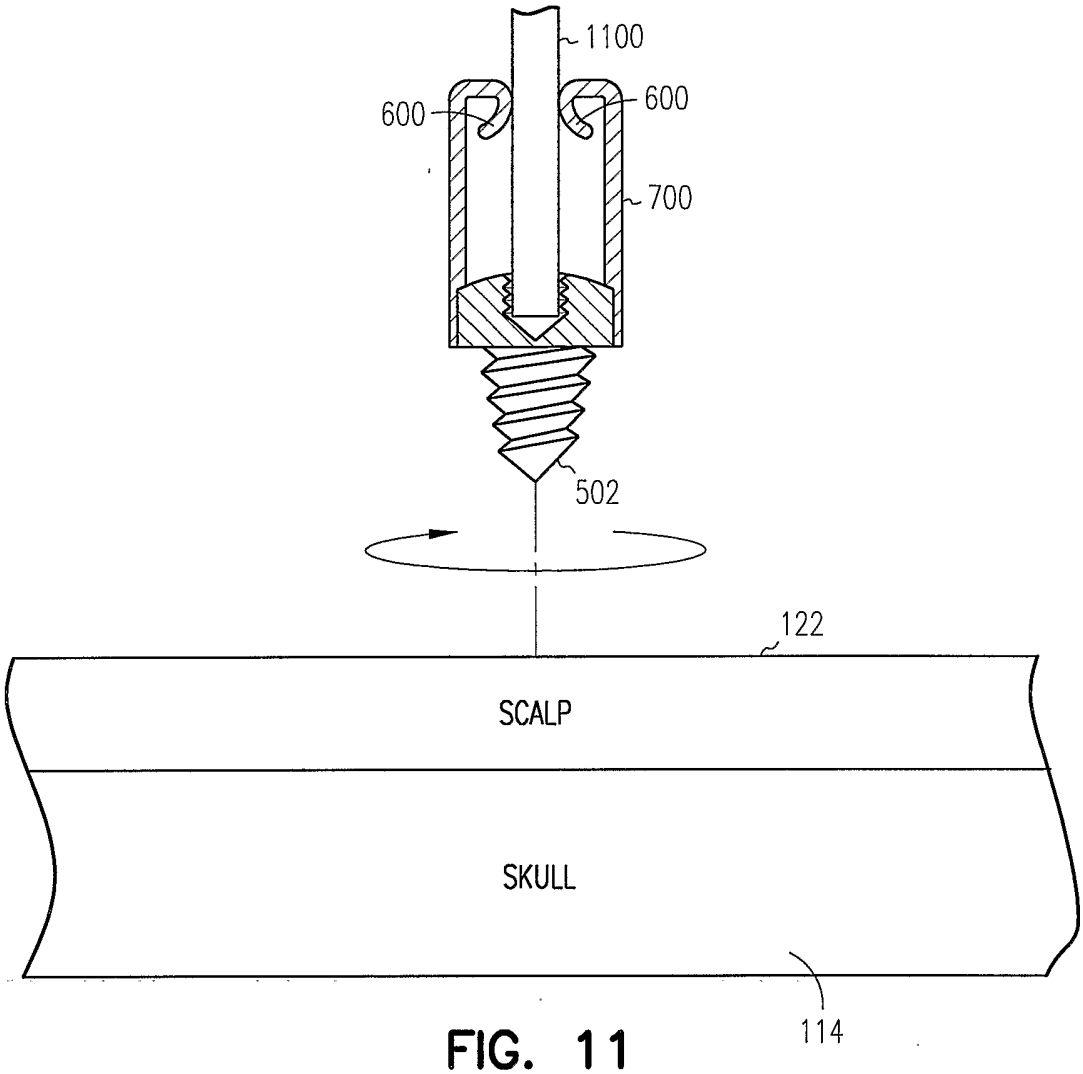


FIG. 9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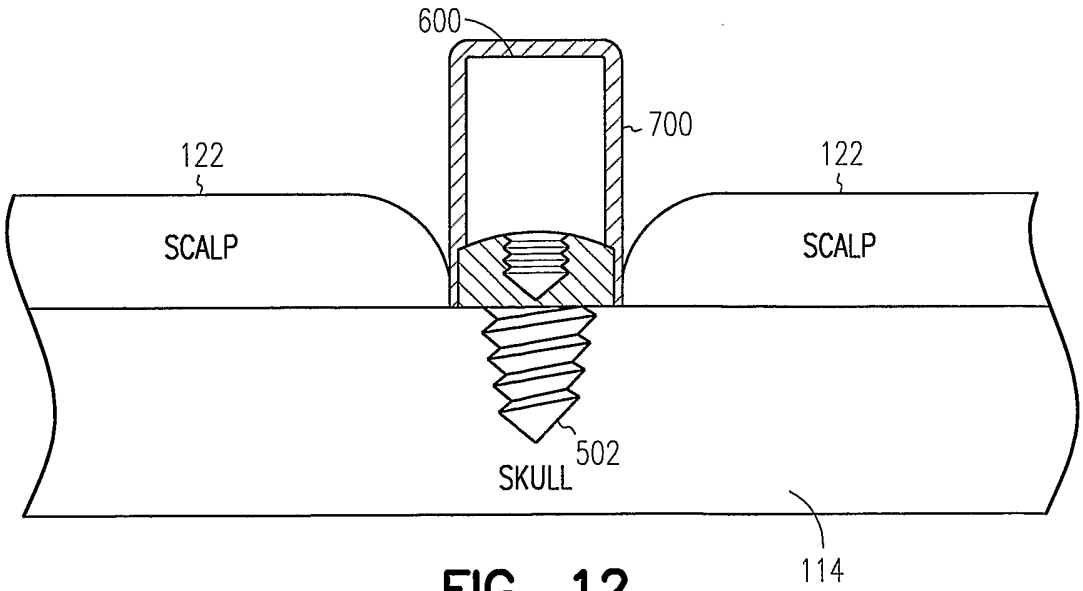
502
122
SCALP
SKULL
114

FIG. 11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SKULL
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FIG. 12

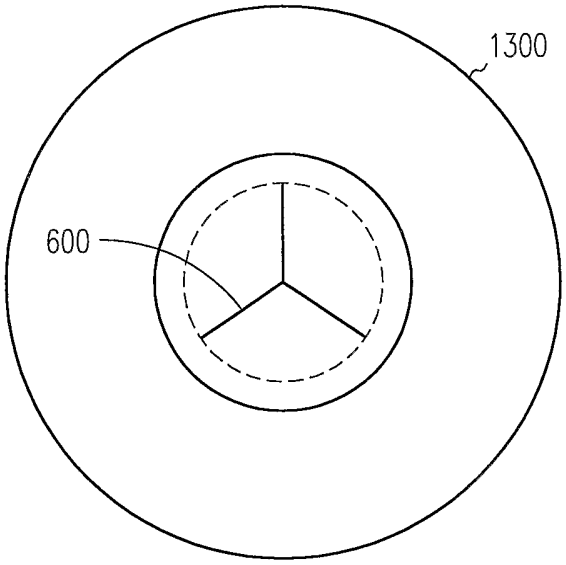


FIG. 14

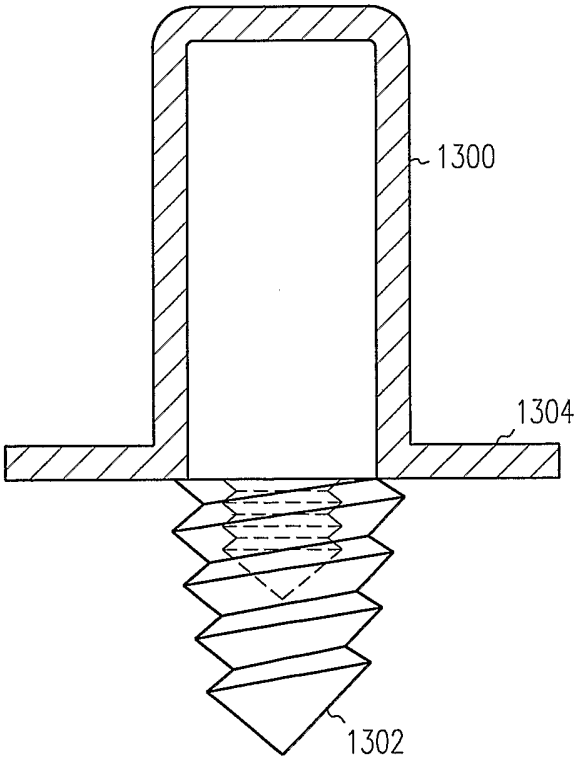


FIG. 13

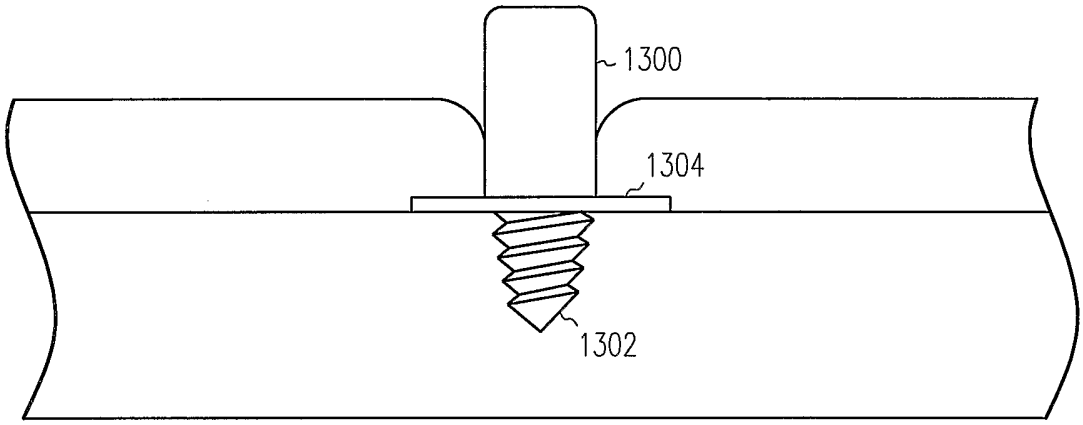


FIG. 15

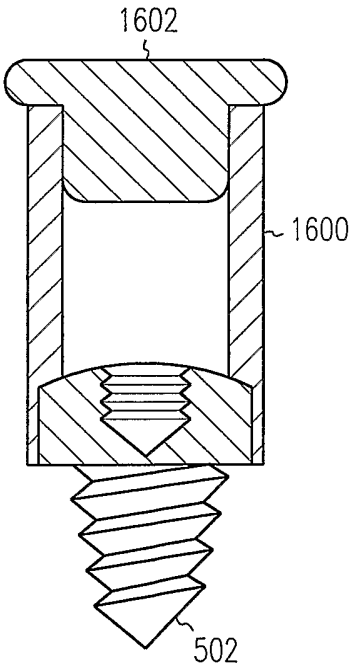


FIG. 16

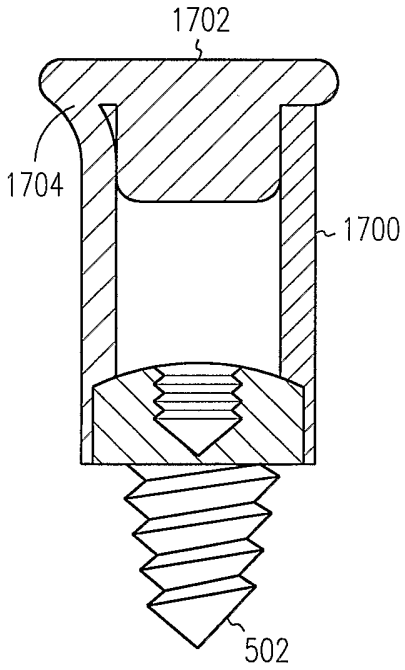


FIG. 17

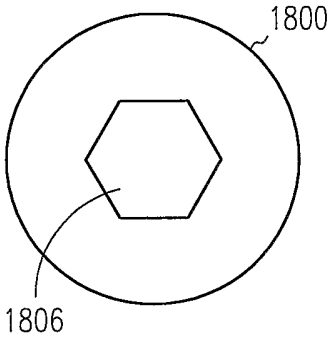


FIG. 19

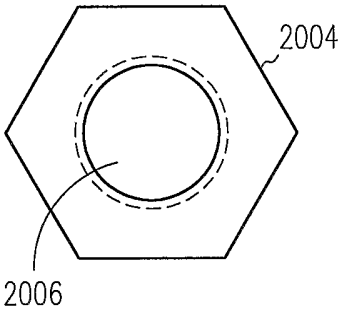
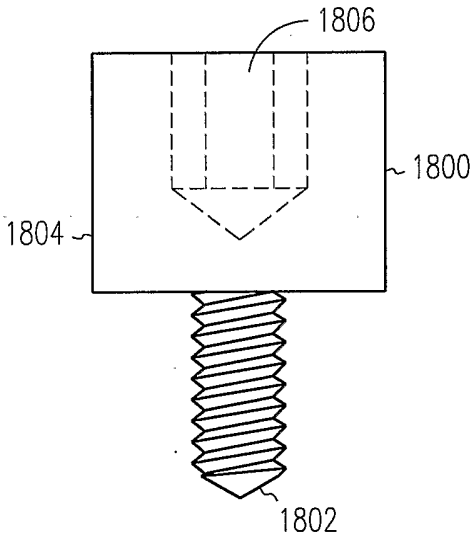


FIG. 21



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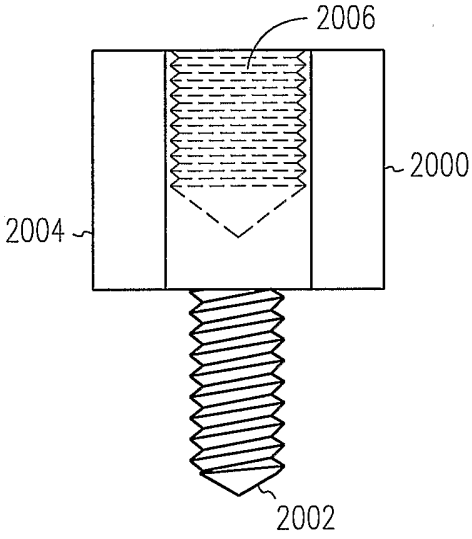

FIG. 20

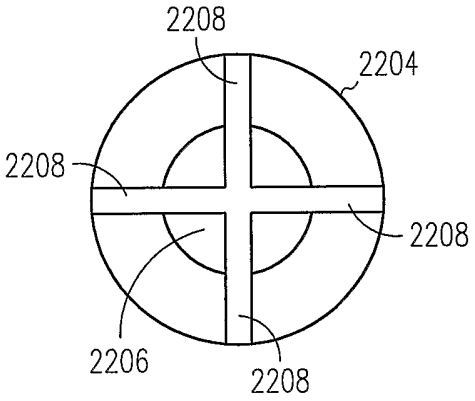

FIG. 23

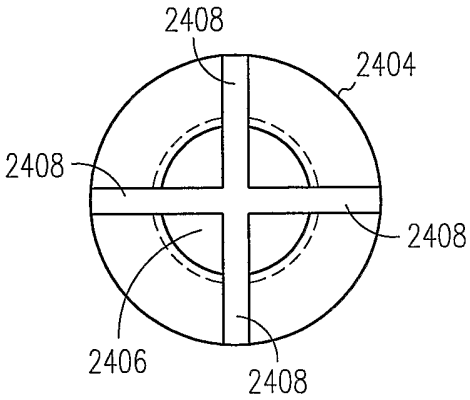

FIG. 25

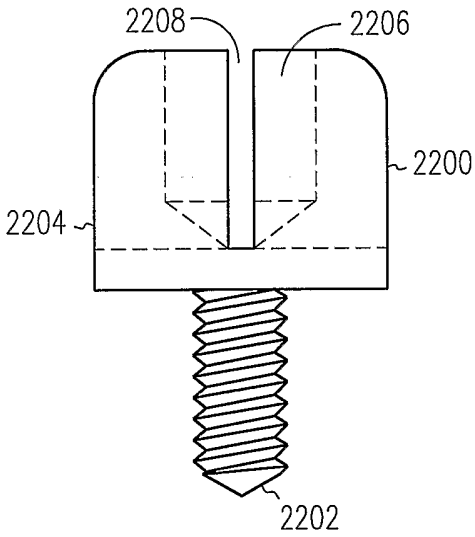

FIG. 22

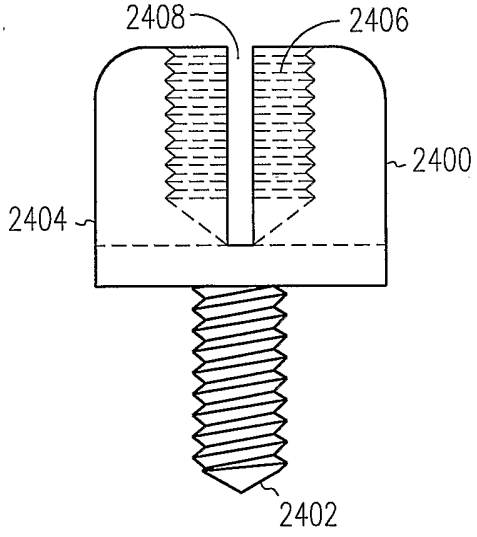

FIG. 24

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/020009

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B19/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 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, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 480 410 A (CUSCHIERI ET AL) 2 January 1996 (1996-01-02) column 4, line 25 - line 37; figure 1	1,3,5-7
X	US 5 913 847 A (YOON ET AL) 22 June 1999 (1999-06-22) column 7, line 4 - line 56; figure 2	1,5-7
X	US 6 551 270 B1 (BIMBO FRANK ET AL) 22 April 2003 (2003-04-22) abstract; figure 3	1,5-7
A	US 2004/030236 A1 (MAZZOCCHI RUDY A ET AL) 12 February 2004 (2004-02-12) paragraph '0050!; figure 12b	1,8,14
A	US 2004/068260 A1 (COSSETTE SEBASTIEN ET AL) 8 April 2004 (2004-04-08) paragraph '0032!; figure 1	1,8,14

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

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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

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

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

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

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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 September 2005	29/09/2005

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/020009

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17, 18
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2005/020009

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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			EP	0750472 A1	02-01-1997
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			WO	2004030557 A1	15-04-2004
			EP	1562510 A1	17-08-2005