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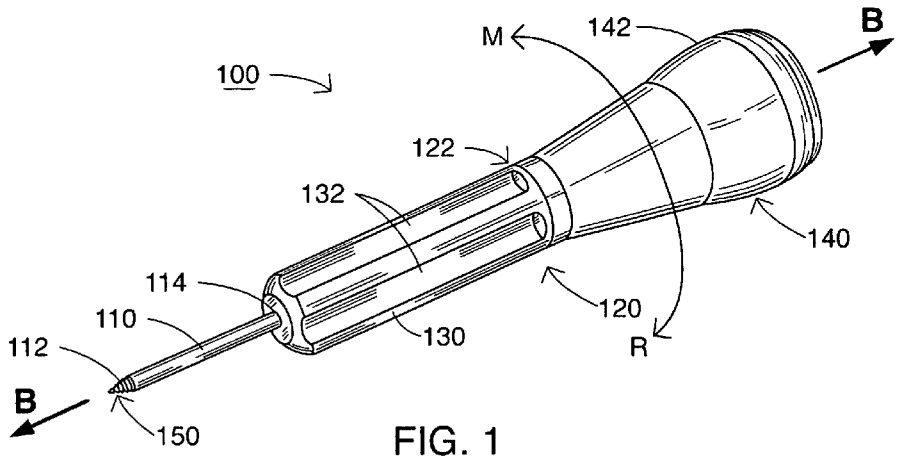

FIG. 1

(57) Abstract: A surgical marking tool (100) for marking a location on a patient includes a cutting head (150) and a handle (120). The cutting head includes a screw thread (154). The handle is coupled to the cutting head to rotate the cutting head. The screw thread is configured to progressively embed in the patient to mark the location when the cutting head is placed in contact with the patient and rotated with respect to the patient using the handle.

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SURGICAL MARKING TOOLS AND METHODS FOR MARKING A PATIENT

Related Application(s)

[001] The present application claims the benefit of U.S. Provisional Patent Application No. 61/041,500, filed April 1, 2008, and U.S. Provisional Patent Application No. 60/974,821, filed September 24, 2007, the disclosures of which are incorporated herein by reference in their entireties.

Field of the Invention

[002] The present invention relates to medical devices and, more particularly, tools and methods for marking a patient.

Background of the Invention

[003] It is often desired to mark a patient to designate a location for incision or entry into the patient with a medical interventional device. For example, a physician may wish to mark a location on a patient's head to indicate the desired placement of a burr hole.

Summary of the Invention

[004] According to embodiments of the present invention, a surgical marking tool for marking a location on a patient includes a cutting head and a handle. The cutting head includes a screw thread. The handle is coupled to the cutting head to rotate the cutting head. The screw thread is configured to progressively embed in the patient to mark the location when the cutting head is placed in contact with the patient and rotated with respect to the patient using the handle.

[005] In some embodiments, the screw thread includes a self tapping screw thread. The marking tool is a burr hole marking tool and the self tapping screw thread

is configured to self tap into a human skull. The cutting head can have a sharp leading end section configured to easily pierce through the patient's scalp. In some embodiments, the cutting head has a lead end and a limiter feature spaced apart a distance from the lead end, and an axial boring length extending from the lead end to a proximal end of the limiter feature is less than a thickness of the patient's skull.

[006] According to some embodiments, the handle includes first and second handle members that cooperate and are rotatable with respect to one another, and the cutting head is affixed to the first handle member for rotation therewith. In some embodiments, the first handle member is a lower handle member and the second handle member is an upper handle member, and the upper handle member is configured and positioned to be held by a user's hand while the user rotates the cutting head using the lower handle member. The upper handle member may have an upper end portion with a bulbous shape. The lower handle member can include flutes.

[007] The marking tool can be constructed entirely of MRI-compatible material or materials.

[008] According to method embodiments of the present invention, a method for marking a location on a patient includes: providing a surgical marking tool including a cutting head having a screw thread; and placing the cutting head in contact with the patient and rotating the cutting head with respect to the patient to progressively embed the screw thread in the patient to mark the location.

[009] According to some embodiments, the screw thread includes a self tapping screw thread, and the method includes cutting into the patient using the self tapping screw thread.

[0010] In some embodiments, placing the marking tool in contact with the patient and rotating the marking tool with respect to the patient includes progressively embedding the screw thread into a skull of the patient to mark the location in the skull. The method can include piercing through the scalp of the patient with a sharp leading end section of the cutting head. In some embodiments, the screw thread includes a self tapping screw thread, and the method includes cutting into the patient's skull using the self tapping screw thread. According to some embodiments, the method includes embedding the cutting head into the patient's skull only to a maximum depth less than the thickness of the skull, and thereafter removing the cutting head from the skull. The method can further include forming a burr hole in the patient's skull proximate the marked location after the marking tool is removed.

[0011] The marking tool may include a handle coupled to the cutting head to rotate the cutting head. In some embodiments, the handle includes first and second handle members that are rotatable with respect to one another, the cutting head is affixed to the first handle member, and rotating the cutting head with respect to the patient includes rotating the first handle member with respect to the second handle member. According to some embodiments, the first handle member is a lower handle member and the second handle member is an upper handle member, and the method includes holding the upper handle member in a user's hand and simultaneously rotating the cutting head using the first handle member.

[0012] According to some embodiments, the marking tool is constructed entirely of MRI-compatible material or materials, and the steps of placing the cutting head in contact with the patient and rotating the cutting head with respect to the patient are executed in or adjacent a magnet of an MRI scanner.

[0013] The method may include counter-rotating the cutting head with respect to the patient to progressively remove the cutting head from the patient.

[0014] According to further embodiments of the present invention, a surgical kit for an MRI-guided interventional surgery on a patient includes a surgical marking tool and sterile packaging containing the marking tool. The marking tool includes a cutting head and a handle. The cutting head includes a screw thread. The handle is coupled to the cutting head to rotate the cutting head. The screw thread is configured to progressively embed in the patient to mark a location on the patient when the cutting head is placed in contact with the patient and rotated with respect to the patient using the handle. The marking tool is constructed entirely of MRI-compatible material or materials.

[0015] Further features, advantages and details of the present invention will be appreciated by those of ordinary skill in the art from a reading of the figures and the detailed description of the preferred embodiments that follow, such description being merely illustrative of the present invention.

Brief Description of the Drawings

[0016] **Figure 1** is a front, perspective view of a surgical marking tool according to embodiments of the present invention.

[0017] **Figure 2** is a side elevational view of the marking tool of **Figure 1**.

[0018] **Figure 3** is a cross-sectional view of the marking tool of **Figure 1** taken along the line **3-3** of **Figure 2.**

[0019] **Figure 4** is a side elevational view of a driver shank forming a part of the marking tool of **Figure 1.**

[0020] **Figure 5** is a front plan view of the driver shank of **Figure 4.**

[0021] **Figure 6** is a cross-sectional view of the driver shank of **Figure 4** taken along the line **6-6** of **Figure 5.**

[0022] **Figure 7** is an enlarged view of **Detail 7** of **Figure 6.**

[0023] **Figure 8** is an enlarged view of **Detail 8** of **Figure 6.**

[0024] **Figure 9** is a schematic view of a patient in an MRI scanner being marked with the marking tool of **Figure 1.**

[0025] **Figure 10** is an enlarged, fragmentary view of the patient's head with the marking tool of **Figure 1** embedded therein.

[0026] **Figure 11** is an enlarged, fragmentary view of the patient's head after being marked with the marking tool of **Figure 1.**

[0027] **Figure 12** is an enlarged view of the patient's head with a burr hole formed therein.

[0028] **Figure 13** is an enlarged view of the patient's head with a burr hole ring mounted thereon.

[0029] **Figure 14** is a perspective view of a medical kit including the marking tool of **Figure 1.**

Detailed Description of Embodiments of the Invention

[0030] The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which illustrative embodiments of the invention are shown. In the drawings, the relative sizes of regions or features may be exaggerated for clarity. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

[0031] It will be understood that, although the terms first, second, etc. may be used herein to describe various elements, components, regions, layers and/or sections, these elements, components, regions, layers and/or sections should not be limited by

these terms. These terms are only used to distinguish one element, component, region, layer or section from another region, layer or section. Thus, a first element, component, region, layer or section discussed below could be termed a second element, component, region, layer or section without departing from the teachings of the present invention.

[0032] Spatially relative terms, such as "beneath", "below", "lower", "above", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if the device in the figures is turned over, elements described as "below" or "beneath" other elements or features would then be oriented "above" the other elements or features. Thus, the exemplary term "below" can encompass both an orientation of above and below. The device may be otherwise oriented (rotated 90° or at other orientations) and the spatially relative descriptors used herein interpreted accordingly.

[0033] As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless expressly stated otherwise. It will be further understood that the terms "includes," "comprises," "including" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. It will be understood that when an element is referred to as being "connected" or "coupled" to another element, it can be directly connected or coupled to the other element or intervening elements may be present. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items.

[0034] Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of this specification and the relevant art and will not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

[0035] According to embodiments of the present invention, surgical marking tools and methods for using the same are provided for marking a location on a patient for surgical entry, for example. According to some embodiments, the marking tools and methods are used or usable to mark a patient's skull. Such marking may be employed to indicate to a physician a designated location for entry into the patient (for example, through the patient's skull). According to some embodiments, a mark formed by the marking tool is used as a reference point (for example, a centering point) for subsequent formation of a burr hole or other access port in the patient.

[0036] With reference to **Figures** 1-8, a marking tool **100** according to embodiments of the present invention is shown therein. The marking tool **100** includes a driver shank 110, a handle assembly 120, and a cutting head **150.**

[0037] The handle assembly **120** can be ergonomically configured, for example, as shown. The handle assembly **120** includes a distal or lower handle member **130** and a proximal or upper handle member **140.** The lower handle member **130** can be coupled to the upper handle member **140** to permit rotation relative to the upper handle member **140** in each of a clockwise direction M and a counterclockwise direction R (as viewed from the upper handle member end) about a driver axis B-B and at an interface **122.** According to some embodiments, the relative axial positions of the lower handle member **130** and the upper handle member **140** are fixed.

[0038] The lower handle member **130** and the upper handle member **140** may be rotatably coupled by any suitable mechanism or means. According to some embodiments and with reference to **Figure** 3, the lower handle member **130** includes an upper extension **134** that is rotatably received in a bore **144** (optionally, and as shown, a through bore) of the upper handle member **140.** As shown, a bolt **102** extends through a bearing washer **104** and is threadedly secured in a fastener bore **130A** of the extension **134.** The lower handle member **130** is thereby axially captured in the through bore **144** by a shoulder **136** of the lower handle member **130** and the bearing washer 104, which slidably engages a flange **146** of the upper handle member **140.** According to other embodiments, the lower handle portion **130** may have one or more snap fit features in place of the bolt **102** to rotatably secure the lower handle member **130** to the upper handle member **140.**

[0039] According to some embodiments and as illustrated, the lower handle member **130** is provided with ribs or flutes **132** to facilitate manipulation of the lower handle member **130** by the operator's fingers. According to some embodiments and as

illustrated **in Figure** 1, the upper handle member **140** includes an enlarged or bulb-shaped portion **142** on its upper end to facilitate the grip and manipulation of the upper handle member **140** by the operator's hand or palm.

[0040] Referring to **Figure 3,** the driver shank **110** has a lower section **112** on which the cutting head **150** is affixed or integrally formed. An upper section **114** of the driver shank **110** is affixed to the lower handle member **130.** According to some embodiments, the upper section **114** is received in a shank bore **130B** in the lower handle member **130.** The upper section **114** of the driver shank **110** may be securely held in the bore **130B** by molding, adhesive, and/or knurling **114A** (on the exterior of the upper section 114), for example, to prevent relative rotation between the driver shank **110** and the lower handle member **130.** According to some embodiments, the upper section **114** may have a geometric shape that resists relative rotation between the upper section **114** and the lower handle member **130.** In this manner, the driver shank **110** and the cutting head **150** are together rotatable relative to the upper handle member **140.**

[0041] According to some embodiments, the cutting head **150** includes a threaded screw shank. According to some embodiments, the threaded screw shank is a self-tapping or self-drilling screw structure. According to some embodiments, the cutting head **150** is configured as a self-tapping bone screw configured to make a controlled and visually detectable hole in bone without undue force against the scalp/skull.

[0042] A cutting head **150** according to embodiments of the present invention is shown in enlarged detail in **Figures** 4-8, wherein the cutting head **150** includes a tapered root or shank 152, a screw thread **154** helically wound about the shank **152** and having a crest **156 (Figure** 7), a leading end section **160** terminating in a leading tip or point 160A, a limiter feature or land **162 (Figures 4** and **6)** opposite the tip 160A, and a cutting notch or flute **164 (Figures 6** and **8)** formed in the leading end section **160.**

[0043] According to some embodiments, the root **152** is uniformly tapered. According to some embodiments, the root 152 has a minor diameter half angle **G (Figure 6)** in the range of from about 10 to 35 degrees.

[0044] According to some embodiments, the thread **154** is a generally V-shaped or U-shaped thread. According to some embodiments, the thread **154** has a substantially uniformly tapered major diameter. According to some embodiments, the

taper half angle **O (Figure 6)** of the major diameter is in the range of from about 10 to 35 degrees. According to some embodiments, the angle E **(Figure 7)** of the leading flank **154A** with respect to the minor diameter is less than the angle **F** of the trailing flank **154B** with respect to the minor diameter. According to some embodiments, the leading flank angle E is in the range of from about 30 to 60 degrees, and the trailing flank angle F is in the range of from about 50 to 100 degrees. The relatively lesser angle of the leading flank reduces the wedge angle upon insertion and the relatively greater angle of the trailing flank can reduce pullout by maintaining the trailing flank more nearly parallel with the penetrated surface.

[0045] According to some embodiments, the pitch **D (Figure 7)** of the thread **154** is substantially constant. According to some embodiments, the pitch **D** is in the range of from about 0.5 to 2 mm.

[0046] **As** shown in **Figure** 6, the leading end section **160** can be generally conical. According to some embodiments, the thread **154** extends substantially fully to the tip **160A.** However, according to other embodiments, a distal portion of the leading end section **160** may be sharp and nonthreaded (not shown).

[0047] The flute **164 (Figures 6** and **8)** can define a bone chip collection pocket within the cutting head **150** to receive bone or other material through which the cutting head **150** is driven. As shown in **Figure 6,** for example, the flute **164** defines a cutting face **164**A having a sharp cutting edge **164B** and an opposed inner edge **164C.** According to some embodiments, the cutting face **164A** extends fully to the tip **160A.** According to some embodiments, the cutting face **164A** is substantially coplanar with a mid-plane **MP (Figure 5)** of the screw shank **152.** According to some embodiments, the inner edge **164C** extends transverse to and across the centerline B-**B** of the shank **152.** According to some embodiments, an axis of the inner edge **164C** crosses the centerline B-B (within the shank **152)** and forms an angle **P (Figure 8)** in the range of from about 0 to 60 degrees with respect to the centerline B-B. According to some embodiments, the inner edge **164C** extends across the centerline **B-B** at the tip **160A** a distance **Q (Figure 8)** in the range of from about **0** to **0.5 mm.**

[0048] According to some embodiments, the land **162** is nonthreaded and tapers at a substantially steeper angle **I (Figure 6)** than the angle **G** of the root **152.** According to some embodiments, the angle **I** of the land **162** is in the range of from about 30 to 90 degrees.

[0049] According to some embodiments, the working or axial boring length **J (Figure 6)** of the cutting head **150** *(i.e.,* the lengthwise distance from the tip **160A** to the proximal end of the land **162)** is in the range of from about **2.5** to **7** mm and, according to some embodiments, in the range of from about **3** to **5 mm.**

[0050] According to some embodiments, the outer diameter **L (Figure 6)** of the land **162** is in the range of from about 2 to 6 mm. According to some embodiments, the width **K** of the land **162** is in the range of from about 0.5 to 1.5 mm.

[0051] According to some embodiments, the cutting head **150** complies with ASTM Standard F543-02 (Standard Specification and Test Methods for Metallic Medical Bone Screws), the disclosure of which is incorporated herein by reference.

[0052] The components of the marking tool **100** may be formed of any suitable biocompatible materials. According to some embodiments, the driver shank **110** and the cutting head **150** are formed of a metal such as titanium or stainless steel. According to some embodiments, the handle members 130, **140** are formed of a suitable polymeric material such as ABS or polycarbonate.

[0053] In some embodiments, the marking tool **100** comprises MRI-compatible material(s) and, according to some embodiments is constructed entirely of MRI-compatible material or materials. The term "MRI compatible" means that the so-called component(s) are safe for use in an MRI environment *(e.g.,* in a high magnetic field of an MRI scanner) and are typically made of non-ferromagnetic MRI compatible material(s) suitable to reside and/or operate in a higher magnetic field environment. The term "high magnetic field" refers to field strengths above about 0.5T, typically between 1.5T and 1OT associated with MRI/MRS scanners.

[0054] Operation and use of the marking tool **100** and methods according to embodiments of the present invention will be further described with reference to **Figures 9-13.** Referring to **Figure** 10, a portion of a patient's head **10** is shown therein in schematic cross-section. The head **10** includes an outer skin (and other soft tissue) layer (referred to herein as the scalp) 12, a skull 14, and underlying brain tissue **16.** The skull **14** includes an outer compact bone layer 14A, an inner compact bone layer 14C, and a spongy bone layer **14B** between the compact bone layers **14A** and **14C.**

[0055] Initially, a location on the head **10** may be identified by a suitable technique and/or apparatus. This location may be suitably temporarily marked or

designated. Once the desired location is determined, the operator can grasp the marking tool **100** such that the upper handle member **140** is held in the palm of the operator's hand **H** to stabilize the marking tool **100** *(e.g.,* as shown in **Figure 9).** The operator's fingers **F** and thumb **T** may rest on the lower handle member **130.** The operator places the cutting head **150** in contact with the patient's head **10.** The operator may press the cutting head **150** into the patient's head **10** such that the cutting head **150** penetrates through the skin 12 and may partially penetrate into the skull **14.** More particularly, the sharp tip **160A** and leading end section **160** easily pierce through the skin **12.**

[0056] The operator then holds the marking tool **100** steady and simultaneously rotates the lower handle member **130** using his or her fingers F and thumb T to thereby rotate the cutting head **150** in the clockwise direction M. The operator may apply pressure along the axis B-B toward the skull **14** simultaneously with rotating the cutting head **150.** In this manner, the self tapping screw thread **154** cuts into the skull **14** to progressively embed the cutting head **150** into the skull **14** as shown in **Figure 10.** More particularly, the self tapping screw thread **154** initiates and cuts or forms a corresponding thread on the skull 14 as the cutting head **150** is rotated in the direction of the thread **154.** The sharp crests **156** may minimize or reduce the torque required to penetrate, engage and self tap into both the soft tissue **12** and the skull **14.**

[0057] According to some embodiments, the cutting head **150** is configured to limit the penetration distance **N (Figure 10)** of the cutting head **150** *(i.e.,* to the tip **160A)** into the skull **14.** The relatively steep and constant taper angle G of the cutting head **150** may prevent or substantially inhibit the user from rotatively driving or embedding the cutting head **150** into the skull **14** beyond the prescribed maximum permitted depth. The steep, threadless land **162** may also reduce the risk of overpenetration. According to some embodiments, the cutting head **150** is configured to permit the operator to screw the cutting head **150** through the scalp 12 and into the skull 14, but not fully through the thickness of the skull **14.** According to some embodiments, the cutting head **150** is configured to permit the operator to screw the cutting head **150** through the scalp 12, through the outer compact bone layer 14A, and into the spongy bone layer 14B, but to prevent the operator from penetrating the inner compact bone layer **14C.**

[0058] The operator may thereafter use his or her fingers F, T to rotate the lower handle member **130** in the counterclockwise direction R while holding the marking tool 100 steady via the upper handle member **140.** In this manner, the screw thread **154** is unscrewed from the skull **14** and the cutting head 150 is thereby backed out of the skull 14. The operator may then remove the marking tool **100** fully from the patient **10.**

[0059] A visually identifiable mark 20 will thereafter remain in the surface of the skull for the physician's visual reference. The mark 20 includes both a small threaded hole 22 in the skull layers 14A, **14B** (but which does not extend into the brain) and an opening or hole 24 in the skin 12. According to some embodiments, the depth N of the mark 20 in the skull **14** will be between about 10 and 100 percent of the working length J of the cutting head **150.**

[0060] The marking tool **100** according to embodiments of the present invention can thus be used to form a precisely positioned, readily visually detectable, persistent mark on the patient.

[0061] According to some embodiments, the marking procedure is executed with the patient's head in or adjacent a bore **3OA** of a high-field magnet of an MRI scanner **30** as shown in **Figure 9** (can be open bore or closed bore magnets).

[0062] A burr hole **34 (Figure 12)** can thereafter be formed in the head 10 at the location of the mark 20 using any suitable technique or device. For example, the burr hole **34** may be formed using a burr hole forming tool configured to drill, cut or otherwise form the burr hole **34** through the patient's skull 14. An exemplary bun-hole forming tool may include a drill. According to some embodiments, the burr hole forming tool *(e.g.,* the drill) is also formed of MRI-compatible material(s). A bun-hole ring 36 (Figure **13)** can be mounted about the bun hole **34** to prepare the patient's head **10** for a surgical procedure.

[0063] Driver shanks *(e.g.,* the driver shank **110)** and cutting heads *(e.g.,* the cutting head **150)** can be used with handles of other types and configurations in accordance with further embodiments of the present invention. For example, while the lower handle member **130** is described herein as independently rotatable with respect to the upper handle member 140, according to some embodiments, the upper and lower handle members 130, **140** may be fixed or of a one-piece or unitary construction so that they are not rotatable with respect to one another.

[0064] According to some embodiments and **as** shown in **Figure** 14, the marking tool **100** is packaged in sterile packaging 40 to provide a medical kit. The packaging **40** may include an inner packaging 4OA *(e.g.,* a semi-rigid and/or vacuum formed polymeric packaging) and an outer packaging **4OB *(e.g.,*** a loose, breathable polymeric bag). According to some embodiments, the marking tool **100** is packaged together with the burr hole ring 36, a burr hole forming tool, and/or one or more fiducial markers in the sterile packaging **40** and to form the medical kit.

[0065] In some embodiments, the marking tool **100** and methods form a part of or operate with MRI compatible interventional systems. An MRI apparatus may be used to determine the desired location to be marked on the patient using the marking tool **100.** In some embodiments, the MRI compatible interventional systems include trajectory guide systems and/or apparatus and related components and methods. According to some embodiments, the trajectory guide apparatus and methods are frameless stereotactic trajectory guide apparatus that may be particularly suitable for deep brain interventional procedures, but may be used in other target anatomical locations as well.

[0066] Some embodiments of the invention are directed to MRI interventional procedures and provide interventional tools and/or therapies that may be used to locally place surgical interventional objects, tools or therapies *in vivo* to site specific regions using an MRI system. The interventional tools can be used to define an MRI-guided trajectory or access path to an *in vivo* treatment site.

[0067] In some embodiments, MRI can be used to visualize (and/or locate) a therapeutic region of interest inside the brain and utilize an MRI to visualize (and/or locate) an interventional tool or tools that will be used to deliver therapy and/or to place a permanently implanted device that will deliver therapy. Then, using the imaging data produced by the MRI system regarding the location of the therapeutic region of interest and the location of the interventional tool, the system and/or physician can make positional adjustments to the interventional tool so as to align the trajectory of the interventional tool, so that when inserted into the body, the trajectory of the interventional tool will intersect with the therapeutic region of interest. With interventional tool now aligned with the therapeutic region of interest, an interventional probe can be advanced, such as through an open lumen inside of the interventional tool, so that the interventional probe follows the trajectory of the interventional tool and proceeds to the therapeutic region of interest. The

interventional tool and the interventional probe may or may not be part of the same component or structure.

[0068] Tools, methods and systems in accordance with the present invention may be used with apparatus and methods as described in one or more of the following patent applications: U.S. Provisional Patent Application No. 60/933,641, filed June 7, 2007; U.S. Provisional Patent Application No. 60/974,821, filed September 24, 2007; and PCT Application No. PCT/US2006/045752, published as PCT Publication No. WO/2007064739 A2, and U.S. Patent Application No. 12/134,412, filed June 6, 2008, the disclosures of which are hereby incorporated by reference.

[0069] According to some embodiments, instrumentation and equipment are inserted through a targeting cannula to execute a diagnostic and/or surgical procedure. According to some embodiments, the procedure includes a deep brain stimulation procedure wherein one or more electrical leads are implanted in a patient's brain. The apparatus described herein can serve to designate an entry point into a patient for an established trajectory for installing the lead or leads or other interventional devices such as, for example, but not limited to, ablation probes, injection catheters and the like.

[0070] Some embodiments can be configured to deliver tools or therapies that stimulate a desired region of the sympathetic nerve chain. Other uses inside or outside the brain include stem cell placement, gene therapy or drug delivery for treating physiological conditions. Some embodiments can be used to treat tumors.

[0071] In some embodiments, the interventional tools can be configured to facilitate high resolution imaging via integral imaging coils (receive antennas), and/or the interventional tools can be configured to stimulate local tissue, which can facilitate confirmation of proper location by generating a physiologic feedback (observed physical reaction or via fMRI).

[0072] Some embodiments can be used to deliver bions, stem cells or other target cells to site-specific regions in the body, such as neurological target and the like. In some embodiments, the systems deliver stem cells and/or other cardio-rebuilding cells or products into cardiac tissue, such as a heart wall via a minimally invasive MRI guided procedure, while the heart is beating *(i.e.,* not requiring a non-beating heart with the patient on a heart-lung machine). Examples of known stimulation treatments and/or target body regions are described in U.S. Patent Nos. 6,708,064; 6,438,423; 6,356,786; 6,526,318; 6,405,079; 6,167,31 1; 6539,263;

6,609,030 and 6,050,992, the contents of which are hereby incorporated by reference as if recited in full herein.

[0073] The foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention. Therefore, it is to be understood that the foregoing is illustrative of the present invention and is not to be construed as limited to the specific embodiments disclosed, and that modifications to the disclosed embodiments, as well as other embodiments, are intended to be included within the scope of the invention.

That Which Is Claimed Is:

1. A surgical marking tool for marking a location on a patient, the marking tool comprising:

a cutting head including a screw thread; and

a handle coupled to the cutting head to rotate the cutting head;

wherein the screw thread is configured to progressively embed in the patient to mark the location when the cutting head is placed in contact with the patient and rotated with respect to the patient using the handle.

2. The marking tool of Claim 1 wherein the screw thread includes a self tapping screw thread.

3. The marking tool of Claim 2 wherein the marking tool is a burr hole marking tool and the self tapping screw thread is configured to self tap into a human skull.

4. The marking tool of Claim 3 wherein the cutting head has a sharp leading end section configured to easily pierce through the patient's scalp.

5. The marking tool of Claim 3 wherein the cutting head has a lead end and a limiter feature spaced apart a distance from the lead end, and an axial boring length extending from the lead end to a proximal end of the limiter feature is less than a thickness of the patient's skull.

6. The marking tool of Claim 1 wherein:

the handle includes first and second handle members that cooperate and are rotatable with respect to one another; and

the cutting head is affixed to the first handle member for rotation therewith.

7. The marking tool of Claim 6 wherein:

the first handle member is a lower handle member and the second handle member is an upper handle member; and

the upper handle member is configured and positioned to be held by a user's hand while the user rotates the cutting head using the lower handle member.

8. The marking tool of Claim 7 wherein the upper handle member has an upper end portion with a bulbous shape.

9. The marking tool of Claim 8 wherein the lower handle member includes flutes.

10. The marking tool of Claim 1 wherein the marking tool is constructed entirely of MRI-compatible material or materials.

11. A method for marking a location on a patient, the method comprising:

providing a marking tool including a cutting head having a screw thread; and

placing the cutting head in contact with the patient and rotating the cutting head with respect to the patient to progressively embed the screw thread in the patient to mark a location for a surgical procedure.

12. The method of Claim 11 wherein the screw thread includes a self tapping screw thread, and the method includes cutting into the patient using the self tapping screw thread.

13. The method of Claim 11 wherein placing the marking tool in contact with the patient and rotating the marking tool with respect to the patient includes progressively embedding the screw thread into a skull of the patient to mark the location in the skull.

14. The method of Claim 13 including piercing through the scalp of the patient with a sharp leading end section of the cutting head.

15. The method of Claim 13 wherein the screw thread includes a self tapping screw thread, and the method includes cutting into the patient's skull using the self tapping screw thread.

16. The method of Claim 15 including embedding the cutting head into the patient's skull only to a maximum depth less than the thickness of the skull, and thereafter removing the cutting head from the skull.

17. The method of Claim 13 further including forming a burr hole in the patient's skull proximate the marked location.

18. The method of Claim 11 wherein the marking tool includes a handle coupled to the cutting head to rotate the cutting head.

19. The method of Claim 18 wherein:

the handle includes first and second handle members that are rotatable with respect to one another;

the cutting head is affixed to the first handle member; and

rotating the cutting head with respect to the patient includes rotating the first handle member with respect to the second handle member.

20. The method of Claim 19 wherein:

the first handle member is a lower handle member and the second handle member is an upper handle member; and

the method includes holding the upper handle member in a user's hand and simultaneously rotating the cutting head using the first handle member.

21. The method of Claim 11 wherein:

the marking tool is constructed entirely of MRI-compatible material or materials; and

the steps of placing the cutting head in contact with the patient and rotating the cutting head with respect to the patient are executed in or adjacent a magnet of an MRI scanner.

22. The method of Claim 11 including counter-rotating the cutting head with respect to the patient to progressively remove the cutting head from the patient.

23. A surgical kit for an MRI-guided interventional surgery on a patient, the kit comprising:

a surgical marking tool including:

a cutting head including a screw thread; and

a handle coupled to the cutting head to rotate the cutting head;

wherein the screw thread is configured to progressively embed in the patient to mark a location on the patient when the cutting head is placed in contact with the patient and rotated with respect to the patient using the handle; and

wherein the marking tool is constructed entirely of MRI-compatible material or materials; and

sterile packaging containing the marking tool.

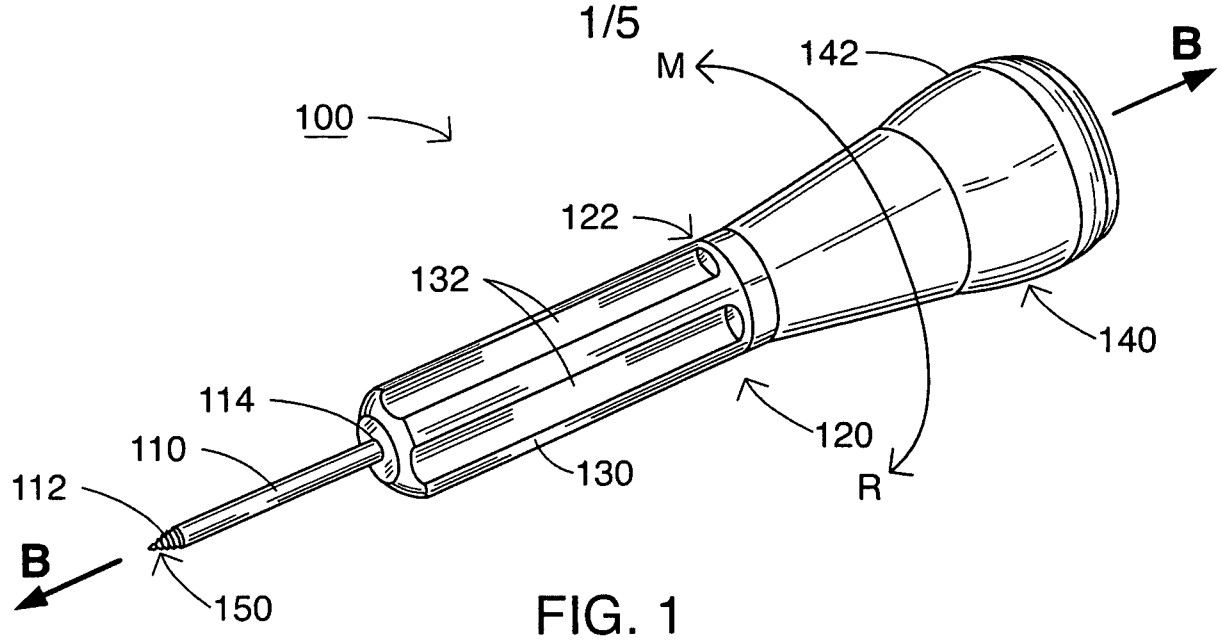


FIG. 1

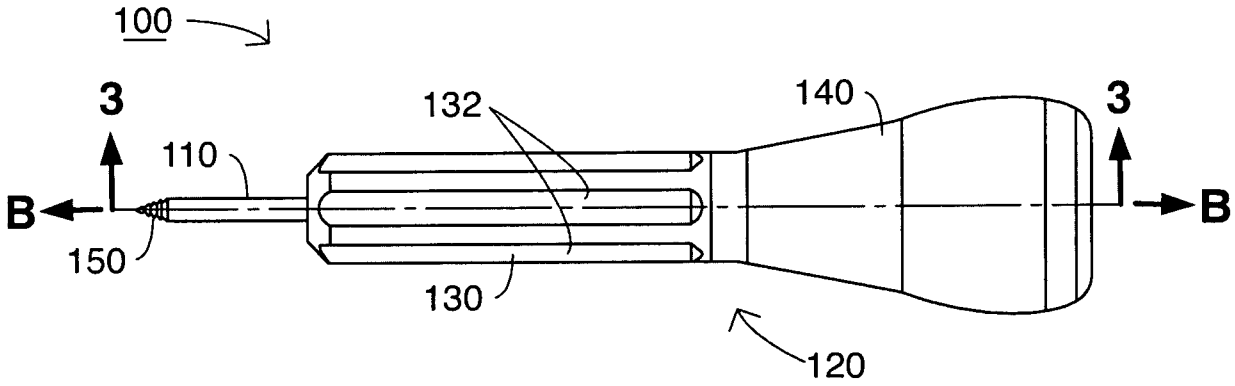


FIG. 2

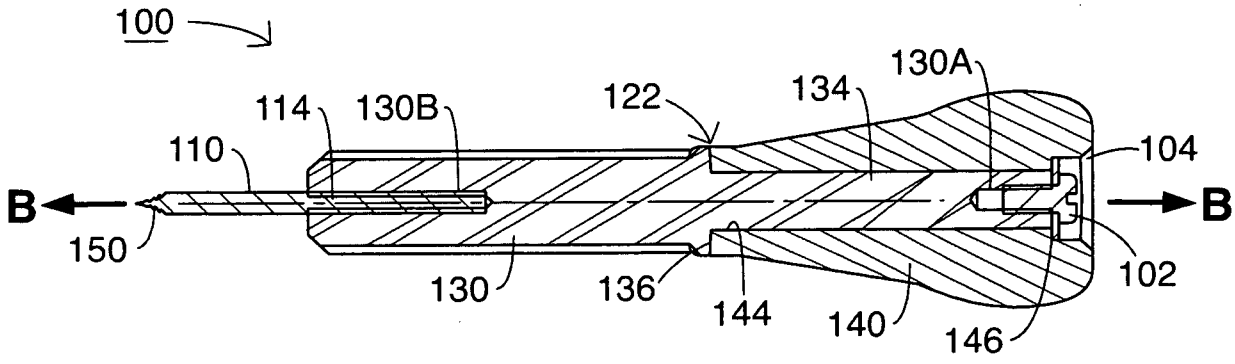


FIG. 3

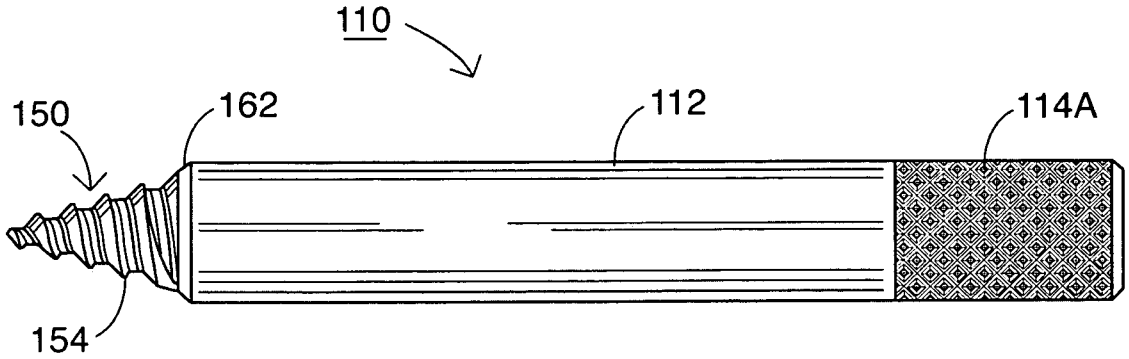


FIG. 4

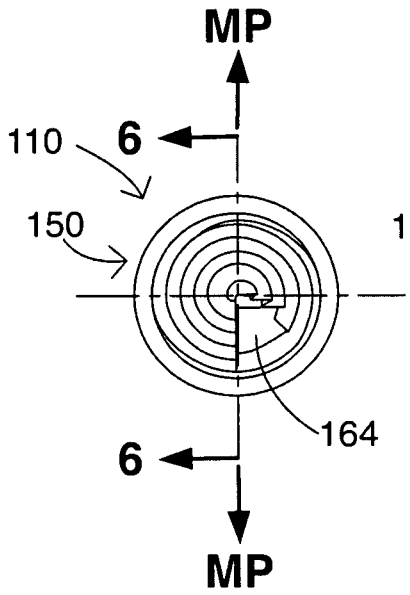


FIG. 5

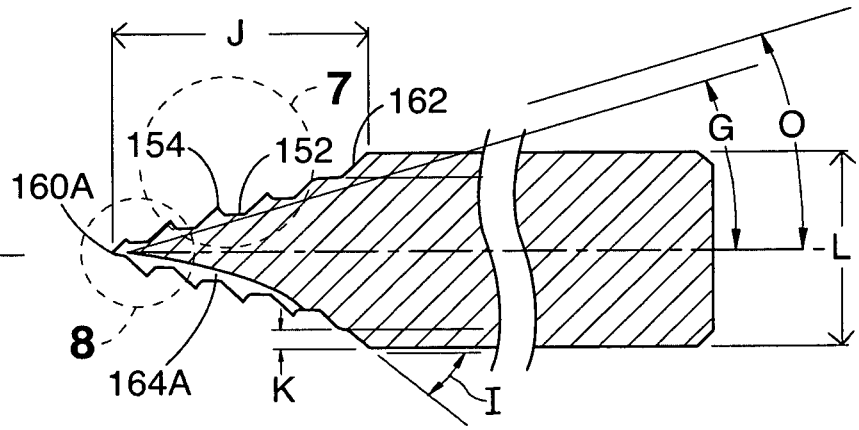


FIG. 6

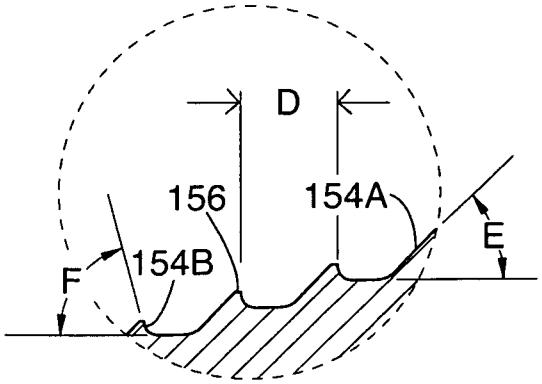


FIG. 7

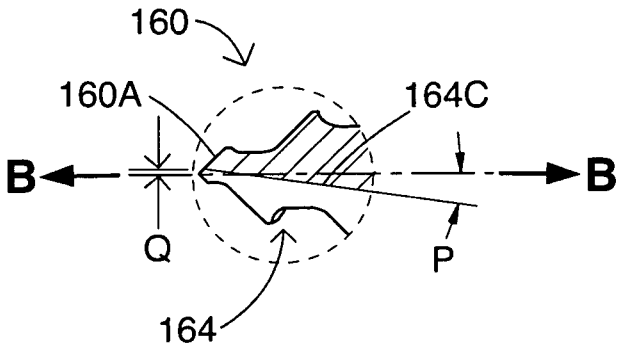


FIG. 8

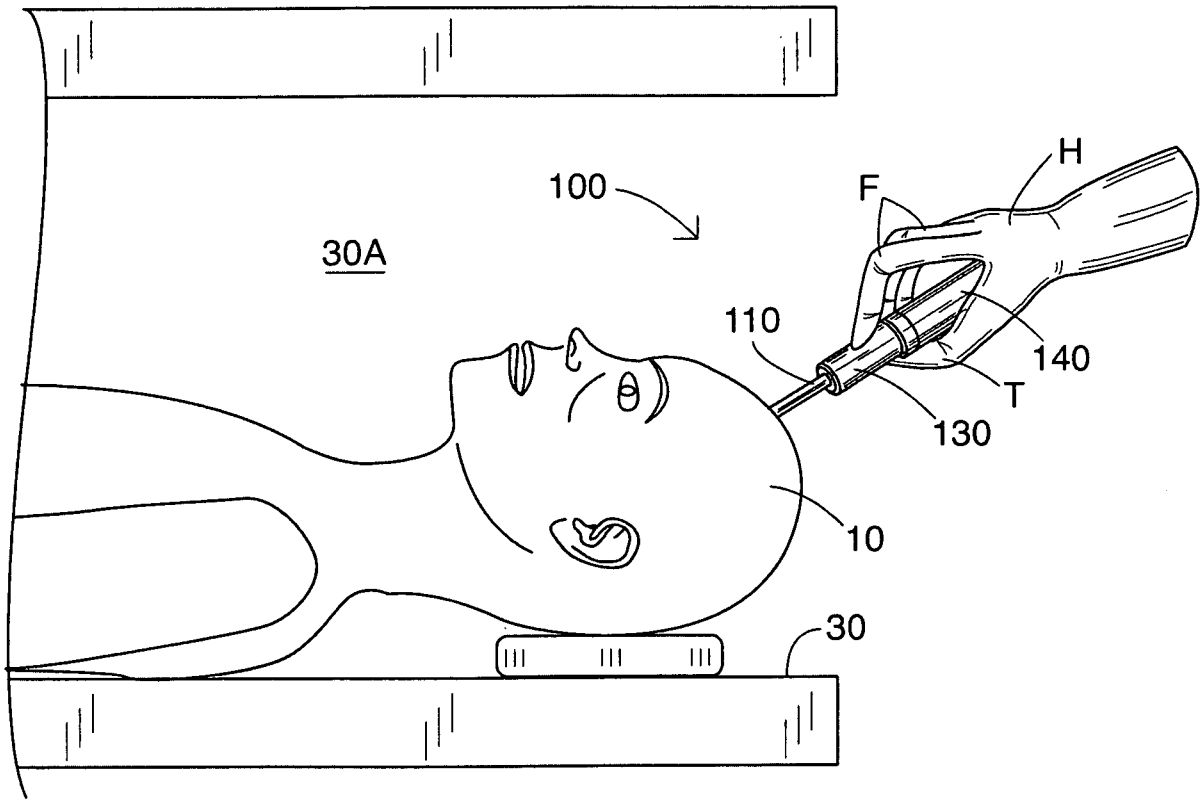
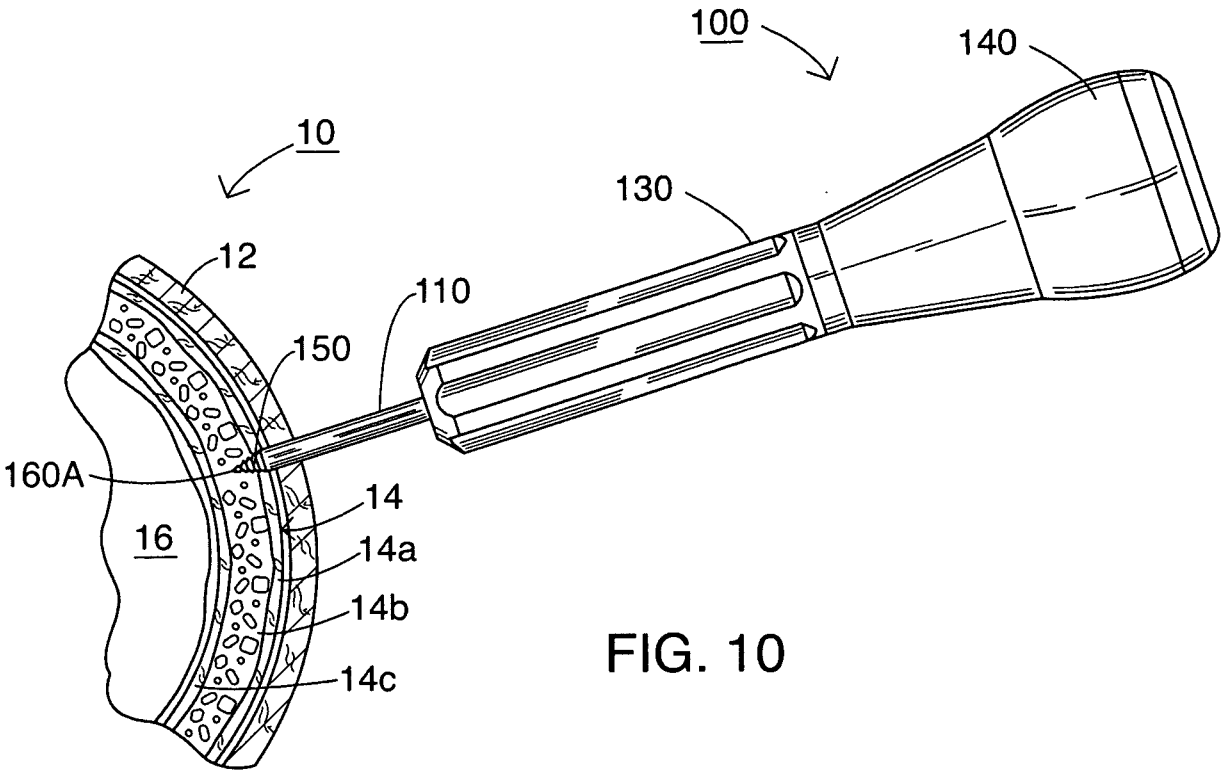


FIG. 9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130
12
110
150
160A
14
16
14a
14b
14c

FIG. 10

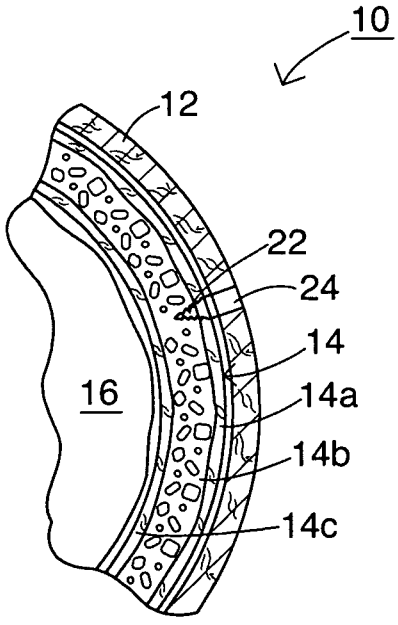
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FIG. 11

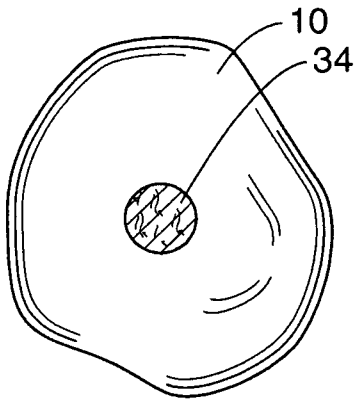

FIG. 12

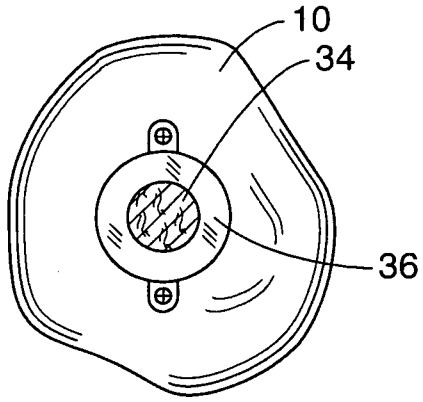

FIG. 13

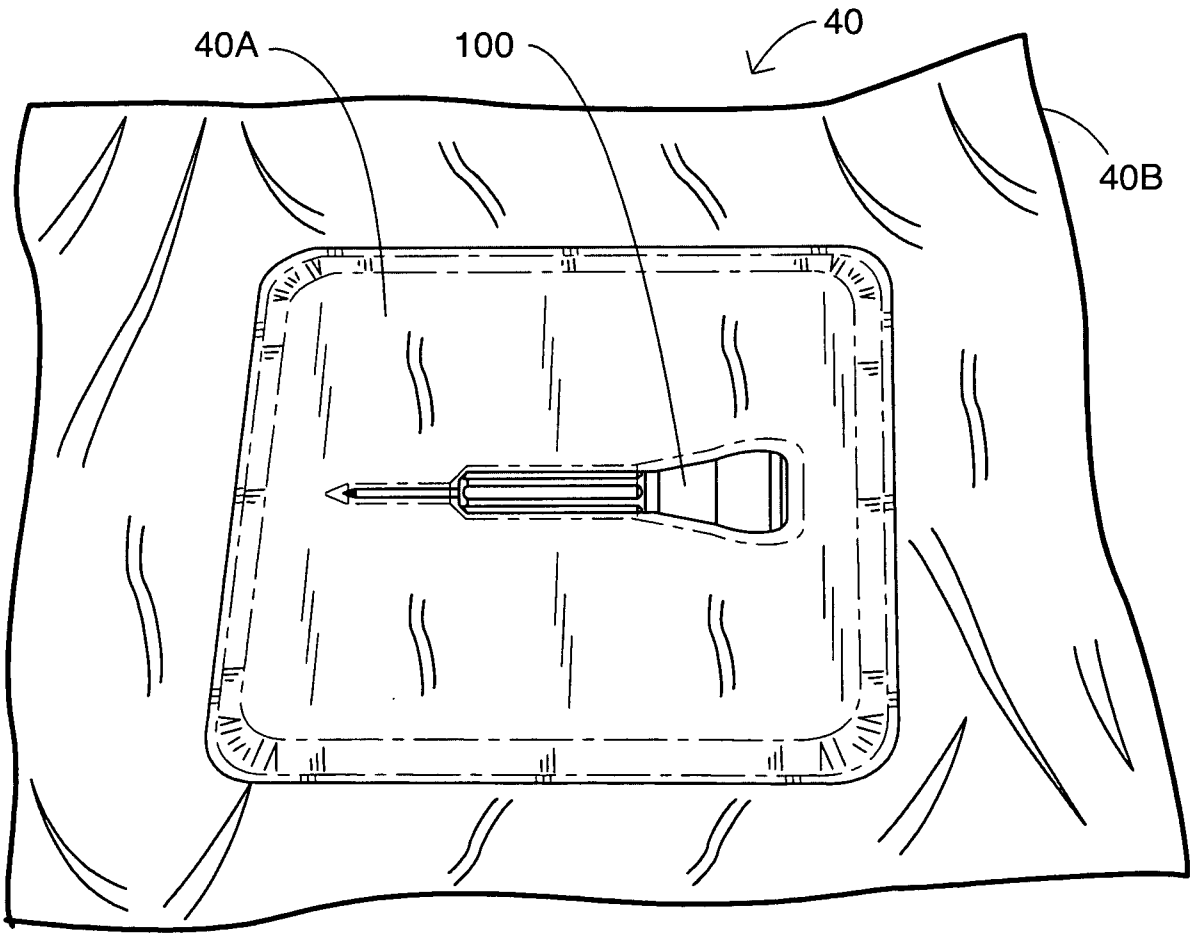

FIG. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/011083

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/16 B25G1/04
ADD. 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)
A61B B25G

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropnate, of the relevant passages	Relevant to claim No.
X	US 2005/070907 Al (ABERNATHIE DENNIS L [US]) 31 March 2005 (2005-03-31)	1-5
Y	figure 1	10,23
X	US 2002/193799 Al (CHAPPUIS JAMES L [US] ET AL) 19 December 2002 (2002-12-19)	1.2
Y	figures 5,6	6-10,23
Y	DE 296 11 140 Ul (LANDANGER LANDOS [FR]; BLANC JEAN LOUIS [FR]; CARRIOU JEAN LOUIS [FR];) 19 September 1996 (1996-09-19) figure 1	6-9
Y	US 2 775 276 A (ROSSNER ALBERT G) 25 December 1956 (1956-12-25) figures 1,2	6-9

-/-

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

[X] See patent family annex.

" Special categories of cited documents

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

'E' earlier document but published on or alter the International filing data

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

'O[1] document referπng to an oral disclosure, use, exhibition or other means

[1]P[1] documenl 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

[1]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

[1]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 docu¬ments, 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
10 December 2008	22/12/2008

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, Fax (+31-70) 340-3016	Schieβi , Werner

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/011083

C(Co πtinuatIon). DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document with indication, where appropriate of the relevant passages	Relevant Io claim No
Y	EP O 508 849 A (FACOM [FR]) 14 October 1992 (1992-10-14) figure 1	6-9
Y	WO 2005/084572 A (DEPUY INT LTD [GB]; REVIE IAN [GB]; ASHBY ALAN [GB]; NITZAN YAACOV [IL) 15 September 2005 (2005-09-15) page 24, paragraph 3	10,23
Y	US 2007/162018 Al (JENSEN DAVID G [US] ET AL) 12 July 2007 (2007-07-12) paragraph [0095] - paragraph [0101]	23
A	US 5 643 269 A (HAERLE ANTON [DE]) 1 July 1997 (1997-07-01) figure 1	1

INTERNATIONAL SEARCH REPORT

International application ND.
PCT/US2008/C1 1083

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

This international search report has rot been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. |Y| Claims Nos.: 11-22
because they relate to subject matter not required to be searched by this Authority, namely:

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

2. |__| Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful International search can be carried out, specifically:

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

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

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

1. |__| As all required additional search fees were timely paid by the applicant, this international search report covers alsearchable claims.

2. |__| As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. |__| As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers 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 feeswere accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

|__| The additional search feeswere accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

|__| No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/011083

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005070907 Al	31-03-2005	**NONE**	
us 2002193799 Al	19-12-2002	**WO** 02102256 **Al**	27-12-2002
		US 2005033303 **Al**	10-02-2005
DE 29611140 Ul	19-09-1996	**DE** 19625416 **Al**	02-01-1997
		FR 2735677 **Al**	27-12-1996
US 2775276 A	25-12-1956	**NONE**	
EP 0508849 **A**	14-10-1992	**DE** 69204883 Dl	26-10-1995
		DE 69204883 T2	15-05-1996
		ES 2077365 T3	16-11-1995
		FR 2675069 Al	16-10-1992
		JP 5104452 A	27-04-1993
WO 2005084572 **A**	15-09-2005	**EP** 1727486 A2	06-12-2006
		JP 2007526065 T	13-09-2007
		US 2008121242 Al	29-05-2008
us 2007162018 **Al**	12-07-2007	**US** 2007055249 Al	08-03-2007
		WO 2007146165 A2	21-12-2007
us 5643269 **A**	01-07-1997	**NONE**	