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(54) **NATURAL ORIFICE SURGERY SYSTEM**

CHIRURGISCHES SYSTEM FÜR EINE NATÜRLICHE ÖFFNUNG

SYSTÈME DE CHIRURGIE POUR ORIFICE NATUREL

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## Description

### BACKGROUND

#### Technical Field

**[0001]** This application is generally directed to surgical devices, and more particularly, to a retractor adapted for use with a cap, that is useful in natural orifice single-port surgical procedures.

#### Description of the Related Art

**[0002]** Access devices are commonly used in surgery to facilitate the introduction of various surgical instruments into natural biological vessels, conduits, orifices, cavities, and other interior regions of the body. These access devices include, for example, devices that facilitate the introduction of a needle into a vessel, and trocars that facilitate the introduction of laparoscopic instruments into the abdomen of the body.

**[0003]** Some of these access devices are introduced into regions that include a fluid or gas under pressure. In the case of a needle access device, the pressure may be from a liquid, such as blood. In the case of a trocar, the pressure may be from a gas, such as an insufflation gas. In either case, it is desirable to provide for the introduction of the surgical instrument into the cavity without permitting the escape of the pressurized fluid or gas.

**[0004]** In the case of trocars, a cannula at the distal end of the trocar is typically connected to a seal housing at the proximal end of the trocar. Together the cannula and housing form a working channel through which various instruments can be inserted to access the cavity. Seal mechanisms are commonly disposed in the housing and include a septum valve that seals the working channel when an instrument is in place, and a zero closure valve that seals the working channel when the instrument is removed.

**[0005]** Current surgical access ports allow for single instrument access through each port, or allow for multiple instrument access through a rigid cannula. Some devices, such as transanal endoscopic microsurgery (TEMS) units require that the device be attached to the surgical table to support the weight of the device, as well as to locate the position of the device respective to the patient. These devices do not provide flexibility to the surgeon in selecting instrument size, and they restrict instrument movement with their rigid cannulas. Additionally, surgeons are performing laparoscopic surgical procedures through a single or a limited number of access ports. The procedures may be performed through a single two (2) centimeter incision at the umbilicus, or in certain cases, trans-vaginally or trans-anally. What is needed is a system that meets the needs of these new procedures, facilitating more flexible movement of laparoscopic instruments through a single or limited number of ports while preventing the escape of pressured fluids or gasses and permitting large specimen removal.

WO01/26559 A1 discloses a retractor for retracting the margins of an abdominal wound opening, comprising inner and outer O-rings and a sleeve extending between the inner O-ring and the outer O-ring.

WO 2010/045253 A1 discloses a surgical access system comprising a flexible sleeve extending between an inner ring and an outer ring.

### SUMMARY OF THE INVENTION

**[0006]** The invention is directed to a surgical access port system according to claim 1. Preferred embodiments are defined in the dependent claims.

**[0007]** The surgical access port system comprises a retractor that is adapted for being coupled to a cap and that is adapted for performing natural orifice surgery. The retractor comprises an outer ring, wherein the outer ring is configured to be disposed proximate the natural orifice of the patient and substantially surround the orifice; a tubular body; and a funnel segment extending between and coupling the outer ring and the tubular body, wherein the funnel segment provides a diametric reduction between the relatively large diameter of the outer ring and the relatively smaller diameter of the tubular body, which is sized to fit within a natural orifice with minimal distention of the orifice.

**[0008]** According to the invention, the tubular body comprises a substantially flexible material, such as a KRATON® material, a PELLETHANE® material or a silicone rubber material. The tubular body defines a generally cylindrical sufficiently large such that two or more surgical instruments positioned therethrough can be translated or pivoted relative to one another. In one aspect, the tubular body comprises one or more coatings, such as an antimicrobial coating. In one aspect, the tubular body comprises perforations. In another aspect, the tubular body has opening or windows along the length of the body, to provide access by surgical instruments to the body cavity or orifice.

**[0009]** In one aspect, the funnel segment comprises an inner surface that can provide a bearing surface for an obturator used to advance to the retractor into a body cavity. The funnel segment can have a substantially linear taper between the relatively large diameter of the outer ring and the relatively smaller diameter of the tubular body. In one aspect, the funnel segment has a curved profile between the relatively large diameter and the relatively smaller diameter. In one aspect, the surgical access port system further comprises an obturator.

**[0010]** According to the invention, the surgical access port system further comprises an inner ring, wherein the inner ring is sufficiently flexible to be compressed for insertion into a body orifice, substantially returning to its original shape upon release inside the body orifice. The shape of the inner ring can be one of several geometric shapes, including substantially circular.

**[0011]** These and other features and advantages of

the invention will become more apparent with a discussion of embodiments in reference to the associated drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0012]**

FIG. 1 is a side view of a patient in surgery illustrating an access device positioned on the abdomen and in use.

FIG. **2** is a cross-sectional side view illustrating an access device, with the wound retractor retracting the vagina of a patient, and the gel cap sealing the opening of the wound retractor.

FIG. **3** is a front view illustrating an access device deployed and in use at the mouth of the patient.

FIG. **4** is a top view illustrated a patient in the prone position with an access device deployed and in use at the anus of the patient.

FIG. **5** is a perspective view of an access device comprising a cap and a retractor.

FIG. **6A** is a side view of an embodiment of a natural orifice retractor. FIG. **6B** is a top view of the natural orifice retractor of FIG. **6A.** FIG. **6C** is a partial cut away of the natural orifice retractor of FIG. **6A.**

FIG. **6D** is a side view of another natural orifice retractor. FIG. **6E** is a top view of the natural orifice retractor of FIG. **6D.** FIG. **6F** is a perspective view of the natural orifice retractor of FIG. **6A.**

FIG. **6G** is a perspective view of an obturator adapted to facilitate introduction of a natural orifice retractor into a body orifice such as an anus. FIG. **6H** is a side view of the obturator of FIG. **6G.**

FIG. **7A** is a partial side cross section of the natural orifice retractor of FIG. **6A** with a gel cap coupled therewith to form one embodiment of natural orifice access device.

FIG. **7B** is a side cross section of the natural orifice retractor of FIG. **6D.**

FIG. **7C** is a perspective view of a natural orifice retractor formed from sections and having cut-out portions or windows in the tubular body of the retractor.

FIG. **7D** is a cutaway view of the retractor of FIG. **7C** showing the slidable engagement of the sections.

FIG. **7E** is a cutaway view of the retractor of FIG. **7C** showing the snap-lock mechanism securing the sections together.

FIG. **7F** is a perspective view and a side view of an alternative retractor having cut-out portions or windows in the tubular body of the retractor.

FIG. **8A** is a side view of the natural orifice access device of FIG. **7A.** FIG. **8B** is a top view of the natural orifice access device illustrated in FIG. **7A.** FIG. **8C** is a perspective view of the natural orifice access device illustrated in FIG. **7A.**

FIG. **8D** is a perspective view of the natural orifice retractor of FIG. **6D** with a gel cap therewith to form one embodiment of natural orifice access device.

FIG. **9A** is a perspective view of an embodiment of a natural orifice access device including a cap having a plurality of trocars extending therethrough. FIG. **9B** is a perspective view of another natural orifice access device including a cap having a plurality of trocars extending therethrough.

FIG. 9C is an exploded view of a trocar access device and optional obturator, which is a component of some of the access device systems.

**[0013]** Similar components have similar reference numbers throughout.

## DETAILED DESCRIPTION OF CERTAIN EMBODIMENTS

**[0014]** Surgical instrument access device system are useful, for example, for single incision, single port, and/or limited port laparoscopic surgical procedures, for example, abdominal (FIG. 1), transvaginal (FIG. 2), transoral (FIG. 3), and transanal (FIG. 4) procedures. Various surgical instrument access devices are described in U.S. Patent Application Publication No. 2009/0187079, entitled "SURGICAL INSTRUMENT ACCESS DEVICE," filed January 22, 2009, and U.S. Patent No. 7,727,146, entitled "WOUND RETRACTOR WITH GEL CAP".

**[0015]** FIG. **5** illustrates a perspective view of an access device system **5000** comprising a retractor **5100** and a cap **5500,** which is useful in single port and/or limited port procedures. The retractor or surgical wound retractor **5100** is placed and/or positioned into, across, and/or through a surgical incision and/or body orifice to enlarge, reshape, and/or isolate the incision or body orifice. The cap **5500** provides an artificial body wall through which instruments access the interior of a patient's body, for example, a body cavity. The components of the access device **5000** comprise any suitable biologically compatible materials. The examples of access devices systems shown in FIGS. 1-5 are described in US Patent Application Publication No. US2009/0187079 and PCT Patent Application Publication No. WO2010/045253.

**[0016]** Examples of natural orifice access ports or retractors **6100, 7100** sharing certain similarities are illustrated in FIGS. **6-9.** One embodiment of retractor **6100** is illustrated in FIGS. **6A-6C, 7A, 8A-8C,** and **9A.**

**[0017]** The embodiment of the natural orifice access port or retractor **6100** illustrated in a side view in FIG. **6A** can be adapted for use in a transanal surgical procedure. The retractor **6100** comprises an inner or distal ring **6110,** an outer or proximal ring **6120,** a tubular body **6130,** and a funnel segment **6140** extending between and coupling the inner ring **6110** and the outer ring **6120.** The tubular body **6130** comprises a relatively flexible material such as a KRATON® material or a silicone rubber material, which is substantially cylindrical in the illustrated embodiment. In other embodiments, the tubular body **6130** has another shape, for example, an oval cross section. Some

embodiments of the tubular body **6130** comprise one or more coatings that provide additional functionality, for example, an anti-microbial coating.

**[0018]** Embodiments of the inner ring **6110** are sufficiently flexible and compliant to be compressed and/or deformed for insertion into a body orifice such as a patient's anus during a transanal surgical procedure. When subsequently released within an associated body cavity, the inner ring **6110** substantially returns to its original shape or footprint. In some embodiments, the inner ring **6110** assumes a substantially circular shape in a relaxed state, for example, when released within a body cavity. In other embodiments, the inner ring **6110** has another shape in the relaxed state, for example, an oval. The inner ring **6110** assumes a different shape when compressed for insertion through an incision or body orifice, for example, a substantially oval shape, a generally linear shape, a tear-drop shape, or another suitable shape. Those skilled in the art will recognize that in other embodiments, the inner ring **6110** in the relaxed state has a shape other than round, for example, oval, elliptical, or D-shaped. In other embodiments, the inner ring **6110** is substantially rigid, that is, non-compliant under the ordinary conditions under which it is used. In some embodiments, the inner ring extends outward from the surface of the tubular body, as shown, for example, in FIG. 6A, to thereby aid in retaining the retractor in the body cavity after it is deployed.

**[0019]** Embodiments of the inner ring **6110** can comprise a generally circular cross section. In other embodiments, the inner ring **6110** comprises another cross-sectional shape, for example, at least one of oval or elliptical, tear-drop shaped, and D-shaped. Those skilled in the art will understand that other cross sections are used in other embodiments. As further discussed herein with respect to the flexion region of the inner ring **6110,** some embodiments of the inner ring **6110** comprise at least one notch and/or weak spot, which facilitate folding or deforming the inner ring **6110,** thereby facilitating insertion and/or removal of the inner ring **6110.**

**[0020]** Returning to FIG. **6A,** the outer ring **6120** is proximal the funnel section **6140.** In the illustrated embodiment, the outer ring **6120** has a substantially circular footprint. As further discussed herein, the outer ring **6120** can be sized and configured to sealingly couple to a cap or other access device thereon. In some embodiments, one or more suture points **6160** can be disposed on the retractor **6110** adjacent the outer ring **6120.**

**[0021]** With reference to FIG. **6B,** a top view of retractor **6100** is illustrated. In the illustrated embodiment, outer ring **6120** has a generally circular profile. Additionally, in the illustrated embodiment, two suture points **6160** are generally diametrically opposed relative to the generally circular profile of the outer ring **6120.** In other embodiments, the retractor can include more or fewer than two suture points disposed of various locations relative to the outer ring **6120.**

**[0022]** With continued reference to FIG. **6B,** the tubular body **6130** has a generally circular profile defining a generally cylindrical passage **6150.** The generally cylindrical passage **6150** is desirably large enough to accommodate more than one laparoscopic instrument therethrough such that a single natural orifice access device can be used to provide access for multiple surgical instruments in a body cavity. Moreover, generally cylindrical passage **6150** is desirably large enough such that multiple surgical instruments positioned therethrough can be translated or pivoted relative to one another, allowing a surgeon to manipulate the instruments as desired during a surgical procedure. The generally cylindrical passage extends between a proximal end **6152** of the retractor **6100** adjacent the outer ring **6120** to a distal end **6154** of the retractor **6100** adjacent the inner ring **6110** (FIG. **6A**).

**[0023]** With continued reference to FIG. **6B,** in the illustrated embodiment, the funnel segment **6140** provides a diametric reduction between the relatively large diameter of the outer ring **6120,** which is sized and configured to be removably coupled to an access device such as a cap, and the relatively smaller diameter of the passage **6150,** which is sized to fit within a natural orifice with minimal distention of the orifice. The funnel segment **6140** has an inner surface **6142** which can provide a bearing surface for an obturator used to advance to the retractor **6100** into a body cavity. In some embodiments, the funnel segment **6140** can have a substantially linear taper between the relatively large diameter and the relatively smaller diameter such that the inner surface **6142** is a frusto-conical segment. In other embodiments, the funnel segment **6140** can have a curved profile between the relatively large diameter and the relatively smaller diameter.

**[0024]** In some embodiments, a natural orifice access system can include a retractor **6100** and an optional obturator **6400** (FIG. **6G-6H**). The obturator can have a proximal bearing surface **6410** sized and configured to bear against the inner surface **6142** of the funnel segment **6140** and a distal dilation surface **6420** sized and configured to expand a natural orifice for passage of the retractor **6100.** Thus, during insertion of the retractor **6100** into a natural orifice, the dilation surface **6420** expands a pathway to a surgical site in a body cavity while the obturator bears on the inner surface **6142** of the funnel segment **6140** to advance the retractor **6100** into position in the surgical site. Furthermore, in some embodiments, the obturator can have a handle **6430** at a proximal end thereof adapted to facilitate selective twisting or rotation of the obturator about a longitudinal axis thereof during insertion.

**[0025]** It can be desirable that the outer ring **6120** is relatively stiff compared with the relatively flexible tubular body **6130** of the retractor **6100** so that the outer ring **6120** can sealingly engage an access device such as a cap. With reference to FIG. **6C,** a perspective view of the retractor is illustrated with a partial cutaway of the outer ring **6120.** In the illustrated embodiment, the outer ring **6120** includes an annular groove **6122** formed therein in

which a reinforcing member **6124** is disposed. In some embodiments, the reinforcing member **6124** can comprise a metallic member such as a wire formed into a ring shape. For example, in some embodiments the reinforcing member **6124** can comprise a stainless steel ring positioned within the groove **6122** during manufacture of the retractor **6100.** In other embodiments, the reinforcing number **6124** can comprise an injectable nonmetallic member. For example, in some embodiments, a glass filled polymer or polycarbonate material can be injected into the groove **6122** during manufacture of the retractor **6100.**

**[0026]** While the illustrated embodiments of retractor **6100** include a reinforcing member to enhance the rigidity of the outer ring **6120,** in other embodiments, the retractor 6100 can be formed in a multiple-shot molding process. For example, in some embodiments, an inner segment of the retractor defined by the tubular body **6130** and the inner ring **6110** is formed in one molding operation from a flexible material, and an outer segment of the retractor **6100** defined by the funnel segment **6140** and the outer ring **6120** is formed in another molding operation from a relatively rigid material such as a polycarbonate material or other suitable material. One example of a retractor **7100** formed in a multiple-shot molding process is illustrated in FIGS. **6D-F, 7B, 8D,** and **9B.**

**[0027]** With continued reference to FIG. **6C,** the illustrated embodiment includes a continuous generally annular groove. In other embodiments, a plurality of non-contiguous recesses can each receive one of a plurality of reinforcing members. Moreover, in some embodiments, the outer ring can include two or more concentric generally annular grooves, which each receive a corresponding reinforcing member.

**[0028]** With reference to FIG. **7A,** a cross-sectional view of a natural orifice access device including a retractor **6100** and a removable cap **6200** is shown. In the illustrated embodiment, the tubular body **6130** is formed of a flexible material having a predetermined fixed length L, inner diameter D, and wall thickness T. The fixed length L, inner diameter D, and wall thickness T are selected to accommodate the anatomy of a natural orifice, such as the anal orifice of a majority of patients. It is contemplated that the retractor **6100** can be scaled to different sizes for patients of different ages. Furthermore, in some embodiments, it is contemplated that the retractor can include a telescopic tubular body such that the tubular body can be selectively positioned at a variety of lengths depending on patient anatomy and the location of the surgical site within the body cavity. Desirably, the wall thickness T and material of the tubular body **6130** are selected such that the tubular body **6130** is resilient enough to maintain the passage **6150** therethrough when positioned in the natural orifice. Moreover, desirably, the inner diameter, D is sufficiently large to accommodate multiple surgical instruments. For example, in embodiments of the retractor **6100** adapted for use in a TEMS procedure, the inner diameter D and thickness T can be sized such that an outer diameter of the retractor can be between approximately 30 mm and 70 mm, desirably between approximately 35 mm and 50 mm, and in one embodiment approximately 40 mm. Additionally, desirably, the fixed length L is sufficiently long such that the inner ring **6110** can be positioned at a surgical site within a body cavity and the outer ring **6120** can be positioned outside the natural orifice. In some embodiments, the fixed length L is of a length such that the device has an overall length between the proximal end **6152** and the distal end **6154** of between approximately 10 mm and approximately 100 mm, desirably between approximately 20 mm and 80 mm, more desirably between approximately 30 mm and 60 mm, and in one embodiment, approximately 40 mm.

**[0029]** With continued reference to FIG. **7A,** in some embodiments, the annular groove **6122** can be open to an inner surface of the outer ring **6120.** Thus, the retractor **6100** can be formed of a flexible material in a single molding operation with the annular groove **6122** having an opening, and the reinforcing member **6124** can be subsequently inserted into the upper groove **6122.**

**[0030]** With continued reference to FIG. **7A,** in some embodiments, the retractor **6100** can include a flexion region between the tubular body **6130** and the inner ring **6110,** such as an undercut **6170.** Advantageously, the flexion region can allow the inner ring **6110** to flex or rotate relative to the tubular body **6130** during insertion such that the inner ring **6110** presents a relatively small outer diameter in an insertion configuration and a relatively larger outer diameter in an undisturbed configuration. In other embodiments, the inner ring **6110** can comprise an inflatable member such as an annular balloon coupled to a fluid source that can be selectively inflated and deflated between a deflated, relatively small diameter state for insertion and removal, and an inflated, relatively high diameter state for retention in a body cavity.

**[0031]** With reference to FIG. **8A,** a side view of a natural orifice access device having a cap **6200** removably coupled to a retractor **6100** is illustrated. In the illustrated embodiment, the cap **6200** comprises a sealable access surface **6210** such as a gel pad surface as described in further detail herein. In certain embodiments, the cap **6200** can also comprise at least one gas or fluid port **6220, 6230.** In the illustrated embodiment, the cap **6200** comprises two gas or fluid ports **6220, 6230,** such that one port can be used for gas insufflation and the other port can be used for ventilation for example when electrosurgery is performed through the access device. In certain embodiments, at least one of the gas or fluid ports **6220, 6230** comprises a valve such as a stopcock valve to selectively control the flow of fluid therethrough.

**[0032]** With reference to FIG. **8B,** a top view of the natural orifice access device is illustrated. The sealable access surface **6210** can be encircled by and restrained by an annular frame **6240** such as a split ring having a clamp **6250.** The clamp **6250** can be movable between an open configuration in which the cap **6200** is selectively removable from the retractor **6100** and a clamped con-

figuration in which the cap **6200** can be secured to the retractor **6100.** For example, the annular frame **6240** can be positioned peripherally around the outer ring **6120** with the clamp **6250** in the open configuration and the clamp moved to the clamped configuration to sealingly fix the cap **6200** to the retractor **6100.** Accordingly, the cap **6200** can be easily removed during a surgical procedure to facilitate removal of excised tissue from a surgical site through the retractor **6100.**

**[0033]** With reference to FIG. **8C,** a perspective view of the natural orifice access device is illustrated. In the illustrated embodiment, the clamp **6250** can have a distal flange **6252** positioned to interface with the outer ring **6120** of the retractor when the clamp is in the clamped configuration. As illustrated, the clamp **6250** engages a distal surface of the outer ring **6120** of the retractor **6100.** In some embodiments, the annular frame **6240** can further comprise at least one distal flange sized and positioned to interface with a retractor. In the illustrated embodiment, the annular frame **6240** comprises a distal flange **6260** positioned to engage a distal surface of the outer ring **6120** of the retractor. As illustrated, the flange **6260** is generally diametrically opposed to the distal flange of the clamp **6250.** In other embodiments, the annular frame **6240** can include more than one distal flange positioned substantially equally spaced about the periphery of the annular frame **6240** or spaced irregularly about the periphery of the annular frame.

**[0034]** With reference to FIG. **9A,** another embodiment of natural orifice access device is illustrated with a cap **6300** removably coupled to a retractor **6100** such as that described above with respect to FIGS. **6A-6C, 7A, 8A-8C,** and **9A.** In the illustrated embodiment, the cap **6300** includes multiple trocar access devices **6310** positioned through an access surface **6320** thereof. Advantageously, the multiple trocar access devices **6310** allow for easy placement and manipulation of multiple laparoscopic instruments in a surgical site through a single natural orifice.

**[0035]** In some embodiments, the inner ring **6110** and the outer ring **6120** independently have different footprint shapes and/or footprint diameters. An inner ring **6110** with a larger diameter permits a greater retraction force, but is more difficult to insert and remove from a body cavity.

**[0036]** With reference to FIGS. **6D-6F,** in some examples, a natural orifice access port or retractor **7100** can be adapted for use in a transanal endoscopic microsurgery (TEMS) procedure. The retractor **7100** comprises an inner or distal ring **7110,** an outer or proximal ring **7120,** a tubular body **7130,** and a funnel segment **7140** extending between and coupling the inner ring **7110** and the outer ring **7120.** The tubular body **7130** comprises a relatively flexible material such as a KRATON® material or a silicone rubber material, which is substantially cylindrical in the illustrated embodiment. In other embodiments, the tubular body **7130** has another shape, for example, an oval cross section. Some embodiments of the tubular body **7130** comprise one or more coatings that provide additional functionality, for example, an anti-microbial coating.

**[0037]** In the illustrated examples of retractors, the inner ring **7110** is substantially flush with a distal end of the tubular body **7130** such that the retractor **7100** has a generally tubular configuration extending distally of the funnel segment **7140** to the distal end. Examples of the inner ring **7110** are sufficiently flexible and compliant to be compressed and/or deformed for insertion into a body orifice such as a patient's anus during a transanal surgical procedure. When subsequently released within an associated body cavity, the inner ring **7110** substantially returns to its original shape or footprint. In some examples, the inner ring **7110** assumes a substantially circular shape substantially flush with the generally cylindrical tubular body **7130** in a relaxed state, for example, when released within a body cavity. In other examples, the inner ring **7110** has another shape in the relaxed state, for example, an oval. The inner ring **7110** assumes a different shape when compressed for insertion through an incision or body orifice, for example, a substantially oval shape, a generally linear shape, a tear-drop shape, or another suitable shape. In other examples, the inner ring **7110** is substantially rigid, that is, non-compliant under the ordinary conditions under which it is used.

**[0038]** With continued reference to FIGS. **6D-6F,** in some examples of a retractor, the inner ring **7110** can be shaped and configured to facilitate insertion through a natural orifice. For example, in the illustrated example, the inner ring **7110** can include a radiused edge to facilitate atraumatic entry through a natural orifice. In other examples, the inner ring **7110** can include a beveled edge to facilitate entry through a natural orifice. Furthermore, in the illustrated example, the inner ring **7110** can be formed at an angle transverse to a longitudinal axis defined by the tubular body **7130.** Advantageously, such an angled inner ring **7110** can facilitate insertion of the retractor **7100** through a natural orifice. In other examples, the inner ring **7110** can be substantially perpendicular to the longitudinal axis defined by the tubular body.

**[0039]** With continued reference to FIGS. **6D-6F,** the outer ring **7120** is proximal the funnel section **7140.** In the illustrated example, the outer ring **7120** has a substantially circular footprint. As further discussed herein, the outer ring **7120** can be sized and configured to sealingly couple to a cap or other access device thereon. In some embodiments, as discussed above with reference to the embodiments of FIGS. **6A-6C,** one or more suture points can be disposed on the retractor **7100** adjacent the outer ring **7120.**

**[0040]** With continued reference to FIGS. **6D-6F,** the tubular body **7130** can have a generally circular profile defining a generally cylindrical passage **7150.** The generally cylindrical passage **7150** is desirably large enough to accommodate more than one laparoscopic instrument therethrough such that a single natural orifice access device can be used to provide access for multiple surgical

instruments in a body cavity. Moreover, generally cylindrical passage **7150** is desirably large enough such that multiple surgical instruments positioned therethrough can be translated or pivoted relative to one another, allowing a surgeon to manipulate the instruments as desired during a surgical procedure. The generally cylindrical passage extends between a proximal end **7152** of the retractor **7100** adjacent the outer ring **7120** to a distal end **7154** of the retractor **7100** adjacent the inner ring **7110** (FIG. **6D**).

**[0041]** With reference to FIG. **6D,** in the illustrated example, the funnel segment **7140** provides a diametric reduction between the relatively large diameter of the outer ring **7120,** which is sized and configured to be removably coupled to an access device such as a cap, and the relatively smaller diameter of the passage **7150,** which is sized to fit within a natural orifice with minimal distention of the orifice. The funnel segment **7140** has an inner surface **7142** which can provide a bearing surface for an obturator used to advance to the retractor **7100** into a body cavity. In some examples, the funnel segment **7140** can have a substantially linear taper between the relatively large diameter and the relatively smaller diameter such that the inner surface **7142** is a frusto-conical segment. In other examples, the funnel segment **7140** can have a curved profile between the relatively large diameter and the relatively smaller diameter.

**[0042]** In some embodiments, a natural orifice access system can include a retractor **7100** and an optional obturator, such as described above with reference to FIG. **6G.** The obturator can have a proximal bearing surface **6410** sized and configured to bear against the inner surface **7142** of the funnel segment **7140** and a distal dilation surface **6420** sized and configured to expand a natural orifice for passage of the retractor **7100.** Thus, during insertion of the retractor **7100** into a natural orifice, the dilation surface expands a pathway to a surgical site in a body cavity while the obturator bears on the inner surface **7142** of the funnel segment **7140** to advance the retractor **7100** into position in the surgical site. Furthermore, in some embodiments, the obturator can have a handle **6430** at a proximal end thereof adapted to facilitate selective twisting or rotation of the obturator about a longitudinal axis thereof during insertion.

**[0043]** With reference to FIG. **7B,** it can be desirable that the outer ring **7120** is relatively stiff compared with the relatively flexible tubular body **7130** of the retractor **7100** so that the outer ring **7120** can sealingly engage an access device such as a cap. In the illustrated example, the retractor **7100** is formed in a multiple-shot molding process. For example, an inner segment of the retractor **7100** defined by the tubular body **7130** and the inner ring **7110** is formed in one molding operation from a flexible material, and an outer segment of the retractor **7100** defined by the funnel segment **7140** and the outer ring **7120** is formed in another molding operation from a relatively rigid material such as a polycarbonate material or other suitable material.

**[0044]** In other examples of a surgical access port system, a multiple-shot molding process can be varied such that the resulting inner and outer segments are different from those illustrated. For example, the inner segment can include the tubular body **7130,** the inner ring **7110,** and a portion of the funnel segment **7140,** while the outer segment can include a portion of the funnel segment **7140** and the outer ring **7120.** Alternatively, the inner segment can include the inner ring **7110** and a portion of the tubular body **7130,** while the outer segment can include a portion of the tubular body **7130,** the funnel segment **7140,** and the outer ring **7120.**

**[0045]** With reference to FIGS. **6D** and **7B,** a retractor **7100** formed in a multiple-shot molding process can include one or more retention members **7160** on the inner segment and the outer segment to maintain the position of the inner segment relative to the outer segment. For example, a distal end of the outer segment can include one or more protrusions **7162** extending radially outwardly from the funnel segment **7140** and one or more recesses **7164** recessed radially inwardly from the funnel segment **7140** at an interface region of the inner segment and the outer segment of the retractor **7100.** In the illustrated example, the distal end of the outer segment includes a plurality of protrusions **7162** alternating with a plurality of recesses **7164** therebetween. Moreover, in some examples, the outer segment can include an annular groove **7170** formed in the funnel segment **7140** at an interface region of the inner segment and the outer segment of the retractor **7100.** The inner segment of the retractor **7100** can include an annular member **7166** disposed within and matingly engaging the groove **7170** to maintain the position of the inner segment relative to the outer segment.

**[0046]** With reference to FIG. **7B,** a cross-sectional view of retractor **7100** is shown. In the illustrated example, the tubular body **7130** is formed of a flexible material having a predetermined fixed length L2, inner diameter D2, and wall thickness T2. The fixed length L2, inner diameter D2, and wall thickness T2 are selected to accommodate the anatomy of a natural orifice, such as the anal orifice of a majority of patients. It is contemplated that the retractor **7100** can be scaled to different sizes for patients of different ages. Desirably, the wall thickness T2 and material of the tubular body **7130** are selected such that the tubular body **7130** is resilient enough to maintain the passage **7150** therethrough when positioned in the natural orifice. Moreover, desirably, the inner diameter, D2 is sufficiently large to accommodate multiple surgical instruments. For example, in examples of the retractor **7100** adapted for use in a transanal surgical procedure, the inner diameter D2 and thickness T2 can be sized such that an outer diameter of the retractor can be between approximately 30 mm and 70 mm, desirably between approximately 35 mm and 50 mm, and in one embodiment approximately 40 mm. Additionally, desirably, the fixed length L2 is sufficiently long such that the

inner ring **7110** can be positioned at a surgical site within a body cavity and the outer ring **7120** can be positioned outside the natural orifice. In some examples, the fixed length L2 is of a length such that the device has an overall length between the proximal end **7152** and the distal end **7154** of between approximately 100 mm and approximately 200 mm, desirably between approximately 120 mm and 180 mm, more desirably between approximately 140 mm and 160 mm, and in one embodiment, approximately 150 mm.

**[0047]** With reference to FIG. **8D,** a perspective view of a natural orifice access device having a cap **6200** substantially similar to that described with respect to FIGS. **8A-8C** removably coupled to a retractor **7100** is illustrated. The cap **6200** comprises a sealable access surface **6210** such as a gel pad surface as described in further detail herein. The cap **6200** can also comprise at least one gas or fluid port **6220, 6230.** In the illustrated example, the cap **6200** comprises two gas or fluid ports **6220, 6230,** such that one port can be used for gas insufflation and the other port can be used for ventilation for example when electrosurgery is performed through the access device. In certain examples, at least one of the gas or fluid ports **6220, 6230** comprises a valve such as a stopcock valve to selectively control the flow of fluid therethrough.

**[0048]** With continued reference to FIG. **8D,** a top view of the natural orifice access device is illustrated. The sealable access surface **6210** can be encircled by and restrained by an annular frame **6240** such as a split ring having a clamp **6250.** The clamp **6250** can be movable between an open configuration in which the cap **6200** is selectively removable from the retractor **7100** and a clamped configuration in which the cap **6200** can be secured to the retractor **7100.** For example, the annular frame **6240** can be positioned peripherally around the outer ring **7120** with the clamp **6250** in the open configuration and the clamp moved to the clamped configuration to sealingly fix the cap **6200** to the retractor **7100.** Accordingly, the cap **6200** can be easily removed during a surgical procedure to facilitate removal of excised tissue from a surgical site through the retractor **7100.**

**[0049]** With reference to FIG. **9B,** another example of a natural orifice access device is illustrated can include a cap **6300** substantially similar to that described above with reference to FIG. **9A** removably coupled to a retractor **7100** such as that described above with respect to FIGS. **6D-F, 7B,** and **8D.** The cap **6300** can include multiple trocar access devices **6310** positioned through an access surface **6320** thereof. Advantageously, the multiple trocar access devices **6310** allow for easy placement and manipulation of multiple laparoscopic instruments in a surgical site through a single natural orifice.

**[0050]** As discussed herein, the retractors shown in FIGs. **7A** and **7B** can include a telescopic tubular body such that the tubular body can be selectively positioned at a variety of lengths depending on patient anatomy and the location of the surgical site within the body cavity. In another example, illustrated in FIG. **7C,** the tubular body may be formed in sections of varying length that slidingly engage and snap lock together to provide a variety of lengths, depending of the number and size of the sections selected and assembled. With reference to FIG. **7C,** a perspective view of a retractor **6500** is shown having three sections: an outer ring section **6510,** an inner ring section **6520,** and an intermediate section **6530** disposed between the other two sections. The three sections are held together by a snap lock mechanism **6540.** Each section terminates at the distal end with an annular groove **6550** that slidingly engages with the proximal end **6560** of the next section, best shown in the cross section view of FIG. **7D.** The snap lock mechanism is shown in cross-section in FIG. **7E.** The tubular body of the retractor shown in FIG. **7C-E** is preferably formed from a relatively stiff material, such as a polycarbonate.

**[0051]** Optionally, as shown in FIG. **7C-7F,** the tubular body of the retractor can include cut-out portions or windows **6570,** to provide access to regions of the anatomy that would otherwise be obscured by the tubular body while the retractor is in place. Thus, the retractor can be inserted into the body orifice or incision to provide retraction and to protect the lining of the body cavity, and then manipulated to align the window(s) to the sites of interest in the body cavity for access by surgical instruments.

**[0052]** As will be appreciated, such cut-out portions may be provided in retractors having tubular bodies of both rigid and flexible construction, as well as tubular bodies formed as a single piece or in sections.

**[0053]** In the illustrated embodiments of FIG. **9A,** the trocar access devices **6310** have a relatively low profile, that is, protrude minimally above the access surface **6320** and/or below the distal surface of the cap **6300.** Accordingly, the trocar access devices **6310** are shorter than a length of a typical trocar and comprise a seal assembly positioned above the access surface **6320** and a cannula extending through the gel pad of the cap **6300.** The reduced length of the trocar access devices **6310** allows increased angular or pivotal motion for instruments extending therethrough, and also permits the use of curved and/or angled instruments.

**[0054]** FIG. **9C** is an exploded view of a trocar access device **6310** and optional obturator **6600,** which is a component of some embodiments of the access device system. In the illustrated device, the obturator **6600** comprises a pointed, puncture tip **6610.**

**[0055]** The trocar access device **6310** comprises a proximal end, a distal end, and a longitudinal axis. The trocar access device **6310** comprises a cannula **6620** extending along the longitudinal axis. A trocar seal **6630** is disposed at the proximal end of the cannula **6620,** contained within a housing **6640.** A retainer **6650** is disposed at the distal end or tip of the cannula **6620.**

**[0056]** The cannula **6620** comprises a tubular body dimensioned to accommodate an instrument or instruments received therethrough. In the illustrated embodiment, the cannula **6620** is a substantially cylindrical tube, and extends through the cap **6300** in use. In the illustrated

embodiment, the cannula **6620** is comparatively short because the cannula need only traverse the cap 6300 (FIG. **9A-B**), which has a known and consistent thickness, rather than a body wall. Accordingly, some embodiments of the cannula **6620** are not more than about 2-times longer, about 1.5-times longer, about 1.2-times longer, or about 1.1-times longer than the thickness of the gel pad. In some embodiments, the cannula **6620** is less than about 20 mm, about 10 mm, or about 5 mm longer than the thickness of the gel pad. In some embodiments, the cannula **6620** is about as long as the gel pad is thick. In other embodiments, the cannula **6620** has a different length, for example, a length typical for a cannula used for traversing a body wall. Shorter length cannula permit increased angular degrees of freedom for instruments passing therethrough. Embodiments of shorter cannula also accommodate curved instruments. The cannula **6620** comprises any suitable biocompatible material. In some embodiments, the cannula **6620** comprises a flexible material.

**[0057]** The illustrated trocar seal **6630** comprises an instrument or septum seal **6660** and a zero seal **6670.** Optionally, a shield **6680** may be disposed within the instrument seal **6660.** The instrument seal **6660** seals instruments passing therethrough, thereby maintaining pressurization in a body cavity such as pneumoperitoneum or pneumorectum. The zero seal **6670** provides a seal when no instrument passes through the trocar seal **6630.** The instrument seal **6660** and zero seal **6670** are received in a housing **6640** disposed at the proximal end of the cannula **6620** and secured therein by a seal cover **6690.**

**[0058]** The retainer **6650** is disposed at or near the distal end of the cannula **6620.** In some embodiments, the retainer **6650** and cannula **6630** are integrated, while in other embodiments, the retainer **6650** and cannula **6630** are not integrated. In the illustrated embodiment, the proximal end of the retainer **6650** comprises a flange **6655** that is generally flat and perpendicular to the longitudinal axis, while the distal end is tapered, narrowing toward the distal end of the cannula **6620.** The flange **6655** reduces the likelihood of accidental or inadvertent removal of the trocar access device **6310** from the cap. Some embodiments of the proximal face of the flange **6655** comprise additional anchoring features, for example, at least one of barbs, spikes, ridges, texturing, and the like, which are configured to penetrate or bite into a distal face of the cap **6300.** In some embodiments, a diameter of the flange **6655** is from about 1.2 to about 2.5 times wider, or from about 1.5 to about 2.0 times wider than an outer diameter of the cannula **6630.** Some embodiments of the trocar access device **6310** are 5-mm trocars, in which the outer diameter of the cannula **6620** is from about 7 mm to about 8 mm.

**[0059]** The tapered end of the retainer **6650** facilitates insertion of the trocar access device **6310** through the cap, either by itself, or when assembled with the obturator **6600** extending therethrough. For example, in some embodiments, the retainer **6650** is inserted through a preformed opening in the cap **6300.**

**[0060]** In some embodiments in which the retainer **6650** and cannula **6620** are not integrated, that is, are separate components, the retainer **6650** is secured to the cannula **6620** after the cannula **6620** is inserted through the cap. In some embodiments, the cannula **6620** and retainer **6650** are secured mechanically, for example, using latches, screw threads, clips, lock rings, ratchets, and the like. In some embodiments, the cannula **6620** and retainer **6650** are secured adhesively. In some embodiments, the position of the retainer **6650** is adjustable, for example, to accommodate caps of different thicknesses. In some embodiments, the cannula **6620** and/or retainer **6650** is secured to the cap, for example, adhesively.

**[0061]** An exemplary procedure for retracting a body orifice is described with reference to the embodiments of the retractor **6100** illustrated in FIGS. **6A-6C, 7A, 8A-8C,** and **9A,** although the procedure is applicable to all of the embodiments of the retractor disclosed herein. In use, the surgical wound retractor **6100,** is inserted into a body orifice, such as the vagina (FIG. **2**), mouth (FIG. **3**) or anus (FIG. **4**). The inner ring **6110,** is folded or compressed into an oval or other suitable shape and urged through the incision or body orifice into an associated body cavity. Once the inner ring **6110,** is fully disposed within the associated body cavity, it is allowed to resume its original, relaxed shape, for example, substantially circular, oval, or other original shape. In some embodiments, the inner ring **6110** is then pulled upward against the inner surface of the body cavity, for example, by pulling the outer ring **6120** upward. An outer surface of the tubular body **6130,** retracts the natural orifice.

**[0062]** While certain embodiments have been particularly shown and described with reference to exemplary embodiments thereof, it will be understood by those of ordinary skill in the art that various changes in form and details may be made therein without departing from the scope thereof as defined by the following claims.

## Claims

**1.** A surgical access port system adapted for performing laparoscopic surgical procedures at a natural orifice comprising:

a relatively rigid outer ring (6120), wherein the outer ring (6120) is configured to be disposed proximate the natural orifice of the patient and substantially surround the orifice;
a tubular body (6130) defining a generally cylindrical passage (6150), wherein the passage (6150) is intended to be able to accommodate multiple surgical instruments positioned therethrough and is formed of a flexible material having a predetermined fixed length (L), wherein

the wall thickness (T) and material of the tubular body (6130) are selected such that the tubular body (6130) is sufficiently resilient to, in use, maintain a passage through the natural orifice;
a funnel segment (6140) extending between and coupling the outer ring (6120) and the tubular body (6130), wherein the funnel segment (6140) provides a diametric reduction between the relatively large diameter of the outer ring (6120) and the relatively smaller diameter of the tubular body (6130), which is sized to fit within a natural orifice with minimal distention of the orifice;
an inner ring (6110) disposed on the distal edge of the tubular body (6130) the inner ring (6110) having an out diameter greater than the outer diameter of the tubular body (6130); and
a removable cap (6300), wherein the cap comprises a generally flat sealable access surface (6320) and is adapted to sealing by engage the outer ring (6120).

**2.** The surgical access port system of claim 1, wherein the flexible material is selected from the group consisting of a KRATON ® material, a PELLETHANE ® material and a silicone rubber material.

**3.** The surgical access port system of claim 1, wherein the tubular body (6130) comprises one or more coatings.

**4.** The surgical access port system of claim 3, wherein the coating comprises an anti-microbial coating.

**5.** The surgical access port system of claim 1, wherein the tubular body (6130) comprises at least one window.

**6.** The surgical access port system of claim 1, wherein the tubular body (6130) comprises at least one perforation.

**7.** The surgical access port system of claim 1, wherein the inner ring (6110) is sufficiently flexible to be compressed for insertion into a body orifice, substantially returning to its original shape upon release inside the body orifice.

**8.** The surgical access port system of claim 1, wherein the inner ring (6110) comprises at least one notch to thereby facilitate folding or deforming the inner ring (6110) for insertion and/or removal of the inner ring (6110).

**9.** The surgical access port system of claim 1, wherein the outer ring (6120) comprises a wire disposed within a lumen of the outer ring (6120).

**10.** The surgical access port system of claim 1, wherein the sealable access surface (6320) is a gel pad.

**11.** The surgical access port system of claim 1, wherein the cap (6300) comprises at least one gas port.

**12.** The surgical access port system of claim 1, further comprising two or more trocar access devices (6310), wherein the trocar access devices (6310) are adapted to be positioned through the sealable access surface (6320).

**13.** The surgical access port system of any preceding claim wherein the outer diameter of the tubular body (6130) is between 35mm and 50mm.

**14.** The surgical access port system of any preceding claim further comprising an obturator (6400) and wherein the funnel segment (6140) has an inner surface (6142) arranged to engage with and act as a bearing surface for the obturator (6400) to urge the surgical access port system into position.

**15.** The surgical access port system of any preceding claim wherein the inner ring (6110) and at least a portion of the tubular body (6130) are formed from a relatively flexible material and the outer ring (6120) and at least a portion of the funnel section (6140) are formed of a relatively rigid material.

**16.** The surgical access port system of claim 15 wherein the inner ring (6110) and the tubular body (6130) are moulded from a relatively flexible material and the outer ring (6120) and the funnel segment (6140) moulded from a relatively rigid material.

**Patentansprüche**

**1.** Chirurgisches Zugangsportsystem, das geeignet ist, um laparoskopische chirurgische Eingriffe an einer natürlichen Öffnung durchzuführen, umfassend:

einen relativ starren Außenring (6120), wobei der Außenring (6120) konfiguriert ist, um nahe bei der natürlichen Öffnung des Patienten angeordnet zu sein und im Wesentlichen die Öffnung zu umgeben;
einen Rohrkörper (6130), der einen im Allgemeinen zylindrischen Durchgang (6150) definiert, wobei der Durchgang (6150) in der Lage sein soll, mehrere chirurgische Instrumente, die durch ihn hindurch positioniert werden, unterzubringen und der aus einem flexiblen Material geformt ist, das eine vorher festgelegte fixe Länge (L) hat,
wobei die Wanddicke (T) und das Material des Rohrkörpers (6130) so ausgewählt sind, dass der Rohrkörper (6130) genügend nachgiebig ist,

um im Einsatz einen Durchgang durch die natürliche Öffnung aufrechtzuerhalten;
ein Trichtersegment (6140), das sich zwischen dem Außenring (6120) und dem Rohrkörper (6130) erstreckt und den Außenring (6120) und den Rohrkörper (6130) verbindet, wobei das Trichtersegment (6140) eine Durchmesserreduktion zwischen dem relativ großen Durchmesser des Außenrings (6120) und dem relativ kleineren Durchmesser des Rohrkörpers (6130) bereitstellt, der so dimensioniert ist, dass er bei minimaler Dehnung der Öffnung in eine natürliche Öffnung hineinpasst;
einen Innenring (6110), der am distalen Rand des Rohrkörpers (6130) angeordnet ist, wobei der Innenring (6110) einen Außendurchmesser aufweist, der größer ist als der Außendurchmesser des Rohrkörpers (6130); und
einen abnehmbaren Deckel (6300), wobei der Deckel eine im Allgemeinen flache abdichtbare Zugangsfläche (6320) umfasst und durch Eingreifen in den Außenring (6120) zum Abdichten geeignet ist.

**2.** Chirurgisches Zugangsportsystem nach Anspruch 1, wobei das flexible Material ausgewählt ist aus der Gruppe bestehend aus einem KRATON®-Material, einem PELLETHANE®-Material und einem Silikonkautschukmaterial.

**3.** Chirurgisches Zugangsportsystem nach Anspruch 1, wobei der Rohrkörper (6130) eine oder mehrere Beschichtungen umfasst.

**4.** Chirurgisches Zugangsportsystem nach Anspruch 3, wobei die Beschichtung eine antimikrobielle Beschichtung umfasst.

**5.** Chirurgisches Zugangsportsystem nach Anspruch 1, wobei der Rohrkörper (6130) mindestens ein Fenster umfasst.

**6.** Chirurgisches Zugangsportsystem nach Anspruch 1, wobei der Rohrkörper (6130) mindestens eine Perforation umfasst.

**7.** Chirurgisches Zugangsportsystem nach Anspruch 1, wobei der Innenring (6110) genügend flexibel ist, um für das Einbringen in eine Körperöffnung komprimiert zu werden, wobei er nach Freigabe innerhalb der Körperöffnung im Wesentlichen zu seiner Originalform zurückkehrt.

**8.** Chirurgisches Zugangsportsystem nach Anspruch 1, wobei der Innenring (6110) mindestens eine Aussparung umfasst, um dadurch das Falten oder Verformen des Innenrings (6110) zum Einbringen und/oder Entfernen des Innenrings (6110) zu erleichtern.

**9.** Chirurgisches Zugangsportsystem nach Anspruch 1, wobei der Außenring (6120) einen Draht umfasst, der innerhalb eines Lumens des Außenrings (6120) angeordnet ist.

**10.** Chirurgisches Zugangsportsystem nach Anspruch 1, wobei die abdichtbare Zugangsfläche (6320) ein Gel-Polster ist.

**11.** Chirurgisches Zugangsportsystem nach Anspruch 1, wobei der Deckel (6300) mindestens einen Gas-Port umfasst.

**12.** Chirurgisches Zugangsportsystem nach Anspruch 1, ferner umfassend zwei oder mehr Trokarzugangsvorrichtungen (6310), wobei die Trokarzugangsvorrichtungen (6310) geeignet sind, um durch die abdichtbare Zugangsfläche (6320) positioniert zu werden.

**13.** Chirurgisches Zugangsportsystem nach einem vorhergehenden Anspruch, wobei der Außendurchmesser des Rohrkörpers (6130) zwischen 35 mm und 50 mm beträgt.

**14.** Chirurgisches Zugangsportsystem nach einem vorhergehenden Anspruch, ferner umfassend ein Verschlussstück (6400), und wobei der Trichterabschnitt (6140) eine Innenfläche (6142) aufweist, die angeordnet ist, um in eine Lagerfläche für das Verschlussstück (6400) einzugreifen und als Lagerfläche für dieses zu agieren, um das chirurgische Zugangsportsystem in Position zu drängen.

**15.** Chirurgisches Zugangsportsystem nach einem vorhergehenden Anspruch, wobei der Innenring (6110) und mindestens ein Teil des Rohrkörpers (6130) aus einem relativ flexiblen Material gebildet sind und der Außenring (6120) und mindestens ein Teil des Trichterabschnitts (6140) aus einem relativ starren Material gebildet sind.

**16.** Chirurgisches Zugangsportsystem nach Anspruch 15, wobei der Innenring (6110) und der Rohrkörper (6130) aus einem relativ flexiblen Material geformt sind und der Außenring (6120) und das Trichtersegment (6140) aus einem relativ starren Material geformt sind.

**Revendications**

**1.** Système chirurgical à port d'accès configuré pour réaliser des procédures chirurgicales laparoscopiques au niveau d'un orifice naturel, comprenant :

une bague externe relativement rigide (6120), la bague externe (6120) étant conçue pour être placée à proximité de l'orifice naturel du patient et essentiellement entourer l'orifice ;
un corps tubulaire (6130) définissant un passage généralement cylindrique (6150), le passage (6150) étant conçu pour pouvoir recevoir des instruments chirurgicaux multiples positionnés au travers de celui-ci et étant constitué d'un matériau flexible ayant une longueur fixe prédéterminée (L), l'épaisseur de la paroi (T) et le matériau du corps tubulaire (6130) étant sélectionnés de manière qu'à l'utilisation, le corps tubulaire (6130) est suffisamment résilient pour maintenir un passage au travers de l'orifice naturel ;
un tronçon à entonnoir (6140) se prolongeant entre la bague externe (6120) et le corps tubulaire (6130) et les raccordant, le tronçon à entonnoir (6140) fournissant une réduction diamétrale entre le diamètre relativement important de la bague externe (6120) et le diamètre relativement moindre du corps tubulaire (6130), qui est dimensionné de manière à s'adapter dans un orifice naturel avec une distension minimale de l'orifice ;
une bague interne (6110) située sur la bordure distale du corps tubulaire (6130), la bague interne (6110) ayant un diamètre de sortie plus important que le diamètre externe du corps tubulaire (6130) ; et
un capuchon amovible (6300), le capuchon comprenant une surface d'accès scellable généralement plate (6320) configurée pour produire un scellement par mise en prise de la bague externe (6120).

**2.** Système chirurgical à port d'accès de la revendication 1, dans lequel le matériau flexible est sélectionné dans le groupe consistant en un matériau de type KRATON®, un matériau de type PELLETHANE® et un matériau de caoutchouc silicone.

**3.** Système chirurgical à port d'accès de la revendication 1, dans lequel le corps tubulaire (6130) comprend un ou plusieurs revêtements.

**4.** Système chirurgical à port d'accès de la revendication 3, dans lequel le revêtement comprend un revêtement antimicrobien.

**5.** Système chirurgical à port d'accès de la revendication 1, dans lequel le corps tubulaire (6130) comprend au moins une fenêtre.

**6.** Système chirurgical à port d'accès de la revendication 1, dans lequel le corps tubulaire (6130) comprend au moins une perforation.

**7.** Système chirurgical à port d'accès de la revendication 1, dans lequel la bague interne (6110) est suffisamment flexible pour être comprimée pour être insérée dans un orifice corporel, retournant substantiellement à sa forme originelle après son relâchement à l'intérieur de l'orifice corporel.

**8.** Système chirurgical à port d'accès de la revendication 1, dans lequel la bague interne (6110) comprend au moins une entaille conçue pour faciliter le repliement ou la déformation de la bague interne (6110) à des fins d'insertion et/ou de retrait de la bague interne (6110).

**9.** Système chirurgical à port d'accès de la revendication 1, dans lequel la bague externe (6120) comprend un fil métallique situé dans une lumière de la bague externe (6120).

**10.** Système chirurgical à port d'accès de la revendication 1, dans lequel la surface d'accès scellable (6320) est un coussinet de gel.

**11.** Système chirurgical à port d'accès de la revendication 1, dans lequel le capuchon (6300) comprend au moins un port d'évent.

**12.** Système chirurgical à port d'accès de la revendication 1 comprenant en outre deux ou plusieurs dispositifs d'accès pour trocart (6310), les dispositifs d'accès pour trocart (6310) étant configurés pour être positionnés au travers de la surface d'accès scellable (6320).

**13.** Système chirurgical à port d'accès de l'une quelconque des revendications précédentes, dans lequel le diamètre externe du corps tubulaire (6130) est entre 35 mm et 50 mm.

**14.** Système chirurgical à port d'accès de l'une quelconque des revendications précédentes comprenant en outre un obturateur (6400) et dans lequel le tronçon à entonnoir (6140) a une surface interne (6142) disposée de manière à mettre en prise l'obturateur (6400) et à servir de surface d'appui pour celui-ci pour solliciter le système chirurgical à port d'accès en position.

**15.** Système chirurgical à port d'accès de l'une quelconque des revendications précédentes, dans lequel la bague interne (6110) et au moins une partie du corps tubulaire (6130) sont constituées d'un matériau relativement flexible et la bague externe (6120) et au moins une partie du tronçon à entonnoir (6140) sont constituées d'un matériau relativement rigide.

**16.** Système chirurgical à port d'accès de la revendication 15, dans lequel la bague interne (6110) et le

corps tubulaire (6130) sont moulés à partir d'un matériau relativement flexible et la bague externe (6120) et le tronçon à entonnoir (6140) sont moulés à partir d'un matériau relativement rigide.

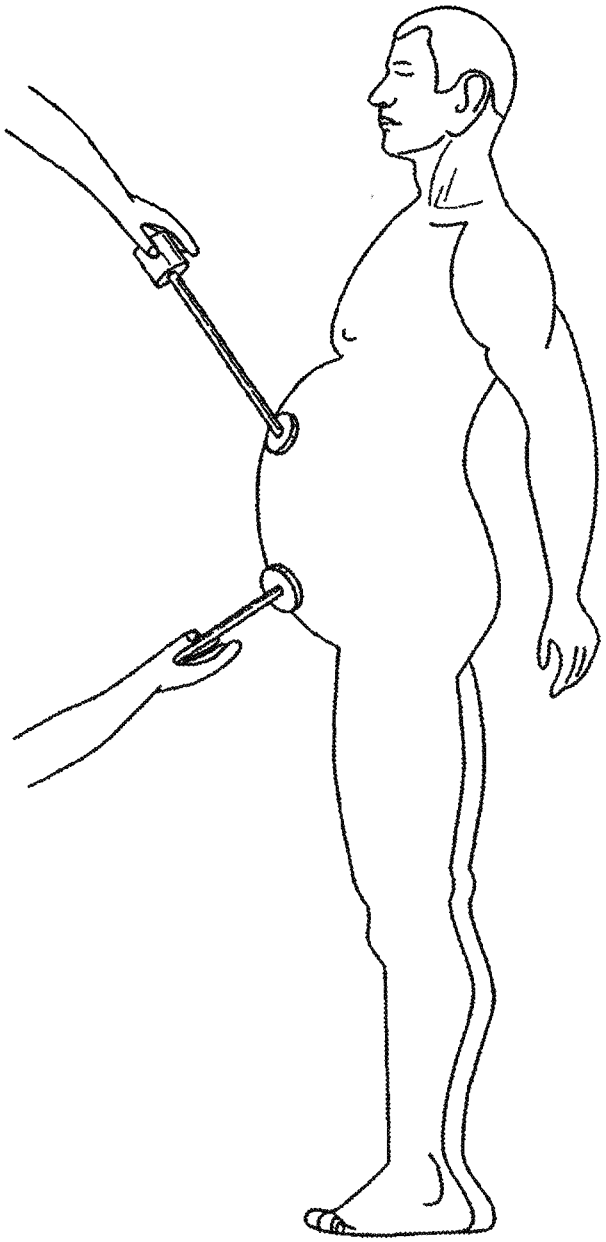


FIG. 1

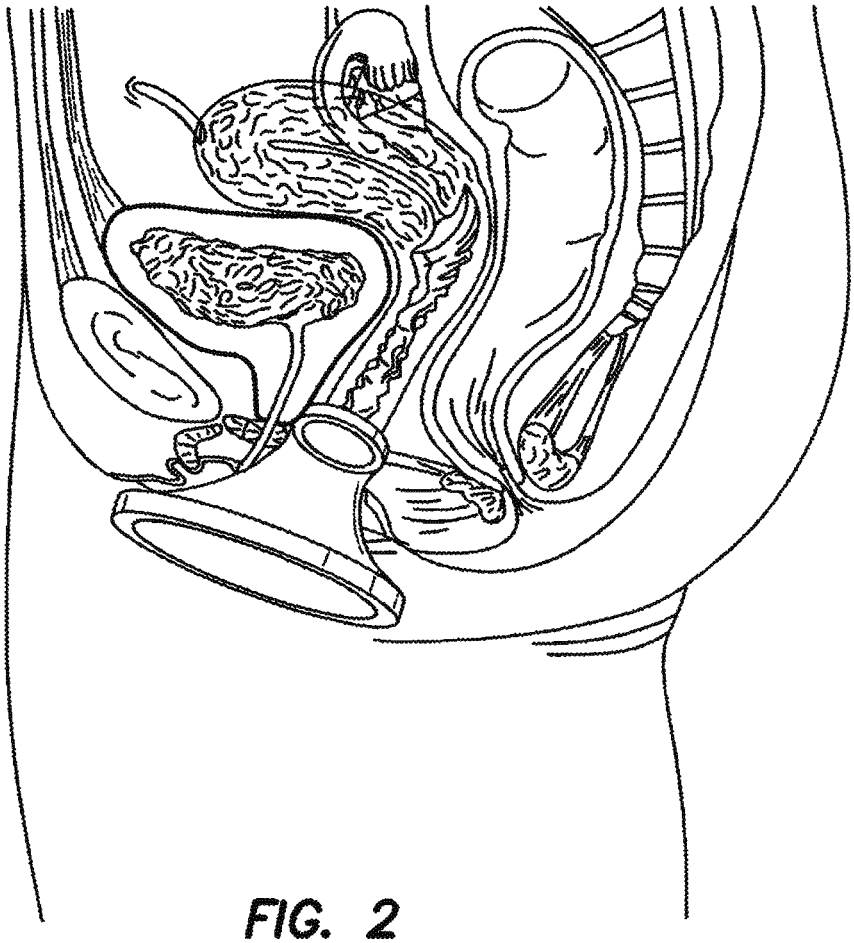


FIG. 2

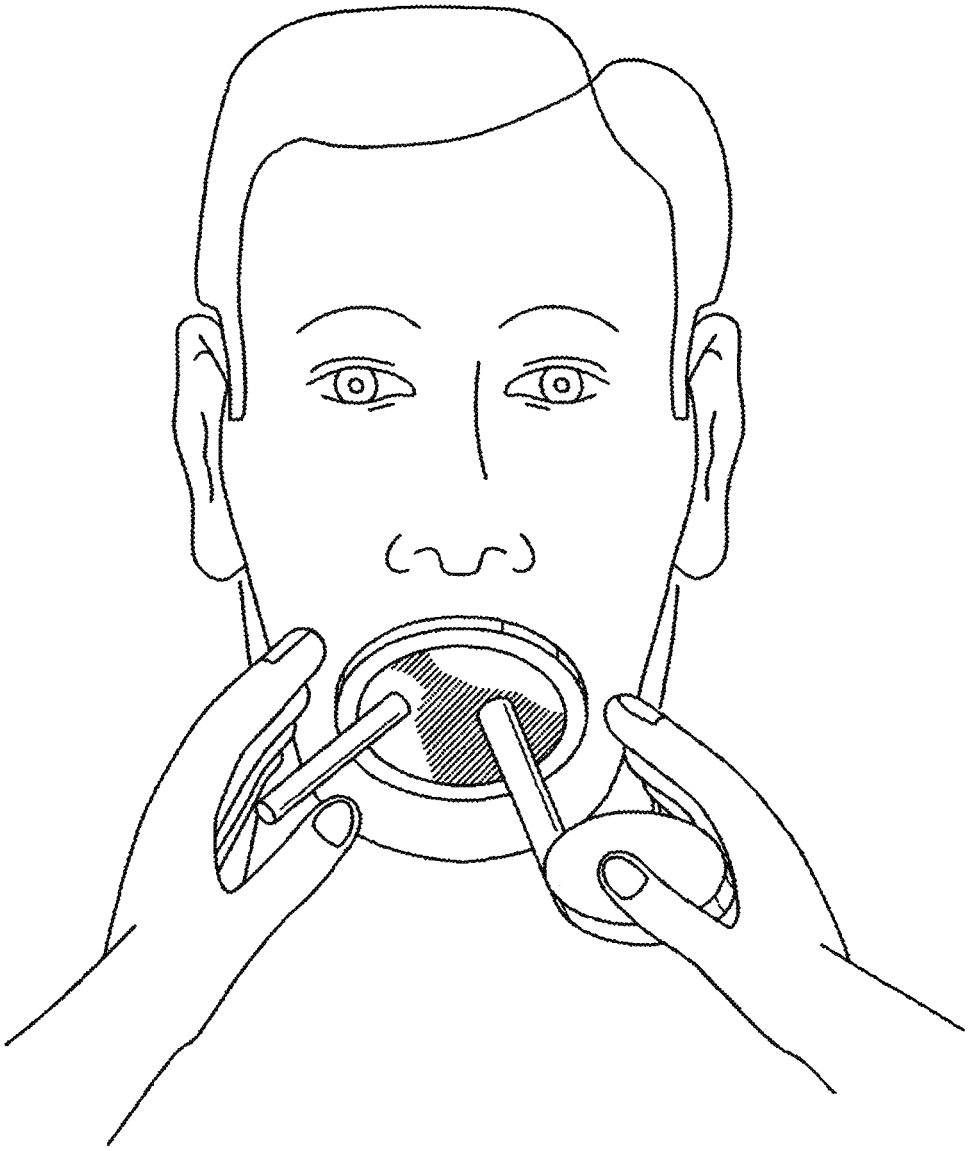


FIG. 3

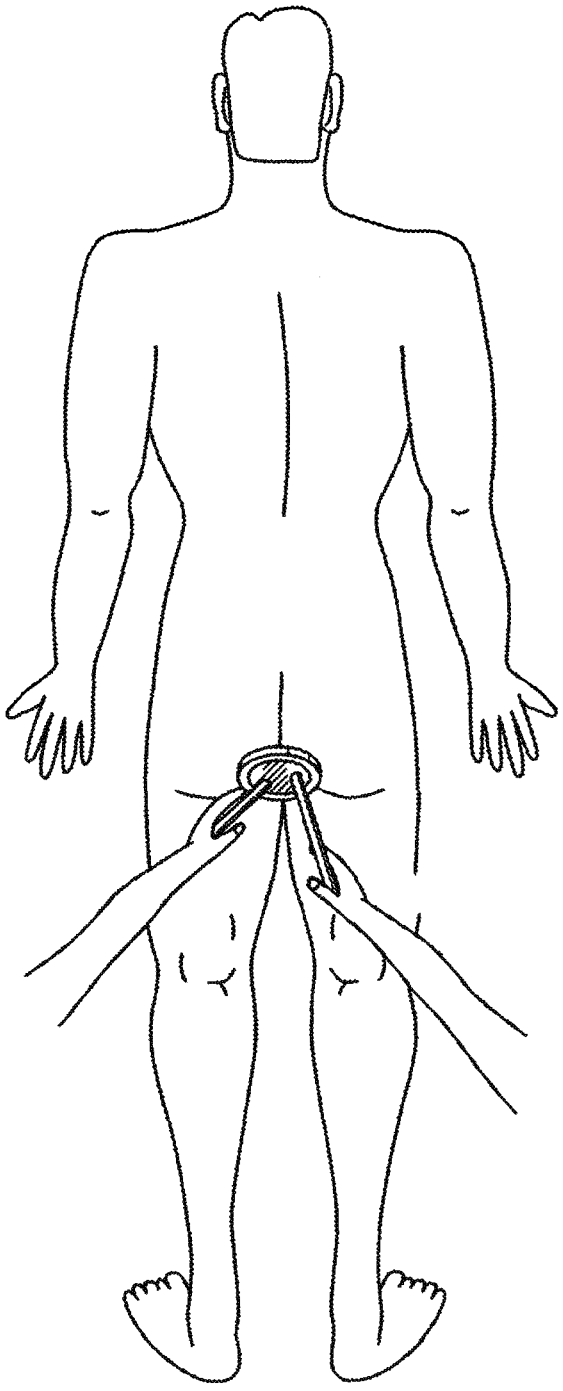


FIG. 4

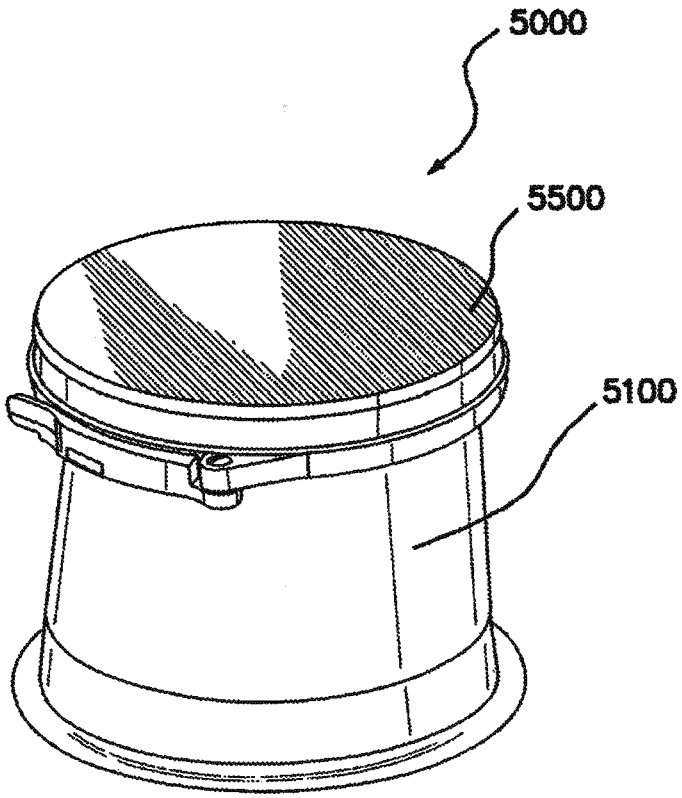



FIG. 5

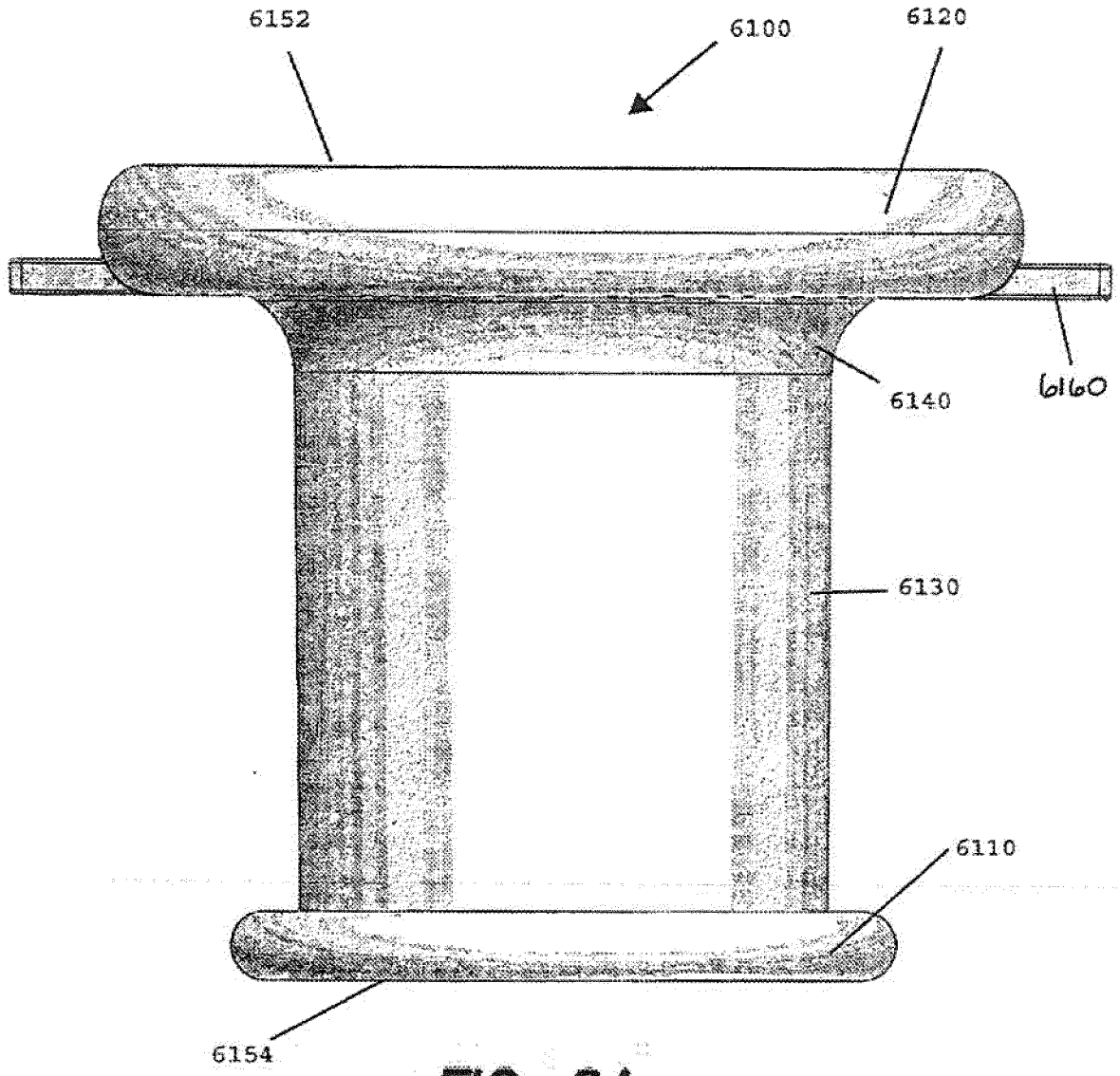



FIG. 6A

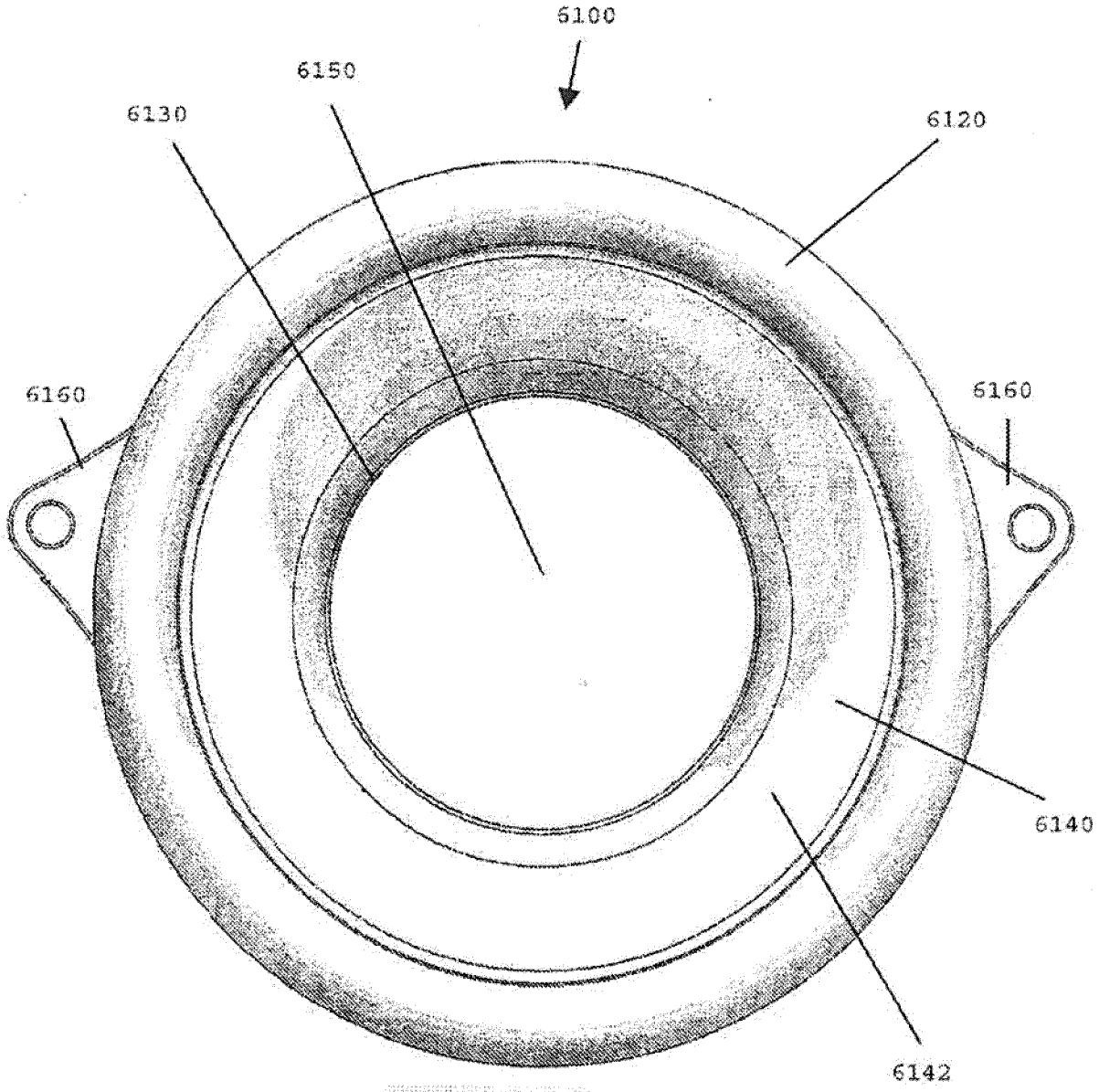



FIG. 6B

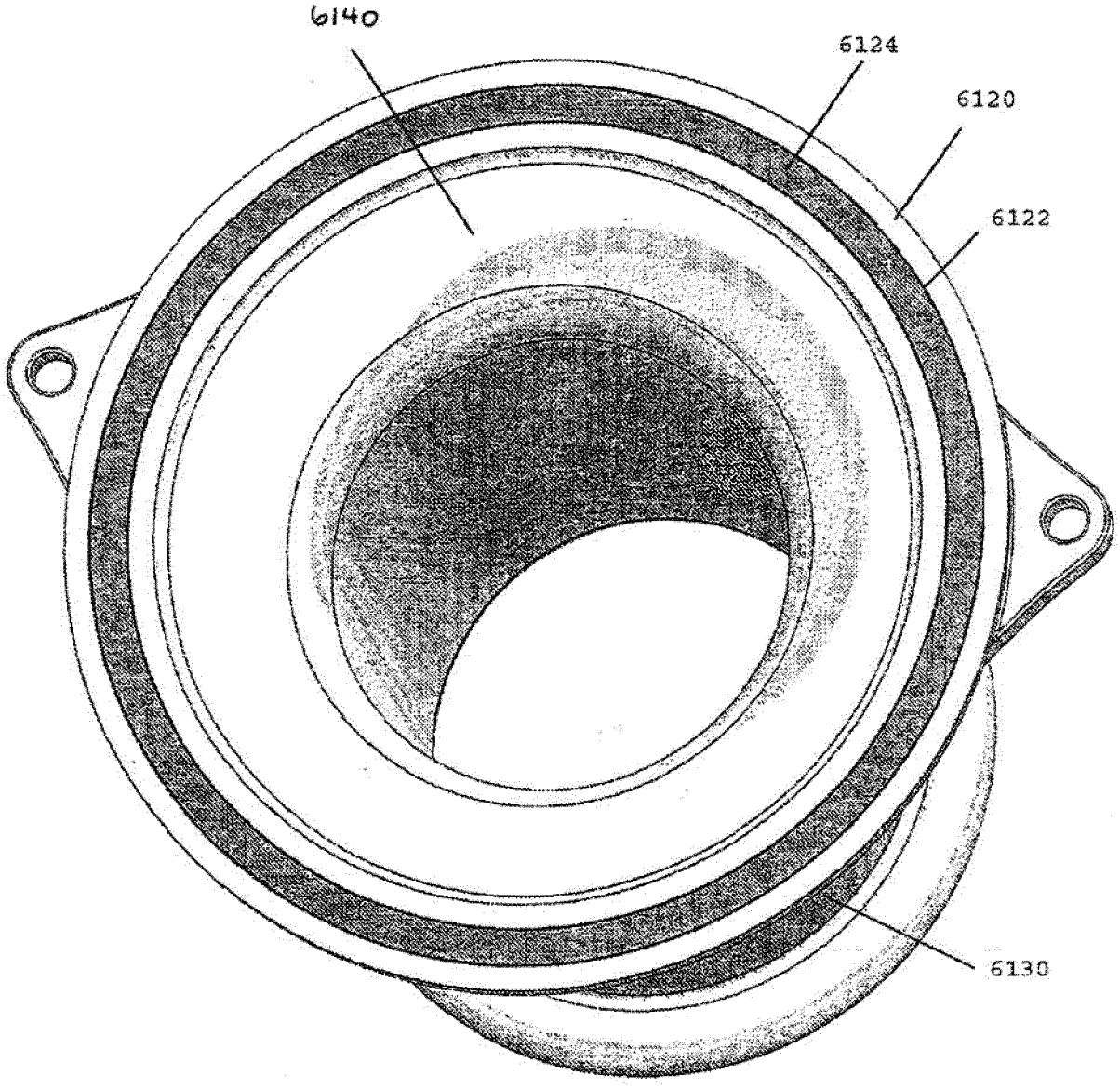



FIG. 6C

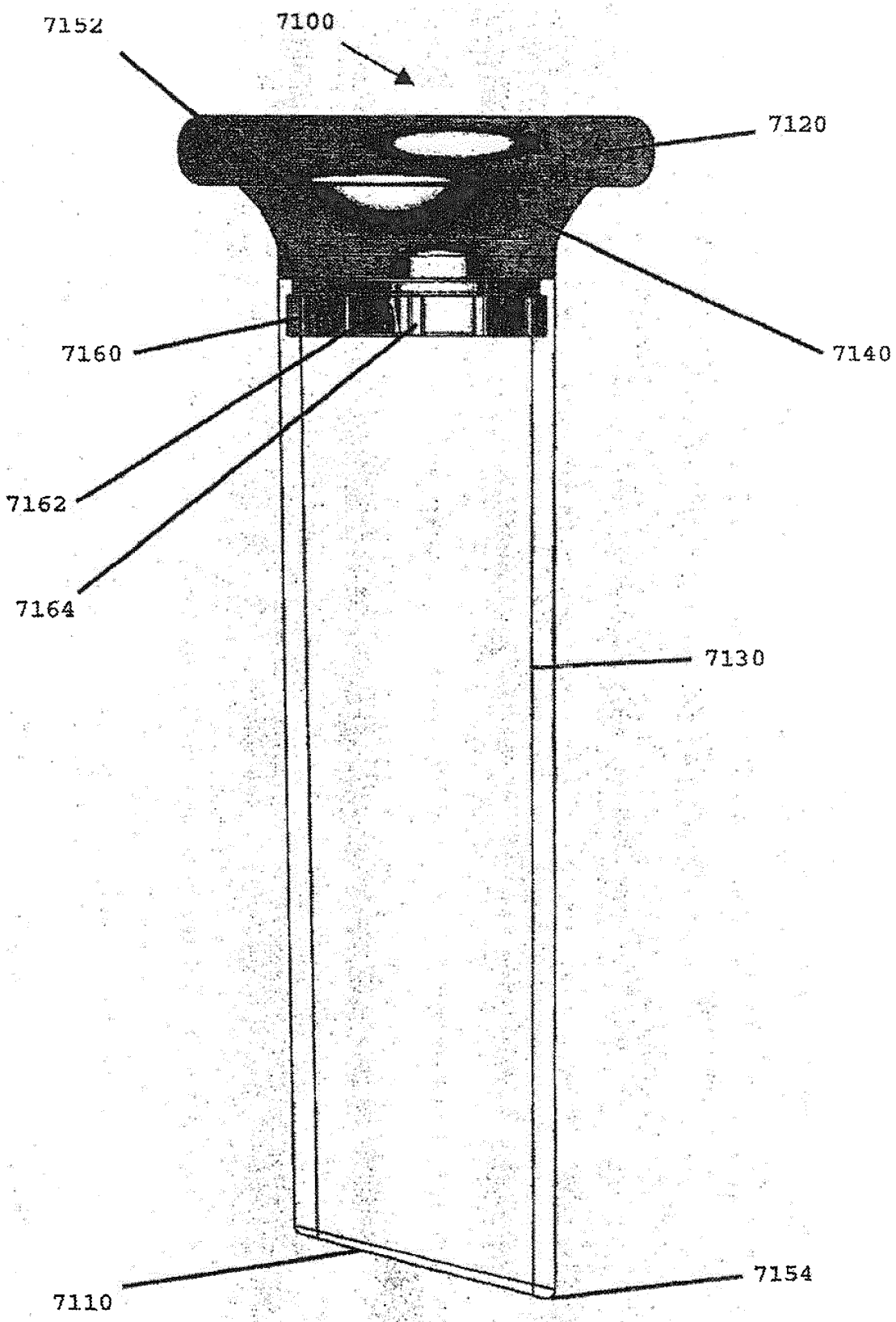



FIG. 6D

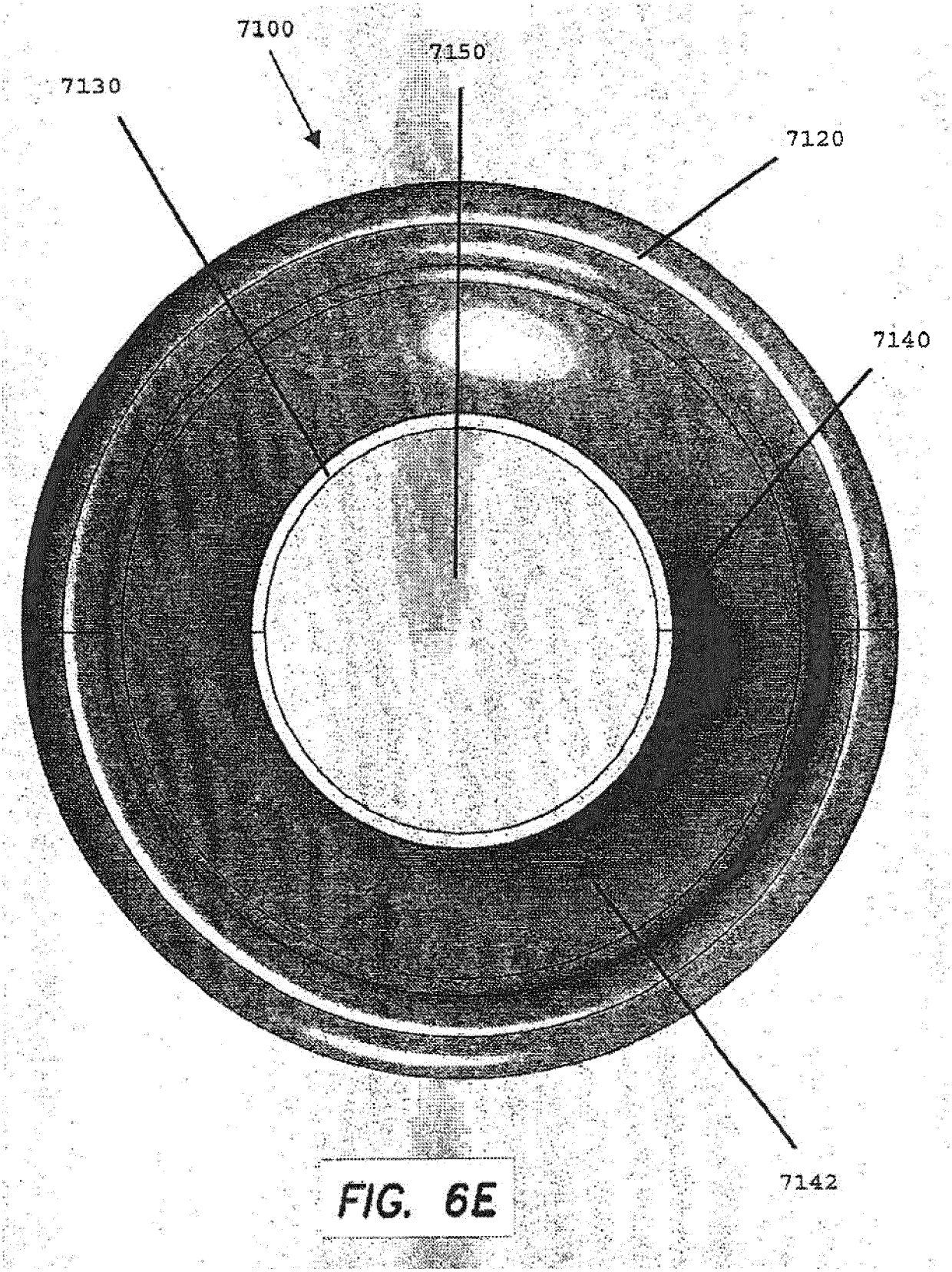



FIG. 6E

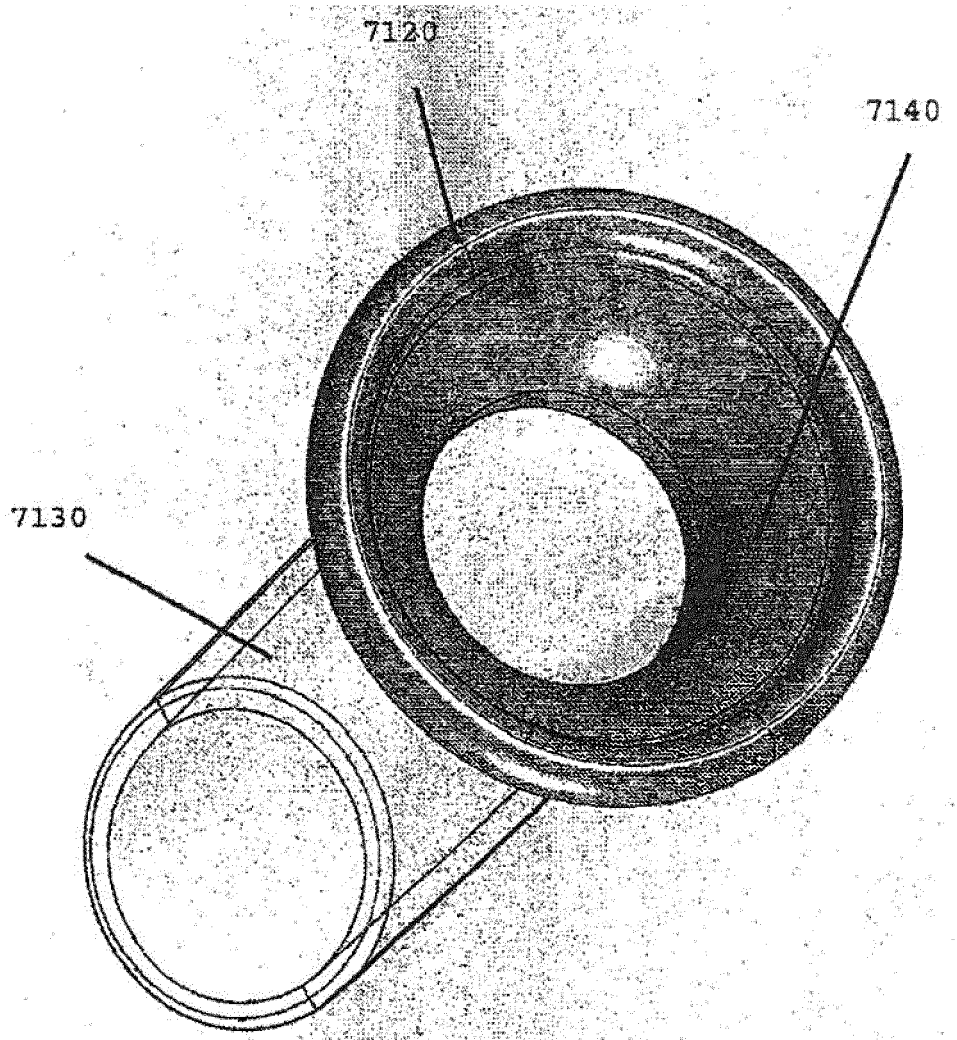



FIG. 6F

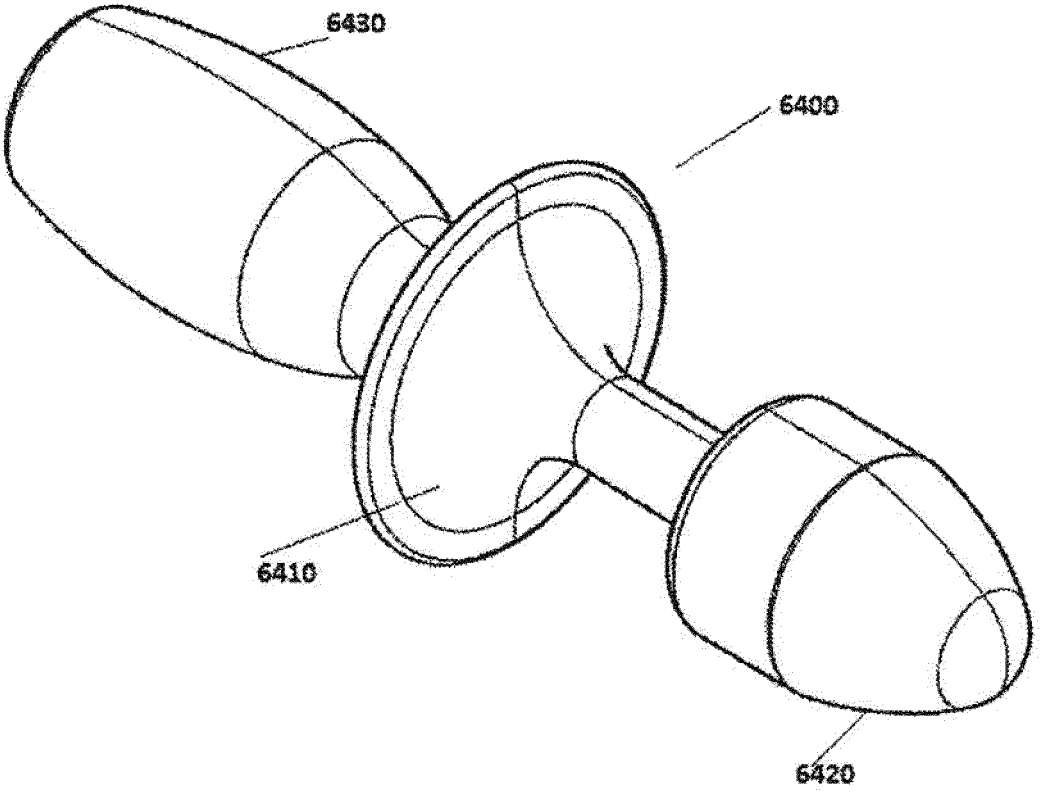



FIG. 6G

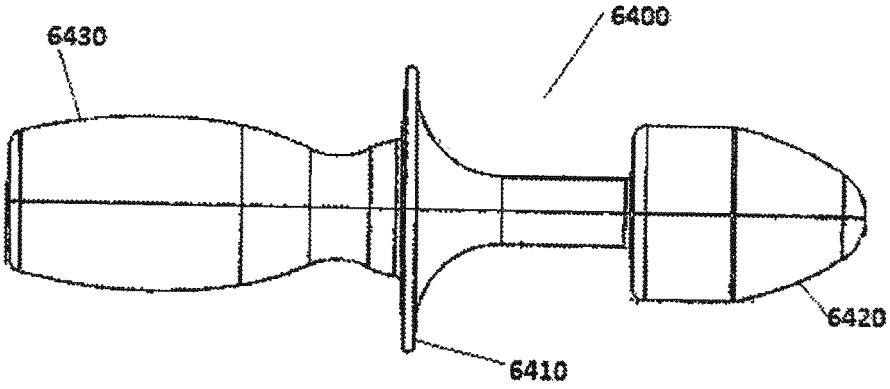



FIG. 6H

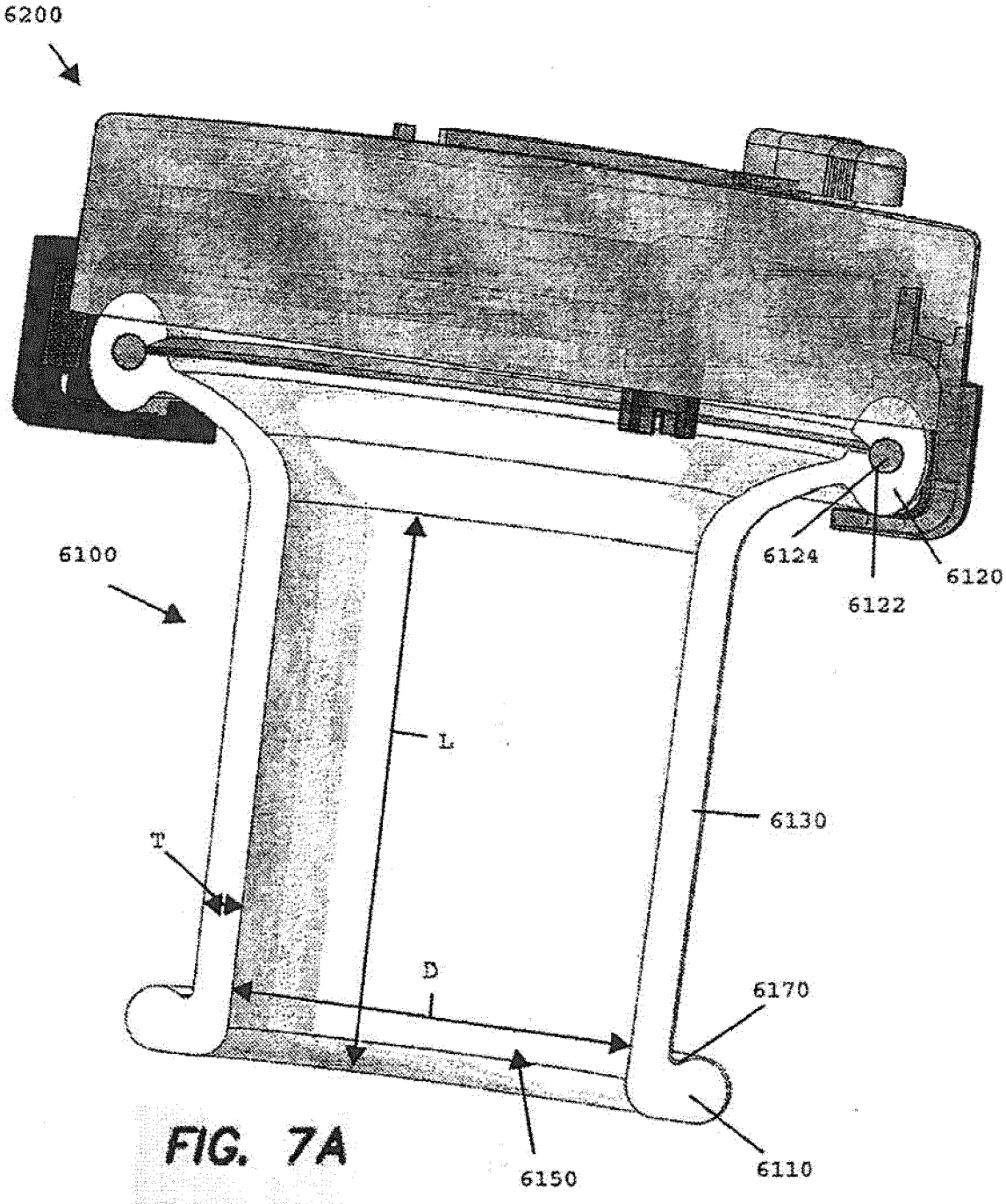
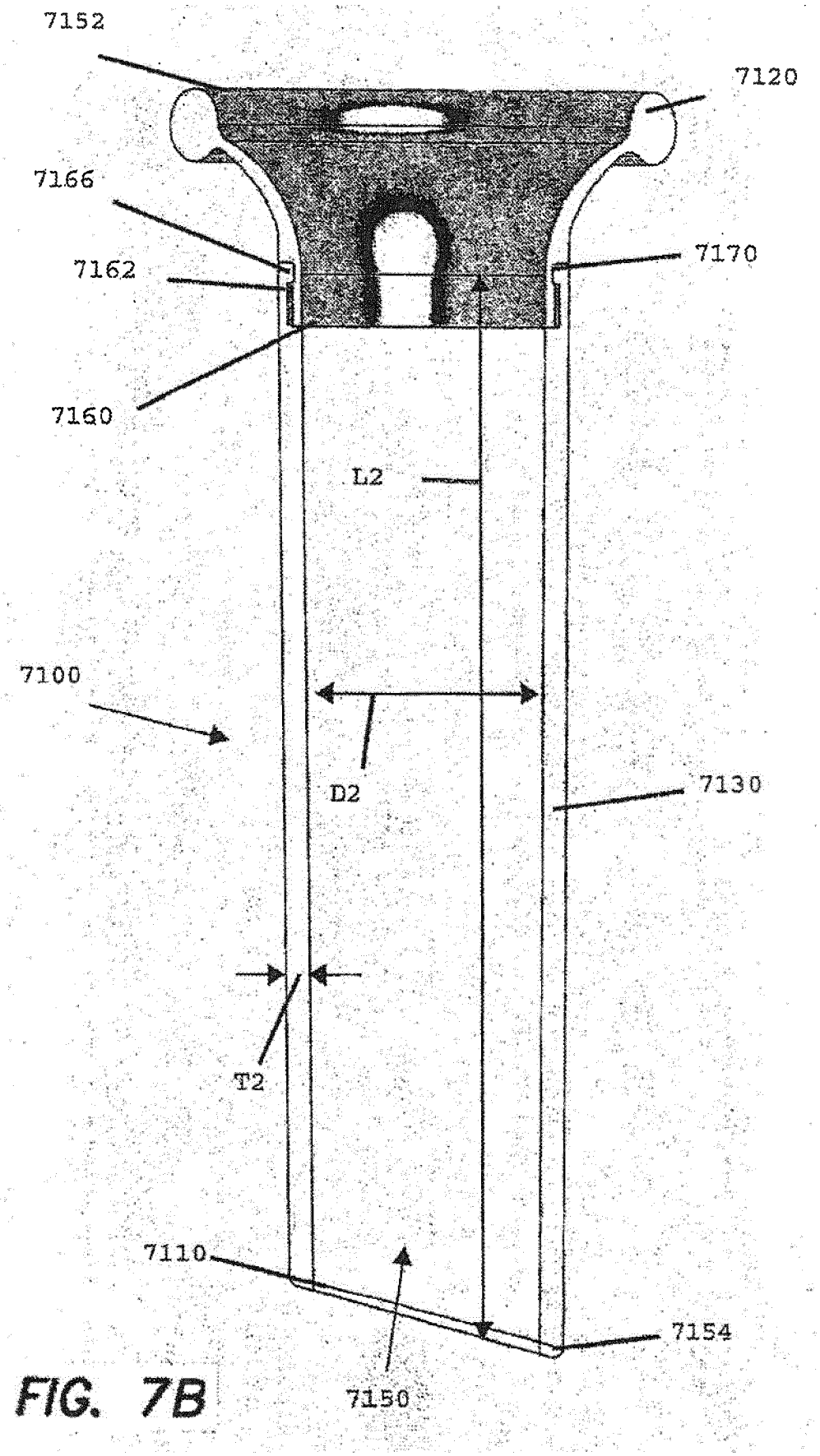



FIG. 7A


7152
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L2
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D2
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T2
7110
7154
7150

FIG. 7B

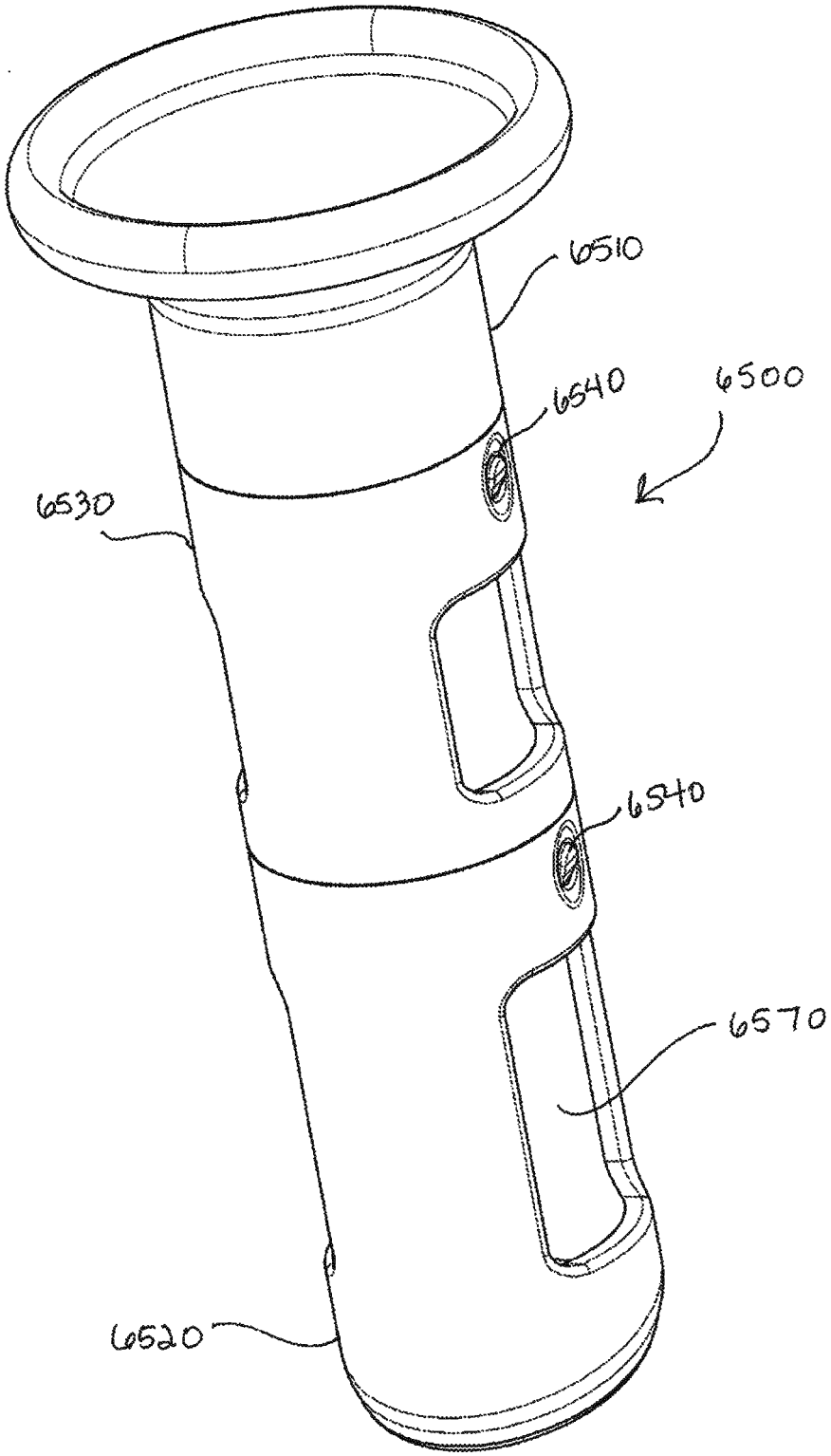


FIG. 7C

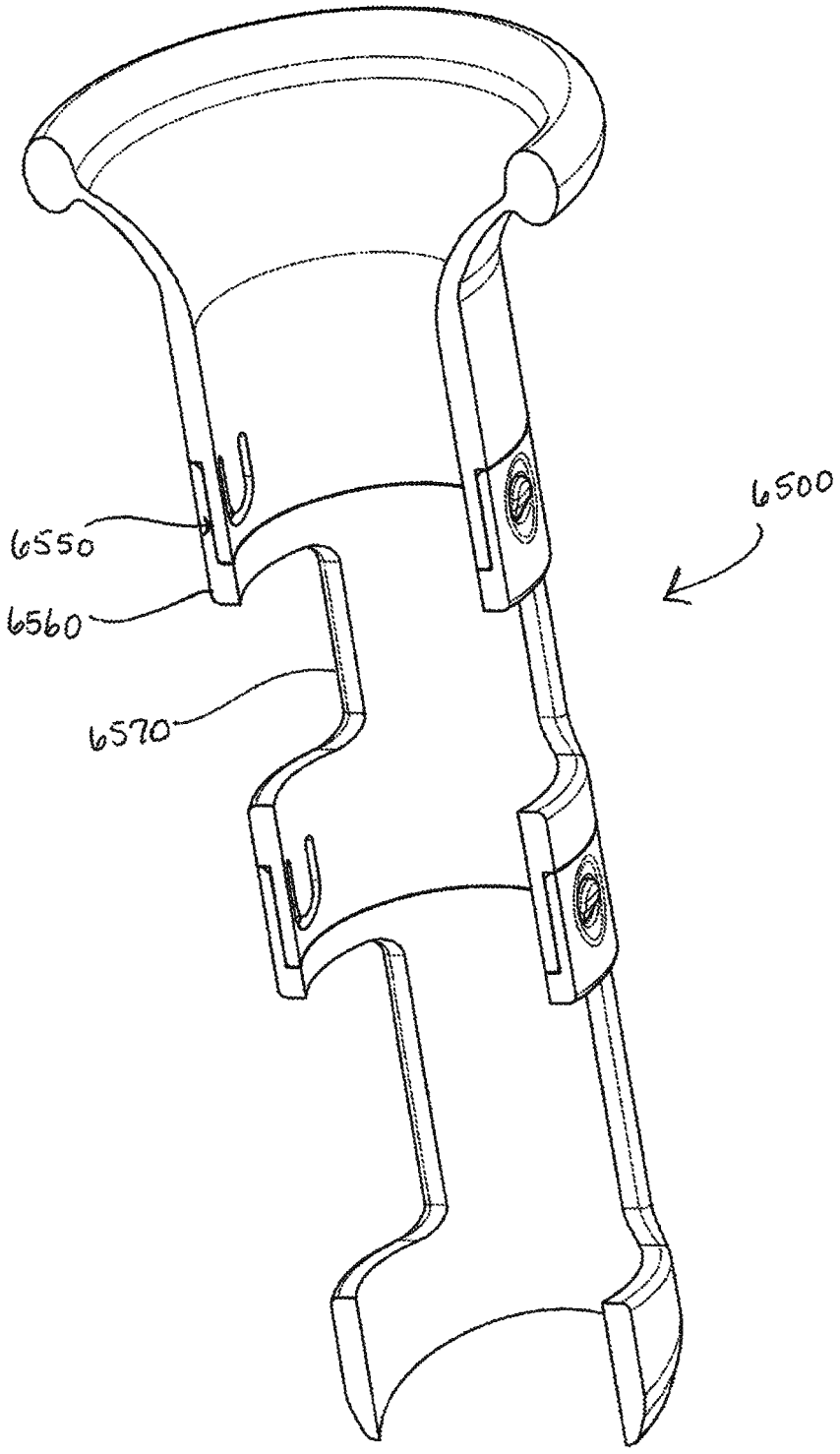


FIG. 7D

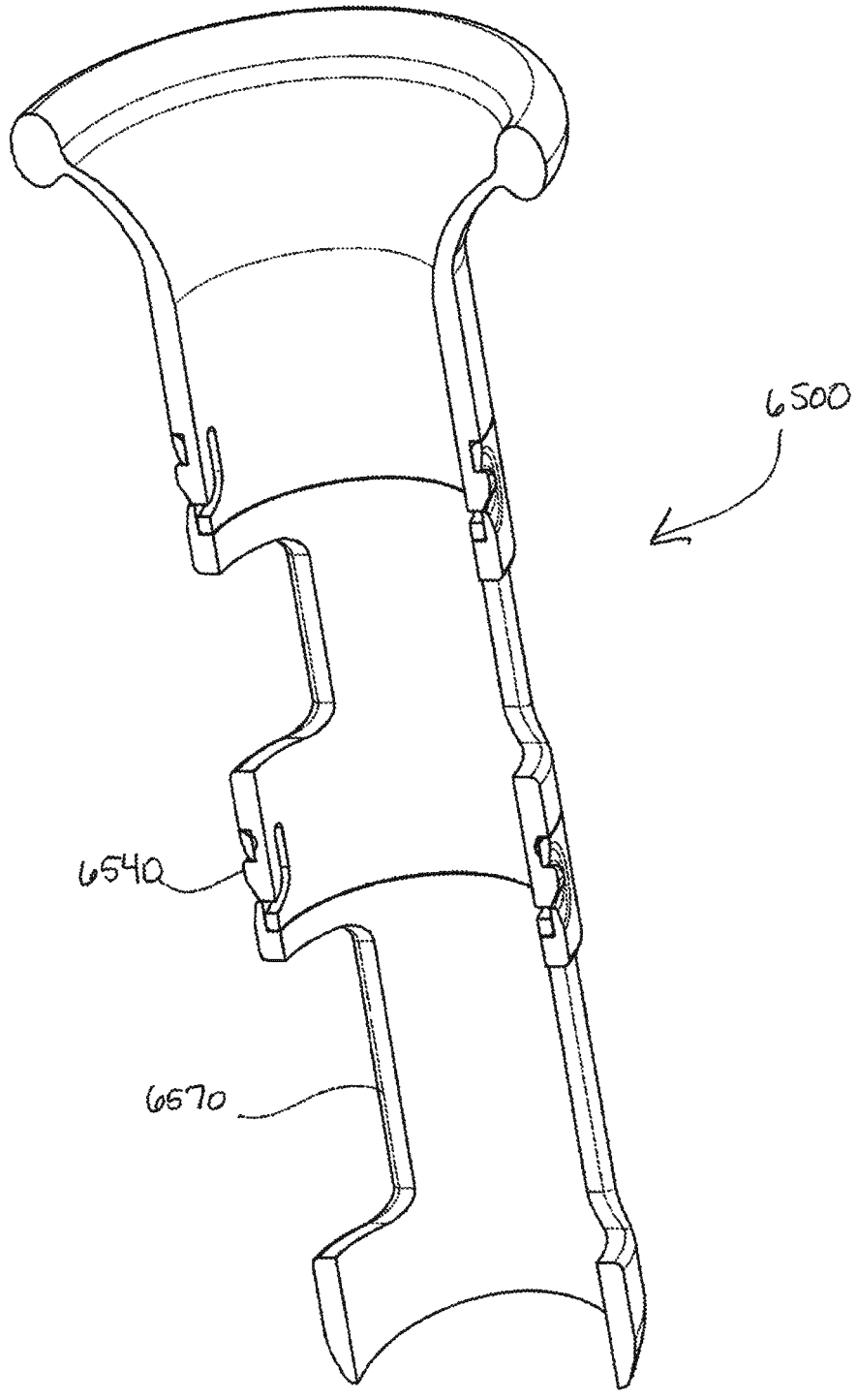


FIG 7E

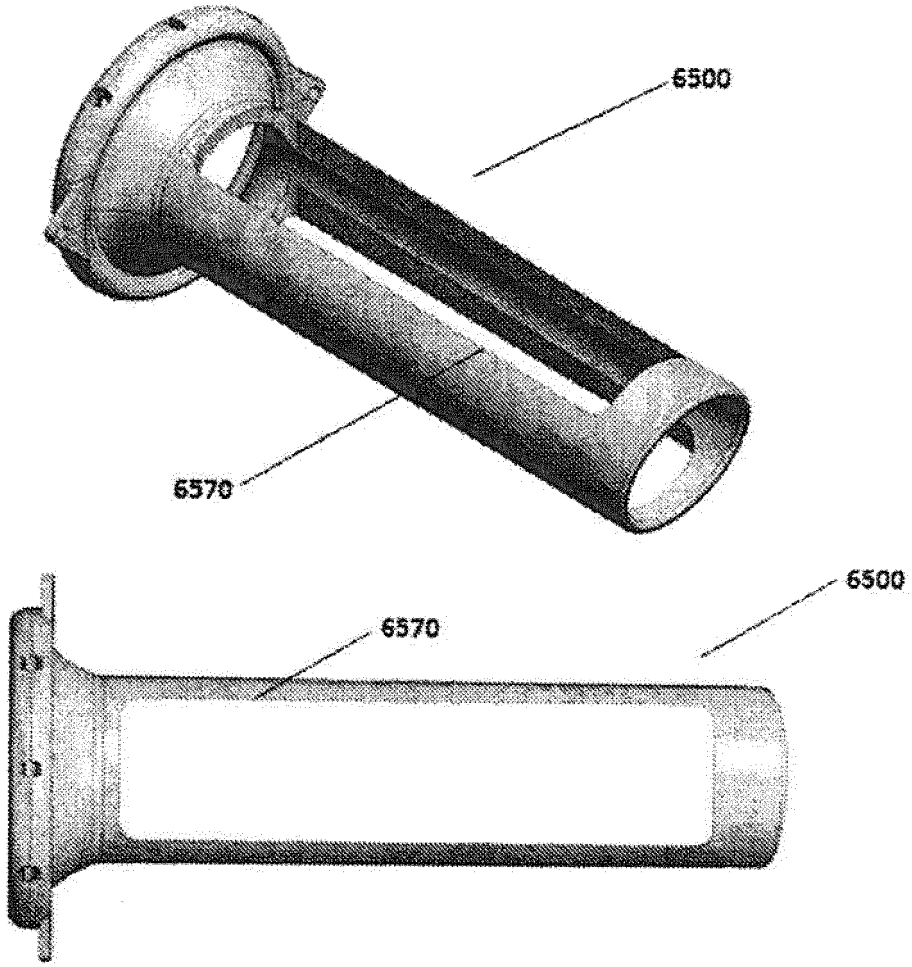


FIG. 7F

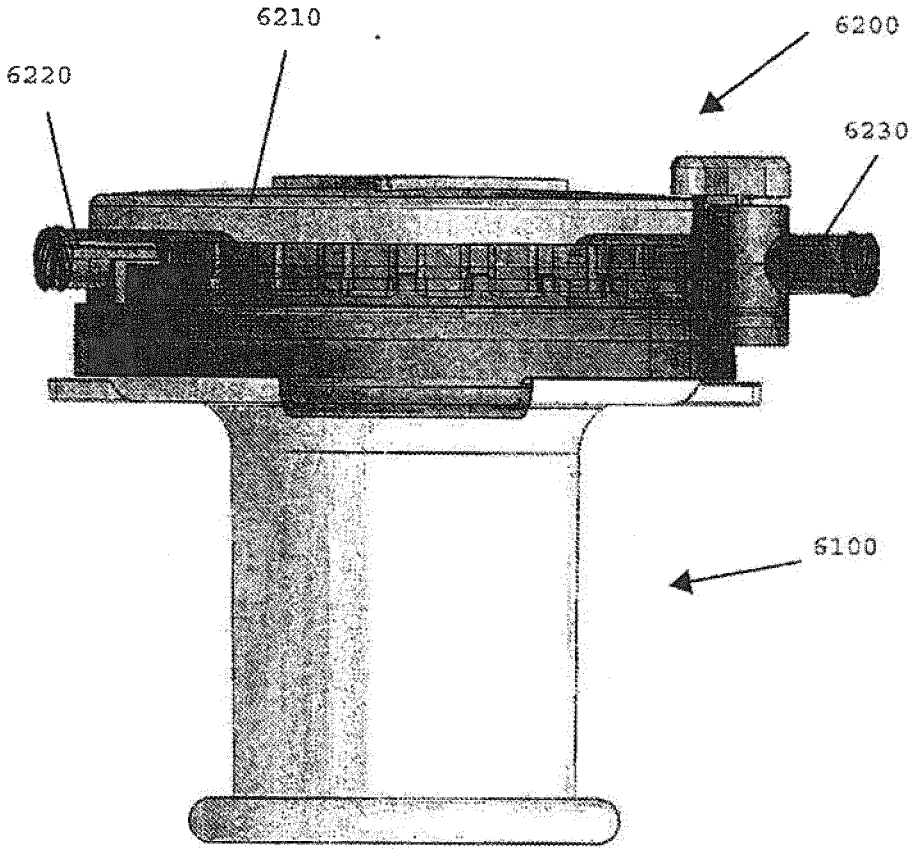


FIG. 8A

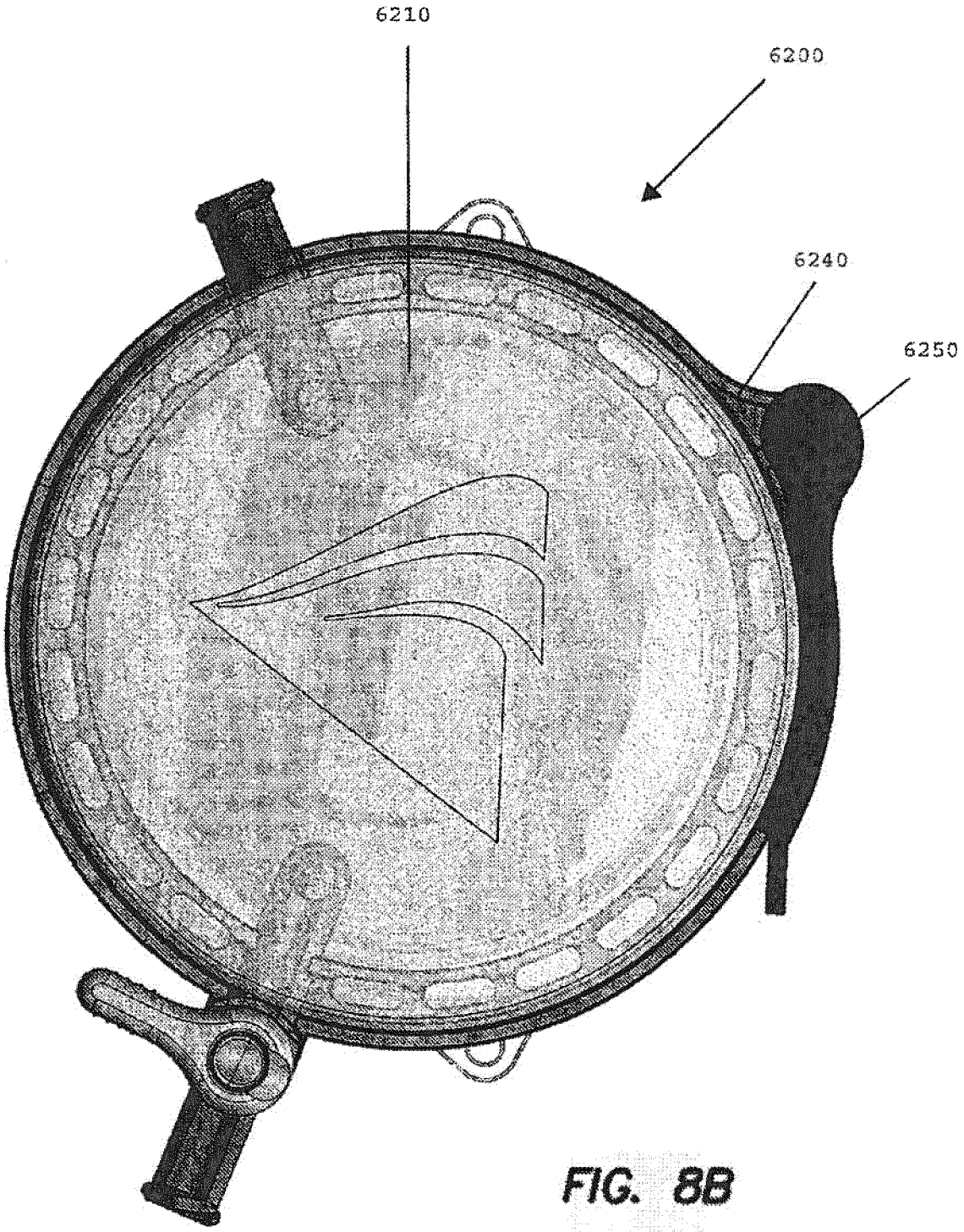


FIG. 8B

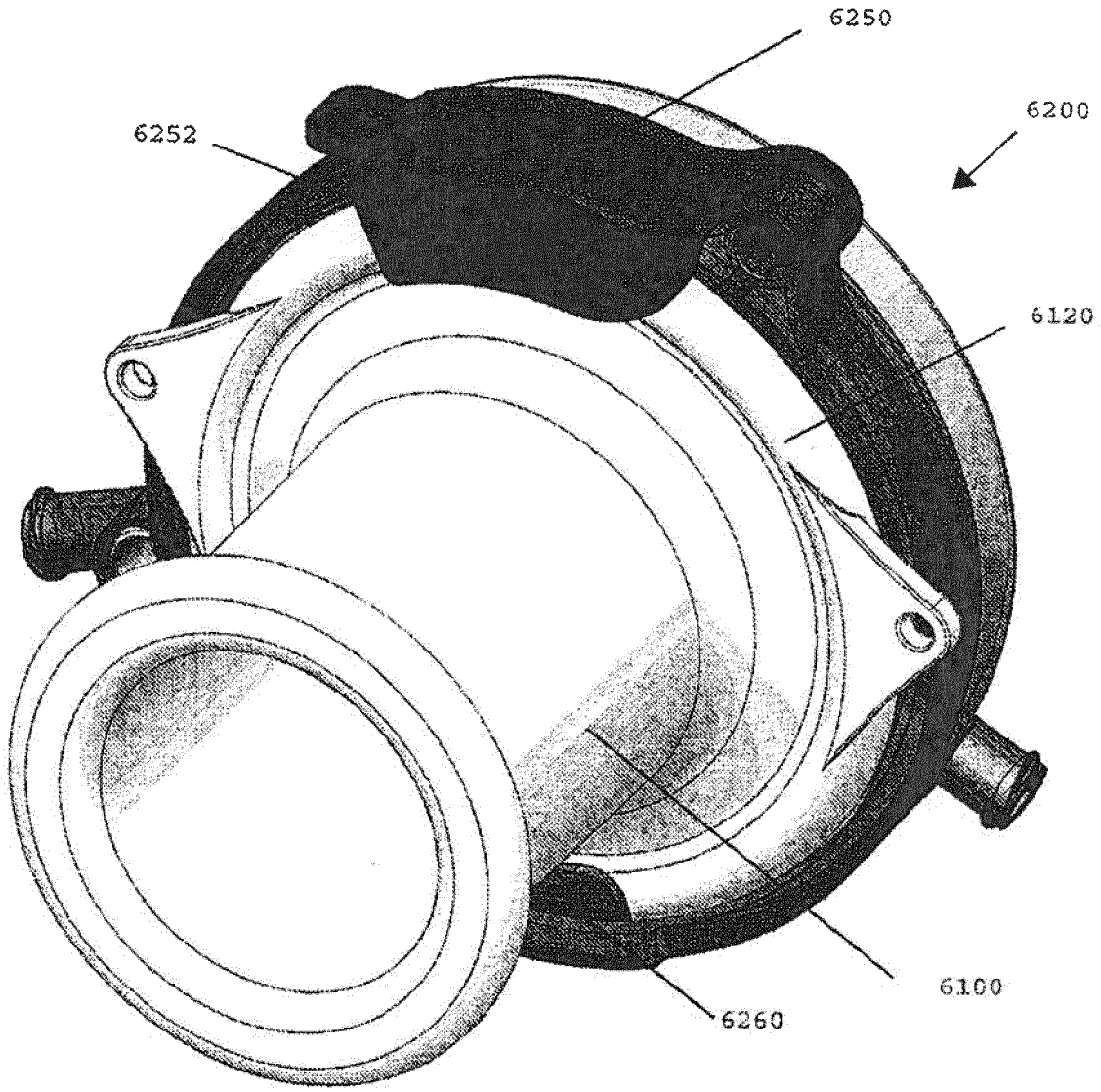


FIG. 8C

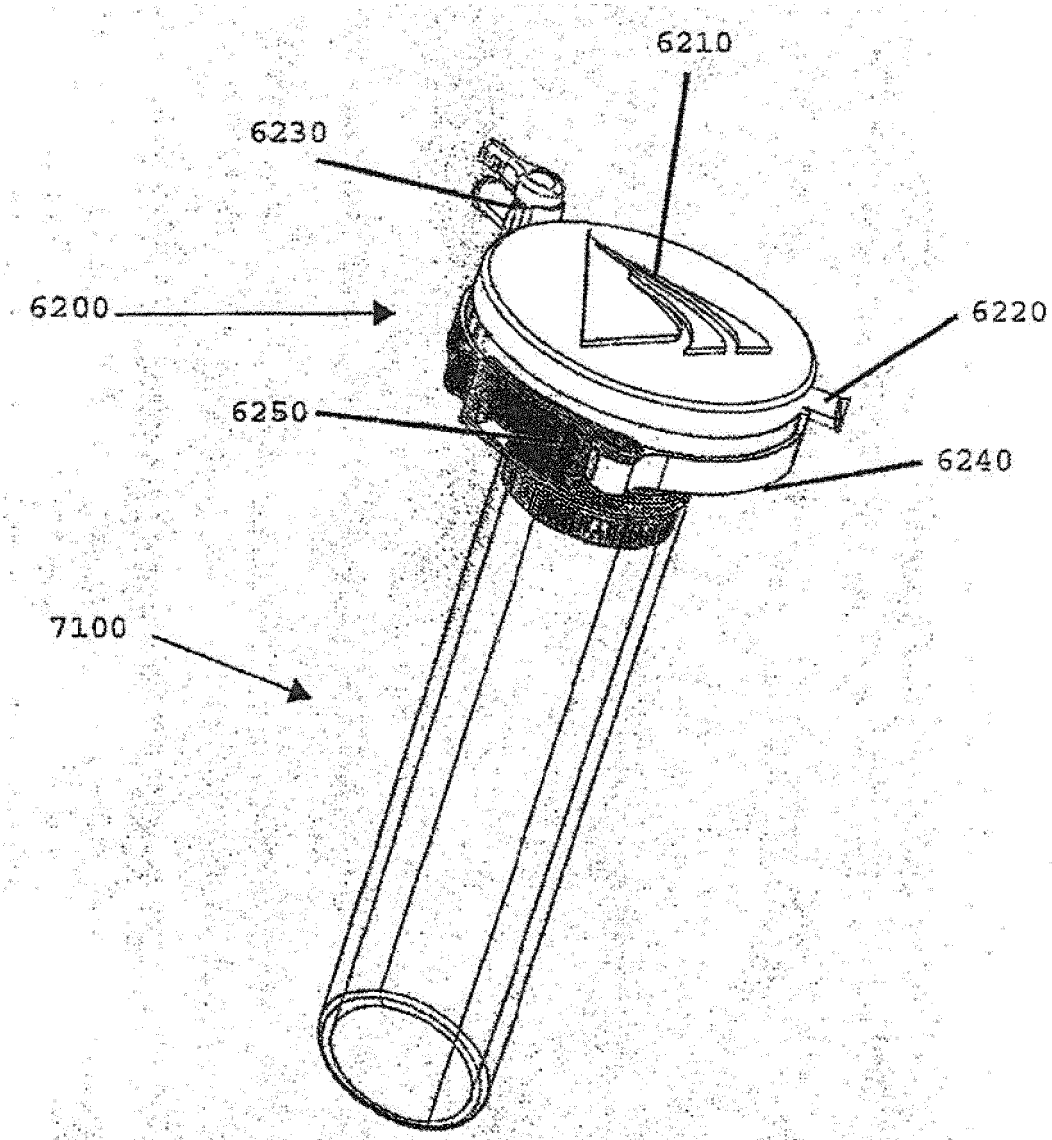


FIG. 8D

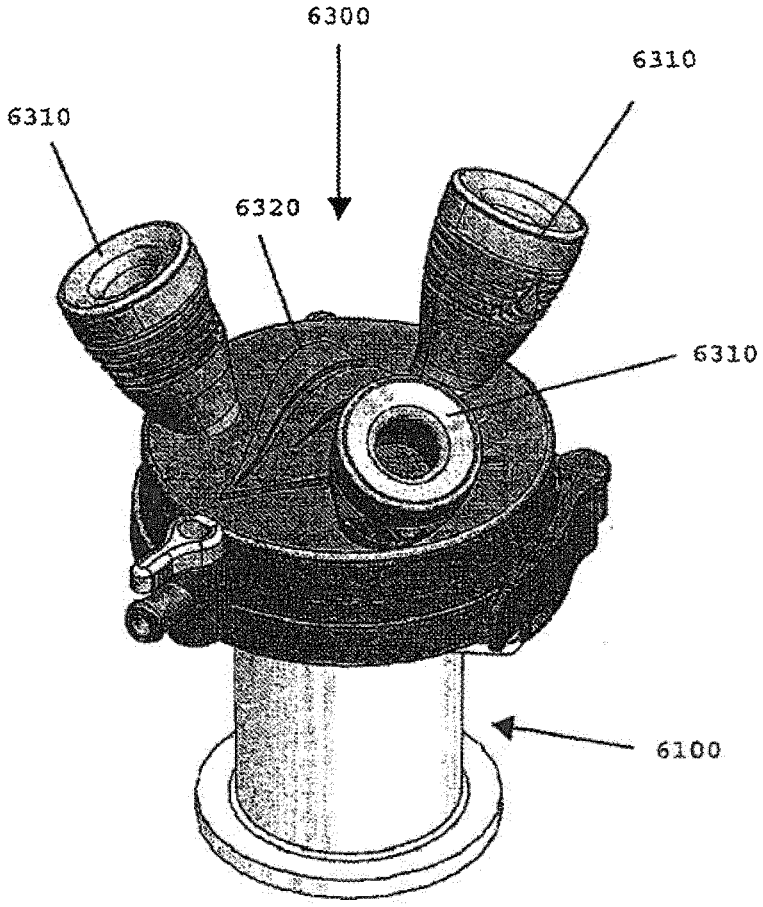


FIG. 9A

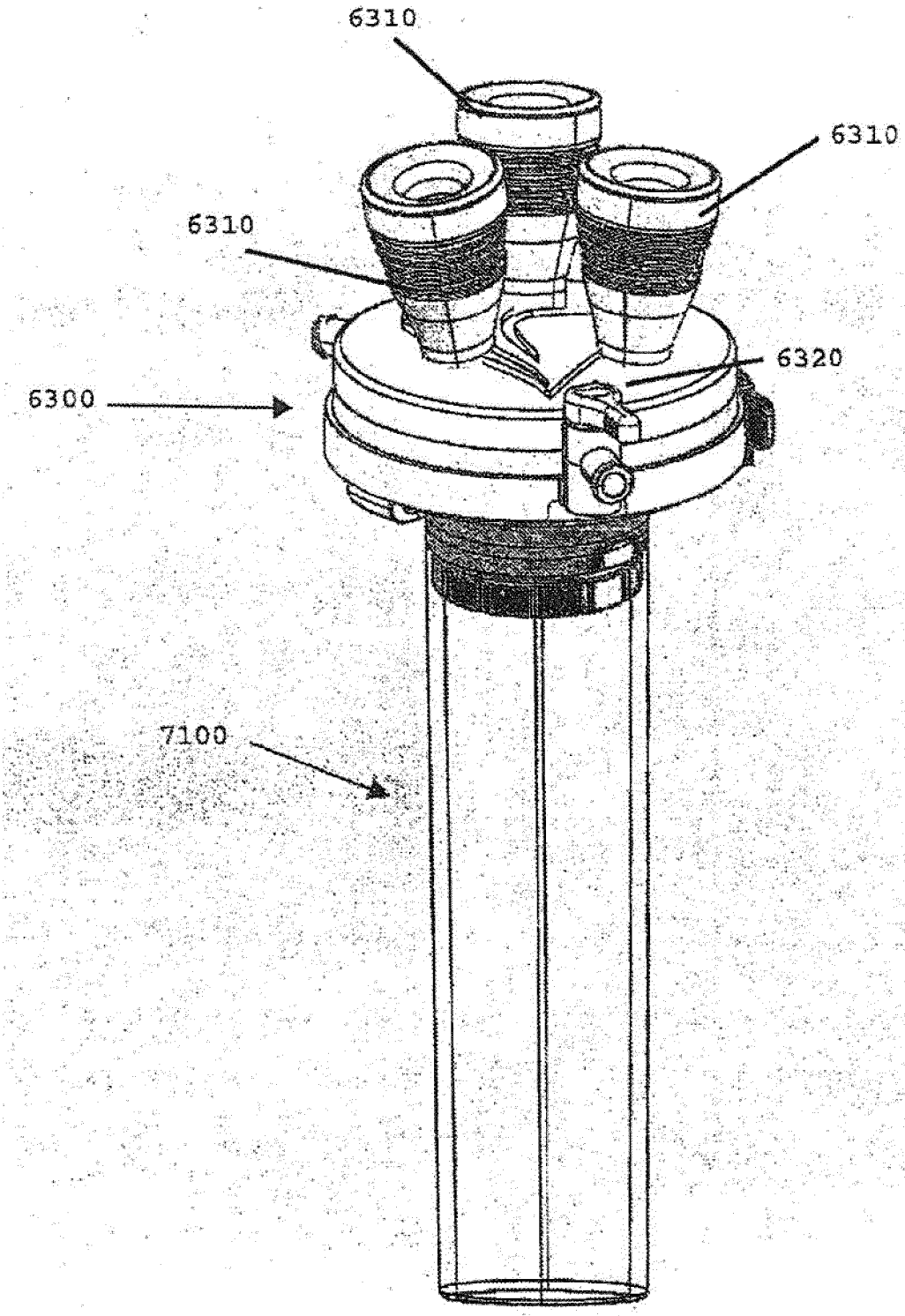


FIG. 9B

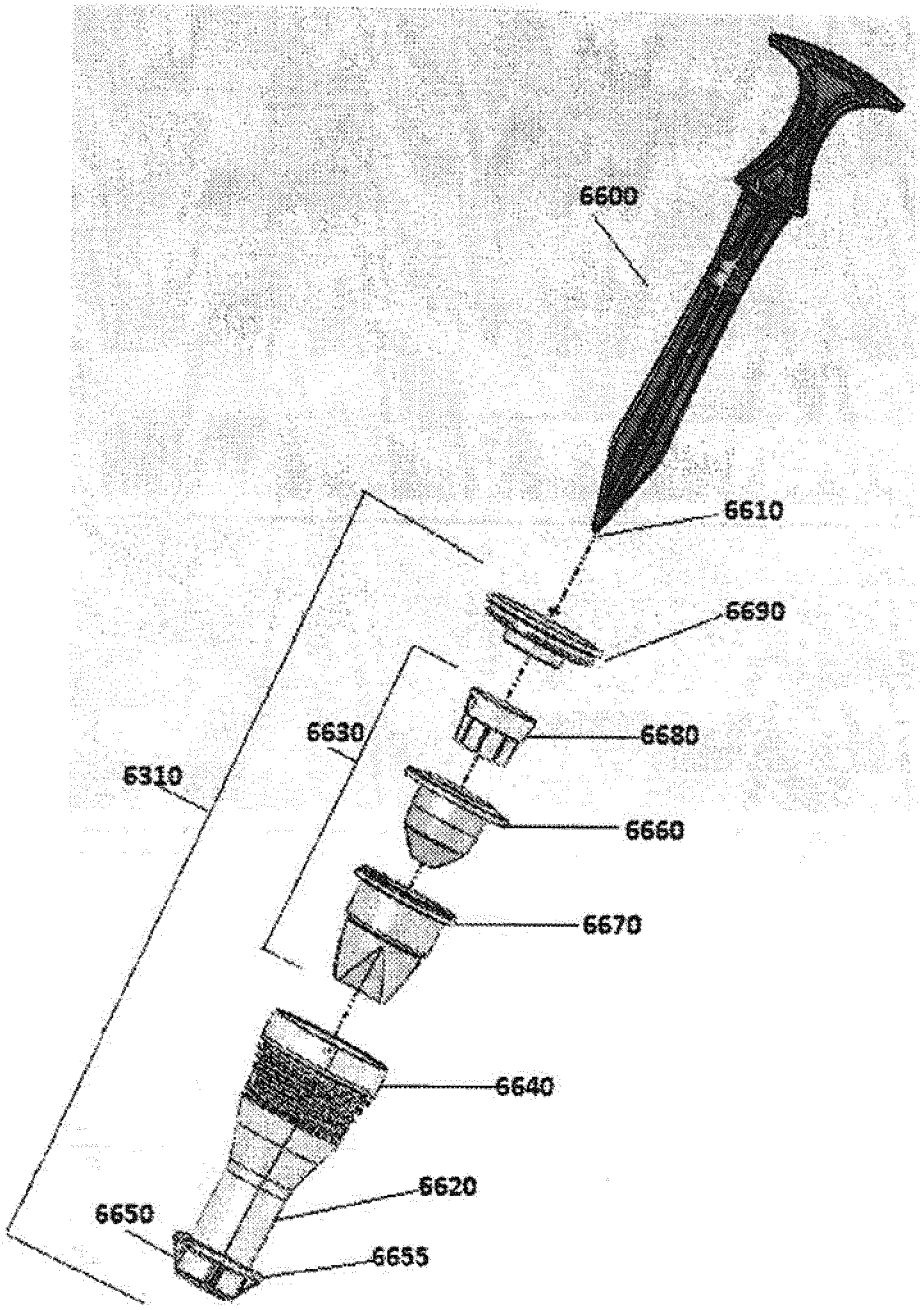


FIG. 9C

## REFERENCES CITED IN THE DESCRIPTION

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- WO 2010045253 A1 **[0005]**
- US 20090187079 A **[0014] [0015]**
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|---|---|---|---|
| 专利名称(译) | 自然口腔手术系统 | | |
| 公开(公告)号 | EP2621348B1 | 公开(公告)日 | 2019-06-12 |
| 申请号 | EP2011767588 | 申请日 | 2011-09-30 |
| [标]申请(专利权)人(译) | 应用医疗资源 | | |
| 申请(专利权)人(译) | 应用医疗资源CORPORATION | | |
| 当前申请(专利权)人(译) | 应用医疗资源CORPORATION | | |
| [标]发明人 | DANG KEVIN K<br>ALBRECHT JEREMY J<br>BROWN BLAZE<br>HOKE ADAM<br>FILEK JACOB J<br>JOHNSON GARY M | | |
| 发明人 | DANG, KEVIN K.<br>ALBRECHT, JEREMY J.<br>BROWN, BLAZE<br>HOKE, ADAM<br>FILEK, JACOB J.<br>JOHNSON, GARY M. | | |
| IPC分类号 | A61B17/02 A61B17/34 | | |
| CPC分类号 | A61B17/0218 A61B17/0293 A61B17/3423 A61B17/3431 A61B2017/3419 A61B2017/3443 A61B2017/345 A61B2017/3452 A61B17/3439 A61B2017/3441 A61B2017/3445 A61B2017/3456 A61B2017/3484 A61B2017/3492 | | |
| 优先权 | 61/389091 2010-10-01 US<br>61/485321 2011-05-12 US | | |
| 其他公开文献 | EP2621348A1 | | |
| 外部链接 | Espacenet | | |


摘要(译)

描述了包括牵开器的外科进入端口系统的实施例，该牵开器适于联接到帽并且在自然孔口手术中特别有用。牵开器包括外环，其中外环构造成靠近患者的自然孔设置并且基本上围绕孔口;管状体;以及在外环和管状体之间延伸并连接的漏斗段，其中漏斗段在外环的相对大的直径和管状体的相对较小的直径之间提供直径减小，其尺寸适合于在自然孔口，孔口膨胀最小。


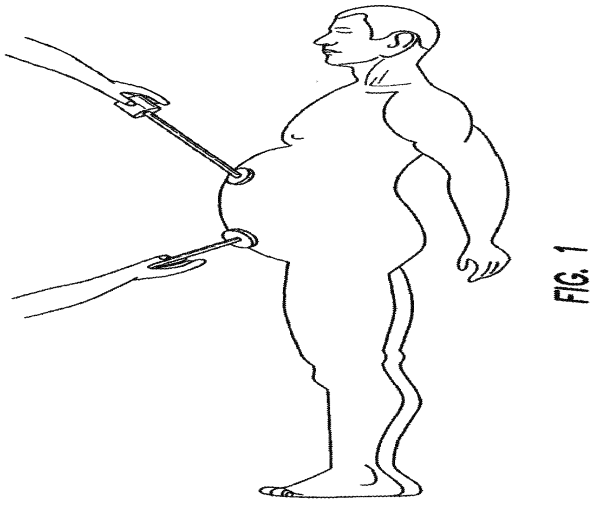

FIG. 1