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- (71) **Applicants:** **BOSTON SCIENTIFIC SCIMED, INC.** [US/US]; One Scimed Place, Maple Grove, Minnesota 55311-1566 (US). **MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH** [US/US]; 200 First Street S.W., Rochester, Minnesota 55905 (US).
- (72) **Inventors:** **EGGERT, Joel T.**; 6105 Deerwood Lane N., Plymouth, Minnesota 55442 (US). **PENNINGTON, Douglas**; 213 Elm Street W., Stillwater, Minnesota 55082 (US). **ROHL, James P.**; W11595 County Road MM, Prescott, Wisconsin 54021 (US). **PAGORIA, Douglas D.**; 5897 212th Street North, Forest Lake, Minnesota 55025 (US). **FAUBION, William A.**; 1005 8th Avenue SW, Rochester, Minnesota 55902 (US). **DOZOIS, Eric J.**;

1000 Weatherhill Woods Lane SW, Rochester, Minnesota 55905 (US). **FETTIG, Jonathan P.**; 22497 Janero Avenue N., Forest Lake, Minnesota 55025 (US).

- (74) **Agents:** **KACVINSKY DAISAK BLUNI PLLC** et al.; Attn: Scott Bluni, 50 Doaks Lane, Marblehead, MA 01945 (US).

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- (54) **Title:** CONTINENT OSTOMY VALVE AND METHOD OF USE

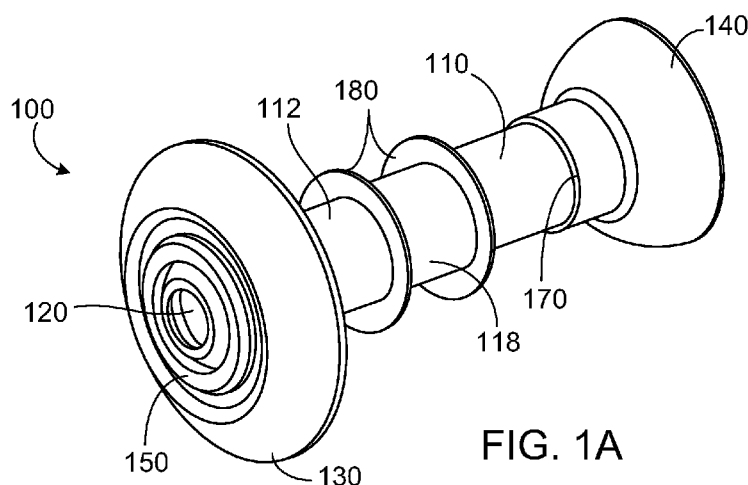


FIG. 1A

- (57) **Abstract:** Methods and materials related to ostomy devices, and particularly to valves for use with continent ostomies (e.g., ileostomies) are provided herein.

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- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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CONTINENT OSTOMY VALVE AND METHOD OF USE

CLAIM OF PRIORITY

This application claims priority to U.S. Provisional Application Serial No.
5 62/142,206, filed on April 2, 2015, the entire contents of which are hereby
incorporated by reference.

BACKGROUND

1. Technical Field

10 This document relates to ostomy devices. For example, this document relates
to continent ostomy (e.g., continent ileostomy) valve devices.

2. Background Information

Treating some diseases of the digestive or urinary system can involve
15 removing all or part of a patient's small intestine, colon, rectum, or bladder. In these
cases, waste must be rerouted to exit the body of the subject. The rerouting surgery,
known as an ostomy, can involve creating an opening in the abdominal wall so that a
portion of the intestinal tract can be brought out to the skin level, resulting in what is
called a stoma. Three common types of abdominal wall stomas result from, and may
20 be classified as, a colostomy, ileostomy, and urostomy, which involve patients who
have had surgery on their large intestine, small intestine, and urinary bladder,
respectively. Typically, a medical prosthetic known as an ostomy pouching system
can be used to collect waste from a diverted biological system as it exits a stoma. In a
surgical variation of an ileostomy, a reservoir pouch is created inside the abdomen
25 with a portion of the terminal ileum. A valve can be constructed in the pouch, and a
stoma can be brought through the abdominal wall. A catheter or tube inserted into the
pouch can be used drain feces from the reservoir.

SUMMARY

30 This document provides methods and materials related to ostomy devices, and
particularly to valves for use with ostomies (e.g., ileostomies, including standard
ileostomies and surgically created continent pouches). The devices provided herein

may be readily inserted and removed by a user, and may be used to anchor a continent ostomy device in place without the use of inflation balloons. In addition, the valves provided herein may be useful with urostomy devices, colostomy devices, feeding tubes, G tubes, anal plugs, and enteral access devices in general. In some
5 embodiments, the valve can be used as an anal plug for fecal incontinence, either for ambulatory patients (e.g., used as a plug that is removed to empty), or in patients who are bed-ridden (e.g., due to a spinal cord injury or other condition), where a care-giver can use the valve as a means to facilitate the bowel program or stool removal, mini-enema, etc. This document also provides devices that can engage a valve device as
10 provided herein, and can be used to insert and remove the valve devices.

In one aspect, this document features an ostomy valve. The valve can include a hollow tubular member having a first end, a second end, an outer surface, an inner surface, and a lumen extending axially through the tubular member between the first and second ends; a sealing element contained within the lumen; and an anchoring
15 element at or adjacent to the second end; where the ostomy valve is reversibly adjustable between a radially expanded configuration for retention in a stoma, and a non-radially expanded configuration for insertion into or removal from the stoma. The ostomy valve can further have a housing connected to the first end, where the housing defines an opening that is continuous with the lumen of the hollow tubular
20 member. The sealing element can be contained within the opening of the housing. The hollow tubular member can contain high elongation tubing. The sealing element can contain silicone or isoprene. The sealing element can be configured to allow passage of a tube or catheter through the sealing element, and can effectively seal the valve after the tube or catheter is removed from the sealing element. The anchoring
25 element can be defined by a widening of the hollow tubular member, such that a cross-sectional diameter of the hollow tubular member through the anchoring element is greater than a cross-sectional diameter of the hollow tubular member through the first end. The widening can include one or more fins defined by the outer surface of the hollow tubular member. The ostomy valve can further have one or more
30 protrusions extending circumferentially around the outer surface of the hollow tubular member, where the one or more protrusions are configured to reduce the likelihood that mucous, waste, or other bodily fluids will leak from a stoma when the ostomy valve is seated in the stoma. The ostomy valve can have a length from the first end to

the second end of about 1 cm to about 10 cm, and an external diameter of about 0.5 cm to about 2 cm, exclusive of the anchoring element.

In another aspect, this document features an insertion/removal device for use with an ostomy valve, such as the ostomy valve described herein. The
5 insertion/removal device can include a hollow outer tube having a first end and a second end, where the first end is attached to a first handle; an inner shaft positioned axially and slidably within the hollow outer tube, where the inner shaft has a first end and a second end, where the first end is attached to a second handle, and where a
10 portion of the inner shaft proximate to its first end passes through an opening in the first handle; an inflatable balloon positioned on an outer surface of the hollow outer tube distal to the first handle; and an inflation port in fluid communication with the inflatable balloon, where the inflation port extends from the inflatable balloon toward the first handle. Force exerted on the first and second handles to bring them closer
15 together can cause the second end of the inner shaft to extend beyond the second end of the hollow outer tube. The second end of the inner shaft can define a protrusion configured to engage a complementary feature of the inner surface of a hollow tubular member of an ostomy valve as provided herein.

In another aspect, this document features an article of manufacture or kit containing packaging and one or more ostomy valves as described herein. The article
20 of manufacture can further include an insertion/removal device as described herein.

In still another aspect, this document features an ostomy valve that includes a hollow tubular member having a first end, a second end, an outer surface, an inner surface, and a lumen extending axially through the tubular member between the first and second ends; a housing connected to the first end, where the housing defines an
25 opening that is continuous with the lumen of the hollow tubular member; a sealing element contained within the lumen of the hollow tubular member or the opening of the housing; and an anchoring element at or adjacent to the second end; where the ostomy valve is reversibly adjustable between a radially expanded configuration for retention in a stoma, and a non-radially expanded configuration for insertion into or
30 removal from the stoma. The sealing element can be contained within the opening of the housing. The hollow tubular member can include high elongation tubing. The sealing element can include silicone or isoprene. The sealing element can be configured to allow passage of a tube or catheter therethrough, and to effectively seal

the valve after the tube or catheter is removed from the sealing element. The anchoring element can be defined by a widening of the hollow tubular member, such that a cross-sectional diameter of the hollow tubular member through the anchoring element is greater than a cross-sectional diameter of the hollow tubular member through the first end. The widening can include one or more fins defined by the outer surface of the hollow tubular member. The widening can include a portion of the outer surface of the hollow tubular member that is at an obtuse angle with respect to the outer surface at the first end of the hollow tubular member. The ostomy valve can further define one or more protrusions extending from the outer surface of the hollow tubular member, where the one or more protrusions are configured to reduce the likelihood that mucous, waste, or other bodily fluids will leak from a stoma when the ostomy valve is seated in the stoma. The one or more protrusions can extend circumferentially around the outer surface of the hollow tubular member. The ostomy valve can have a length from the first end to the second end of about 1 cm to about 10 cm, and an external diameter of about 0.5 cm to about 2 cm, exclusive of the anchoring element.

In another aspect, this document features an insertion/removal device for use with an ostomy valve as provided herein, where the insertion/removal device includes a hollow outer tube having a first end and a second end, where the first end is attached to a first handle; an inner shaft positioned axially and slidably within the hollow outer tube, where the inner shaft has a first end and a second end, where the first end is attached to a second handle, and where a portion of the inner shaft proximate to its first end passes through an opening in the first handle; an inflatable balloon positioned on an outer surface of the hollow outer tube distal to the first handle; and an inflation port in fluid communication with the inflatable balloon, where the inflation port extends from the inflatable balloon toward the first handle. Force exerted on the first and second handles to bring them closer together can cause the second end of the inner shaft to extend beyond the second end of the hollow outer tube. The second end of the inner shaft can define a protrusion configured to engage a complementary feature on the inner surface of an ostomy valve that includes a hollow tubular member having a first end, a second end, an outer surface, an inner surface, and a lumen extending axially through the tubular member between the first and second ends; a sealing element contained within the lumen; and an anchoring element at or adjacent

to the second end, where the ostomy valve is reversibly adjustable between a radially expanded configuration for retention in a stoma, and a non-radially expanded configuration for insertion into or removal from the stoma. When the protrusion is engaged with the complementary feature, force exerted on the first and second
5 handles to bring them closer together can cause the second end of the inner shaft to extend beyond the second end of the hollow outer tube, such that the ostomy valve elongates into a non-radially expanded configuration.

In yet another aspect, this document features an article of manufacture containing one or more ostomy valves and a packaging material, where each valve
10 includes a hollow tubular member having a first end, a second end, an outer surface, an inner surface, and a lumen extending axially through the tubular member between the first and second ends; a sealing element contained within the lumen; and an anchoring element at or adjacent to the second end, where each ostomy valve is reversibly adjustable between a radially expanded configuration for retention in a
15 stoma, and a non-radially expanded configuration for insertion into or removal from the stoma. Each ostomy valve can have a length from the first end to the second end of about 1 cm to about 10 cm, and an external diameter of about 0.5 cm to about 2 cm, exclusive of the anchoring element. The article of manufacture can further include an insertion/removal device that has a hollow outer tube with a first end and a second
20 end, where the first end is attached to a first handle; an inner shaft positioned axially and slidably within the hollow outer tube, where the inner shaft has a first end and a second end, where the first end is attached to a second handle, and where a portion of the inner shaft proximate to its first end passes through an opening in the first handle; an inflatable balloon positioned on an outer surface of the hollow outer tube distal to
25 the first handle; and an inflation port in fluid communication with the inflatable balloon, where the inflation port extends from the inflatable balloon toward the first handle. The second end of the inner shaft of the insertion/removal device can define a protrusion configured to engage a complementary feature on the inner surface of the one or more ostomy devices.

30 Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention pertains. Although methods and materials similar or equivalent to those described herein can be used to practice the invention, suitable methods and

materials are described below. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. 1A is a perspective view of an embodiment of a valve device as provided herein.

FIG. 1B is a side view of an embodiment of a valve device as provided herein.

FIG. 1C is an exploded perspective view of an embodiment of a valve device as provided herein.

FIG. 1D is a perspective view of an embodiment of the tubular member of a valve device as provided herein.

FIG. 1E is a perspective view of an embodiment of the stoma cover of a valve device as provided herein.

FIG. 1F is a cross-sectional side view of the stoma cover depicted in **FIG. 1E**.

FIG. 1G is a perspective view of an embodiment of the housing of a valve device as provided herein.

FIG. 1H is a cross-sectional view of the housing depicted in **FIG. 1G**.

FIG. 1I is a cross-sectional view of an embodiment of an anchoring element of a valve device as provided herein.

FIG. 1J is a perspective view of an embodiment of the nose of a valve device as provided herein.

FIG. 1K is a cross-sectional view of an embodiment of a valve device as provided herein.

FIG. 1L is a cross-sectional view of another embodiment of a valve device as provided herein.

FIG. 2A is a side view of an embodiment of a valve device as provided herein, in an extended configuration.

FIG. 2B is a cross-sectional view of an embodiment of a valve device as provided herein, in an extended configuration.

5 **FIG. 3A** is a side view of an embodiment of a valve device as provided herein.

FIG. 3B is a side view of an embodiment of a valve device as provided herein, in an extended configuration.

10 **FIG. 4** is a cross-sectional view of an embodiment of a valve device as provided herein, positioned within a stoma.

FIG. 5A is a perspective view of an embodiment of an insertion/removal device as provided herein, engaged with an embodiment of a valve device as provided herein.

15 **FIG. 5B** is a cross-sectional view of an embodiment of an insertion/removal device as provided herein, engaged with an embodiment of a valve device as provided herein.

FIG. 6A is a perspective view of an embodiment of an insertion/removal device as provided herein, engaged with an embodiment of a valve device as provided herein, and positioned near a stoma.

20 **FIG. 6B** is a perspective view of an embodiment of an insertion/removal device as provided herein, engaged with an embodiment of a valve device as provided herein, with the valve device positioned within a stoma.

FIG. 6C is a cross-sectional view of an embodiment of an insertion/removal device as provided herein, engaged with an embodiment of a valve device as provided
25 herein, with the valve device positioned within a stoma.

FIG. 7A is a perspective view of an embodiment of a valve device as provided herein, positioned within a stoma.

FIG. 7B is a cross-sectional view of an embodiment of a valve device as provided herein, positioned within a stoma.

30 **FIG. 8A** is a perspective view of a drainage device as provided herein, where the drainage device is connected to drainage tubing and engaged with an embodiment of a valve device as provided herein, and where the valve device is positioned within a stoma.

FIG. 8B is a cross-sectional view of a drainage device as provided herein, where the drainage device is connected to drainage tubing and engaged with an embodiment of a valve device as provided herein, and where the valve device is positioned within a stoma.

5 **FIG. 9A** is a perspective view of a drainage device as provided herein, where the drainage device is connected to a waste collection bag and engaged with an embodiment of a valve device as provided herein, and where the valve device is positioned within a stoma.

10 **FIG. 9B** is a cross-sectional view of a drainage device as provided herein, where the drainage device is connected to a waste collection bag and engaged with an embodiment of a valve device as provided herein, and where the valve device is positioned within a stoma.

15 **FIG. 10A** is a cross-sectional view of an embodiment of an insertion/removal device as provided herein, engaged with an embodiment of a valve device as provided herein, with the valve device positioned within a stoma.

FIG. 10B is a perspective view of an embodiment of an insertion/removal device as provided herein, engaged with an embodiment of a valve device as provided herein, and positioned near a stoma.

 Like reference symbols in the various drawings indicate like elements.

20

DETAILED DESCRIPTION

 This document provides methods and materials related to ostomy devices. For example, this document provides valve devices that can provide a route for accessing an abdominal reservoir pouch, and can be used to anchor a continent ostomy device in place without the use of inflation balloons. The devices and methods provided herein can be used to effectively seal a stoma opening and prevent waste material and/or gas from escaping a waste reservoir of an ostomy patient.

25 In general, this document features a self-collapsing device that can be inserted by a user through a stoma in a gentle manner that minimizes damage and trauma to tissue. When deployed, the device can remain firmly in place, without the risks of deflation or over inflation that might be encountered with a device having a balloon. The devices provided herein also can be readily removed from the stoma, with minimal (e.g., no) harm to the tissue.

With reference to **FIGS. 1A-1L**, a valve device 100 can include a tubular member 110, a sealing element 120, a stoma cover 130, and an anchoring element 140. In some embodiments, a device 100 also can have one or more of: a housing 150 for the sealing element 120, a nose piece 160, and a grip 170. In some embodiments,
5 the device 100 also can have one or more ribs 180.

With respect to **FIGS. 1A-1D**, the tubular member 110 can have a proximal portion 112, a distal portion 114, and a lumen extending axially therethrough such that the tubular member 110 has an interior surface 116, and an exterior surface 118.

The sealing element 120 can be located within the proximal portion of the
10 tubular member 110, although it is to be noted that a sealing element could be located anywhere within the tubular member 110. In some embodiments, a device as provided herein may include more than one (e.g., two or three) sealing elements. In some embodiments, the device 100 can include the housing 150, with the sealing element 120 positioned therein. When the housing 150 is present, it defines an
15 opening therethrough that is in fluid communication with the lumen of the tubular member 110. The sealing element 120 can be retained within the tubular member 110 or the housing 150 by one or more collars (e.g., collar 152), which can be formed as part of the housing 150, for example. The sealing element 120 can contain or be made from a material such as silicone, polyurethane, latex, or isoprene, such that it can
20 allow passage of a catheter or tube through the tubular member 110, but will effectively provide a seal once the catheter or tube has been removed from the tubular member 110.

With reference to **FIGS. 1A-1C, 1E, 1F, and 1K**, the stoma cover 130 can be located at or adapted to attach to the proximal portion 112 of the device 100. In some
25 embodiments, as depicted in **FIGS. 1A-1C**, for example, the stoma cover 130 can extend circumferentially around the proximal portion 112 of the tubular member 110 or around the housing 150. In some embodiments, the housing 150 can define threads or another structure to facilitate engagement of the housing 150 with the stoma cover 130. For example, the housing 150 depicted in **FIGS. 1G and 1H** defines threads
30 158, which can be adapted to engage the stoma cover 130.

The stoma cover 130 can be adapted for removable attachment to the proximal portion 112 of the tubular member 110. In some embodiments, the stoma cover 130 can be made from a material that is capable of absorbing mucous and other fluids that

may leak from the stoma. For example, the stoma cover 130 can be made from an absorbent, disposable material such as bamboo, polyester, hemp, polypropylene, or any diaper material. In some embodiments, the stoma cover 130 can have layers of material that can wick away and then absorb mucous and fluid. When the stoma cover 130 becomes soiled by mucous or other bodily fluids, it can be removed and replaced by a user. In some embodiments, the material from which the stoma cover 130 is made can be flexible, which can aid in installation and removal of the stoma cover 130. The stoma cover 130 can be held in place by one or more collars or other protrusions that can extend from the exterior surface 118 of the tubular member 110 or the housing 150. As depicted in **FIG. 1K**, for example, the stoma cover 130 can be held in place on the housing 150 by a circumferential ring 155, which can be configured to fit into a groove 135 on the stoma cover 130.

With reference to **FIGS. 1A-1C, 1I, and 1K**, the anchoring element 140 can be located at the distal portion 114 of the tubular member 110. In some embodiments, the anchoring element 140 can comprise part or all of the distal portion 114 of the tubular member 110. In some embodiments, the anchoring element 140 can be constructed separately from the tubular member 110, such that it is adapted for attachment to the distal portion 114 of the tubular member 110. The anchoring element 140 can define an opening therethrough, such that it is in fluid communication with the lumen of the tubular member 110.

In some embodiments, when the anchoring element 140 is separately constructed from the tubular member 110, the external surface 118 of the tubular member 110, or the internal surface of the anchoring element 140, can include a structure to facilitate secure attachment of the anchoring element 140 to the distal portion 114 of the tubular member 110. For example, the device 100 can have a circumferential grip 170 on the external surface 118 of the tubular member 110, which can contact the internal surface of the anchoring element 140 when it is engaged with the tubular member 110. The grip 170 can be made from the same material as the tubular member 110, or can include a different material (e.g., a resin or thermoplastic material such as polyetherimide).

The anchoring element 140 can be configured such that it has a greater external (cross-sectional) diameter than the proximal portion 112 of the tubular member 110. Such a configuration can provide a mechanism for holding the

anchoring element 140 firmly against the interior wall of the remaining intestine or a waste reservoir within a user, adjacent to the user's internal abdominal wall.

In some embodiments, the tubular member 110 can be extendable and retractable, such that its length can be adjusted depending on the length of a user's stoma. Thus, when the device 100 is in place, the stoma cover 130 can be positioned against the user's external abdominal wall around the periphery of the stoma, and the anchoring element 140 can be positioned against the interior wall of the remaining intestine or the waste reservoir to hold it against the user's internal abdominal wall.

In some embodiments, the tubular member 110 can include or be made from high elongation tubing, or can include two or more nested sections of tubing that can telescope to elongate or shorten the tubular member 110. As used herein, "high elongation" tubing has at least 30% (e.g., at least 35%, 40% or 45%) elastic elongation. High elongation tubing can contain, for example, silicone, latex, isoprene, or polyurethane-based material. In some embodiments, if the anchoring element 140 is constructed separately from the tubing member 110 and is attached at the distal portion 114 of the tubing member 110, the anchoring element 140 and the tubular member 110 can telescope relative to one another.

Any of a number of suitable means can be used to achieve a configuration in which the anchoring element 140 has a greater external diameter than the proximal portion 112 of the tubular member 110. As shown in **FIG 1L**, for example, the distal portion 114 of the tubular member 110 can define one or more fins, such as the fin 145. The fin 145 can be formed from a folded portion of the material from which the tubular member 110 is made. Such a configuration can allow the fin 145 to become unfolded as the device 100 is elongated (e.g., by a user or a clinician), thus lowering the profile of the anchoring element 140 and facilitating insertion of the device 100 into and through a stoma. An elongated configuration of an ostomy device in which the anchoring element has a lower profile is referred to herein as a "non-radially expanded" configuration, while a configuration in which the anchoring element has a higher profile is referred to herein as a "radially expanded" configuration. Methods for inserting or removing a valve device as provided herein are described below, as are methods for retracting a valve device to be in a shortened (e.g., "original") configuration for retention in a stoma.

As depicted in **FIG. 2A**, the fin 145 can be angled such that a portion of the exterior surface 118 that forms the fin 145 is at an obtuse angle with respect to the exterior surface 118 at the proximal portion 112 of the tubular member 110. The exemplary embodiments of **FIGS. 2A and 2B** depict a device 100 having a fin 145
5 formed from a folded portion of the tubular member 110, in partially extended form. In some embodiments, when the device 100 is in a fully extended, non-radially expanded configuration, the fin 145 can be completely unfolded such that the external diameter of the tubular member 110 is essentially constant along its axial length. In some embodiments, when the device 100 is in a fully extended configuration, the
10 diameter of the distal portion 114 of the tubular member 110 may still be greater than the cross-sectional diameter of the proximal portion 112, but the difference between the diameters can be decreased to an extent that the device 100 can be readily inserted or removed from a stoma by a user.

In some embodiments, an anchoring element of a device as provided herein
15 can include more than one (e.g., two, three, four, five, or more than five) fins or other structures to achieve an anchoring configuration. For example, the valve devices shown in **FIGS. 3A and 3B** have anchoring elements with four or five fins. **FIG. 3A** shows the device 100 having five fins (190, 192, 194, 196, and 198). In some embodiments, the fins 190, 192, 194, 196, and 198 can be formed from folded
20 portions of the material from which the tubular member 110 is made. Fins 190, 192, 194, 196, and 198 can be of increasing size such that they extend progressively further from the axial exterior surface 118 of the tubular member 110, resulting in a distal portion 114 that has a gradually greater external diameter than the proximal portion 112. The device 100 depicted in **FIG. 3B** has fins 190, 192, 194, and 196, which as
25 shown are in an at least partially unfolded state such that the device 100 is in an extended configuration. In some embodiments, when the device 100 is in a fully extended configuration, the fins 190, 192, 194, and 196 can be completely unfolded such that the diameter of the tubular member 110 is essentially constant along its axial length. In some embodiments, when the device 100 is in a fully extended
30 configuration, the diameter of the distal portion 114 of the tubular member 110 may still be greater than the diameter of the proximal portion 112, but the difference between the diameters can be decreased to an extent that the device 100 can be readily inserted or removed from a stoma by a user.

In some embodiments, a valve device as provided herein can include a nose piece 160 (**FIGS. 1C and 1J**), which can be positioned at or attached to the distal portion 114 of the tubular member 110, or connected to the anchoring element 140 at a distal portion of the device 100.

5 It is to be noted that a device as provided herein can include any suitable number of fins, ribs, or “wipers,” or other elements that can, in addition to holding the device in place within the stoma of a user, serve to reduce the likelihood of mucous or other bodily fluids from leaking out through the stoma around the device 100. Such elements can be integrally formed as part of the exterior surface 118 of the tubular member 110, or can be elements that are formed separately from the tubular member 110 and are held in place on the exterior surface 118 of the tubular member 110 by, for example, a friction fit, an elastic fit, or by seating in a groove or depression on the exterior surface 118. As an example, the device 100 shown in **FIGS. 1A and 4** can have the fin 145, as well as circumferential ribs 180. The ribs 180 can contact the surface of a stoma 300 within the abdominal wall, and can prevent mucous or waste from leaking out of the stoma 300 along the valve device 100. The ribs 180 can be made from a material such as, for example, silicone, latex, polyurethane, or isoprene.

This document also provides tools that can be used to extend or retract a valve device as provided herein, and can be used for insertion of a valve device into a stoma, continent placement of a valve device in a stoma, and removal of a valve device from a stoma. An embodiment of such a tool is depicted in **FIGS. 5A and 5B**. The insertion/removal device 200 can have an inner shaft 210 that is slidably and coaxially contained within a hollow outer shaft 220. The inner shaft 210 can have a proximal portion 212 connected to a handle 230, and a distal portion 214. The hollow outer shaft 220 can have a proximal portion 222 connected to a handle 240, and a distal portion 224. The inner shaft 210 can be longer than the hollow outer shaft 220, such that it extends through an opening in the handle 240 before connecting to the handle 230. The distal portion 214 of the inner shaft 210 can have (e.g., can define or be connected to) one or more structures (e.g., the paddle 215) configured to engage a corresponding structure on the interior surface 116 of the distal portion 114 of the tubular member 110 (e.g., the ridge 115). In some embodiments, for example, a structure such as the paddle 215 can be inserted into the distal portion 114 of the tubular member 110, and then rotated or snapped into place such that it engages the

ridge 115. The insertion/removal device 200 also can have an inflation port 250 that is in fluid communication with the interior of a balloon 260 on an exterior surface 226 of the hollow outer shaft 220. The balloon 260, when inflated, can hold the hollow outer shaft 220 of the insertion/removal device 200 firmly within the tubular member 110 of the valve device 100.

FIGS. 5A and 5B depict an embodiment of an insertion/removal device in use to extend a valve device. The insertion/removal device 200 is inserted into the tubular member 110 of the device 100 via the sealing element 120, and the paddle 215 is engaged with the ridge 115 within the distal portion 114 of the tubular member 110. Fluid passed through the inflation port 250 is used to inflate the balloon 260, which can hold the insertion/removal device 200 securely within the valve device. Force exerted on the handles 230 and 240 by a user or clinician pushes the handle 230 closer to the handle 240 and/or pulls the handle 240 closer to the handle 230, such that the distal portion 214 of the inner shaft 210 is extended beyond the distal portion 224 of the hollow outer shaft 220. Due to the interaction between the paddle 215 and the ridge 115, the actuation of the handles 230 and 240 causes the valve device 100 to elongate, as shown in **FIGS. 5A and 5B**. The elongated, non-radially expanded device 100 then can be inserted or removed from a stoma.

FIGS. 6A-6C depict the insertion of the valve device 100 into a stoma 300, while engaged with the insertion/removal device 200. In **FIG. 6A**, the devices 100 and 200 are in position to be inserted into the stoma 300. In **FIGS. 6B and 6C**, the devices 100 and 200 have been inserted into the stoma 300, and the insertion/removal device 200 remains engaged with the valve device 100, which is still in an extended configuration.

FIGS. 7A and 7B show the valve device 100 seated in the stoma 300, after the insertion/removal device 200 has been removed. Before removal of the insertion/removal device 200, force exerted on the handles 230 and 240 by a user or clinician moves the handles 230 and 240 away from each other, such that the distal portion 214 of the inner shaft 210 moves toward the distal portion 224 of the hollow outer shaft 220. Since the inner shaft 220 is engaged with the distal portion 114 of the tubular member 110, via the interaction between the paddle 215 and the ridge 115, the movement of the inner shaft 210 causes the tubular member 110 to shorten, such that the distance between the distal portion 114 and the proximal portion 112 is reduced,

and the valve device 100 “cinches” together for secure retention of the valve device 100 in the stoma 300. The balloon 260 can be deflated and the insertion/removal device 200 can be removed from the valve device 100 via the sealing element 120, rendering the user continent.

5 **FIGS. 8A and 8B** depict devices and a method for draining waste from a reservoir pouch. A drainage device 400 can include a relatively short, rigid segment of tubing 410, and a one way valve 420. The device 400 can be connected to a catheter or longer segment of tubing (e.g., the tubing 430) to facilitate drainage into a toilet, for example. The drainage device 400 can be inserted into the valve device 100
10 via the sealing element 120. The configuration and material of the sealing element 120 can allow the drainage device 400 to pass through the sealing element 120 without exterior leakage of waste, and also can allow the sealing element 120 to act as a wiper when the drainage device 400 is removed from the valve device 100. The one way valve 420 can prevent waste from flowing back out through the drainage device
15 400 when the drainage device 400 is removed from the valve device 100.

In some embodiments, such as when longer periods of continence are desired by a user, a drainage bag can be connected to the valve device 100. As depicted in **FIGS. 9A and 9B**, for example, the drainage device 400 can be inserted into the valve device 100, but rather than connecting the drainage device 400 to a catheter or tubing,
20 a drainage bag 500 can be connected to the drainage device 400. The drainage bag 500 can be made from any suitable material, including materials used to make ostomy bags that are standard in the art, for example. The drainage bag 500 can be disposable, or can be emptied and washed out. As described above, the one way valve 420 can prevent waste from flowing back out through the drainage device 400 when
25 the drainage bag 500 and the device 400 are removed from the valve device 100. Any suitable means (e.g., clips, threaded head, sutures, tie downs, or adhesive) can be used for connecting the bag 500 to the drainage device 400.

FIGS. 10A and 10B depict the removal of the valve device 100 from the stoma 300 of a user. The procedure is essentially the reverse of that used to insert the
30 valve device 100 into the stoma 300. The insertion/removal device 200 can be inserted into the valve device 100 via the sealing element 120, the paddle 215 can be engaged with the ridge 115, and the balloon 260 can be inflated via the port 250. Force exerted on the handles 230 and 240 by a user or clinician pushes the handle 230

closer to the handle 240 and/or pulls the handle 240 closer to the handle 230, such that the distal portion 214 of the inner shaft 210 is extended beyond the distal portion 224 of the hollow outer shaft 220. Due to the interaction between the paddle 215 and the ridge 115, the actuation of the handles 230 and 240 causes the valve device 100 to
5 elongate, as shown in **FIGS. 10A and 10B**. The elongated, non-radially expanded valve device 100 then can be removed from the stoma 300 along with the insertion/removal device 200.

This document also provides articles of manufacture, or kits, that include one or more of the devices described herein. For example, an article of manufacture or kit
10 can include one or more valve devices, one or more insertion/removal devices, one or more drainage devices, and combinations thereof, as well as packaging and instructions for using the devices. In some embodiments, an article of manufacture can include at least one valve device as described herein, and an insertion/removal device. Such embodiments also can include instructions for inserting and removing
15 the valve device.

It is noted that the valve devices described herein can be of various sizes (e.g., lengths and diameters), to accommodate different users. In some embodiments, for example, a valve device can have a length along its tubular member, in a non-extended configuration, of about 2 cm to about 10 cm (e.g., about 2, 3, 4, 5, 6, 7, 8, 9,
20 or 10 cm, or about 2 cm to about 5 cm, about 3 cm to about 6 cm, about 4 cm to about 7 cm, about 5 cm to about 8 cm, or about 6 cm to about 9 cm). When extended, the length of a valve device can be increased by at least about 0.5 cm to about 5 cm (e.g., about 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, or 5 cm, or about 0.5 cm to about 2 cm, about 1 cm to about 3 cm, or about 2 cm to about 4 cm). An insertion/removal device as
25 provided herein can have a length that is compatible with a range of lengths of the valve devices described herein.

The valve devices provided herein also can be of different diameters. In some embodiments, for example, a valve device can have a tubular member with an exterior diameter (excluding fins and ribs, for example) of about 0.5 cm to about 3 cm (e.g.,
30 about 0.5, 1, 1.5, 2, 2.5, or 3 cm, or about 0.5 to about 1.5 cm, about 1 to about 2 cm, about 1.5 to about 2.5 cm, or about 2 to about 3 cm). The ribs, fins, or other structures on the external surface of the tubular member can extend beyond the external surface by about 0.3 cm to about 2 cm (e.g., about 0.3, 0.5, 0.7, 1, 1.2, 1.5,

1.7, or 2 cm, or about 0.3 to about 0.7, about 0.5 to about 1, about 1 to about 1.5, or about 1.5 to about 2 cm). In some embodiments, the interior diameter of the tubular member (the diameter of the lumen) can be about 0.3 cm to about 1 cm (e.g., about 0.3, 0.5, 0.7, 0.9, or 1 cm, or about 0.3 to about 0.6, about 0.4 to about 0.7, about 0.5 to about 0.8, about 0.6 to about 0.9, or about 0.7 to about 1 cm). Articles of manufacture can include valve devices of particular sizes, so that individual users can obtain devices that are appropriate for their own use.

It is noted that if a device as provided herein is to be used as an anal plug for fecal incontinence, a device length of about 4 cm to about 9 cm (e.g., about 4 cm to about 7 cm, about 5 cm to about 8 cm, or about 6 cm to about 9 cm) may be particularly useful. In such cases, particularly when a valve is to be used as an anal plug for a bed-ridden patient, the diameter of the valve may be larger than that disclosed above (e.g., about 4, about 5, or about 6 cm), to accommodate the evacuation of solid stool. Devices to be used as anal plugs in ambulatory subjects do not require such a large diameter, as the devices can be removed for evacuation and then replaced for continence. In addition, a valve for use as an anal plug may lack external ribs or fins, which can facilitate anchoring the device across the anal musculature.

OTHER EMBODIMENTS

It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the following claims.

WHAT IS CLAIMED IS:

1. An ostomy valve comprising:
a hollow tubular member having a first end, a second end, an outer surface, an inner surface, and a lumen extending axially through the tubular member between the first and second ends;
a sealing element contained within the lumen; and
an anchoring element at or adjacent to the second end;
wherein the ostomy valve is reversibly adjustable between a radially expanded configuration for retention in a stoma, and a non-radially expanded configuration for insertion into or removal from the stoma.
2. The ostomy valve according to claim 1, further comprising a housing connected to the first end, wherein the housing defines an opening that is continuous with the lumen of the hollow tubular member.
3. The ostomy valve according to claim 2, wherein the sealing element is contained within the opening of the housing.
4. The ostomy valve according to any of claims 1-3, wherein the hollow tubular member comprises high elongation tubing.
5. The ostomy valve according to any of claims 1-4, wherein the sealing element comprises silicone or isoprene.
6. The ostomy valve according to any of claims 1-5, wherein the sealing element is configured to allow passage of a tube or catheter through the sealing element, and effectively seals the valve after the tube or catheter is removed from the sealing element.
7. The ostomy valve according to any of claims 1-6, wherein the anchoring element is defined by a widening of the hollow tubular member, such that a cross-sectional diameter of the hollow tubular member through the anchoring element is greater than a cross-sectional diameter of the hollow tubular member through the first end.

8. The ostomy valve according to claim 7, wherein the widening comprises one or more fins defined by the outer surface of the hollow tubular member.
9. The ostomy valve according to any one of claims 1-8, further comprising one or more protrusions extending circumferentially around the outer surface of the hollow tubular member.
10. The ostomy valve according to any one of claims 1-9, wherein the valve has a length from the first end to the second end of about 1 cm to about 10 cm, and an external diameter of about 0.5 cm to about 2 cm, exclusive of the anchoring element.
11. A device for use with an ostomy valve comprising:
a hollow outer tube having a first end and a second end, wherein the first end is attached to a first handle;
an inner shaft positioned axially and slidably within the hollow outer tube, wherein the inner shaft has a first end and a second end, wherein the first end is attached to a second handle, and wherein a portion of the inner shaft proximate to its first end passes through an opening in the first handle;
an inflatable balloon positioned on an outer surface of the hollow outer tube distal to the first handle; and
an inflation port in fluid communication with the inflatable balloon, wherein the inflation port extends from the inflatable balloon toward the first handle.
12. The device according to claim 11, wherein force exerted on the first and second handles to bring them closer together causes the second end of the inner shaft to extend beyond the second end of the hollow outer tube.
13. The device according to claim 11 or claim 12, wherein the second end of the inner shaft defines a protrusion configured to engage a complementary feature of the inner surface of the hollow tubular member of the ostomy valve according to any one of claims 1-10.

14. A system or kit comprising packaging and one or more of the ostomy valve of any of claims 1-10.

15. The system or kit according to claim 14, further comprising the device of any one of claims 11-13.

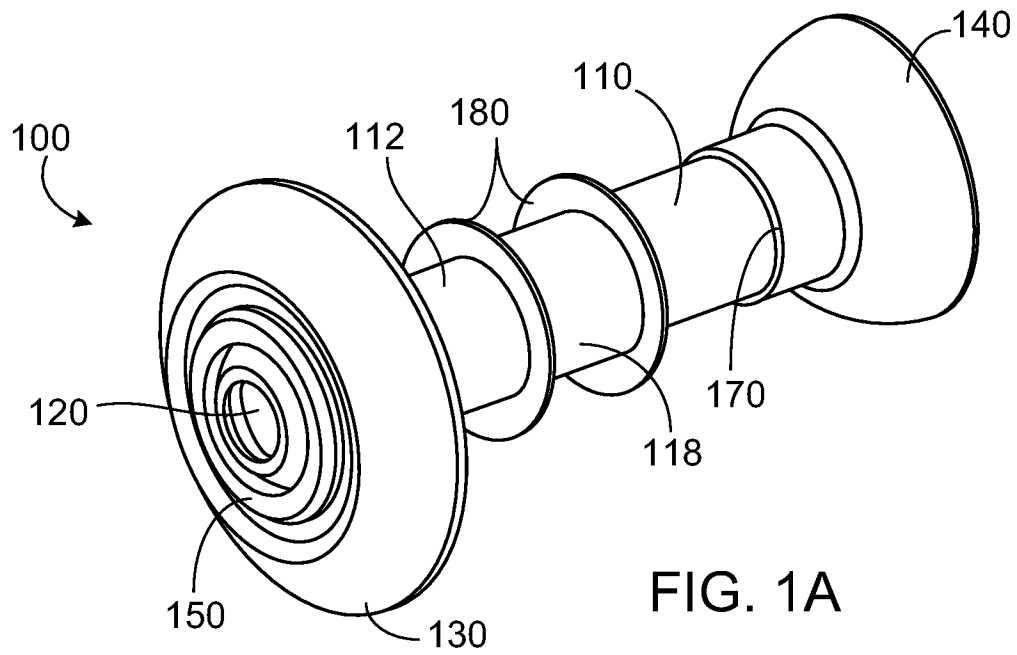


FIG. 1A

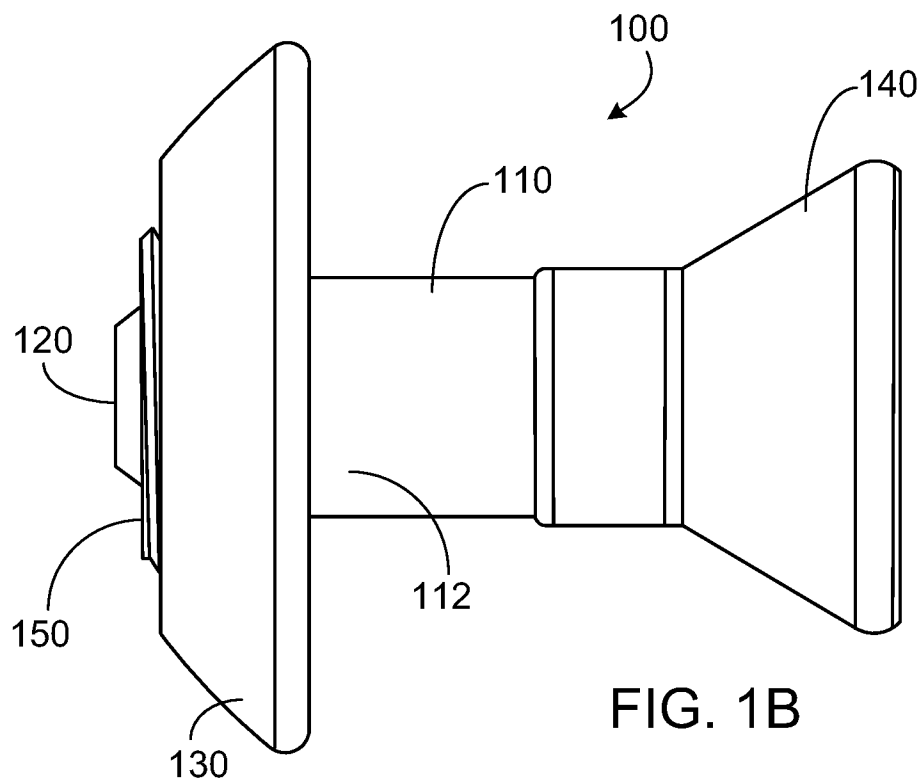
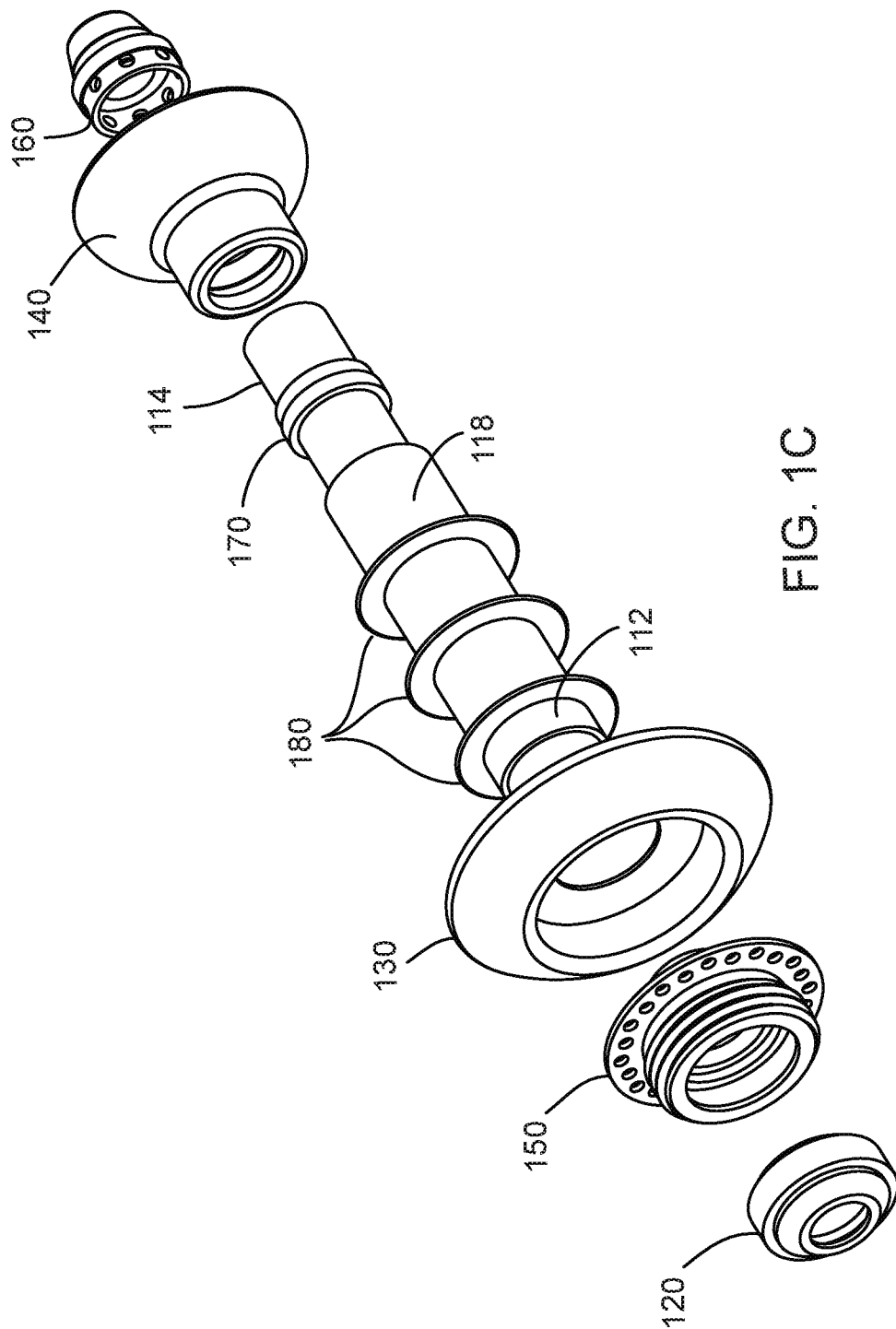


FIG. 1B



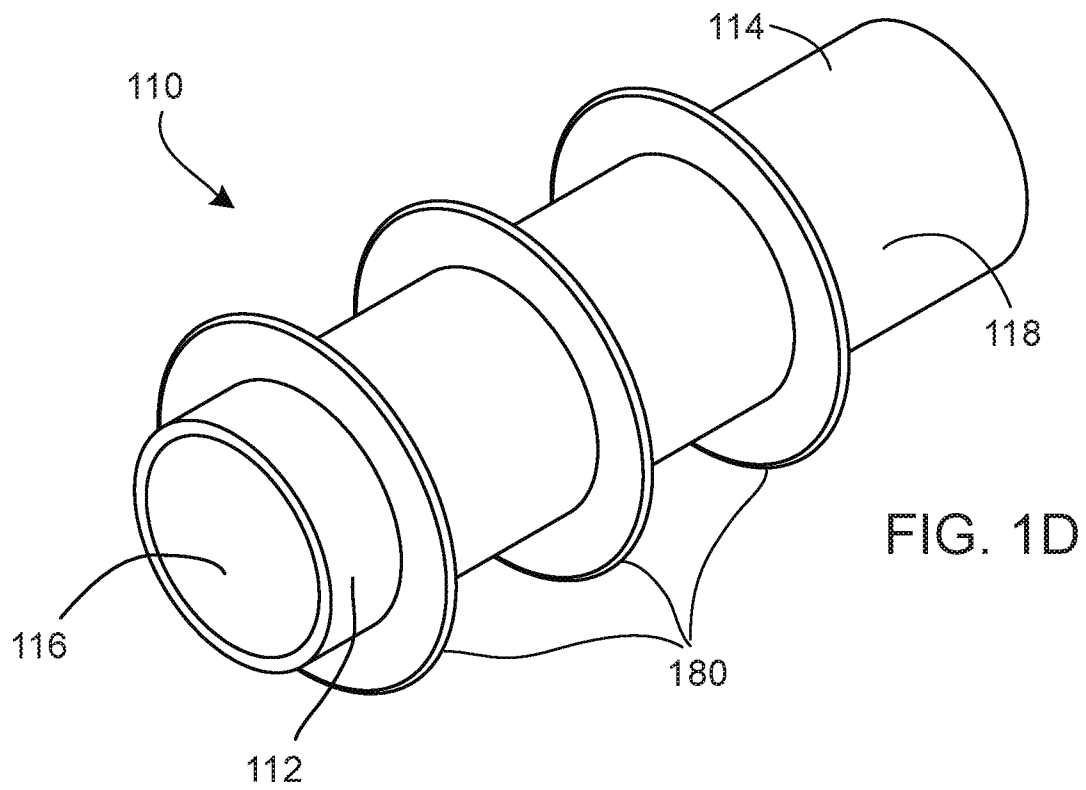


FIG. 1D

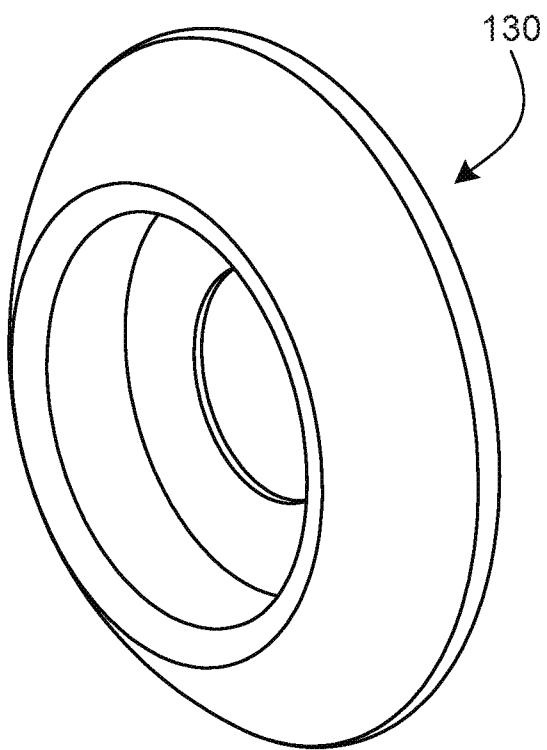


FIG. 1E

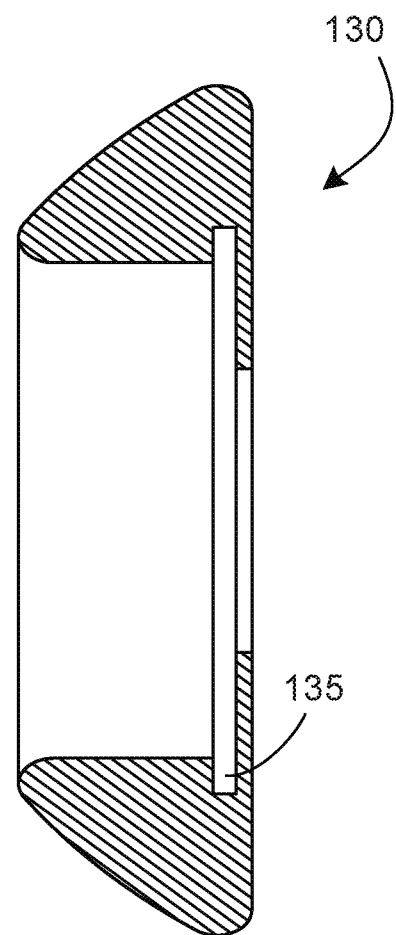


FIG. 1F

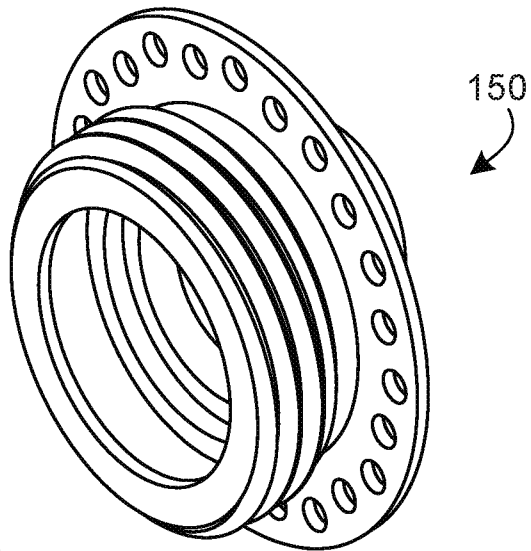


FIG. 1G

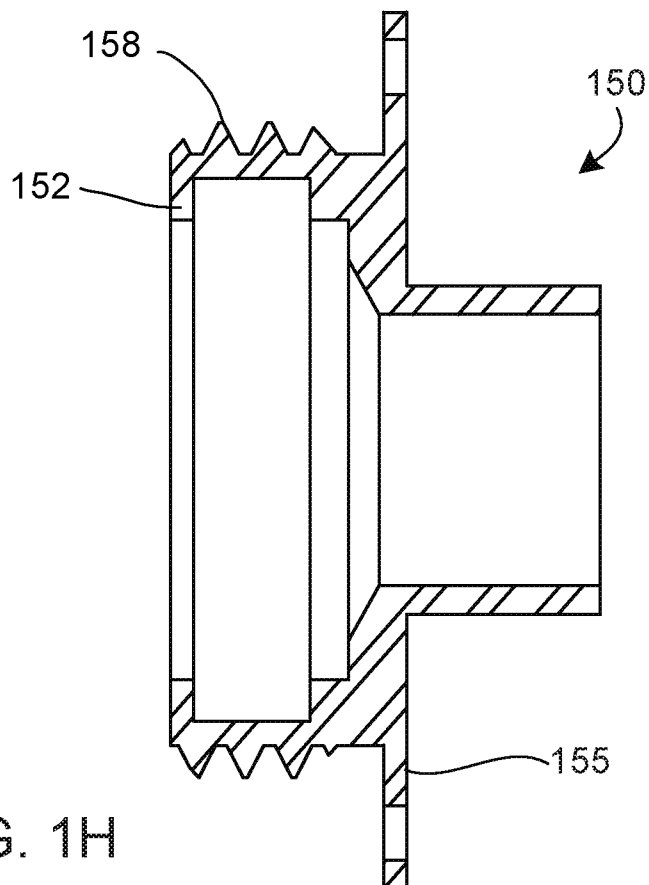
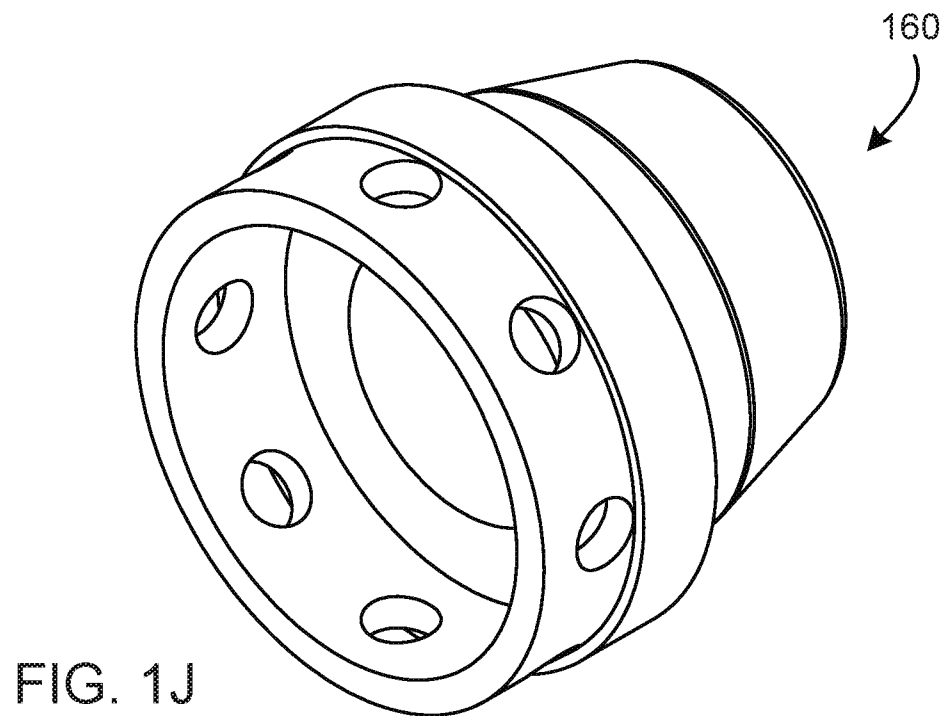
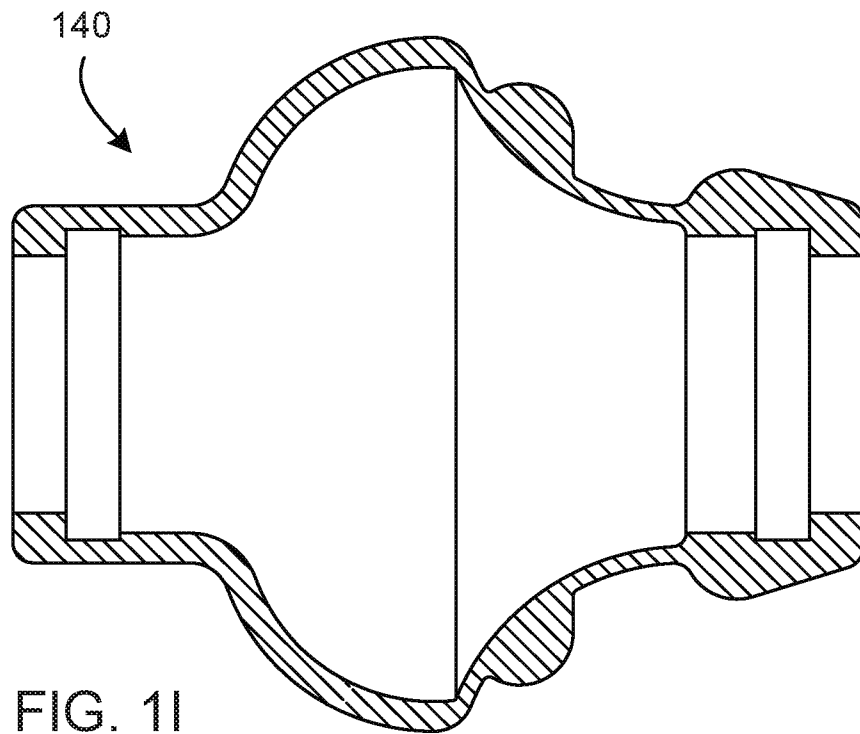


FIG. 1H



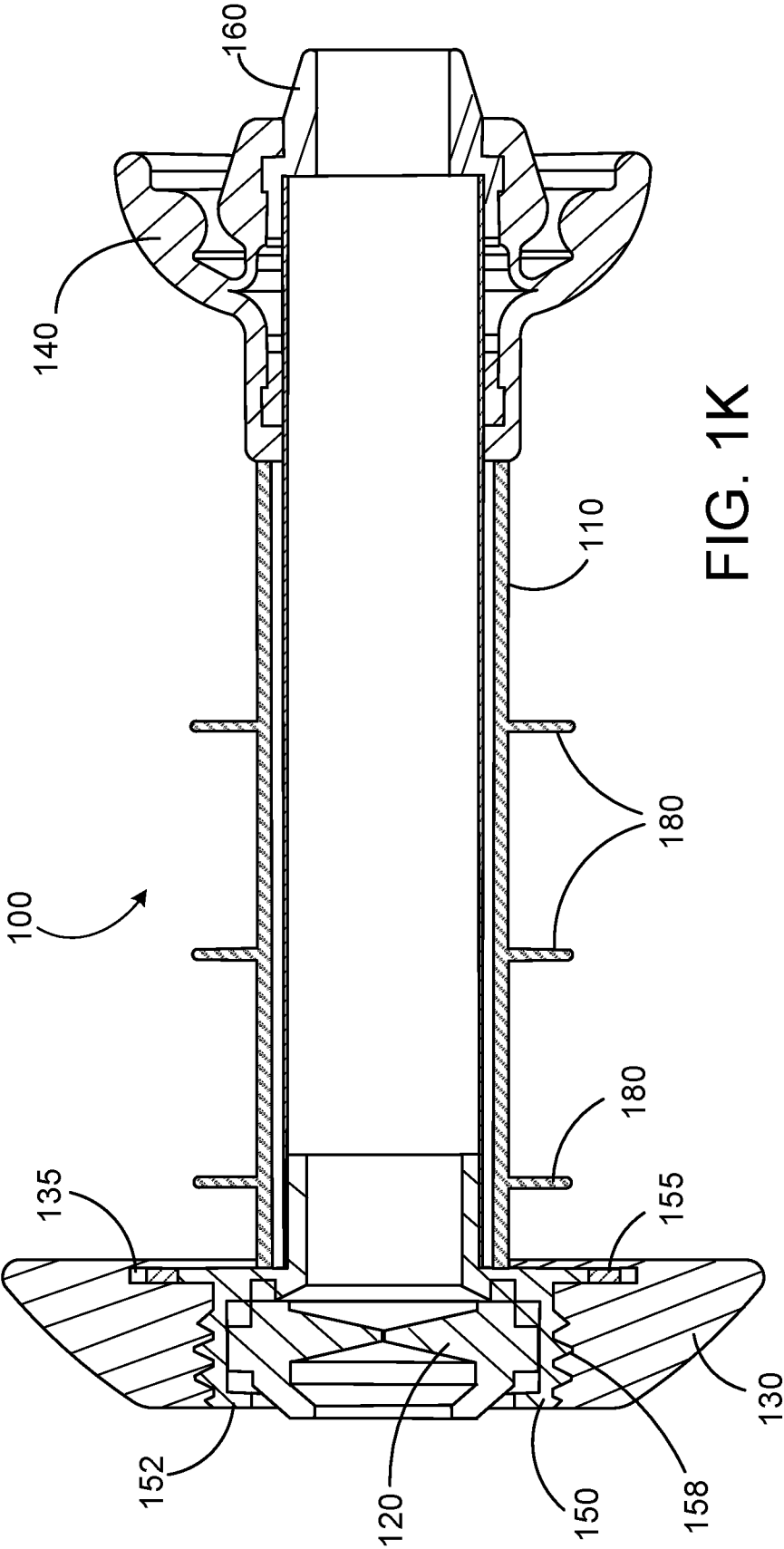
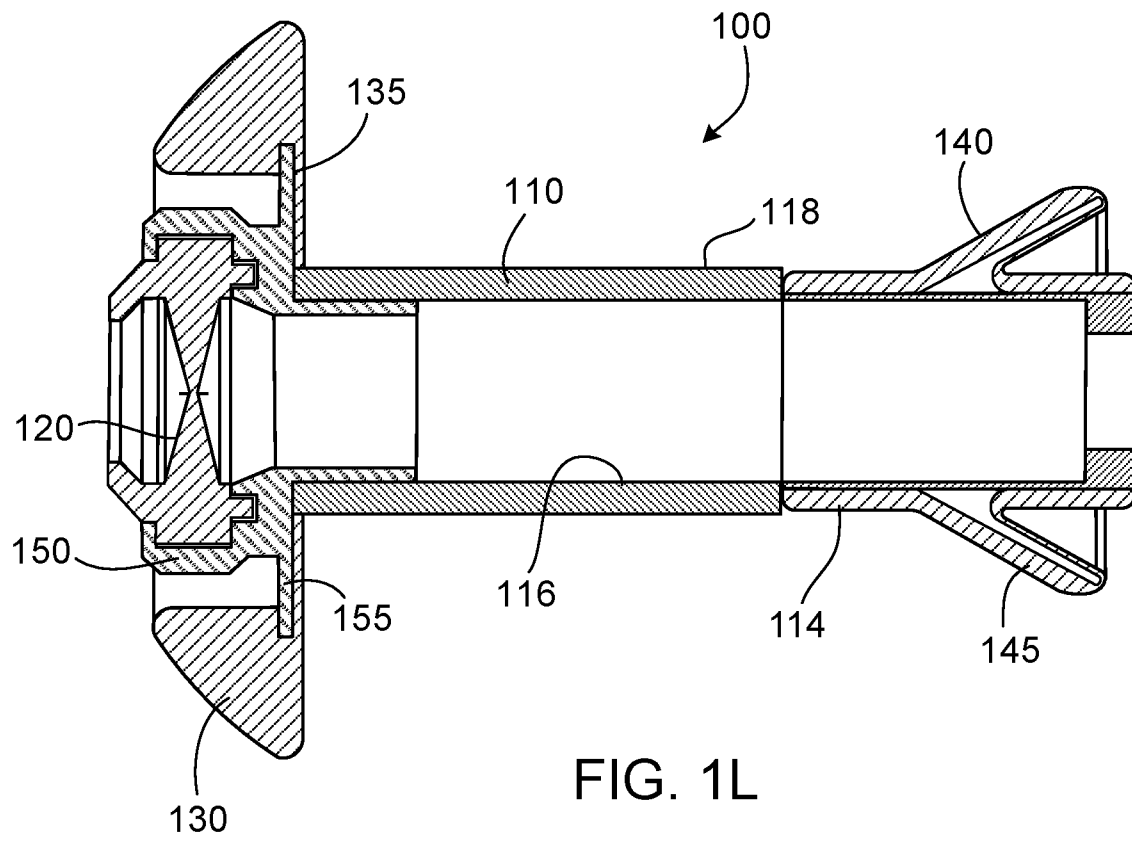
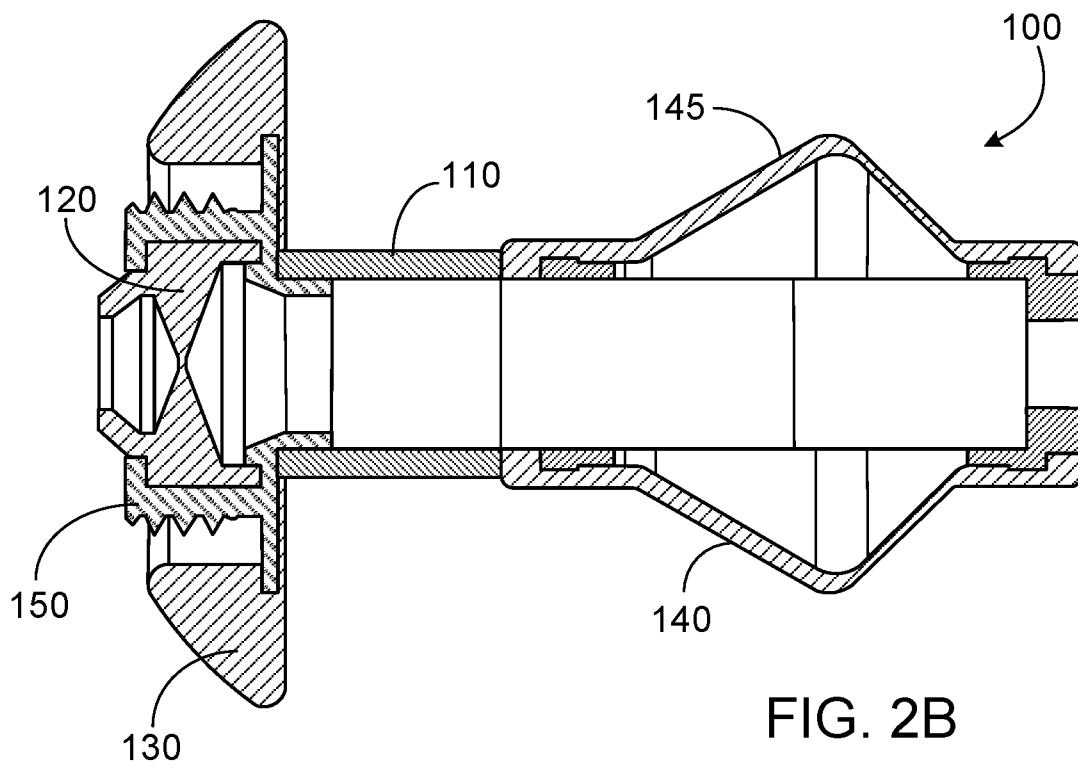
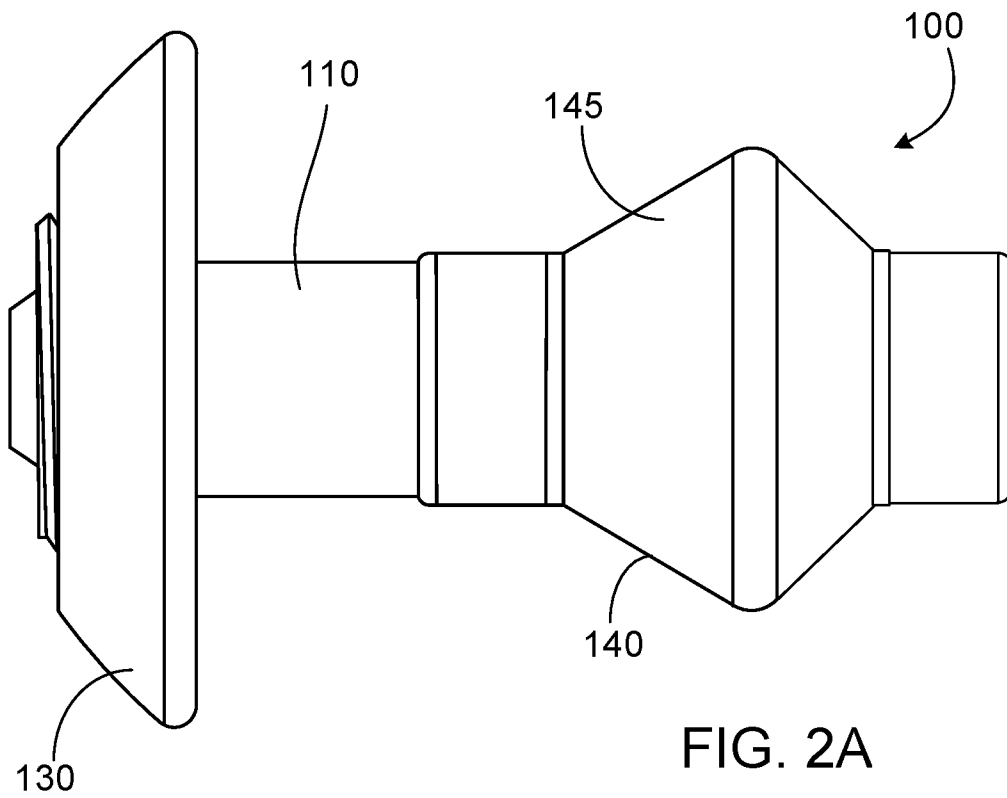


FIG. 1K





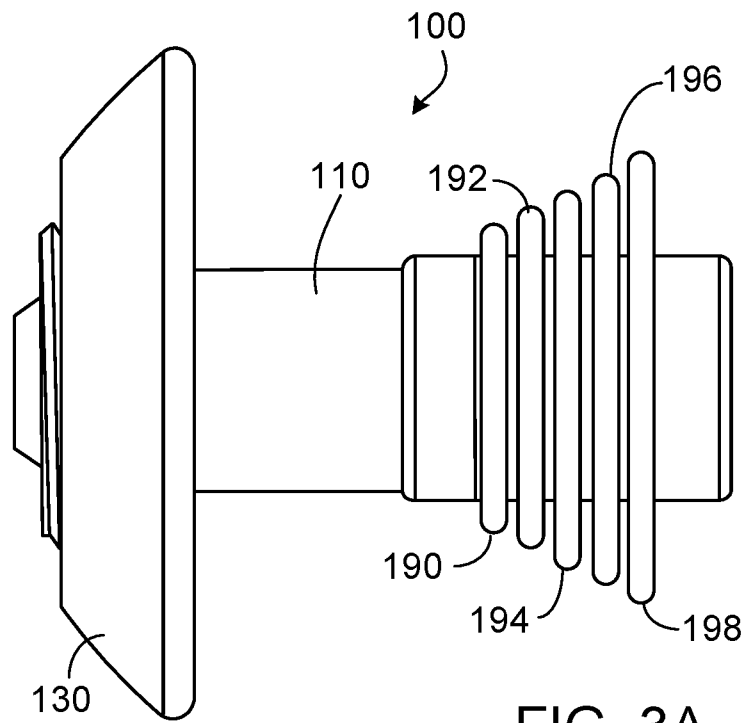


FIG. 3A

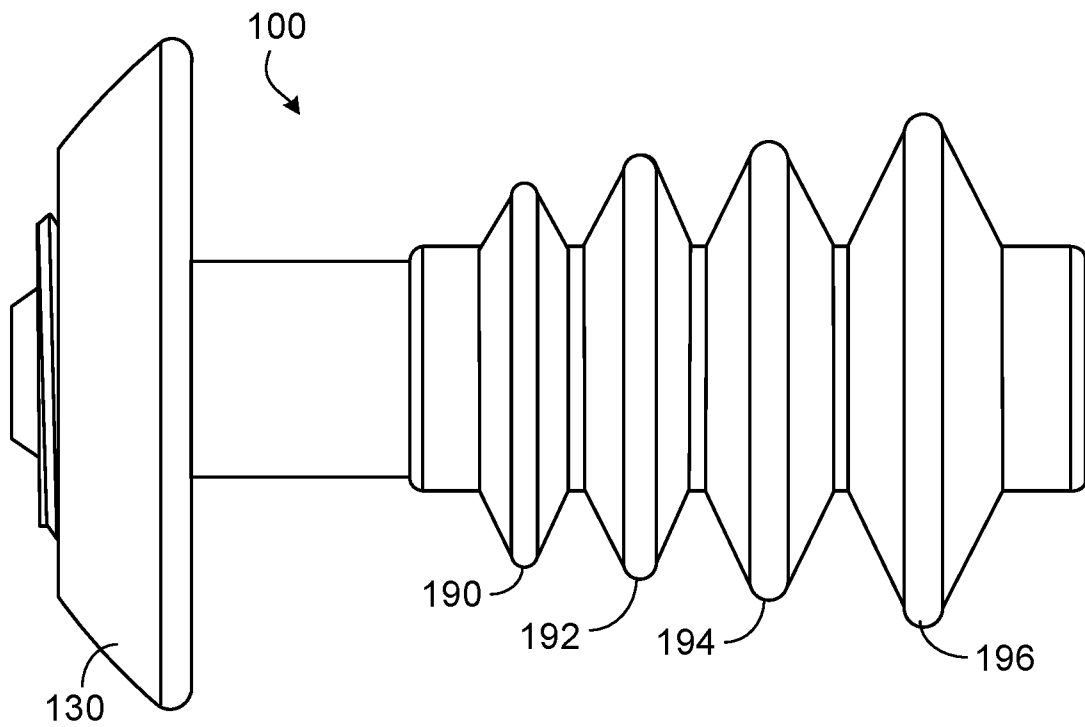


FIG. 3B

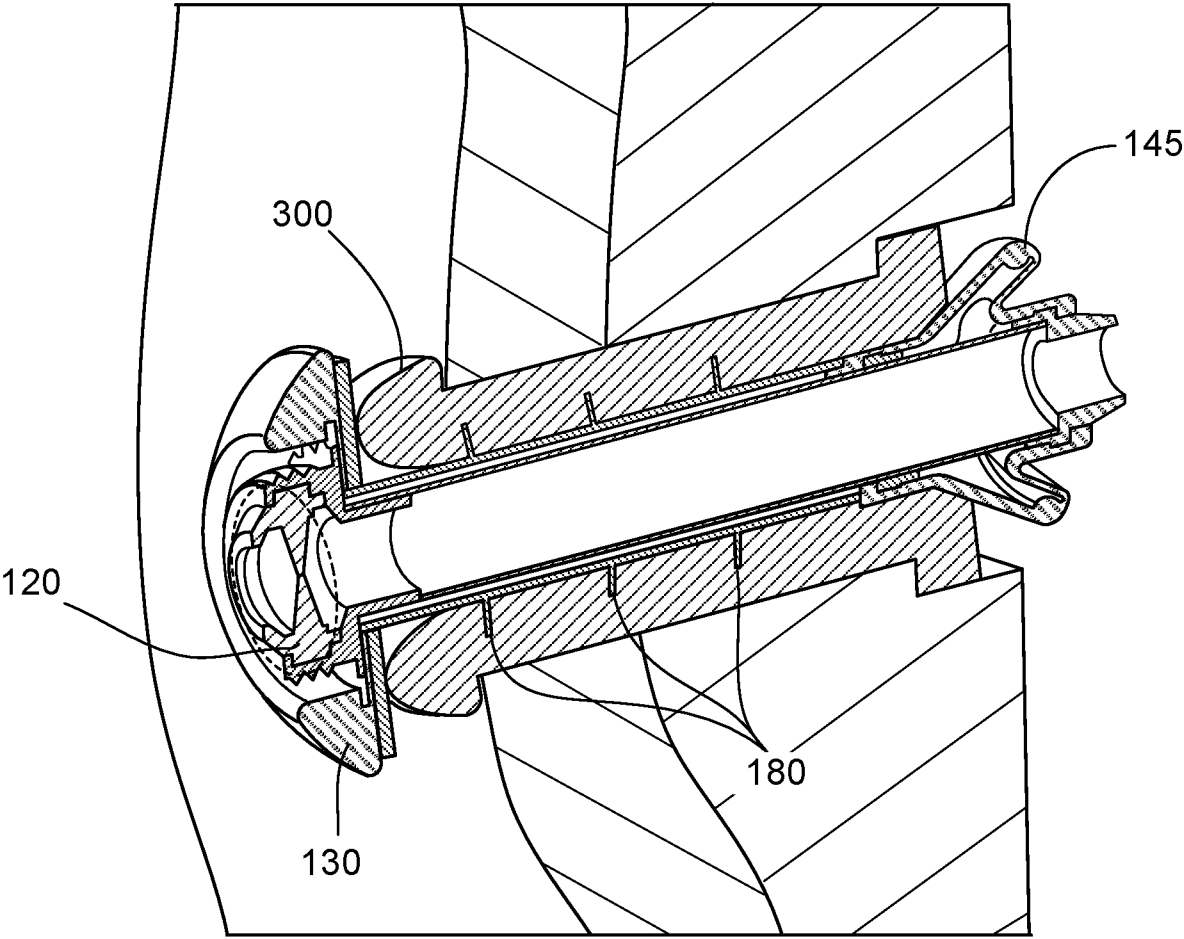
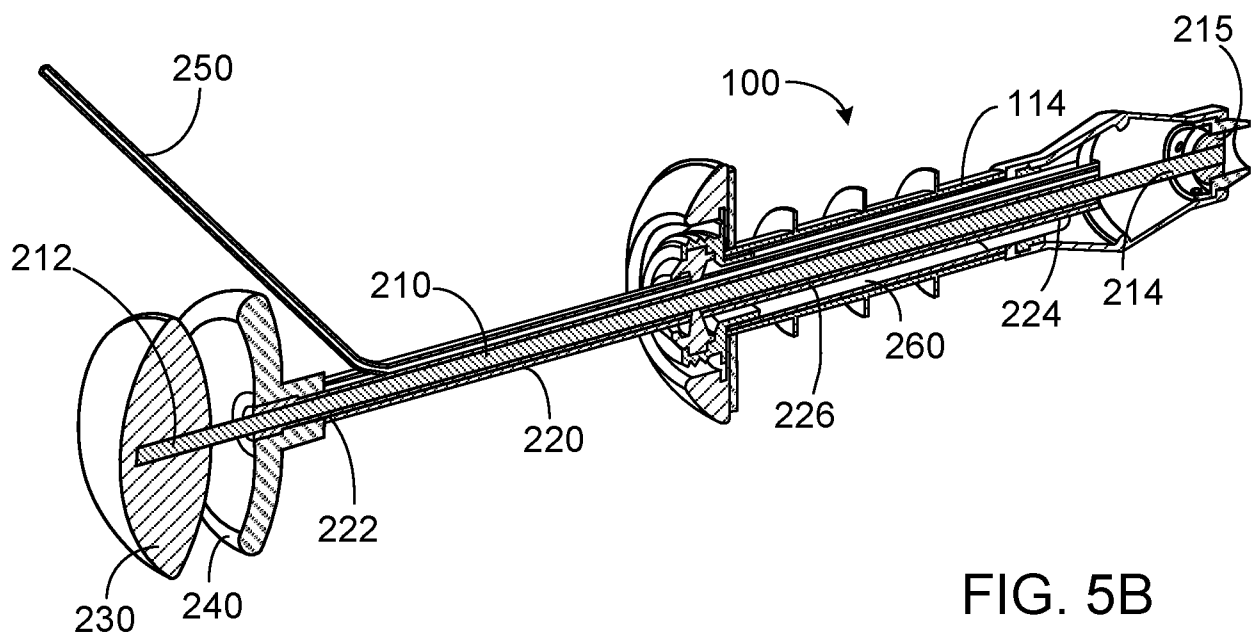
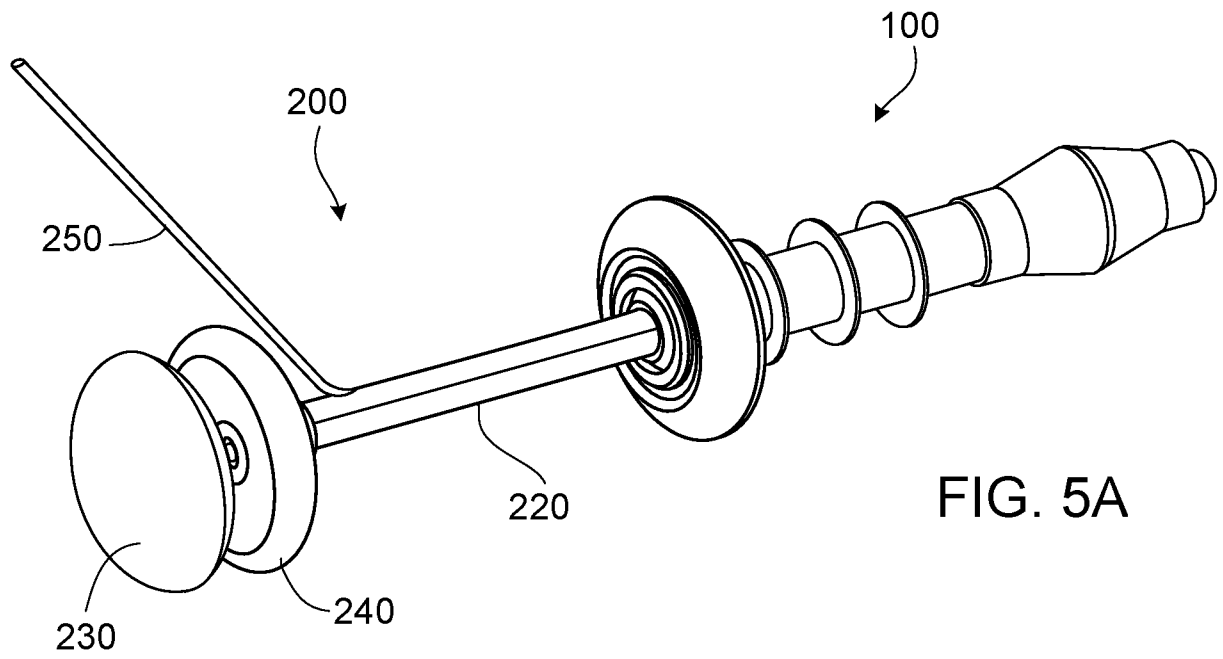


FIG. 4



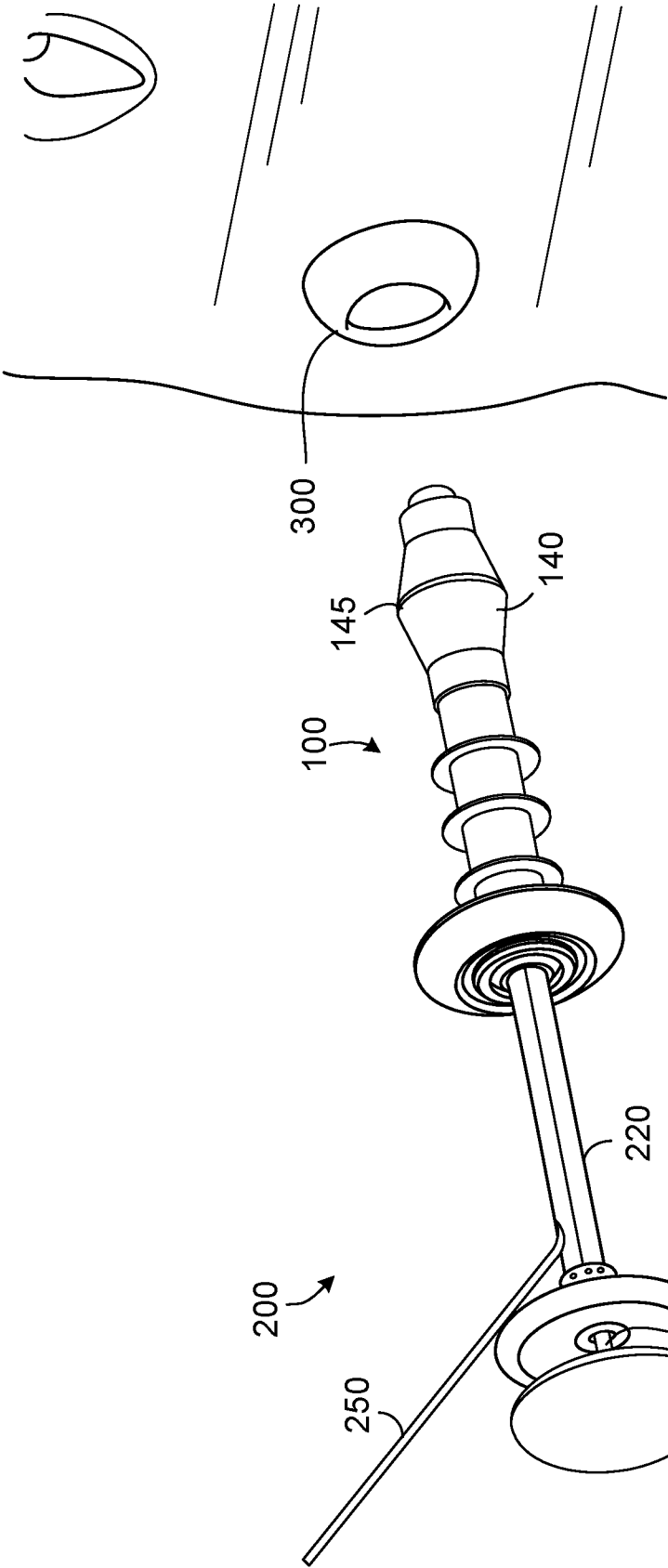


FIG. 6A

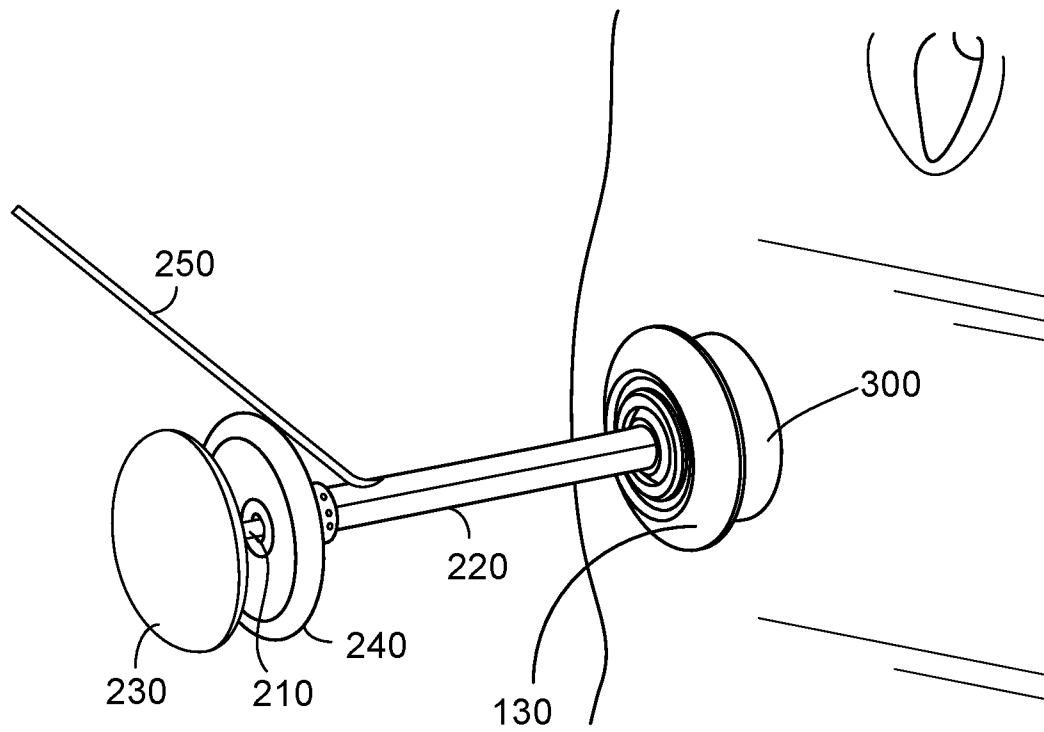


FIG. 6B

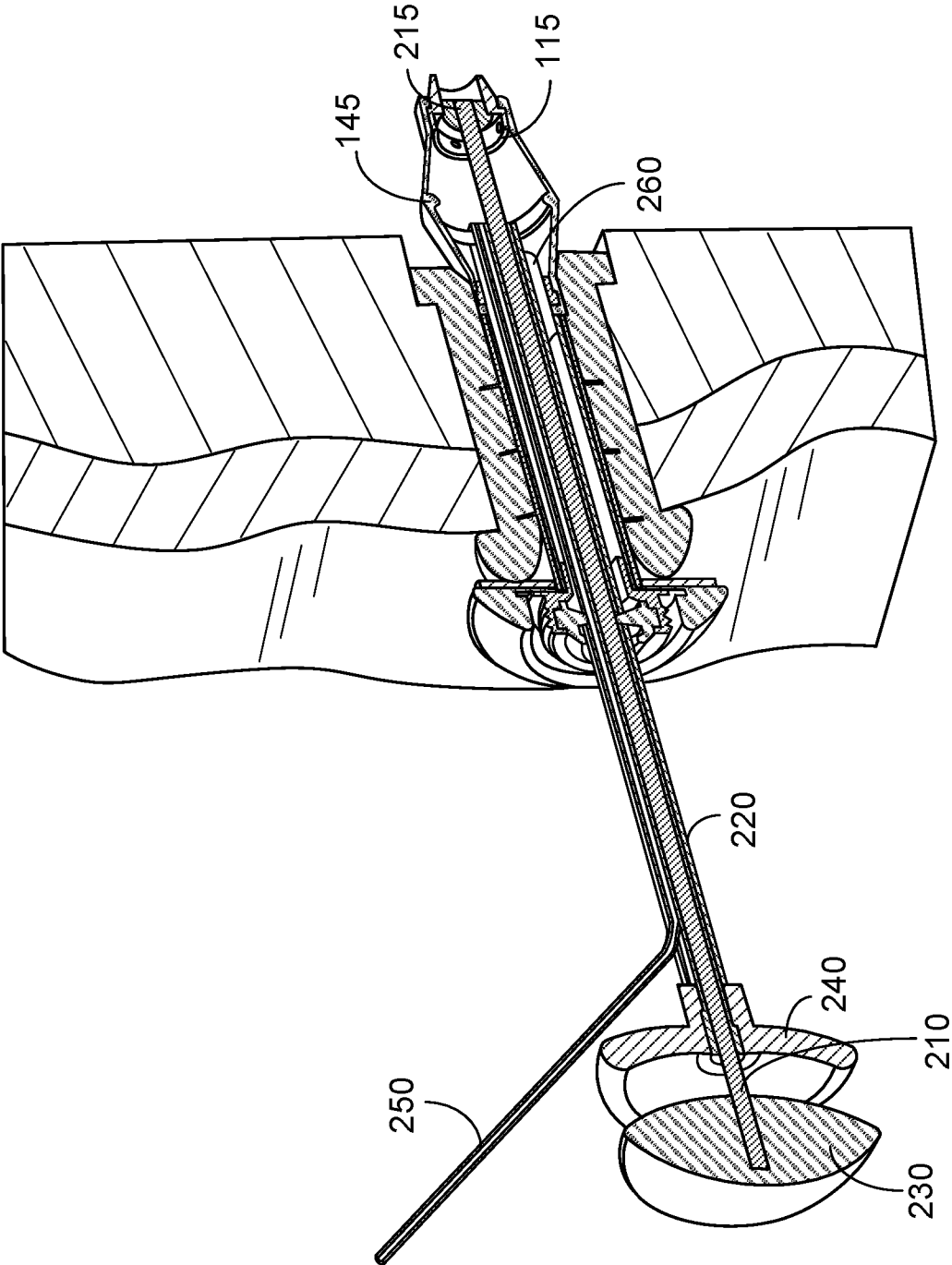


FIG. 6C

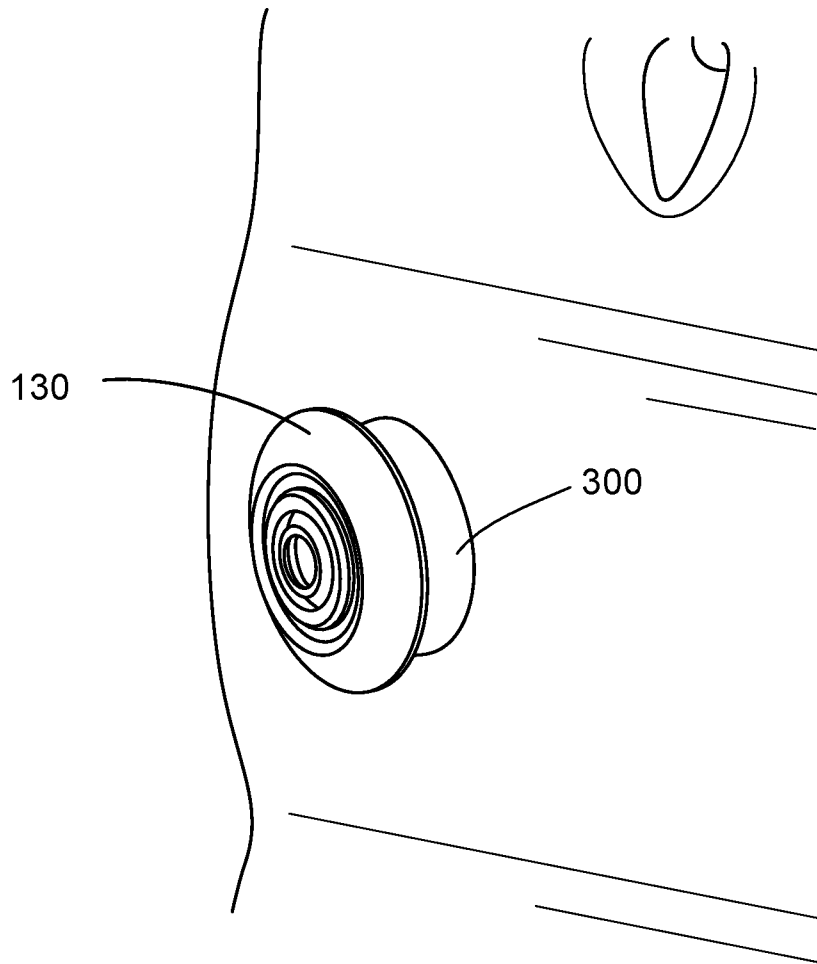


FIG. 7A

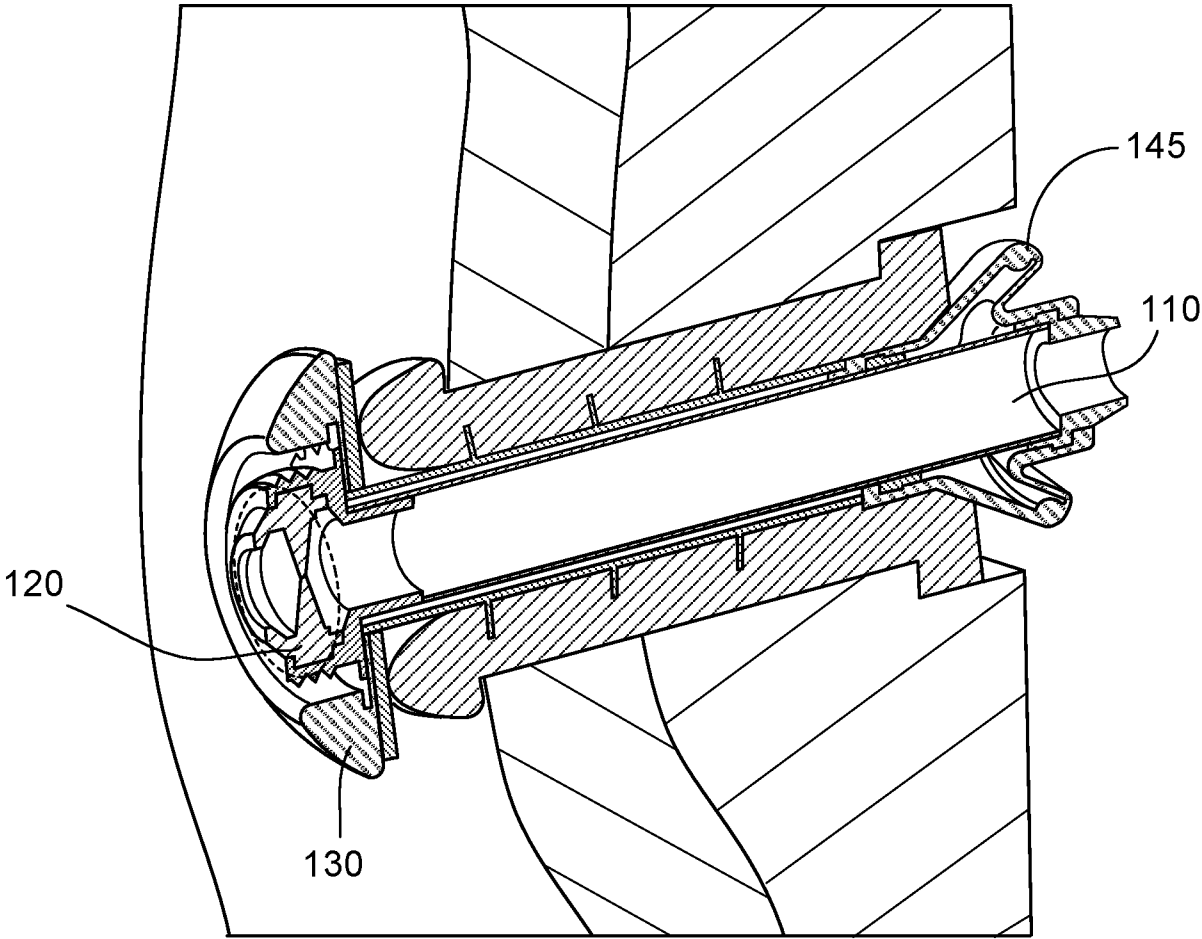
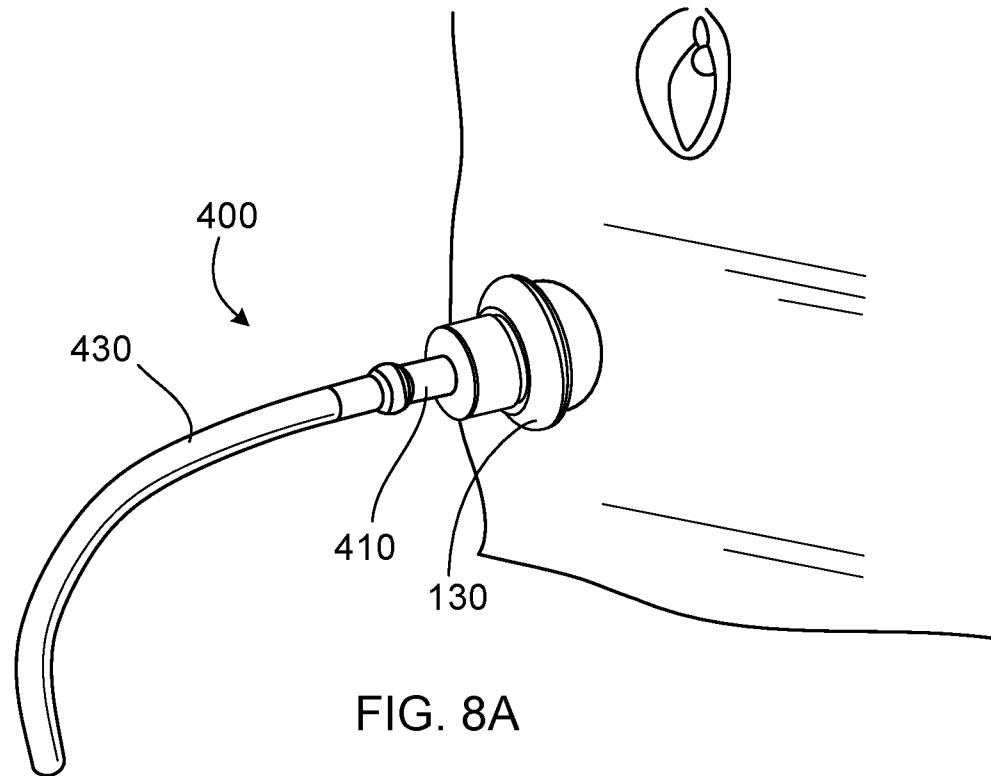


FIG. 7B



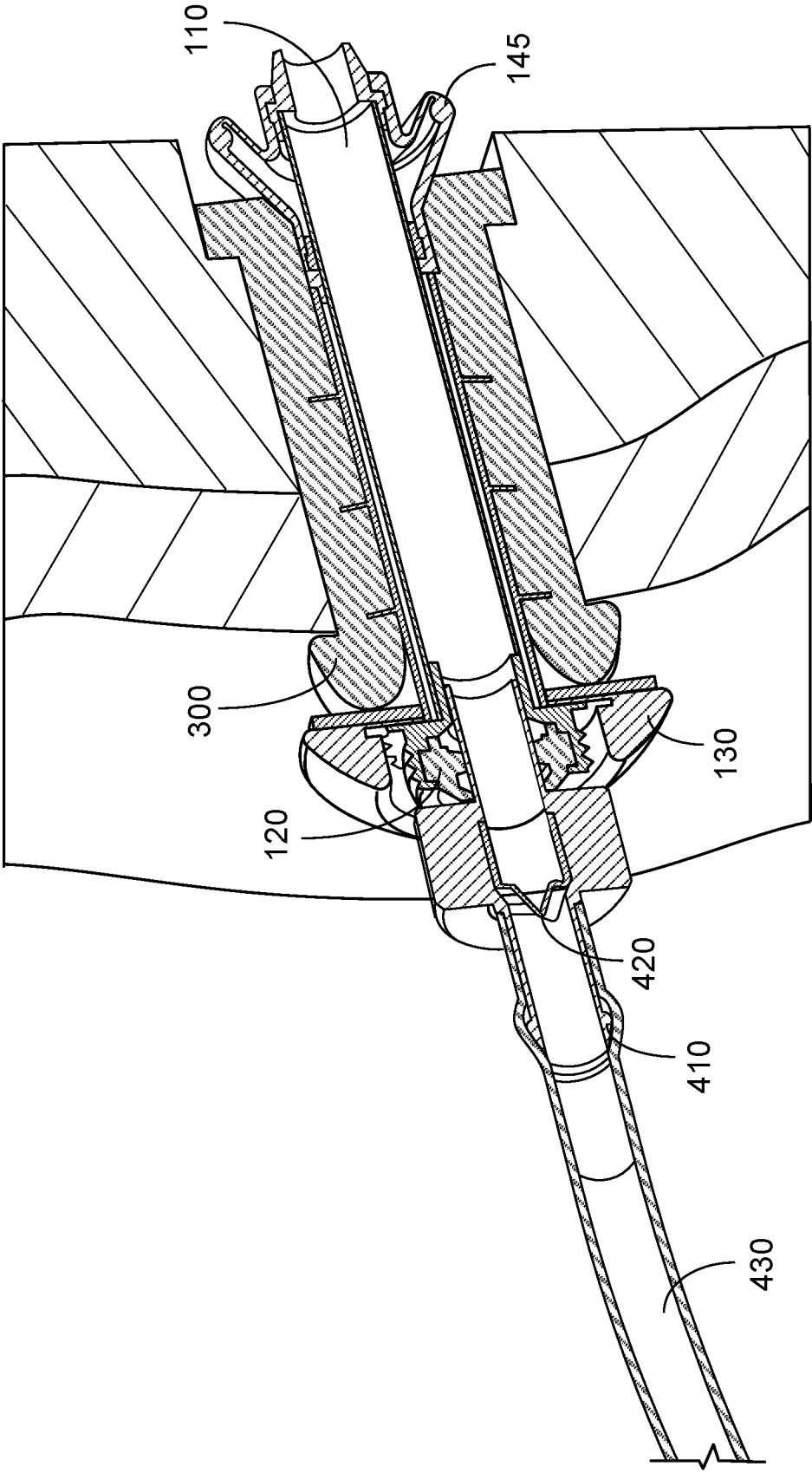


FIG. 8B

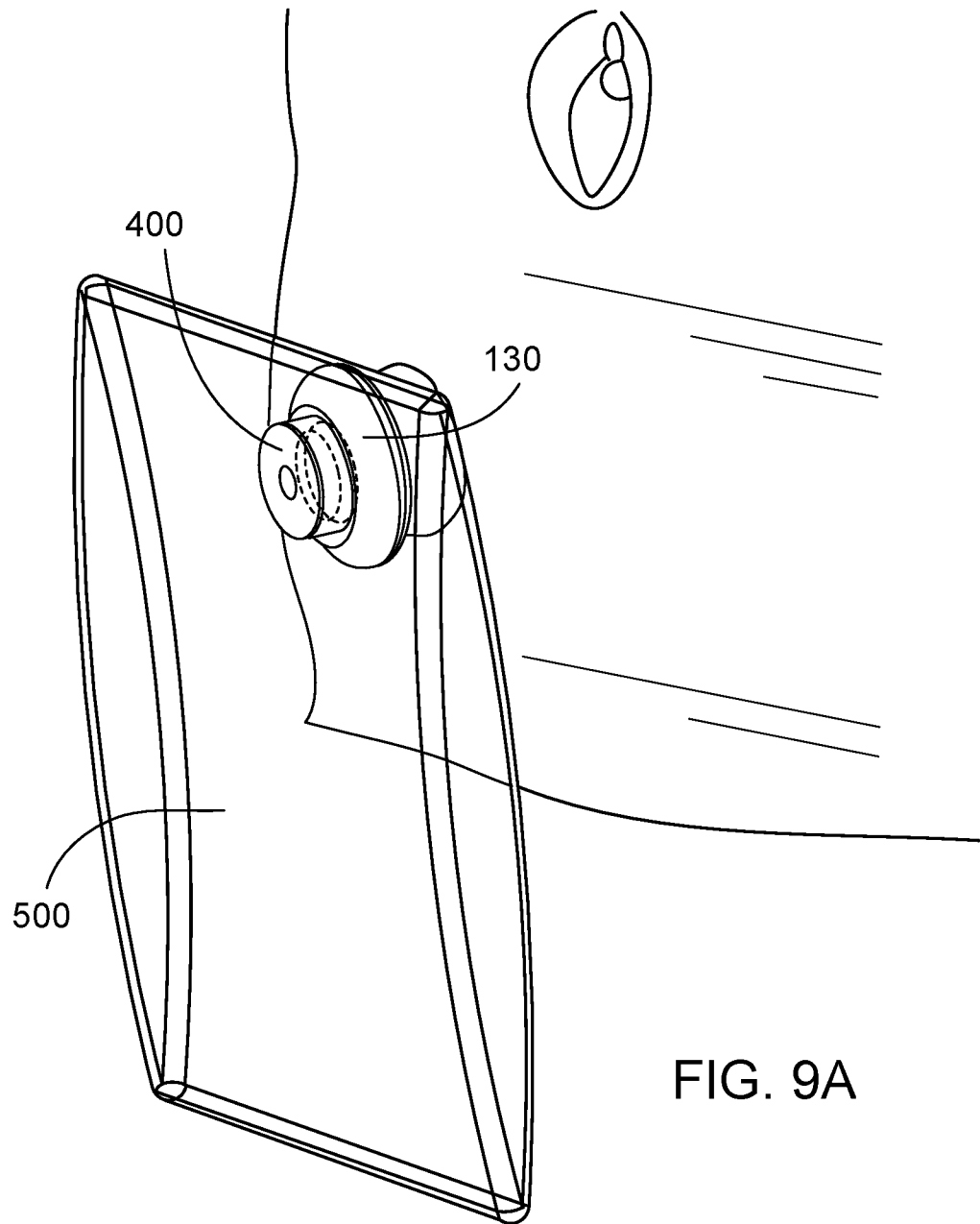
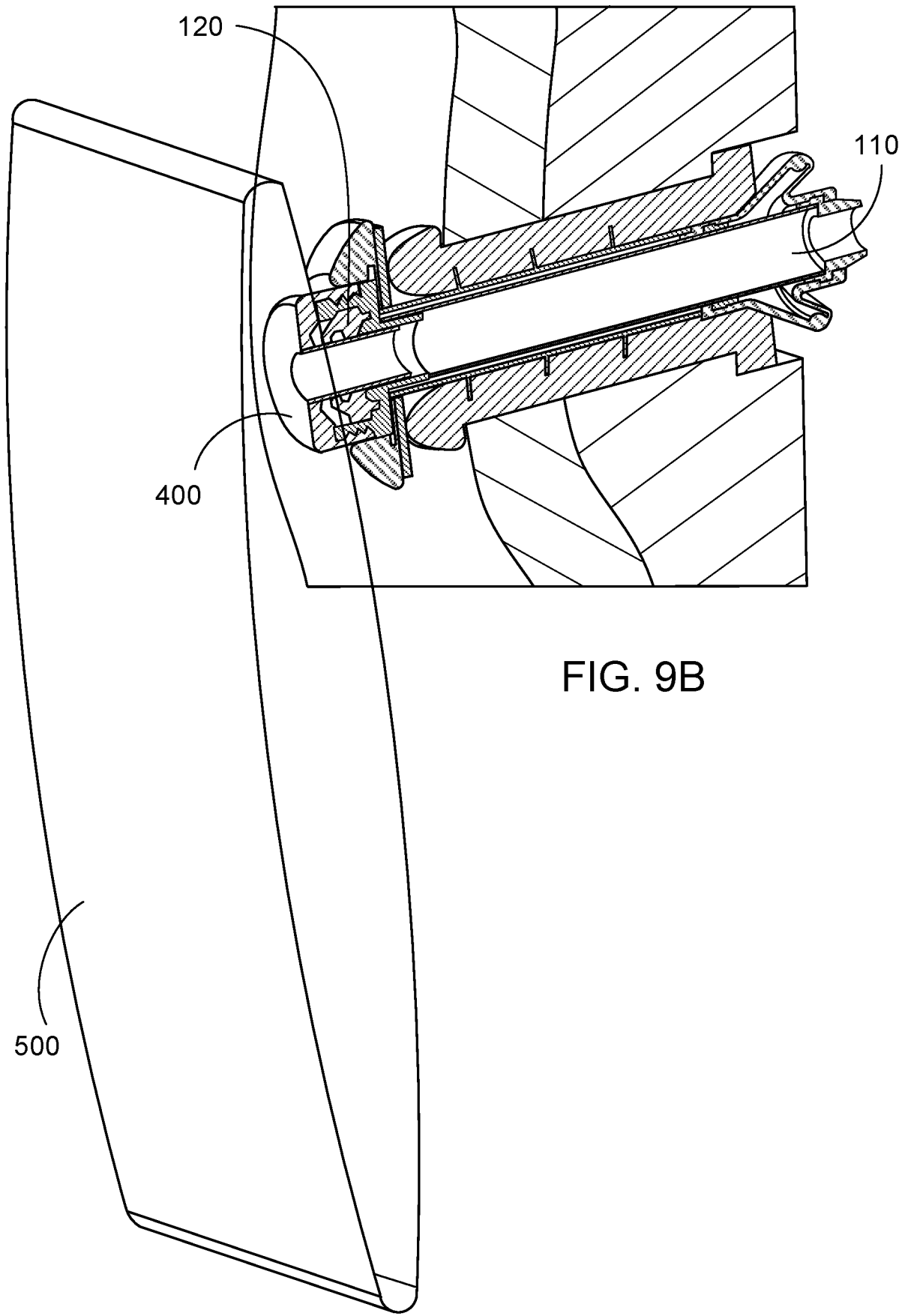


FIG. 9A



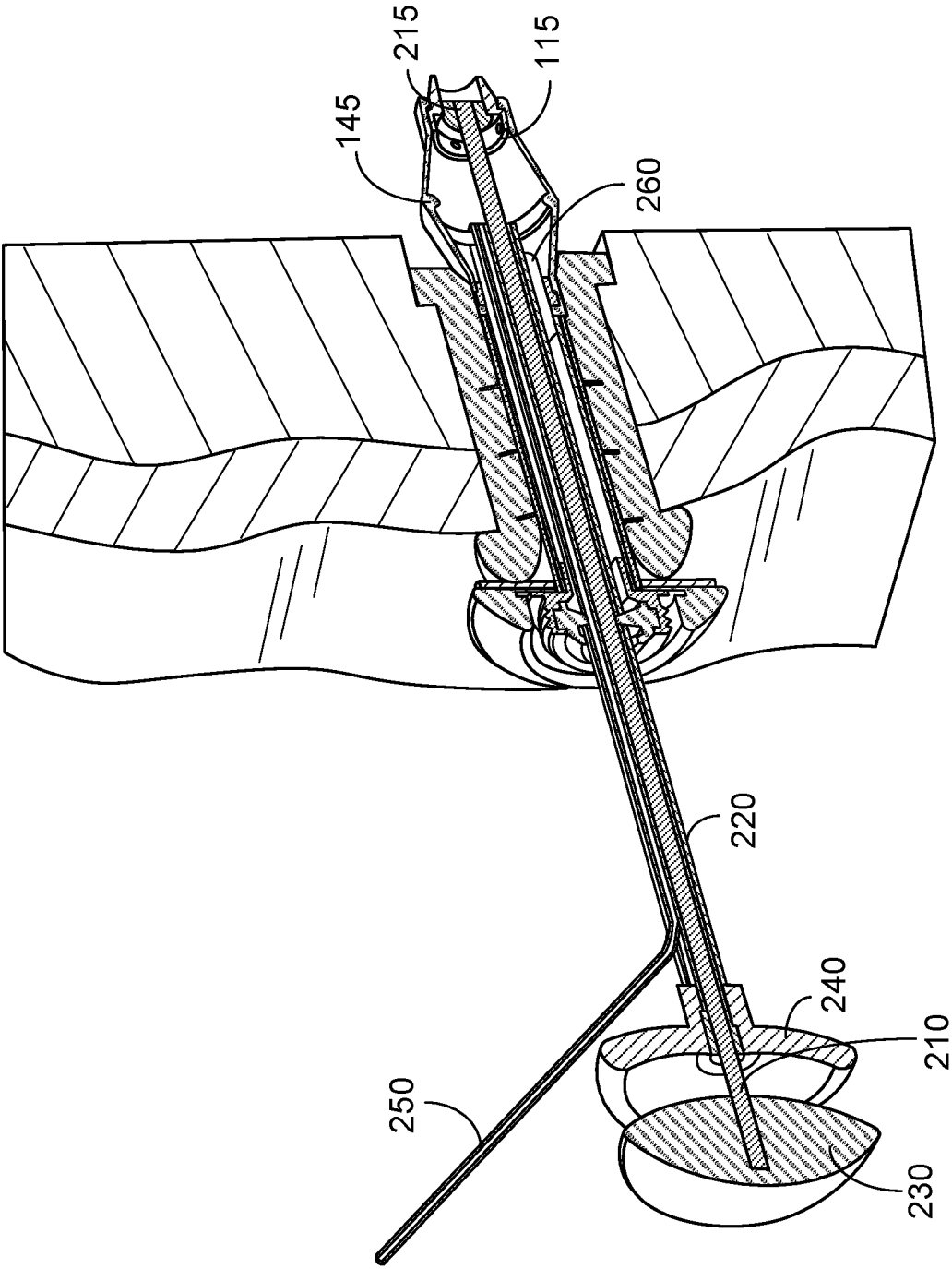


FIG. 10A

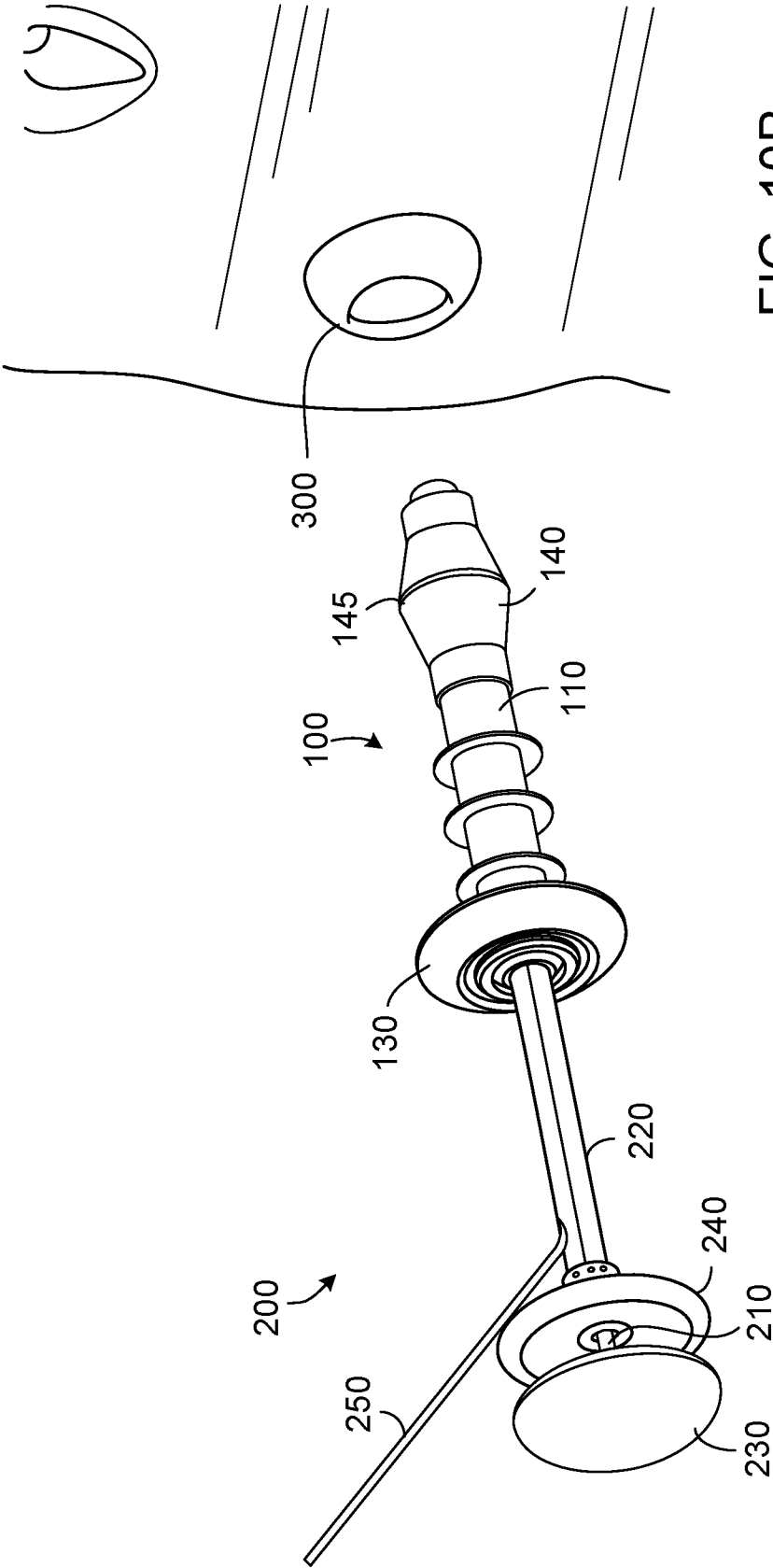


FIG. 10B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/024034

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

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
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.:

1-10, 14, 15

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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/024034

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/44 A61F5/445
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 344 434 A (ROBERTSON WILLIAM G) 17 August 1982 (1982-08-17) column 5, line 47 - column 7, line 32; figure 6	1-10, 14, 15
A	----- US 2003/220621 A1 (ARKINSTALL WILLIAM W [CA]) 27 November 2003 (2003-11-27) paragraph [0008] - paragraph [0010] paragraph [0028] - paragraph [0031]; figure 4	1, 10
A	----- WO 2011/138728 A2 (STIMATIX GI LTD [IL]; HANUKA DAVID [IL]; OR MEIR [IL]) 10 November 2011 (2011-11-10) page 18, line 21 - line 31 page 25, line 1 - line 12; figures 1, 12A -----	1, 4



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

21 June 2016

Date of mailing of the international search report

24/08/2016

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

Arjona López, G

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2016/024034

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4344434	A	17-08-1982	NONE
US 2003220621	A1	27-11-2003	CA 2425915 A1 16-10-2003 US 2003220621 A1 27-11-2003
WO 2011138728	A2	10-11-2011	CN 102970947 A 13-03-2013 CN 103108615 A 15-05-2013 EP 2566421 A1 13-03-2013 EP 2566422 A2 13-03-2013 EP 2568934 A2 20-03-2013 EP 2856984 A1 08-04-2015 JP 2013528423 A 11-07-2013 RU 2012151570 A 10-06-2014 WO 2011138727 A1 10-11-2011 WO 2011138728 A2 10-11-2011 WO 2011138730 A1 10-11-2011 WO 2011138731 A2 10-11-2011

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-10, 14, 15

An ostomy valve comprising a hollow tubular member having a first end, a second end, an outer surface, an inner surface, and a lumen extending axially through the tubular member between the first and second ends, a sealing element contained within the lumen, and an anchoring element at or adjacent to the second end, wherein the ostomy valve is reversibly adjustable between a radially expanded configuration for retention in a stoma, and a non-radially expanded configuration for insertion into or removal from the stoma.

2. claims: 11-13, 15

A device for use with an ostomy valve comprising a hollow outer tube having a first end and a second end, wherein the first end is attached to a first handle, an inner shaft positioned axially and slidably within the hollow outer tube, wherein the inner shaft has a first end and a second end, wherein the first end is attached to a second handle, and wherein a portion of the inner shaft proximate to its first end passes through an opening in the first handle, an inflatable balloon positioned on an outer surface of the hollow outer tube distal to the first handle, and an inflation port in fluid communication with the inflatable balloon, wherein the inflation port extends from the inflatable balloon toward the first handle.
