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(54) Title: IMPLANTABLE INJECTION PORT

(57) Abstract: An implantable injection port facilitates filling and/or draining an inflatable portion of a gastric band. In an embodiment, the port comprises a movable cap that causes anchor wires to extend from anchor devices in order to implant the injection port in the tissue of a patient. In another embodiment, the port comprises a handle that rotates to implant curved anchors into the tissue of a patient. In yet another embodiment, a cap is configured to move towards a base of the port in order to cause the curved anchors to rotate into the tissue of a patient. The cap may also rotate with respect to the base in order to lock the cap and the anchors in position. Further, surfaces of the injection port may be textured to increase adhesiveness to the patient's tissue during installation and to facilitate simpler installation.

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IMPLANTABLE INJECTION PORT

RELEATED APPLICATION

[0001] This application claims the benefit of U.S. Patent Application Serial Number 12/703,515, filed on February 10, 2010, the entire disclosure of which is incorporated herein by this specific reference.

FIELD OF THE INVENTION

[0002] The present invention generally relates to medical systems and apparatus and uses thereof for treating obesity and/or obesity-related diseases, and more specifically, relates to gastric banding systems that utilize an injection port that is implantable, typically laproscopically.

BACKGROUND

[0003] Adjustable gastric banding apparatus have provided an effective and substantially less invasive alternative to gastric bypass surgery and other conventional surgical weight loss procedures. Despite the positive outcomes of invasive weight loss procedures, such as gastric bypass surgery, it has been recognized that sustained weight loss can be achieved through a laparoscopically-placed gastric band, for example, the LAP-BAND® (Allergan, Inc., Irvine, CA) gastric band or the LAP-BAND AP® (Allergan, Inc., Irvine, CA) gastric band. Generally, gastric bands are placed about the cardia, or upper portion, of a patient's stomach forming a stoma that restricts food's passage into a lower portion of the stomach. When the stoma is of an appropriate size that is restricted by a gastric band, food held in the upper portion of the stomach provides a feeling of

satiety or fullness that discourages overeating. Unlike gastric bypass procedures, gastric band apparatus are reversible and require no permanent modification to the gastrointestinal tract.

[0004] Over time, a stoma created by a gastric band may need adjustment in order to maintain an appropriate size, which is neither too restrictive nor too passive. Accordingly, prior art gastric band systems provide a subcutaneous fluid access port connected to an expandable or inflatable portion of the gastric band. By adding fluid to or removing fluid from the inflatable portion by means of a hypodermic needle inserted into the access port, the effective size of the gastric band can be adjusted to provide a tighter or looser constriction.

[0005] Some existing access ports are connected to the rectus muscle sheath using sutures. Suturing these access ports may be difficult because of the obesity of the patient who is receiving the gastric band. For example, the ports are generally placed below several centimeters of fatty tissue which increases the difficulty of suturing the port.

[0006] Some existing access ports may be implanted without using sutures. However, these sutureless ports generally require specialized tools to activate the implanting mechanisms. Such specialized tools increase the cost of the sutureless ports. Thus, injection ports that may be implanted laproscopically without sutures and/or additional specialized tools are disclosed herein.

SUMMARY

[0007] Generally described herein are implantable injection ports for gastric banding systems, and methods of use thereof. The apparatus, systems and methods described herein aid in facilitating obesity control and/or treating obesity-related diseases.

[0008] In an embodiment, an implantable injection port for use in conjunction with a gastric band and for attaching to bodily tissue comprises a base with a first opening. The port also comprises a cap with a handle, and the cap is moveable, using the handle, between an undeployed position and a deployed position. Further, the cap is spaced apart from the base when it is in the deployed position. The port includes a self sealing, needle-penetrable material to facilitate filling and/or draining the gastric band.

[0009] Additionally, the port comprises a first anchor positioned in the first opening of the base, and the first anchor has a cavity, a hole, an inner shaft, and an anchor wire. The inner shaft is coupled to the cap such that moving the cap from the undeployed position to the deployed position causes a portion of the anchor wire to move through the hole and to be positioned outside the cavity. Moving the cap from the deployed position to the undeployed position causes a portion of the anchor wire to move through the hole to be positioned inside the cavity. A locking rod may be utilized to lock the cap in the deployed position.

[0010] In accordance with an embodiment, the port has a press-fit and/or interference-fit fitting for securing the handle adjacent to the cap. For example, the cap may have a center opening and an outer portion surrounding the center opening, and the fitting may be located in this outer portion. Also, the base may have a center opening and an outer portion surrounding the center opening, and the fitting may be located in this outer portion of the base.

[0011] In accordance with another embodiment, an implantable injection port comprises a body having a first opening and a handle attached to the body. The handle is moveable between a detached position and an attached position. The port further

comprises a first anchor device positioned in the first opening of the body, and the first anchor device is attached to the handle such that moving the handle from the detached position to the attached position causes a portion of the first anchor device to move through the first opening. As the needle moves through the opening, it is positioned outside the body of the port. Moving the handle from the attached position to the detached position causes a portion of the first anchor device to move through the first opening to be positioned inside the body of the port.

[0012] Further, in accordance with an embodiment, an implantable injection port comprises a base and a curved anchor attached to a handle that is rotatably attached to the base. When the handle is rotated, the curved anchor moves to an implanted position. The port further comprises a quick-connect and strain relief fitting coupled to a reservoir disposed in the base. The base of the port may further comprise a suture tab to facilitate attaching the port to a patient. The quick-connect and strain relief fitting may be configured to interface with gastric band tubing that connects the gastric band to the reservoir.

[0013] Another embodiment of an implantable injection port comprises a cap and a base coupled to the cap. The base has a first textured surface that provides adhesiveness between the base and a contact surface. The port further comprises a hook rotatably disposed within the base, and when the cap moves towards the base, the hook moves to an implanted position.

[0014] In various embodiments, the cap may have an engagement surface, and the base may be configured to nest within the cap. An internal ring is attached to the base and the hook is rotatably connected to the internal ring. The hook is configured to move through a slot in the base from an undeployed position to a deployed position when the cap moves toward the

base. Such movement facilitates implanting the injection port in tissue of a patient. The port further comprises a locking mechanism in the cap, and rotating the cap with respect to the base causes the locking mechanism to engage the hook to lock the hook in place and to prevent the cap from moving with respect to the base.

[0015] In various embodiments, a surface of the implantable injection port may comprise a textured surface. For example, the base, cap, and/or other surface may be textured to facilitate implanting of the port. Various textures such as parallel wavy lines and/or micro-papillae may be utilized.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1 illustrates a perspective view of an implantable injection port according to an embodiment of the present invention.

[0017] FIG. 2 illustrates a side, cut-away view of the embodiment illustrated in FIG. 1.

[0018] FIG. 3 illustrates another perspective view of an implantable injection port according to the embodiment illustrated in FIG. 1.

[0019] FIGS. 4A-4B illustrate cross-sectional views of an anchoring pin according to the embodiment illustrated in FIG. 1.

[0020] FIG. 5 illustrates another side, cut-away view of the embodiment illustrated in FIG. 1.

[0021] FIG. 6 illustrates yet another side, cut-away view of the embodiment illustrated in FIG. 1.

[0022] FIG. 7 illustrates a portion of an injection port according to the embodiment illustrated in FIG. 1.

[0023] FIG. 8 illustrates an exploded, perspective view of an injection port according to another embodiment of the present invention.

[0024] FIG. 9 illustrates a perspective view of the injection port illustrated in FIG. 8.

[0025] FIG. 10 illustrates an exploded, perspective view of another injection port according to a further embodiment of the present invention.

[0026] FIG. 11 illustrates a perspective view of the injection port illustrated in FIG. 10.

[0027] FIG. 12 illustrates a cross-sectional view of a quick-connect and strain relief mechanism according to an embodiment of the present invention.

[0028] FIG. 13 illustrates an exploded, perspective view of an implantable injection port according to yet another embodiment of the present invention.

[0029] FIG. 14 illustrates an exploded, cross-sectional view of the injection port illustrated in FIG. 13.

[0030] FIG. 15 illustrates a side view of a hook according to an embodiment of the present invention.

[0031] FIG. 16 illustrates a bottom view of an internal ring of the injection port illustrated in FIG. 13.

[0032] FIG. 17 illustrates a side view of an internal ring of the injection port illustrated in FIG. 13.

[0033] FIG. 18 illustrates a side, cross-sectional view of a base of the injection port illustrated in FIG. 13.

[0034] FIG. 19 illustrates a bottom view of a base of the injection port illustrated in FIG. 13.

[0035] FIG. 20 illustrates a top view of a cap of the injection port illustrated in FIG. 13.

[0036] FIG. 21 illustrates a side, cross-sectional view of a base of the injection port illustrated in FIG. 13.

[0037] FIG. 22 illustrates a gripping structure according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0038] The present invention generally relates to implantable injection ports for gastric banding systems, for example, for treatment of obesity and obesity related conditions. The injection ports may be implanted without using specialized implantation equipment, except for laproscopic tools. For example, a doctor's thumb and/or fingers may be utilized to implant the injection port. Standard forceps or hemostats may also be used.

[0039] Turning now to FIGS. 1 and 2, an implantable injection port **110** comprises a base **130** with a plurality of anchor devices **120** (e.g., anchor needles or anchor pins) passing through openings and/or holes in the base **130** and protruding from the base **130**. The anchor devices **120** protrude into the tissue of a patient, for example, into the rectus muscle sheath, so that the port **110** may be implanted into the patient. The port **110** may comprise any number of anchor devices **120** in order to facilitate secure implantation of the port **110**. An exit port **112** delivers fluid via flexible tubing to a gastric band.

[0040] The port **110** further comprises a shell **133** and a base shaft **134** that both guide a cap **132** as it moves up and down with respect to the base **130**. For example, the cap **132** may be movable between a detached position and an attached position with respect to a patient's tissue. A septum **105** for saline injections is located within the base shaft **134**. The septum **105** may comprise any self sealing, needle penetrable material, such as silicone. After implantation of the port **110**, a syringe needle may be inserted into the septum **105** to facilitate

increasing or decreasing the amount of fluid within the gastric band.

[0041] A handle **114** is rotatably attached to the cap **132** and facilitates securing the port **110** within the patient's tissue. A locking rod **113** is located at each end of the handle **114**, and the locking rod **113** is substantially perpendicular with respect to the handle **114**. The locking rod **113** facilitates locking the cap **132** in a raised position to facilitate securing the port **110** within the patient.

[0042] In accordance with an embodiment, and with reference to FIG. 3, each anchor device **120** of the port **110** comprises anchor wires **125**. The anchor wires **125** protrude into the patient's tissue at an angle that prevents removal of the port **110** from the patient's tissue. The anchor wires **125** emerge from the anchor device **120** into the patient's tissue as the cap **132** moves away from the base **130**.

[0043] The cap **132** may move away from the base **130** as a doctor pulls on the handle **114**, until the top of the cap **132** is substantially flush with the top edge of the shell **133**. The handle **114** may then be rotated toward the surface of the cap **132** until it is substantially flush with the surface of the cap **132**. The surface of the cap **132** may comprise a recess that receives the handle **114** so that the handle **114** does not protrude above the surface of the cap **132**.

[0044] In accordance with various embodiments, and with reference to FIGS. 4A and 4B, the anchor device **120** includes an anchor mechanism **115** for securing the anchor device **120** within the patient's tissue. The anchor mechanism **115** comprises an inner shaft **121** and the anchor wires **125** attach to a portion of the inner shaft **121**. The inner shaft **121** is disposed within a cavity **122** of the anchor device **120** and the shaft **121** can move linearly within the cavity **122**. In an embodiment, the anchor

device **120** has an attachment end coupled to the cap **132** and a free end and/or penetrating end in the shape of a pin. Further, in an embodiment, the anchor device **120** may be formed in the shape of a spiral with a pointed end.

[0045] As the shaft **121** moves out of the cavity **122**, the anchor wires **125** protrude from the anchor device **120** by passing through anchor openings and/or holes **126** in the anchor device **120**. Lips **127** of the anchor device **120** are angled to guide the anchor wires **125** to move out of the anchor device **120**. For example, as the shaft **121** moves out of the cavity **122**, the lips **127** guide the anchor wires **125** out of the cavity **122**. When the anchor wires **125** protrude sufficiently from the anchor device **120**, the shaft **121** ceases to move.

[0046] With reference to FIG. 5, it can be seen that, in an embodiment, each anchor device **120** includes a shaft **121** and anchor wires **125**. The shaft **121** is attached to the cap **132** and is moved out of the anchor device **120** as the cap **132** moves away from the base **130**. The cap **132** moves away from the base **130** as force is applied to the handle **114**, for example, by a physician's hand and/or by forceps or hemostats. The shell **133** is appropriately dimensioned so that the anchor wires **125** are adequately extended from the anchor device **120** when the cap **132** is substantially flush with a top edge **135** of the shell **133**.

[0047] With reference to FIGS. 6 and 7, once the cap **132** is in the appropriate position with the anchor wires **125** extended, the handle **114** may be locked to prevent the cap **132** from moving toward the base **130**. For example, the handle **114** may be rotated towards the cap **132**. As the handle **114** rotates, the locking rods **113** rotate toward the base **130**, such that when the handle **114** is substantially parallel with the cap **132**, the locking rods **113** interface with the base **130**.

[0048] In various embodiments, the handle **114** may nest within the cap **132** such that an interference and/or press fit is formed between the handle **114** and the cap **132** to prevent the handle **114** from unintentionally rotating out of the cap **132.** Further, in an embodiment, the locking rods **113** may fit within a detent, notch and/or catch within the base **130** to prevent the locking rods **113** from unintentionally moving out of the base **130.** For example, the cap **132** and/or the base **130** may be described as having a center opening and an outer portion surrounding the center opening, the outer portion having a fitting for securing the handle **114** adjacent to the cap **132.** As noted above, the fitting may be at least one of a detent, notch or catch that forms a press-fit and/or interference fit with the locking rods **113** and/or the handle **114.**

[0049] When the locking rods **113** and/or the handle **114** are in a locked position, the locking rods **113** prevent the cap **132** from moving toward the base **130,** thereby preventing the anchor wires **125** from unintentionally retracting into the anchor device **120.** The locking rods **113** may be substantially perpendicular with respect to the handle **114** so that when the handle **114** is substantially parallel to the cap **132,** the locking rods **113** are substantially perpendicular to the cap **132** and the base **130,** thereby preventing the cap **132** from moving toward the base **130.**

[0050] In order to implant the port **110** within a patient, a physician may grip the port **110** on the outside of the base **130** and the shell **132** using the physician's hand, forceps, hemostat, or other standard surgical tool. In various embodiments, the outside of the base **130** and/or the shell **133** may be textured to provide a better gripping surface for the physician. The bottom of the base **130** may be similarly textured, as discussed further below, in order to create a more secure adhesive contact between the base **130** and the patient's tissue.

[0051] Gripping the port **110**, the physician may then insert the anchor device **120** through the patient's tissue, for example, through the patient's rectus muscle sheath. The anchor device **120** may be constructed to be various lengths depending on the anatomy of the patient. For example, the anchor device **120** may be approximately 1-2 centimeters long in an embodiment where the port **110** is approximately 2 centimeters in diameter.

[0052] Once the port **110** is in place, the physician may pull on the handle **114** using the physician's hand, forceps, hemostat, and/or other surgical tool. Pulling on the handle **114** causes the anchor wires **125** to emerge from the anchor device **120** and move into the patient's tissue. In such a configuration, the port **110** is restricted from moving out of the patient's tissue. The physician may then rotate the handle **114** toward the cap **132** to facilitate locking the handle **114**, the cap **132** and the anchor wires **125** in place. The physician may feel a toggling action when a press fit and/or interference fit is created between the handle **114** and the cap **132** and/or between the locking rods **113** and the base **130**.

[0053] The port **110** may be removed without substantial tissue damage by unlocking the handle **114** and rotating the handle **114** away from the cap **132**. The handle **114** and/or the cap **132** are then pressed, causing the cap **132** to move toward the base **130**. This motion causes the anchor wires **125** to return into the cavity **122** of the anchor device **120** so that the port **110** may be removed from the patient. Because the physician may insert and remove the port **110** without specialized equipment, implantable ports according to embodiments of the present invention overcome difficulties associated with the prior art.

[0054] Turning now to FIGS. 8-11, an implantable injection port **210** comprises curved anchors **247** attached to a handle **245** that may be rotated with respect to a base **240** to facilitate

implanting the curved anchors **247** into the tissue of a patient. Although two anchors **247** are described herein, it should be understood that other numbers of anchors **247** may be utilized to facilitate appropriately implanting the injection port **210**. Furthermore, it should be understood that the anchors **247** may be of various lengths and may have different curvatures depending on various parameters, such as anticipated force to which the injection port **210** will be subjected and physical characteristics of the area of the patient in which the injection port **210** will be located.

[0055] The port **210** further comprises a reservoir **257** disposed within the base **240** to hold a fluid and dispense the fluid into the gastric band. The fluid may be introduced into the reservoir **257** via an injection through a self-sealing septum **253** located proximate to the reservoir **257** and disposed within the base **240**. The base **240**, in various embodiments, comprises a needle impenetrable housing to prevent an injection needle from damaging the injection port **210**. A cap **255** covers the septum **253** and is attached to the base **240**.

[0056] A discharge port, for example, a port tubing **259**, is connected to the reservoir **257**. A quick-connect and strain relief fitting **250** is coupled to the port tubing **259** and to the gastric band tubing **265**. As is discussed further below, the quick-connect and strain relief fitting **250** facilitates easier, quicker connection of the port **210** to the gastric band tubing **259**, and it also prevents leakage from the junction between the fitting **250** and the tubing **259** as the injection port **210** is subjected to movement.

[0057] The handle **245** is attached to a pivot and/or hinge **266** (see, e.g., FIG. 11) located on the base **240**. The handle **245** may be rotated between an undeployed position and a deployed position. In the undeployed position, the anchors **247** are

substantially above the attachment surface **241** of the base **240**. In the deployed position, the anchors **247** are substantially below the surface **241** of the base **240** in an implanted orientation.

[0058] In the undeployed position, a press-fit notch **263** on the handle **245** forms a press-fit with and/or receives press-fit hub **262** on the base **240**. This press-fit maintains the anchors **247** in the undeployed position to prevent unwanted movement of the anchors **247**. For example, as a physician is positioning the port **210** within the patient, the anchors **247** remain within the base **240** until the port **210** is in the appropriate location. A press-fit may also be utilized to maintain the anchors **247** in a deployed position within a patient's tissue.

[0059] Due to the slippery environment where the port **210** is intended to be located, it may be difficult to hold the port **210** in a desired position during implantation of the anchors **247**. The attachment surface **241** and/or other surfaces of the port **210** may comprise various textures, as discussed further below, to increase friction between the patient's tissue and the attachment surface **241** and facilitate more accurate placement of the port **210**.

[0060] In accordance with various embodiments, suture tabs **242** may be located on the base **240** of the port **210**. The suture tabs **242** may provide an additional mechanism for securing the port **210** to the patient together with and/or separately from implantation of the anchors **247**.

[0061] FIG. 12 illustrates a cross section of the quick-connect and stress relief fitting **250**. The section of the fitting **250** with the larger diameter receives the port tubing **259** from the port **210**. The section of the fitting **250** with the smaller diameter interfaces with the gastric band tubing **265**. The smaller diameter portion comprises a plurality of flanges **251**

that create a sealed connection with the gastric band tubing **265**. As the gastric band tubing **265** flexes, the fitting **250** also flexes, and the flanges **251** facilitate maintaining contact between the fitting **250** and the gastric band tubing **265** during such motion to prevent leakage of the fluid being transported from the port **210** to the gastric band.

[0062] Furthermore, the fitting **250** makes it easier to connect the port **210** to the gastric band tubing **265** than to make similar connections with existing implantable injection ports. For example, existing ports generally include a substantially rigid discharge port, and the tubing leading to the gastric band is manipulated to fit around the rigid discharge port. The fitting **250**, according to various embodiments, is more flexible than the standard discharge ports. Furthermore, the flanges **251** are pliable such that the fitting **250** may be more readily inserted into the gastric band tubing **265**, rather than attempting to stretch the tubing **265** around the discharge port.

[0063] Releasing the handle **245** from the press-fit hub **262** in the undeployed position, and moving it over the port **210** deploys the anchors **247** into the patient's tissue. This motion may be carried out using a physician's hand, thumb, forefinger, and/or with common operating room equipment such as hemostats or forceps. In the deployed position, the handle **245** is locked using nibs **249**. For example, the nibs **249** may be located on either side of the base **240** and may slide into notches on either side of the handle **245**. An audible sound and/or tactile feedback may be utilized to confirm that locking has occurred.

[0064] Turning now to FIGS. 13-22, an embodiment of an injection port **310** comprises a base **375** that slidably and rotatably nests within a cap **370**. As with the other ports discussed above, the port **310** may be utilized to provide fluid to a gastric band and to remove fluid from a gastric band. For example, the port **310**

may comprise a fluid port in the base **375** and/or the cap **370** to facilitate providing fluid to, and removing fluid from, a gastric band.

[0065] In accordance with various embodiments, a plurality of hooks **382** are circumferentially and rotatably located around a ring **380** that is disposed within the base **375.** As the cap **370** slides toward the base **375,** the cap **370** interacts with the hooks **382** to cause the hooks **382** to protrude through a plurality of slots **376** in the base **375** into the tissue of a patient. The cap **370** may then be rotated with respect to the base **375** in order to lock the hooks **382** into place.

[0066] The port **310** is advantageously configured to allow a physician to implant the port **310** in the patient's tissue without the use of special tools. For example, the port **310** may be implanted using the physician's hand and/or using common operating room tools such as forceps or hemostats. Although variations of the dimensions of the port **310** contemplated within the scope of this disclosure will be apparent to one skilled in the art, in various embodiments, the port **310** is approximately 25-27 millimeters in diameter and approximately 8-10 millimeters in height, and the hooks **382** have a height of approximately 7-10 millimeters.

[0067] With reference to FIG. 15, the hooks **382** have a curvature that facilitates implantation of the hooks **382** into the tissue of a patient. For example, an engagement surface **384** of the hook **382** interacts with the cap **370** as the cap **370** moves towards the base **375,** and this interaction causes the hook **382** to enter the patient's tissue.

[0068] With reference to FIG. 16, the hook **382** comprises a loop or eyelet **383** that facilitates connection of the hook **382** to the internal ring **380.** A plurality of hooks **382** are circumferentially disposed around the internal ring **380** and are

rotatably connected to the internal ring **380** via the eyelets **383.** Any number of hooks **382** may be used to secure the port **310** to the patient's tissue. However, in accordance with an embodiment, five hooks **382** may be used.

[0069] The internal ring **380** comprises a plurality of feet **381** that facilitate connection of the ring **380** to the base **375.** With reference to FIG. 18, the base **375** comprises a plurality of apertures or holes **378** configured to receive the plurality of feet **381.** In accordance with an embodiment, the plurality of feet **381** are cylindrical and the plurality of holes **378** are also cylindrical and are dimensioned to receive the plurality feet **381** via a press and/or interference fit. It should be understood that the plurality of feet **381** and the plurality of holes **378** may be any complementary geometry that facilitates connection of the ring **380** to the base **375.** For example, the plurality of feet **381** may have triangular cross-sections dimensioned for a press-fit in the circular holes **378** in the base **375.**

[0070] With reference to FIG. 19, the base **375** comprises a plurality of slots **376** through which the plurality of hooks **382** are configured to pass. As illustrated in FIGS. 14 and 16-19, the plurality of hooks **382** and corresponding slots **376** are located between pairs of feet **381** and corresponding holes **378.** Thus, in various embodiments, the port **310** comprises one pair of feet **381** and one pair of holes **378** for each hook **382.** However, it should be understood that other configurations of feet **381,** holes **378,** and slots **376** that allow the hooks **382** to rotate about the ring **380** and through the base **375** are contemplated within the scope of the present invention.

[0071] With reference to FIGS. 14, 18, and 20-21, the cap **370** is configured to receive the base **375,** the ring **380** and the hooks **382.** A cylindrical base receiving the slot **372** is

circumferentially located near the outside diameter of the cap **370**. A corresponding cylindrical cap engagement portion **377** is located near the outside diameter of the base **375**. The base receiving slot **372** and the cap engagement portion **377** are dimensioned to allow the base **375** to rotate and/or translate within the cap **370**. The cap **370** is configured to allow the hooks **382** to rotate within the port **310** as the cap **370** moves toward and/or away from the base **375**.

[0072] The cap **370** further comprises a septum hole **371** configured to receive a septum for saline injections. As noted above, the septum may comprise any self-sealing needle-penetrable material, such as silicone. After implantation of the port **310**, a syringe needle may be inserted into the septum to facilitate increasing or decreasing the amount of fluid within the gastric band.

[0073] Additionally, the cap **370** comprises a cylindrical hook manipulation surface **373** configured to interface with and cause the hooks **382** to extend from the port **310** to penetrate a patient's tissue. As the cap **370** moves towards or away from the base **375**, the hook manipulation surface **373** is configured to slide along the hook engagement surface **384** on the hook **382**. The curvature of the hook engagement surface **384** causes the hook **382** to rotate about the ring **380** as the hook manipulation surface **373** slides along the hook engagement surface **384**. For example, in an embodiment, the hook points **386** are configured to emerge through the slots **376** in the bottom of the base **375** in response to the cap **370** moving towards the base **375**. Such a configuration facilitates implanting the hooks **382** into the patient's tissue when the cap **370** moves towards the base **375**.

[0074] In accordance with various embodiments, the port **310** comprises a locking mechanism configured to lock the hooks **382** and/or the cap **370** into place once the hooks **382** have been

implanted in the patient's tissue. For example, the cap **370** may comprise a plurality of hook locking arms **385** spaced circumferentially around the cap **370**. The hook locking arms **385** are dimensioned and located within the cap **370** to allow each locking arm **385** to contact each hook **382** in order to prevent movement of the hook **382**. For example, the cap **370** may be rotated so that the locking arms **385** may engage the hooks **382** once the hooks **382** have been implanted in the patient's tissue. This configuration facilitates preventing the cap **370** from moving away from the base **375**, and preventing the hooks **382** from rotating out of the patient's tissue once the port **310** is in a desired location in the patient.

[0075] In accordance with various embodiments, surfaces of the port **310** (and other port embodiments disclosed herein and contemplated by this disclosure) may be textured to facilitate easier and/or more secure implantation of the port **310**. The base **375** may be textured to provide better surface adhesion and/or contact between the base **375** and the patient's tissue during installation of the port **310**. Furthermore, sides of the port **310** and/or the cap **370** may be textured to allow a physician to grip the port **310** during installation and/or removal of the port **310**. Due to the slippery environment where the port **310** is commonly installed, such texture may allow for simpler and/or more accurate placement of the port **310**. It should be understood that the same and/or different textures may be used at various locations on the port **310**. It should also be understood that similar textures may be utilized in connection with any of the embodiments disclosed herein and/or that are contemplated by this disclosure.

[0076] Although any texture may be used that facilitates appropriate placement of the port **310**, in accordance with an embodiment, and with reference to FIG. 22, a gripping structure **390** may comprise substantially parallel, wavy lines that extend

over all and/or a portion of the base **375** and/or the cap **370**. Such lines may comprise a conical cross-section that increases the contact surface area between the base **375** and the patient's tissue. The increased contact surface area increases the forces that facilitate maintaining the port **310** in a desired location.

[0077] In accordance with an embodiment, the gripping structure **390** may comprise papillae projections and/or micro-papillae (similar to hairs (setae) on the feet of geckos) which enhance covalent bonding, van der Waals forces and/or capillary interactions between the base **375** and the patient's tissue. Furthermore, such micro-papillae increase the surface area of contact between the base **375** and the patient's tissue and strengthen the bond therebetween. These micro-papillae may comprise any dimension configured to obtain the results discussed above. In an embodiment, multi-walled carbon nanotubes may be utilized to create such micro-papillae on various surfaces of the port **310**.

[0078] Further information on such micro-papillae may be found in the following documents, all of which are incorporated herein in their entirety by this specific reference: (1)Yurdumakan B., Raravikar N., Ajayan P., Dhinojawala A. "Synthetic Gecko Foot-Hairs from Multiwalled Carbon Nanotubes." The Royal Society of Chemistry. (2005): 3799-3801; (2) Geim AK., Dubonos SV., Grigorieva IV., Novoselov KS., Zhukov AA., Shapoval SY. "Mircrofabricated advhesive mimicking gecko foot-hair." Nature Materials. (2003) 2: 461-463; (3)Autumn K., Sitti M., Liang Y., Peattie A., Hansen W., Sponberg S., Kenny T., Fearing R., Israelachvili J., Full R. "Evidence of van der Waals adhesion in gecko setae." PNAS (2002); 99(19): 12252-12256.

[0079] Implantation of the port **310**, according to an embodiment, comprises first locating an appropriate place in the patient for implantation of the port **310**. The cap **370** is drawn away from

the base **375** so that the hooks **382** are substantially within the port **310**. Once the port **310** is in a desired location, a physician presses down on the cap **370** using a hand, finger, thumb and/or a common operating room tool. As the physician presses on the cap **370**, the hook manipulation surface **373** in the cap **370** acts on the engagement surface **384** of the hooks **382**, causing the hooks **382** to rotate with respect to the ring **380** and causing the hook points **386** to penetrate the patient's tissue. Once the hooks **382** have been implanted, the cap **370** is rotated so that the locking arms **385** engage the hooks **382** to prevent the hooks **382** from rotating away from the patient's tissue and to prevent the cap **370** from moving away from the base **375**. Removal of the port **310** may be accomplished by following the above steps in reverse. The port **310** may thus be efficiently implanted into and/or removed from a patient's tissue using only a physician's hand and/or common operating room tools.

[0080] Unless otherwise indicated, all numbers expressing quantities of ingredients, volumes of fluids, and so forth used in the specification and claims are to be understood as being modified in all instances by the term "about." Accordingly, unless indicated to the contrary, the numerical parameters set forth in the specification and attached claims are approximations that may vary depending upon the desired properties sought to be obtained by the present invention. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical value, however, inherently contains certain errors

necessarily resulting from the standard deviation found in their respective testing measurements.

[0081] The terms "a," "an," "the" and similar referents used in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. Recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[0082] Groupings of alternative elements or embodiments of the invention disclosed herein are not to be construed as limitations. Each group member may be referred to and claimed individually or in any combination with other members of the group or other elements found herein. It is anticipated that one or more members of a group may be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

[0083] Certain embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Of course, variations on these described embodiments will become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

[0084] Furthermore, certain references have been made to patents and printed publications throughout this specification. Each of the above-cited references and printed publications are individually incorporated herein by reference in their entirety.

[0085] Specific embodiments disclosed herein may be further limited in the claims using consisting of or and consisting essentially of language. When used in the claims, whether as filed or added per amendment, the transition term "consisting of" excludes any element, step, or ingredient not specified in the claims. The transition term "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s). Embodiments of the invention so claimed are inherently or expressly described and enabled herein.

[0086] In closing, it is to be understood that the embodiments of the invention disclosed herein are illustrative of the principles of the present invention. Other modifications that

may be employed are within the scope of the invention. Thus, by way of example, but not of limitation, alternative configurations of the present invention may be utilized in accordance with the teachings herein. Accordingly, the present invention is not limited to that precisely as shown and described.

CLAIMS

WHAT IS CLAIMED IS:

1. An implantable injection port for use in conjunction with a gastric band and for attaching to bodily tissue, the implantable injection port comprising:

a base having a first opening;

a cap having a handle, the cap moveable between an undeployed position and a deployed position using the handle, the cap spaced apart from the base when in the deployed position; and

a first anchor configured to be positioned in the first opening of the base, the first anchor having a cavity, a hole, an inner shaft, and an anchor wire, the inner shaft coupled to the cap such that moving the cap from the undeployed position to the deployed position causes a portion of the anchor wire to move through the hole to be positioned outside the cavity and moving the cap from the deployed position to the undeployed position causes a portion of the anchor wire to move through the hole to be positioned inside the cavity.

2. The implantable injection port of claim 1 wherein the inner shaft moves within the cavity to cause the anchor wire to move through the hole.

3. The implantable injection port of claim 1 wherein the first anchor has an attachment end coupled to the cap and a free end configured in the shape of a pin.

4. The implantable injection port of claim 1 wherein the first anchor has an anchor opening for passing the anchor wire.

5. The implantable injection port of claim 1 wherein the first anchor is formed in the shape of a spiral and has a pointed end.

6. The implantable injection port of claim 1 wherein the cap has a center opening and an outer portion surrounding the center opening, the outer portion having a fitting for securing the handle adjacent to the cap.

7. The implantable injection port of claim 1 wherein the base has a center opening and an outer portion surrounding the center opening, the outer portion having a fitting for securing the handle adjacent to the cap.

8. The implantable injection port of claim 7 further comprising a septum positioned within the center opening of the base and made of a self sealing needle penetrable material.

9. The implantable injection port of claim 7 wherein the fitting forms at least one of an interference fit and a press fit with a locking rod of the handle.

10. The implantable injection port of claim 7, wherein the fitting comprises at least one of a detent, a catch and a notch.

11. The implantable injection port of claim 1 further comprising a locking rod for locking the cap in the undeployed position or the deployed position.

12. The implantable injection port of claim 11 wherein the locking rod is connected to the handle such that rotating the handle locks the locking rod and the handle.

13. The implantable injection port of claim 1 wherein the base has a second opening.

14. The implantable injection port of claim 13 further comprising a second anchor configured to be positioned in the second opening.

15. An implantable injection port for use in conjunction with a gastric band and for attaching to bodily tissue, the implantable injection port comprising:

a body having a first opening;

a handle attached to the body, the handle moveable between a detached position and an attached position; and

a first anchor device configured to be positioned in the first opening of the body, the first anchor device attached to the handle such that moving the handle from the detached position to the attached position causes a portion of the first anchor device to move through the first opening to be positioned outside the body and moving the handle from the attached position to the detached position causes a portion of the first anchor device to move through the first opening to be positioned inside the body.

16. The implantable injection port of claim 15 wherein the first anchor device is formed in the shape of a spiral and has a pointed end.

17. The implantable injection port of claim 15 wherein the body has a center opening and an outer portion surrounding the center opening, the outer portion having a fitting for securing the handle adjacent to the body.

18. The implantable injection port of claim 15 wherein the body has a second opening.

19. The implantable injection port of claim 18 further comprising a second anchor device configured to be positioned in the second opening.

20. An implantable injection port, comprising:

a base;

a curved anchor attached to a handle rotatably attached to the base, and when the handle is rotated, the curved anchor moves to an implanted position; and

a quick-connect and strain relief fitting coupled to a reservoir disposed in the base.

21. The implantable injection port of claim 20 further comprising a nib in the base to lock the handle in the implanted position.

22. The implantable injection port of claim 20 further comprising a suture tab on the base.

23. The implantable injection port of claim 20 further comprising a textured surface on the base to prevent slipping during implantation of the implantable injection port.

24. The implantable injection port of claim 20 wherein the quick-connect and strain relief fitting interfaces with gastric band tubing that connects a gastric band to the reservoir.

25. The implantable injection port of claim 20 further comprising port tubing that connects the reservoir to the quick-connect and strain relief fitting.

26. The implantable injection port of claim 20 wherein a press-fit slot on the handle receives a press-fit hub on the base when the anchor is in an undeployed position.

27. An implantable injection port for use in conjunction with a gastric band and for attaching to bodily tissue, the implantable injection port comprising:

a cap;

a base coupled to the cap, the base having a first textured surface providing adhesiveness between the base and a contact surface; and

a hook rotatably disposed within the base, and when the cap moves towards the base, the hook moves to an implanted position.

28. The implantable injection port of claim 27 wherein the first textured surface comprises parallel wavy lines.

29. The implantable injection port of claim 27 wherein the first textured surface comprises a papillae projection.

30. The implantable injection port of claim 27 further comprising a second textured surface.

31. The implantable injection port of claim 27 further comprising a septum positioned within a center opening of the cap and made of a self sealing, needle penetrable material.

32. An implantable injection port comprising:

a cap having an engagement surface;

a base that nests within the cap and comprises a slot;

an internal ring attached to the base;

a curved anchor rotatably connected to the internal ring, wherein the curved anchor moves through the slot from an undeployed position to a deployed position when the cap moves toward the base to facilitate implanting the injection port in tissue; and

a locking mechanism in the cap, wherein rotating the cap with respect to the base causes the locking mechanism to engage the curved anchor to lock the curved anchor in place and to prevent the cap from moving with respect to the base.

33. The implantable injection port of claim 32 wherein the base comprises a hollow cylinder that receives a foot of the internal ring.

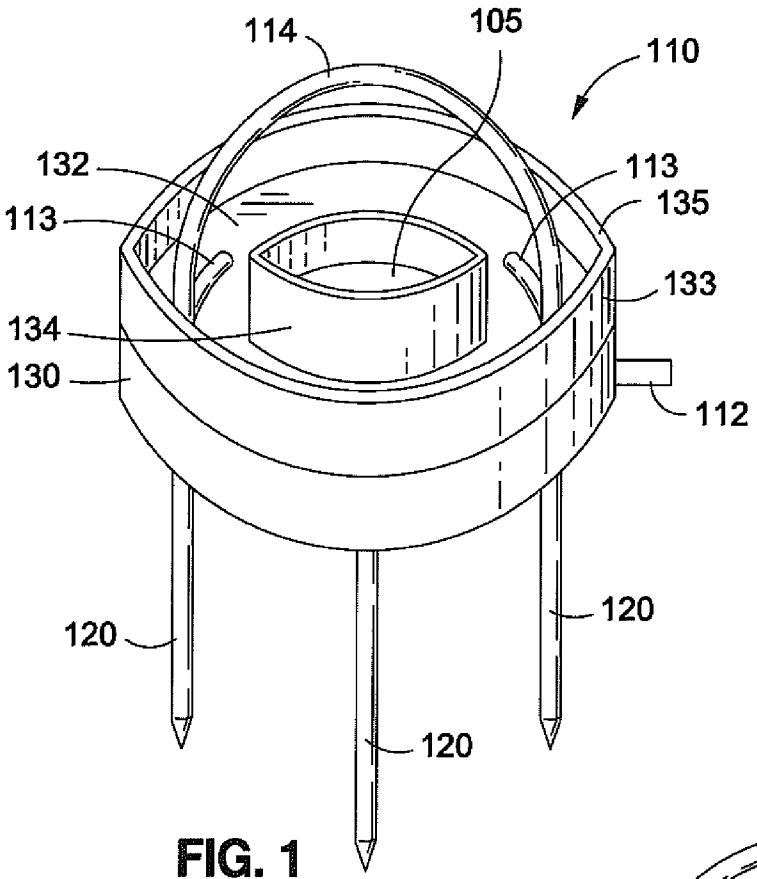

FIG. 1

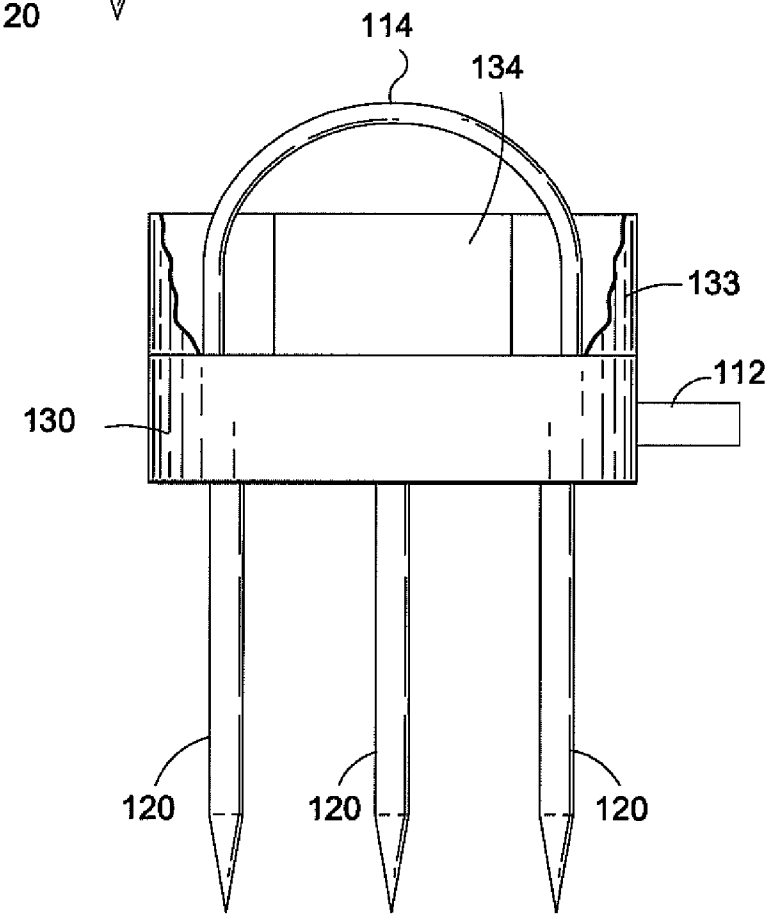

FIG. 2

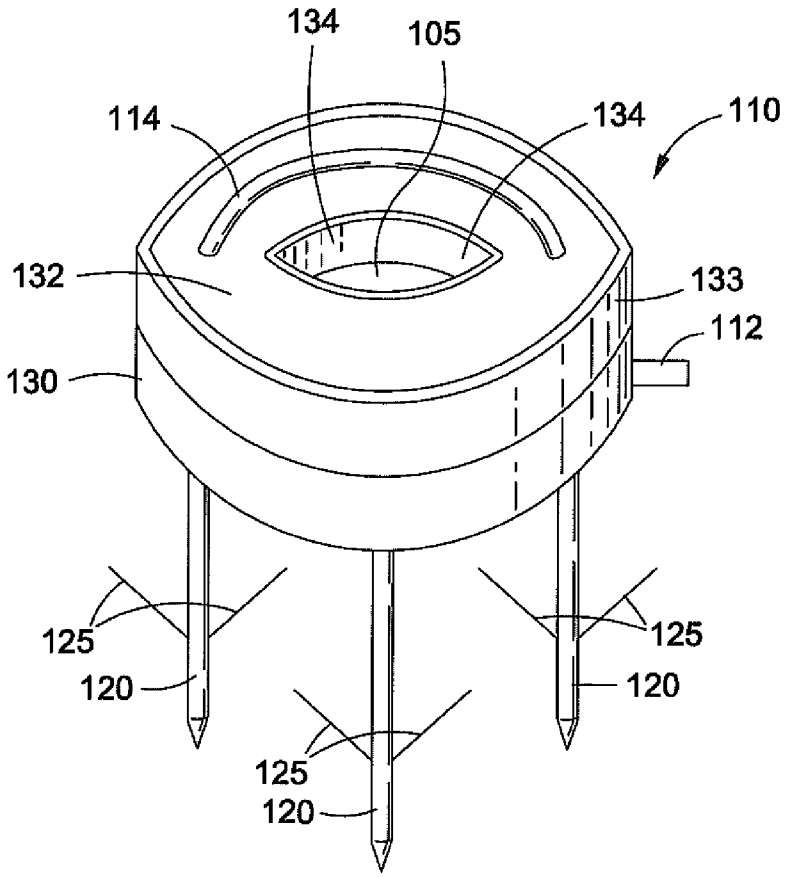

FIG. 3

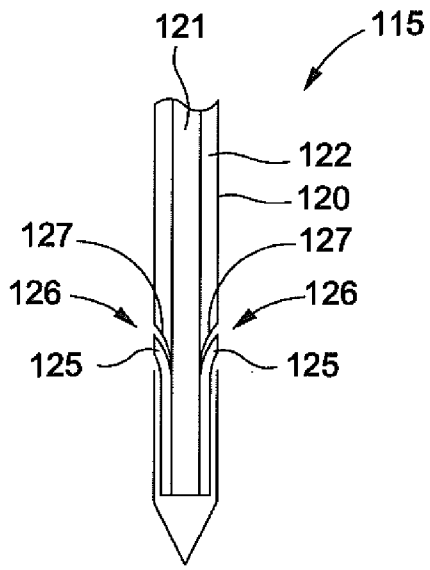

FIG. 4A

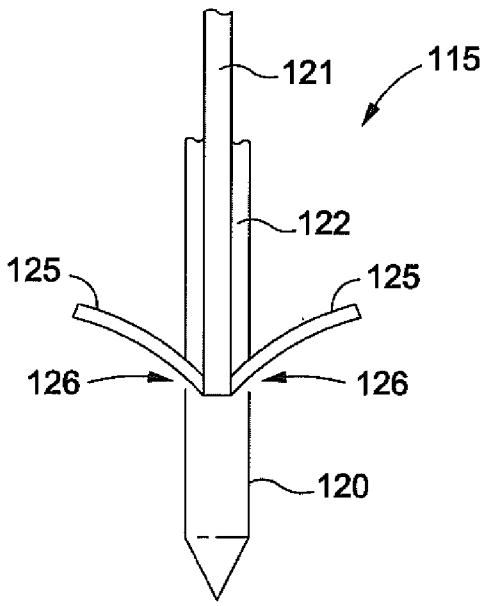

FIG. 4B

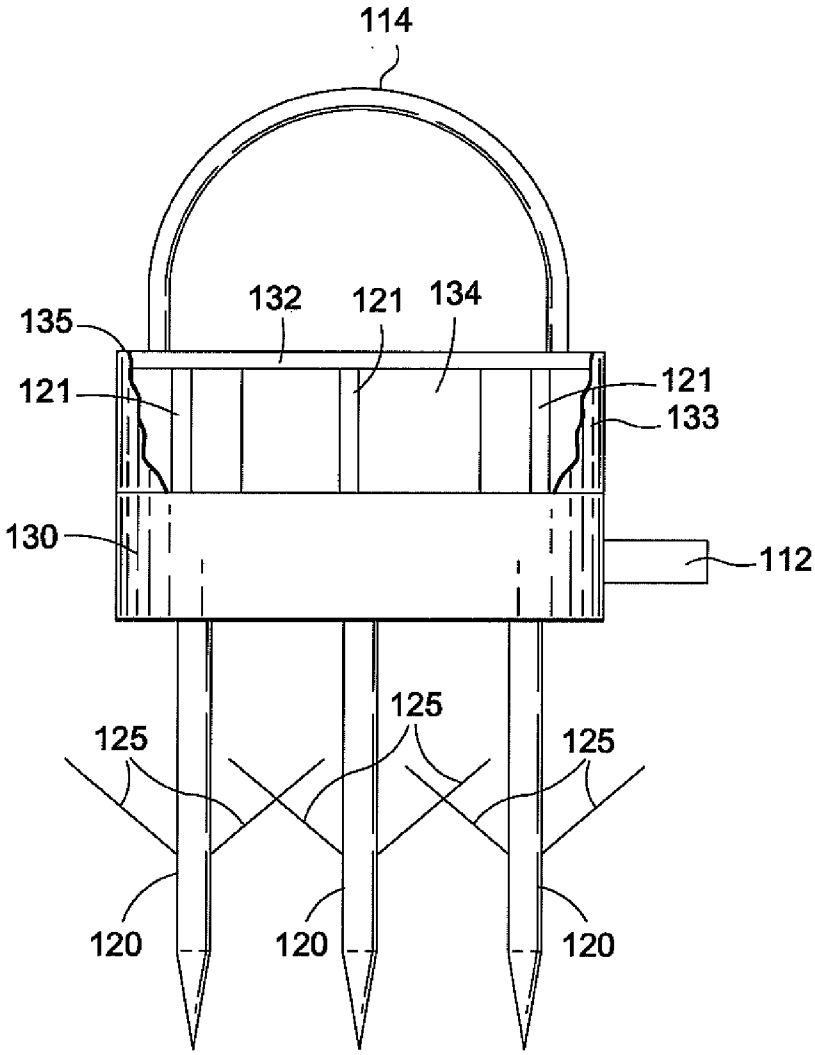

FIG. 5

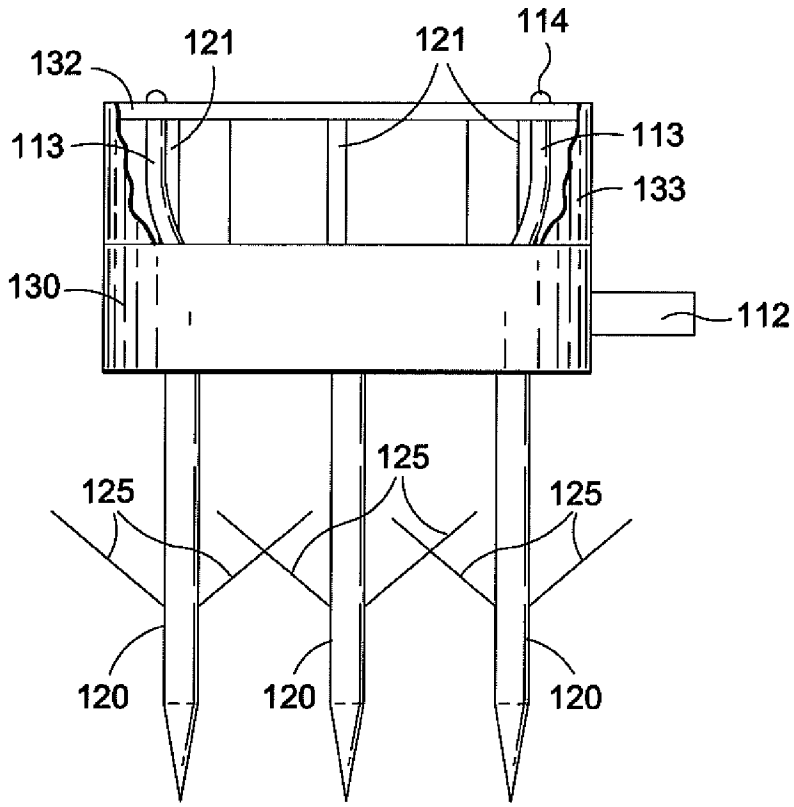

FIG. 6

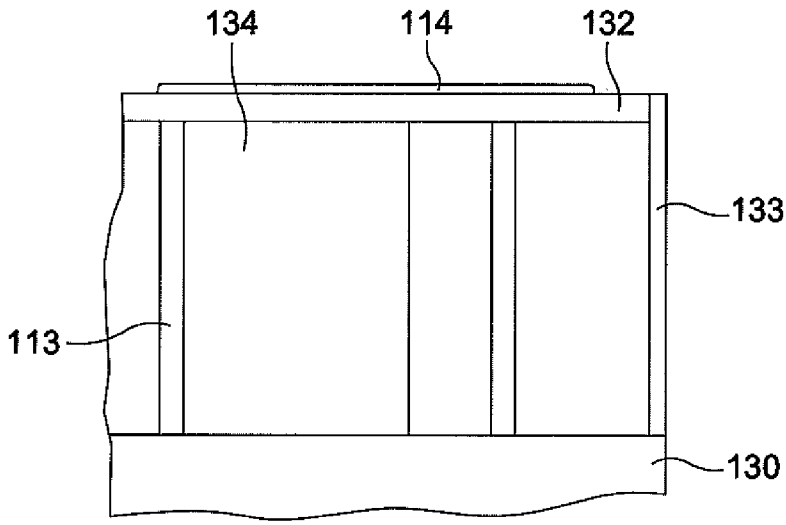

FIG. 7

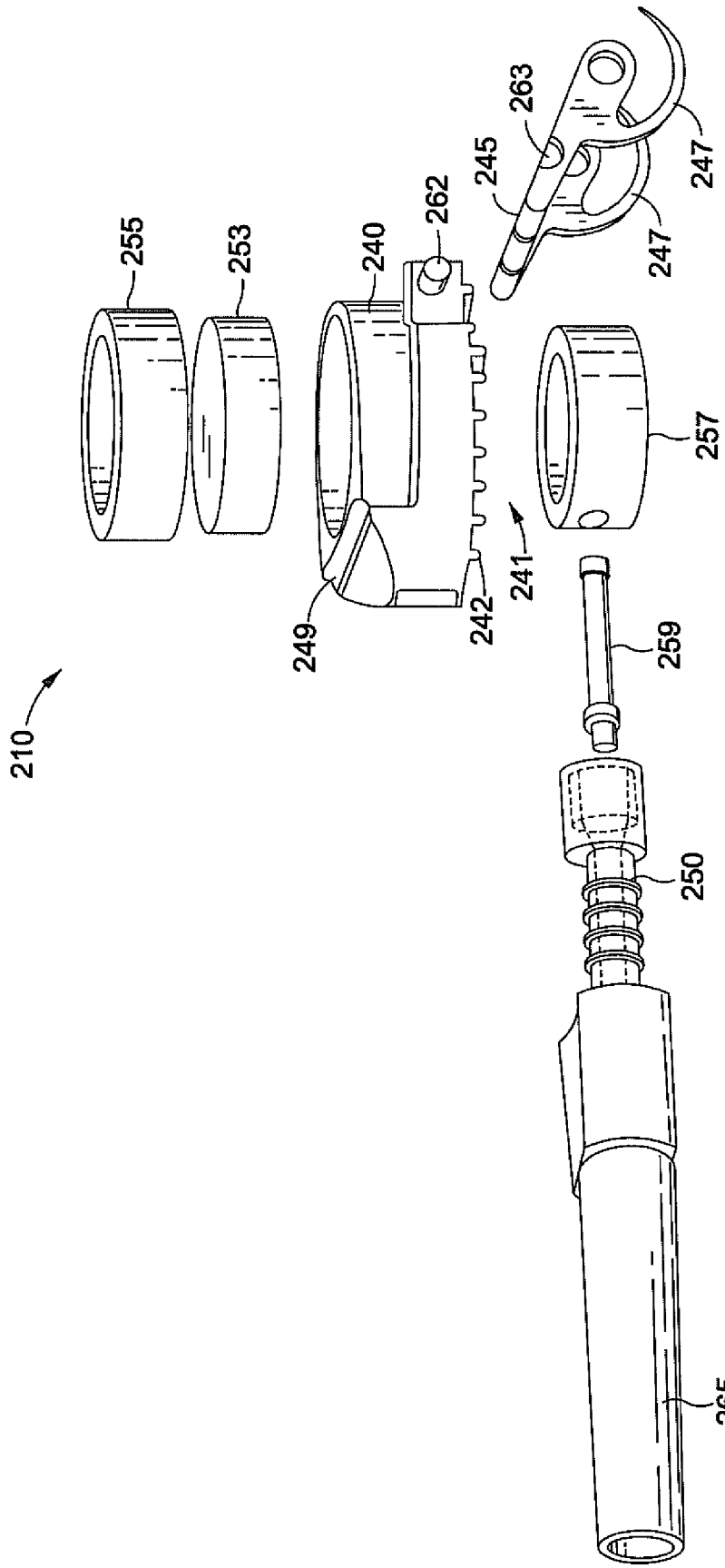

FIG. 8

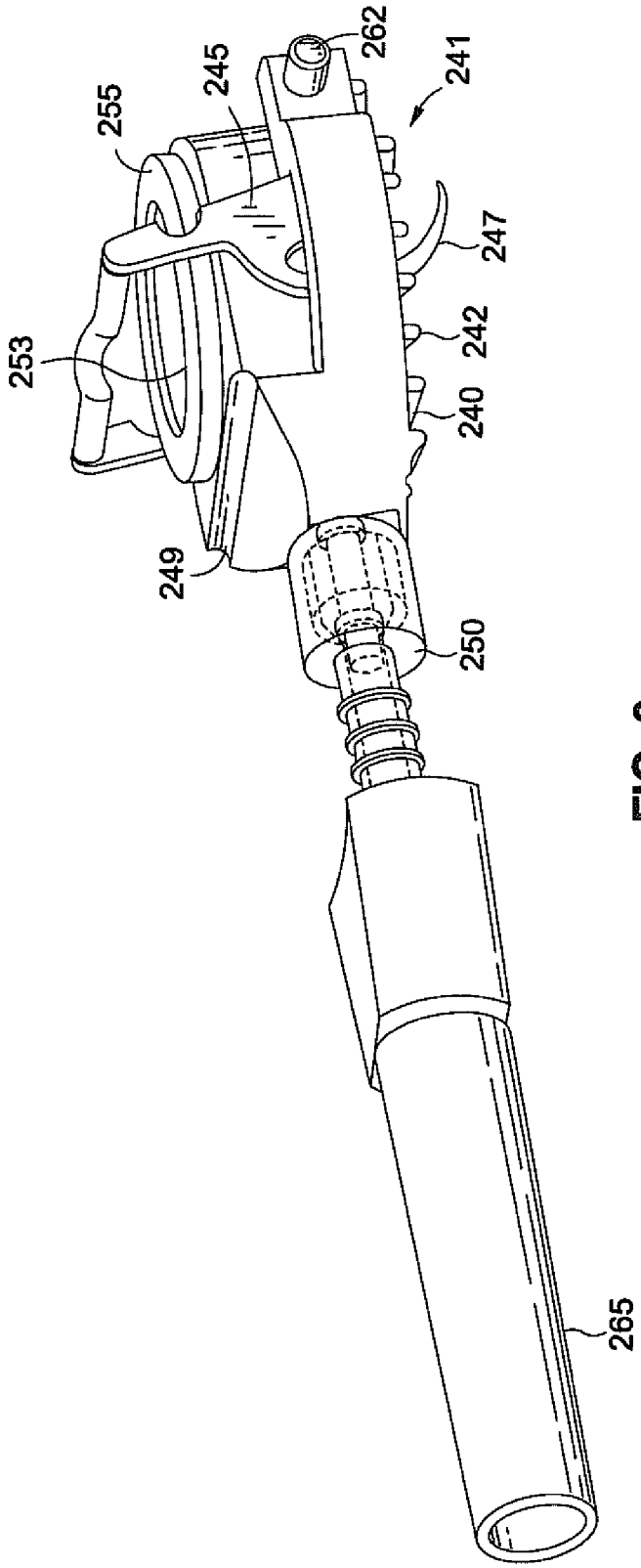

FIG. 9

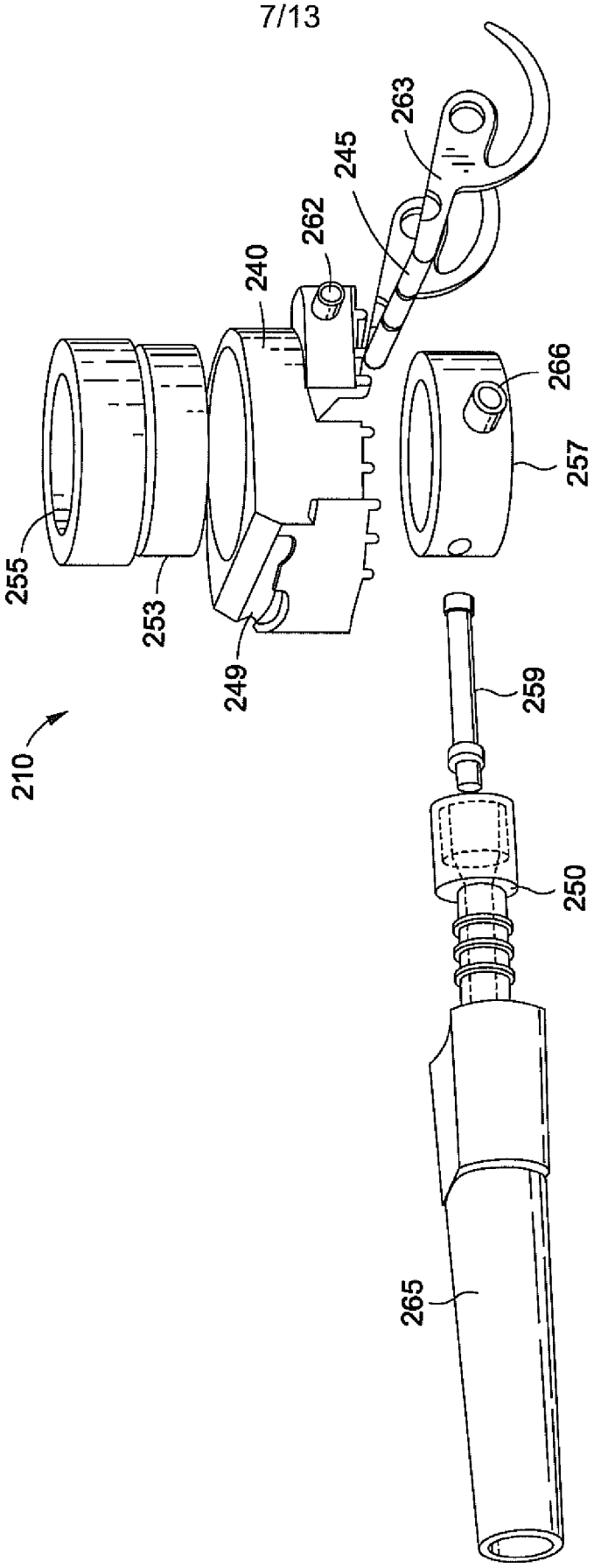

FIG. 10

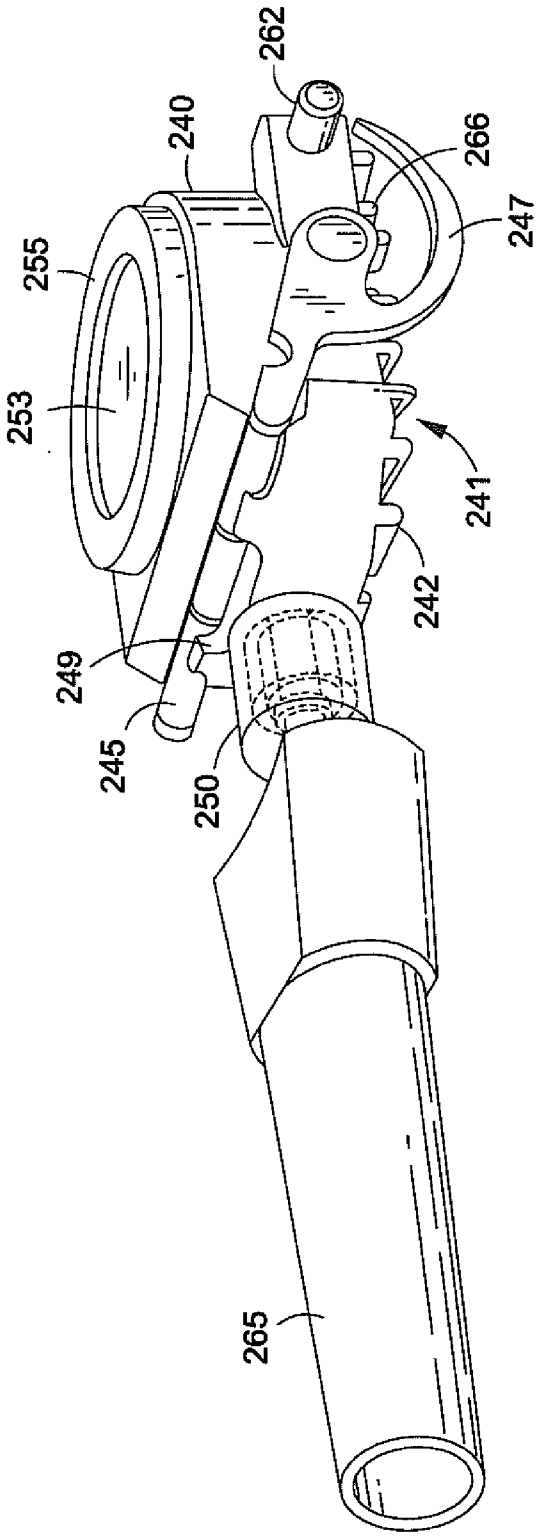

FIG.11

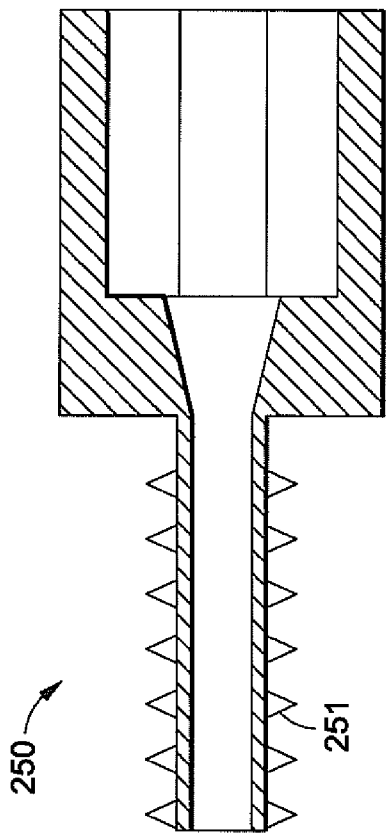

FIG. 12

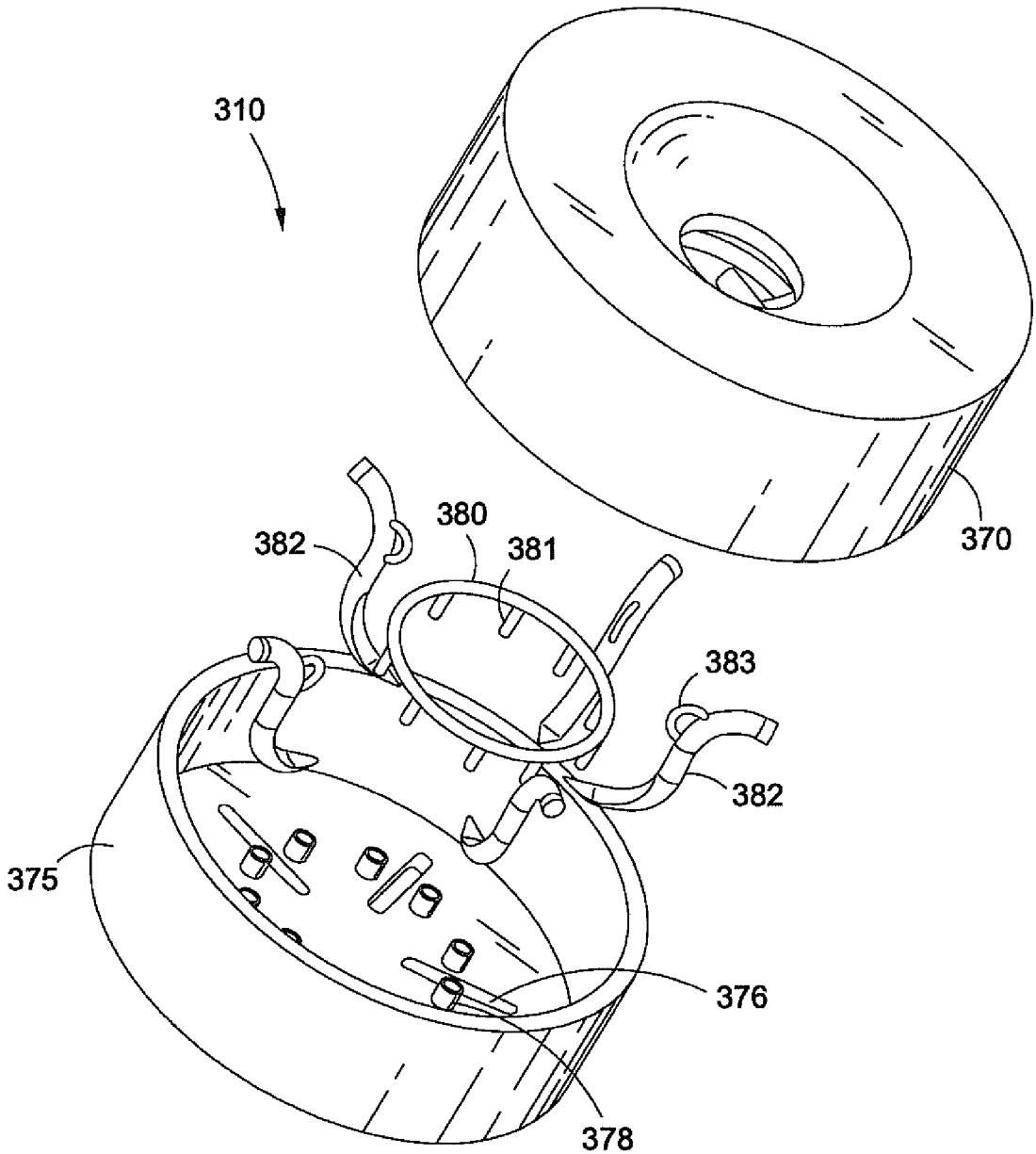

FIG. 13

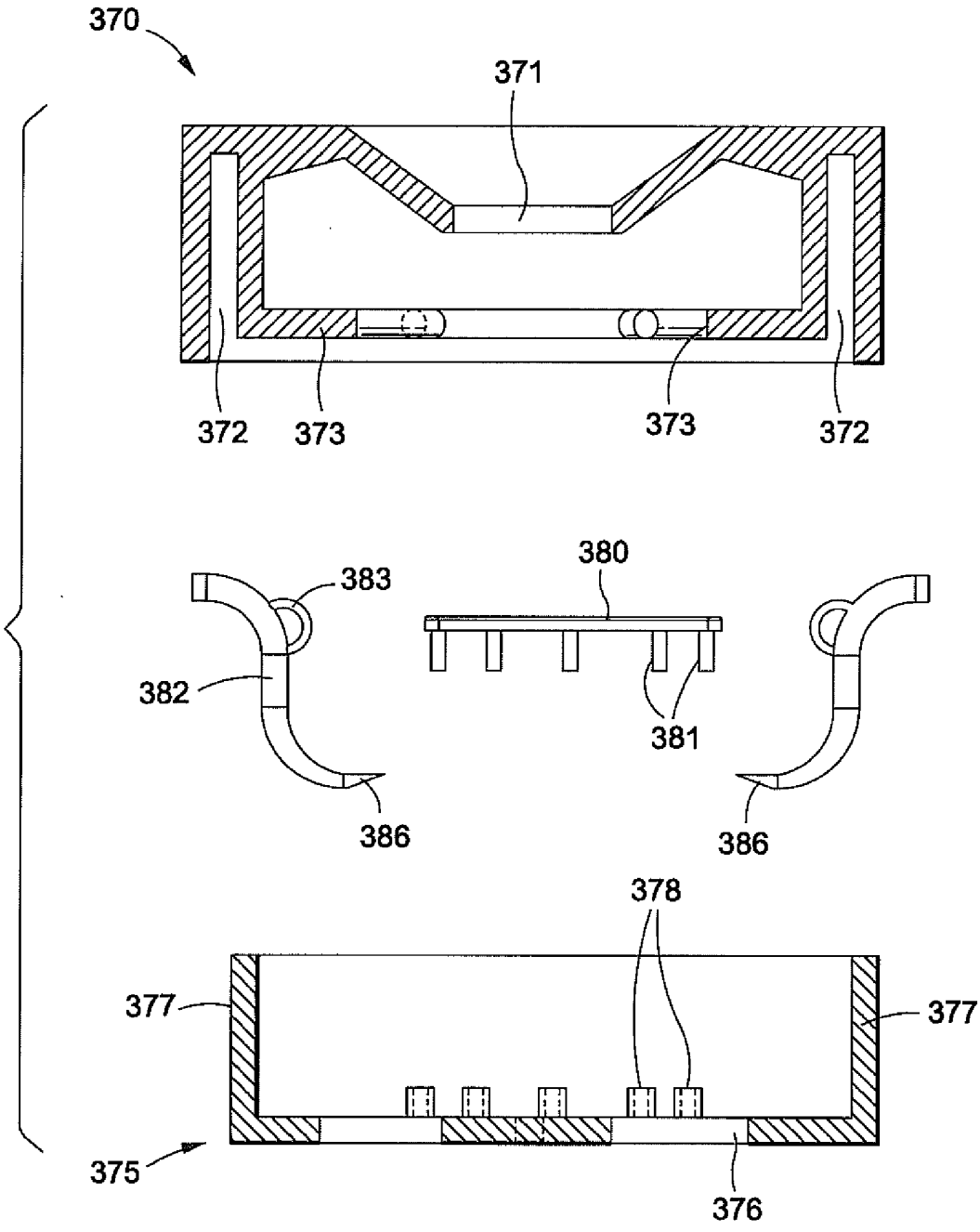
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FIG. 14

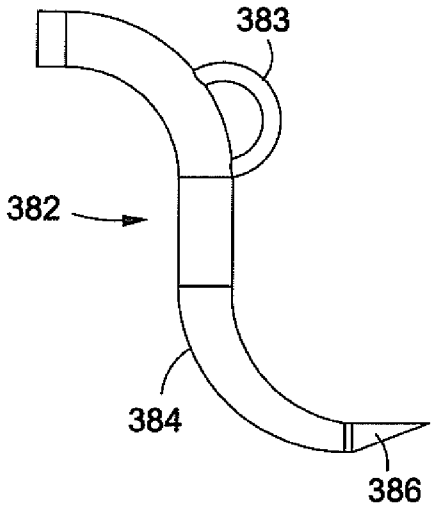

FIG. 15

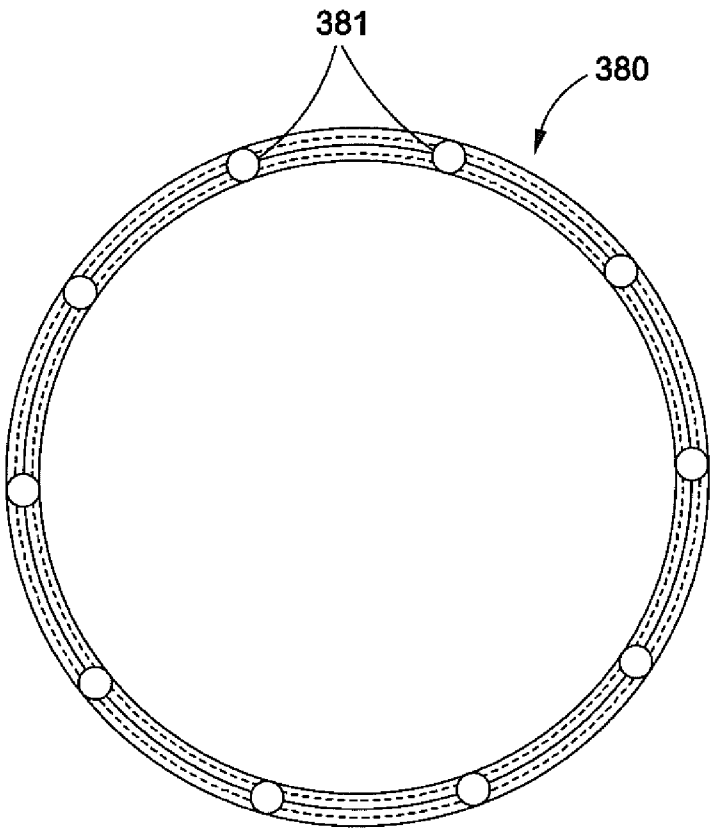

FIG. 16

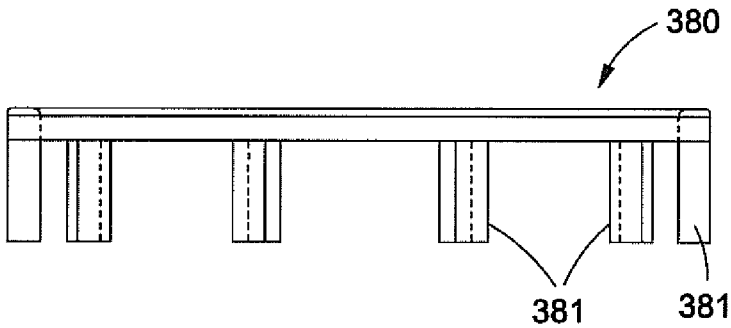

FIG. 17

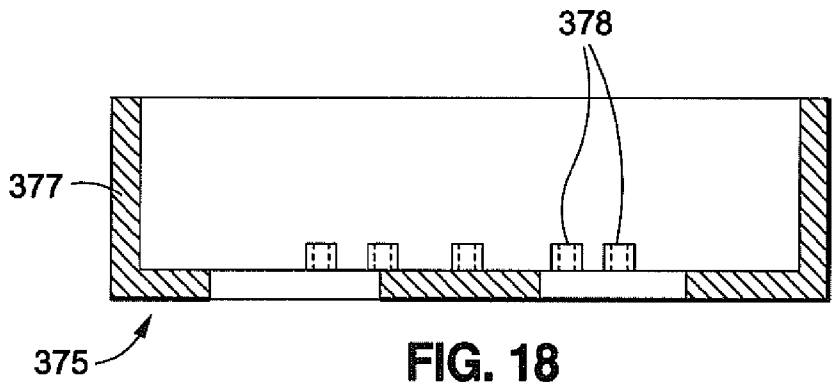

FIG. 18

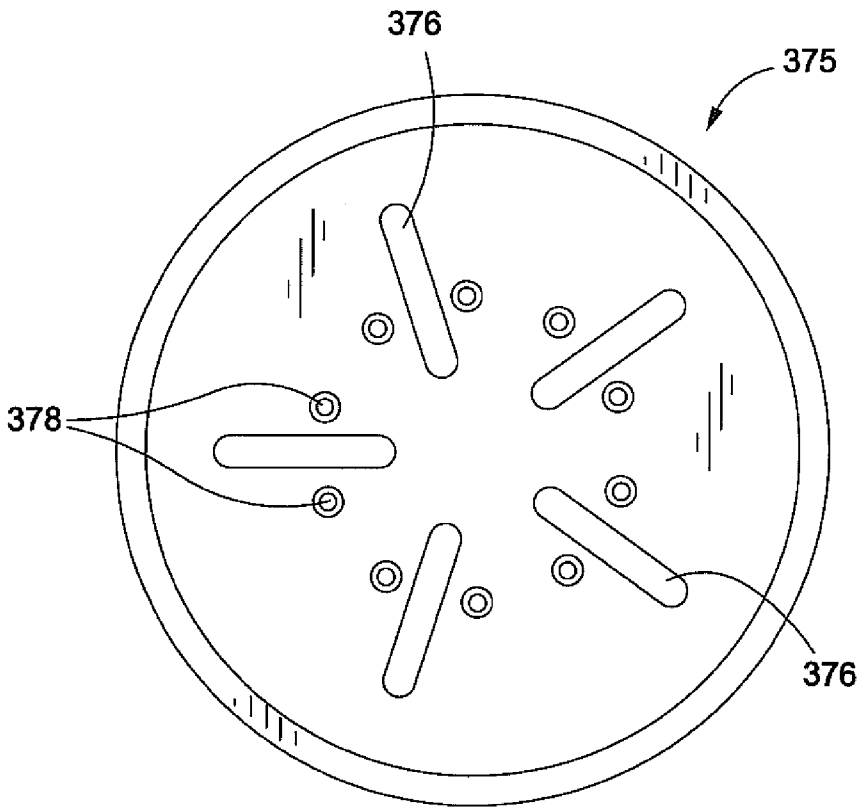

FIG. 19

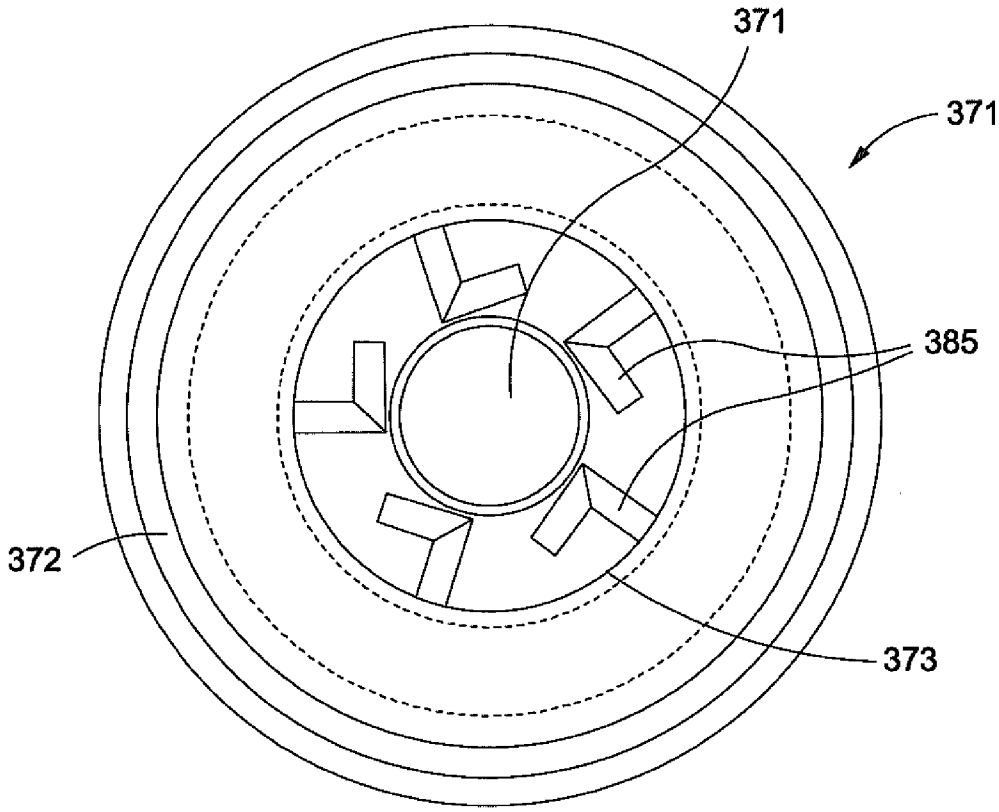

FIG. 20

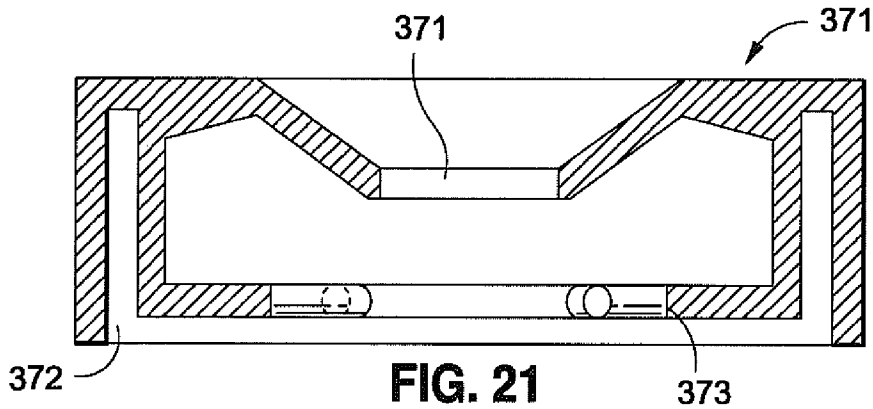

FIG. 21

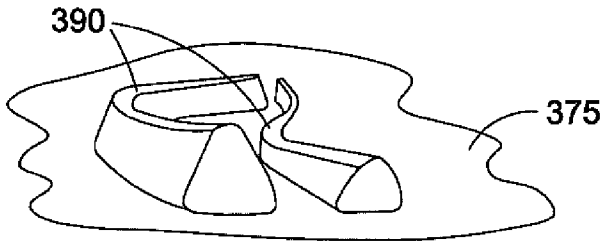

FIG. 22

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/023894

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/00
ADD.

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)
A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 488 824 A1 (ETHICON ENDO SURGERY INC [US]) 22 December 2004 (2004-12-22) abstract; figures 2,22-32	1-33
X	WO 2009/129474 A1 (ALLERGAN INC [US]; FRANKLIN ETHAN [US]; BIRK JANEL A [US]) 22 October 2009 (2009-10-22) abstract; figures 5, 6, 11, 12	1-33
X	WO 2005/037055 A2 (INAMED MEDICAL PRODUCTS CORP [US]; BIRK JANEL [US]; COE FREDERICK L [U) 28 April 2005 (2005-04-28) abstract; figures 1-8, 25-37	1-33
X	US 2005/283119 A1 (UTH JOSHUA [US] ET AL) 22 December 2005 (2005-12-22) abstract; figures 1-11, 19, 29	1-33

-/--

[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 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
14 April 2011	26/04/2011

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	Lager, Johan

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/023894

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/277899 A1 (CONLON SEAN P [US] ET AL) 15 December 2005 (2005-12-15) abstract; figures ----- US 2007/149947 A1 (BYRUM RANDAL T [US]) 28 June 2007 (2007-06-28) abstract; figures 1-19 -----	1-33 1-33

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/023894

Box No. 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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 1-33(partially)
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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 all searchable 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 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 and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 1-33(partially)

Although claims 1, 15, 20, 27 and 32 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT. Moreover, the applicant has not filed any drawings. It was also indicated on page 7/7 of the PCT Request that the application shall not contain any drawings. This fact and the way the description is built up render the application to not fulfilling the requirements of Articles 5 and 6 PCT. The different definitions of the subject-matter in the 5 independent claims render the application itself unclear, Article 6 PCT. The description could have helped in order to interpret the claims. However, the description relies merely on references to the not present drawings rendering the application not sufficiently disclosed, Article 5 PCT. It is presently, in the absence of the drawings, not possible to figure out what is meant by the features defined in the claims or referred to in the description. In order to enable some sort of search, an implantable injection port having a base/body, a cap (?), a handle (?) and anchoring means has been searched.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/023894

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