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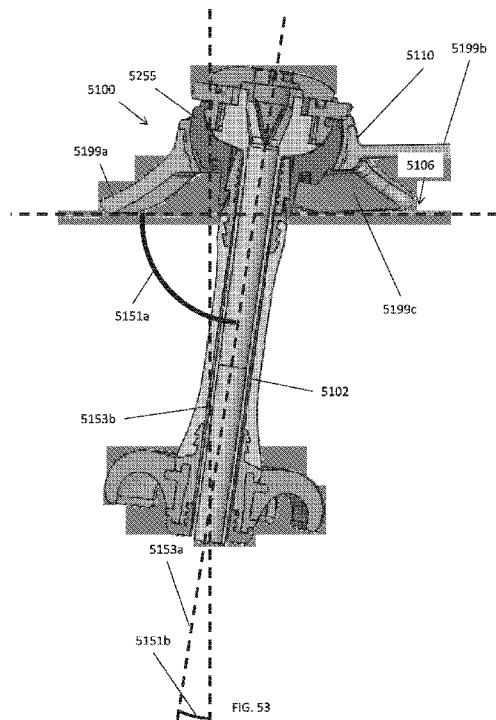
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(57) Abstract: In some embodiments a PEG feeding device includes a tube sized to bridge a channel between a stomach and an outer abdominal surface; an internal bolster, and an external bolster. Optionally the bolsters are connected to the tube. The internal bolster may be sized to resist movement out of the stomach through the stoma. The external bolster may be sized to resist movement into the stoma from the outer abdominal surface. The external bolster may include an underside which extends from the tube in a radial direction between the external bolster and the outer abdominal surface. The underside of the outer bolster may contact the outer abdominal surface at a distance from an external opening of the stoma. Optionally the distance between the internal bolster and the external bolster is adjustable. Optionally an angle between one or both of the bolsters and the tube is adjustable.



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DEVICES AND METHODS FOR PERCUTANEOUS ENDOSCOPIC
GASTRONOMY AND OTHER OSTOMY PROCEDURES

FIELD AND BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to ostomy devices and procedures and, more particularly, but not exclusively, to devices and procedures for percutaneous endoscopic gastronomy (PEG).

U.S. Patent No. US 7,582,072 discloses “A device for creating a channel between the stomach lumen and the abdominal surface of a patient. The device includes a tube and a first bolster. The tube has a proximal end, a distal end, and a wall, the wall having an inner surface and an outer abdominal surface, and each end having an opening therein. The first bolster is attached to the distal end of the tube and the tube is adapted to slidably receive a feeding device having a shaft, wherein at least a portion of the outer diameter of the shaft of the feeding device is substantially the same size as that of the inner wall of the tube. The first bolster is adapted to sealingly engage with the patient so as to minimize or avoid fluid leakage about the tube. The present invention is also directed to a method of using an artificial stoma.”

U.S. Patent Application Publication No. US2003/0163119 discloses “A medical catheter assembly including a removable inner sleeve. In one embodiment, the assembly is a low profile percutaneous endoscopic gastrostomy (PEG) device and comprises a body, a clamp, a feeding tube, a cap and an inner sleeve assembly. The body includes a base portion and a sleeve portion, the base portion being dimensioned to engage the skin of a patient and having a transverse bore, the sleeve portion extending upwardly from the base portion and having a longitudinal slot aligned with the transverse bore and a transverse slot intersecting the longitudinal bore. The clamp, which is slidably mounted on the base portion and across the transverse slot of the sleeve, comprises a plate having a transverse opening. The transverse opening has a wide region and a narrow region, the two regions being alternately alignable with the longitudinal bore to open and to close, respectively, the feeding tube. The feeding tube has a distal end adapted to be anchored to the inside of a patient and a proximal end inserted up through the base portion and the sleeve portion, including the transverse opening of the clamp situated within the sleeve, and then inverted over the top edge of the sleeve. The cap is then mounted on top of the

sleeve so as to secure the inverted end of the catheter to the exterior of the sleeve. The cap is provided with an opening through which access to the catheter may be gained. An inner sleeve, sized to engage the inside surface of the feeding tube, is removably inserted through the cap and the feeding tube, the inner sleeve having a proximal end to which a tubular fitting is secured. Food and/or medications are dispensed to the patient through the fitting and the inner sleeve and, in this manner, prevent clogging of the feeding tube.”

SUMMARY OF THE INVENTION

According to an aspect of a first embodiments of the invention, there is provided a PEG feeding device for conducting fluid through a stoma to a stomach comprising:
a tube sized to bridge a channel between a stomach and an outer abdominal surface; an internal bolster, sized to resist movement out of the stomach through the stoma and connected to the tube; an external bolster, sized to resist movement into the stoma and connected to the tube; wherein the external bolster includes at least one element including an underside which extends from the tube in a radial direction and then towards the external bolster contacting the outer abdominal surface at a distance from an external opening of the stoma.

According to a second and optionally according to the first embodiments of the invention, the distance is at least 5mm.

According to a third and optionally according to any of the first to the second embodiments of the invention, at least a portion of the external bolster is elastically deflectable in an axial direction.

According to a fourth and optionally according to any of the first to the third embodiments of the invention, the external bolster includes a plurality of portions which are individually elastically deflectable.

According to a fifth and optionally according to the fourth embodiments of the invention, the portions are at least partially circumferentially separated.

According to a sixth and optionally according to any of the first to the fifth embodiments of the invention, at least a portion of the inner bolster is elastic with respect to a long axis of the tube.

According to a seventh and optionally according to any of the first to the sixth embodiments of the invention, the internal bolster includes a plurality of parts connected by at least one connector.

5 According to an eighth and optionally according to any of the first to the seventh embodiments of the invention, the internal bolster includes circumferential separations.

According to a ninth and optionally according to any of the first to the eighth embodiments of the invention, the PEG feeding device comprises an inner tube sized to fit into the tube and to bridge a channel between a stomach and a patient outer abdominal surface.

10 According to a tenth and optionally according to the ninth embodiments of the invention, the inner tube is permanently attached to a food reservoir.

According to an eleventh and optionally according to any of the ninth to tenth embodiments of the invention, the PEG feeding device comprises a rigid connector connecting the inner tube and the external bolster.

15 According to a twelfth and optionally according to any of the ninth to eleventh embodiments of the invention, the PEG feeding device according comprises a sealing element occluding a channel between the tube and the inner tube.

According to a thirteenth and optionally according to any of the ninth to twelfth embodiments of the invention, the inner tube includes at least one cleaning portion sized
20 to contact inner walls of the tube.

According to a fourteenth and optionally according to the thirteenth embodiments of the invention, the cleaning portion elastically applies radial pressure to the inner walls of the tube.

According to a fifteenth and optionally according to any of the first to the
25 fourteenth embodiments of the invention, the tube connects to one of the internal bolster and the external bolster by a rigid connector.

According to a sixteenth and optionally according to any of the first to the fifteenth embodiments of the invention, a height of the device above a patient outer abdominal surface is less than 5cm.

30 According to a seventeenth and optionally according to any of the first to the sixteenth embodiments of the invention, an axial height of the external bolster is less than 5cm.

According to a eighteenth and optionally according to any of the first to the seventeenth embodiments of the invention, the external bolster is connected to the outer tube by a rigid connector.

5 According to an nineteenth and optionally according to any of the first to the eighteenth embodiments of the invention, the PEG further comprises: a variable angle joint joining the external bolster to the tube and allowing the external bolster to tilt with respect the tube.

10 According to an aspect of a twentieth embodiment of the invention, there is provided a PEG feeding device for conducting fluid through a stoma to a stomach comprising: a tube sized to bridge a channel between a stomach and an outer abdominal surface; a bolster sized to resist movement into the stoma; and a rigid connector comprising a lumen and connecting the tube to the bolster; wherein a portion of the rigid connector is disposed within a first end of the tube.

15 According to a twenty first and optionally according to the twentieth embodiments of the invention, the portion of the rigid connector comprises a fitted friction fit with the tube.

According to a twenty second and optionally according to any of the first to the twenty first embodiments of the invention, the first end of the tube comprises thickened walls.

20 According to a twenty third and optionally according to any of the first to the twenty second embodiments of the invention, the tube comprises an internal supporting structure and within a sheath.

According to a twenty forth and optionally according to the twenty third embodiments of the invention, the internal structure includes a mesh.

25 According to a twenty fifth and optionally according to any of the first to the twenty fourth embodiments of the invention, the internal structure includes elongated elements.

30 According to a twenty sixth and optionally according to any of the first to the twenty fifth embodiments of the invention, the PEG feeding device comprises a second bolster sized to resist movement into the stoma; wherein the second bolster is connected to a second end of the tube.

According to a twenty seventh and optionally according to any of the first to the twenty sixth embodiments of the invention, the rigid connector connects to a rigid part of the bolster.

5 According to a twenty eighth and optionally according to any of the first to the twenty seventh embodiments of the invention, the rigid connector connects to the bolster by an interference connection.

According to an aspect of a twenty ninth and optionally according to any of the first to the twenty eighth embodiments of the invention, there is provided a PEG feeding device for conducting fluid through a stoma to a stomach comprising: a tube sized
10 to bridge a channel between a stomach and an outer abdominal surface; an internal bolster, sized to resist movement out of the stomach through the stoma and connected to the tube comprising: a plurality of parts held together by one or more connector; and an external bolster, sized to resist movement into the stoma and connected to the tube; wherein the plurality of parts overlap axially by less than 20%.

15 According to a thirtieth and optionally according to any of the first to the twenty ninth embodiments of the invention, the connector includes a torque connection.

According to an aspect of a thirty first embodiment of the invention, there is provided a method of installing a PEG feeding device comprising: selecting an approximately sized tube; installing the tube in a stoma connecting a stomach and an
20 outer abdominal surface of a patient where an installed tube is held by an inner bolster disposed within the stomach and an external bolster at an abdominal outer surface; compensating for a discrepancy between the tube length and a length of the stoma.

According to a thirty second and optionally according to the thirty first
25 embodiments of the invention, the compensating comprises: adjusting a minimum separation between the inner bolster and the external bolster.

According to a thirty third and optionally according to the thirty second
embodiments of the invention, the adjusting comprises changing a position of attachment of the bolster with respect to the tube.

According to a thirty fourth and optionally according to any of the thirty second
30 to the thirty third embodiments of the invention, the adjusting comprises: selecting an axial extent of a compressible element between an inner bolster and a lumen inner wall.

According to a thirty fifth and optionally according to any of the thirty second to the thirty fourth embodiments of the invention, the adjusting comprises: axially elastically deflecting a portion of the external bolster.

5 According to a thirty sixth and optionally according to any of the thirty second to the thirty fifth embodiments of the invention, the adjusting comprises: axially elastically deflecting a portion of the inner bolster.

According to a thirty seventh and optionally according to any of the thirty second to the thirty sixth embodiments of the invention, the adjusting is self adjusting of the PEG device.

10 According to an aspect of a thirty eight and optionally according to any of the thirty first to the thirty seventh embodiments of the invention, there is provided a method of use of a PEG feeding device: installing a PEG feeding device comprising an inner and outer tube the outer tube forming a channel between a lumen and a patient outer abdominal surface, the inner tube forming a channel between a lumen and a
15 patient outer abdominal surface and within the outer tube; and replacing the inner tube periodically.

According to a thirty ninth and optionally according to any of the thirty first to the thirty eighth embodiments of the invention, the replacing comprises cleaning said outer tube.

20 According to a fortieth and optionally according to the thirty eighth embodiments of the invention, the method further comprises: pivoting an angle between at least one of the internal bolster and the external bolster with respect to the tube.

According to a forty first and optionally according to the fortieth embodiments of the invention, pivoting compensates for a difference between an axis of the tube and
25 a normal from at least one of an inner surface of a stomach and an outer surface of an abdomen at the location of a stoma.

According to an aspect of a forty second and optionally according to any of the first to the thirtieth embodiments of the invention, there is provided a PEG feeding device for conducting fluid through a stoma to a stomach comprising: a tube sized to
30 bridge a channel between a stomach and an outer abdominal surface; an external bolster, sized to resist movement into the stoma and connected to the tube; a variable

angle joint joining the external bolster to the tube and allowing the external bolster to tilt with respect the tube.

According to a forty third and optionally according to the forty second embodiments of the invention, the PEG further comprises: an adjuster for setting a resistance of the external bolster to tilt with respect to an axis of the tube.

According to a forty fourth and optionally according to any of the fortieth to the forty third embodiments of the invention, the PEG further comprises: at least one element including an underside which extends from the tube in a radial direction and then towards the external bolster contacting the outer abdominal surface at a distance from an external opening of the stoma.

According to a forty fifth and optionally according to any of the fortieth to the forty fourth embodiments of the invention, the PEG further comprises: an internal bolster, sized to resist movement out of the stomach through the stoma and connected to the tube.

According to a forty sixth and optionally according to any of the fortieth to the forty fifth embodiments of the invention, the PEG further comprises: an elastic biasing element biasing an angle of the tilting of the external bolster to a preferred angle.

According to an aspect of a forty seventh and optionally according to any of the first to thirtieth and the fortieth to the forty sixth embodiments, there is provided a PEG device for conducting material through a stoma to or from a lumen comprising: a tube sized to bridge a channel between a lumen and an outer surface of a patient; an internal bolster, sized to resist movement out of the lumen through the stoma and connected to the tube; an external bolster, sized to resist movement into the stoma and connected to the tube; wherein the external bolster includes at least one element including an underside which extends from the tube in a radial direction and then towards the external bolster contacting the outer surface at a distance from an external opening of the stoma.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent

specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the figures generally, like components are indicated with like numerals, however, it should be noted that in some figures similar elements to those indicated in previous figures are provided with a new leading figure number. For example, the component labeled 316 in Figure 9 is generally the same type of component as the component labeled 116 in Figure 1.

In the drawings:

FIG. 1A is a simplified schematic cross section of an ostomy device which provides a channel between an internal patient lumen and an outer abdominal surface of the patient, according to some embodiments of the invention;

FIG. 1B is a simplified schematic cross section of an ostomy device with a flexible tube, according to some embodiments of the invention;

FIG. 2A is a simplified schematic sectional view of ostomy device including an inner tube, according to some embodiments of the invention;

FIG. 2B is a simplified schematic side view of a ostomy device body and an inner tube portion, according to some embodiments of the invention;

FIG. 3 is a flow diagram of a method of feeding, according to some embodiments of the invention;

FIG. 4A is a simplified schematic of a patient with an installed ostomy device, and a feeding device, according to some embodiments of the invention;

FIG. 4B is a simplified schematic of a patient with an installed ostomy device, where a feeding device is connected to ostomy device, according to some embodiments of the invention;

FIG. 5A is a simplified schematic of a patient with an installed ostomy device, and a feeding device, according to some embodiments of the invention;

FIG. 5B is a simplified schematic of a patient with an installed ostomy device, where a connector forms an ostomy device inner tube, according to some embodiments
5 of the invention

FIG. 6 is a simplified schematic of a feeding device where a connector is directly attached to a food reservoir, according to some embodiments, of the invention;

FIG. 7 is a simplified schematic of a feeding device where a connector, which includes a tube, is directly attached to a food reservoir, according to some embodiments,
10 of the invention;

FIG. 8 is a simplified schematic cross sectional view of a tip of a portion of an ostomy device including a sealing element between an inner tube and an outer tube, according to some embodiments of the invention;

FIG. 9A is a simplified schematic cross sectional view of a portion of an ostomy
15 device during insertion of an inner tube which includes an expanding sealing element, according to some embodiments of the invention;

FIG. 9B is a simplified schematic cross sectional view of a portion of an ostomy device and an expanded sealing element, according to some embodiments of the invention;

FIG. 10 is a simplified schematic of a portion of an ostomy device including a
20 sealing element, according to some embodiments of the invention;

FIG. 11 is a simplified schematic of a portion of an ostomy device including a sealing element and an angled outer tube edge in contact with the sealing element, according to some embodiments of the invention;

FIG. 12A is a simplified schematic cross sectional view of an inner tube before
25 insertion into an outer tube which has accumulated residue, according to some embodiments of the invention;

FIG. 12B is a simplified schematic cross sectional view of an inner tube during
30 insertion into an outer tube which has accumulated residue, according to some embodiments of the invention;

FIG. 13A is a simplified schematic cross sectional view of a portion of an ostomy device where an inner tube is disposed within an outer tube which has accumulated residue, according to some embodiments of the invention;

FIG. 13B is a simplified schematic cross sectional view of an inner tube during
5 removal from an outer tube which has accumulated residue, according to some embodiments of the invention;

FIG. 14A is a simplified schematic cross sectional view of insertion of an inner tube including multiple cleaning elements into an outer tube, according to some embodiments of the invention;

FIG. 14B is a simplified schematic cross sectional view of an inner tube
10 including multiple cleaning elements after exiting an outer tube, according to some embodiments of the invention;

FIG. 15A is a simplified schematic cross section of a bolster coupled to an inner tube by an elastic element, according to some embodiments of the invention;

FIG. 15B is a simplified schematic cross section of an inner tube released from
15 an elastic element, according to some embodiments of the invention;

FIG. 16 is a simplified section view of an external bolster fitting over an inner tube portion, according to some embodiments of the invention;

FIG. 17 is a simplified schematic cross sectional view of a connection between
20 an inner tube portion and an external bolster, according to some embodiments of the invention;

FIG. 18A is a simplified schematic isometric view of an ostomy device including a plug-socket connection between an inner tube portion and a rigid connector, according to some embodiments of the invention;

FIG. 18B is a simplified schematic section view of an ostomy device including a
25 plug-socket connection between an inner tube portion and a rigid connector, according to some embodiments of the invention;

FIG. 18C is a simplified schematic section view of an ostomy device inner tube portion including a plug connector, according to some embodiments of the invention;

FIG. 19 is a simplified schematic of an outer tube including anti-rotation
30 elements, according to some embodiments of the invention;

FIG. 20A is a simplified schematic of an external bolster including a hollow, according to some embodiments of the invention;

FIG. 20B is a simplified schematic of an inner tube portion head including a protrusion, according to some embodiments of the invention;

5 FIG. 21 is a simplified schematic side view of an inner tube portion head including more than one hollow, according to some embodiments of the invention;

FIG. 22 is a simplified schematic cross sectional view of a portion of an inner bolster connected to an outer tube (not illustrated) by interlocking connecting elements, according to some embodiments of the invention;

10 FIG. 23 is a simplified schematic cross sectional view of an ostomy device, according to some embodiments of the invention

FIG. 24 is a simplified schematic of a tube including a mesh and connectors, according to some embodiments of the invention

15 FIG. 25 is a simplified schematic of a wire-reinforced tube and connectors, according to some embodiments of the invention;

FIG. 26 is a simplified schematic cross sectional view of tube including thickened tube wall portions, and connectors, according to some embodiments of the invention;

20 FIG. 27 is a simplified schematic cross section of an ostomy device with an adjustable tube length within the patient body, according to some embodiments of the invention;

FIG. 28A is a simplified schematic section view of a portion of an ostomy device, according to some embodiments of the invention;

25 FIG. 28B, FIG. 28C and FIG. 28D are simplified schematic cross sectional views of exemplary interlocking connection between external bolster and connector, according to some embodiments of the invention;

FIG. 29A is a simplified schematic cross section of an ostomy device with adjustable axial length, according to some embodiments of the invention;

30 FIG. 29B is a simplified schematic cross section of an ostomy device with adjustable axial length within swollen tissue, according to some embodiments of the invention;

FIG. 30 is a simplified schematic section view of a portion of an ostomy device where a protrusion of the device above a patient outer abdominal surface is adjustable, according to some embodiments of the invention;

FIG. 31A is a simplified schematic section view of an external bolster bending
5 to fit an abdominal outer surface, according to some embodiments of the invention;

FIG. 31B is a simplified schematic section view of a device where an external bolster is bending to fit the device to a patient anatomy, according to some embodiments of the invention;

FIG. 32A is a simplified schematic section view of a portion of an elastic internal
10 bolster, according to some embodiments of the invention;

FIG. 32B is a simplified schematic cross sectional view of an inner bolster, a lumen inner wall and a compressible component therebetween, according to some embodiments of the invention;

FIG. 33 is a simplified schematic isometric view of an external bolster including
15 a plurality of notches 3360, according to some embodiments of the invention;

FIG. 34 is a flow chart of a method of ostomy device removal, according to some embodiments of the invention;

FIG. 35A is a simplified schematic side view of an internal bolster including a plurality of petals, according to some embodiments of the invention;

FIG. 35B is a simplified schematic side view of a dismantled internal bolster
20 including a plurality of petals, according to some embodiments of the invention;

FIG. 36 is a simplified section view of a portion of an internal bolster including a tool channel for a dismantling tool, according to some embodiments of the invention;

FIG. 37A is a simplified schematic side view of an inner tube portion where
25 inner tube is non-cylindrical, according to some embodiments of the invention;

FIG. 37B illustrates an inner tube portion including two channels, a feeding channel and a tool channel, according to some embodiments of the invention;

FIG. 38A is a simplified schematic section view of an internal bolster with a screw dismantling mechanism, according to some embodiments of the invention;

FIG. 38B is a simplified schematic side view of a screw dismantling mechanism
30 tool 3868, according to some embodiments of the invention;

FIG. 39 is a simplified schematic of a portion of a bolster and an expanding dismantling tool, according to some embodiments of the invention;

FIG. 40A is a simplified schematic side view of a disassembly tool, according to some embodiments of the invention;

5 FIG. 40B is a simplified schematic side view of a disassembly tool inserted into an inner bolster, according to some embodiments of the invention;

FIG. 41A is a simplified schematic side view of an inner bolster where each petal of the inner bolster is attached to an elongated element, according to some embodiments of the invention;

10 FIG. 41B illustrates removal of disassembled inner bolster portions through an outer tube by pulling, force P on an elongated element 4188, according to some embodiments of the invention;

FIG. 42 is a flow chart of a method of ostomy device installation, according to some embodiments of the invention;

15 FIG. 43 is a simplified schematic cross sectional view of an outer tube being pulled into a stoma by a pushing device 4380, according to some embodiments of the invention;

FIG. 44A is a simplified schematic side view of a pushing device, according to some embodiments of the invention.

20 FIG. 44B is a simplified schematic side view of a pushing device threaded with an elongated element, according to some embodiments of the invention;

FIG. 45A is a simplified schematic side view of a pushing device including a tapered end, according to some embodiments of the invention;

25 FIG. 45B is a simplified schematic side view of a pushing device within an outer tube attached to an inner bolster where a portion of the pushing device protrudes through the outer tube, according to some embodiments of the invention;

FIG. 46A is a simplified schematic side view of a pushing device, according to some embodiments of the invention;

30 FIG. 46B is a simplified schematic side view of a pushing device within an outer tube attached to an internal bolster where a portion of the pushing device protrudes through the outer tube, according to some embodiments of the invention;

FIG. 47 is a simplified schematic side view of an ostomy device where an external bolster is being attached to an outer tube, according to some embodiments of the invention;

FIG. 48 is a simplified schematic section view of device installation including
5 insertion of an outer tube into a stoma, according to some embodiments of the invention;

FIG. 49A is a simplified schematic cross sectional view of an inner bolster attached to an outer tube being inserted through an esophagus, according to some embodiments of the invention;

10 FIG. 49B is a simplified schematic cross sectional view of an inner bolster attached to an outer tube where the outer tube is installed within a stoma, according to some embodiments of the invention;

FIG. 49C is a simplified schematic section view of device installation including insertion of an outer tube into a stoma according to some embodiments of the invention;

15 FIG. 49D is a simplified schematic cross sectional view of a inner bolster connected to an outer tube being inserted through an esophagus, according to some embodiments of the invention;

FIG. 50A and FIG. 50B are flow chart of a method of use of an ostomy device, according to some embodiments of the invention;

20 FIG. 51 is a photograph illustrating a device with a pivoting external bolster inserted at an angle through simulated tissue in accordance with some embodiments of the current invention;

FIG. 52 is a simplified perspective view of a device with a pivoting external bolster inserted at an angle to an external body surface in accordance with some
25 embodiments of the current invention;

FIG. 53 is a cross sectional view of a device with a pivoting external bolster inserted at an angle to an external body surface in accordance with some embodiments of the current invention; and

FIG. 54 is a block diagram of an adjustable bolster 5100 in accordance with an
30 embodiment of the current invention.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to ostomy devices and procedures and, more particularly, but not exclusively, to devices and procedures for percutaneous endoscopic gastronomy.

5 Overview

An aspect of some embodiments of the invention relates to an ostomy device including an external and/or an internal bolster connected to a tube forming a channel through a stoma into a lumen (e.g. stomach) where one or both bolsters do not contact tissue and/or opening/s of the stoma.

10 For example, in some embodiments, an external bolster connected to the tube holds the tube by contacting a patient outer abdominal surface at an axial distance (e.g. distance from a long axis of the tube) from an opening of the stoma and/or from an opening of the tube. The opening of the stoma and/or the opening of the tube may optionally project from the abdominal outer surface and/or be on the abdominal outer
15 surface. In some embodiments, the external bolster contacts the patient outer abdominal surface only at a separation from the opening of the stoma on the patient outer abdominal surface at a distance from the stoma of between 2-30mm, between 5-25mm, or between 5-15mm, or smaller, or larger, or intermediate distances. In some embodiments, the external bolster mainly contacts the outer abdominal surface at a
20 distance, where over 80%, or over 90%, or over 95%, or lower, or higher, or intermediate percentages, of a surface area of the external bolster contacting the outer abdominal surface is at a distance of between 2-30mm, between 5-25mm, or between 5-15mm, or smaller, or larger, or intermediate distances.

Contact of the external bolster at a distance from the opening of the stoma
25 prevents irritation and/or inflammation at the stoma opening from pressure applied to and/or movement of the external bolster.

In an exemplary embodiment, the ostomy device is a PEG feeding device, where fluid food and/or liquid are supplied directly to the stomach through the channel.

In some embodiments, an underside of the external bolster (e.g. facing the inner
30 bolster e.g. a portion facing the tube), includes a shape that extends away from a long

axis of the tube and towards the inner bolster (for example, an underside the external bolster is concave e.g. dome shaped).

In some embodiments, an underside of the external bolster includes one or more concave portion (e.g. hollow 210h, FIG. 2). In some embodiments, an underside of the
5 internal bolster includes one or more concave portion (e.g. hollow 3208h, FIG. 32).

In some embodiments, the external bolster includes portions separated by spaces. In some embodiments, the external bolster contacts the outer abdominal surface at discrete points. In some embodiments, spaces between contacting points of the external bolster allow aeration and/or venting and/or facilitating cleaning of skin under
10 the external bolster.

Optionally, the device includes an (optionally replaceable) inner tube (e.g. as described herein) disposed within the tube, where flow of material between the lumen and outside of the patient is through the inner tube. Optionally, the device includes soft and/or flexible inner bolster, for example, in some embodiments, the inner bolster is
15 removable from the lumen through the stoma. For example, the inner bolster may be removed by pulling on the tube (directly or indirectly).

A broad aspect of some embodiments of the invention relates to an ostomy device with an adjustable axial length where, for example, a smallest separation between inner and external bolsters is adjustable. In some embodiments, the smallest
20 separation between inner and external bolsters is adjustable by 5-30mm.

In some embodiments, a device is installed within a patient by initially inserting a tube into a stoma where the tube is approximately sized for the stoma, for example, the tube is longer than the stoma. In some embodiments, a smallest separation between bolsters connected one on each end of the tube is adjusted, for example, fitting the
25 device including an approximately sized tube to patient anatomy.

In some embodiments, adjustment is by moving a position of attachment of a bolster with respect to the tube, e.g. a position of an external bolster with respect to a connector connecting the external bolster to the tube.

In some embodiments, position of bolster/s is adjusted when the device is
30 installed within a patient. In some embodiments, position of bolster/s is adjusted periodically for example, in response to a change in patient anatomy e.g. weight change and/or swelling.

In some embodiments, adjustment is through elasticity of one or more of the internal bolster, external bolster and tube, an axial length of the device thereby automatically adjusting to a range of lengths of stoma. In some embodiments, the tube includes a portion which is axially elastic. In some embodiments, one or more bolster
5 includes a deflectable portion. Optionally the deflectable portion may be elastic. In some embodiments, one or more part elastically moves, changing a minimum separation between the bolsters. In some embodiments, a minimum separation between changes, fitting the device to the stoma, for example, during changes in stoma length, e.g. before, during and after post operative swelling of tissue around a stoma and/or patient weight
10 gain and/or patient tissue change in fat percentage.

In some embodiments, a bolster (e.g. inner and/or external bolster) includes one or more portion which elastically bends and/or flexes. In some embodiments, the portion/s bend at pressures which are physiologically acceptable to patient tissue. For example, in some embodiments, a portion of a bolster in contact with patient tissue
15 deflects before a pressure which causes damage and/or pain and/or discomfort to the patient tissue. In some embodiments, deflection of one or more elastic portion of a bolster changes a minimum axial separation between the bolsters. For example, in some embodiments, an elastic portion of a bolster extends towards the other bolster, a minimum separation between the bolsters defined from the elastic portion, deflection of
20 the elastic portion changing the minimum separation between bolsters.

In some embodiments, the external bolster (and/or inner bolster) includes separate protrusions (e.g. petals) which, in some embodiments, elastically bend and/or flex and/or deflect independently (e.g. to different extents), for example, fitting the device to non-planar patient anatomy.

25 In some embodiments, the internal bolster includes inlets between separate parts (e.g. petals), for example allowing bending and/or flexing of the parts without overlapping of the parts.

In some embodiments, axial elasticity and/or flexibility of the internal bolster, where, for example, portion/s of the internal bolster bend under pressure (e.g. from the
30 lumen walls), for example, bending towards an inner shaft of the internal bolster. In some embodiments, deflection of portion/s of the inner bolster prevents high pressure (e.g. associated with irritation of the lumen walls and/or the inner bolster becoming

embedded in the lumen walls).

In an exemplary embodiment, the internal bumper includes portions (e.g. deflectable portions) with stiffness of 40-70 shore A, or 40-80 shore A, or 50-70 shore A, or lower, or higher, or intermediate stiffness.

5 In an exemplary embodiment, the internal bumper includes portions (e.g. deflectable portions) with stiffness of 40-70 shore A or 40-80 shore A, or 50-70 shore A, or lower, or higher, or intermediate stiffness.

In some embodiments, a force required to fully deflect deflectable portions of the external bumper is less than 10N, or less than 5N, or 1-10N.

10 In some embodiments, during delivery of the internal bolster through the esophagus to the stomach portion/s of the inner bolster bend and/or fold, optionally elastically, for example, reducing an extent of the inner bolster. In some embodiments, deflectable internal bolster portions have a maximum deflection, where, for example, in some embodiments, the internal bolster includes one or more blocking part which
15 prevents bending beyond a maximum deflection.

In some embodiments, a spacer prevents the internal bolster from irritating the stomach wall, and/or for example, a compressible component (e.g. inflatable balloon, sponge, spring) placed (e.g. during installation of the ostomy device) between the internal bolster and the stomach.

20 In some embodiments, a spacer positioned between the inner bolster and lumen wall is adjusted from outside the body, for example, by pulling and/or releasing a component attached to the compressible component.

Optionally, in some embodiments, one or component deflects and/or extends non-elastically (e.g. plastically), for example, fitting the device to an expanding stoma.

25 Optionally, the device with adjustable axial length includes an (optionally replaceable) inner tube (e.g. as described herein) disposed within the tube, where flow of material between the lumen and outside of the patient is through the inner tube.

Optionally, the device with adjustable axial length includes soft and/or flexible inner bolster, for example, in some embodiments, the inner bolster is removable from
30 the lumen through the stoma by pulling on the tube (directly or indirectly).

A broad aspect of some embodiments of the invention relates to an ostomy device including an outer tube and an inner tube, the inner tube forming a channel to a

patient lumen. In some embodiments, the inner tube is removable for replacement and/or cleaning. In some embodiments, cleaning extends a life time of the ostomy device within the patient.

In some embodiments, the inner tube extends into the stomach. In some
5 embodiments, the inner tube extends into the stomach and through the stomach to the jejunum, e.g. for feeding directly into the jejunum, the inner tube, being 1-30cm long or 5-25cm long, or shorter, or longer, or intermediate lengths or ranges.

In some embodiments, a seal (e.g. between the inner and outer tube) prevents flow within the outer tube around the inner tube.

10 An aspect of some embodiments of the invention relates to an inner tube which includes one or more protrusion where, for example, during insertion and/or removal of the inner tube from the outer tube, the protrusion/s contact the outer tube, for example, cleaning the outer tube.

Optionally, in some embodiments, the device including an inner tube includes
15 soft and/or flexible inner bolster, for example, in some embodiments, the inner bolster is removable from the lumen through the stoma by pulling on the tube (directly or indirectly).

A broad aspect of some embodiments of the invention relates to an ostomy device including an internal bolster including a plurality of separate coupled parts. In
20 some embodiments, the ostomy device is removed by decoupling the separate parts of the inner bolster to dismantle the inner bolster.

In some embodiments, the inner bolster includes a plurality of optionally flexible parts (herein termed petals) connected by optionally rigid connectors. In some embodiments, flexible petals are held between rigid connectors.

25 In an exemplary embodiment the petals substantially do not overlap. For example, the petals may substantially not overlap axially (overlap being where petals contact each other in a planes approximately perpendicular to the long axis of the tube). In some embodiments, petals at most overlap axially with adjacent (e.g. radially adjacent) petals.

30 In some embodiments, residue (e.g. stomach contents) coating the inner bolster (e.g. coating contact areas between petals) prevents and/or slows disassembly of inner bolster petals. In some embodiments, the inner bolster includes one or more notch

and/or inlet separating portions of the inner bolster e.g. between petals. For example, reducing an area of contact between petals potentially reduces friction of movement of petals away from each other.

In some embodiments, the internal bolster includes a plurality of petals which
5 are held by one or more connectors (e.g. in some embodiments, petals are held between two or more connectors) where disconnecting the connectors decouples the petals.

In some embodiments, the device includes a channel between an inner bolster dismantling mechanism and another portion of the device (e.g. the outer bolster). In some embodiments, the inner and/or outer tube forms the channel to the inner bolster.
10 For example, in some embodiments, a user dismantles the inner bolster by accessing the internal bolster through the dismantling mechanism channel, from outside the patient (e.g. an endoscopic procedure is not required to dismantle the inner bolster).

In some embodiments, the inner bolster is dismantled by breaking at least a portion of a connector, for example, by applying pressure to the portion of the connector
15 for example, applying pressure e.g. with a shaft. In some embodiments, the inner bolster is dismantled by moving and/or deflecting at least a portion of a connector, for example, moving an interlocking element, for example, by applying pressure e.g. with a shaft.

In some embodiments, pressure is applied by a non-designated tool, for example a hypodermic needle shaft or syringe.

In some embodiments, petals are coupled by a rotation attachment mechanism
20 (e.g. screw mechanism, e.g. a mechanism with an open rotational configuration and a closed rotational configuration). In some embodiments, dismantling of the inner bolster includes rotating an inner bolster connector (e.g. unscrewing) to release petals of the inner bolster.

Optionally, the device with an inner bolster including a plurality of connected portions includes an (optionally replaceable) inner tube (e.g. as described herein) disposed within the tube, where flow of material between the lumen and outside of the patient is through the inner tube.
25

An aspect of some embodiments of the invention relates to an ostomy device
30 where a flexible tube is connected to one or both bolsters by rigid connector/s. In some embodiments, a flexible tube is connected to a bolster including flexible part/s by

connection (e.g. snap lock) of two rigid connector elements, one connected to the outer tube and the second to the flexible bolster.

In some embodiments, the tube has hardness of at least 40 shore A, or 50-80 shore A, or lower, or higher, or intermediate hardness. In some embodiments, the tube
5 has a maximum radius of curvature of 1-25mm, or 5-15mm, or approximately 10mm.

In some embodiments, a rigid connector is partially disposed within the flexible tube, for example, elasticity of the tube and/or a fitted friction fit of the connector holding the connector and tube together. In some embodiments, one or more connector is attached to the tube by injection molding the tube and connector as one part
10 (optionally, where the connector includes different material to the tube). In some embodiments, one or more connector is attached to the tube by adhesion (e.g. gluing, heat treatment). In some embodiments, the tube is not folded around a connector.

In some embodiments, connection between the connector/s and the outer tube is non-smooth. For example, a diameter of the connector within the tube is less than a
15 diameter of the tube, for example there is a step between the outer tube and the connector of 0.05mm-1mm, or 0.05mm-0.5mm, or lower, or higher, or intermediate values or ranges. In some embodiments, the inner tube prevents issues that would otherwise be associated with a non-smooth topography between the outer tube and the connector within the outer tube (e.g. build up of residue in the step).

20 Optionally, the device with adjustable axial length includes an (optionally replaceable) inner tube (e.g. as described herein) disposed within the flexible tube, where flow of material between the lumen and outside of the patient is through the inner tube.

25 Optionally, in some embodiments, the inner tube is flexible. In some embodiments, the inner tube has a maximum radius of curvature of 1-50mm, or 5-25mm, or approximately 20mm.

In some embodiments, connection is to the flexible tube, which is non-smooth (e.g. stepped), while the flow of material to the lumen is through a smooth walled channel (e.g. the inner tube).

30 In some embodiments, the flexible inner tube (e.g. attached to rigid connector/s) includes a mesh of rigid material (e.g. within a sealing sheath) where free space within the mesh maintains tube flexibility.

An aspect of some embodiments of the invention relates to an ostomy device where a flexible tube is connected to one or both bolsters by a variable angle joint. For example, the variable joint may compensate for differences between the axis of the tube to the surface of the tissue and/or for changes and/or for movement of the surface. For example the angle of the joint may vary over a range of between 0 to 5 degrees and/or between 5 to 15 degrees and/or between 15 to 40 degrees and/or between 40 to 60 degrees. Optionally the bolster may float freely over the joint. Alternatively or additionally the bolster may be biased to a particular angle (for example with the axis of bolster parallel and/or concentric to the axis of the tube and/or may be biased to one side for example to increase pressure on that side and/or decrease pressure on an opposite side).

In some embodiments, the tube may have a single unambiguous axis. For example the tube may be straight and/or have substantially the form of a right circular cylinder and/or have a -circular cross-section. In some embodiments, the tube may be curved and/or non-cylindrical and/or flexible and/or have a non-circular cross-section and/or may not have a single unambiguous axis. For the sake of this disclosure, where the tube does not have a clearly defined unambiguous single longitudinal axis, the longitudinal axis of the tube will refer to a line joining the center of gravity of the cross section of the tube where it intersects the outer surface of the tissue (e.g. the outer surface of the abdomen of a patient) to the center of gravity of the cross section of the tube where it intersects the inner surface of the tissue (e.g. the inner surface of the stomach of the patient). An outer axis of the tube will refer to an axis perpendicular to the cross section of the tube and passing through the center of gravity of the cross section along a plane where the tube meets the outer surface of the tissue. An inner axis of the tube will refer to an axis perpendicular to the cross section of the tube and passing through the center of gravity of the cross section along a plane where the tube meets the outer surface of the tissue.

In some embodiments, the ostomy device is additionally or alternatively used to collect material (e.g. waste) from a lumen. For example, in some embodiments, the ostomy device is used to collect and/or release material from the stomach, optionally in addition to providing food to the stomach. In some embodiments, the ostomy device is used to reduce pressure within the stomach (e.g. by allowing material e.g. gas and/or food to escape through the device).

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings and/or the Examples. The invention is capable of other embodiments or of being practiced or carried out in various ways.

Ostomy device

FIG. 1A is a simplified schematic cross section of an ostomy device 100 which provides a channel 102 between an internal patient lumen 104 and an outer abdominal surface of the patient 106, according to some embodiments of the invention.

In an exemplary embodiment, ostomy device 100 is a device for insertion during PEG, and lumen 104 is a patient stomach. In some embodiments, channel 102 passes through stomach wall 104a and abdominal wall 104b.

In some embodiments, tube 112 is at least partially disposed within a stoma 105 between lumen 104 and patient outer abdominal surface 106.

In some embodiments, ostomy device 100 includes an internal bolster 108 and an external bolster 110 which are each attached to tube 112. In some embodiments, bolsters 108 and 110 are attached at opposite ends of tube 112.

In some embodiments, inner bolster 108 is larger, in at least one direction perpendicular to an opening of the stoma within lumen 104, such that inner bolster 108 prevents tube 112 from falling out of stoma 105. In some embodiments, inner bolster 108 is larger, in at least one direction perpendicular to an opening of the stoma within outer abdominal surface 106, for example, preventing tube 112 from moving into the lumen.

In some embodiments, stoma 105a does not follow a straight path between the lumen 104 and outer abdominal surface 106 (e.g. as illustrated in FIG. 1B). In some embodiments, the stoma is non-perpendicular to the lumen wall and/or outer abdominal surface. In some embodiments, a flexible tube (and/or bolster flexibility e.g. a described below) prevents pressure of the device on patient anatomy due to such non-planar patient anatomy. In some embodiments, one or more portions of the inner and/or outer bolster adjust to non-planar patient anatomy (e.g. as described below). In some

embodiments, connection between the tube and the inner and/or outer bolster adjusts to non-planar patient anatomy.

FIG. 1B is a simplified schematic cross section of an ostomy device with a flexible tube 112a, according to some embodiments of the invention. In some
5 embodiments, the patient moves without device 100 causing discomfort and/or injury, for example, due to tube 112 flexibility.

Inner tube

In some embodiments, an ostomy device includes an inner tube providing a
10 channel through which material passes e.g. from outside the patient into a patient lumen. FIG. 2A is a simplified schematic sectional view of ostomy device 200 including an inner tube 214, according to some embodiments of the invention. In some
embodiments, ostomy device 200 is deployed in a patient where an internal bolster 208 is within a patient lumen (not illustrated) and an external bolster 210 is outside the
15 patient and where an outer tube 212 and an inner tube 214 pass between the lumen and the outside of the patient e.g. as illustrated by tube 112 in FIG. 1.

In some embodiments, inner tube 214 is disposed within outer tube 212 where inner tube 214 provides a channel 202 from outside a patient to a lumen (e.g. stomach).

In some embodiments, inner tube 214 and/or outer tube 212 are flexible, in some
20 embodiments, bending of the outer tube causing the inner tube to bend, for example preventing stress between the two components and/or surrounding tissue. For example, preventing damaging stress (e.g. sufficient to cause necrosis) between outer tube 212 and
and

In some embodiments, inner tube 214 is removable, for example, allowing
25 cleaning of the inner and/or outer tube and/or replacement of inner tube 214.

In an exemplary embodiment, inner tube is sufficiently rigid for insertion of the inner tube 214 into the outer tube 212.

In an exemplary embodiment, inner tube 214 and/or outer tube 212 are
sufficiently rigid (e.g. axially rigid) such that movement of the patient and/or movement
30 of the outer bolster and/or pressure of patient tissue on the tubes do not cause buckling and/or collapse of outer tube 212 and/or inner tube 214. In some embodiments, inner

tube 212 is sufficiently rigid to prevent closure of the channel, for example, due to pressure from patient tissue and/or collapse of the outer tube.

In an exemplary embodiment, inner tube 112 is part of an inner tube portion which, in some embodiments, is removed and replaced or cleaned e.g. to provide a
5 clean channel. FIG. 2B is a simplified schematic side view of an ostomy device body 200a and an inner tube portion 216, according to some embodiments of the invention. In some embodiments, ostomy device body 200a includes an internal bolster 208, an outer tube 212 and an external bolster 210.

10 Exemplary method of feeding

FIG. 3 is a flow diagram of a method of feeding, according to some embodiments of the invention.

At 302, a food reservoir, for example, bag of fluid nutritional supplement, is attached to an ostomy device tube (e.g. inner tube 214). Exemplary contents of a food
15 reservoir include liquid (e.g. water) and/or medication and/or any other substance desired for direct insertion into the stomach.

FIG. 4A is a simplified schematic of a patient 422 with an installed ostomy device 400, and a feeding device 423, according to some embodiments of the invention. In some embodiments, feeding device 423 includes a food reservoir 424 and a
20 connector 426.

FIG. 4B is a simplified schematic of a patient 422 with an installed ostomy device 400, where a feeding device 423 is connected to ostomy device 400, according to some embodiments of the invention.

In some embodiments, food reservoir 424 is attached to an inlet 430 of an
25 ostomy device tube (e.g. inner tube 214 illustrated in FIG. 2A-B) by connector 426. In some embodiments, connector 426 includes a pipe 428 through which food flows from food reservoir 424 into the patient 422. In some embodiments, connector 426 and/or fluid reservoir 424 and/or pipe 428 are commercially available components, used with PEG feeding devices.

30 In some embodiments, a feeding device includes a connector which is sized and shaped to fit into an ostomy device outer tube (e.g. outer tube 212), optionally forming a seal (e.g. as described herein). In some embodiments, the feeding device connector,

when inserted into the ostomy device outer tube (e.g. outer tube 212) forms an inner tube of the ostomy device. FIG. 5A is a simplified schematic of a patient 522 with an installed ostomy device 500, and a feeding device 523, according to some embodiments of the invention. FIG. 5B is a simplified schematic of a patient 522 with an installed
5 ostomy device 500, where a connector 526 forms an ostomy device inner tube, according to some embodiments of the invention. In some embodiments, connector 526 (which optionally includes a pipe 528) connects a food reservoir 524 to a patient stomach.

10 In some embodiments, the method of feeding includes removing an inner tube portion (e.g. inner tube portion 216 illustrated in FIG. 2A-B) and then attaching a food reservoir to ostomy device 430.

In some embodiments, the connector is directly attached to the food reservoir (e.g. the feeding device does not include a tube). FIG. 6 is a simplified schematic of a feeding device 623 where a connector 626 is directly attached to a food reservoir 624,
15 according to some embodiments, of the invention. FIG. 7 is a simplified schematic of a feeding device 723 where a connector 724, which includes a tube 714, is directly attached to a food reservoir 724, according to some embodiments, of the invention.

Returning back to FIG. 3, at 304, food (e.g. fluid food) flows from the food reservoir through a channel (e.g. channel 202) into the patient's stomach. In some
20 embodiments, fluid flows into the stomach under gravity, for example the food reservoir is raised above height of the patient's stomach. In some embodiments, pressure is applied e.g. to the food reservoir, to dispense fluid into the stomach e.g. the fluid reservoir is a syringe, e.g. a patient or caregiver manually squeezes on the food reservoir.

25 In some embodiments, a feeding device (e.g. 423, 523, 626, 623) includes a feeding pump (e.g. a commercially available feeding pump) which regulates, for example, rate and/or quantity and/or pressure of fluid introduced into the patient through the ostomy device.

In some embodiments, once feeding is completed, the feeding device is
30 removed, for example, from a body of the device, which remains in situ (e.g. partially within the patient, e.g. the inner tube is removed while the outer tube remains in position at least partially within the stoma).

In some embodiments, the inner tube is removed and cleaned or replaced periodically (e.g. every feed, once a day, once a week, once a month, or shorter, or longer, or intermediate time periods).

5 Inner tube portion

Exemplary seal between inner tube and outer tube

Returning back to FIG. 2, in some embodiments, sealing between inner tube 214 and another part of the device prevents flow and/or material accumulating within tube 212 (e.g. outwards from the stomach) around inner tube 214. In some embodiments, sealing is of an opening into the lumen of the outer tube. In some embodiments, sealing is between inner tube 214 and outer tube 212. Alternatively, in some embodiments, sealing is between other parts preventing flow within the outer tube around the inner tube, for example, in some embodiments, sealing (e.g. a sealing element) is between the internal bolster (e.g. 208) and the inner tube (e.g. 214).

In some embodiments, e.g. as illustrated in FIG. 2, inner tube 214 closely fits outer tube 212, preventing flow around inner tube 214.

In some embodiments, device 200 includes a sealing portion between inner tube 214 and outer tube 212.

FIG. 8 is a simplified schematic cross sectional view of a tip of a portion of an ostomy device including a sealing element 832 between an inner tube 814 and an outer tube 812, according to some embodiments of the invention. In some embodiments, sealing element 832 is a ring of flexible material (e.g. rubber, silicone rubber) around inner tube 814. In some embodiments, sealing element 832 is mounted on (e.g. attached to) inner tube 814. Alternatively, in some embodiments, sealing element 832 is mounted on (e.g. attached to) outer tube 812.

In some embodiments, sealing is axial, for example, a seal between inner tube (e.g. 214) and outer tube (e.g. 214) is between a portion of the inner tube and a tip of the outer tube.

In some embodiments, axial sealing is achieved by the inner tube including an expanding sealing element (e.g. elastic and/or compressible and/or inflatable). FIG. 9A is a simplified schematic cross sectional view of a portion of an ostomy device during insertion of an inner tube 914 which includes an expanding sealing element 932,

according to some embodiments of the invention. FIG. 9B is a simplified schematic cross sectional view of a portion of an ostomy device and an expanded sealing element 932, according to some embodiments of the invention. In some embodiments, once inner tube 914 is inserted such that expanding sealing element 932 emerges from the
5 ostomy device (e.g. as described herein) outer tube 912, expanding sealing element 932 unfolds or expands to close, e.g. at the stomach end of outer tube 912, a channel between outer and inner tubes 912, 914. In some embodiments, sealing element 932 and a rim 934 of outer tube 912 are sized and shaped such that pressure P of stomach contents on sealing element 932 holds and/or pushes sealing element to rim 934 of outer
10 tube 912, improving sealing.

FIG. 10 is a simplified schematic of a portion of an ostomy device including a sealing element 1032, according to some embodiments of the invention

In some embodiments, a portion of the outer tube which is in contact with the sealing element is sized and shaped to provide an increased surface area over which
15 sealing occurs. FIG. 11 is a simplified schematic of a portion of an ostomy device including a sealing element 1132 and an angled outer tube edge 1134 in contact with the sealing element, according to some embodiments of the invention. The angled end of the outer tube, in contrast to a straight cut outer tube end, provides an increased contact area between the outer tube and the sealing element, and potentially a stronger seal
20 associated with this larger surface area. In some embodiments, the angled end of the outer tube enables tube pull-out of the inner tube, for example, by facilitating retraction of the expanding portion of the inner tube.

In some embodiments, sealing element 1132 extends beyond outer tube 1112, the additional surface area under pressure from the stomach contents potentially
25 increasing the force between sealing element 1132 and outer tube edge 1134.

In some embodiments, sealing is between walls of the outer and inner tube, e.g. as illustrated in FIG. 8 and FIG. 13A. Alternatively, or additionally, in some embodiments, sealing is between an edge or rim of the outer tube and the inner tube, e.g. as illustrated in FIG. 9B, FIG. 10 and FIG. 11. In some embodiments, sealing is
30 between a surface of the outer tube and the inner tube, for example, in some embodiments, a sealing element wraps around and/or folds over the outer tube.

In some embodiments, a sealing element provides tactile feedback to a user that the inner tube portion is in position. For example, in some embodiments, the inner tube inserts freely until the sealing element engages, resistance of movement of the inner tube is increased.

5 *Exemplary inner tube which cleans outer tube*

In some embodiments, the inner tube portion (e.g. 216) includes one or more portion for cleaning the outer tube, for example, on insertion and/or removal of the inner tube. In some embodiments, an inner tube sealing element also acts as a cleaning portion.

10 In some embodiments, a sealing element also cleans the outer tube, for example, on insertion and/or removal of the outer tube. For example, in some embodiment sealing element 832 (FIG. 8) is a cleaning and/or sealing element.

FIG. 12A is a simplified schematic cross sectional view of an inner tube 1214 before insertion into an outer tube which has accumulated residue 1236 (e.g. food residue), according to some embodiments of the invention. FIG. 12B is a simplified schematic cross sectional view of an inner tube 1214 during insertion into an outer tube which has accumulated residue 1236, according to some embodiments of the invention. FIG. 12B illustrates that residue 1236 has been cleaned from outer tube 1212, by cleaning portion 1232, and, in some embodiments, is removed from the ostomy device by pushing into the patient's stomach (e.g. if inner tube 1214 is inserted to a tip of outer tube 1212). In some embodiments, cleaning portion 1232 pushes against outer tube walls, potentially elasticity improving cleaning the outer tube (e.g. cleaning portion is elastic and is elastically compressed within outer tube). Flexibility and/or elasticity of cleaning element/s is illustrated by bending of cleaning elements 1432 in FIG. 14A

25 FIG. 13A is a simplified schematic cross sectional view of a portion of an ostomy device where an inner tube 1314 is disposed within an outer tube 1312 which has accumulated residue 1336, according to some embodiments of the invention. FIG. 13B is a simplified schematic cross sectional view of an inner tube 1314 during removal from an outer tube 1312 which has accumulated residue 1336, according to some
30 embodiments of the invention. FIG. 13B illustrates that residue 1336 has been cleaned from outer tube 1312. In some embodiments, residue 1336 is removed from the ostomy device during removal of inner tube 1314.

In some embodiments, an inner tube includes more than one cleaning element (and/or sealing element). FIG. 14A is a simplified schematic cross sectional view of insertion of an inner tube 1414 including multiple cleaning elements 1432 (which, in some embodiments are alternatively or additionally sealing elements) into an outer tube 1432, according to some embodiments of the invention. FIG. 14B is a simplified schematic cross sectional view of an inner tube 1414 including multiple cleaning elements 1432 after exiting an outer tube 1432, according to some embodiments of the invention.

Additionally or alternatively, in some embodiments, a cleaning device for example, including a cleaning element (e.g. as described above) is used to clean the outer tube. For example, the inner tube is removed; a cleaning tool is inserted and removed (optionally more than one time).

Exemplary Valve

Returning back to FIG. 2, in some embodiments, ostomy device 200 includes one or more valve.

In an exemplary embodiment, a valve 218 is disposed in channel 202. In some embodiments, valve 218 is a one way valve, for example, allowing flow of food from a food reservoir to the stomach, but preventing back-flow from the stomach outwards. Alternatively, in some embodiments, valve 218 is a one way valve, allowing flow from the lumen out of the ostomy device, but preventing flow into the lumen. In some embodiments, valve 218 is a two directional valve, for example, which allows flow into the lumen of fluid and prevents flow in the opposite direction, below a certain pressure, once reached valve 218 allows flow out of the lumen (e.g. providing venting of the lumen potentially preventing pressure build up in the lumen).

In some embodiments, channel is connected to a component including two branches, each including a valve. For example, in some embodiments, a first valve, disposed in a first branch is a one way valve only allowing movement of material into the valve. In some embodiments, a second valve, disposed in a second branch is a one way valve only allowing movement of material out of the valve e.g. once a threshold pressure is exceeded.

In some embodiments, the ostomy device (e.g. as described herein) is used to depressurize the stomach, continuously and/or periodically, e.g. by allowing flow of material out of the stomach e.g. gas and/or other stomach contents.

In some embodiments, valve 218 remains closed until a feeding device (e.g. 423, 523) is attached to ostomy device 200, the attachment of which, in some embodiments, opens valve 218. Alternatively or additionally, in some embodiments, ostomy device 200 includes a closing element for example, a plug which is inserted into and/or over outlet 230 between feeds. For example, plug 3772 illustrated in FIG. 37.

In an exemplary embodiment, valve 218 is located within head 220.

10 *Exemplary Coupling of inner tube to body of ostomy device*

In some embodiments, inner tube 214 is attached at one or more point to one or more portion of a body of the ostomy device 200, for example, preventing movement of the inner tube.

For example, as described previously, in some embodiments, inner tube 214 is coupled (e.g. to outer tube 212 and/or to internal bolster 208) by a sealing element, e.g. the inner tube is coupled to the outer tube by a sealing element (e.g. as illustrated in FIG.s 8, 9A-B, 10, 11).

In some embodiments, an inner tube portion 216 includes inner tube 214 and a head 220 which attaches to external bolster 210. In some embodiments head 220 is rigid. In some embodiments, head 220 is larger in a direction perpendicular to a long axis of the inner tube, providing a larger surface area for attachment to external bolster 210 and/or for attachment to a feeding device. In some embodiments inner tube portion 216 including inner tube 214 and head 220 is a single piece (e.g. molded as a single piece and/or assembled by connecting tube 214 and head 230). For example, some embodiments, inner tube 214 and head 220 are formed of the same material (e.g. silicone and/or polyurethane), where inner tube 214 (e.g. due to thickness of walls of the inner tube) is flexible and head 220 is a substantially rigid part (e.g. due to thickness of material in the part), for example forming a stable connector to other portions e.g. external bolster 220 and/or a feeding device.

In some embodiments, connection of the inner tube is by connection of the inner tube both at a lumen end of the inner tube (e.g. by a sealing element) and by connection of the inner tube (or inner tube portion) to the external bolster.

In an exemplary embodiment, a sealing ring is disposed in a ridge between the outer tube and a connector connecting the outer tube to a bolster (e.g. the inner bolster). In some embodiments, a connector connecting the outer tube to a bolster (e.g. the inner bolster) itself forms a sealing element against the inner tube.

Exemplary Connection of inner tube portion, elastic element

In some embodiments, inner tube 214 is coupled to external bolster 210. In some embodiments, an elastic element couples an inner tube portion (e.g. 216) to an external bolster (e.g. 210). FIG. 15A is a simplified schematic cross section of a bolster 1510 coupled to an inner tube by an elastic element 1538, according to some embodiments of the invention. FIG. 15B is a simplified schematic cross section of an inner tube released from an elastic element 1538, according to some embodiments of the invention.

In some embodiments, elastic element 1538 is relaxed when an elastic element cross section smallest dimension, D , is larger than the diameter ($D1$) of inner tube portion 216, such that, when inner tube portion 216 is disposed inside elastic element 1538 (e.g. as illustrated in FIG. 15A) the elastic element holds the inner tube portion (with elastic element cross section smallest dimension $D1 > D$). To remove inner tube portion 216, in some embodiments, buttons 1540, 1542 are pushed inwards by pressure, P (e.g. applied by a user) which deforms elastic element 1538 into a shape (e.g. a more circular shape) with larger cross section smallest dimension, $D2$. Elastic element 1538 no longer holds inner tube portion 1516 and, in some embodiments, inner tube portion 1516 is free to be removed.

In some embodiments, elastic element 1538 holds the inner tube itself (e.g. 214 as illustrated in FIG. 2). Alternatively, in some embodiments, elastic element 1538 holds an element connected to the inner tube (e.g. head 220 as illustrated in FIG. 2)

In some embodiments, elastic element 1538 holds inner tube portion 1516 in an inlet of inner tube portion 1516. Returning back to FIG. 2B, in an exemplary embodiment, an elastic element 238, when inner tube portion 216 is inserted into the body of ostomy device 200, is located within a groove 221 in the inner tube portion.

In some embodiments, an inner tube portion is held in position by an external bolster including two portions, a first external bolster portion fitting over the inner tube portion (e.g. overlaps axially inner tube portion head 220). FIG. 16 is a simplified section view of an external bolster including a portion 1610a which fits over an inner tube portion 1616, according to some embodiments of the invention. In some embodiments, external bolster 1610 holds inner tube portion 1616 against the outer tube 1612. In some embodiments, external bolster 1610 is a flexible component which elastically holds inner tube portion 1616 onto an external bolster second portion 1636 attached to an outer tube 1612. In some embodiments, when inner tube portion 1616 is removed and/or replaced, external bolster 1610 is detached and/or a portion of the external bolster which holds inner tube portion 1616 is moved.

In some embodiments, first external bolster portion 1610a is an axially flexible portion, (e.g. as described herein) and second external bolster portion 1636 is sized to prevent movement into the stoma.

Exemplary Connection of inner tube portion, interconnecting elements, e.g. push-lock

In some embodiments, an inner tube portion attaches to an external bolster by a protruding portion of the inner tube portion plugging into a hollow (also herein termed recess) in the external bolster (e.g. a plug-socket mechanism). In some embodiments, more than one protrusion plugs, each protrusion into a matching hollow or recess. Alternatively, in some embodiments, the inner tube portion includes one or more recess and the external bolster includes matching plug/s.

In some embodiments, one or more part of an inner tube plug is elastic, holding the inner tube plug in position within a bolster socket, for example, inner tube plug includes a by an interference mechanism (e.g. push-lock mechanism).

In some embodiments, an inner tube portion is held in position by an interference mechanism (e.g. push-lock mechanism). FIG. 17 is a simplified schematic cross sectional view of a connection between an inner tube portion 1716 and an external bolster 1710, according to some embodiments of the invention. In some embodiments, as inner tube portion 1716 is pushed into an outer tube (not illustrated) protrusions of the inner tube portion enter into hollows in the external bolster, elastic portions of the inner tube portion 1740, 1742 and/or interlocking shape of the hollows and protrusions

holding inner tube portion and external bolster together (e.g. by an interference mechanism (e.g. push-lock mechanism)). FIG. 33 illustrates a side view of the inner tube portion illustrated in FIG. 17, 1716 inserted into an external bolster 3310. In some embodiments, a user pushes, P on inner tube portion 1740, 1742, separating at least
5 some inner tube portion and external bolster interlocking portion/s to free the inner tube portion.

In some embodiments, inner tube portion is connected indirectly to the external bolster by connection to a rigid connector. FIG. 18A is a simplified isometric view of an ostomy device 1800 including a plug-socket connection between an inner tube portion
10 1816 and an rigid connector 1810b, according to some embodiments of the invention.

FIG. 18B is a simplified schematic section view of an ostomy device 1800 including a plug-socket connection between an inner tube portion 1816 and an rigid connector 1810b, according to some embodiments of the invention. FIG. 18B illustrates the section taken along line C-C in FIG. 18A.

15 FIG. 18C is a simplified schematic section view of an ostomy device inner tube portion 1816 including a plug connector, according to some embodiments of the invention.

In some embodiments, rigid connector 1810b forms a base for connection of flexible devices, for example, external bolster 1810 and/or outer tube 1812 and/or inner
20 tube 1814 (connected via inner tube head 1820). In some embodiments, inner tube portion 1816 is held in position by a by an interference mechanism (e.g. push-lock mechanism) where elements of head 1820 interlock with elements of connector 1810b. In some embodiments, a user pushes, P on inner tube portion buttons 1840, 1842, separating at least some inner tube portion and external bolster interlocking portion/s to
25 remove the inner tube portion from the device.

In some embodiments, the connection between the inner tube portion and the external bolster is shaped such that, upon release of the inner tube portion (e.g. by pressing on buttons 1840, 1842) the inner tube portion moves outwards (e.g. partially) from the inner tube portion.

30 In some embodiment, removal of the inner tube portion includes releasing a connection between the inner tube portion and the external bolster (e.g. pressing on one or more button (e.g. pressing concurrently on two buttons)). In some embodiments,

release of the inner tube portion is followed by pulling on the inner tube portion to remove it from the body of the ostomy device. In some embodiments, release and removal of the inner tube portion is performed concurrently e.g. release of the inner tube portion from connection with the external bolster includes pulling on the inner tube portion.

Exemplary Anti-rotation

In some embodiments, one or more part of an ostomy device (e.g. 200, 1800, as described herein) includes anti-rotation feature/s to prevent rotation of parts of the device with respect to each other.

In some embodiments, anti rotation feature/s ensure that torque applied to a part of the device transfers axially along the device. For example, in some embodiments, rotating external portion/s of the device (e.g. external bolster) causes internal portions of the device (e.g. inner bolster and/or outer tube) to rotate.

In some embodiments, an inner bolster is rotated periodically (e.g. by rotating the outer bolster), for example, as part of a care protocol, e.g. to prevent encapsulation of the inner bolster into the stomach wall.

In some embodiments, anti-rotation element/s facilitate attachment of feeding device connector/s via rotation, for example, in some embodiments, attachment of a feeding device to an inner tube by rotation (e.g. screw attachment) is assisted by lack of rotation of the inner tube within the device.

In some embodiments, one or more anti-rotation element prevents rotation of the inner tube within the device.

In some embodiments, one or more anti-rotation element prevents rotation of one or more bolster with respect to the outer tube.

In some embodiments, rotation of inner tube portion 216 with respect to the ostomy device body and/or external bolster 210 is prevented by anti-rotation elements on inner tube portion 216 and/or external bolster 210. In some embodiments, lack of rotation of the inner tube portion prevents twisting and/or tangling (e.g. associated with constricted flow and/or loosening of attachment of the feeding device) of portions of a feeding device attached to the ostomy device (e.g. twisting and/or tangling of feeding device tube 428, 528 closing and/or collapsing the tube).

In some embodiments, one or more part of an ostomy device (e.g. 200, 1800, as described herein) includes anti-rotation features to prevent rotation of the inner tube within a body of the ostomy device (body of the device including internal bolster, outer tube and external bolster).

Returning back to FIG. 15A and FIG. 15B protrusions 1544, 1546 of or connected to elastic element 1538 fit within indentations 1548, 1550 respectively hold elastic element 1538 in axial and/or rotational position, e.g. preventing rotation of external bolster 1510 and inner tube portion 1520 with respect to each other. Additionally or alternatively, in some embodiments, protrusions 1544, 1546 and indentations 1548, 1550 prevent movement and/or slipping of elastic element with respect to external bolster 1510, e.g. during insertion and/or removal of inner tube portion 1516.

In some embodiments, at least a portion of buttons 1530, 1542, fit through holes in external bolster 1510. In some embodiments, buttons 1530, 1542, additionally or alternatively prevent rotation external bolster 1510 and inner tube portion 1520 with respect to each other.

In some embodiments, anti-rotation elements include interlocking elements. FIG. 20A is a simplified schematic of an external bolster 2010 including a hollow 2052, according to some embodiments of the invention. FIG. 20B is a simplified schematic of an inner tube portion head 2020 including a protrusion 2054, according to some embodiments of the invention. When inner tube portion head 2020 is within external bolster, protrusion 2054 fits within hollow 2052 preventing rotation of inner tube portion head 2020 with respect to external bolster 2010.

In some embodiments, connected portions include more than one interlocking element. In some embodiments an external bolster includes protrusions and the inner tube portion includes hollows. FIG. 21 is a simplified schematic side view of an inner tube portion head 2120 including more than one hollow 2156, according to some embodiments of the invention. In some embodiments, each of a pair of connected pieces includes both hollows and protrusions.

In some embodiments, connection between an outer tube (e.g. 212) and a bolster include anti-rotation element/s, for example texture and/or interlocking elements. FIG. 19 is a simplified schematic of an outer tube 1912 including anti-rotation elements

1954, according to some embodiments of the invention. In some embodiments, anti-rotation elements 1952 are serrations on an outer surface of outer tube 1912 and/or on an outer surface of a connector attached to the outer tube. Alternatively or additionally, in some embodiments, a bolster and/or or connector attached to a bolster includes anti-rotation elements, e.g. serrations shaped to interlock with serrations 1954.

Other anti-rotation mechanisms on connecting portions, for example connection between bolster/s and the outer tube and connection of the inner tube to bolster/s and/or the outer tube are envisioned and encompassed by the present invention. For example, matching hollows/protrusions and/or other anti-rotation shapes such as non cylindrical cross section, e.g. triangular, square, octagonal, oval.

Exemplary Connection of flexible parts

In some embodiments, a device outer tube (e.g. 112) is flexible and/or portion/s of an internal bolster and external bolster are flexible (e.g. as described herein).

In some embodiments, bolsters (e.g. 108, 110) are connected to tube 112, where connection between the bolsters and the tube is sufficiently strong such that movement of the patient and/or connection and disconnection of a feeding device (e.g. 423, 523, 623, 723) do not cause loosening and/or disassembly of bolsters 108, 110 from tube 112.

In some embodiments, secure connection of flexible components is using rigid connectors.

In some embodiments, flexible portion/s of each bolster (e.g. 208, 210) are connected to a flexible outer tube (e.g. 212) by one or more rigid connecting element (e.g. 234, 236).

In some embodiments, more than one (optionally rigid) connecting element is used to connect two parts (e.g. flexible parts) where a first connecting element connects to a first flexible part (e.g. a bolster), a second connecting element connects to a second flexible part (e.g. an outer tube) and the connecting elements then connect together (e.g. with a snap lock mechanism, e.g. with a screw mechanism).

In some embodiments, a connection between a bolster (e.g. 208, 210) and the outer tube (e.g. 212) includes a first rigid connecting element attached to the outer tube which attaches to a second rigid connecting element attached to the bolster. For

example, referring to FIG. 2, connecting element 236 attached to the inner tube connects

In some embodiments, one or more connector attaches to a bolster with a snap lock connection for example, as illustrated by connection between connector 234 and external bolster 210.

In an exemplary embodiment, connector 234 is permanently connected to internal bolster 208, for example by injection molding and/or adhesion (e.g. by gluing). Alternatively, in some embodiments, connector 234 and internal bolster 208 are one part. In some embodiments, internal bolster 208 and outer tube 212 are one part.

In another exemplary embodiment, connector 236 is permanently connected to external bolster 210, for example by injection molding and/or adhesion (e.g. by gluing). Alternatively, in some embodiments, connector 236 and external bolster 210 are one part. Alternatively, in some embodiments, internal bolster 210 and outer tube 212 are one part.

In some embodiments, a same material is used to form both rigid and flexible parts. For example, in some embodiments, a single material component including a flexible bolster and a rigid connector (e.g. molded as one piece) where the bolster is sized such that it is flexible and the connector is sized such that it is rigid. For example, in some embodiments, flexible inner bolster 208 and rigid connector 234 are one molded part.

FIG. 22 is a simplified schematic cross sectional view of a portion of an internal bolster 2208 connected to an outer tube (not illustrated) by interlocking connecting elements 2234a, 2234b, according to some embodiments of the invention. An exemplary axis of symmetry of the device is illustrated as a dash-dot line. In some embodiments a first connecting element 2234a connects an (optionally flexible) internal bolster portion 2208 to a second connecting element 2234b, where second connecting element 2234b is connected to the outer tube. In some embodiments, connecting elements 2234a, 2234b, are rigid. In some embodiments, connecting elements 2234a, 2234b, connect by a snap lock mechanism where one of connecting elements 2234a, 2234b, includes one or more protruding portion which interlocks with one or more hollow in the other portion. For example, in some embodiments, first connecting element 2234a includes a protruding portion. As connecting element 2234b is inserted

into connecting element 2234a, connecting element 2234a elastically deflects the elastic return force pushing protruding portion 2234c into hollow 2234d.

FIG. 23 is a simplified schematic cross sectional view of an ostomy device, according to some embodiments of the invention. An exemplary axis of symmetry of the device is illustrated as a dash-dot line. In some embodiments, an internal bolster 2308 is permanently attached to outer tube 2312 by gluing and/or injection molding of internal bolster 2308 and outer tube 2312 with an optionally rigid connector 2334. In some embodiments, connection between an external bolster 2310 and outer tube 2312 is by a snap lock connection between the two parts, e.g. between a rigid connector and a flexible part (e.g. connector 2336 is rigid and external bolster 2310 is flexible) and/or between two rigid parts (e.g. connector 2336 is rigid and external bolster 2310 is rigid).

In some embodiments, one or more alternative or additional methods and/or types of connector of attachment between bolsters and the inner tube is used, for example, screw attachment, other types of rotation locking, collet, adhesion (e.g. gluing).

Exemplary Connection of flexible tube to rigid connector/s

Referring back to FIG. 2, in some embodiments, connecting elements 234 and 236 connect to the outer tube by contacting the inside of the outer tube 212. For example, in some embodiments tube 212 is stretched around a connector (e.g. 234, 236), a reactive force (e.g. elastic reactive force) from the tube holding the connector in place.

In some embodiments, tube 212 and/or one or more connector 234, 236 are shaped such that a force required to insert the connector into the tube is less than that required to remove the connector. For example, in some embodiments connector/s 234 and/or 236 attach to outer tube 212 by tapered friction fit components, for example, the connectors have one or more angled (e.g. serrated) edge or component.

In some embodiments, connection between outer tube 212 and connector/s and/or other parts of the device is by gluing and/or clamping the outer tube between two rigid parts.

In some embodiments, connection between a flexible outer tube, for example connected to one or more rigid connector (e.g. tube 212 and connectors 234 and/or 236)

includes an internal structure (e.g. providing support to the connectors). FIG. 24 is a simplified schematic of a tube 2412 including a mesh 2412a and connectors 2434, 2436, according to some embodiments of the invention.

In some embodiments, an ostomy device tube is reinforced by elongated elements (e.g. wires). FIG. 25 is a simplified schematic of a wire-reinforced tube 2512 and connectors 2534, 2536, according to some embodiments of the invention.

In some embodiments, a tube includes an internal structure (e.g. mesh 2412, elongated elements 2512) within a sheath and/or coating (e.g. silicone), for example, the internal structure providing structural strength (e.g. crush resistance and/or axial tensile strength) and the sheath providing sealing. In some embodiments, a tube includes an internal structure with a high percentage of open space on the outer surface of the tube (e.g. more than 30%, more than 50%, more than 80% open space, or lower, or higher or intermediate percentages of open space). For example, in some embodiments, a tube internal structure provides a stable base (e.g. internal structure is of metal) for while high percentage of open space maintains tube flexibility.

In some embodiments, an ostomy device tube is reinforced by thickened walls adjacent to and/or overlapping connectors. FIG. 26 is a simplified schematic cross sectional view of tube 2612 including thickened tube wall portions 2612a, 2612b, and connectors 2634, 2636, according to some embodiments of the invention.

Exemplary Support from bolsters

As described previously, bolsters, in some embodiments, reduce and/or prevent moving and/or sliding of the outer tube within the stoma. In some embodiments, one or both bolsters are shaped such that a portion of patient tissue that the bolster contacts is at a distance from the opening of the stoma. A potential advantage may include reduction in irritation and/or inflammation to the delicate tissue around the stoma.

In some embodiments, one or more bolster has a shape where a contour of the bolster facing to the patient tissue surface (e.g. the bolster underside contour) extends away from a central axis of the device (central axis passing through the patient stoma) and towards the patient tissue surface such that contact areas of the bolster with the patient tissue surface (abdomen surface for external bolster, stomach lining for internal bolster) are at a distance from the opening of the stoma.

For example, in some embodiments, contact point/s between the external bolster and the patient outer abdominal surface is at a distance from an opening of the stoma on the patient outer abdominal surface between 2-30mm, between 5-25mm, or between 5-15mm, or smaller, or larger, or intermediate distances.

5 For example, in some embodiments, contact point/s between the internal bolster and the lumen inner wall is at a distance from an opening of the stoma inside the lumen of between 1-15mm, and/or between 2-10mm, and/or smaller, and/or larger, and/or intermediate distances.

10 In some embodiments, the external and/or internal bolster are dome shaped, with the peak of the dome connected to the outer tube, where contact between the bolster and the tissue surface is a ring, for example as illustrated in FIG. 2A and FIG. 49B.

15 In some embodiments, contact between the external bolster and the patient outer abdominal surface provides support to the ostomy device. In some embodiments, the external bolster, at least when it is elastically relaxed, includes a shape with a planar end edge, potentially providing a continuous contour of contact with patient outer abdominal surface (e.g. skin surface). For example, returning back to FIG. 2A-B where contact between external bolster 210 and patient skin is a ring shape corresponding to a rim of the external bolster). In some embodiments, the external bolster includes a dome shape.

20 Alternatively, in some embodiments, e.g. as described herein, the external and/or internal bolster include separate sections. For example, in some embodiments, contact between the bolster and the tissue surface is at more than one discrete points, for example, providing aeration to an area of skin under the external bolster, for example allowing different portions of the stomach lining to support the device at different times (e.g. the inner bolster, in some embodiments, is rotated periodically, portions of the stomach lining contacting the inner bolster changing with the rotation).

25 In some embodiments, an external bolster includes a plurality of petals, for example, as illustrated in FIG. 18A which illustrates a device with three petals 1899. In some embodiments, the external fixation device has two petals, or more than three petals, e.g. four petals, up to 10 petals, up to 20 petals.

Alternatively or additionally, in some embodiments, external bolster includes notches and/or ducts and/or or holes e.g. to provide aeration. FIG. 33 is a simplified

schematic side view of an external bolster including a plurality of notches 3360, according to some embodiments of the invention.

Exemplary Adjustable length of ostomy device

5 In some embodiments, an ostomy device (e.g. as described herein) is deployable into a range of thicknesses of stoma, where bolsters hold the device in position. In some embodiments, a height of one or both bolsters is set, for example, upon installation of the device.

10 *Exemplary Adjustable position of external bolster*

 In some embodiments, an axial length of an ostomy device (e.g. 100, 200, 1800 as described herein) is adjustable, for example, when installing the device within a patient and/or when the device is installed within a patient.

 In some embodiments, a position of attachment of one or more bolster (e.g. the
15 external bolster) with respect to the outer tube is adjustable meaning that a single device is adjustable to different lengths of stoma. FIG. 27 is a simplified schematic cross section of an ostomy device 2700 with an adjustable tube length within the patient body, according to some embodiments of the invention. A position of an external bolster is adjustable from position illustrated by 2710 on tube 2712 when patient outer abdominal
20 surface is at 2706 to a position illustrated by 2710a.

 FIG. 28A is a simplified schematic section view of a portion of an ostomy device, according to some embodiments of the invention. FIG. 28A illustrates an embodiment where an outer tube 2812 is connected to an external bolster 2810 by a connector 2836. In some embodiments, external bolster 2810 is a flexible component
25 coupled to connector 2836 by elastic tension of external bolster 2810. In some embodiments, the position of external bolster 2810 in an ostomy device axial direction is adjustable e.g. by manually moving the bolster.

 In some embodiments, a position of an external bolster (e.g. 2810) with respect to a connector (e.g. 2836) and/or an outer tube (e.g. 2812) is adjustable by a screw
30 mechanism. For example, external bolster 2810 and a connector 2836 include matching thread.

In some embodiments, connection between external bolster 2810 and connector 2836 where a position of external bolster 2810 on connector 2836 is optionally axially adjustable, is strengthened by interlocking elements (e.g. by increasing resistance to axial movement of the external bolster). FIG. 28B, FIG. 28C and FIG. 28D are simplified schematic cross sectional views of exemplary interlocking connection between external bolster and connector, according to some embodiments of the invention. FIG. 20A, FIG. 20B also illustrate interlocking connection between an external bolster 2010 and a portion connected to the external bolster 2020; interlocking threads 2090, 2091.

In some embodiments, the external bolster is connected to one or more additional part and/or is not attached to a tube connector. For example, in some embodiments the external bolster is connected to an inner tube portion head (e.g. as described herein).

In some embodiments, position of the external bolster on the tube is adjustable by up to 50mm, or up to 30mm, or 10-40mm, or lower, or higher, or intermediate ranges or distances.

Exemplary Adjustable position of inner bolster

In some embodiments, a position of one or more portion of an inner bolster is adjusted, for example, adjusting a minimum dimension between the inner and outer bolsters. In some embodiments, adjustment is during installation, and/or once the ostomy device is installed (e.g. periodically). In some embodiments, the inner bolster is adjusted from outside the patient.

For example, referring to FIG. 32A, in some embodiments, an element attached to one or more petal 3208a (and e.g. running through the inner bolster is used to adjust a deflection of the petal (e.g.) from a relaxed position illustrated by 3208a. In some embodiments, the element is connected to bumper 3258 and, for example, pulling on the element deflects the petal, releasing the element reduces deflection of the petal.

Exemplary Axial length of device related to pressure on bolsters

In some embodiments, an axial length of the tube within patient tissue and/or a minimum separation between an inner and an external bolster changes in reaction to a

pressure applied to the internal and/or external bolsters by the patient tissue therebetween, for example, pressure related to swelling and/or reduction in swelling of patient tissue.

FIG. 29A is a simplified schematic cross section of an ostomy device 2900 with adjustable axial length, according to some embodiments of the invention. Ostomy device 2900 is installed within a stoma 2905, with internal and external bolsters, 2908 and 2910 respectively holding a tube 2912 in position within stoma 2905. A length of tube 2912 within the stoma is L1.

In some embodiments (e.g. post operatively) patient tissue swells around stoma 2912. FIG. 29B is a simplified schematic cross section of an ostomy device 2900 with adjustable axial length within swollen tissue, according to some embodiments of the invention. In some embodiments FIG. 29B illustrates the device of FIG. 29 where patient tissue has swollen, increasing a length of stoma 2905 to L2 ($L2 > L1$). In some embodiments, under pressure from patient tissue internal bolster 2908 and/or external bolster 2910 (FIG. 29B illustrates both) bend (optionally elastically) and/or pivot to increase a length of tube 2902 within stoma 2905 (e.g. by reducing a height of the bolster/s above the lumen wall/patient outer abdominal surface). Alternatively or additionally, in some embodiments, tube 2902 is axially elastic, elastically increasing a tube length e.g. upon tissue swelling and/or decreasing a tube length e.g. upon subsidence of tissue swelling.

FIG. 30 is a simplified schematic section view of a portion of an ostomy device where a protrusion of the device above a patient outer abdominal surface is adjustable, according to some embodiments of the invention. In some embodiments, adjustment is by bending and/or deflection of the bolster. FIG. 30 illustrates elastic bending of an external bolster 3010 to change a tube length within the patient. This adjustment corresponds to a change in height of the device above the patient outer abdominal surface. External bolster 3010 bends to a second position 3010a decreasing a height of the device above a patient outer abdominal surface from H1 to H2, corresponding to a change in height of $\Delta H = H2 - H1$. In some embodiments, change in height (ΔH) is 1-15mm, or 2-10mm, or 3-7mm, or up to 5mm, or up to 10mm, or lower, or higher, or intermediate ranges or lengths.

In some embodiments, a bolster includes protrusions which are unattached, for at least a portion of the protrusion, and, in some embodiments, each protrusion deflects and/or bends (optionally elastically) to a different extent.

In some embodiments, the external bolster includes elastically deflectable petals which contact the patient outer abdominal surface at discrete points (e.g. petals 1899). In some embodiments, each petal 1899 elastically deflects a different extent, for example, the bolster to provide support in the case of non planar patient anatomy.

In some embodiments, different portions of an external bolster bending to different extents allow the device to fit an abdominal outer surface. FIG. 31A is a simplified schematic section view of an external bolster 3110 bending to fit an abdominal outer surface 3106, according to some embodiments of the invention. First petal 3199a bends to a larger extent than second petal 3106, fitting external bolster 3110 to a non-planar topography of abdominal outer surface 3106. Similarly, in some embodiments, different portions of an inner bolster deflect to different extents, fitting the inner bolster to non-planar topography of a lumen inner wall.

FIG. 31B is a simplified schematic section view of a device where an external bolster 3120 is bending to fit the device to a patient anatomy, according to some embodiments of the invention. In some embodiments, a lumen inner wall 3104a and an abdominal outer surface 3106 are non-parallel and, in some embodiments, external bolster petals 3199a, 3199b bend to different extents to fit the device to the patient anatomy. In some embodiments, bending of bolster portions is in addition to bending of a flexible outer tube.

Additionally or alternatively, in some embodiments, different portions of an inner bolster deflect to different extents, fitting the inner bolster to non-parallel patient anatomy.

FIG. 32A is a simplified schematic section view of a portion of an elastic internal bolster 3208, according to some embodiments of the invention.

FIG. 32A illustrates elastic bending of an internal bolster 3210 to change a tube length within the patient. This adjustment corresponds to a change in height of the device above the patient outer abdominal surface. Petal 3264 bends to a second position 3264a decreasing a depth of the device within the lumen (e.g. stomach). In some embodiments, change in depth (ΔD) is 1-15mm, or 2-10mm, or 3-7mm, or up to 5mm,

or up to 10mm, or lower, or higher, or intermediate ranges or lengths. In some embodiments, internal bolster is designed to have a maximum change in depth, the device locking and becoming rigid. In some embodiments, internal bolster includes (e.g. for each petal of internal bolster) a bumper 3258 which is shaped to prevent bending (e.g. by contacting another portion of the device) of the bolster beyond a maximum change in depth, as illustrated by internal bolster 3208a.

In some embodiments, such elasticity of the internal bolster prevents embedding of the internal bolster within the stomach wall.

In some embodiments, one or more compressible component for example, a sponge, a balloon, a spring (e.g. ring-shaped) disposed between the inner bolster and the lumen inner wall.

In some embodiments, a dimension (e.g. axial extent of the component between the inner bolster and the lumen wall) of the compressible component is adjustable during installation (e.g. a size of the component is selected before insertion at installation). In an exemplary embodiment, an axial dimension of the compressible component is adjustable after installation, for example, from outside the patient, e.g. without needing an endoscopic procedure.

FIG. 32B is a simplified schematic cross sectional view of an inner bolster 3208, a lumen inner wall 3204a and a compressible component 3209 therebetween, according to some embodiments of the invention. In some embodiments, an elongated element 3209a is connected to compressible component 3209 and passes through an outer tube 3212 (alternatively, or additionally, in some embodiments, compressible component 3209 passes through an inner tube 3212 and/or a stoma 3205 and/or another abdominal incision). In some embodiments, an axial extent of compressible component 3209 is adjusted by pulling or releasing elongated element 3209a optionally, compressible component is pulled and/or released and then fixed in position, e.g. by a ratchet mechanism. In some embodiments, compressible component 3209 is elastic (e.g. it is a spring) optionally including plastic.

In an exemplary embodiment, an external bolster (e.g. as described herein) provides more axial elasticity than an internal bolster (e.g. as described herein), for example, with a maximum ΔH at least double a maximum ΔD . In some embodiments,

external bolster holds ostomy device (e.g. as described herein) in position by applying gentle pressure to the patient skin.

In some embodiments, adjustable position of the external bolster and/or elasticity of the external bolster mean that the device is well fitting, e.g. at all times, and/or meaning that the device has a low profile, e.g. a small height above the patient outer abdominal surface, for example, 0.2mm-18cm, 0.5mm-5cm, 0.5mm-3cm, or lower, or higher, or intermediate ranges or values.

Exemplary Removal

Exemplary Method of Removal

FIG. 34 is a flow chart of a method of ostomy device removal, according to some embodiments of the invention.

At 3402, an inner bolster (e.g. as described herein) is dismantled into more than one piece. In some embodiments, connector/s coupling portions of the internal bolster are loosened and/or removed, for example, releasing the portions. In some embodiments, the portions of the inner bolster then move away from the inner tube, for example, due to movement of the stomach and/or stomach contents. In some embodiments, a user moves the outer tube, for example, rotates and/or shakes the outer tube (e.g. by moving the external bolster) to separate the de-coupled inner bolster portions and/or move them from the inner tube. In some embodiments, removing the outer tube moves the inner bolster portions away from the outer tube.

In an exemplary embodiment, a user dismantles the internal bolster externally, for example, without approaching the device from within the lumen, (e.g. without performing an endoscopic procedure). In some embodiments, the dismantled portions of the internal bolster are free within the lumen (e.g. stomach), for example, then passing through the digestive system. Alternatively, in some embodiments, the disassembled portions are then removed from the lumen (e.g. by pulling through the stoma).

At 3404, in some embodiments, once the internal bolster is dismantled, the outer tube and external bolster are removed e.g. by a user pulling on the external bolster.

Exemplary Dismantling of internal bolster

In an exemplary embodiment the petals substantially do not overlap, for

example, substantially do not overlap axially (overlap being where petals contact each other in a planes approximately perpendicular to the long axis of the tube). In some embodiments, petals at most overlap axially with adjacent (e.g. radially adjacent) petals.

In some embodiments, residue (e.g. stomach contents) coating the inner bolster (e.g. coating contact areas between petals) prevents and/or slows disassembly of inner bolster petals. In some embodiments, the inner bolster includes one or more notch and/or inlet separating portions of the inner bolster e.g. between petals. For example, reducing an area of contact between petals potentially reduces friction of movement of petals away from each other.

In some embodiments, the internal bolster includes a plurality of petals which are held by one or more connectors (e.g. in some embodiments, petals are held between two or more connectors) where disconnecting the connectors decouples the petals.

FIG. 35A is a simplified schematic side view of an internal bolster including a plurality of petals 3564, according to some embodiments of the invention.

FIG. 35B is a simplified schematic side view of a dismantled internal bolster including a plurality of petals 3564, according to some embodiments of the invention.

In some embodiments, petals 3564 do not overlap. In some embodiments, each petal overlaps with one or both radially adjacent petals. In some embodiments, axial overlap between petals 3564 is small, for example, less than 20%, or less than 10%, or less than 5%, or less than 3%, or lower, or higher, or intermediate percentages, of a petal surface area is in contact with another petal, before dismantling.

Referring back to FIG. 18A, in an exemplary embodiment petals 1864 are separate, where the inner bolster includes notches 1865 separating petals 1864.

In some embodiments, internal bolster 3508 dismantles into a plurality of parts (e.g. including petals 3564) upon release of a connecting cap 3562 which holds portions of the internal bolster together. In some embodiments, one or more part holding portion/s of the internal bolster together is rigid.

In an exemplary embodiment, internal bolster portions are held between two rigid parts. Referring back to FIG. 18B, a cap 1862 and connector 1834 hold between them internal bolster 1808.

In some embodiments, cap 3562 holds internal bolster petals 3564 onto an internal bolster shaft 3566 and, in some embodiments, upon removal and/or of cap

3562, petals 3564 are released. In some embodiments, internal bolster shaft 3566 is also a connector to outer tube 3512. Alternatively, in some embodiments, internal bolster shaft 3566 (an optionally rigid part) attaches to a connector connecting internal bolster 3508 to outer tube 3512.

5 *Exemplary Dismantling using a tool*

In some embodiments, dismantling of the internal bolster is by use of a tool. In some embodiments, a tool engages a connector connecting portions of the inner bolster, for example, disconnecting and/or loosening the connector, for example, by withdrawing and/or applying pressure and/or torque to the connector.

10 In some embodiments, cap 3562 is detached from petals 3564 and/or from an internal bolster shaft 3566 by a tool inserted through outer tube 3512 or inner tube 3514.

In some embodiments, a tool accesses a hollow within a connector and applies a force (e.g. a torque) to the connector via the hollow (e.g. hollow 2291 FIG. 22, 2391 FIG. 23).

15 In some embodiments, an outer tube and/or an inner tube portion include a separate channel for insertion of a dismantling tool. FIG. 36 is a simplified section view of a portion of an internal bolster including a tool channel 3674 for a dismantling tool 3668, according to some embodiments of the invention. In some embodiments, channel 3674 is within inner tube 3612. Alternatively, in some embodiments, inner tube portion
20 (e.g. 216, e.g. as described herein) includes two channels, a first channel for food and a second channel for insertion and/or guiding of a dismantling tool.

Exemplary Dismantling by breaking an attachment element

In some embodiments, dismantling is by breaking of a cap attachment 3670. In
25 some embodiments, cap attachment 3670 is broken by pressure applied by a tool 3668. In some embodiments, once cap attachment 3670 is broken, the tool is inserted further towards the lumen, for example, detaching cap 3662 from attachment 3670. In some embodiments, cap hingedly opens e.g. around an interlocked portion 3676, for example, before disengaging from other parts of the internal bolster (e.g. petals 3664).

30 In some embodiments, tool 3668 is a part sized and shaped for insertion into channel 3674. In some embodiments, tool 3668 is a readily available medical tool, for

example, a needle (e.g. syringe needle). In some embodiments, cap attachment 3670 is broken by application of hydraulic pressure (e.g. applied by a syringe). For example tool channel 3674 may run along and/or parallel to a feeding tube 3614.

In some embodiments, an inner tube portion is shaped to accommodate tool channel 3674. FIG. 37A is a simplified schematic side view of an inner tube portion 3716 where inner tube 3714 is non-cylindrical, according to some embodiments of the invention. In this embodiment, tool channel 3774 is defined in a space between the outer tube (not illustrated) and inner tube 3714.

In some embodiments, an inner tube portion inlet includes a tool guide. FIG. 37B is a simplified schematic of an inner tube inlet including a tool guide 3678, according to some embodiments of the invention. In some embodiments, a plurality of tool guides is disposed along a length of the outer tube. Alternatively, in some embodiments, FIG. 37B illustrates an inner tube portion including two channels, a feeding channel 3702 and a tool channel 3774.

Exemplary Turn mechanism dismantling

In some embodiments, an internal bolster is dismantled by turning and/or rotating a part with respect to another part, for example, by rotating (e.g. unscrewing) an internal bolster cap (e.g. 3562), for example, from a connector (e.g. 3566).

FIG. 38A is a simplified schematic section view of an internal bolster with a screw dismantling mechanism, according to some embodiments of the invention.

FIG. 38B is a simplified schematic side view of a screw dismantling mechanism tool 3868, according to some embodiments of the invention.

FIG. 38 is a simplified schematic side view of a screw dismantling mechanism tool 3868, according to some embodiments of the invention.

In some embodiments, thread 3880 on a chamber within internal bolster, for example, within an internal bolster cap (e.g. cap 3862) matches thread 3882 on tool 3868. In some embodiments, to dismantle internal bolster 3808, tool 3868 is inserted through a tube (e.g. an inner and/or outer tube), and rotated to dismantle internal bolster 3808.

In an exemplary embodiment, a tool for dismantling an internal bolster includes applies a torque onto a top portion 3993 of the internal bolster. FIG. 39 is a simplified

schematic of a portion of a bolster and an expanding dismantling tool 3968, according to some embodiments of the invention. A dash-dot line illustrates an exemplary axis of symmetry of the device. In some embodiments, during insertion of dismantling tool 3968 arms 3967 of the tool are elastically compressed, once the arms exit outer tube the arms expand and a user applies torque to the top of the internal bolster by pulling and rotating the tool. In some embodiments, arms fit into a screw drive 3991 (e.g. two arms fit into a slot screw drive, four arms fit into a Phillips head screw drive).

In some embodiments, a tool including one or more expanding portion is used to apply force (e.g. not only torque) to the top of the internal bolster.

FIG. 40A is a simplified schematic side view of a disassembly tool 4068, according to some embodiments of the invention. FIG. 40B is a simplified schematic side view of a disassembly tool inserted into an internal bolster, according to some embodiments of the invention. In some embodiments, a torque multiplier is attached to disassembly tool to increase the torque which is applied. In some embodiments, disassembly tool 4068 includes a connector for attachment 4068a to a torque multiplier.

In some embodiments, disassembled portions of the internal bolster are removed from the stomach by pulling on element/s attached to the internal bolster portions. FIG. 41A is a simplified schematic side view of an internal bolster where each petal 4164 of the internal bolster is attached, according to some embodiments of the invention. In some embodiments, internal bolster 4408 is a single piece including separations 4188a between petals 4164 where, in some embodiments, separations extend but do not reach a central area 4410c of the inner bumper. In some embodiments, separations 4188a are cut into inner bumper 4408 after the inner bumper is formed as a single piece.

FIG. 41B illustrates removal of disassembled internal bolster portions through an outer tube 4112 by pulling, force P on an elongated element (not illustrated) according to some embodiments of the invention.

Alternatively in some embodiments, internal bolster petals 4164 are attached one to another by connectors, for example, each petal is attached to adjacent petals by connectors (e.g. hinges and/or flexible portions which allow the petals to disassemble from each other) and, for example, a single petal is attached to an elongated element used to withdraw a chain of connected petals. In some embodiments, petal connectors

are of the same material as the petals. Alternatively, in some embodiments, petal connectors are of different material to the petals.

Also illustrated in FIG. 41A are hollows 4191 (e.g. screw drive) of a rotation disassembly mechanism.

5 In some embodiments, the internal bolster is dismantled by pulling on one or more elongated element 4188.

Alternatively, in some embodiments, the internal bolster is sufficiently flexible to be removed by pulling on the tube from outside the stomach. Alternatively, in some embodiments, the device is dismantled during an endoscopic procedure where, for
10 example, the internal bolster is detached from the tube and, is optionally then removed through the esophagus or the internal bolster attached to the tube is removed through the esophagus.

Installation

15 *Exemplary Method of installation*

FIG. 42 is a flow chart of a method of ostomy device installation, according to some embodiments of the invention.

At 4201, a stoma between a lumen (e.g. stomach) and an outer abdominal surface of the patient is created, for example, using an endoscopic procedure and/or
20 laparoscopy. Alternatively, in some embodiments, a stoma is pre-existing.

In some embodiments, a stoma is made by making an initial channel with a needle (or other narrow instrument) and creating a stoma by pulling a dilator through the initial channel. In an exemplary embodiment a dilator is connected to one or more portion of the ostomy device and, for example, as the dilator is pulled through patient tissue,
25 portions of the device are installed (e.g. outer tube is installed into the stoma).

In some embodiments, a dilator is pulled and/or pushed through patient tissue and the tube is then inserted into the stoma.

At 4202, one or more portion of the ostomy device is inserted into the lumen (e.g. 104), for example, into the stomach by way of the esophagus. In some
30 embodiments, one or more portion of the ostomy device and/or a dilator and/or pushing device are inserted into the lumen prior to creation of a stoma. In some embodiments, an

internal bolster (e.g. 108) and optionally an outer tube (e.g. 112) are inserted into the lumen (e.g. 104).

In some embodiments, an internal bolster has hinged and/or flexible and/or elastic portions (e.g. petals as described herein) which move towards each other to contact a cross section of the bolster, for example, allowing the bolster to be inserted into the lumen through the esophagus.

FIG. 49A is a simplified schematic cross sectional view of an inner bolster 4908 attached to an outer tube 4912 being inserted through an esophagus 4986, according to some embodiments of the invention. In some embodiments, petals 4964 bend and/or rotate towards each other, optionally elastically, contracting a cross section of inner bolster 4908.

FIG. 49B is a simplified schematic cross sectional view of an inner bolster 4908 attached to an outer tube 4912 where the outer tube is installed within a stoma 4905, according to some embodiments of the invention.

Alternatively or additionally, in some embodiments, the internal bolster is inserted into the stomach (e.g. through the esophagus) in several portions and the portions are then assembled within the stomach.

In some embodiments, the outer tube is also inserted into the stomach (e.g. through the esophagus), the outer tube is then attached to the internal bolster. Alternatively, in some embodiments, the internal bolster attached to the outer tube is inserted into the stomach through the esophagus.

At 4204, in some embodiments, the outer tube is inserted into the stoma (e.g. as described above). In some embodiments, the outer tube (previously inserted into the lumen) is pushed and/or pulled through the surgically created stoma from the stomach.

In some embodiments, the tube is pulled through the stoma by pulling on one or more elongated element, (e.g. including wire and/or cord and/or cable and/or thread) coupled to the outer tube. In some embodiments, once the outer tube is in position, the elongated element is removed from the outer tube.

In some embodiments, a pushing device which is too large to be pulled through the outer tube is used to pull the outer tube (and optionally an internal bolster attached to the outer tube) through the stoma. In some embodiments, once the outer tube is in position, the pushing device is removed from the lumen (e.g. by pulling on an elongated

component connected to the pushing device and extending out of the esophagus). FIG. 43 is a simplified schematic cross sectional view of an outer tube 4312 being pulled into a stoma 4305 by a pushing device 4380, according to some embodiments of the invention. In some embodiments a pulling force, F is applied to elongated element 4382a by a user to pull outer tube 4312 into position. In some embodiments a second elongated element 4382b is attached to pushing device 4380 and is used to extract pushing device 4380 from the patient (e.g. through the esophagus).

In some embodiments pushing elongated element 4305 (where elongated element optionally includes a dilator with a tapered portion) attaches to pushing device 4380 by a screw mechanism or a different connection mechanism e.g. snap lock, e.g. gluing.

In some embodiments, a single elongated element is used to pull the pushing device for insertion of the outer tube and is used to remove the pushing device from the lumen. FIG. 44A is a simplified schematic side view of a pushing device 4480, according to some embodiments of the invention. FIG. 44B is a simplified schematic side view of a pushing device 4480 threaded with an elongated element 4482, according to some embodiments of the invention. In some embodiments, change in direction of elongated element 4482 within pushing device 4480 is sufficient to hold the pushing device in position on the elongated element allowing the device to be moved by pulling on either end of elongated element 4282.

In some embodiments, channels within pushing device 4480 change in radius along a length of the pushing device. In some embodiments, pushing device 4480 includes two components, A and B, where A plugs into B, channels C illustrated in fitting into plugs of D (or plugs C fitting into channels D). In some embodiments B fits into the tube and A plugs into portion B.

In some embodiments, the outer tube includes a sharp end and/or a sharp attachment is fitted to the outer tube and/or a tapered portion (also herein termed dilator), and the stoma is created by the insertion of the inner tube.

In some embodiments, a portion of a pushing device is sized to protrude from the outer tube. FIG. 45A is a simplified schematic side view of a pushing device 4580 including a tapered end 4584, according to some embodiments of the invention. FIG. 45B is a simplified schematic side view of a pushing device within an outer tube 4512

attached to an internal bolster 4508 where a portion of the pushing device protrudes through the outer tube, according to some embodiments of the invention. In some embodiments, tapered end 4584 which protrudes from outer tube 4512 gradually opens and/or dilates stoma as the outer tube is inserted, for example reducing trauma of installation of the device on the stoma.

FIG. 46A is a simplified schematic side view of a pushing device 4680, according to some embodiments of the invention. FIG. 46B is a simplified schematic side view of a pushing device within an outer tube 4612 attached to an internal bolster 4608 where a portion of the pushing device protrudes through the outer tube, according to some embodiments of the invention.

In some embodiments, pushing device 4680 attaches to portions of the device using a screw attachment or other type of attachment optionally other than sizing (e.g. snap-lock connection, adhesion etc.). In some embodiments, pushing device 4680 includes thread 4681, for example, for screw-mechanism attachment for attachment to a portion of the device (e.g. inner bolster 4608). Alternatively, in some embodiments, additional or alternative connection between the pushing device and the device are employed, e.g. snap lock, gluing.

In some embodiments, an incision is made from the stomach to the outer abdominal surface of a patient with a threaded needle. A loop 4683 (e.g. of thread, wire, cord) is attached to a suture and pulled through the incision, a tapered end 4484 (also herein termed “dilator”) of the pushing device acting as a dilator, dilating tissue e.g. to create a stoma.

At, 4206, in some embodiments, an outer tube within the stoma is connected to a bolster. In some embodiments, once the outer tube is in position the external bolster is attached to the outer tube.

FIG. 47 is a simplified schematic side view of an ostomy device 4700 where an external bolster 4710 is being attached to an outer tube 4712, according to some embodiments of the invention. In some embodiments, pulling force F1 applied to an external element and a pushing force F2 acting on external bolster 4710 act to connect outer tube 4712 (optionally connected to an internal bolster 4708) to external bolster 4710 e.g. with a by an interference mechanism (e.g. push-lock mechanism).

Alternatively, in some embodiments other forces are applied to connect components e.g. torque to connect components with screw connectors.

In some embodiments, the internal bolster is attached to the outer tube after the tube is inserted into the stoma. The external bolster is then connected to the outer tube.

5 In some embodiments, the outer tube is not inserted into the stoma from the lumen, the outer tube (optionally pre-attached to an external bolster) is inserted from outside the patient into the stoma, and, in some embodiments, the internal bolster is then connected to the tube. FIG. 48 is a simplified schematic section view of device installation including insertion of an outer tube 4812 into a stoma 4805, according to
10 some embodiments of the invention. In some embodiments, outer tube 4812 and an internal bolster 4808 are connected by concurrent insertion of the outer tube 4812 into stoma 4805 by applying a force F2 and pulling by a force F1 applied to an elongated element 4882.

Alternatively, in some embodiments, outer tube 4812 is inserted into a stoma,
15 from outside the patient, followed by connection of bolsters to the outer tube.

In some embodiments, an internal bolster connected to an outer tube is inserted into the stomach through the esophagus in a first direction (bolster first) with respect to the esophagus walls and then rotated inside the stomach for insertion in the opposite direction (outer tube first) to first direction (with respect to the stoma walls).

20 In some embodiments, the internal bolster is permanently attached (e.g. glue and/or injection molding) to the tube and/or internal bolster and outer tube are one part.

FIG. 49C is a simplified schematic cross sectional view of an internal bolster 4908 connected to an outer tube 4912 being inserted through an esophagus 4986, according to some embodiments of the invention.

25 In some embodiments, one or more portion of internal bolster 4908 bends and/or pivots (e.g. one or more petal is hingendly attached) contracts under pressure exerted by walls of the esophagus 4986. In an exemplary embodiment, petals 4964 elastically deflect towards outer tube 4912.

In some embodiments, once an internal bolster connected to an outer tube (e.g.
30 4912 and 4908) reach the lumen (e.g. stomach) the internal bolster connected to the outer tube is positioned and inserted into a stoma, tube first. FIG. 49D is a simplified schematic cross sectional view of an outer tube 4912 within a stoma connected to an

internal bolster 4908, according to some embodiments of the invention. FIG. 49B illustrates an inner bolster 4908 where the bolster contacts patient tissue (stomach wall) at a distance from an opening of stoma 4905 into the stomach.

Returning now to FIG. 42, at 4208, once the body of the device is installed, an inner tube portion is inserted.

Exemplary materials

In some embodiments, an internal bolster and/or external bolster and/or outer tube (e.g. as described here) include and/or, and the internal bolster and/or outer tube optionally includes material in one or more portion. In some embodiments, an inner tube portion includes silicone and/or polyurethane, optionally with radiopaque material in one or more portion. In some embodiments, rigid portion/s of the device for example, connectors (e.g. as described herein) include plastic/s, for example acrylonitrile butadiene styrene (ABS), polyamide (PA), polycarbonate (PC), polyethylene (PE).

Exemplary Detailed method of use

FIG. 50A and FIG. 50B are flow chart of a method of use of an ostomy device, according to some embodiments of the invention.

At 5002, in some embodiments, a stoma is surgically created between a desired lumen (e.g. stomach) and a patient outer abdominal surface. In some embodiments, the stoma site measured (e.g. a stoma position is selected based on measurement), for example, imaging, e.g. ultrasound and/or endoscopy and/or CT and/or MRI and/or X-ray imaging.

At 5004, in some embodiments, the surgically created stoma is measured, optionally during creation of the stoma, for example, a length of the stoma is measured.

In some embodiments, during surgical creation of the stoma, an element (e.g. needle) is inserted between the stomach and the outer abdominal surface of the patient. In some embodiments, markings on the needle (e.g. numbers, different colors) are used to measure the stoma (e.g. a stoma length). In some embodiment, measurement is taken from within the lumen (e.g. using endoscopic visualization) and/or from outside the patient. In some embodiments, the needle is anchored inside the stomach and measurement of a stoma length (e.g. using markings on the needle) is only taken at the

abdominal outer surface of the patient. In some embodiments, a sheath with markings is inserted into the stoma, and measurement is made using the markings on the sheath. In an exemplary embodiment, a needle within a sheath (the sheath including markings) is inserted into tissue. In some embodiments, measurement of the stoma is alternatively or additionally made during imaging.

At 5006, in some embodiments, a device is selected, optionally based on measurement of the stoma. In some embodiments, a length of an outer tube is selected based on measurements, for example, of the stoma length and/or of patient anatomy around the stoma (e.g. stoma site). In some embodiments, a length of the outer tube is selected to approximately for a length of the stoma, for example, a length of the tube being 10% or 20% or 30% or 40% longer or shorter than the stoma. In some embodiments, a length of the tube is selected to be longer than the stoma, for example % or 20% or 30% or 40% longer, for example, to allow for swelling of tissue surrounding the stoma. In some embodiments a size and/or shape and/or type of inner and external bolster are selected based on measurement and/or on treatment type and/or other patient parameters. In some embodiments, the device is selected based on an age and/or weight of a patient and/or prescribed feeding protocol (e.g. time, amount) and/or prescribed feed type.

At 5008, in some embodiments, one or more portion of the device (e.g. as described herein) is inserted into a desired patient lumen (e.g. the stomach).

At 5010, in some embodiments, the outer tube is inserted into the stoma. Optionally, in some embodiments insertion of the outer tube into patient tissue creates and/or or dilates the stoma.

At 5012, in some embodiments, one or both bolsters are attached to tube, where at least one bolster is attached to the tube after the tube is inserted into the stoma.

At 5014, in some embodiments axial dimensions of the device are adjusted, for example, compensating for miss-match between a length of the outer tube and length of the stoma. For example, in some embodiments, position of an inner bolster and/or outer bolster are changed with respect to the outer tube, thereby changing a minimum dimension between the bolsters. In some embodiments, compensating is by up to 2mm, or up to 5mm, or up to 10mm, or lower, or higher, or intermediate values or ranges.

At 5016, the device is optionally adjusted and/or self adjusts, for example to fit the patient. Optionally, the device may be passively adjusted (e.g. self adjusting) and/or actively adjusted. For example the distance between an inner and an outer bolster (e.g. the axial extent of the device) may be lengthened and/or shortened. Alternatively or additionally, an angle between a bolster and an axis of a tube may be adjusted. Alternatively or additionally, a radial extent of a petal and/or a radial distance between a stoma and a contact zone of a petal and tissue may be adjusted.

In some embodiments, the axial dimension of the device may be adjusted. For example, as described in Figs. 27 to 32.

In some embodiments, one or more bolsters may be adjusted be mounted on a variable angle joint. For example, the bolster may passively adjust itself to balance pressure around the stoma. Alternatively or additionally, the bolster may be actively adjusted. For example, a variable angle joint may have a control mechanism. Optionally a user may set the angle of the bolster according the needs (for example due to the anatomy of the patient and/or the placement of the stoma). After the angle of the bolster has been set, the bolster may be tightened to retain it at the chosen angle.

In some embodiments the width and/or the stiffness of a bolster and/or an associated petal and/or a force of a bolster on the patient and/or around the stoma may be adjusted. For example, petals may be elastic and self adjust to the shape of the surface of the tissue around the stoma. Alternatively or additionally, there may be a mechanism to tighten or loosen a bolster and/or a petal thereof. For example a threaded element and/or a wedge may be used to change the angle at which a petal extends from a bolster.

In some embodiments a bolster may be adjusted in use to temporarily reduce pressure at a certain location (for example where there is swelling and/or sensitivity and/or infection and/or a sore). Alternatively or additionally, a device may be adjusted prior placement and/or during placement according to the particular characteristics of a patient that are known and/or have been measured.

In some embodiments, an inner tube is inserted into the outer tube, forming a channel between outside the patient and the lumen. In some embodiments, the inner tube extends through the stomach into the jejunum. In some embodiments, the inner tube during and/or after insertion, is connected to the external bolster. In some

embodiments an opening of the tube (for example the outer opening) may be attached to, covered by and/or within the bolster (for example the external bolster). Alternatively or additionally a tube may extend through a bolster. For example the inner tube may extend outward through the external bolster. For example the inner tube may extend
5 outward from the patient less than 1 cm and/or between 1 cm to 1 m and/or between 1 m to 5 m or further.

In some embodiments, insertion and/or positioning of parts of the device into the lumen and/or stoma is assisted by imaging e.g. endoscopic imaging, ultrasound imaging. In some embodiments, one or more portion of the device includes radiopaque
10 material and/or radiopaque marker/s and imaging includes, e.g. X-ray and/or CT and/or MRI.

At 5018, in some embodiments, the patient is fed, at discrete feeds or continuously by attaching a food reservoir to the ostomy device, such that, at 5020, food flows from the reservoir into the patient through the inner tube. In some embodiments, a
15 food pump controls dispensing of food from the food reservoir into the patient.

At 5022, in some embodiments, various care protocols are performed by a caregiver and/or the patient e.g. periodically, for example, in some embodiments, the device is rotated (e.g. by rotating the outer bolster) periodically, for example to prevent encapsulation of the inner bolster into the lumen (e.g. stomach inner wall), for example,
20 to change portions of tissue under pressure from the inner and/or outer bolster. For example, in some embodiments, an outer portion of the device is periodically cleaned.

In some embodiments, fit of the device to the patient anatomy is periodically checked and/or adjusted.

For example, in some embodiments, freedom of movement of the device in situ
25 is manually checked, in order to ascertain what level of pressure the inner bolster is applying to the lumen inner wall. In some embodiments, points of contact of the outer bolster and/or tissue around and/or under the outer bolster and/or a level of elastic deflection of outer bolster is visually checked to ascertain pressure levels of the bolster/s on patient tissue (e.g. outer abdominal surface and/or stomach lining).

30 For example, in some embodiments, upon patient weight change and/or a change in level of tissue swelling and/or signs of physiologically unacceptable pressure

between patient tissue and the device, a minimum axial separation between bolsters is adjusted (e.g. as described herein), for example, by a caregiver.

In some embodiments, the inner tube is flushed and/or massaged to prevent blockage.

5 At 5024, in some embodiments, the inner tube is removed and the cleaned and/or replaced while the bolsters and outer tube remain in position within the patient.

At 5026, for example, when an ostomy device is no longer required and/or when the ostomy device requires replacement, the inner bolster is dismantled by disassembling the inner bolster into a plurality of portions. In some embodiments, the dismantled portions of the internal bolster are free within the lumen (e.g. stomach), for
10 example, then passing through the digestive system. Alternatively, in some embodiments, the disassembled portions are then removed from the lumen (e.g. by pulling through the stoma).

Alternatively, in some embodiments, the internal bolster is sufficiently flexible
15 to be removed by pulling on the tube from outside the stomach. Alternatively, in some embodiments, the device is dismantled during an endoscopic procedure where, for example, the inner bolster is detached from the tube and, is optionally then removed through the esophagus or the inner bolster attached to the tube is removed through the esophagus.

20 At 5028, in some embodiments, the outer tube and outer bolster are then removed. In some embodiments, the stoma then naturally closes. Alternatively, in some embodiments, the stoma is then surgically closed. Alternatively, in some embodiments, a new ostomy device is installed.

In some embodiments, the ostomy device (e.g. as described herein) is used for
25 purposes other than PEG feeding. For example, jejunum feeding, collection of waste from the colon, connection of two internal lumens.

FIG. 51 is a photograph of a device inserted at an angle through simulated tissue in accordance with some embodiments of the current invention. Optionally the device includes an external bolster attached by variable angle joint to a tube. In some
30 embodiments, a PEG device may include a variable angle joint, for example a ball joint. Optionally, the ball joint may join an outer bolster base 5110 and/or petals 5199a, 5199b and 5199c to a tube 5102. Optionally petals 5199a, 5199b and/or 5199c contact a surface

5106 of tissue 5104. For example, petals 5199a, 5199b and/or 5199c may prevent bolster 5100 and/or tube 5102 from being pulled into the stoma. Alternatively or additionally, one or more extensions may contact a surface 5106 of tissue 5104. For example, the extension may prevent bolster 5100 and/or tube 5102 from being pulled into the stoma.

5 For example an extension may have a dome shape.

In some embodiments, a variable angle joint may improve the fit of a bolster 5100 to an outer surface 5106 of a patient. For example, sometimes an opening, a stoma and/or a tube 5102 may pass through tissue 5104 at an acute angle 5151a to surface 5106. The ball joint may allow adjustment of an angle 5151b between an axis 5153b of
10 bolster 5100 and an axis 5153a of tube 5102. Optionally rotation of the variable angle joint may at least partially compensate for the difference between angle 5151b and a line normal to surface 5106. For example compensation make axis 5153b of bolster 5100 closer than axis 5153a of tube 5102 to a normal to surface 5106.

FIGs. 52 and 53 are a perspective and cross sectional views of a device with a
15 pivoting external bolster inserted at an angle to an external body surface in accordance with some embodiments of the current invention. In some embodiments bolster base 5110 has the form of a skirt that rotates over a ball joint 5255 over a range of angles.

In some embodiments angle 5151b may be passively adjusted to equalize the force on petals 5199a, 5199b and 5199c. For example, base 5110 may float freely on
20 joint 5255. Optionally, when there is an increased force on one of the petals 5199a, 5199b or 5199c the excess force will create a torque rotating bolster 5100 away from that side. The resulting rotation optionally balances the forces on the petals 5199a, 5199b and 5199c. Optionally angle 5151b between bolster 5100 and axis 5153a may help compensate for short term changes in surface 5106, for example swelling on one
25 side of the stoma. Alternatively or additionally, there may be a biasing mechanism that biases the bolster to a certain position, for example coaxial to the tube. For example an elastic element for example a spring and/or an elastomeric element may bias the angle such that deflections from the biased angle require progressively more force for progressively larger deflections.

30 In some embodiments, friction between bolster base 5110 and joint 5255 may be chosen to allow movement to compensate for variations in angle 5151a of axis 5153a of tube 5102 and surface 5106 but to avoid shifting of tube 5102. Optionally, friction

between bolster base 5110 and joint 5255 may be low allowing compensation to short term movements for example due to movement of the patient and/or due to movement of internal organs of the patient. Alternatively or additionally, a variable angle joint may include an adjustment mechanism. For example, an adjustment mechanism may tighten the joint making it resist changing its angle once set. For example, the adjustment mechanism may include a tightening means such as a screw. For example the adjustment mechanism may limit the angular range of the bolster.

FIG. 54 is a block diagram of an adjustable bolster 5100 in accordance with an embodiment of the current invention. In some embodiments, one or more extensions 5499a, 5499b are attached to a bolster base 5410. Base 5410 optionally swivels on a joint 5455. Joint 5455 is optionally attached to a tube 5402.

In some embodiments, when bolster 5400 is in use, tube 5402 passes through a stoma and/or an opening in tissue 5404. Optionally extensions 5499a, 5499b contact a surface of tissue 5404 and/or prevent bolster 5400 from being pulled into the stoma and/or the opening.

In some embodiments, swiveling bolster 5400 may allow it to adjust to a surface of tissue 5404. For example, if tube 5402 is at an angle to the surface of tissue 5404, bolster 5400 may swivel so that a plane of extensions 5499a, 5499b is parallel to the surface. For example, bolster 5400 may swivel so that an axis of bolster 5400 is perpendicular to the surface of tissue 5404.

Optionally an adjuster 5493 mediates the connection between bolster base 5410 and joint 5455. For example adjuster 5493 may include a screw that when tightened increase a force of contact and/or a coefficient of friction between joint 5455 and base 5410. Increasing friction may for example fix the position of base 5410 with respect to joint 5455 hindering further swiveling. Alternatively or additionally, adjuster 5493 may allow swiveling, but increase a resistance thereto.

In some embodiments, a tube 5402 may be flexible. For example, swiveling of bolster 5400 around joint 5455 may compensate for an angle between an outer axis of tube 5402 and a normal to the surface of tissue 5404. Alternatively or additionally, tube 5402 may be rigid and/or have a right cylindrical form.

General

As used herein the term “about” refers to $\pm 20\%$

The terms "comprises", "comprising", "includes", "including", "having" and their conjugates mean "including but not limited to".

The term "consisting of" means "including and limited to".

5 The term "consisting essentially of" means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

10 As used herein, the singular form "a", "an" and "the" include plural refers unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

15 Throughout this application, various embodiments of this invention may be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies
20 regardless of the breadth of the range.

Whenever a numerical range is indicated herein, it is meant to include any cited numeral (fractional or integral) within the indicated range. The phrases "ranging/ranges between" a first indicate number and a second indicate number and "ranging/ranges from" a first indicate number "to" a second indicate number are used herein
25 interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numerals therebetween.

As used herein the term "method" refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques and procedures either known to, or readily developed from known
30 manners, means, techniques and procedures by practitioners of the chemical, pharmacological, biological, biochemical and medical arts.

As used herein, the term “treating” includes abrogating, substantially inhibiting, slowing or reversing the progression of a condition, substantially ameliorating clinical or aesthetical symptoms of a condition or substantially preventing the appearance of clinical or aesthetical symptoms of a condition.

5 It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described
10 embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations
15 will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same
20 extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

WHAT IS CLAIMED IS:

1. A PEG feeding device for conducting fluid through a stoma to a stomach comprising:

a tube sized to bridge a channel between the stomach and an outer abdominal surface;

an internal bolster, sized to resist movement out of the stomach through the stoma and connected to said tube;

an external bolster, sized to resist movement into the stoma and connected to said tube;

wherein said external bolster includes at least one element including an underside which extends from said tube in a radial direction and then towards said external bolster contacting said outer abdominal surface at a distance from an external opening of said stoma.

2. The PEG feeding device according to claim 1, wherein said distance is at least 5mm.

3. The PEG feeding device according to claim 1, wherein at least a portion of said external bolster is elastically deflectable in an axial direction.

4. The PEG feeding device according to claim 1, wherein said external bolster includes a plurality of portions which are individually elastically deflectable.

5. The PEG feeding device according to claim 4, wherein said portions are at least partially circumferentially separated.

6. The PEG feeding device according to claim 1, wherein at least a portion of said inner bolster is elastic with respect to a long axis of said tube.

7. The PEG feeding device according to claim 1, wherein said internal bolster includes a plurality of parts connected by at least one connector.

8. The PEG feeding device according to claim 1, wherein said internal bolster includes circumferential separations.

9. The PEG feeding device according to claim 1, comprising an inner tube sized to fit into said tube and to bridge a channel between a stomach and a patient outer abdominal surface.

10. The PEG feeding device according to claim 9, wherein the inner tube is permanently attached to a food reservoir.

11. The PEG feeding device according to claim 9, comprising a rigid connector connecting said inner tube and said external bolster.

12. The PEG feeding device according to claim 9, comprising a sealing element occluding a channel between said tube and said inner tube.

13. The PEG feeding device according to claim 9, wherein said inner tube includes at least one cleaning portion sized to contact inner walls of said tube.

14. The PEG feeding device according to claim 13, wherein said cleaning portion elastically applies radial pressure to said inner walls of said tube.

15. The PEG feeding device according to claim 1, wherein said tube connects to one of said internal bolster and said external bolster by a rigid connector.

16. The PEG feeding device according to claim 1, wherein a height of said device above a patient outer abdominal surface is less than 5cm.

17. The PEG feeding device according to claim 1, wherein an axial height of said external bolster is less than 5cm.

18. The PEG feeding device according to claim 1, wherein said external bolster is connected to said outer tube by a rigid connector.

19. The PEG of claim 1, further comprising:
a variable angle joint joining said external bolster to said tube and allowing said external bolster to tilt with respect said tube.

20. A PEG feeding device for conducting fluid through a stoma to a stomach comprising:

a tube sized to bridge a channel between the stomach and an outer abdominal surface;

a bolster sized to resist movement into the stoma; and

a rigid connector comprising a lumen and connecting said tube to said bolster;

wherein a portion of said rigid connector is disposed within a first end of said tube.

21. The PEG feeding device according to claim 20, wherein said portion of said rigid connector comprises a fitted friction fit with said tube.

22. The PEG feeding device according to claim 20, wherein said first end of said tube comprises thickened walls.

23. The PEG feeding device according to claim 20, wherein said tube comprises an internal supporting structure and within a sheath.

24. The PEG feeding device according to claim 23, wherein said internal structure includes a mesh.

25. The PEG feeding device according to claim 23, wherein said internal structure includes elongated elements.

26. The PEG feeding device according to claim 20, comprising a second bolster sized to resist movement into the stoma;

wherein said second bolster is connected to a second end of said tube.

27. The PEG feeding device according to claim 20, wherein said rigid connector connects to a rigid part of said bolster.

28. The PEG feeding device according to claim 20, wherein said rigid connector connects to said bolster by an interference connection.

29. A PEG feeding device for conducting fluid through a stoma to a stomach comprising:

a tube sized to bridge a channel between the stomach and an outer abdominal surface;

an internal bolster, sized to resist movement out of the stomach through the stoma and connected to said tube comprising:

a plurality of parts held together by one or more connector; and

an external bolster, sized to resist movement into the stoma and connected to said tube;

wherein said plurality of parts overlap axially by less than 20%.

30. The PEG feeding device according to claim 29, wherein said connector includes a torque connection.

31. A method of installing a PEG feeding device comprising:

selecting an approximately sized tube;

installing said tube in a stoma connecting a stomach and an outer abdominal surface of a patient where an installed tube is held by an inner bolster disposed within said stomach and an external bolster at an abdominal outer surface;

compensating for a discrepancy between said tube length and a length of said stoma.

32. The method according to claim 31, wherein said compensating comprises:

adjusting a minimum separation between said inner bolster and said external bolster.

33. The method according to claim 32, wherein said adjusting comprises changing a position of attachment of said bolster with respect to said tube.

34. The method according to claim 32, wherein said adjusting comprises:
selecting an axial extent of a compressible element between an inner bolster and a lumen inner wall.

35. The method according to claim 32, wherein said adjusting comprises:
axially elastically deflecting a portion of said external bolster.

36. The method according to claim 32, wherein said adjusting comprises:
axially elastically deflecting a portion of said inner bolster.

37. The method according to claim 32, wherein said adjusting is self adjusting of the PEG device.

38. A method of use of a PEG feeding device:
installing a PEG feeding device comprising an inner and outer tube said outer tube forming a channel between a lumen and a patient outer surface, said inner tube forming a channel between the lumen and the patient outer surface and within said outer tube; and
replacing said inner tube periodically.

39. The method of claim 38, wherein said replacing comprises cleaning said outer tube.

40. The method of claim 38, further comprising:

pivoting an angle between at least one of said internal bolster and said external bolster with respect to said tube.

41. The method of claim 40 wherein pivoting compensates for a difference between an axis of said tube and a normal from at least one of an inner surface of a stomach and an outer surface of an abdomen at the location of a stoma.

42. A PEG feeding device for conducting fluid through a stoma to a stomach comprising:

a tube sized to bridge a channel between a stomach and an outer abdominal surface;

an external bolster, sized to resist movement into the stoma and connected to said tube;

a variable angle joint joining said external bolster to said tube and allowing said external bolster to tilt with respect said tube.

43. The PEG of claim 42 further comprising:

an adjuster for setting a resistance of said external bolster to tilt with respect to an axis of said tube.

44. The PEG of claim 42 further comprising:

at least one element including an underside which extends from said tube in a radial direction and then towards said external bolster contacting said outer abdominal surface at a distance from an external opening of said stoma.

45. The PEG of claim 42 further comprising:

an internal bolster, sized to resist movement out of the stomach through the stoma and connected to said tube.

46. The PEG of claim 42 further comprising:

an elastic biasing element biasing an angle of said tilting of said external bolster to a preferred angle.

47. A PEG device for forming a channel through a stoma to a lumen comprising:

a tube sized to bridge a channel between the lumen and an outer abdominal surface;

an internal bolster, sized to resist movement out of the stomach through the stoma and connected to said tube;

an external bolster, sized to resist movement into the stoma and connected to said tube;

wherein said external bolster includes at least one element including an underside which extends from said tube in a radial direction and then towards said external bolster contacting said outer abdominal surface at a distance from an external opening of said stoma.

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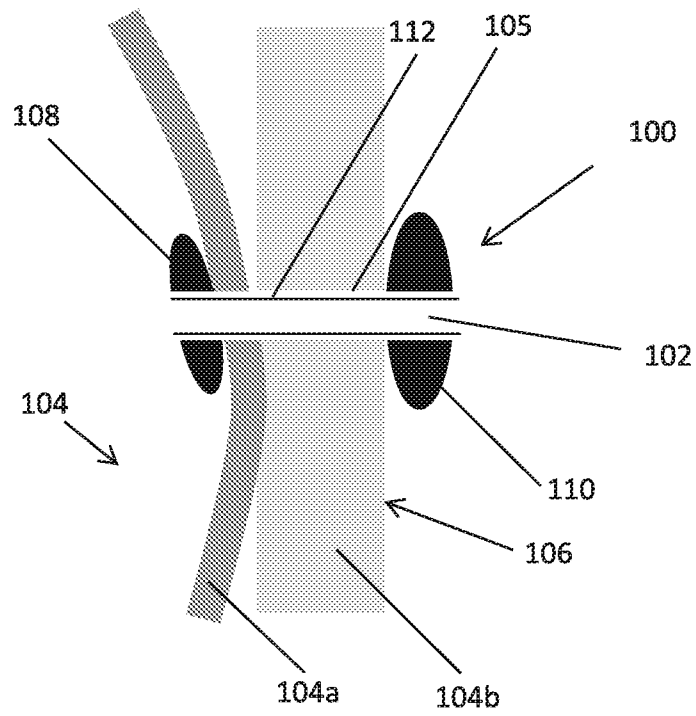


FIG. 1A

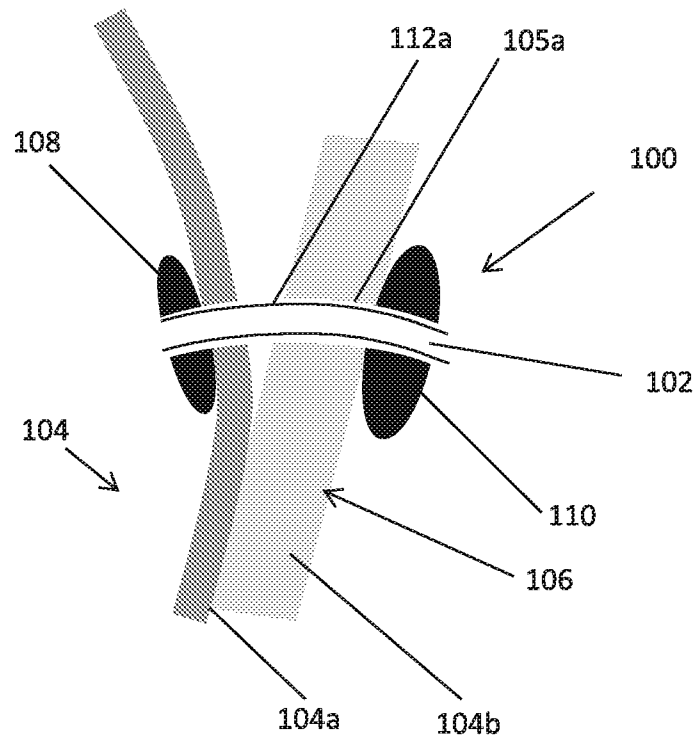


FIG. 1B

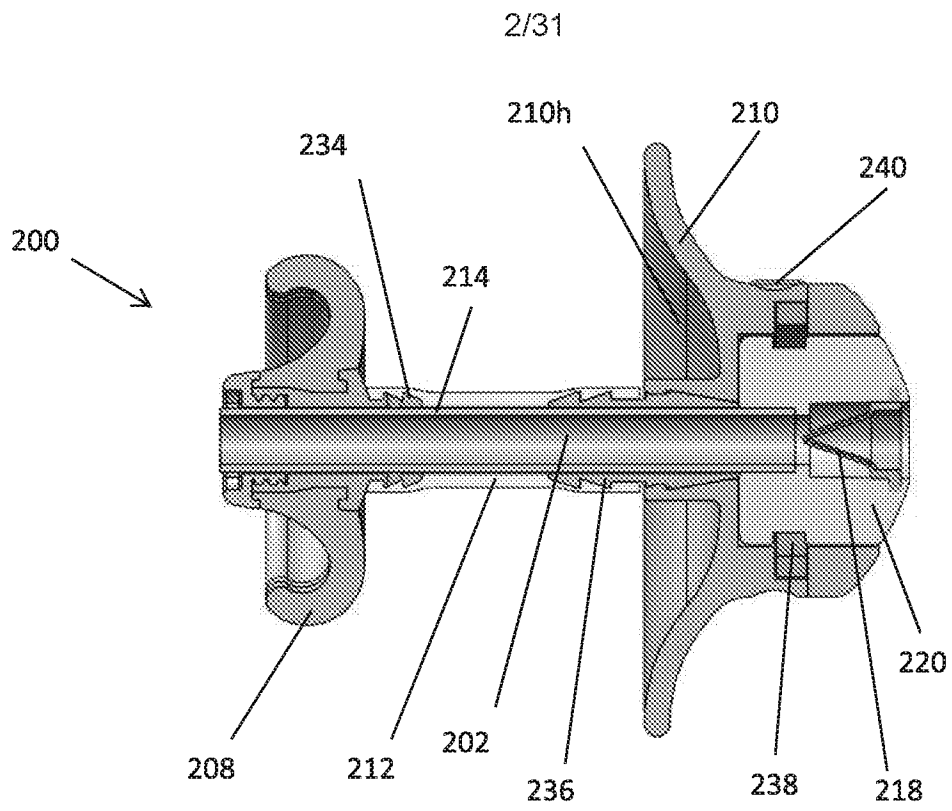


FIG. 2A

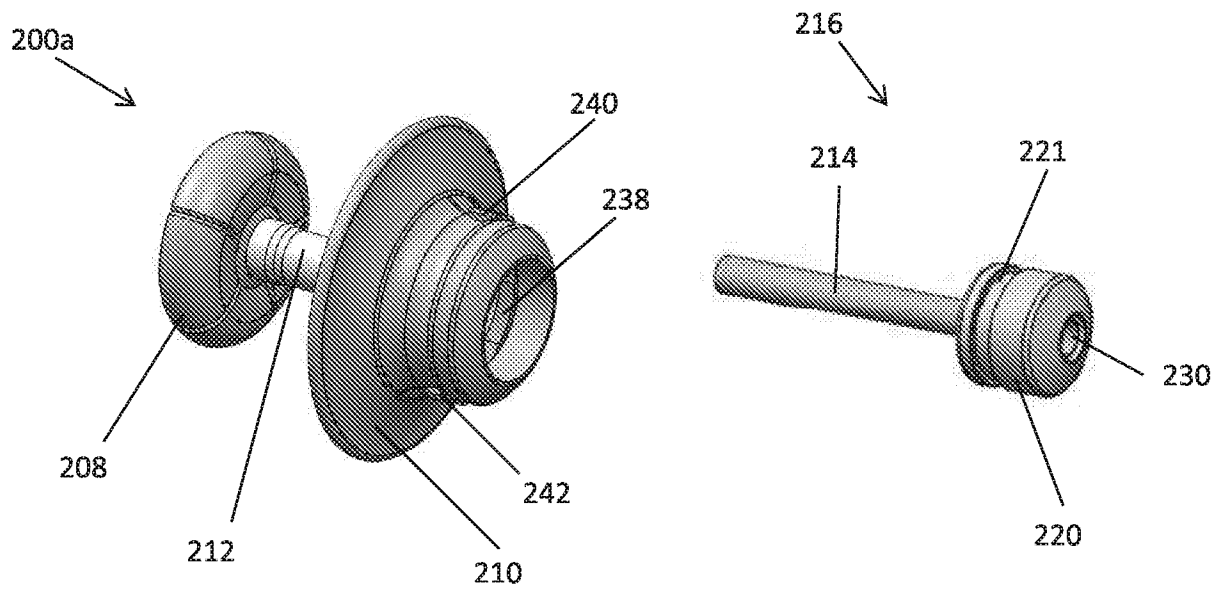


FIG. 2B

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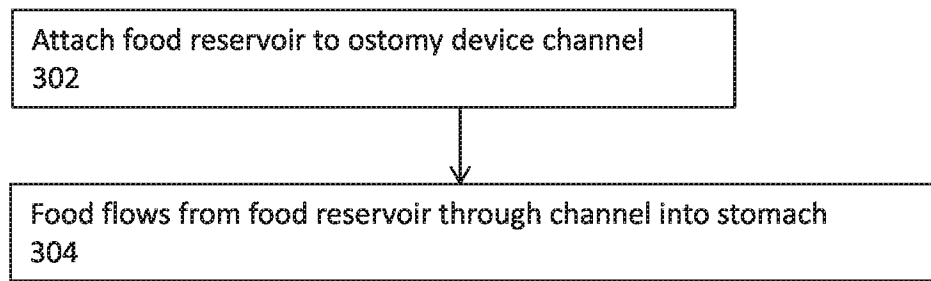
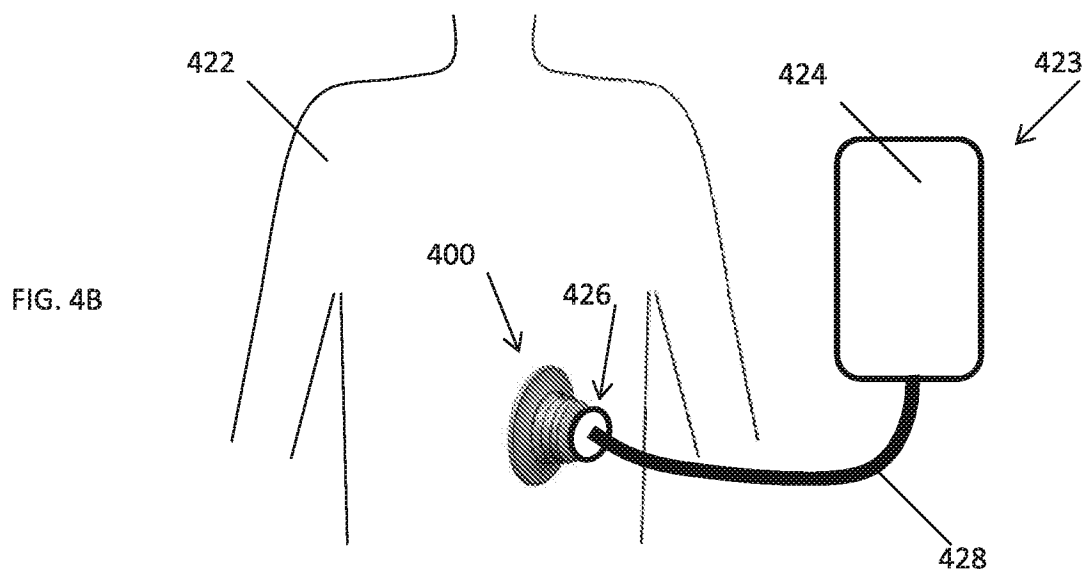
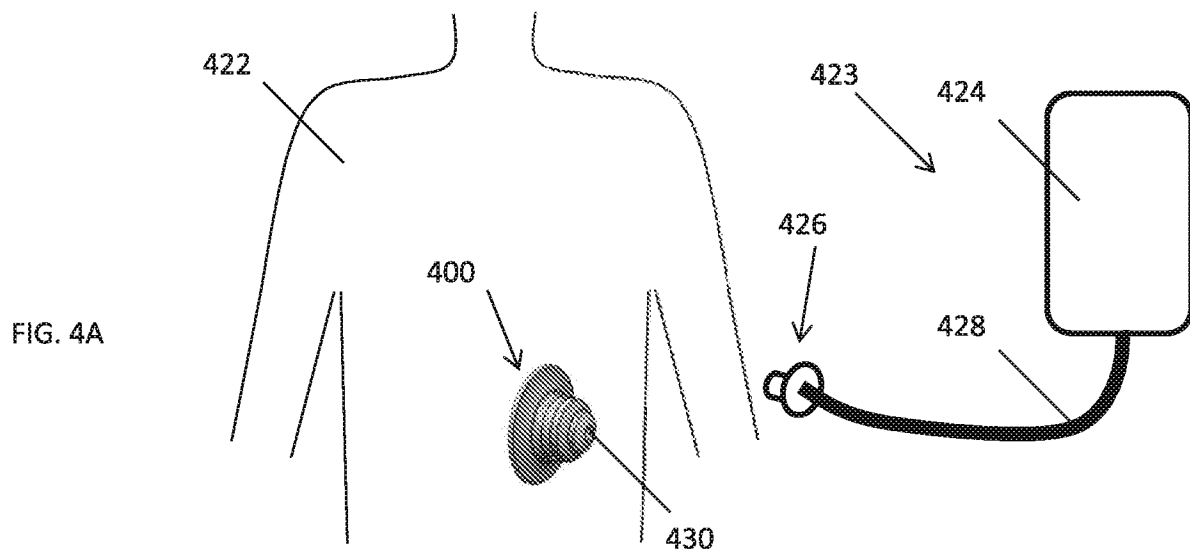
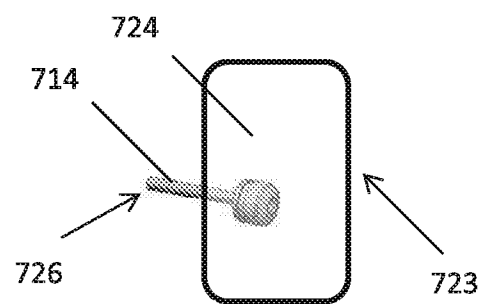
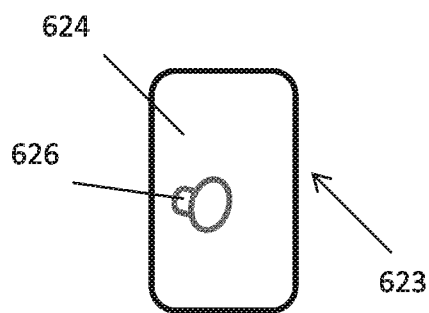
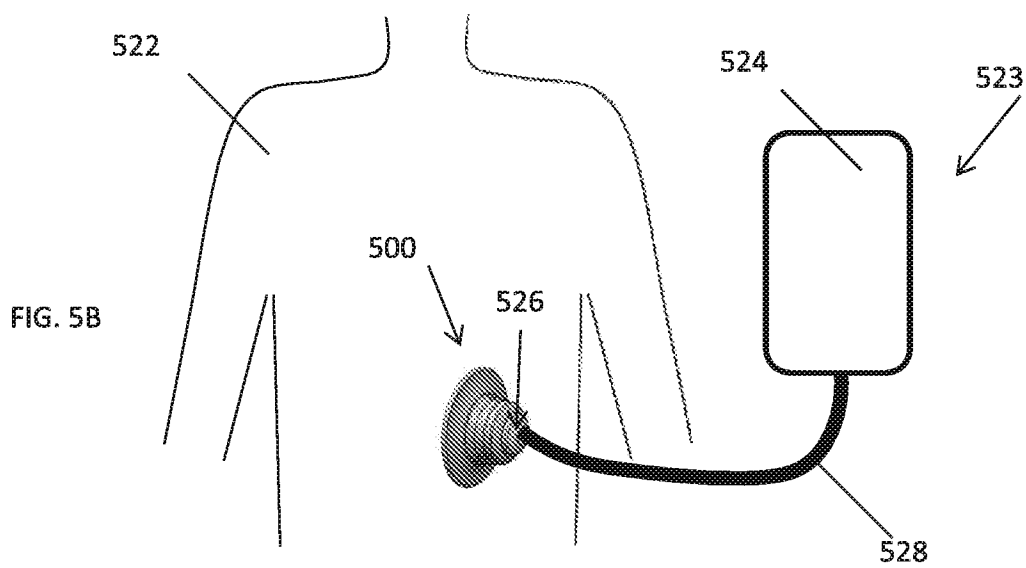
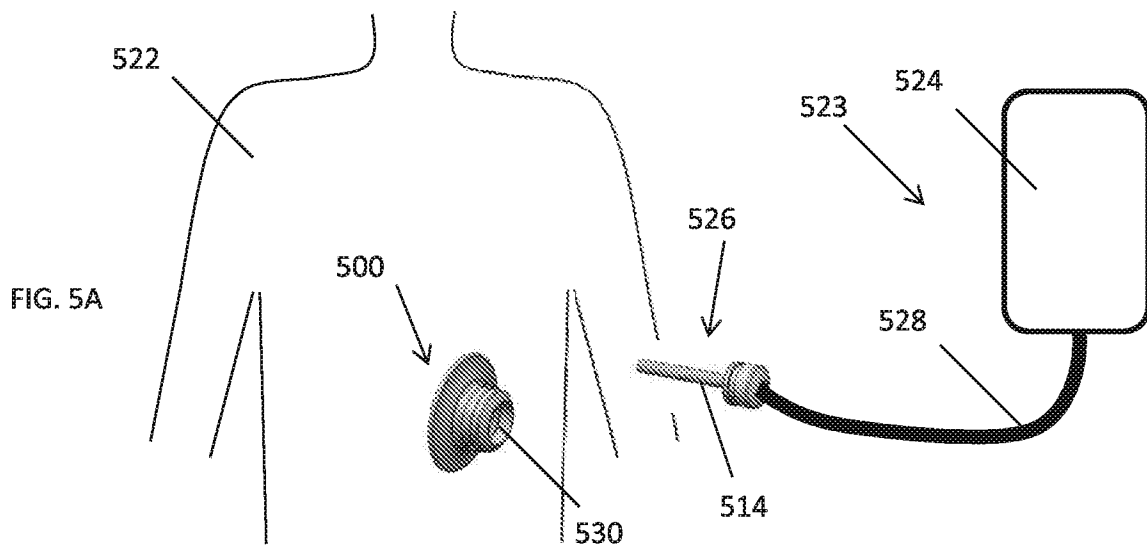


FIG. 3





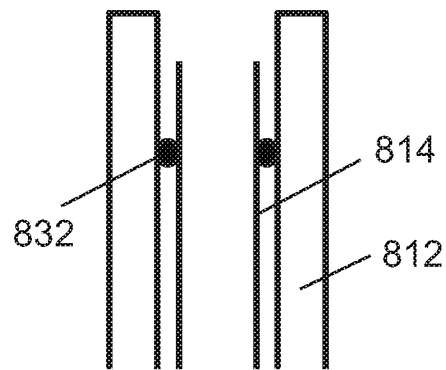


FIG. 8

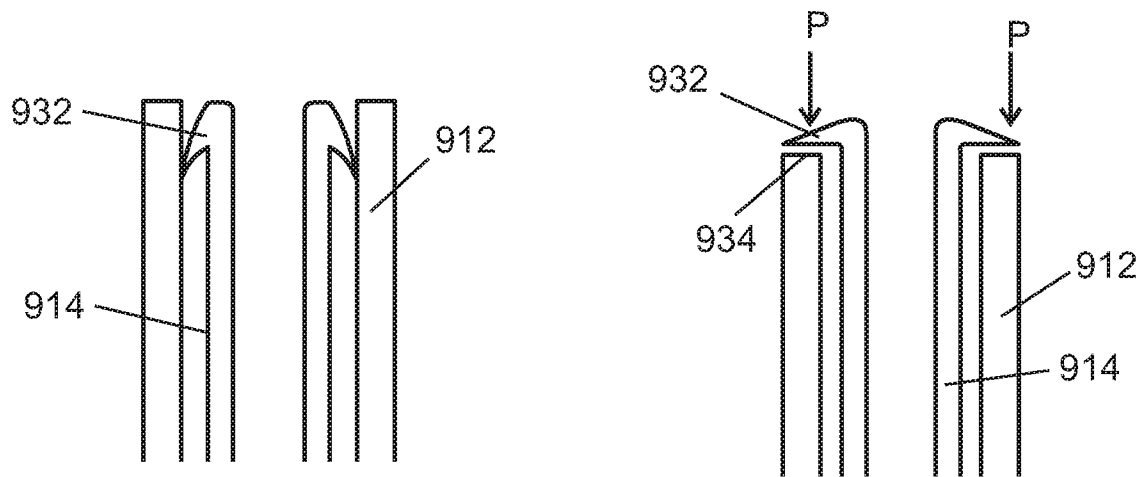


FIG. 9A

FIG. 9B

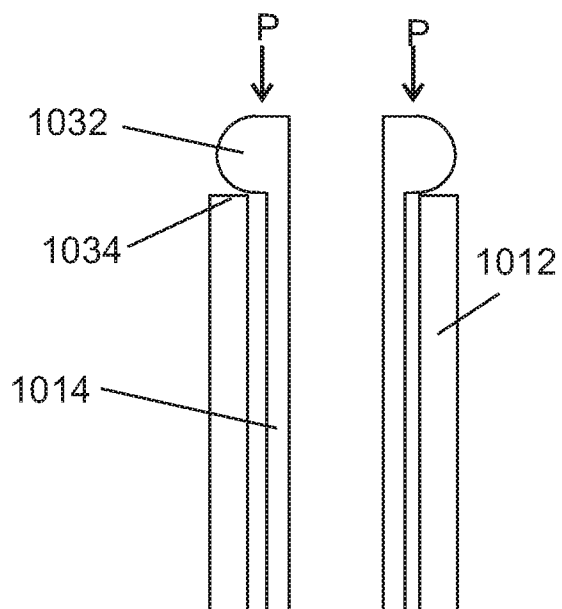


FIG. 10

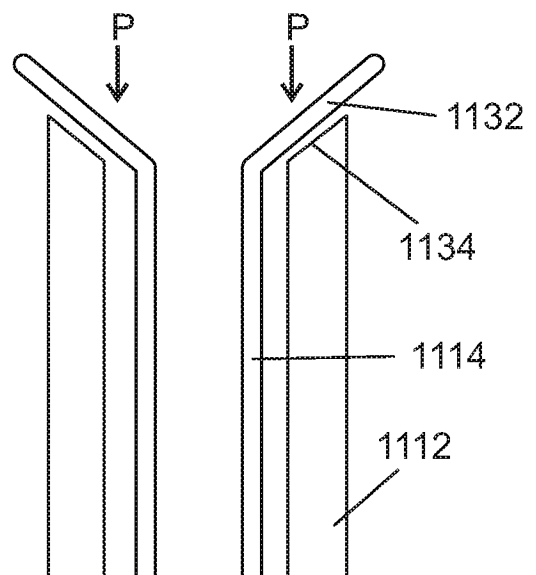


FIG. 11

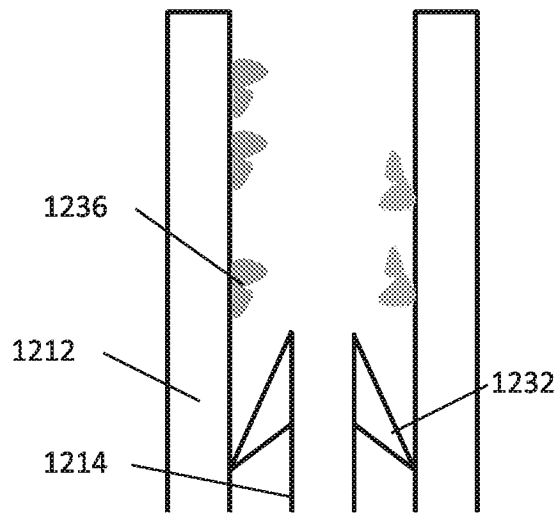


FIG. 12A

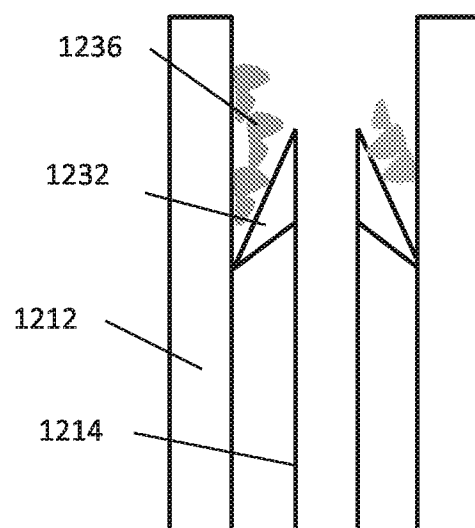


FIG. 12B

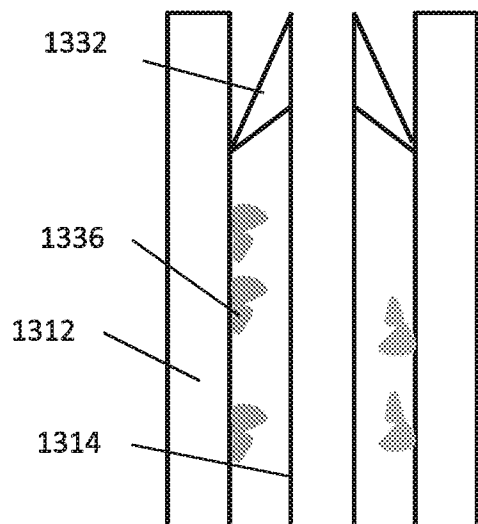


FIG. 13A

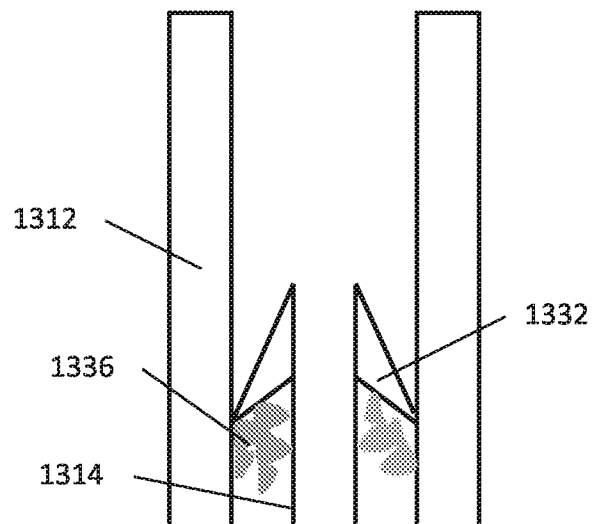


FIG. 13B

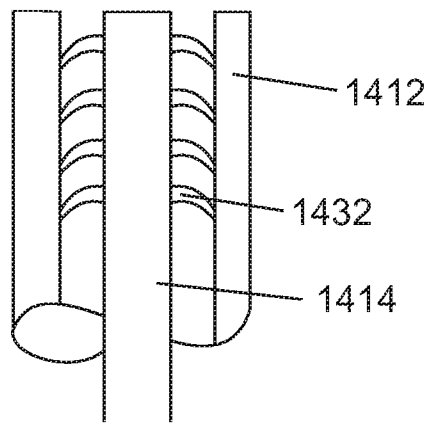


FIG. 14A

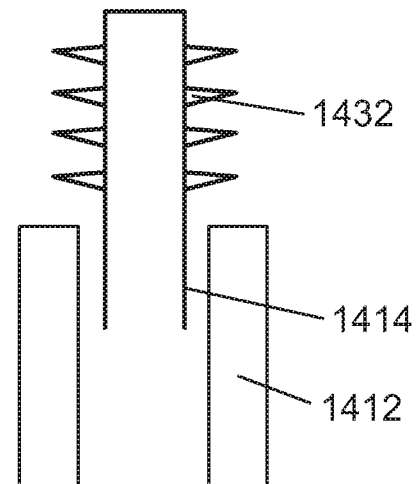


FIG. 14B

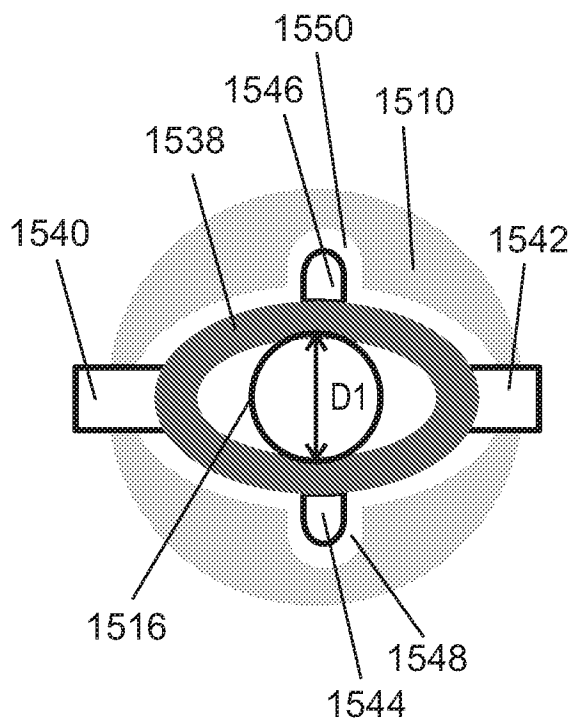


FIG. 15A

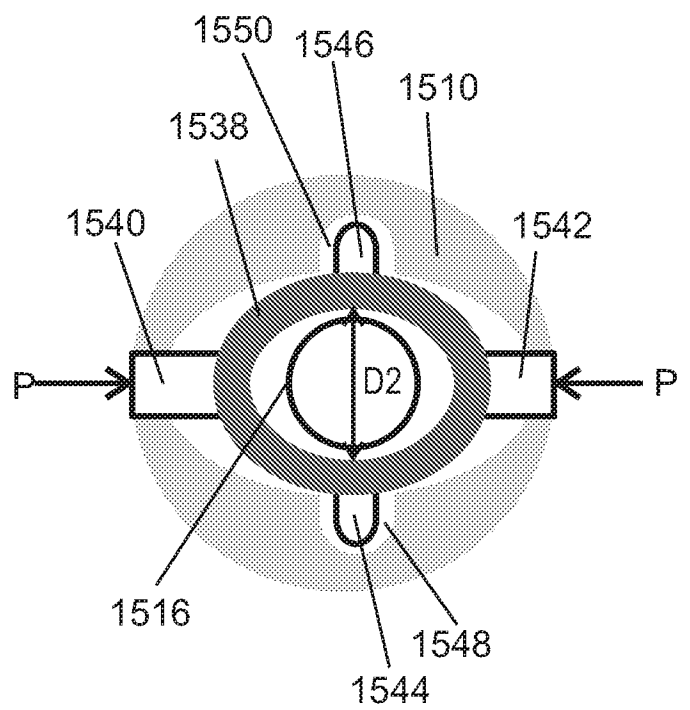


FIG. 15B

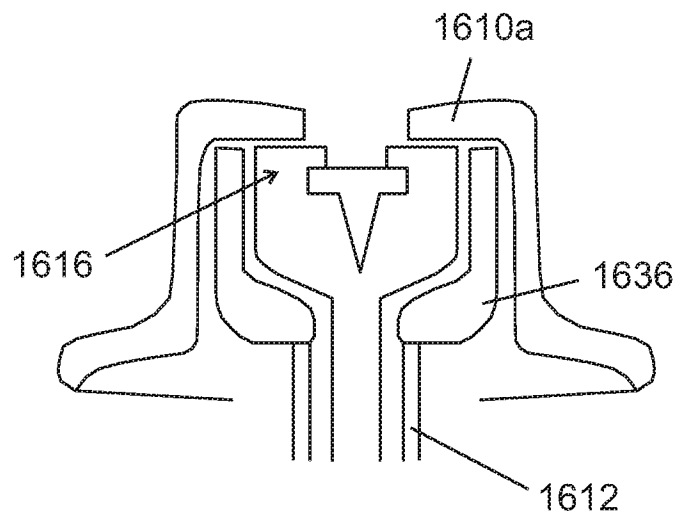


FIG. 16

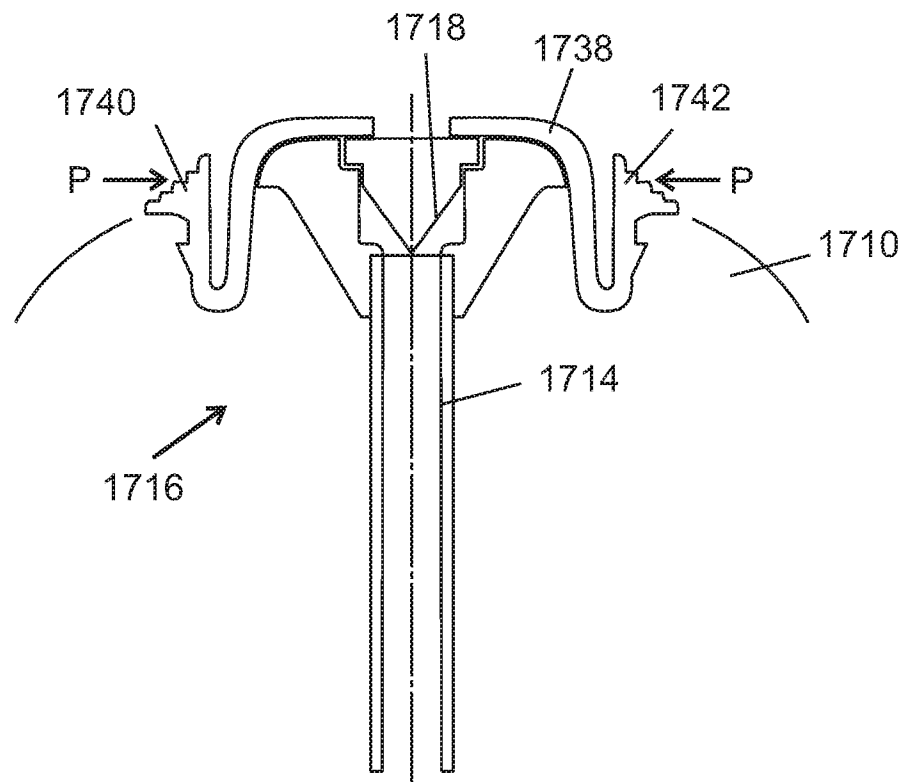


FIG. 17

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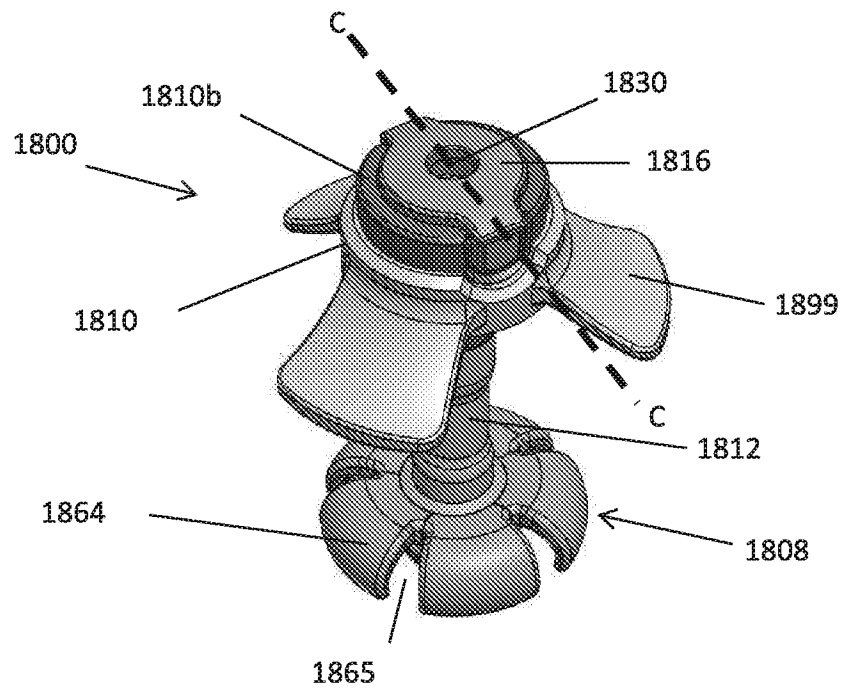


FIG. 18A

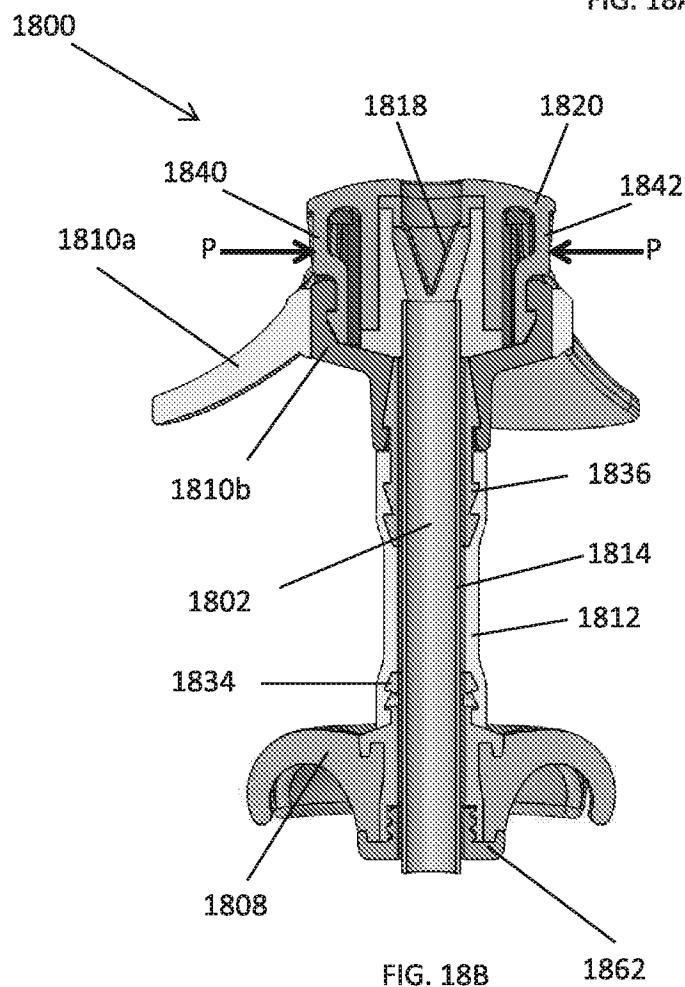


FIG. 18B

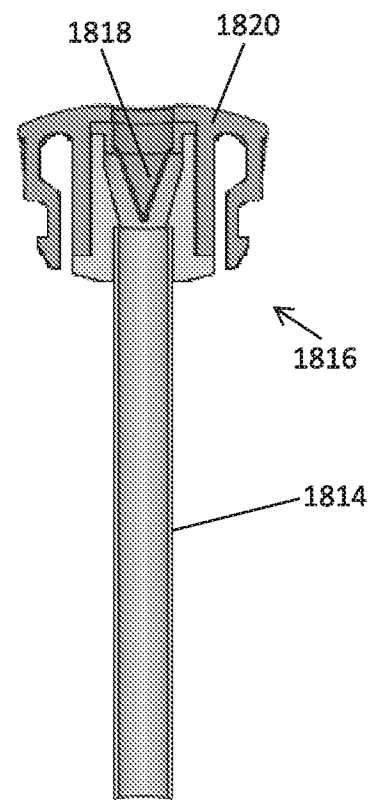


FIG. 18C

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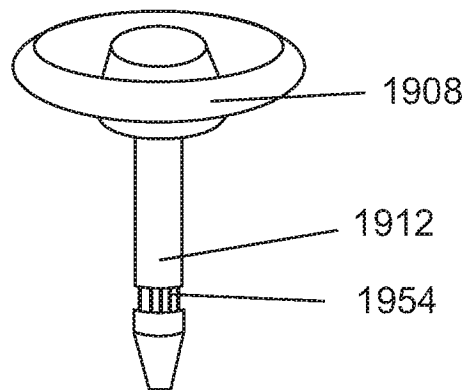


FIG. 19

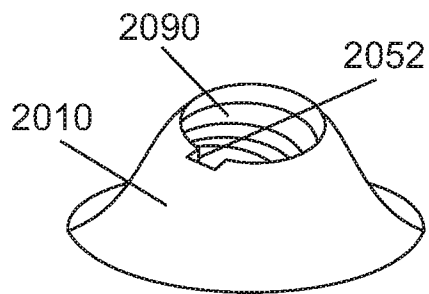


FIG. 20A

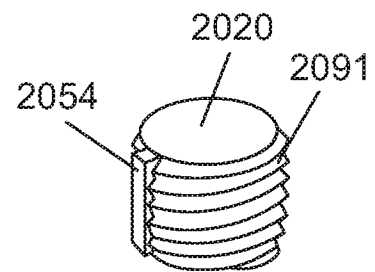


FIG. 20B

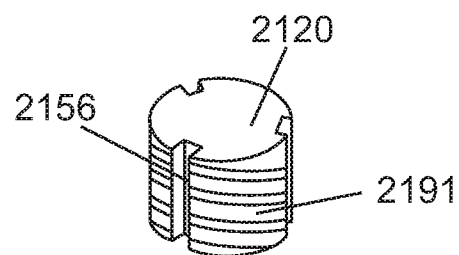


FIG. 21

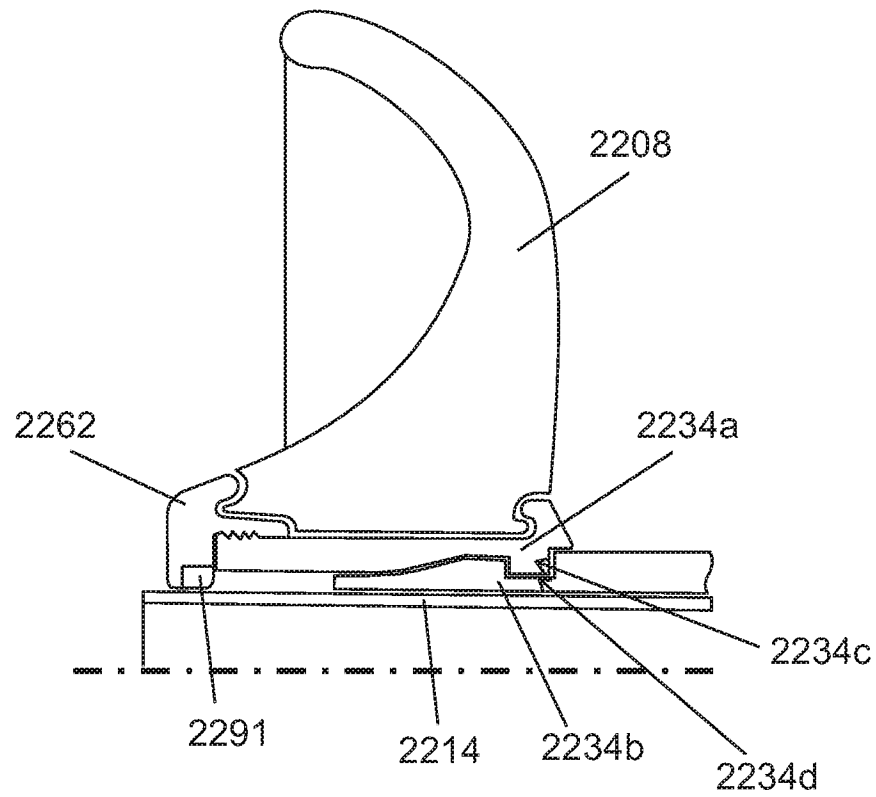


FIG. 22

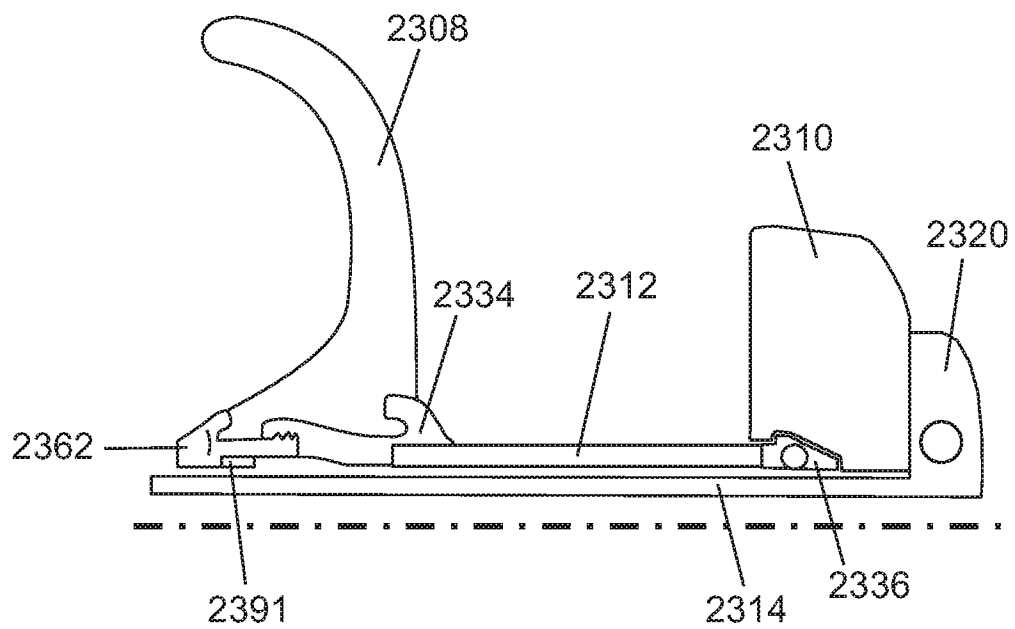


FIG. 23

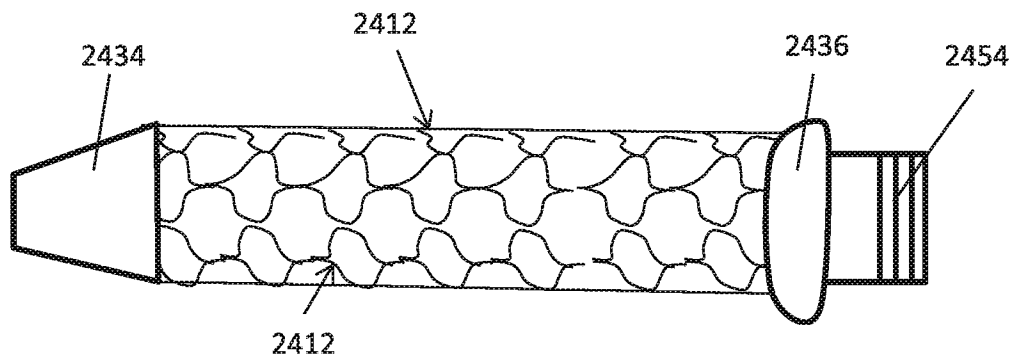


FIG. 24

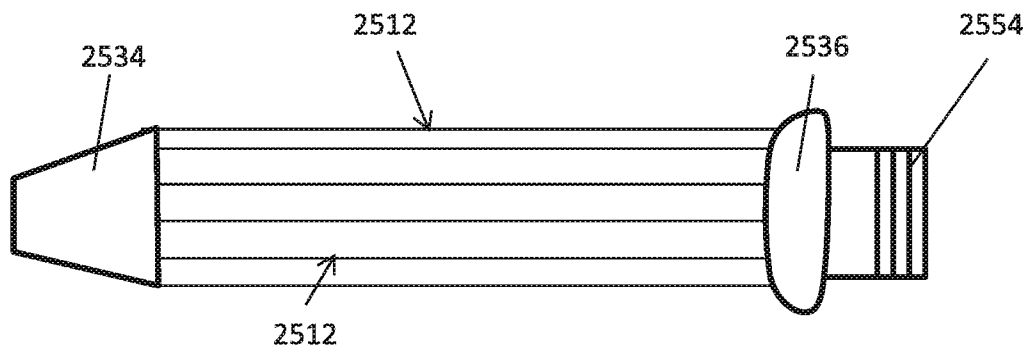


FIG. 25

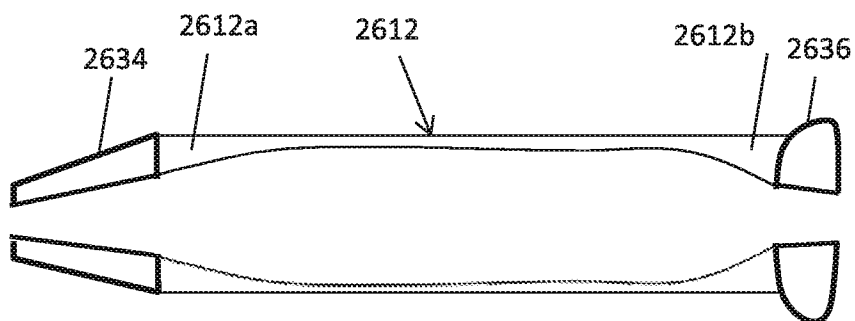


FIG. 26

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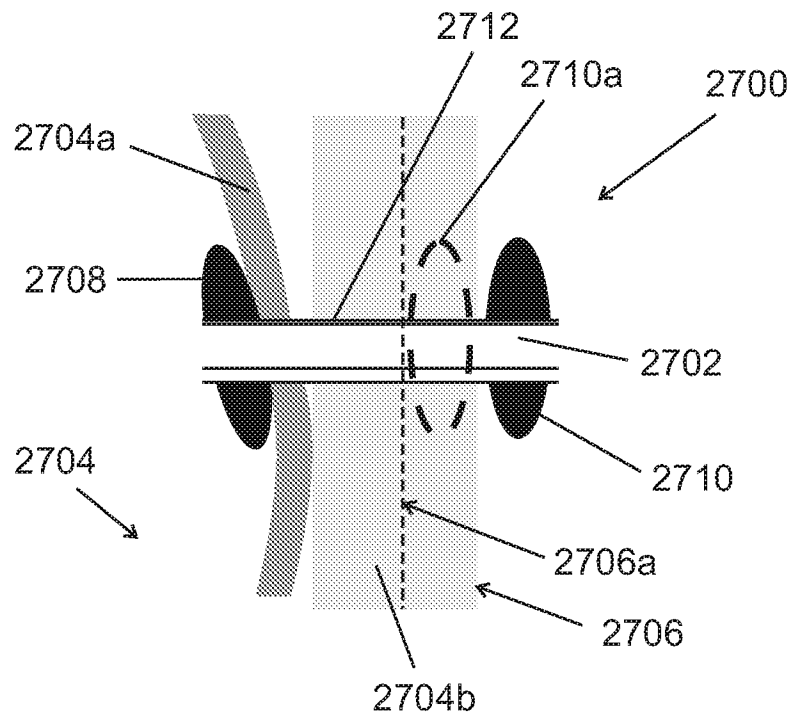


FIG. 27

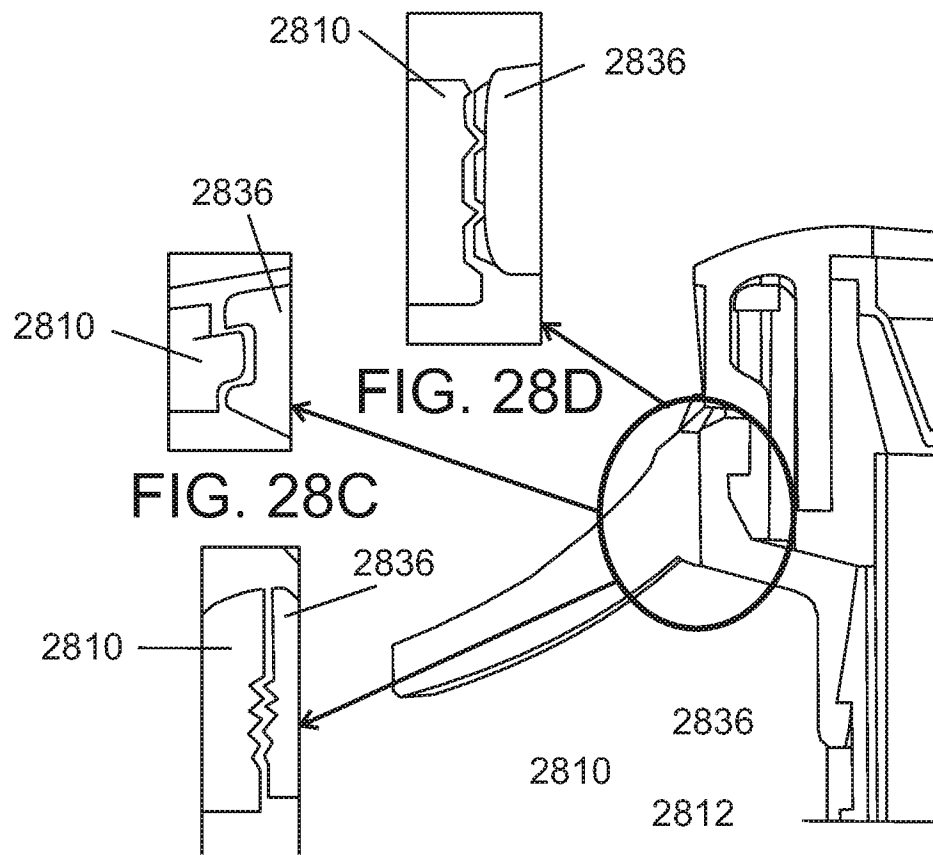
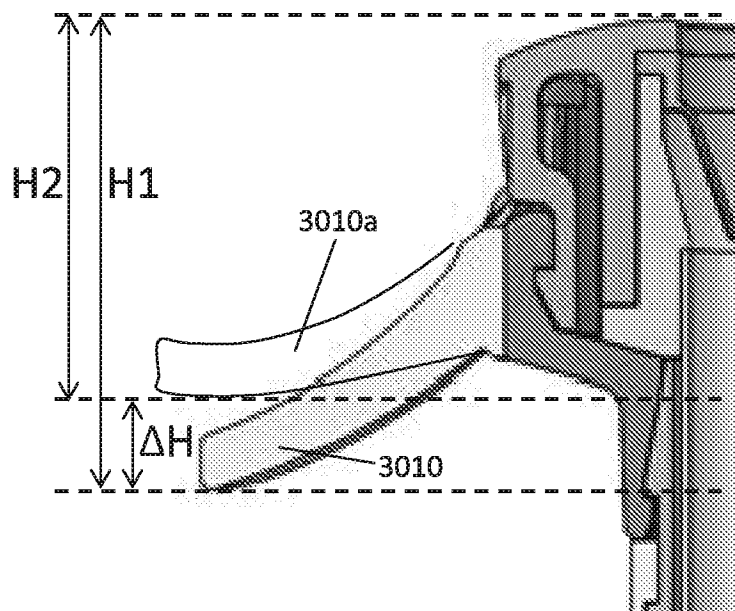
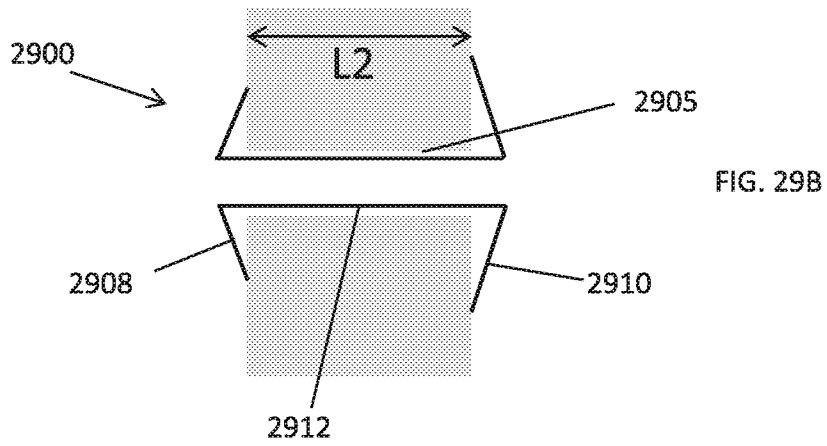
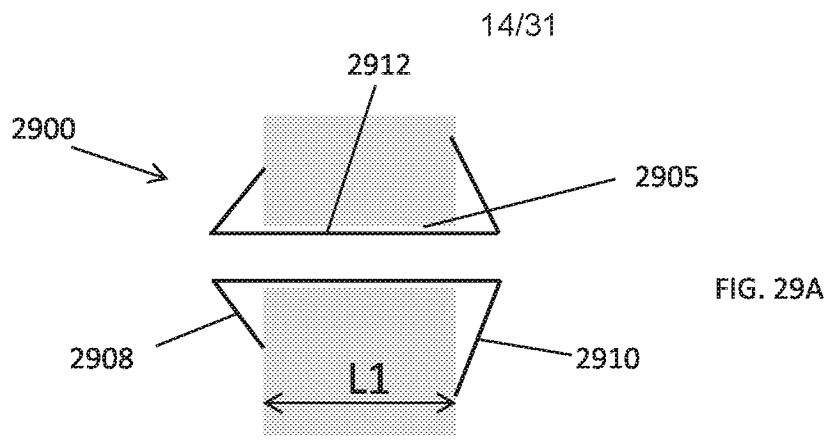


FIG. 28B

FIG. 28A



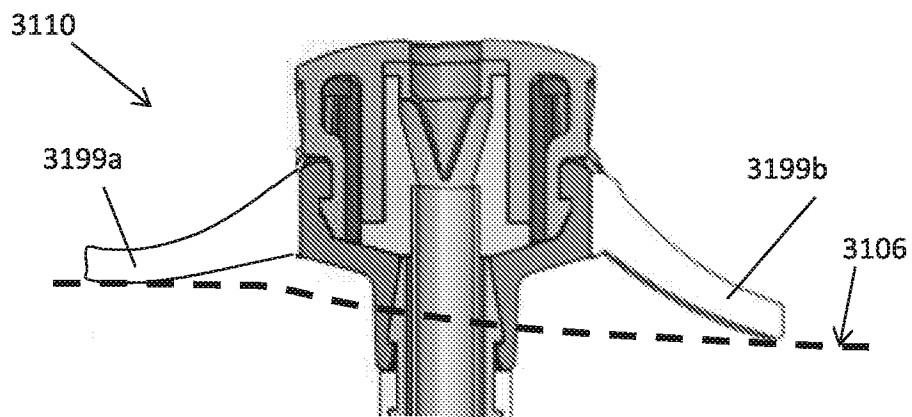


FIG. 31A

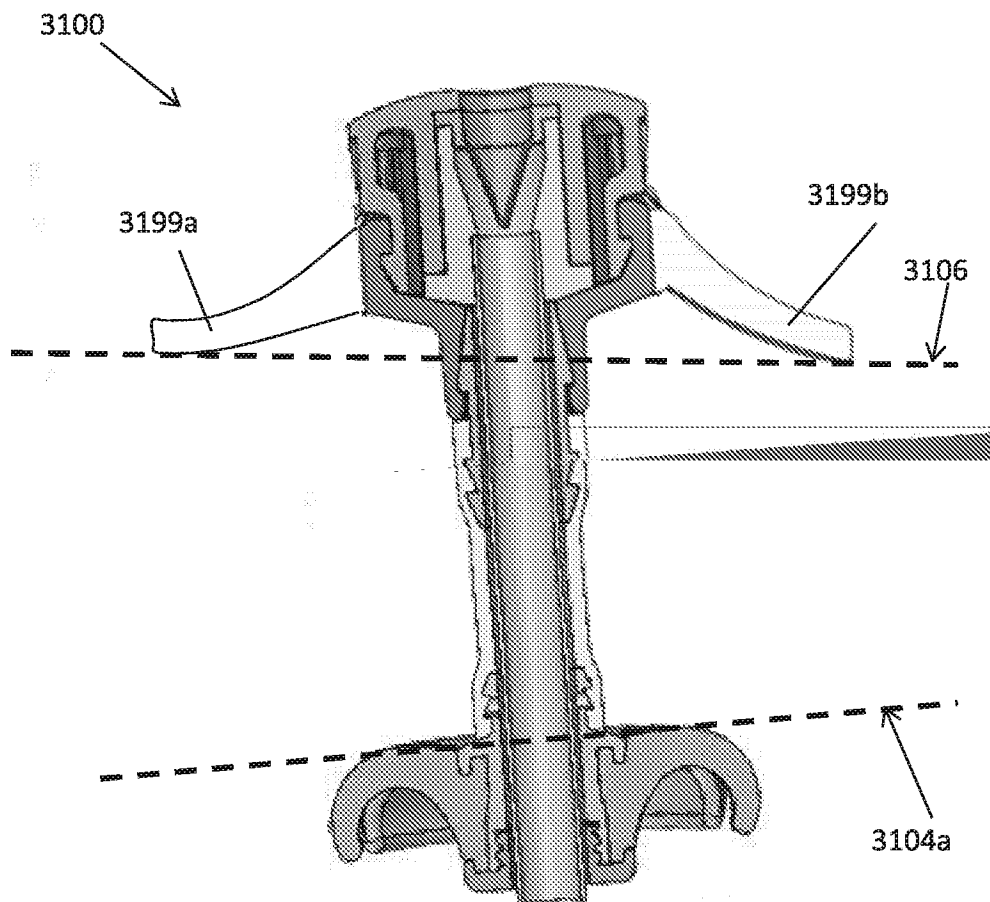


FIG. 31B

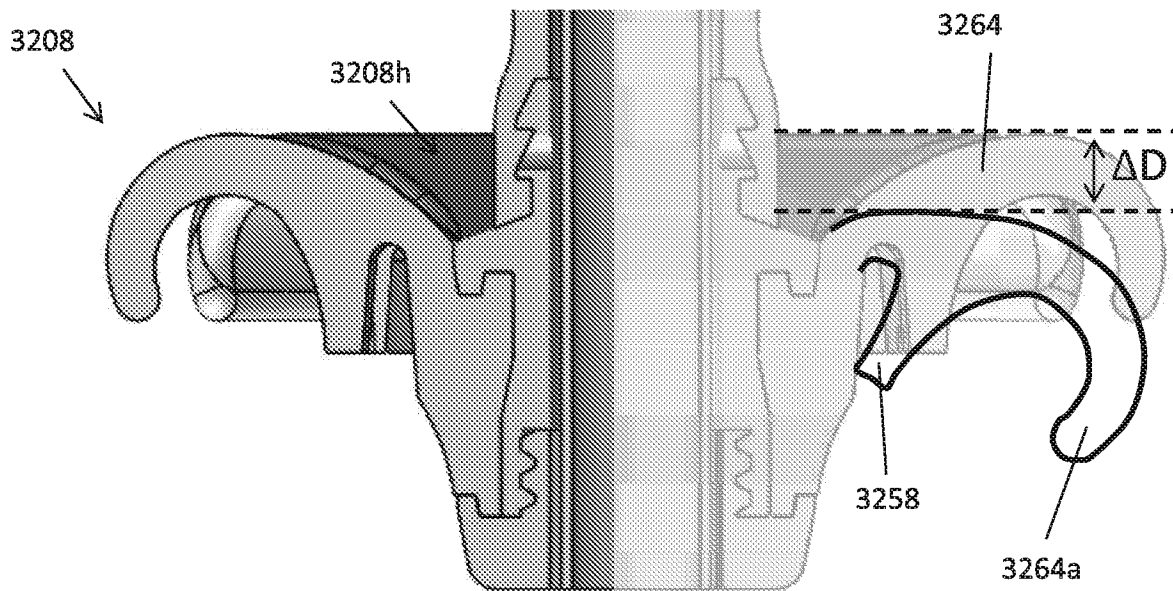


FIG. 32A

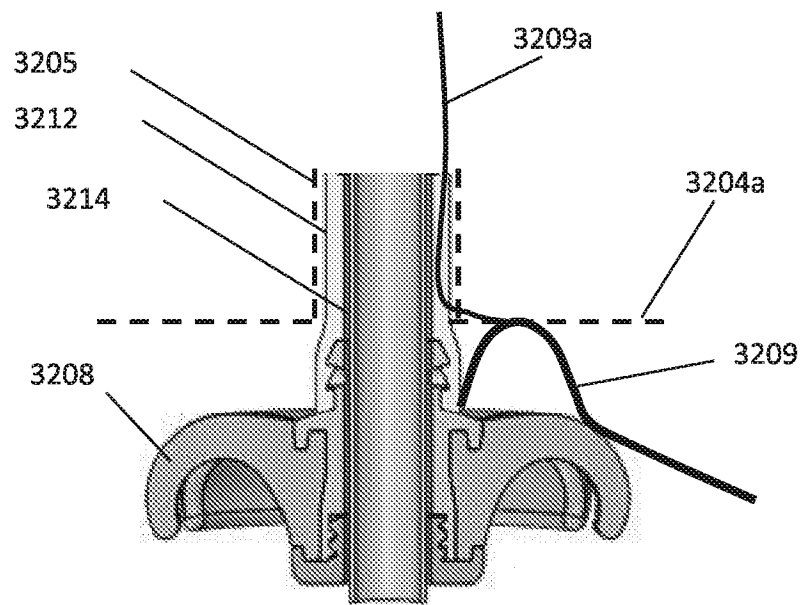


FIG. 32B

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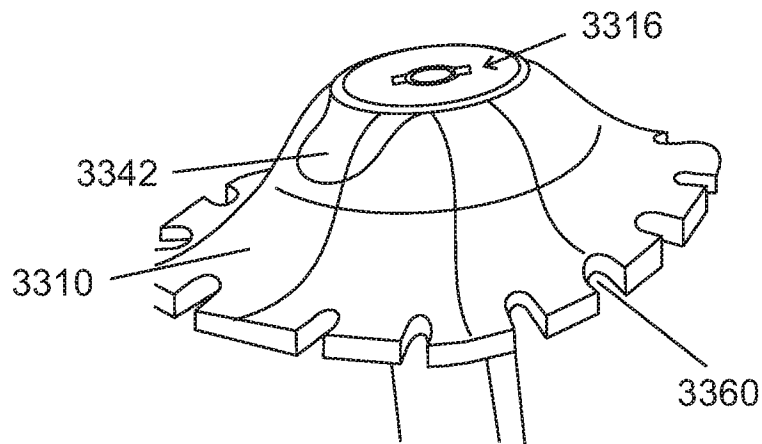


FIG. 33

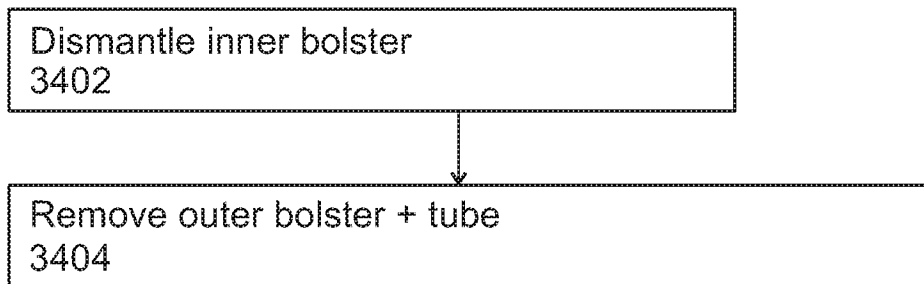


FIG. 34

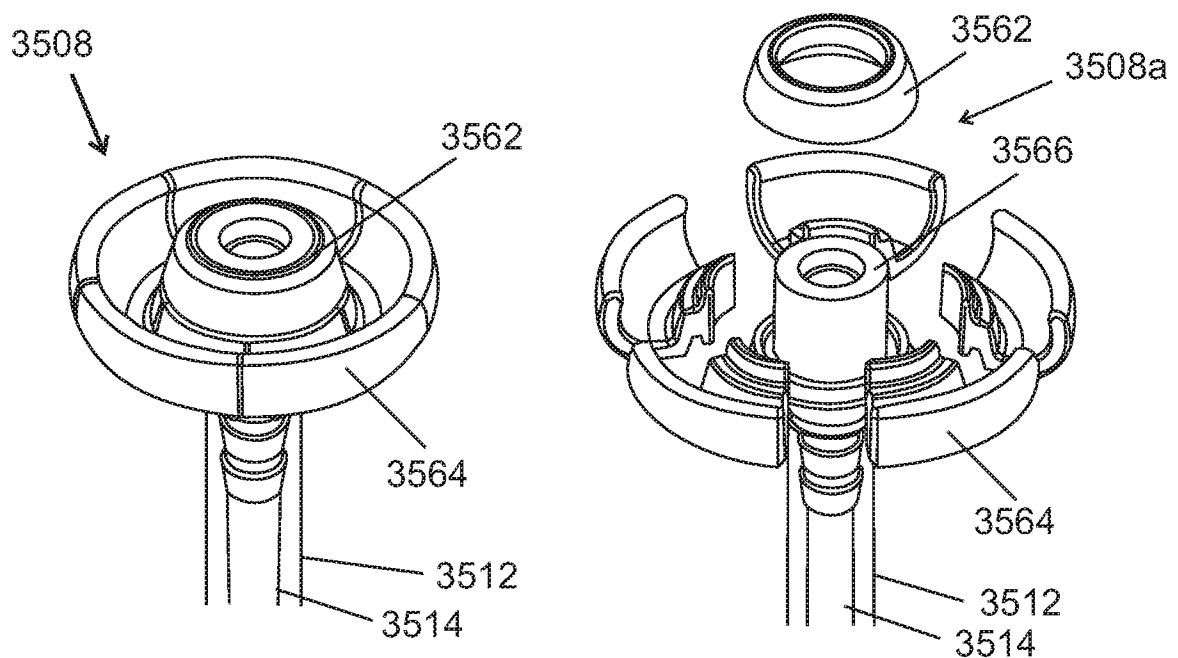


FIG. 35A

FIG. 35B

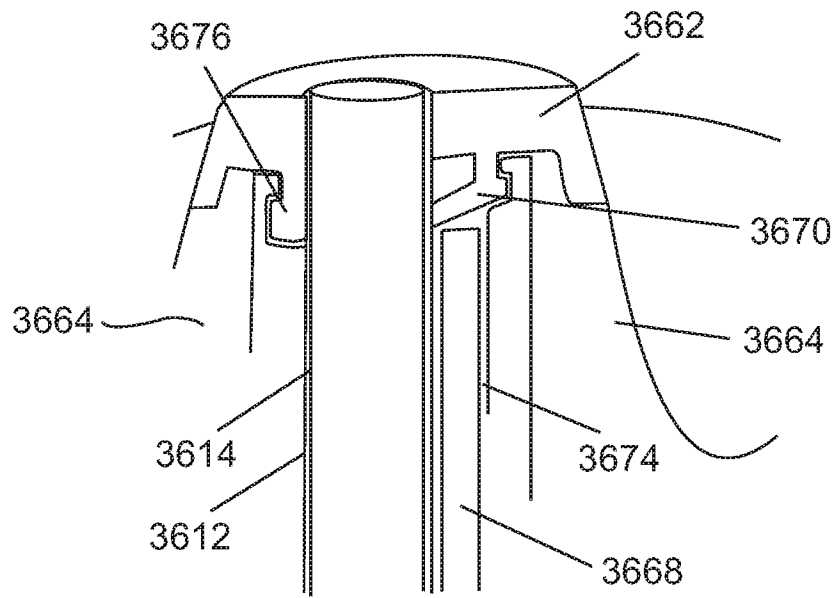


FIG. 36

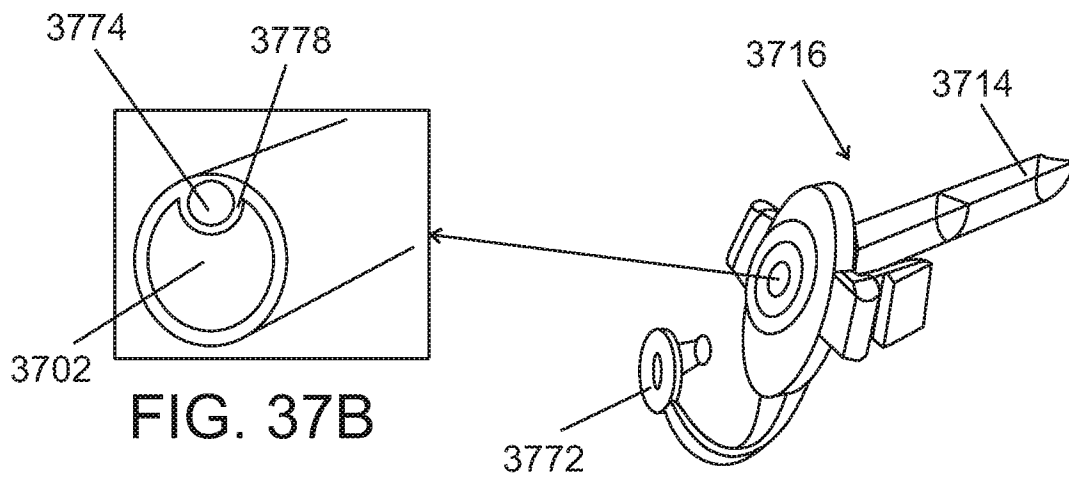


FIG. 37B

FIG. 37A

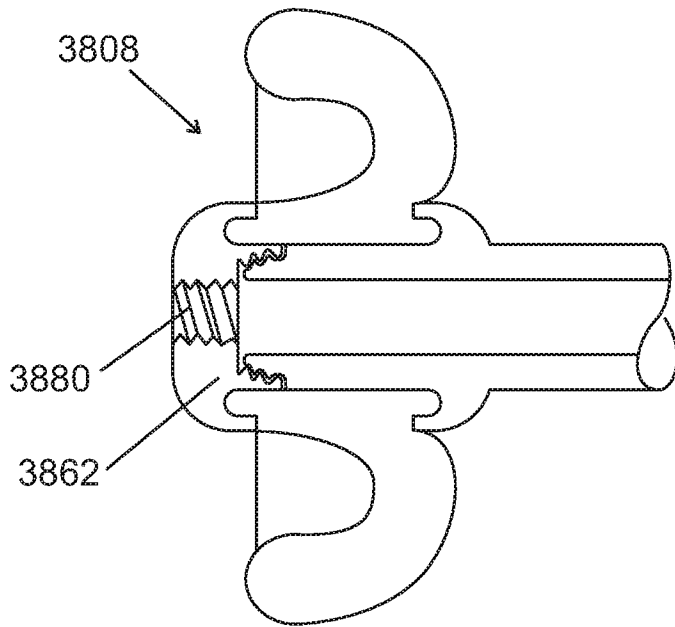


FIG. 38A

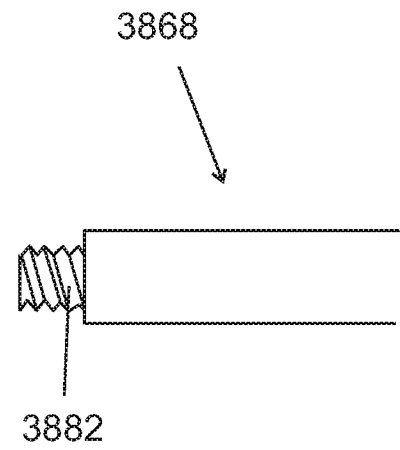


FIG. 38B

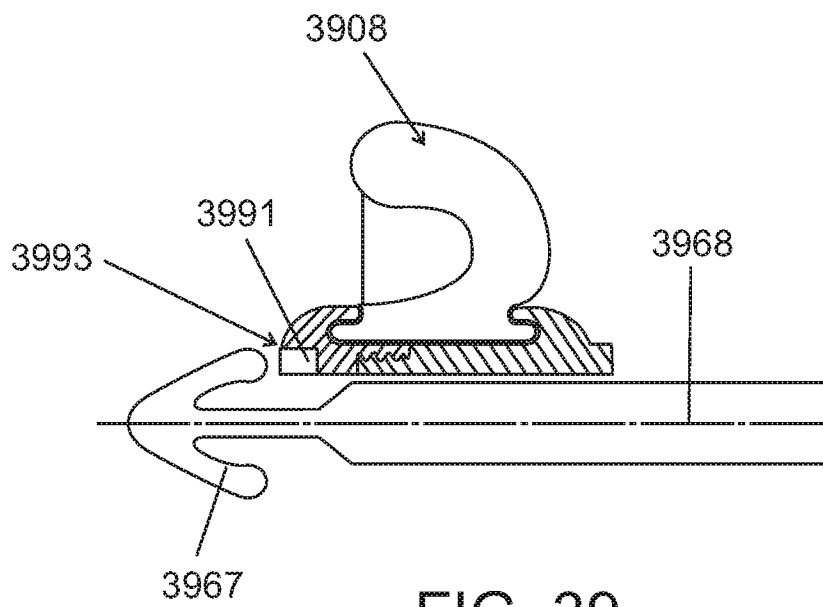


FIG. 39

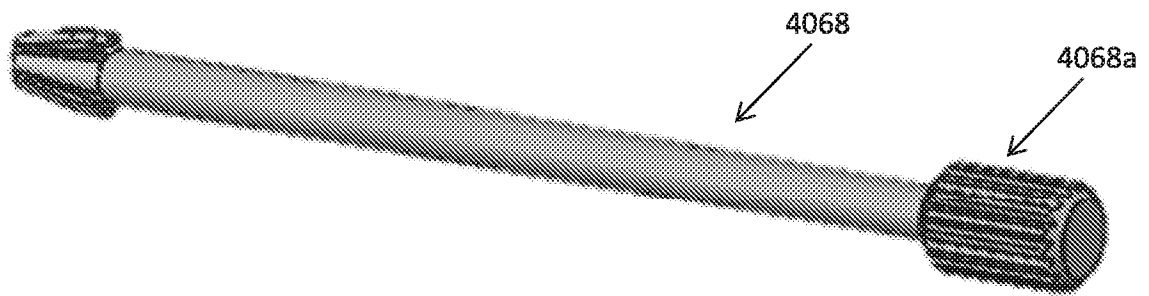


FIG. 40A

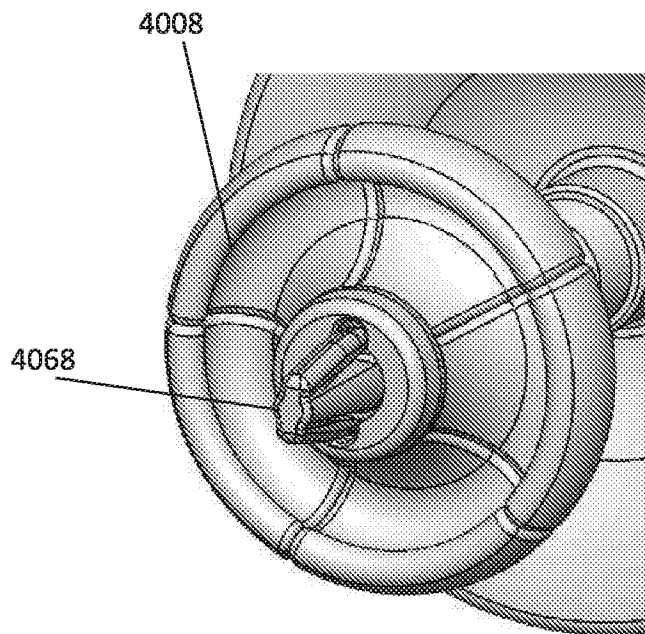


FIG. 40B

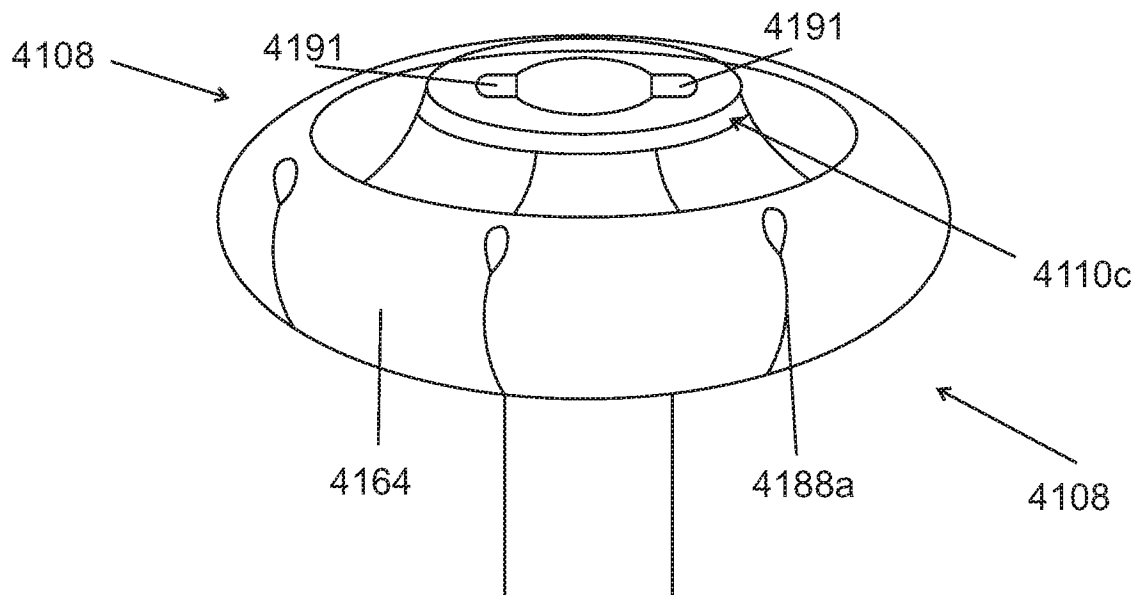


FIG. 41A

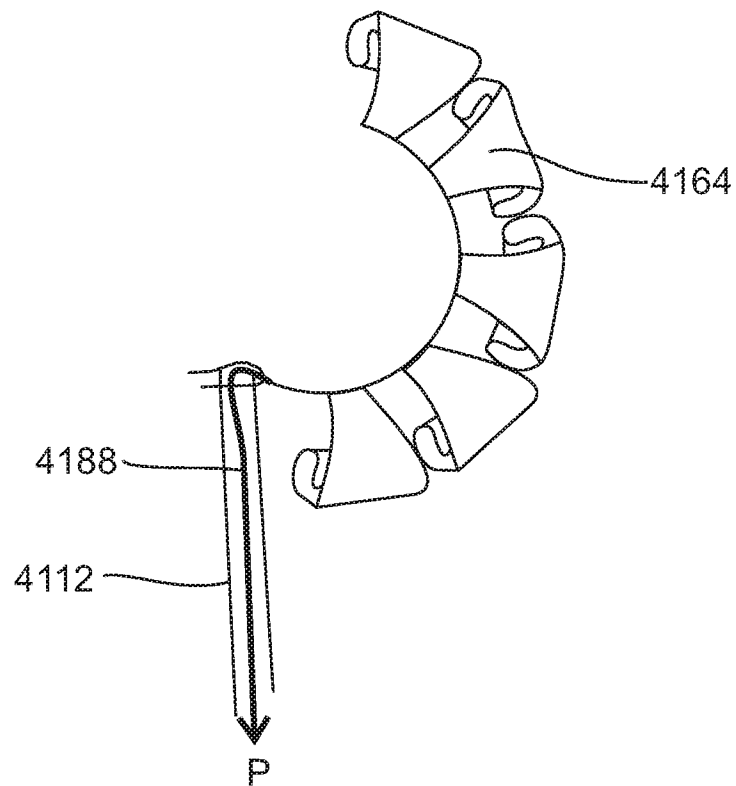


FIG. 41B

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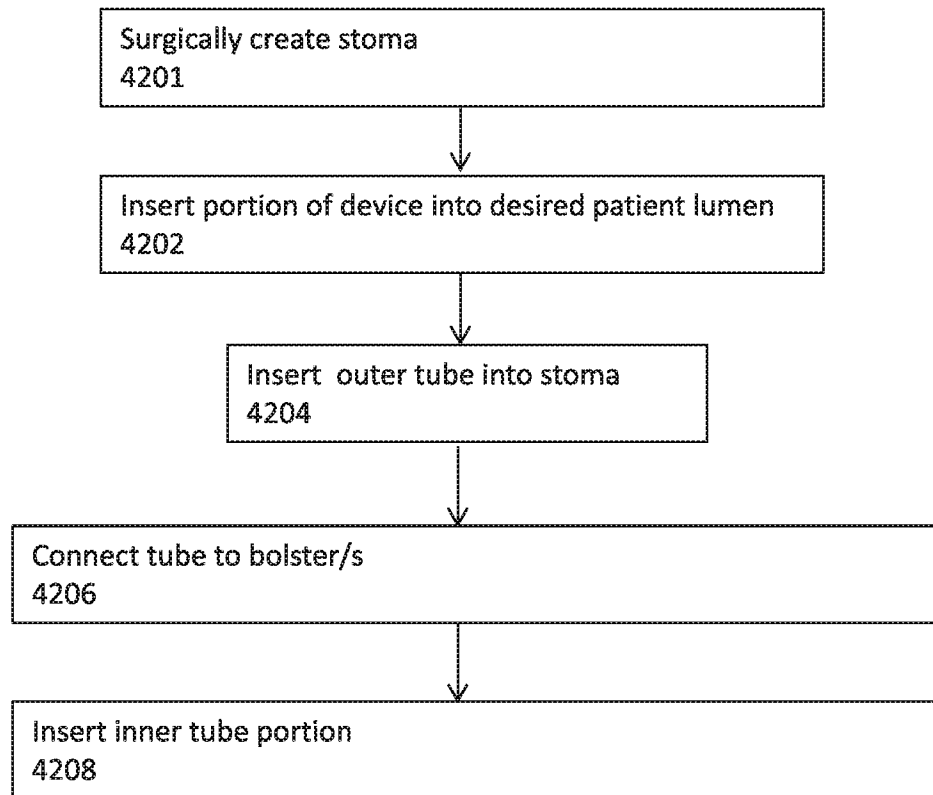


FIG. 42

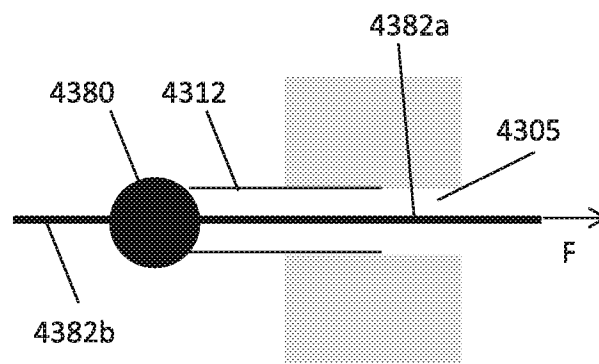


FIG. 43

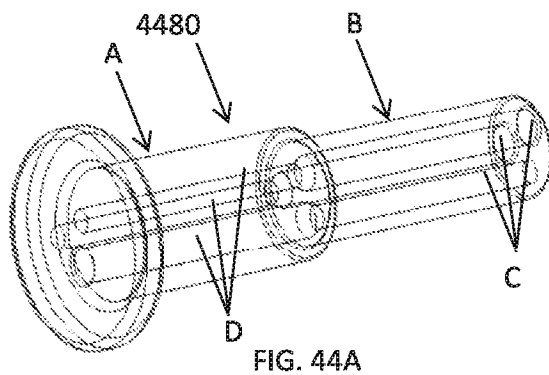


FIG. 44A

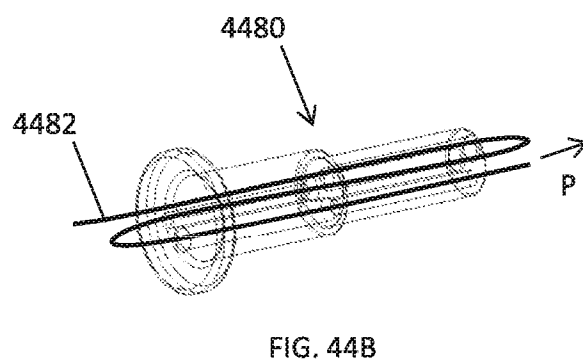


FIG. 44B

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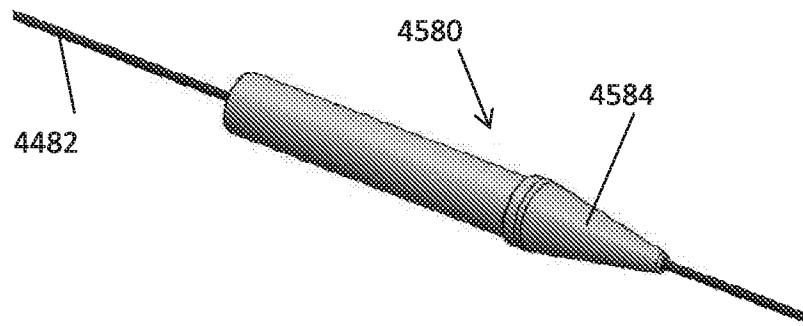


FIG. 45A

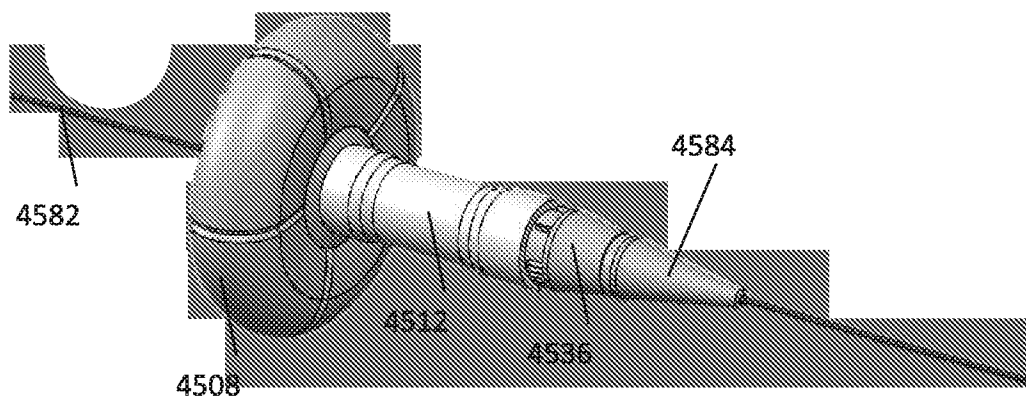


FIG. 45B

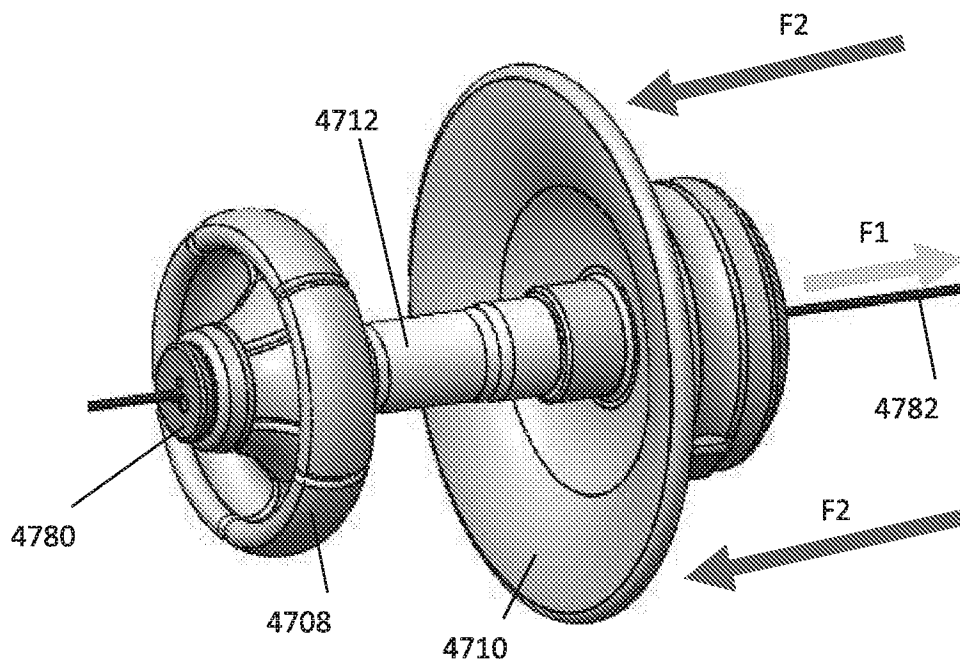
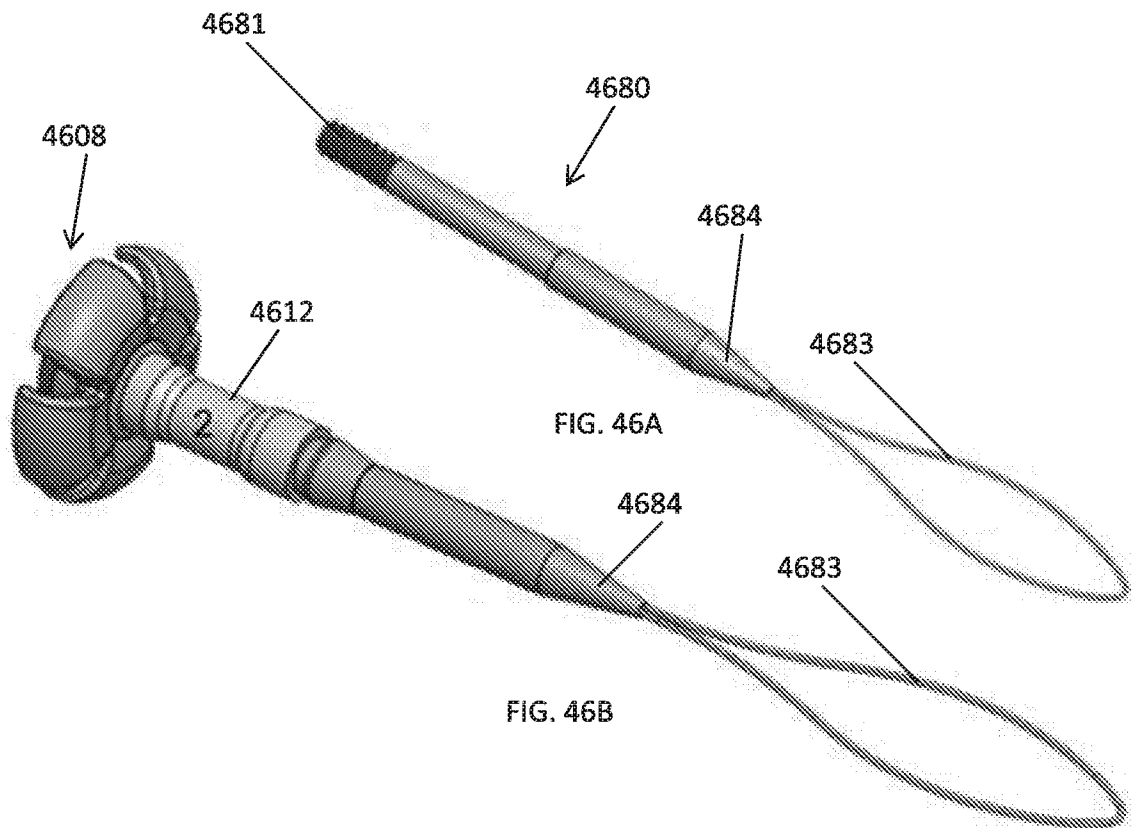


FIG. 47

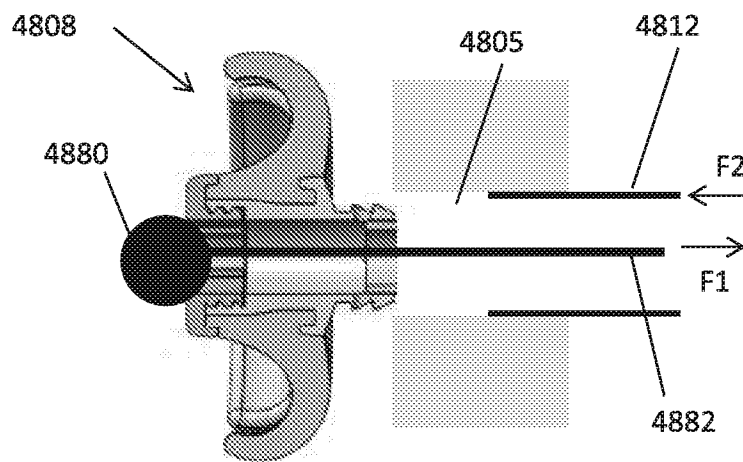


FIG. 48

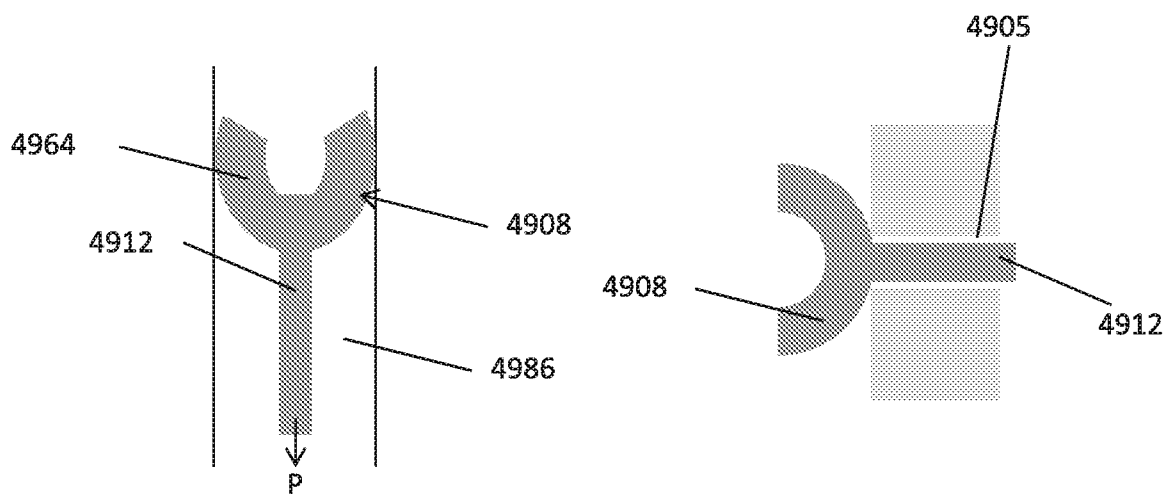


FIG. 49A

FIG. 49B

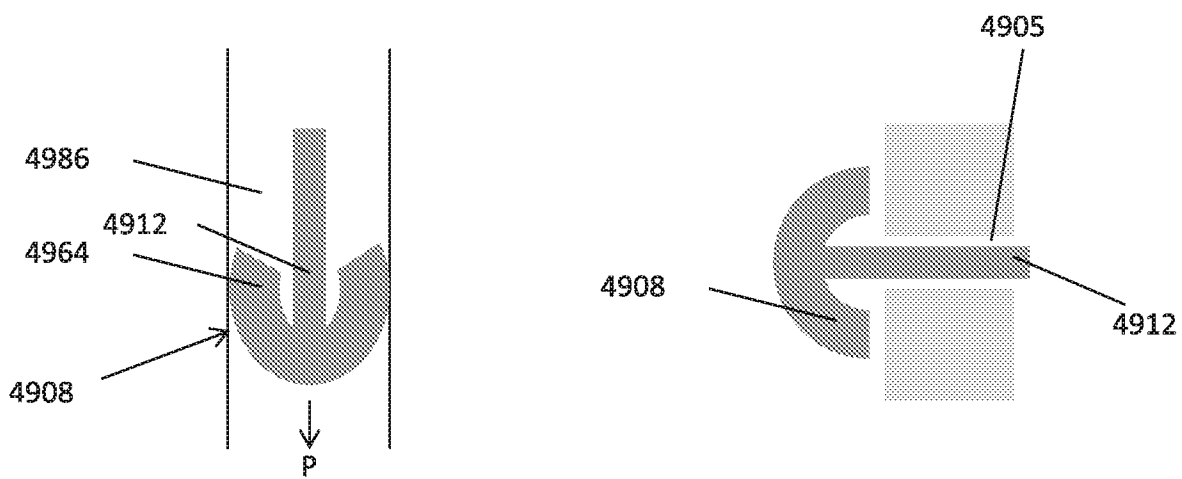


FIG. 49C

FIG. 49D

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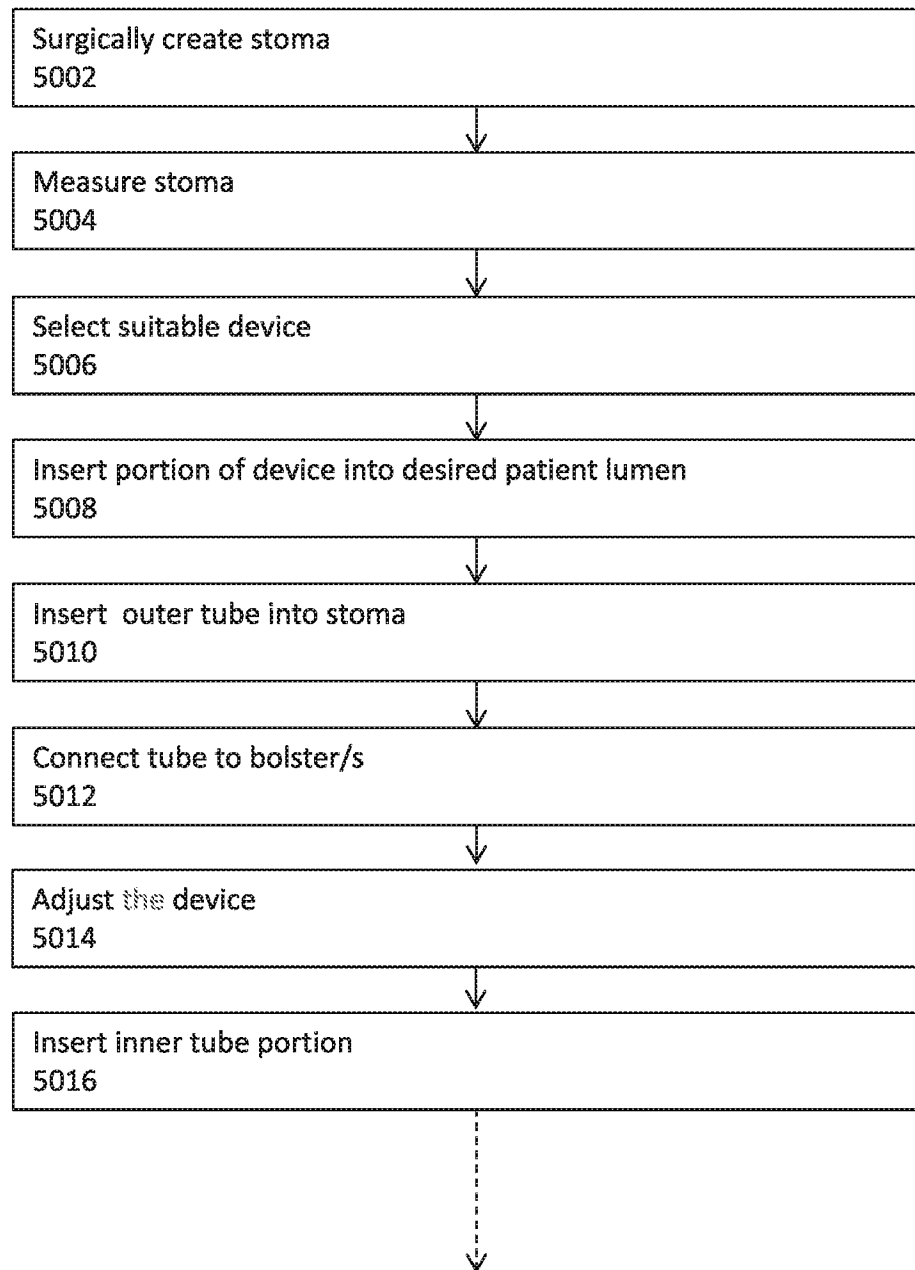


FIG. 50A

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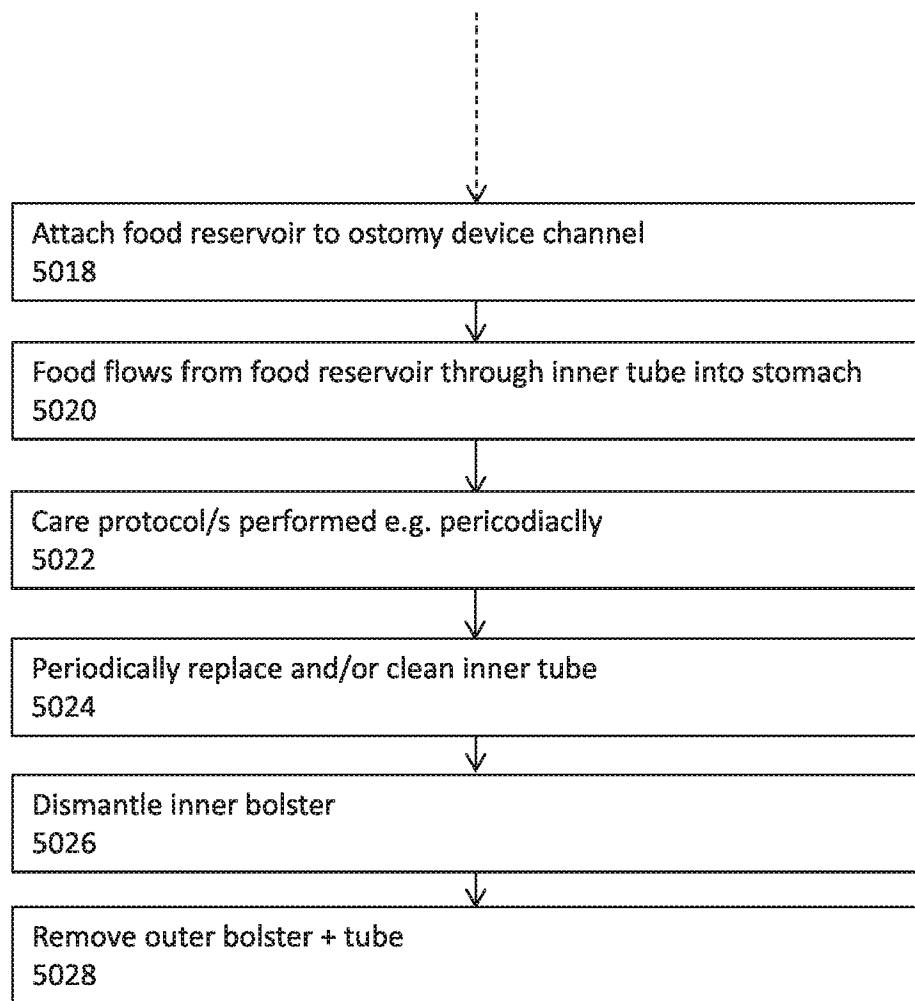


FIG. 50B

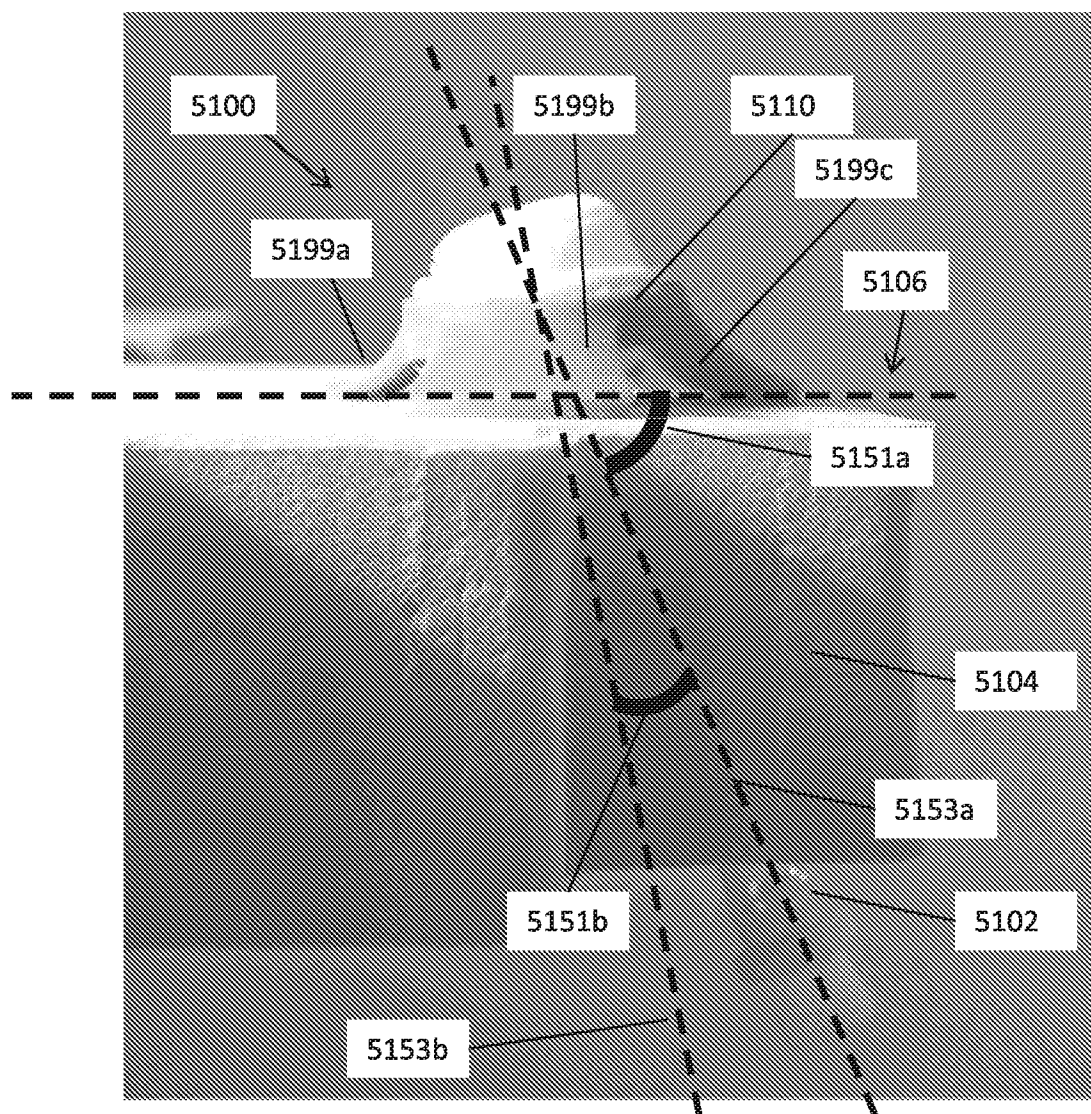
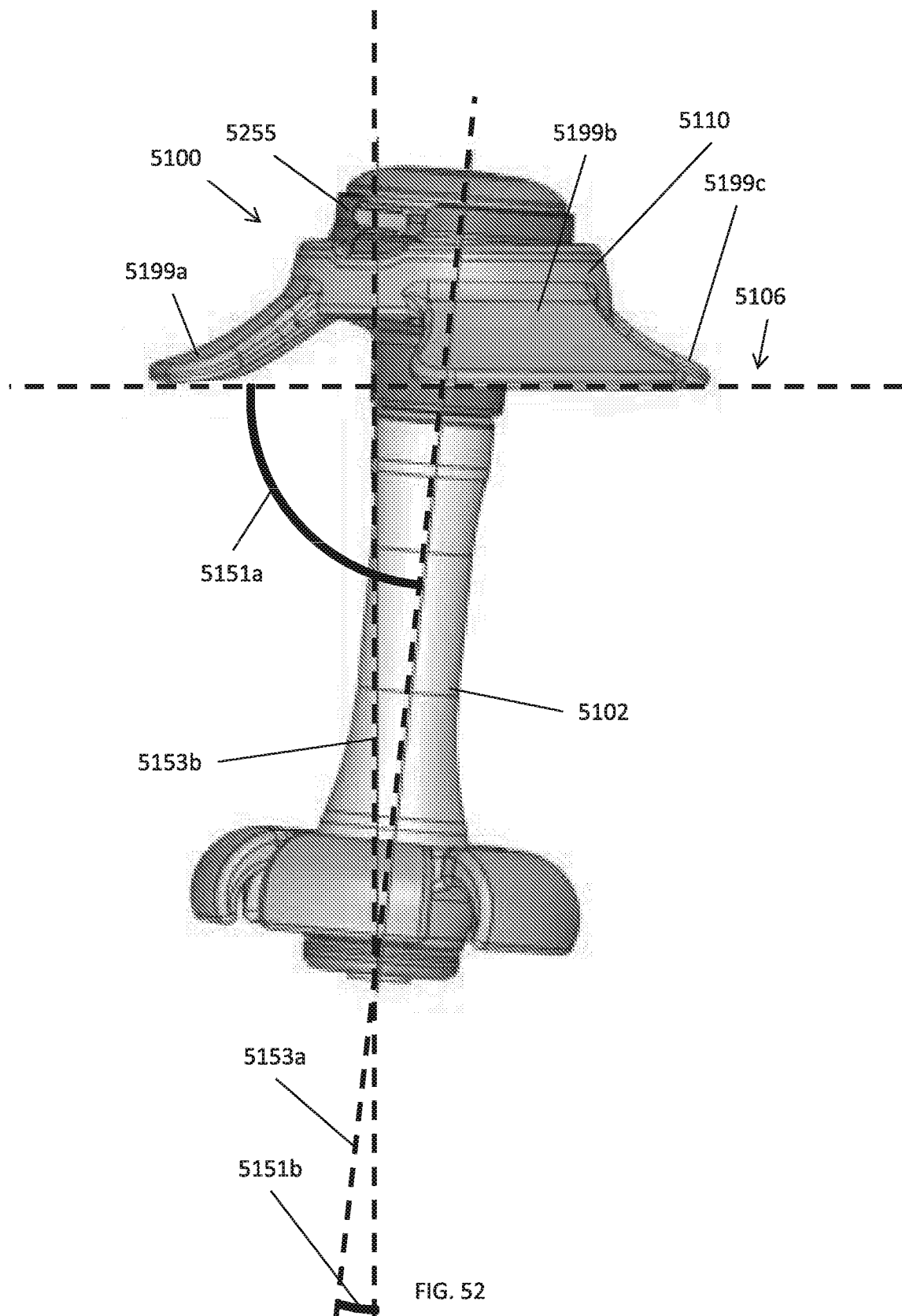
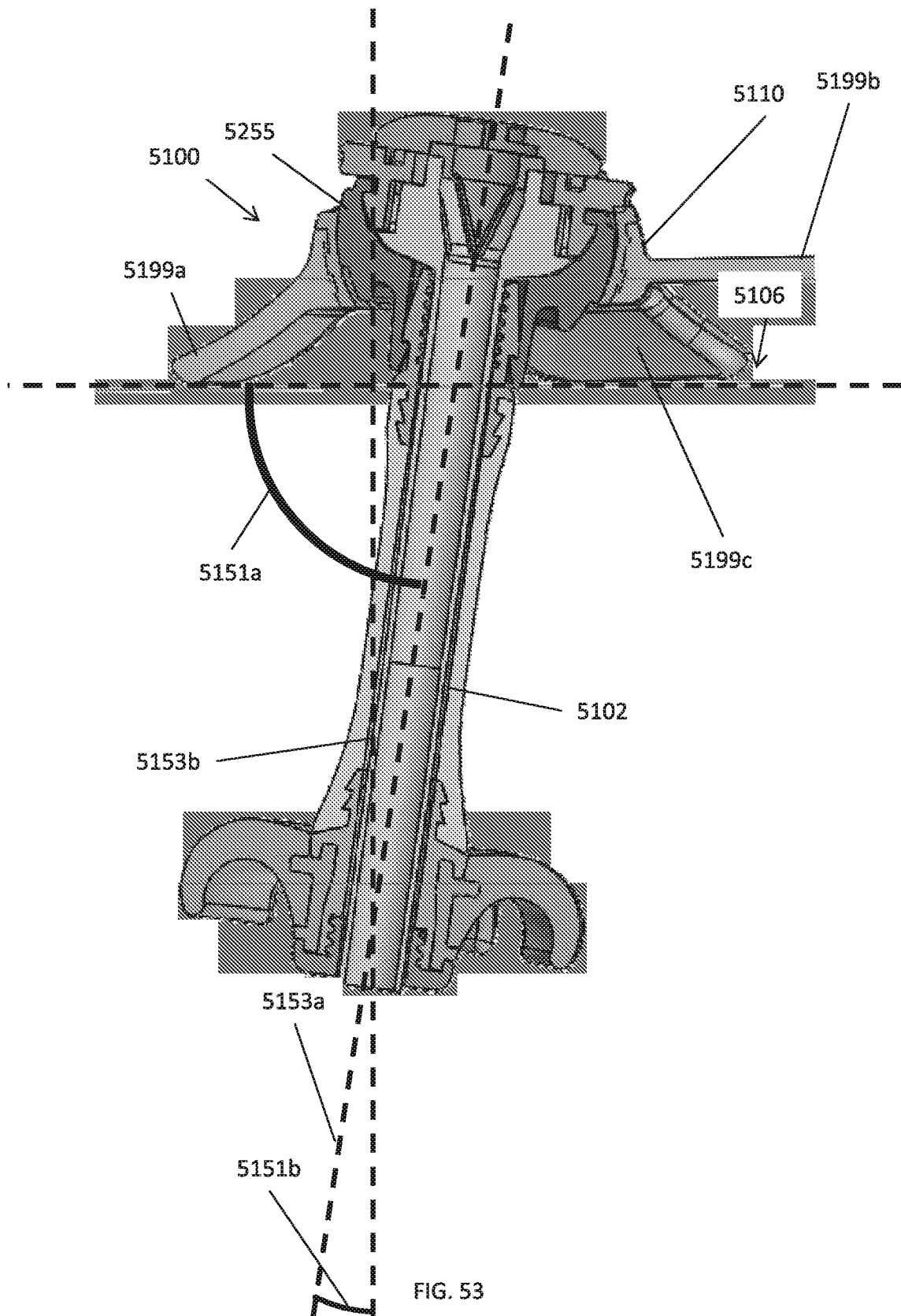


FIG. 51





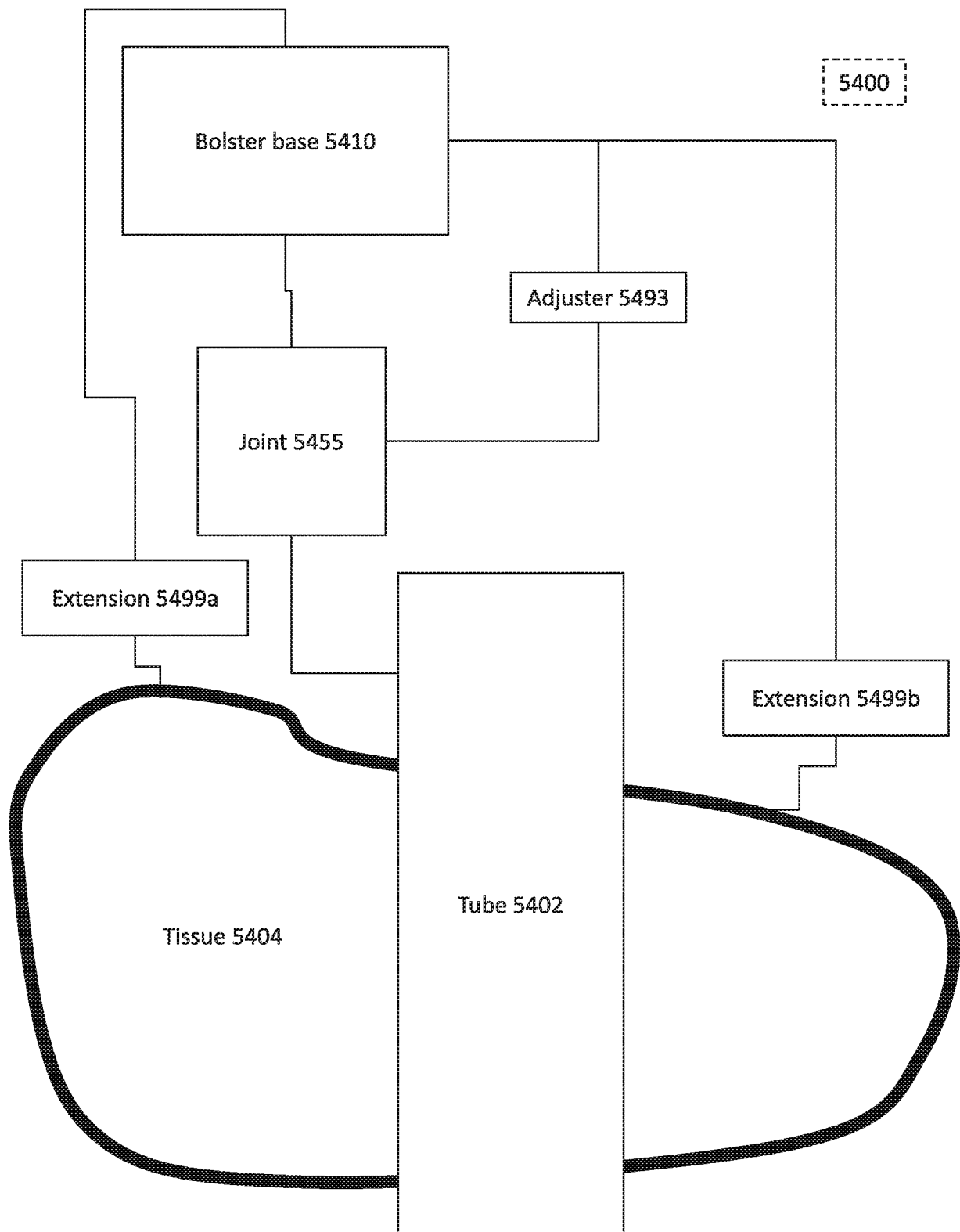


FIG. 54

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2015/051252

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61J 15/00 (2016.01)

CPC - A61J 15/0034, 15/0053 (2016.02)

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)

IPC(8) - A61B 17/34; A61J 15/00; A61M 5/32 (2016.01)

CPC - A61J 15/0015, 15/0034, 15/0038, 15/0053, 15/0057 (2016.02)

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

USPC - 604/103.030, 104, 174 (keyword delimited)

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

Orbit, Google Patents, Google Scholar

Search terms used: feeding tube, ostomy, bolster, stoma, food reservoir, source, percutaneous endoscopic gastronomy, angle, supply, clean, mesh, outer tube, sealing element

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/0052752 A1 (MCMICHAEL) 09 March 2006 (09.03.2006) entire document	1-11, 15-18, 31-35, 37-39, 47
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Y		12
Y	EP 0824929 A2 (FRESENIUS AG) 25 February 1998 (25.02.1998) entire document	12
A	WO 2010/075032 A2 (COOK INCORPORATED et al) 01 July 2010 (01.07.2010) entire document	1-47
A	US 6,039,714 A (CRACAUER et al) 21 March 2000 (21.03.2000) entire document	1-47
A	US 2010/0022969 A1 (RENAUX) 28 January 2010 (28.01.2010) entire document	1-47

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

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"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

01 April 2016

Date of mailing of the international search report

25 APR 2016

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