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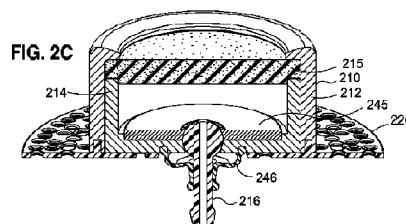
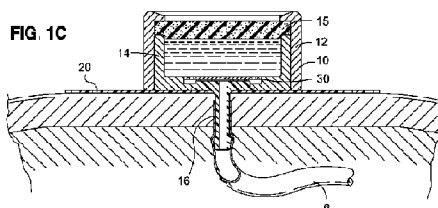
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(54) **Title:** IMPLANTABLE BOTTOM EXIT PORT

(57) **Abstract:** The present invention provides a system for attaching a fluid access port to a patient. The system generally comprises an implantable access port (10, 210) with a bottom exit port (16, 216) and method for attaching an access port to a patient. In addition, a tube guard (30), flexible tube exit port (16, 216), tissue guard, and porous coupling member (20, 220) are disclosed.



IMPLANTABLE BOTTOM EXIT PORT

BY

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RELATED APPLICATIONS

[0001] This application is a continuation-in-part of, and claims priority to and the benefit of U.S. Patent Application No. 12/904,422, entitled "IMPLANTABLE COUPLING DEVICE" filed on October 14, 2010, which is a continuation-in-part of U.S. Patent Application No. 12/772,039, entitled "SYSTEM INCLUDING ACCESS PORT AND APPLICATOR TOOL" filed on April 30, 2010, which claims priority to and the benefit of U.S. Provisional Patent Application No. 61/237,641, filed on August 27, 2009, and U.S. Provisional Patent Application No. 61/236,869, filed on August 26, 2009, all of these applications are hereby expressly incorporated by reference herein.

FIELD

[0002] The present invention generally relates to medical systems and apparatus and uses thereof for treating obesity or obesity-related diseases, and more specifically, relates to access ports and methods for applying the same to bodily tissue.

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, the food held in the upper portion of the stomach may provide 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] Medical implants, including gastric band systems, for performing therapeutic functions for a patient are well known. Such devices include pace makers, vascular access ports, injection ports (such as used with gastric banding systems) and gastric pacing devices. Such implants need to be attached, typically subcutaneously, in an appropriate place in order to function properly.

[0005] Many implantable medical devices are secured with sutures. For example, when inserting a gastric band and an associated access port, the associated access port may be sutured into place with sutures against the rectus muscle sheath. Such placement of the sutures is often challenging because the associated access port is placed below several inches of bodily tissue (e.g., fat), and suturing the associated access port often takes as long as placing the gastric band itself.

[0006] Additionally, the sutures can cause post surgical pain for the patient due to the inherent pulling and slight tearing of the tissue pieces by and adjacent to the suture.

[0007] Also, it is common for medical professionals desiring to add or remove fluid via a needle through the access port to palpitate the skin to locate the implanted port. The medical professional has a general idea of the top surface of the port,

but occasionally will accidentally miss the septum and puncture the tube and/or tissue surrounding or adjacent to the port.

[0008] Further, some body-related systems utilize retention geometry for the access port attachment such as Bestetti, et al., U.S. Patent No. 6,270,475. However, Bestetti discloses a percutaneous access port not a subcutaneous access port. Similarly, Svensson, et al., U.S. Patent No. 5,098,397, discloses a percutaneous access port not a subcutaneous access port.

[0009] Accordingly, there remains a need for a procedure to implant medical devices in a quick, easy and efficient manner, utilizing as small of an incision as possible which reduces the likelihood of future discomfort for the patient and protects the elements from errant needle strikes.

SUMMARY

[0010] The present invention, in one embodiment, includes an implantable fluid access port of an adjustable gastric banding system coupled to the tissue of a patient. The port is configured to facilitate fluid transfer to and from the gastric banding system. The device includes a top housing section including a top opening, a septum surface, a bottom exit tube coupling, and a bottom housing section with a substantially circular side wall. A partial interior vessel may be formed between the fluid seal created between the bottom surface of the septum and the interior surfaces of the bottom housing portion.

[0011] In some embodiments, the implantable port may be configured to shield a coupled tube from inadvertent needle puncture using at least one of the orientation of the bottom exit tube coupling, needle entry orientation, or the structures of the body of the implantable port. The bottom exit tube coupling may be configured to provide a partial anchoring of the implantable port in a pre-selected position.

[0012] The device may include a porous coupling member having a top surface and a bottom surface. The porous coupling member may be integral to the implantable fluid access port or coupled to the implantable fluid access port via a coupling agent proximate to the top surface of the porous coupling member for mating with the base of the implantable access port. The porous coupling member may extend in a plane substantially parallel to the base of the bottom housing section and may be configured for anchoring the port to the tissue of the patient. The porous coupling member may be made from injection moldable plastic or rubber. The porous coupling member may be formed as a partial ring shape or a substantially circular shape. The porous coupling member may extend in a plane substantially parallel to the base of the port, including a first portion (proximate to the implantable access port) and a second portion. The first portion may not include a porous surface and the second portion may include a porous surface. The surface that does not include a porous surface may be configured to shield a portion of the patient from contact with a needle.

[0013] The implantable fluid access port may further include a guard plate configured to shield the bottom exit tube coupling and/or a tube from contact with a needle. The guard plate may include channels or openings configured to allow fluid to pass from the partial interior vessel to the bottom exit tube coupling. The guard plate may be internal to the partial interior vessel. The bottom housing section may include surface features for positioning a guard plate and/or channeling fluid from the partial interior vessel to the bottom exit tube coupling.

[0014] In one embodiment, the bottom exit tube coupling may further include a ball joint socket structure and/or coupling technique. In this embodiment, the bottom exit tube coupling may include a boot.

[0015] In some embodiments, the bottom exit tube coupling may be made from a silicon rubber material. The top housing section and the bottom housing section may couple together to place the septum surface under compression. The top housing section and the bottom housing section may be securably coupled together via locking tabs.

[0016] In some embodiments, the implantable fluid access port may further include a mesh material oriented between the implantable access port and a coupling member. A through hole in the mesh material may be configured to allow the coupler to pass through the through hole to mate with the base of the implantable access port. This way, the mesh may be sandwichably held in position. The mesh material may be a pre-fabricated mesh material made from injection moldable plastic or rubber. The port may be implanted subcutaneously.

[0017] In one embodiment, a method of securably coupling an implantable fluid access port of an adjustable gastric banding system configured to facilitate fluid transfer to and from the gastric banding system is disclosed. The method may include subcutaneously coupling an implantable fluid access port having a bottom exit tube coupling to the tissue of a patient, and coupling the tube of an adjustable gastric banding system to the bottom exit tube coupling.

[0018] The method may include protecting the bottom exit tube coupling via a guard plate internal to the port. In some embodiments, the bottom exit tube coupling is made from a silicon rubber material. The port may include a septum configured to receive a needle for fluid transfer. The subcutaneous coupling may be performed via a mesh material oriented between the implantable access port and a coupling member, sutures, and/or using a porous coupler.

[0019] These and other aspects and embodiments of the present invention may be more clearly understood or appreciated by

referring to the accompanying drawings and the detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1A illustrates a gastric band port according to an embodiment of the present invention.

[0021] FIG. 1B illustrates the gastric band port of FIG. 1A and a coupling device according to an embodiment of the present invention.

[0022] FIG. 1C illustrates the gastric band port of FIGS. 1A and 1B and the coupling device of FIG. 1B secured to the tissue of a patient according to an embodiment of the present invention.

[0023] FIG. 1D illustrates an exploded view of the components of the port of FIG. 1A according to an embodiment of the present invention.

[0024] FIG. 1E illustrates a perspective view of a port and a bottom exit extended tube coupling mated with a tube extension according to an embodiment of the present invention.

[0025] FIG. 1F illustrates a side cut-away view of the port and the bottom exit extended tube coupling of FIG. 1E according to an embodiment of the present invention.

[0026] FIG. 2A illustrates an implantable access port comprising a ball and socket bottom exit tube coupling and a coupling device according to an embodiment of the present invention.

[0027] FIG. 2B illustrates the access port and the coupling device of FIG. 2A mated together according to an embodiment of the present invention.

[0028] FIG. 2C illustrates a side cut-away view of the port and the coupling device of FIG. 2B according to an embodiment of the present invention.

[0029] FIG. 3A illustrates a perspective view of an alternative port according to an embodiment of the present invention.

[0030] FIG. 3B illustrates a perspective bottom view of the port of FIG 3A according to an embodiment of the present invention.

[0031] FIG. 3C illustrates a side cutaway view of the port of FIG 3A according to an embodiment of the present invention.

[0032] FIG. 3D illustrates an exploded view of the components of the port of FIG 3A according to an embodiment of the present invention.

[0033] FIG. 4 illustrates an implantable access port comprising a side exit tube coupler according to an embodiment of the present invention.

[0034] FIG. 5A illustrates a perspective view of an implantable access port comprising a bottom exit tube coupler positioned directly in the tissue of a patient according to an embodiment of the present invention.

[0035] FIG. 5B illustrates a top perspective view of the access port of FIG. 5A according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0036] The present invention relates to implantable medical devices and fasteners therefore and more specifically to access ports and methods for applying the same to bodily tissue. Specifically, the present invention is directed to a subcutaneous implantable gastric banding system including a subcutaneously attached access port coupled to bodily tissue. In some embodiments, a tube and component guard plate, a flexible exit tube coupling and/or a flexibly oriented exit tube coupling, bottom exit tube orientation and/or a tissue guard may reduce pain caused by errant needle sticks / strikes or reduce the need for follow-up surgery to repair damaged components.

[0037] In various embodiments, the present invention utilizes tube guards, component guards, tissue shields, pre-fabricated

mesh and porous coupling devices and/or combinations thereof to protect the patient from unnecessary pain or discomfort. In some embodiments, a mesh material and/or coupling device (described in greater detail below) may be used to anchor an access port to a patient's tissue. For example, the mesh material may encourage tissue ingrowth or tissue engagement through holes and spaces of the mesh material. This use of mesh materials to anchor the access port using the patient's own tissue engagement may obviate the need for sutures during implantation. For example, where access port implantation may occur using sutures, during recovery and beyond, movement of the patient may cause discomfort due to a pulling and slight tearing of the tissue around the implantation site. Use of a porous coupling device or prefabricated mesh material according to embodiments of the present invention may eliminate or substantially reduce this discomfort.

[0038] In accordance with various embodiments, FIGS. 1A-1D illustrate simplified views of an access port **10** for use in conjunction with an implantable medical device, such as an implantable gastric banding system. The access port **10** may comprise a septum **15** for passing fluid into the access port **10**, or removing fluid by means of the access port **10**, via a needle. The access port **10** may provide a convenient means for inflating and/or deflating a conventional gastric band, thereby enabling adjustment of a size of a stoma or a level of restriction on a patient's stomach. A tube **6**, coupled to or integral to the access port **10**, passes the fluid from the access port **10** to and from the gastric band. The access port **10** is generally fixed within the interior of a patient's body, preferably secured to a patient's abdominal muscle.

[0039] In various embodiments, the access port **10** comprises at least one anchoring surface **8**. The anchoring surface **8** may comprise any suitable anchoring surface, such as a latch, clip,

hole, ridge, recess, surface deformity, notch, flange and/or the like. The housing of the access port **10** may comprise any suitable geometry, such as conical, cylindrical, square, block, and/or the like. The side wall of the housing of the access port **10** may comprise a surface transition to assist the operation of the anchoring surface **8**.

[0040] With continued reference to FIG. 1B, and in accordance with various embodiments, a coupler **20** for assisting with the anchoring of the port **10** is depicted. The coupler **20** may comprise any suitable geometry. In one embodiment, the perimeter of the coupler **20** is larger than and extends away from the port **10** in a plane parallel to the bottom surface of the base of the housing of the port **10**. The portion of the coupler **20** extending beyond the base of the housing may extend outwardly from and substantially circumscribe the base, or may extend only partially around the base of the port **10**. The coupler **20** comprises a top surface and a bottom surface. The side surface of the coupler **20** may be any suitable shape such as curved or straight with any suitable thickness. The top surface of the coupler **20** comprises coupling agents **24** configured to attach the coupler **20** to the base of the port **10**. These coupling agents **24** may be any suitable material and shape. For example, these coupling agents **24** may be glue, epoxy, welds, such as ultrasonic welding, posts, surface features, knobs, bolts, screws, barbs, clamps, clips and/or the like, and combinations thereof.

[0041] In one embodiment, as illustrated in FIG. 1B, the coupling agent **24** comprises one or more posts configured to create an interference fit with an opening of the anchoring surface **8** of the port **10**. This interference fit may be a press fit, a friction fit, or a push fit. In one embodiment, the coupling agent **24** may be configured to latch onto the previously described surface transition of a side wall of the port **10** housing (not depicted). In various embodiments, the coupler **20**

may be integrally molded into or as part of the base of the housing of the port **10**.

[0042] Further, in an embodiment, a portion of the coupler **20** may be porous. For example, a plurality of through holes **22** may pass from the top surface to the bottom surface of the coupler **20**. These through holes **22** may be configured to allow for tissue ingrowth or tissue engagement through the through holes **22** to serve as or assist with the anchoring of the port **10** with the patient. The through holes **22** may be formed in any configuration. For example, the spacing of the holes may be regular or irregular. The through holes **22** may be formed in substantially the entire surface of the coupler **20** or the through holes **22** may be located in a particular portion(s) of the coupler **20**. For example, the through holes **22** may be located towards the outer perimeter of the coupler **20** leaving a portion of the surface without through holes **22** proximate the base of the port **10**.

[0043] Further, in accordance with various embodiments, FIG. 1B illustrates a perspective view of the coupler **20** having a tissue shield **90**. For example, the coupler **20** may comprise a first portion **91** without the through holes **22** and a second portion **92** having the through holes **22**. The first portion **91** without the through holes **22** may act as a tissue guard protecting the surface underneath the first portion **91** from contact with the needle. The likelihood of errant needle sticks / strikes is proportional to the distance from the access port **10**. Stated another way, as the distance away from the access port **10** increases, the likelihood of errant needle strikes decreases. Thus, in one embodiment, the second portion **92** comprising through holes **22** is located towards the exterior perimeter of the coupler **20** and the first portion **91** without the through holes **22** is located near the access port **10**. In this embodiment, though it may be any suitable length, the tube guard

60 extends from the access port **10** to the outer perimeter of the coupler **20**.

[0044] In one embodiment, the coupler **20** may comprise one or more flanges (not depicted) configured to support the flexing of the anchoring surface of the patient, such as the patient's abdominal wall adjacent to and coupled to the bottom surface of the coupler **20**. For example, the flange **26** may be formed by forming a groove in the coupler **20**. The coupler **20** may be made from any suitable material. For example, the coupler **20** may be made from an injection molded plastic material, injection molded rubber material, compression molded material, transfer molded material, over-molded plastic over mesh, and/or the like. In one embodiment, the coupler **20** may be integral to a surface, such as the bottom surface of the port **10**.

[0045] Turning now to FIG. 1C, in accordance with an embodiment, the top surface of the coupler **20** is depicted as being mated with the bottom surface of the port **10**. At least a portion of the coupler **20** extends beyond the bottom surface of the port **10**. The coupling agents **24** are sized to create an interference fit with the anchoring surface **8** of the port **10** to facilitate connecting the coupler **20** to the port **10**. The bottom surface of the coupler **20** is depicted as being mated with the top surface of a portion of the patient such as the tissue of the patient. A portion of the coupler **20** may be used as an attachment point to suture, staple, tack or otherwise fasten the access port **10** to the patient's body.

[0046] With further reference to FIG. 1C, according to an embodiment, a portion of the through holes **22** allows tissue growth up through the through holes **22** and above the top surface of the coupler **20**. A portion of the through holes **22** allows tissue growth up through the through holes **22** to the bottom surface of the port **10**. In one embodiment, a spacer disposed between, on, near, or integral to the coupling agents **24** creates

a gap between the coupler **20** and the bottom surface of the port **10** to allow tissue growth through substantially one or more through holes **22**.

[0047] In this manner, the body's own tissue may grow into the coupler **20** and act as an anchoring mechanism. This anchoring mechanism may be more comfortable for the patient post surgery than previous access port anchoring methods and techniques.

[0048] In another embodiment, a mesh material may be molded onto a biocompatible material such as injection molded plastic or a rubber coupler having the coupling agents **24**. In one embodiment, the pre-fabricated mesh material may be sandwichably oriented between the access port **10** and a clip or coupler. Principles of the present disclosure may suitably be combined with design and principles for implantable ports and mesh material as disclosed in a co-pending U.S. Patent Application No. 12/904,422, entitled "IMPLANTABLE COUPLING DEVICE" filed on October 14, 2010, the contents of which is hereby incorporated by reference in its entirety.

[0049] Turning now to FIG. 1D an exploded view of an embodiment of the present device **100** is presented. In this embodiment, the port **10** comprises a top housing section **12**, a septum **15**, a guard plate **30**, a bottom exit tube coupling **16**, a bottom housing section **14**, and a coupler **20**.

[0050] The top housing section **12** comprises a substantially circular side wall and a substantially ring shaped top opening. The top opening may be sized to permit suitable access to the septum surface **15**. The thickness and height of the substantially circular side wall may be any suitable thickness. The interior of the top housing section **20**, as shown in FIG. 1D, comprises a substantially circular smooth interior surface. This substantially circular interior surface may be shaped to mate with a surface of the bottom housing section **14**, such as the exterior surface of the bottom housing section **14**.

[0051] The septum **15** may be any suitable shape or dimension. In one embodiment, the thickness and diameter of the substantially circular septum **15** is sized to be secured in place by an interference fit between the top housing section **12** and the bottom housing section **14**. The septum **15** may be made from any suitable material configured to be self-sealing after the puncture of a needle.

[0052] The bottom exit tube coupling **16** may be configured to be coupled to the tube **6**. In this manner, the bottom exit tube coupling **16** may facilitate the transfer of fluid from the port to the tube **6**. The bottom exit tube coupling **16** is oriented to couple with the tube **6** in a direction substantially normal to the bottom surface of the port **10**, such as the bottom surface of the bottom housing section **14**, away from the port **10**. Stated another way, the connection of the port **10** to the tube **6** is downward (e.g. out the bottom of the port).

[0053] The first end of the bottom exit tube coupling **16** is shaped and sized for any suitable coupling, such as for an interference fit, with a portion of the bottom housing section **14** (as shown in FIGS. 1C and 1D). The bottom exit tube coupling **16** may be made from a relatively flexible material, such as a silicon rubber material for making a fluid tight connection with the bottom exit tube coupling **16**. The second end of the bottom exit tube coupling **16** is shaped and sized for an interference fit with the end of the tube **6** (as shown in FIG. 1C). The second end may be fashioned with a surface feature for securably attaching to the tube **6** or the tube **6** may be fashioned with a surface feature for securably attaching to the bottom exit tube coupling **16** or a combination thereof.

[0054] Moreover, the bottom exit tube coupling **16** may be made from a relatively flexible (non-rigid) material, such as a silicon rubber material, to provide generous strain relief to movement at the base of the port **10** and/or to aid in reducing

the discomfort to the patient as compared with previous rigid tube coupling structures.

[0055] The length of the channel on the bottom exit tube coupling **16** between the bottom of the bottom housing section **14** and the connection with the tube **6** may be any suitable length. For instance, the length between the bottom of the bottom housing section **14** and the connection with the tube **6** may be about a centimeter or the length may be tens of centimeters.

[0056] As discussed above, the bottom housing section **14** is shaped to securably couple to the top housing section **12** via any suitable coupling method, such as via an interference fit or press fit, or by being clamped, adhered using adhesive, or otherwise coupled to the top housing section **12**. The interior of the bottom housing section comprises a substantially ring shaped opening. The bottom surface of the septum **15** and the interior surface of the bottom housing section **14** form a partial interior vessel of the port. The bottom housing section **14** further comprises surface features for housing the guard plate **30**. These surface features may include an opening for the guard plate **30** to be press fit into, where the opening is slightly smaller than the diameter of the guard plate **30** creating a tight press fit between the bottom housing section **14** and the guard plate **30**. The bottom housing section **14** surface features may be raised support elements **31** to lift the guard plate **30** above a channel(s) **35** in the bottom exit tube coupling **34** and/or the bottom interior surface of the bottom housing section **14** may be fashioned into channels to allow the passage of fluid. For instance, these channels allow the passage of a fluid from the partial interior vessel of the port **10** through strategically placed openings **32** in the guard plate **30** to the bottom exit tube coupling **16** and to the tube **6**.

[0057] The guard plate **30** may be secured to the bottom housing section **14** by any suitable means, such as through an

interference fit. In another embodiment, the guard plate **30** may have more or fewer openings (as compared to FIG. 1D) at regular or irregular intervals in any suitable location on the guard plate **30**. The guard plate **30** may be made from any suitable material for protecting device elements from needle strikes. For instance, the guard plate **30** may be made from titanium or stainless steel.

[0058] In one embodiment, the openings **32** in the guard plate **30** may be narrow, long openings sized smaller than the diameter of the needle point to reduce the likelihood of the needle becoming stuck in the opening **32**. These openings **32** may be placed towards the edge of the guard plate **30** passing from the top surface of the guard plate **30** to the bottom surface of the guard plate **30**. The guard plate **30** may be any suitable shape such as a flat disc shape. In other embodiments, the guard plate **30** may be shaped with a tapering bottom or other surface features or markings such as grooves or slots to position the guard plate **30** in a specified orientation.

[0059] Optionally, and with reference to FIGS. 1E and 1F, the coupler **20** may be replaced with a suture, mesh or other coupling means. For instance, the exterior of the top housing section **12** may be fashioned with surface features **18**, such as suture holes, to suture the port **10** to a patient.

[0060] An implantable port device **210** according to various embodiments is depicted in FIGS. 2A-2C. In such embodiments, the implantable port device **210** comprises a top housing section **212**, a septum **215**, an optional guard plate (not shown), a bottom exit tube coupling **216**, a bottom housing section **214**, a boot **246**, a top plate **245** and a coupler **220**.

[0061] The interface between the first end of the bottom exit coupling **216** and the bottom housing section **214** is a fluid tight ball joint system. This ball joint system may include a rounded top section configured to sit in a mating rounded bottom opening

of the bottom housing section **214** having a slight taper. In this manner the bottom exit coupling **216** may move and/or rotate without losing the fluid seal in the internal vessel.

[0062] In this embodiment, the orientation of the tube **6** and/or the position of the surrounding tissue can dictate the orientation of the bottom exit tube coupling **216**. This may reduce discomfort by the patient and reduce stress and strain on the tube **6** as the patient moves. In this embodiment, the bottom exit coupling **216** may be made from any suitable material such as a rubber or a semi-rigid or rigid medical grade plastic or polymer.

[0063] A top plate **245** (as shown in FIG. 2C) may be used for securing the ball joint into position. Stated another way, the bottom exit coupling **216** ball joint may be fed through the opening in the bottom housing section **214** and then a top plate **245** may sandwichably create a sealing joint which allows for pivoting movements due to a low coefficient of friction of the mating materials. The top plate **245** may be secured to the bottom housing section **214** by any suitable means, such as by a press fit, or by being clamped, or adhered using adhesive. In some embodiments, the single opening in the ball joint bottom exit coupling **216** leading from the partial internal vessel may be replaced with one or more smaller holes which couple to the interior channel. This configuration may reduce the chance of the needle becoming stuck in the opening of the ball joint bottom exit coupling **216**. In some embodiments, the ball joint of the bottom exit coupling **216** may pivot up to a 30 degree angle from a central axis in 360 degrees around the axis.

[0064] Optionally, a boot **246** may be coupled around a portion of the bottom exit coupling **216** and to the bottom exterior surface of the bottom housing section **214** to form a secondary fluid seal. The boot **246** may be coupled to the bottom exit coupling **216** by any suitable means such as a press fit. Also, the boot

246 may be coupled to the bottom housing section **214** by any suitable means, such as with a press fit and/or by being adhered. The boot **246** may be made from any suitable material, such as a flexible rubber material.

[0065] In one embodiment, a guard plate **230** may be coupled to the partial interior vessel of the port **210** to protect the internal port **210** elements from needle strikes. Optionally, the coupler **220** may be replaced with a suture, mesh or other coupling means.

[0066] Another configuration of an implantable port device **310**, according to various embodiments, is depicted in FIGS. 3A-3D. In such embodiments, the implantable port device **310** comprises a top cap **352**, a septum **315**, an internal ring **354**, one or more lock tabs **356**, a guard plate **330**, a molded flange **358**, and a bottom cap **360**. The implantable port device **310** may be a low cost option which does not require some of the press fit couplings of previously described embodiments.

[0067] The septum **315** may be inserted up, into and/or partially through the top cap **352**. The internal ring **354** may be placed between the guard plate **330** and the septum **315**. The molded flange **358** may be inserted down into and at least partially through the bottom cap **360**. The septum **315**, the internal ring **354** and the guard plate **330** may be inserted into the bottom cap **360**. The septum **315** and the top cap **352** may be mated with the bottom cap **360** and other elements of port **310**. One or more locking tabs **356** may be inserted into apertures to securably couple the top cap **352** to the bottom cap **360**. An internal fluid seal is created by assembling the implantable port device **310** as described above.

[0068] In one embodiment, the septum **315** may be made from silicon rubber. The formed rim of the septum **315** is under compression creating a fluid tight seal after assembly is

complete. The internal ring **354** holds down the guard plate **330** and aids in creating the seal against the septum **315**.

[0069] In one embodiment, as shown in FIG. 3C, a slight radial interference between the guard plate **330** and the molded flange **358**, plus compression by the internal ring **354**, positions the guard plate **330** in place. In some embodiments, the top cap **352**, the septum **315**, the internal ring **354**, and the bottom cap **360** comprise semi-rigid to rigid materials while the one or more locking tabs **356**, the septum **315**, and the molded flange **358** comprise soft flexible materials. The interference between the rigid components and the soft rubber components create a fluid seal and maintain a load on the locking tabs **356** to hold the locking tabs **356** in place over time.

[0070] The clearance between the edge of the metal plate and several locations (such as indentations **332**) on the molded flange **358** allow the fluid internal to the port **310** to transfer from the internal vessel of the port **310** to the molded flange **358** through the channels **335** molded into the geometry of the molded flange **358**. Additionally, structural support to lift the guard plate **330** above the channels **335** is provided by molded portions **331** in the molded flange **358**. In an embodiment, the coupler **318** may be replaced with a porous coupling member, mesh or other coupling means. The molded flange **358** may be made of any suitable material for flexing, such as molded silicon rubber. Additionally, strain relief on the molded flange **358** may be increased if desired by altering the geometry of the molded flange **358**.

[0071] The conduit towards the bottom of and integral to the molded flange **358** may be made from any suitable material. For instance, the molded flange **358** may be made from one or more materials such as silicon rubber. A silicon rubber conduit allows for generous strain relief at the potential flex points

with no metal or rigid stem connector. The rigid stem connector may increase the joint stress at the tube **6** coupling point.

[0072] Previous ports have utilized side exiting and/or rigid tube coupling structures (as depicted in FIG. 4). These structures may be susceptible to strain and/or needle puncture. Moreover, these side exiting tube **6** coupling structures often utilize an eventual turn of the tube **6** from the relatively horizontal direction to a relatively vertical position depending on the implantation point of the port. This places the tube **6** under stress and under strain at the point of change in direction. Additionally, if these side exiting ports are not suitably secured to the tissue of the patient, they may become misaligned. The flexible down stream tube **6** inserted in the patient may not provide support for the unsecured side exiting ports. For instance, an improperly secured side exit port may flip partially over or become inverted (as depicted by the arrow in FIG. 4). A partially flipped or inverted port may be unsuitable for fluid transfer via needle and/or require a surgical procedure to re-orient the device. For instance, the septum surface may be inaccessible by a needle.

[0073] The bottom exit tube coupling **358** orientation in the downward direction (relative to the base of the port **310**) reduces the stress and strain placed on the tube **6** by reducing the need to bend the tube **6** from the relatively horizontal direction to the relatively horizontal direction as compared with a side exiting tube coupling. Also, the orientation of the bottom exit tube coupling **358** naturally protects the tube **6** from needle puncture. In this manner, the body of the implantable port **310** and the direction of needle insertion substantially in line with the bottom exit tube coupling **358** may protect the needle from puncture. Additionally, the physical structure of the bottom exit tube coupling **358**, which exits via the base of the port **310** substantially inline with the needle insertion

direction, stabilizes the position of the port **310**. This physical structure (i.e., a bottom exit port coupling **358** as shown in FIGS. 5A and 5B) reduces the likelihood that the port **310** will become misaligned and/or partially flip or invert. In some embodiments, a bottom exiting port coupling will physically not be able to flip after insertion in the tissue of the patient. In this manner, the bottom exit port coupling **358** functions as an anchor and/or partial anchor of the device in a pre-selected orientation and/or position. This may also orient the implantable port **310** in a position where the septum is easily targeted by an approaching needle. In some embodiments, the exterior surface of the bottom exit coupler **358** may be altered to comprise surface features for securing and or orienting the port **310**. For instance, in an embodiment, the exterior surface of the bottom exit coupler **358** may be barbed.

[0074] In one embodiment, the elements of the implantable port and/or coupler may be coated with a bioresorbable material, for example, to encourage biological compatibility between the device elements and the body tissue. The coating may cover the entirety of the device elements or only a portion of the device elements. A thickness of the coating may be even, or may vary along the surface of the device elements. The coating may be deposited through a process including a spraying process, dipping process, molding process, wiping process, or other equivalent means of attaching the bioresorbable material to the device elements. The coating thickness may vary between approximately 0.001 inches and 0.25 inches. The bioresorbable material serves to form a biological seal between the access port **10** and the body tissue, and to encourage compatibility between the access port **10** and the body tissue.

[0075] The implantable ports described herein may comprise any suitable shape. For instance, the ports may be generally conical, cylindrical, cubical, rectangular prism, or irregularly

shaped. In this manner, the ports may comprise substantially circular side walls or non-circular side walls. Also, the ports may comprise top and bottom surfaces with any suitable geometric or non-geometric shape.

[0076] 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.

[0077] 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.

[0078] 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 inventor expects 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.

[0079] Specific embodiments disclosed herein may be further limited in the claims using "consisting of" or "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.

[0080] 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 access port for use with a gastric band for the treatment of obesity, the implantable access port comprising:

a septum surface;

a top housing section comprising a top opening for the septum surface;

a bottom exit tube coupling that provides a partial anchoring of the implantable access port in a pre-selected position; and

a bottom housing section, wherein a partial interior vessel is formed by a fluid seal created between a bottom surface of the septum surface and an interior surface of the bottom housing section.

2. The implantable access port of claim 1, wherein the implantable port is configured to shield a coupled tube from inadvertent needle puncture using at least one of the orientation of the bottom exit tube coupling, needle entry orientation, or the structures of body of the implantable port.

3. The implantable access port of claim 1, further comprising a porous coupling member having a top surface and a bottom surface.

4. The implantable access port of claim 3, wherein the porous coupling member is at least one of integral to the implantable fluid access port or coupled to the implantable fluid access port via a coupling agent proximate the top surface of the porous coupling member for mating with a base of the implantable access port.

5. The implantable access port of claim 3, wherein the porous coupling member extends substantially parallel to the base of the bottom housing section, and

wherein the bottom surface of the porous coupling member is configured for anchoring the porous coupling member to the tissue of the patient.

6. The implantable access port of claim 3, wherein the porous coupling member is made from injection moldable plastic or rubber.

7. The implantable access port of claim 3, wherein the porous coupling member is at least one of a partial ring shape or a substantially circular shape.

8. The implantable access port of claim 3, further comprising:
a first portion of the porous coupling member extending substantially parallel to the base of the bottom housing section, wherein the first portion does not comprise a porous surface; and

a second portion of the porous coupling member extending substantially parallel to the base of the bottom housing section, wherein the second portion comprises a porous surface, and wherein the first portion is configured to shield a portion of the patient from contact with a needle.

9. The implantable access port of claim 8, wherein the first portion is proximate to the implantable access port.

10. The implantable access port of claim 1, further comprising a guard plate configured to shield at least one of the bottom exit tube coupling or a tube from contact with a needle.

11. The implantable access port of claim 8, wherein the guard plate comprises channels configured to allow fluid to pass from the partial interior vessel to the bottom exit tube coupling.
12. The implantable access port of claim 10, wherein the guard plate is internal to the partial interior vessel.
13. The implantable access port of claim 1, wherein the bottom exit tube coupling further comprises a ball joint socket.
14. The implantable access port of claim 13, wherein the bottom exit tube coupling further comprises a rubber boot.
15. The implantable access port of claim 1, wherein the bottom exit tube coupling is made from a silicon rubber material.
16. The implantable access port of claim 1, wherein the bottom housing section further comprises surface features for at least one of positioning a guard plate or channeling fluid from the partial interior vessel to the bottom exit tube coupling.
17. The implantable access port of claim 1, wherein the top housing section and the bottom housing section couple together to place the septum surface under compression.
18. The implantable access port of claim 17, wherein the top housing section and the bottom housing section are securably coupled together via lock tabs.
19. The implantable access port of claim 1, further comprising:
a mesh material oriented between the implantable access port and a coupling member; and

a through hole in the mesh material configured to allow the coupling member to pass through the through hole to mate with the base of the implantable access port.

20. The implantable access port of claim 19, wherein the mesh material is a pre-fabricated mesh material made from injection moldable plastic or rubber.

21. The implantable access port of claim 19, wherein the port is implanted subcutaneously.

22. A method of securably coupling an implantable access port of an adjustable gastric banding system configured to facilitate fluid transfer to and from the gastric banding system, the method comprising:

subcutaneously coupling an implantable fluid access port having a bottom exit tube coupling to the tissue of a patient, wherein the port comprises a septum configured to receive a needle for fluid transfer; and

coupling a tube of the adjustable gastric banding system to the bottom exit tube coupling.

23. The method of claim 22, further comprising protecting the bottom exit tube coupling via a guard plate internal to the port.

24. The method of claim 22, wherein the bottom exit tube coupling is made from a silicon rubber material.

25. The method of claim 22, wherein the subcutaneous coupling is performed via at least one of a mesh material oriented between the implantable access port and a coupling member, sutures, or a porous coupler.

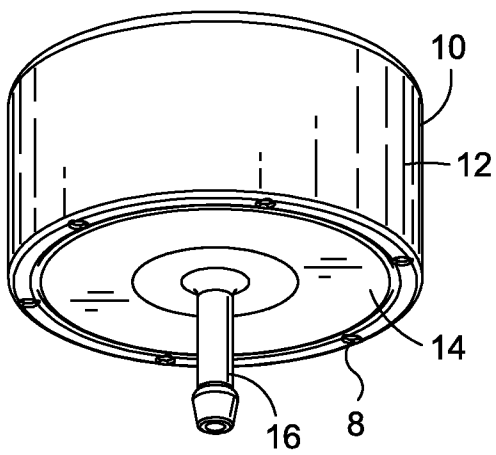


FIG. 1A

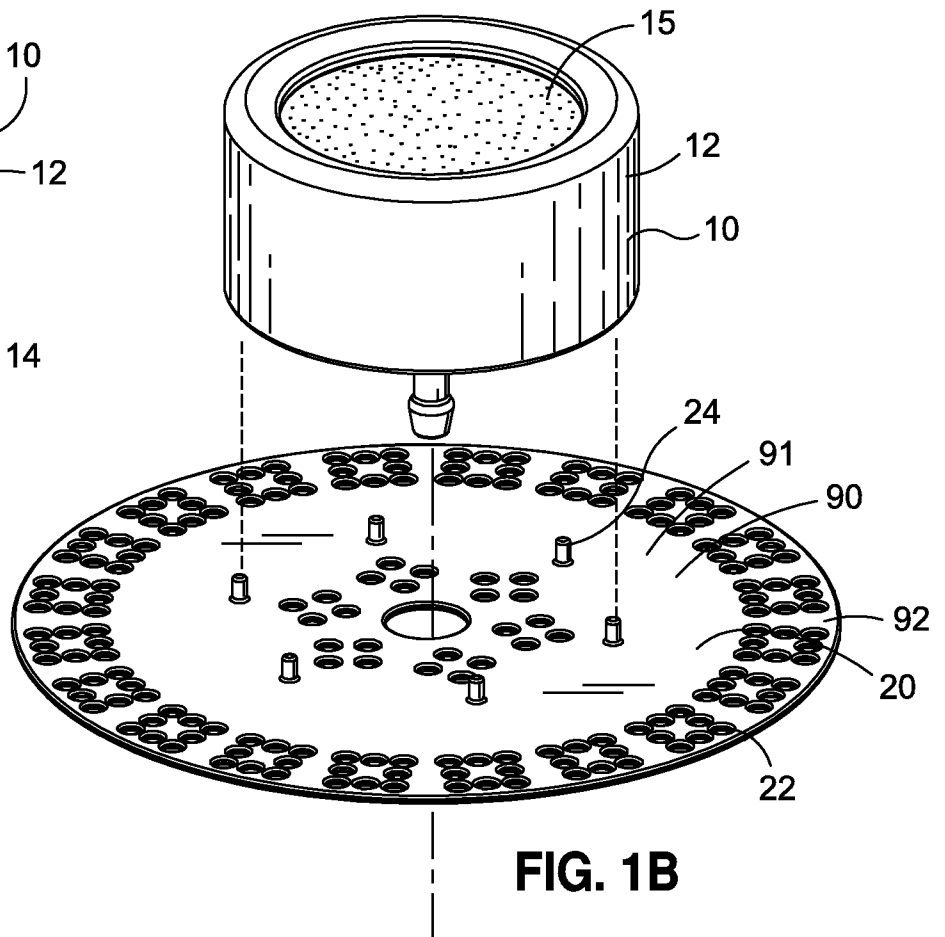


FIG. 1B

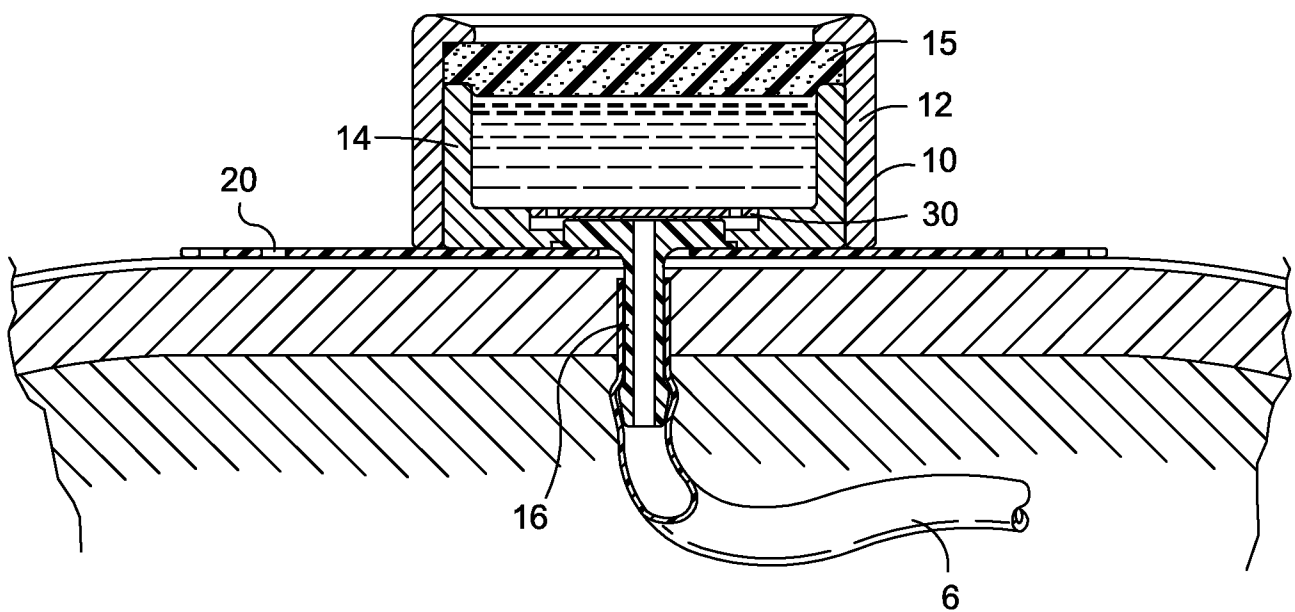


FIG. 1C

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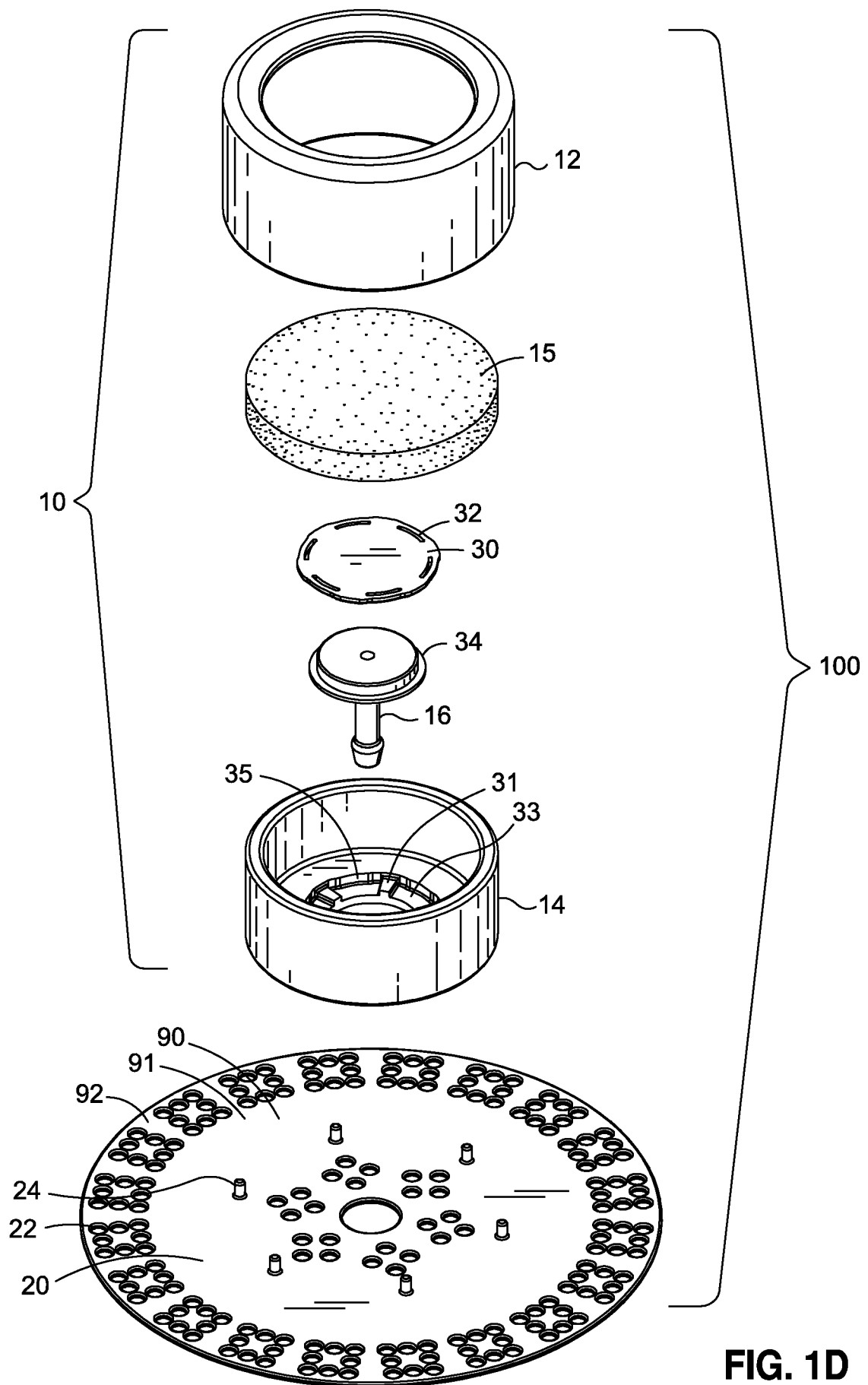


FIG. 1D

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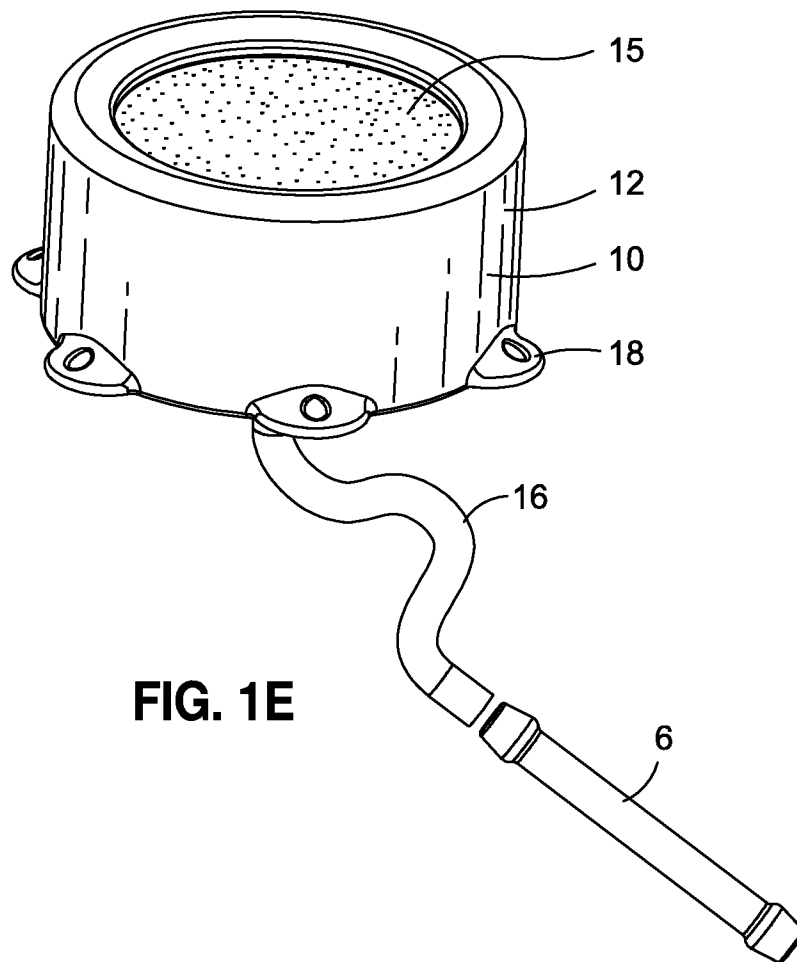


FIG. 1E

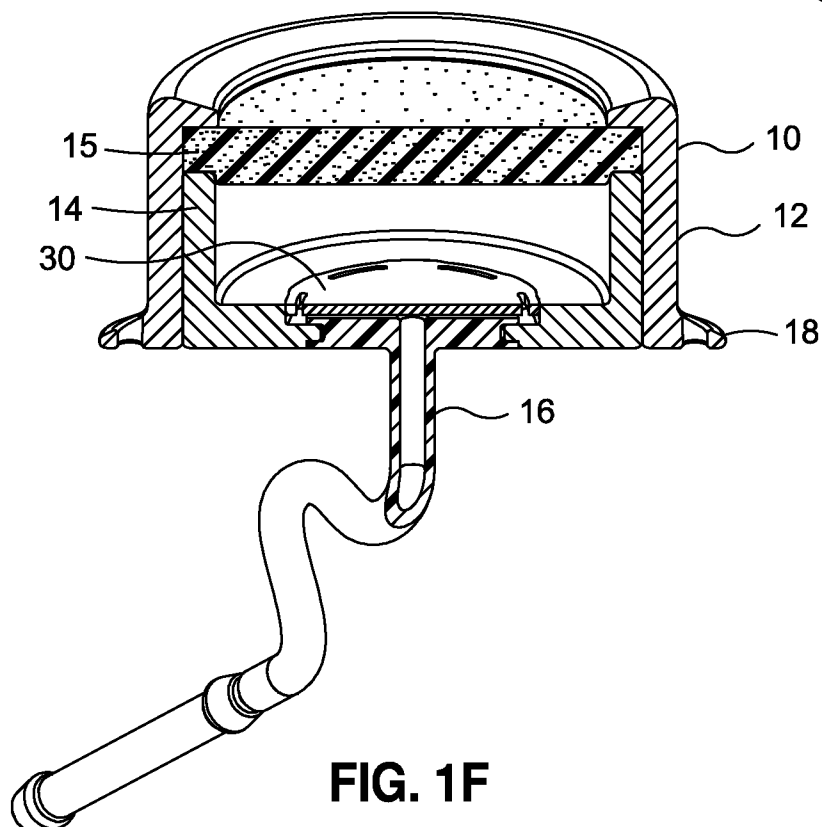
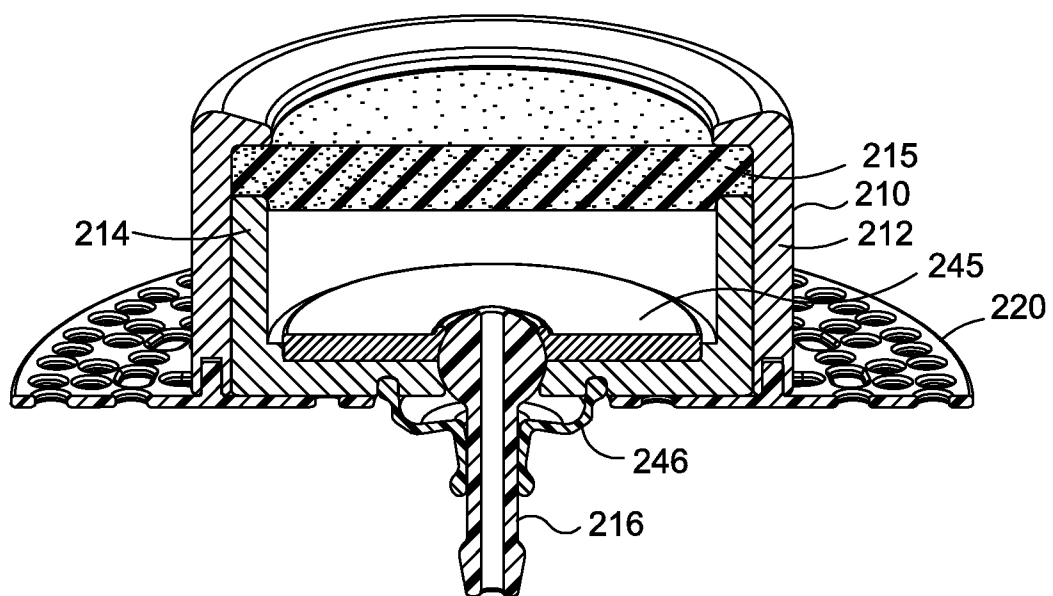
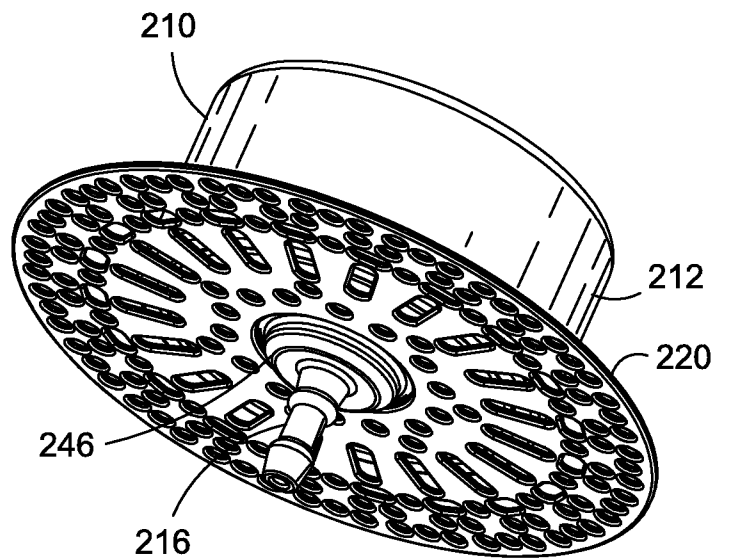
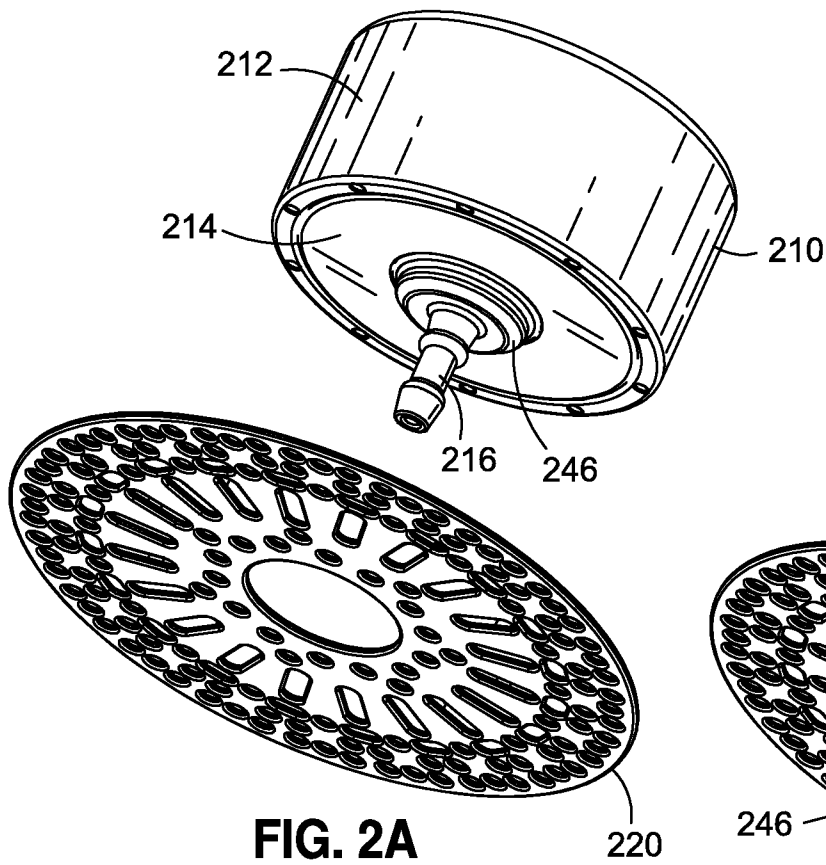


FIG. 1F

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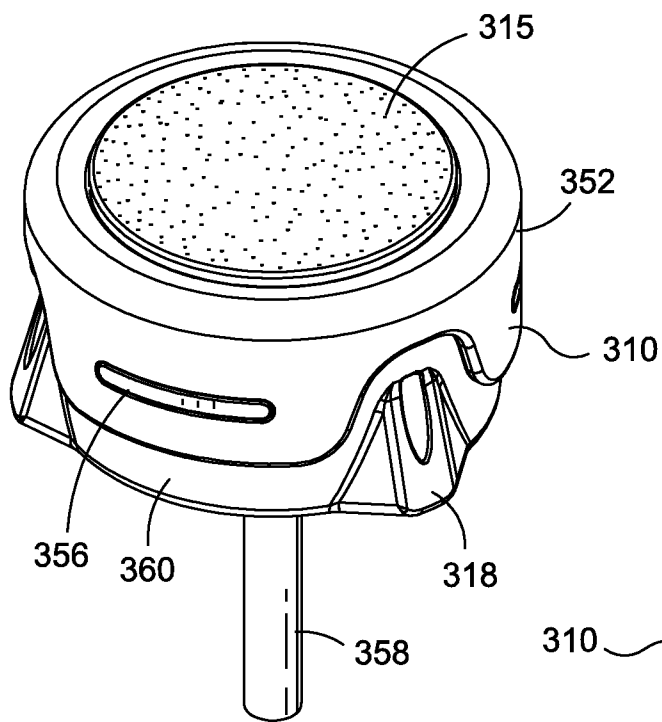


FIG. 3A

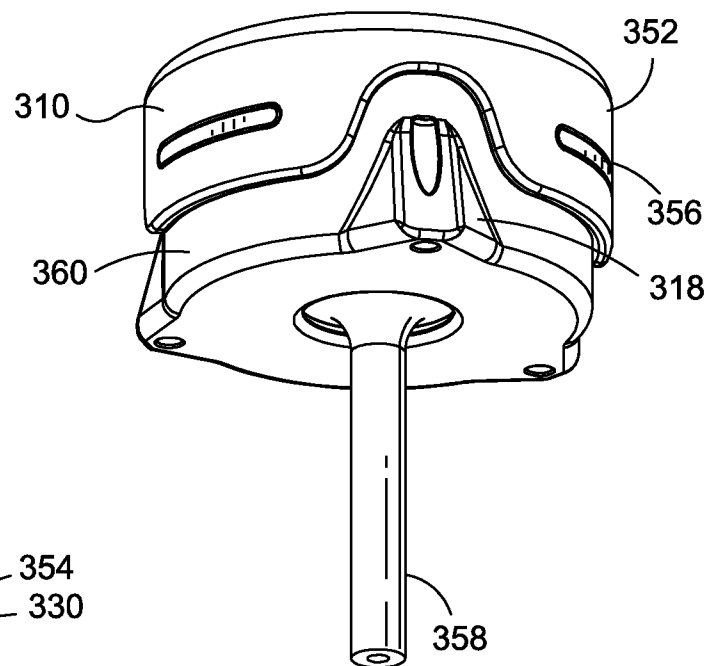


FIG. 3B

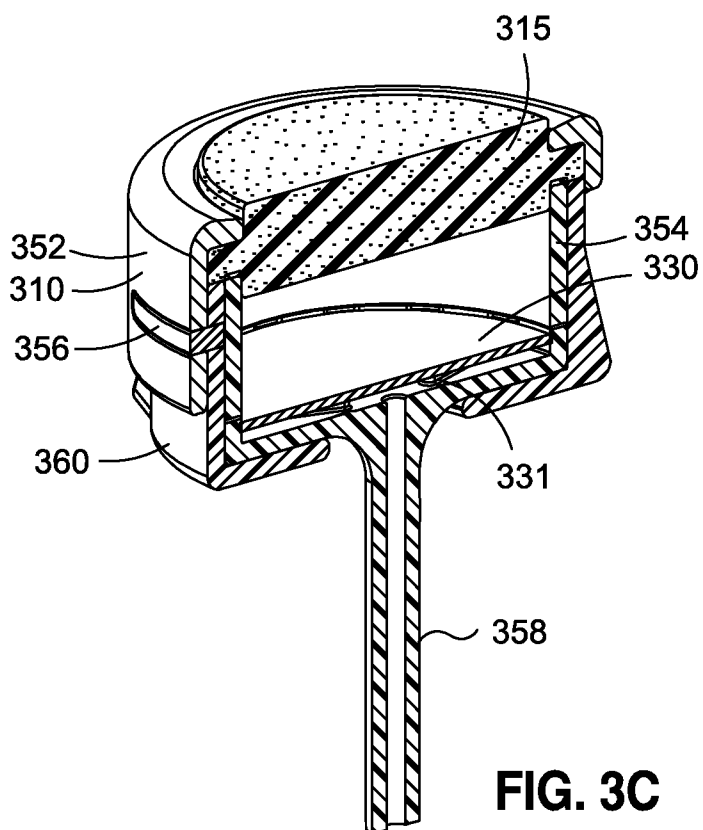
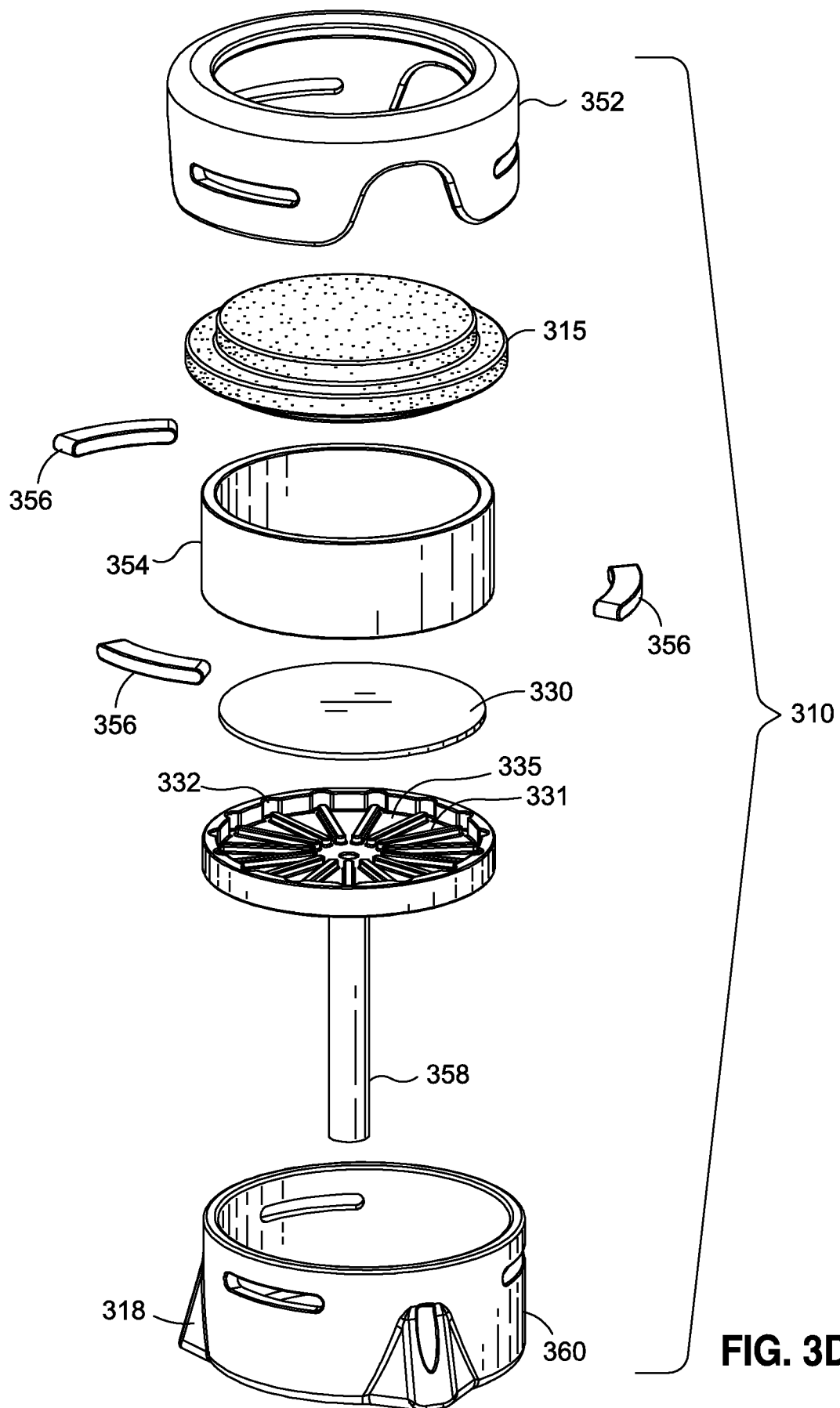


FIG. 3C

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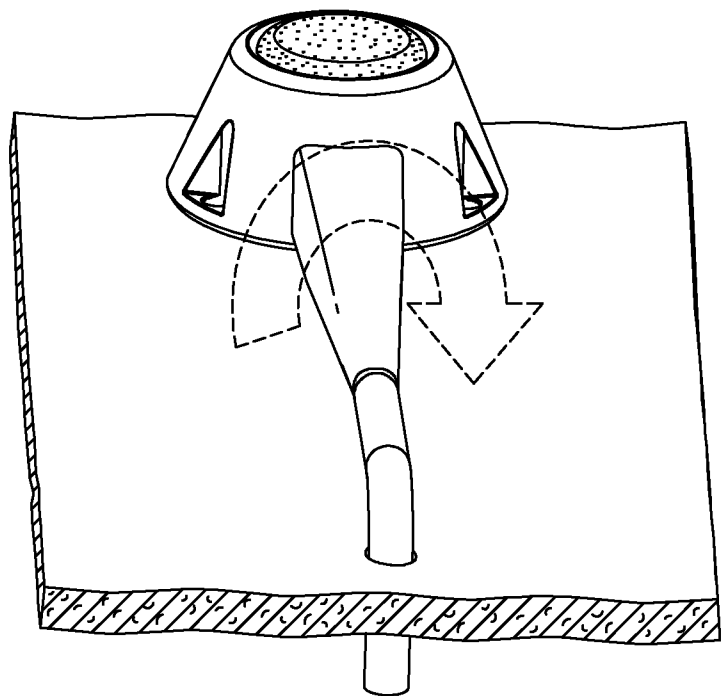


FIG. 4

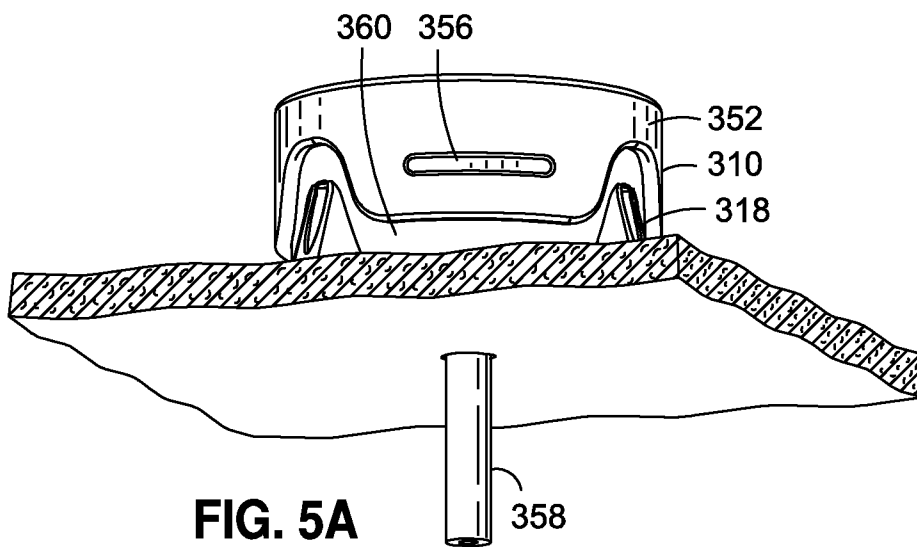


FIG. 5A

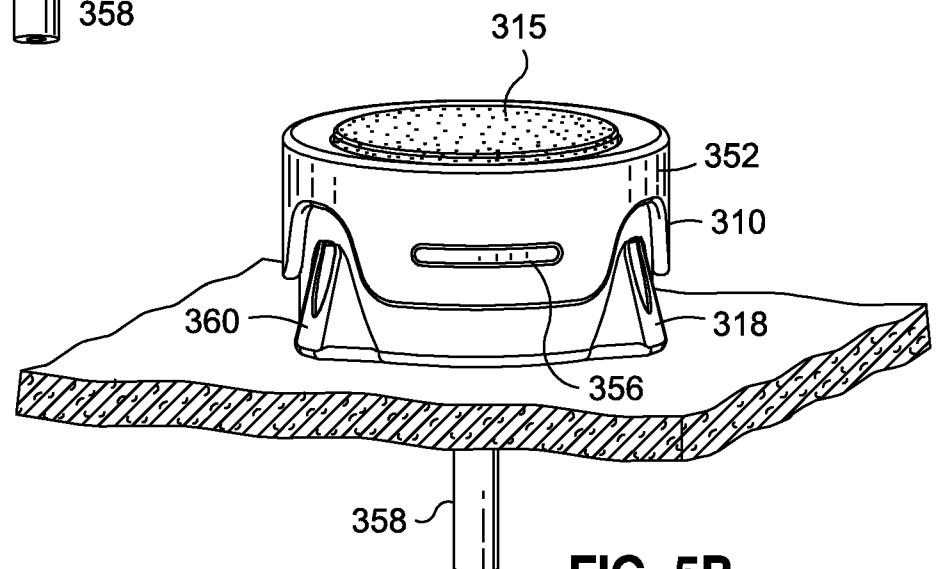
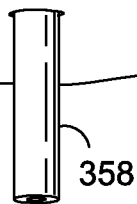


FIG. 5B

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2012/023471

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M39/02

ADD. A61F5/00

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)

A61M 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 practicable, 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	US 2005/240156 A1 (CONLON SEAN P [US]) 27 October 2005 (2005-10-27)	1,2,17
Y	paragraphs [0017] - [0021]; figures 1-3 -----	10-12,16
X	WO 2008/015346 A2 (CIE EURO ETUDE RECH PAROSCOPIE [FR]; ESTEVE MARC JOSE [FR]) 7 February 2008 (2008-02-07)	1,2, 10-12,16
Y	page 7, line 8 - page 28, last line; figures 1-17 -----	10-12,16
X	DE 295 13 230 U1 (TRICUMED GMBH [DE]) 19 October 1995 (1995-10-19)	1,2, 10-12,16
Y	page 3, line 23 - page 7, last line; figures 1-4a -----	10-12,16
X	WO 02/074381 A2 (CONTROL DELIVERY SYSTEMS [US]) 26 September 2002 (2002-09-26)	1,2, 10-12,16
Y	page 4, lines 9-25; figures 1-5 -----	10-12,16
	-/--	



Further documents are listed in the continuation of Box C.



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 application or patent 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

24 April 2012

Date of mailing of the international search report

06/07/2012

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Dennler, Samuel

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2012/023471

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 4 496 343 A (PROSL FRANK R [US] ET AL) 29 January 1985 (1985-01-29)	1,2, 10-12,16
Y	column 4, lines 17-18; figure 2 -----	10-12,16
Y	US 5 137 529 A (WATSON DAVID A [US] ET AL) 11 August 1992 (1992-08-11) column 5, line 12 - column 7, line 22; figures 1-3 -----	10-12,16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/023471

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.: 22-25
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
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:

see additional sheet

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.:
1, 2, 10-12, 16, 17

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

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1, 2, 10-12, 16, 17

An implantable access port comprising a bottom exit tube coupling,
further comprising a guard plate configured to shield at least one of the bottom exit tube coupling or a tube (connected to said tube coupling) from contact with a needle;

2. claims: 3-9, 19-21

An implantable access port comprising a bottom exit tube coupling,
further comprising a porous coupling member with a bottom surface configured for anchoring to the tissue of the patient;

3. claims: 13-15

An implantable access port comprising a bottom exit tube coupling,
wherein the bottom exit tube coupling further comprises specific features allowing it to take various orientations so that stress and strain on the tube as the patient moves;

4. claim: 18

An implantable access port comprising a septum surface, and a housing with a top section housing and a bottom section housing,
wherein the top section housing and the bottom section are adapted to be securably coupled together via lock tabs.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 22-25

Claims 22-25 are related to a method comprising at least the step of subcutaneously coupling an implantable fluid access port to the tissue of a patient. This subject-matter is considered to be covered by the provisions of Rule 39.1(iv) PCT (methods for treatment of the human or animal body by surgery).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/023471

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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