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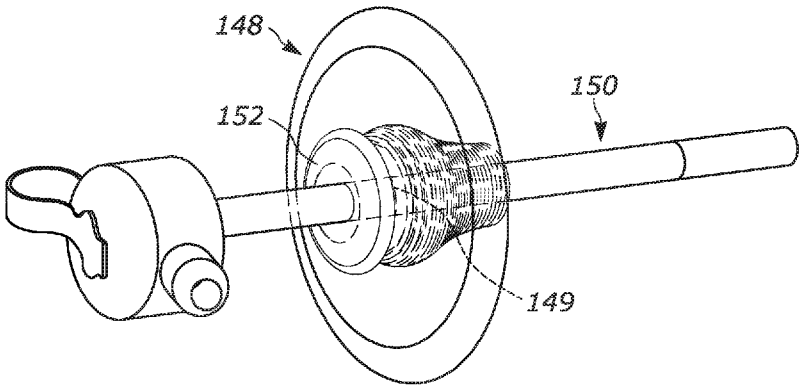

FIG. 21

(57) Abstract: Stoma site protection devices, kits, assemblies and methods are provided that prevent or minimize leakage from a stoma. A stoma site protection device includes a conformal plug that can adapt to the stoma track. Kits and assemblies include additional components such as flexible external bumpers and bandages that provide multiple sealing of the stoma.

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STOMA SITE PROTECTION DEVICES AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 62/736,637, filed September 26, 2018, entitled "STOMA LEAKAGE PREVENTION DEVICES, ASSEMBLIES AND KITS". This provisional application is hereby incorporated by reference in its entirety for all purposes.

TECHNICAL FIELD

[0002] The present disclosure relates to stoma site protection devices and methods that can include or be used with feeding tubes.

BACKGROUND

[0003] Feeding tubes such as a jejunostomy tube (J-tube) and a gastrostomy tube (G-tube) may be used to provide nutritional support for users who are on prolonged artificial ventilation, have suffered central nervous system trauma or other condition in which the user is unable to maintain weight without assistance. The tubes are typically secured by an external retention ring on the outside skin surface and an internal retention feature, such as a small inflated balloon or bumper inside the stomach (G-tube) or small intestine (J-tube). The feeding tube may remain in place for several months either in a hospital or home setting.

[0004] External retention rings may slip, which can break the seal at the stomach /intestinal wall and allows acidic gastric fluid to leak onto the skin. This leakage can cause skin irritation and wounds that can progress to infection, requiring medical intervention or additional operations. Leakage may also occur around drainage tubes, such as chest tubes and surgical drains. These types of tubes generally remain in place for several days while the user is in the hospital. As such, a need exists for a device that addresses the problem of gastric fluid leakage as well as leakage of other fluids from tubes that are inserted in a patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] FIG. 1 is a perspective view of a stoma site protection device according to an aspect of the present disclosure.

[0006] FIG. 2 is a cross-sectional view of the stoma site protection device of FIG. 1.

[0007] FIG. 3 is a perspective view of a stoma site protection device according to an aspect of the present disclosure.

[0008] FIG. 4 is a perspective view of a stoma site protection device and stoma tract patency device according to an aspect of the present disclosure.

[0009] FIG. 5 is a perspective view of a stoma site protection device according to an aspect of the present disclosure.

[0010] FIG. 6 is a perspective view of a stoma site protection device according to an aspect of the present disclosure.

[0011] FIG. 7 is a perspective view of a stoma site protection device in an un-expanded state according to an aspect of the present disclosure.

[0012] FIG. 8 is a perspective view of the stoma site protection device of FIG. 7 in an expanded state.

[0013] FIG. 9 is a perspective view of an external bumper of an assembly or kit according to an aspect of the present disclosure.

[0014] FIG. 10 is a perspective view of a bandage of an assembly or kit according to an aspect of the present disclosure.

[0015] FIG. 11 is a perspective view of a bandage of an assembly or kit according to an aspect of the present disclosure.

[0016] FIG. 12 is a perspective view of a bandage of an assembly or kit according to an aspect of the present disclosure.

[0017] FIG. 13 is a perspective view of a feeding tube assembly according to an aspect of the present disclosure.

[0018] FIG. 14 is a cross-sectional view of the feeding tube assembly of FIG. 13.

[0019] FIG. 15 is a cross-sectional view of an integrated medical device including a bandage, an external bumper and a stoma site protection device according to an aspect of the present disclosure.

[0020] FIG. 16 is a perspective view of an inner portion of a stoma site protection device according to an aspect of the present disclosure.

[0021] FIG. 17 is a cross-sectional view of a feeding tube assembly according to an aspect of the present disclosure.

[0022] FIG. 18 is an exploded view of a stoma site protection device and accompanying components and depicts an image of a stoma site protection device and accompanying components during a step of assembly according to an aspect of the present disclosure.

[0023] FIG. 19 depicts an image of a stoma site protection device and accompanying components during a step of assembly according to an aspect of the present disclosure.

[0024] FIG. 20 depicts an image of a stoma site protection device and accompanying components during a step of assembly according to an aspect of the present disclosure.

[0025] FIG. 21 depicts an image of a stoma site protection device and accompanying components during a step of assembly according to an aspect of the present disclosure.

[0026] FIG. 22 is a side view of a prior art feeding tube inserted in a user's stoma, stoma tract and stomach.

[0027] FIG. 23 depicts an image of a stoma site protection device and other assembled components during a step of insertion into a stoma, stoma tract, and stomach according to an aspect of the present disclosure.

[0028] FIG. 24 depicts an image of a stoma site protection device and other assembled components during a step of insertion into a stoma, stoma tract, and stomach according to an aspect of the present disclosure.

[0029] FIG. 25 depicts an image of a stoma site protection device and other assembled components during a step of insertion into a stoma, stoma tract, and stomach according to an aspect of the present disclosure.

[0030] FIG. 26 depicts an image of a stoma site protection device and other assembled components in their final position on a skin surface and in a stoma, stoma tract, and stomach according to an aspect of the present disclosure.

[0031] FIG. 27 is a cross-sectional view of the stoma site protection device and assembled components of FIG. 26.

DETAILED DESCRIPTION

[0032] The present disclosure refers to the terms "upper," "lower," "top," and "bottom" with respect to certain components. These terms refer to configuration of the components as illustrated in the drawings and as indicated by the character references. Further, as used herein with respect to a described element, the terms "a," "an," and "the" include at least one or more of the described element unless otherwise indicated. Further, the term "or" refers to "and/or" and "combinations thereof" unless otherwise indicated. In addition, when an element is referred to as being "over," "on," "attached" to, "connected" to, "coupled" to etc., another element, it can be directly over, on, attached to, connected to, coupled to, etc. the other element or intervening elements may also be present. In contrast, when an element is referred to as being, for example, "directly over," "directly on," "directly attached" to, "directly connected" to or "directly coupled" to another element, there are no intervening elements present. By "integral" or "integrated" is meant that the described components are fabricated as one piece or multiple pieces affixed during manufacturing or the described components are otherwise not separable using a normal amount of force without damaging the integrity (*i.e.* tearing) of the described components. A normal amount of force is the amount of force a user would use to remove a component meant to be separated from another component without damaging the components.

[0033] The present disclosure relates to stoma site protection device, kits, assemblies and methods of using a stoma site protection device to prevent leakages of fluid from a stoma. Disclosed devices, kits, assemblies, and methods include components, features, and/or steps that create a barrier to leakage at a stoma site. A stoma is an artificial opening made in a patient's skin to create a tract from an area inside the body to the patient's outer skin surface. A stoma is not a surgical incision site that is intended to be permanently closed after completion of the surgical procedure but rather an opening that is intended to remain open for a period of time after the stoma is created so that a percutaneous tube can be inserted through the

stoma and remain in the patient for a period of time to deliver, remove, process, or otherwise accept fluid from the patient's body. A stoma can lead to a hollow organ or cavity such as organs of the gastrointestinal tract or the pleural cavity of the lungs. The below disclosure is described with respect to a feeding tube, which is a vessel through which fluids are delivered as well as through which fluids are drained from internal structures such as the stomach or the intestines via a stoma in the patient's body. However, devices, kits, assemblies and methods as described herein apply to other types of tubes that are inserted into an artificial opening made in a patient's body that extend from an exterior surface of the patient's body to an internal structure of the patient's body as well as other percutaneous tubes. All stoma site protection devices and accompanying components as described herein are used for medical purposes and are therefore sterile. As used herein, a "patient" or "user" is a mammal, such as a human being.

[0034] As stated above, leakage of bodily fluid, such as bile or gastric acid, can occur at the stoma site irritating skin around the stoma site. Such stoma site leakage currently has been described as being due to an incorrectly sized tube, a low water level in the internal retention element (such as a balloon), the stomach being too full of gastric acid or formula/food, and/or stomach gas. However, without wishing to be bound by theory, it is believed that a significant cause of leakage around the stoma site is, in actuality, the friction from the tube rubbing against the patient's skin at the stoma site during regular activity causing irritation and eventually creating a fissure between the skin and the end organ or cavity from which bile or gastric acid can leak. Basic bandages are not enough to keep tubes from moving which results in irritation and increased stoma size, resulting in leakage around the feeding tube. Daily activity, weight loss or gain, users tugging at insecure tubes, tube movement with contractions of the digestive system, for example, can cause tubes to move resulting in leakage. Such movement can break the seal at the stomach/intestinal wall and expand the diameter of the stoma tract through which the tube extends resulting in gastric/biliary fluid leakage onto the skin. This leakage can cause skin irritation and wounds that can progress to infection, cellulitis or abscesses. Such conditions can require medical intervention such emergency room visits, hospital admission, antibiotic use, or additional operations/tube exchange. Leakage may

also occur around drainage tubes, such as chest tubes and surgical drains. Stoma site protection devices as disclosed herein can address this cause by allowing the tube to move freely without rubbing against the patient's skin. Such stoma site protection devices effectively act as bearings reducing the friction between the tube and the patient's skin.

[0035] Referring to FIGs. 1 and 2, a stoma site protection device **10** can comprise a body **11** having a proximal end **12**, a distal end **14**, an outer surface **15**, and an inner bearing surface **17**. Body **11** can comprise a proximal collar **16** having a collar width W_1 and defining a top opening **18**. An indented portion **20** can extend distally from proximal collar **16** and can have an indented portion width W_2 that is less than collar width W_1. W_1 of indented portion **20** can have a width that is substantially equal to the width of a stoma such that indented portion snugly conforms to and fits in stoma. The indented portion can be tubular in shape. As illustrated in FIG. 2, a lumen **19** can extend from top opening **18** to indented portion **20**. Body **11** can also include a distal non-rigid or semi-rigid plug **22** extending distally from indented portion **20**. Plug **22** can have a length L_1 that allows plug **22** to be positioned within the portion of the stoma tract that is the subcutaneous fat layer above the patient's muscle or fascia layer and below the patient's outer skin surface as depicted in FIGs. 24-27. Plug **22** can have an outer surface **24** and an inner bearing surface **27**. Inner bearing surface **27** can define a plug lumen **29** and can define a bottom opening **26**. The inner bearing surface can define a plug lumen having a diameter of between about 6 millimeters and about 10 millimeters in order to accommodate a percutaneous tube. Plug lumen **29** and bottom opening **26** can be axially aligned with and in fluid communication with lumen **19** and top opening **18** of proximal collar **16** to form a single fluid lumen. As shown in FIGs. 1 and 2, outer surface **24** of plug **22** can include ridges **30** about a circumference thereof. The ridges can extend partially or fully about the circumference of the outer wall of the plug. Such ridges can facilitate purchase between the outer wall of the plug and the stoma tract to provide a snug or tight fit of the plug in the stoma tract and prevent the plug from migrating or dislodging from the stoma tract.

[0036] In other embodiments, as illustrated in FIG. 3, the outer surface **32** of a plug **34** of a stoma site protection device **33** can be smooth so as to minimize skin

irritation in patients with sensitive skin, for example. Whether smooth or ridged, the plug can have a tapered or non-tapered shape. For example, referring to FIG. 3, the plug can have an upper portion **36** and a lower portion **38** with upper portion **36** having a bulbous shape and/or lower portion **38** tapering from a top end **40** to a bottom end **42** of lower portion **38**. The bulbous shape of upper portion **36** can increase the surface area of plug **34** that contacts the proximal surface of the stoma track to further secure the plug in the stoma tract and minimize leakage from the stoma as well. The tapered lower portion can allow for a stoma tract having a smaller diameter, easier insertion of the plug, and easier longitudinal adjustment of the plug if necessary.

[0037] FIG. 4 illustrates a stoma site protection device **44** where indented portion **45** and plug **47** have substantially the same uniform diameter along the length of the indented portion and the plug. In this configuration, plug **47** has a substantially non-tapered shape (*e.g.* the diameter of the plug is substantially the same along the length of the plug). Such a configuration can be used while a stoma site is developing, for example. Once a feeding tube is placed, the stoma tract starts maturing in about one to about two weeks and is usually well formed in about four to about six weeks. Such a taperless configuration mimics the path of a maturing stoma. Once the stoma is matured and fully developed, a patient or caregiver can place a stoma site protection device having a tapered plug, for example, into the stoma for greater stability. Such a configuration can benefit temporary as well as chronic feeding tube patients.

[0038] FIG. 5 illustrates a stoma site protection device **48** with a longitudinal slit **50** extending fully or partially along the outer wall **52** of the device. Such a slit allows the stoma site protection device to be placed around an existing percutaneous tube so that the tube does not need to be removed from the stoma. The device can be opened manually by a patient or caregiver, wrapped around the tube, and then closed. The end user can then slide the device distally along the tube into the stoma. Such a configuration can be useful for several different types of tubes, such as, for example, Dangler feeding tubes commonly used when developed a stoma site and other percutaneous tubes such as those used with ventricular assist devices (*e.g.* a left ventricular assist device (LVAD)).

[0039] FIG. 6 illustrates a non-cannulated stoma and stoma tract patency device **54** comprising a solid body **55** comprising a proximal collar **57** and a plug **59** extending distally from proximal collar **57**. Stoma and stoma tract patency device **54** is solid with no lumen extending therethrough. Such a configuration can be used to maintain a stoma site when a patient does not have an internal retention element, such as a balloon, inserted in the stomach or other organ or cavity for some period of time. Because the device is solid in its entirety, it provides enough rigidity to prevent the site from closing but also reduces skin irritation.

[0040] The inner bearing surface of a plug of a stoma site protection device can have a Shore durometer hardness greater than the Shore durometer hardness of the outer wall so that the inner bearing wall is more rigid and the outer surface is more conformal. Such a configuration can allow for the feeding tube to have sufficient structural support within the plug such that the feeding tube stays in place but allows the plug to conform to the user's stoma tract, creating a stronger seal. In other words, the plug can be pliable enough to allow a feeding tube to move slightly as needed when the patient moves but still prevent leaks from occurring. The outer surface of a plug of a stoma site protection device can be fabricated from a semi-rigid material, such as a silicone material, so that the plug conforms to the stoma tract, adapts to varying stoma sizes, and achieves the appropriate fit and anchoring in the stoma tract. The stoma site protection device can be an integral, one-piece device.

[0041] Referring to FIG. 7 and 8, a plug **56** of a stoma site protection device **58** can be a balloon having a top portion **60** and a bottom portion **62** and that can transition from an un-inflated state to an inflated state. Plug **56** can have an inflation lumen **64** with one end **66** in fluid communication with bottom portion **62** of plug **56** and another end **68** in fluid communication with an infusion port **70** at top portion **60** of plug **56**. Such a configuration allows the plug to be inflated upwards from the lowest point of the plug, thereby creating a seal as close as possible to the initial site of potential leakage in the digestive tract (such as the stomach or intestine), for example.

[0042] In certain aspects, a stoma site protection kit or assembly is provided that includes a stoma site protection device and other components that can improve

the functionality of a feeding tube assembly or other medical tube assembly, such as by creating multiple seals of the stoma. For example, referring to FIG. 9, a stoma site protection assembly or kit can include a flexible bumper **72** that defines an opening **74** that can be axially aligned with the longitudinally extending lumen of a stoma site protection device in use and that is sized and configured to be placed about the indented portion of the body of a stoma site protection device as shown in FIGs. 21 and 27 and discussed in more detail below. As shown in FIG. 9, opening **74** can be surrounded by a dome shaped portion **75**, which can be surrounded by a flange **76**. In use, the bumper sits externally on the patient's skin preventing the stoma site protection device from slipping into the stoma and stabilizing the entire feeding tube assembly. For example, after the feeding tube is inserted in the patient, the bumper can be compressed over the stoma putting the entire tube assembly under tension preventing undesirable movement of the tube assembly. Dome shaped portion **75** ensures skin contact with the bumper is minimal and away from the stoma site (see *e.g.* FIG. 27) to prevent irritation at the stoma site. Skin contact can be limited to the area of the skin in contact with flange **76**, which is spaced from the stoma site in use (see *e.g.* FIG. 27). The bumper can have an outer diameter of between about 59 millimeters and about 63 millimeters to adequately cover the stoma site as well as stabilize the percutaneous tube. The bumper can have a height of between about 5 millimeters and about 9 millimeters.

[0043] Referring to FIGs. 10-12, a stoma site protection kit or assembly can include a bandage **78** defining an opening **80** extending therethrough to accommodate the proximal end of a feeding tube. Bandage can secure a stoma site protection device and a bumper (in embodiments including a bumper) to the patient's skin.

[0044] A dressing such as a gauze dressing can be placed over the stoma to prevent leakage from the stoma and protect both the stoma and the feeding tube. Bandage **78** can cover the dressing and provide pressure to the stoma site protection device, the underlying dressing and the feeding tube. The bandage can be a flexible adhesive bandage and fabricated from silicone, for example. It can be taken off to change the gauze and access the feeding tube. The bandage can have a larger surface area than the bumper and can have an annular disc shape.

[0045] Referring to FIG. 11, in certain aspects, a bandage **80** can have a lateral slit **82** extending from and in fluid communication with a medial aperture **84**. A slit can allow a patient or caregiver to place the bandage around the tube just below the proximal end or head of the tube. This allows for the smallest requisite aperture in the bandage and maximal coverage of the bandage over the bumper to assist with securing the device in place. By pulling apart the ends of the bandage defining the slit, a user can remove the bandage from the stoma site without having to remove the feeding tube. When replacing the bandage, the user can overlap the ends of the bandage defining the slit to securely adhere the bandage to the stoma site.

[0046] Referring to FIG. 12, bandage **86** can have a plurality of ribs **88** on top surface **90** thereof to provide sufficient points of contact for a final layer of an adhesive tape or covering to be positioned on the bandage. In particular, ribs **88** can provide enough surface area for proper adhesion of a final covering layer and can reduce tugging during removal of the final covering layer.

[0047] The bandage or other component that is placed over the stoma site protection device can include a moisture-sensitive, color-changing ink incorporated into the bandage or other protective component (such as an external bumper, for example) that changes color in the presence of liquid moisture. Incorporation of such an ink can alert a user or caretaker that fluid is leaking from the stoma. In the event that fluid, such as bile, does exit the stoma, the bandage can absorb such fluid before such fluid damages the stoma site. The bandage or other component that is placed over the stoma site protection device (such as an external bumper) can have a pH sensor to detect the presence of gastric acid, which could also indicate leakage from the stoma.

[0048] In certain embodiment, a feeding tube assembly is provided with a stoma site protection device and other optional components that can improve the functionality of the feeding tube. Referring to FIGs. 13-14, a feeding tube assembly **92** can comprise a proximal portion **94**, a distal portion **96**, and a lumen **98** extending longitudinally therebetween. Proximal portion **94** can comprise a proximal adapter **100** comprising one or more ports **102** and **104**. Port **102** can be a patient or caregiver access port and can be longer than port **104** making it easier for the patient or caregiver to handle. Port **104** can be shorter than port **102** and designated

for use by a doctor. A feeding tube **106** can extend distally from proximal adapter **100**. A first bumper **108** can be disposed about tube **106** below proximal adapter **100** and a second bumper **110** can be disposed about tube **106** below first bumper **108** at distal portion **96**. First bumper **108** can be dome shaped and flexible to facilitate compression of the bumper when a bandage **112** is applied over first bumper **108** (the arrows in FIG. 14 schematically illustrate the flexibility of first bumper **108**. Second bumper **110** can be an expandable balloon or other structure that can positioned against the opening in the stomach or other internal structure. In use, the first bumper sits against the proximal end of the stoma tract on the outer surface of the user's skin and the second bumper sits on the distal end of the stoma tract on the inside surface of the stomach or intestines. Feeding tube assembly **92** can include a stoma site protection device comprising a non-rigid or semi-rigid plug **114** disposed about tube **106** between first bumper **108** and second bumper **110**. The stoma site protection device can have a tapered configuration and can be inflated to plug and block the stoma opening. The feeding tube assembly can also include a flexible adhesive bandage **112** that is configured to be placed against the top surface of the first bumper. Bandage **112** can have a tapered design as shown in FIG. 14 to prevent or minimize snagging or interference with the patient's clothing, for example.

[0049] In certain embodiments, a stoma site protection device is part of an integrated single one-piece device that can plug the stoma tract and stabilize and secure a feeding tube assembly or other medical tube assembly. Referring to FIGs. 15-17, a device **116** can have a proximal portion **118**, a distal portion **120** and a lumen **122** extending longitudinally therethrough. Distal portion **120** can comprise a stoma site protection device **124** that has an inner portion **126** with supporting flexible ribs **128** and is surrounded by a tapered cup **130** that has a flexible outer surface. During insertion into the stoma tract, the ribs can compress and then self-expand within the stoma tract as the taper cup inverts over the ribs as indicated by the arrows in FIG. 15. Device **116** can further comprise a proximal bumper **134** that is above and integral with stoma site protection device **124** and a bandage **136** that is above and integral with proximal bumper **134**. Bumper **134** can be dome-shaped and flexible so that it is compressed as bandage **136** is applied against the user's

skin (the arrows in FIG. 17 schematically illustrate the flexibility of proximal bumper **134**. Bandage **136** can have a tapered surface **138** as shown in FIGs. 17. Bandage **136** can have a tapered port **139** aligned with longitudinally extending lumen **122** of device **116** to aid in feeding tube ingress. FIG. 17 illustrates a feeding tube **140** inserted within longitudinally extending lumen **122** of device **116**. The top surface **142** of bandage **136** can have a plurality of ribs **141** to provide sufficient points of contact for a final layer of an adhesive tape or covering to be positioned on the bandage. The points of contact also reduce the effort to remove the adhesive covering from the bandage and the user's skin. Device **116** can be part of a feeding tube assembly that includes feeding tube **140**, a proximal adapter **143**, and a distal bumper **144** as illustrated in FIG. 17.

[0050] FIG. 18-21 depict images of a stoma site protection device and accompanying components during different steps of assembly with respect to a feeding tube, for example. FIG. 18 depicts a stoma site protection device **146** aligned with a bumper **148** and a feeding tube **150** having an internal retention element, such as a balloon **182** (shown inflated in FIGs. 24-27). Stoma site protection device can comprise a body having a proximal end, a distal end, an outer surface, an inner bearing surface, and a lumen extending longitudinally therethrough. The body can comprise a proximal collar **152** having a collar width and defining a top opening **154**. An indented portion can extend distally from proximal collar **156** and can have an indented portion diameter that is less than the collar diameter. A plug **158** can extend distally from the indented portion and can have an inner bearing surface that defines a bottom opening **160** and a plug lumen **162**. Plug lumen **162** can be axially aligned and in fluid communication with bottom opening **160** and top opening **154**. Bumper **148** can be dome-shaped, for example, and can define a substantially central opening **164**. Feeding tube **150** can be inserted into opening **164** of bumper **148**, top opening **154** of collar **152**, plug lumen **162**, and through bottom opening **160** as shown in FIGs. 19 and 20. Because collar **152** is flexible, it can be urged through opening **164** of bumper **148** such that bumper **148** is positioned about indented portion **149** of stoma site protection device as shown in FIG. 21, which illustrates a fully assembled stoma site protection device **146**, bumper, **148**, and feeding tube **150**.

[0051] Methods of using a stoma site protection device are also provided herein. FIG. 22 illustrates a prior art feeding tube **166** inserted into a stoma **170** with the proximal end of the feeding tube at the stoma site and the distal end of feeding tube **166** in the stomach **172**. As stated above, without wishing to be bound by theory, it is believed a significant cause of leakage around a stoma site is the friction from the tube rubbing against the skin at the stoma site during regular activity causing irritation and the break-down of skin eventually creating a fissure **174** (slightly exaggerated in FIG. 22 of the purposes of illustration) through which bile or gastric acid **176** can leak out of stoma **170** to the patient's skin outer surface **178**. FIGs. 23-26 illustrate a method of using a stoma site protection device with a feeding tube to prevent or mitigate the leakage of fluid from stoma **170**. Referring to FIG. 23, an assembled stoma site protection device **146**, bumper **148**, and feeding tube **150** (referred to herein with respect to FIGs. 23-27 as an "assembly **180**" and as depicted in FIG. 21) is aligned with stoma **170**. Referring to FIG. 24, stoma site protection device **146** and feeding tube **150** are inserted through stoma **170**. Plug **158** is positioned in the subcutaneous fat layer **188** above the patient's muscle layer **190** (and/or fascia layer **151**) and below skin outer surface **178**, balloon **182** of feeding tube **150** is positioned in stomach **172**, and bumper **148** is positioned over stoma **170**. Bumper **148** sits externally on the patient's outer skin surface **178** and is compressed over stoma **170** putting the entire assembly under tension to prevent undesirable movement of assembly **180**. The internal retention element of feeding tube **150** (illustrated in the presently described figures as a balloon **182**) is inflated using a syringe **184**, for example, to secure the distal end of feeding tube in stomach **172**. As schematically illustrated in FIG. 25**,** because stoma site protection device **146** effectively acts as a bearing, there is no friction between the patient's skin outer surface **178** and feeding tube **150**. As such, there is no break-down of skin **178** such that a fissure is created between the stomach and the stoma. With no such fissure, there is no leakage of bile or gastric acid **176** as is the case with prior art feeding tube **166** illustrated in FIG. 22. Referring to FIGs. 25-27, a bandage **186** is placed over collar **152** of stoma site protection device **146** and bumper **148** to secure stoma site protection device **146** and bumper **148** to the patient's skin.

[0052] As stated above, devices, kits, assemblies and methods as described herein can be used for medical tubes, such as percutaneous tubes, that are inserted into a stoma. Such tubes include feeding tubes that are placed through the nose, including nasogastric, nasoduodenal, and nasojejunal tubes; or placed directly into the abdomen, such as a gastrostomy, gastrojejunostomy, or jejunostomy feeding tube. Other medical tubes include chest tubes and surgical drains. Chest tubes include tubes used with ventricular assist devices including left and/or right ventricular assist devices. Non-limiting examples of dimensions of low profile feeding tubes is a length of between about 1.0 centimeters (cm) to about 4.5 cm and a tube diameter of between about 12 French (Fr) to about 24 Fr. Non-limiting examples of dimensions for adult chest tubes are about 20 Fr to about 40 Fr and about 6 Fr to about 26 Fr for children chest tubes. Non-limiting examples of dimensions for percutaneous drainage tubes are about 6.5 Fr to about 20 Fr.

[0053] Stoma site protection devices as disclosed herein prevent acid or other fluids from leaking out of the tube, provide pressure on the tube, and can be released from the tube in order to remove pressure or to allow drainage. The plug can have a depth such that it prevents acid or other fluid from accumulating near the upper end of the skin. As such, a stoma site protection device can prevent skin irritation surrounding the stoma. In addition, the plug does not have a depth so great that it compromises the seal between the feeding tube and the internal site, such as the stomach or intestine.

[0054] Each of the disclosed aspects and embodiments of the present disclosure may be considered individually or in combination with other aspects, embodiments, and variations of the disclosure. Further, while certain features of embodiments and aspects of the present disclosure may be shown in only certain figures or otherwise described in the certain parts of the disclosure, such features can be incorporated into other embodiments and aspects shown in other figures or other parts of the disclosure. Along the same lines, certain features of embodiments and aspects of the present disclosure that are shown in certain figures or otherwise described in certain parts of the disclosure can be optional or deleted from such embodiments and aspects. Additionally, when describing a range, all points within that range are included in this disclosure. Further, unless otherwise specified, none

of the steps of the methods of the present disclosure are confined to any particular order of performance. Furthermore, all references cited herein are incorporated by reference in their entirety.

What is claimed is:

1. A stoma site protection device comprising:

a body having a proximal end, a distal end, an outer surface, an inner bearing surface, and a lumen extending longitudinally therethrough, the body comprising:

a proximal collar having a collar width and defining a top opening;

an indented portion extending distally from the proximal collar and having an indented portion width that is less than the collar width; and

a non-rigid or semi-rigid plug extending distally from the indented portion and having an outer surface, an inner bearing surface, a bottom opening and a plug lumen, the plug lumen axially aligned and in fluid communication with the bottom opening and the top opening, the stoma site protection device being sterile and being sized and dimensioned to prevent or minimize leakage of fluid from a stoma.

2. The stoma site protection device of claim 1, wherein the outer surface of the plug includes ridges about a circumference thereof.

3. The stoma site protection device of claim 1, wherein the inner bearing surface of the plug has a Shore durometer hardness greater than the outer surface of the plug.

4. The stoma site protection device of claim 1, wherein the plug has an upper portion and a lower portion, the upper portion having a bulbous shape, the lower portion tapering from a top end to a bottom end of the lower portion.

5. The stoma site protection device of claim 1, wherein the indented portion and the plug have substantially the same uniform diameter along the length of the indented portion and the plug.

6. The stoma site protection device of claim 1, wherein the plug is a balloon having a top portion and a bottom portion.

7. The stoma site protection device of claim 6, wherein the plug tapers from the top portion of the balloon to the bottom portion of the balloon.

8. The stoma site protection device of claim 6, wherein the plug has an inflation lumen with one end in fluid communication with the bottom portion of the balloon and another end in fluid communication with an infusion port.

9. A stoma site protection kit comprising:

the stoma site protection device of claim 1 and further comprising a bumper defining an opening extending longitudinally therethrough, the opening sized and configured to be placed about the indented portion of the body of the stoma site protection device.

10. The stoma site protection kit of claim 9, wherein the bumper is flexible and has a dome-shaped portion surrounding the opening, the dome-shaped portion surrounded by a flange.

11. The stoma site protection kit of claim 9, further comprising an adhesive bandage defining an opening extending longitudinally therethrough and sized and configured to be placed about the bumper.

12. The stoma site protection kit of claim 11, wherein the opening of the adhesive bandage is in fluid communication with a laterally extending slit.

13. The stoma site protection kit of claim 11, wherein the adhesive bandage has a top surface comprising a plurality of ribs.

14. The stoma site protection kit of claim 11, wherein the adhesive bandage has a surface area greater than the surface area of the bumper.

15. The stoma site protection kit of claim 11, wherein the adhesive bandage has a moisture-sensitive, color-changing ink incorporated therein.

16. A feeding tube assembly comprising:

a proximal adapter comprising one or more ports;

a feeding tube extending distally from the proximal adapter;

a first bumper disposed about the feeding tube below the proximal adapter;

a second bumper disposed about the feeding tube below the first bumper; and

a stoma site protection device comprising a non-rigid or semi-rigid plug disposed about the tube between the first bumper and the second bumper, the stoma site protection device being sterile.

17. The feeding tube assembly of claim 16, wherein the first bumper is flexible and dome-shaped.

18. The feeding tube assembly of claim 16, wherein the plug tapers from a top portion to a bottom portion of the plug.

19. The feeding tube assembly of claim 16, wherein the stoma site protection device further comprises:

a proximal collar having a top opening;

an indented portion extending distally from the proximal collar; and

the non-rigid or semi-rigid plug extending distally from the indented portion and having a bottom opening and a plug lumen axially aligned with the top opening of the proximal collar.

20. A one-piece medical device having a proximal portion, a distal portion, and a lumen extending longitudinally therethrough, the medical device comprising:

a stoma site protection device at the distal portion of the medical device and comprising:

an inner portion having supporting ribs disposed about an outer surface of the inner portion;

a tapered cup surrounding the inner portion and having a flexible outer surface;

a proximal bumper that is above and integral with the stoma site protection device; and

a bandage that is above and integral with the proximal bumper, the medical device being sterile.

21. The one-piece medical device of claim 21, wherein the bandage has a tapered outer surface.

22. The one-piece medical device of claim 21, wherein the bandage has a tapered port aligned with the longitudinally extending lumen.

23. A method of using a stoma site protection device in a patient to prevent or minimize leakage of fluid from the stoma of a patient comprising:

obtaining the stoma site protection device of claim 1;

obtaining a percutaneous tube having a proximal portion with a proximal end, a distal portion having an internal retention element, and a tube shaft therebetween;

inserting the percutaneous tube through the lumen of the body of the stoma site protection device and through the bottom opening of the plug;

inserting the stoma site protection device and percutaneous tube through the stoma;

positioning the plug in at least a portion of a stoma tract in fluid communication with the stoma;

positioning the collar of the stoma site protection device directly or indirectly against the patient's outer skin surface;

positioning the distal portion of the percutaneous tube into a cavity or organ of the patient's body;

deploying the internal retention element to secure the distal portion of the percutaneous tube in the patient's cavity or organ; and

preventing or minimizing leakage of fluid from the stoma.

24. The method of claim 23, further comprising:

obtaining a bumper defining an opening extending longitudinally therethrough;

inserting the percutaneous tube through the opening of the bumper prior to inserting the percutaneous tube through the lumen of the body of the stoma site protection device and through the bottom opening of the plug;

positioning the bumper about the indented portion of the stoma site protection device; and

placing the bumper at the stoma site over the collar after inserting the stoma site protection device and percutaneous tube through a stoma of the patient.

25. The method of claim 24, wherein the bumper is flexible and has a dome-shaped portion surrounding the opening of the bumper, the dome-shaped portion surrounded by a flange.

26. The method of claim 25, further comprising positioning the flange directly against the patient's outer skin surface.

27. The method of claim 25, wherein the flange is the only portion of the bumper that is directly against the patient's outer skin surface.

28. The method of claim 24, further comprising:

obtaining an adhesive bandage defining an opening extending longitudinally therethrough;

placing the adhesive bandage on a top surface of the bumper to cover the bumper and below the proximal end of the proximal portion of the percutaneous tube, the proximal portion of the percutaneous tube extending through the opening of the adhesive bandage.

29. The method of claim 28, wherein the opening of the adhesive bandage is in fluid communication with a laterally extending slit, the method further comprising:

aligning the opening of the adhesive bandage and the laterally extending slit with the proximal portion of the percutaneous tube;

placing the adhesive bandage on a top surface of the bumper to cover the bumper and below the proximal end of the proximal portion of the percutaneous tube, the proximal portion of the percutaneous tube extending through the opening of the adhesive bandage.

30. A method of maintaining the patency of a stoma tract comprising the method of claim 23 and further comprising:

removing the stoma site protection device and percutaneous tube from the patient;

inserting a stoma and stoma tract patency device into the stoma and stoma tract of the patient, the stoma and stoma tract patency device comprising a solid plug; and

maintaining the patency of the stoma and stoma tract.

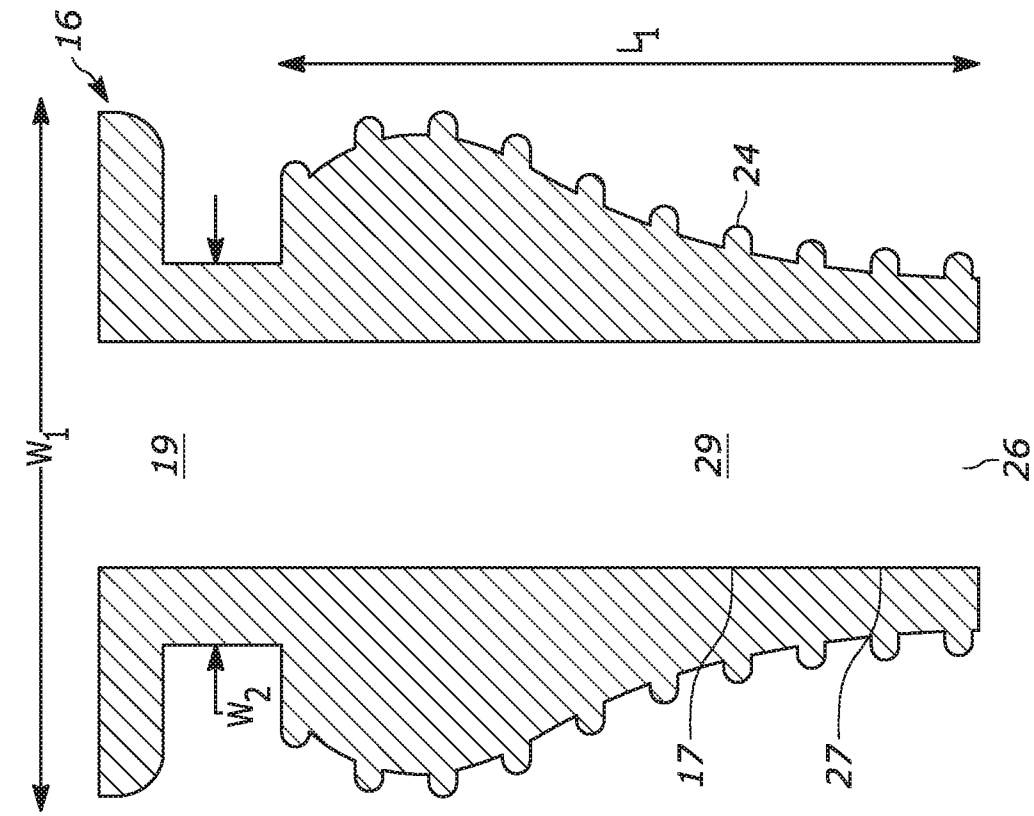

FIG. 2

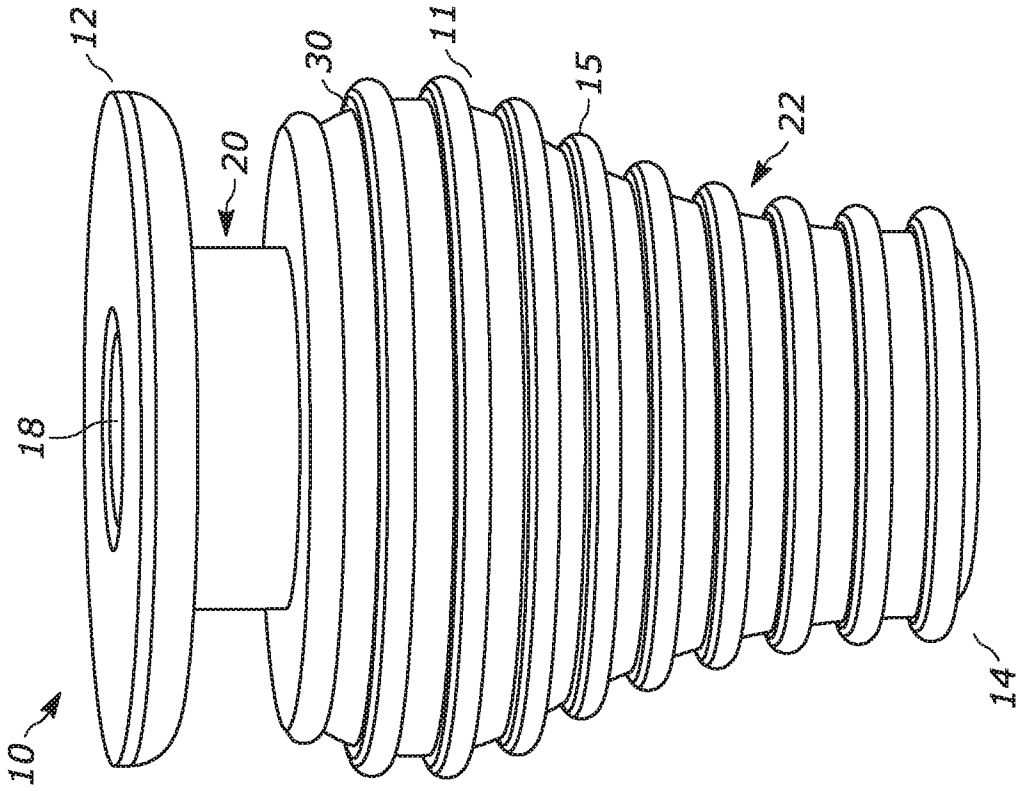

FIG. 1

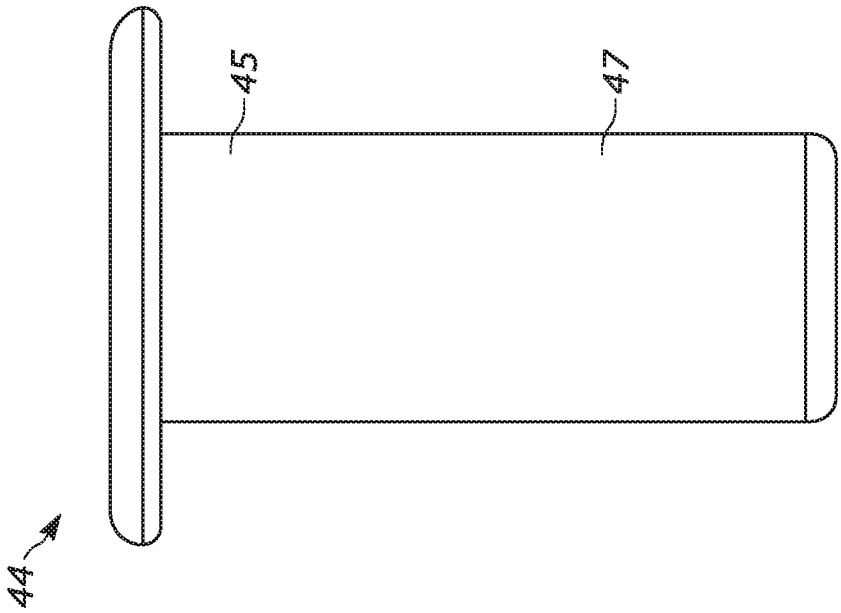

FIG. 4

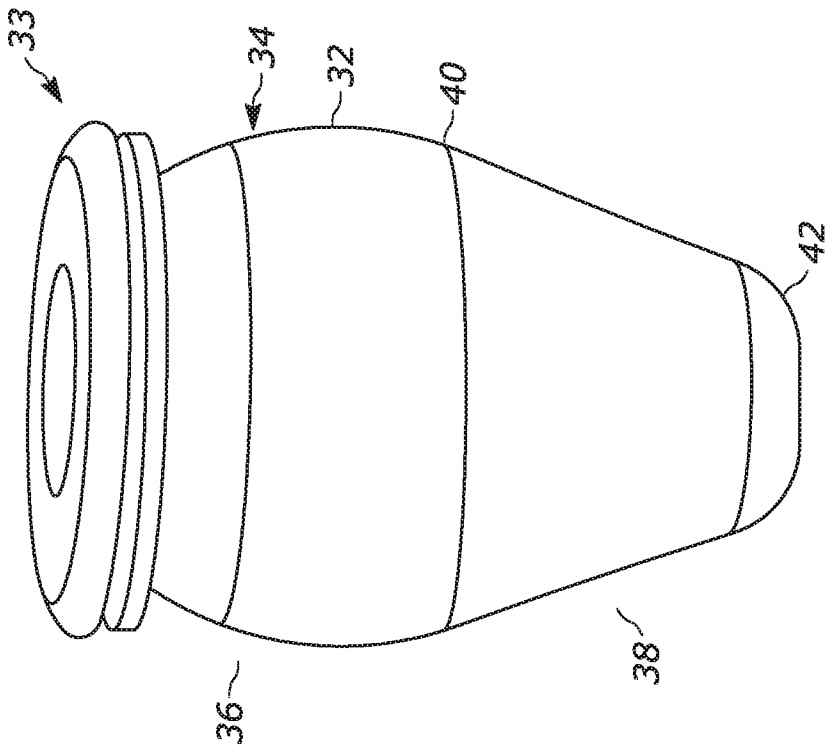

FIG. 3

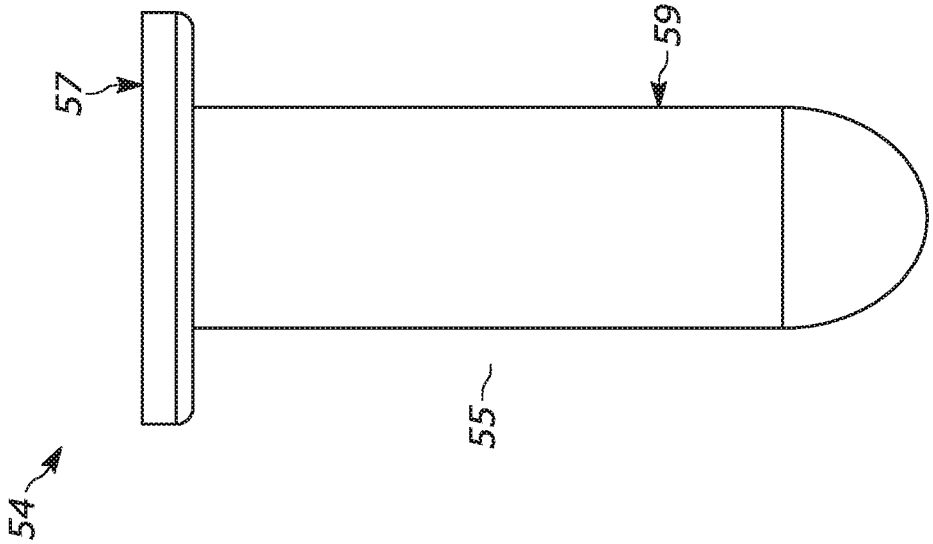

FIG. 6

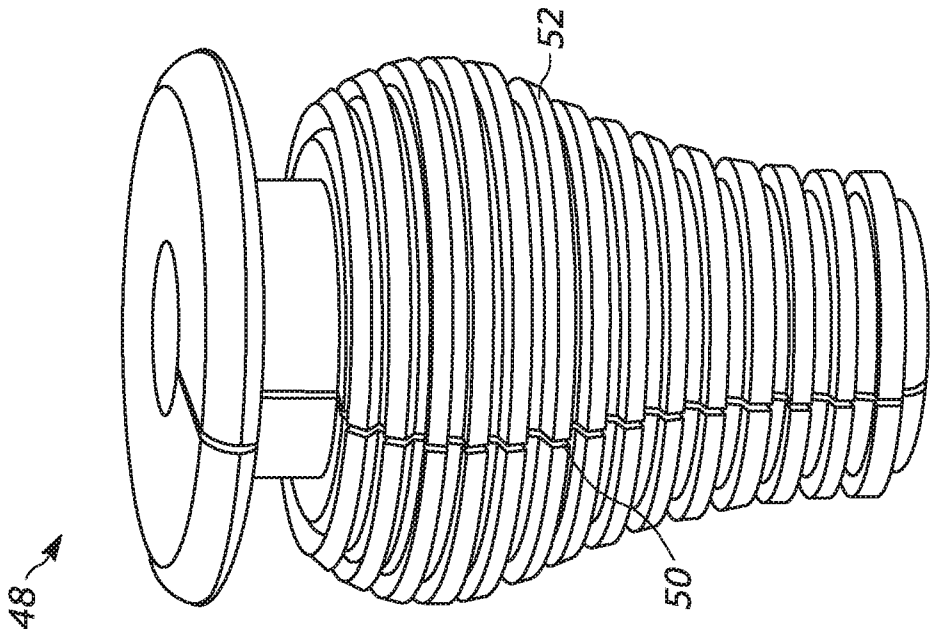

FIG. 5

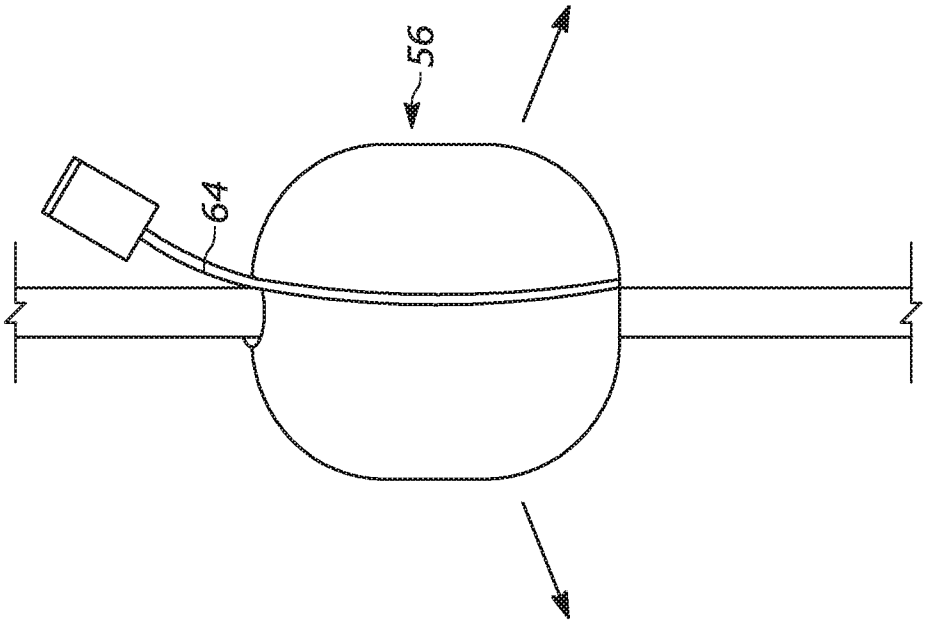

FIG. 8

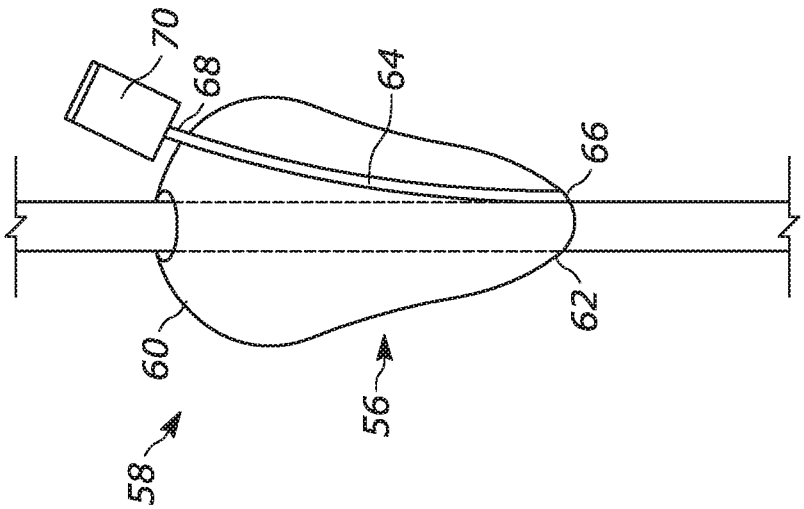

FIG. 7

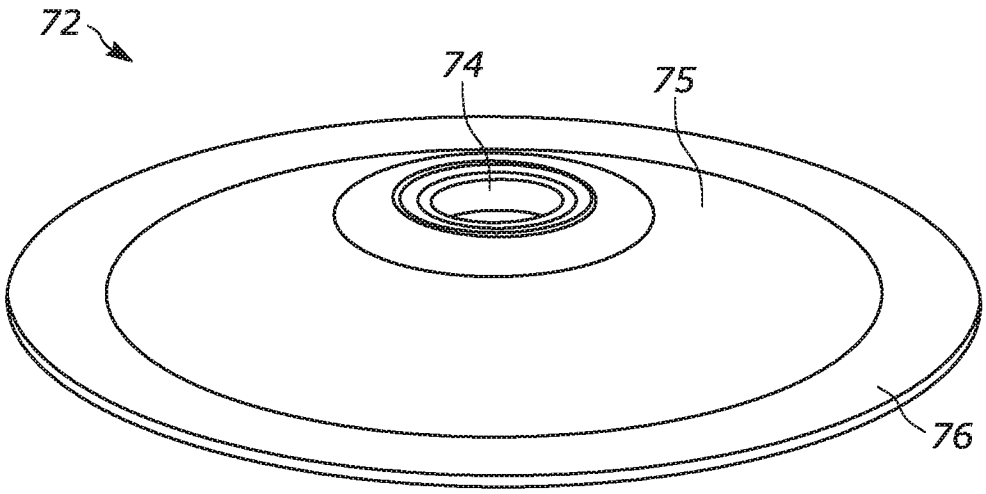

FIG. 9

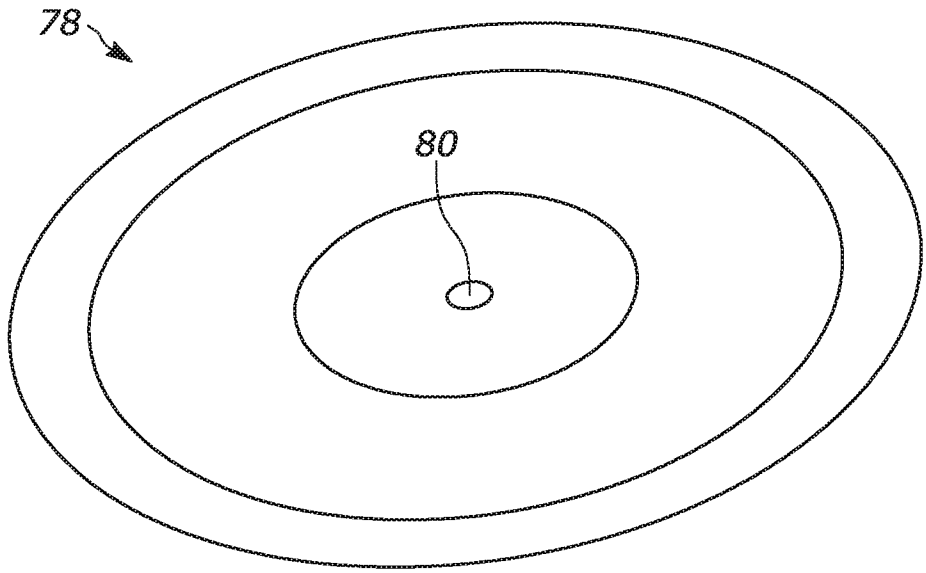

FIG. 10

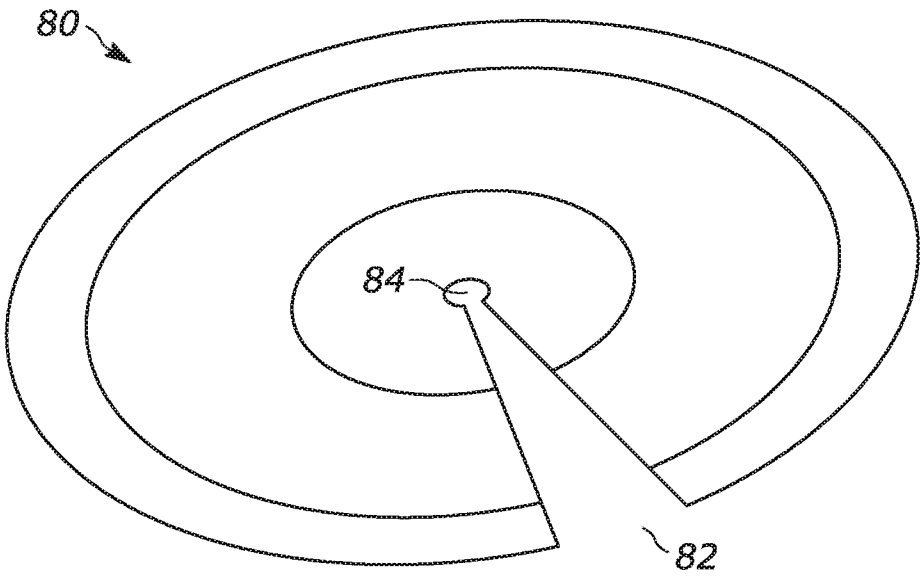

FIG. 11

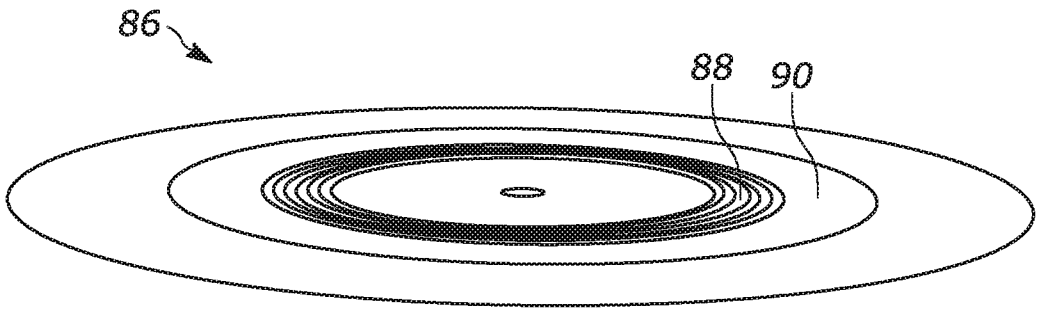

FIG. 12

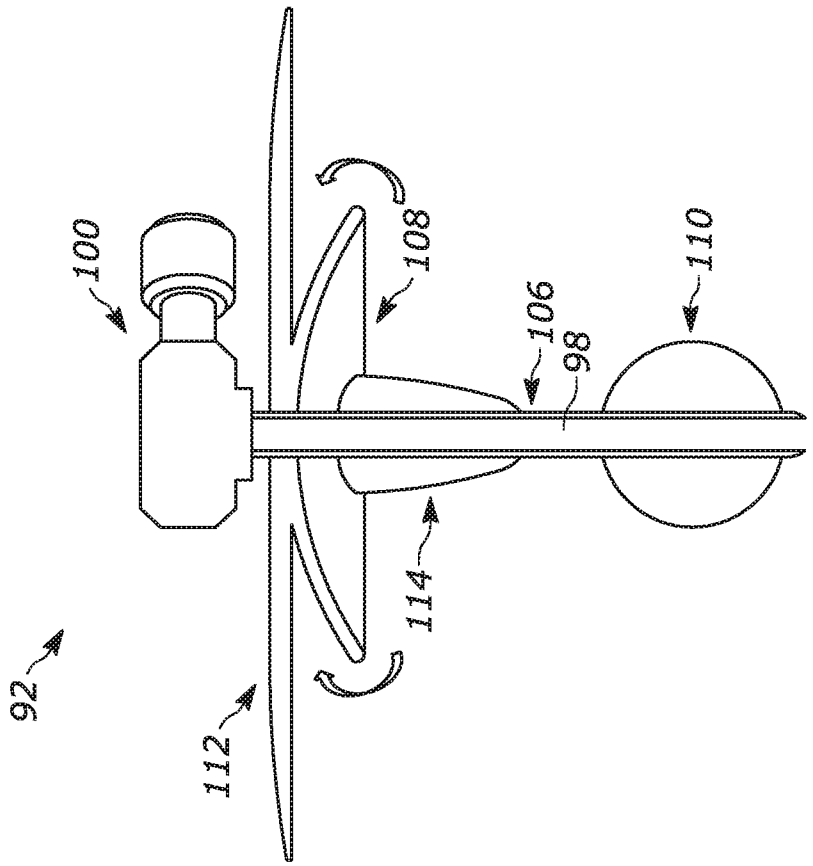
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FIG. 14

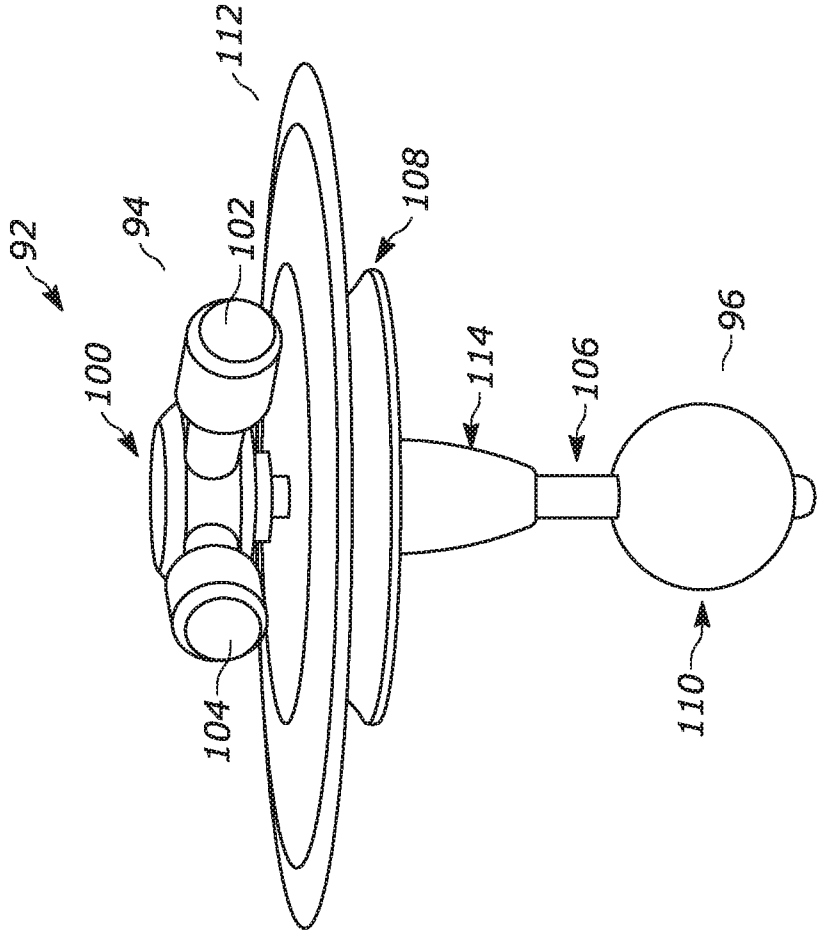
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FIG. 13

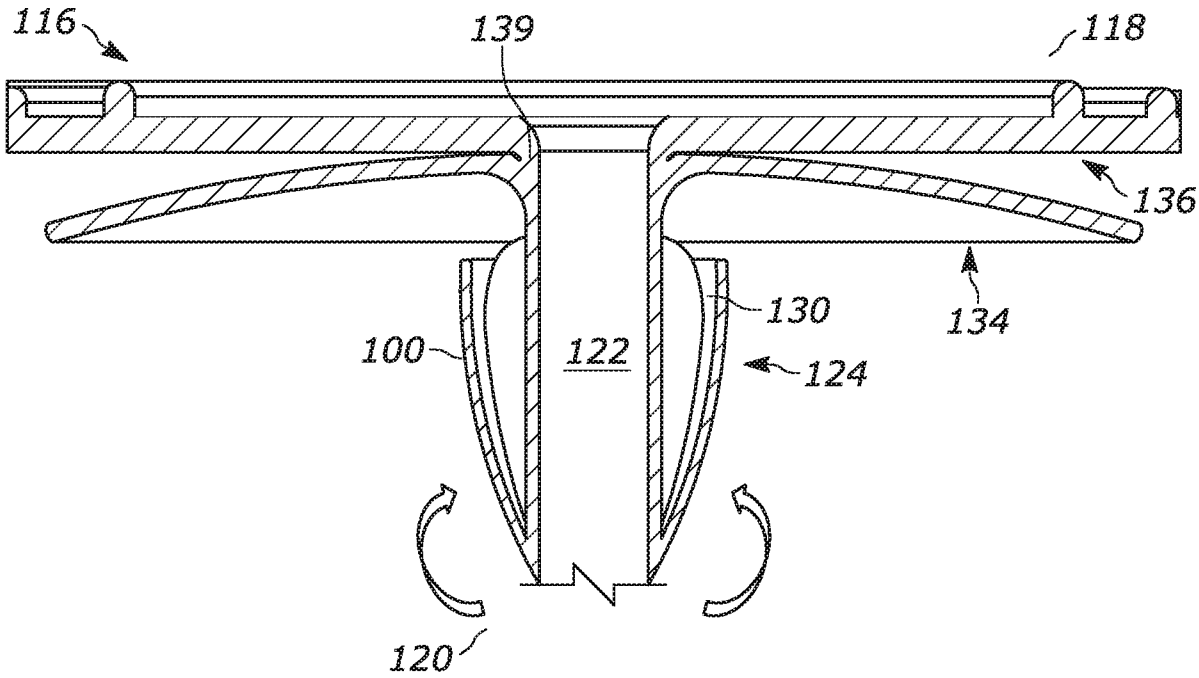


FIG. 15

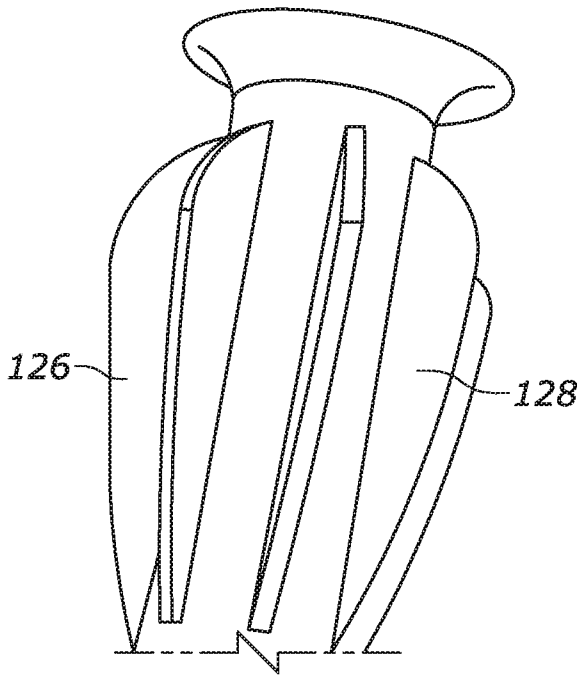


FIG. 16

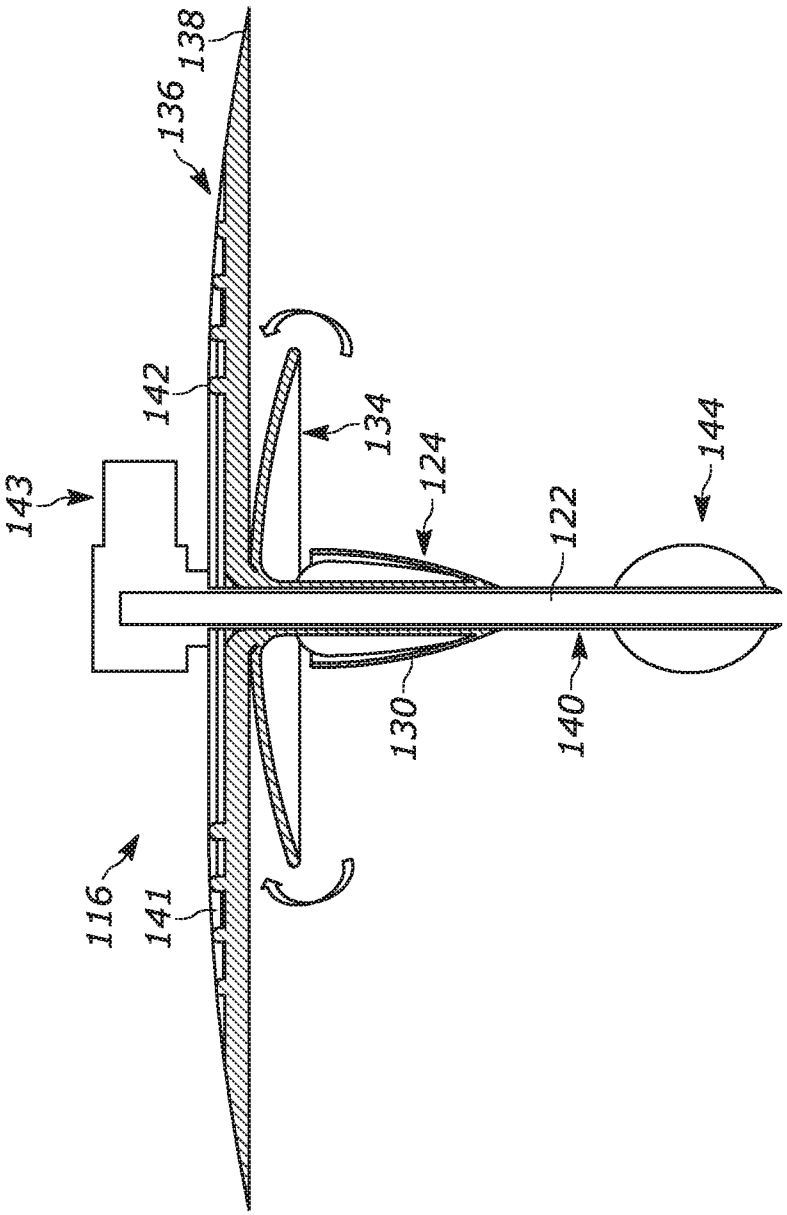


FIG. 17

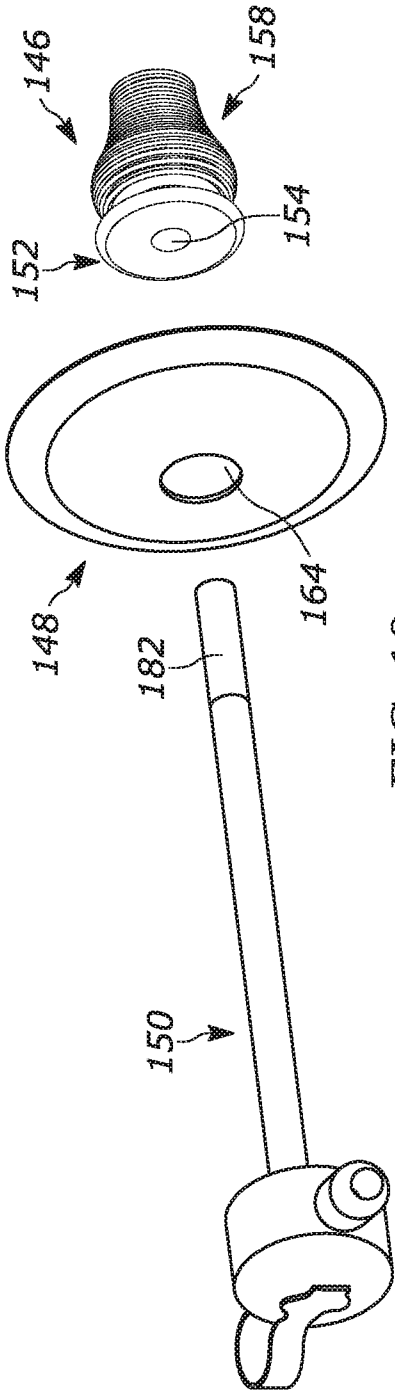


FIG. 18

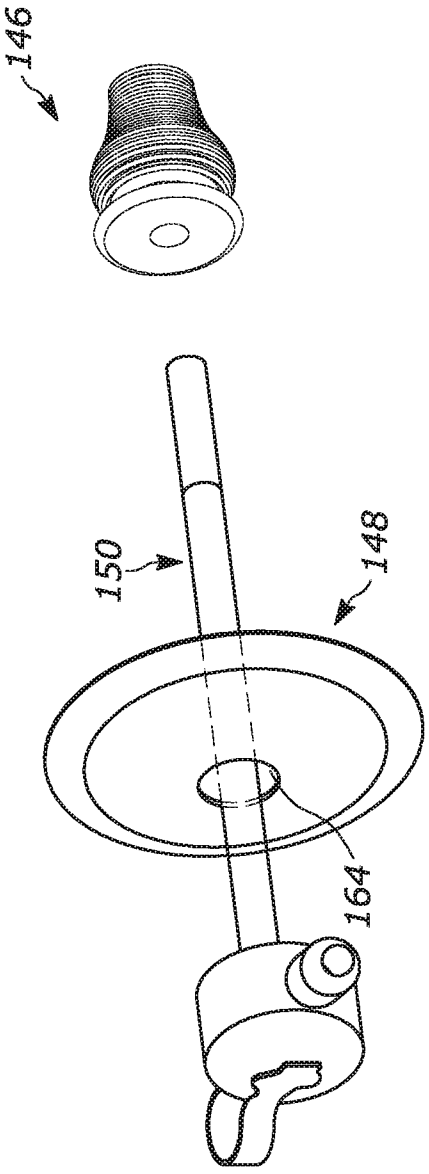


FIG. 19

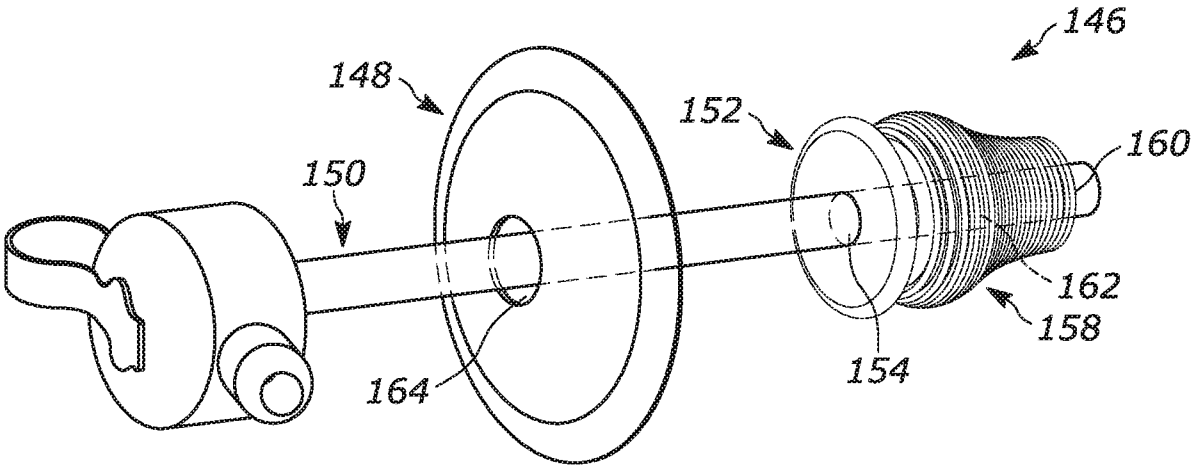


FIG. 20

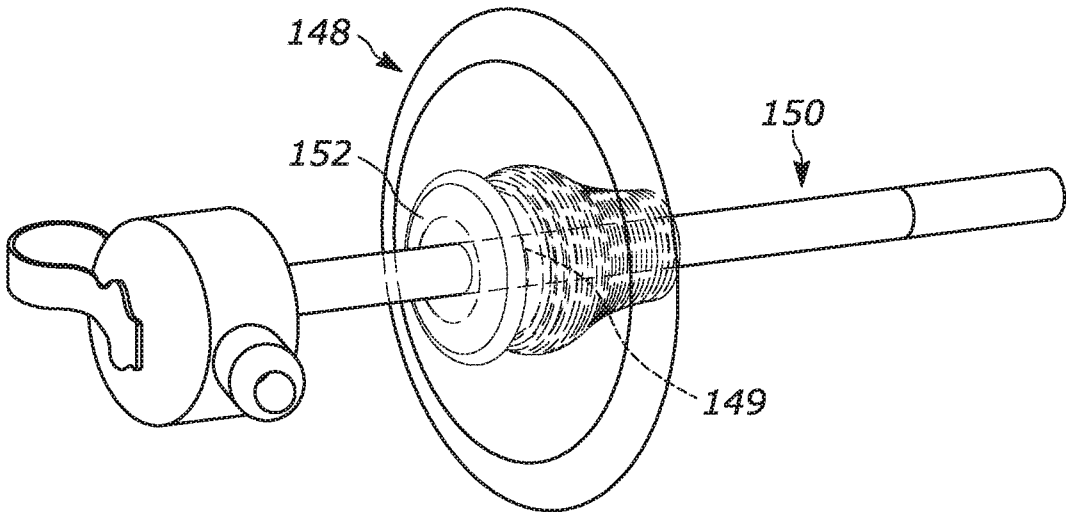
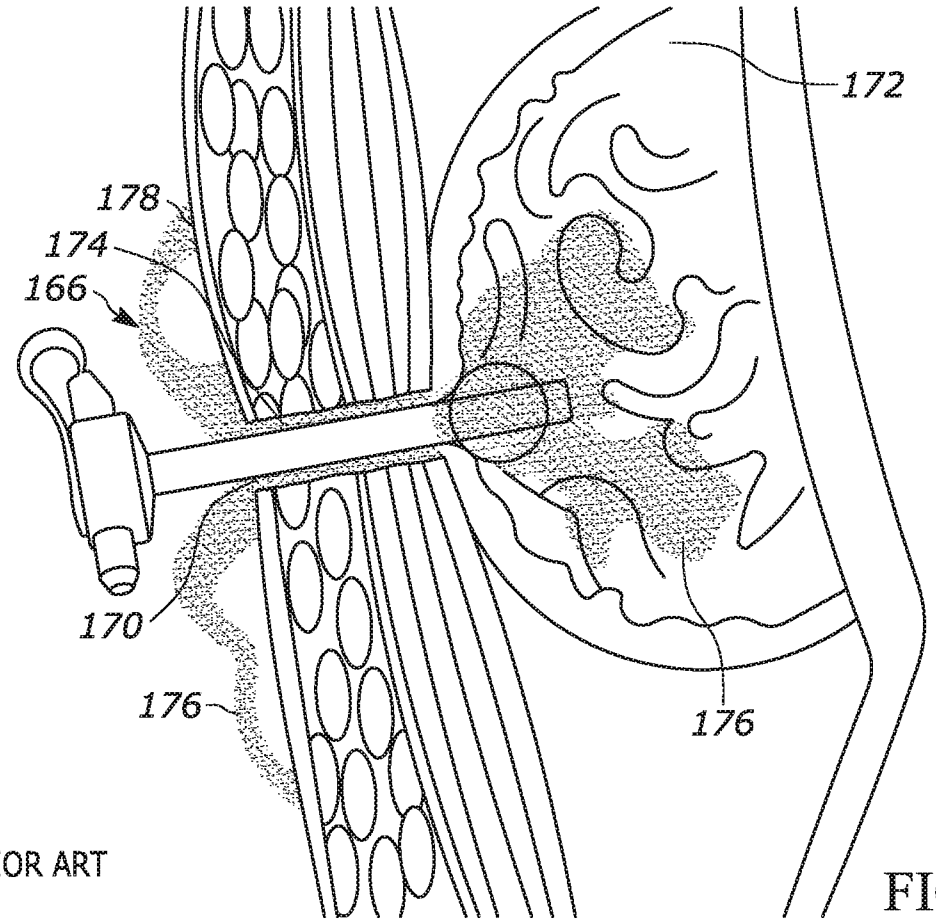


FIG. 21



PRIOR ART

FIG. 22

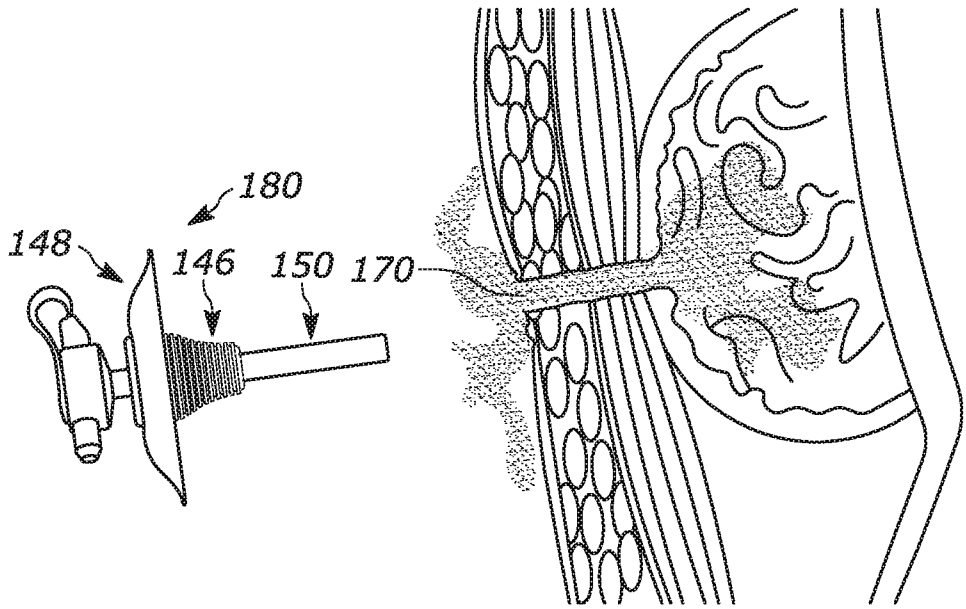


FIG. 23

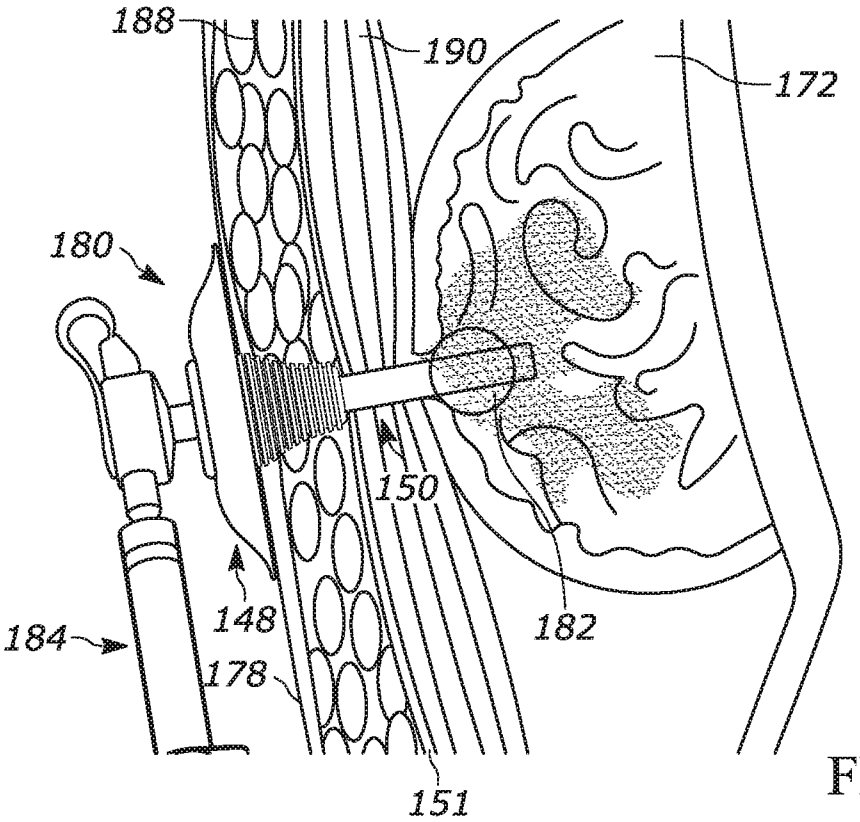

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FIG. 24

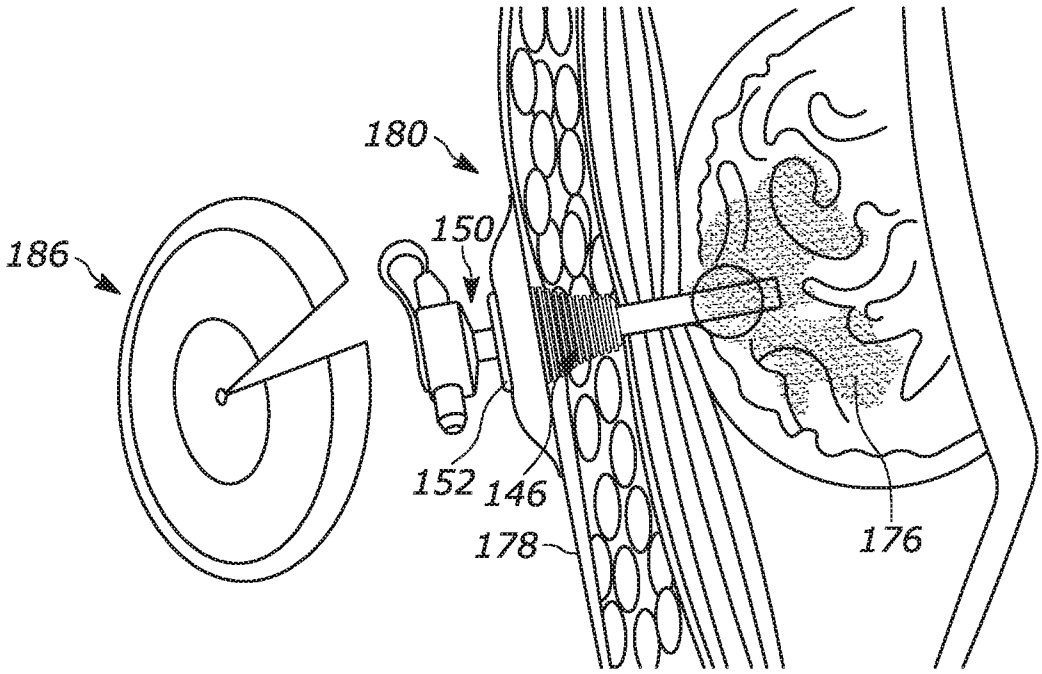
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FIG. 25

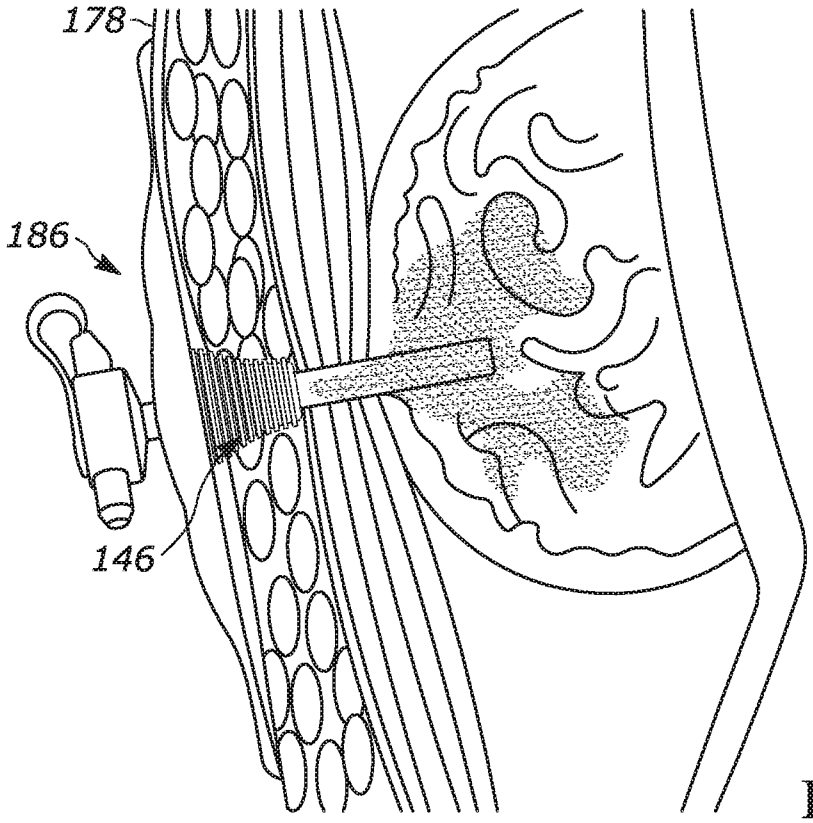

FIG. 26

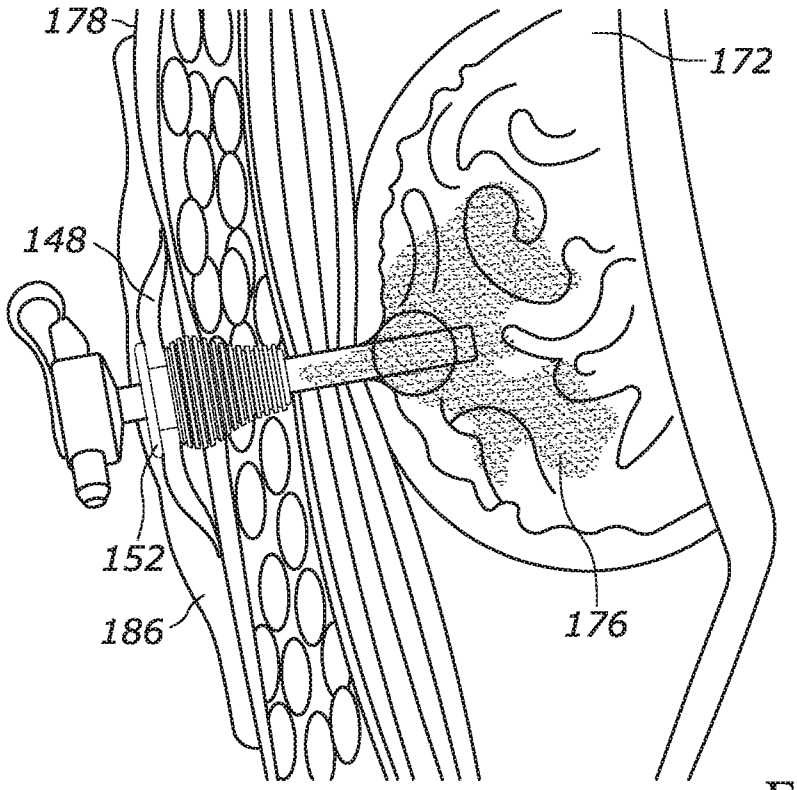

FIG. 27

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/047658

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61J 15/00; A61M 25/02; A61M 25/16; A61M 25/18; A61M 31/00; A61M 39/00 (2019.01)

CPC - A61J 15/0015; A61J 15/0026; A61J 15/0034; A61J 15/0046; A61J 15/0053; A61J 15/0065; A61M 2039/0223; A61M 2039/0255; A61M 2039/0261 (2019.08)

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)

See Search History document

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

USPC - 604/910; 604/174; 604/175; 604/180; 604/236; 604/318; 604/907; 604/909; 604/912; 604/915 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2013/0165862 A1 (GRIFFITH et al) 27 June 2013 (27.06.2013) entire document	1, 2, 4-8
Y	US 5,318,543 A (ROSS et al) 07 June 1994 (07.06.1994) entire document	1, 2, 4-8
Y	US 2017/0050004 A1 (LOMA VISTA MEDICAL, INC.) 23 February 2017 (23.02.2017) entire document	7
A	US 4,668,227 A (KAY) 26 May 1987 (26.05.1987) entire document	1-15, 23-30

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 November 2019	27 DEC 2019
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/047658

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

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

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

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See extra sheet(s).

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15, 23-30

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/047658

Continued from Box No. III Observations where unity of invention is lacking

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-15 and 23-30, are drawn to a stoma site protection device comprising: a body having a proximal end, a distal end, an outer surface, an inner bearing surface, and a lumen extending longitudinally therethrough, the body.

Group II, claims 16-19, are drawn to a feeding tube assembly comprising: a proximal adapter comprising one or more ports.

Group III, claims 20-22, are drawn to a one-piece medical device having a proximal portion, a distal portion, and a lumen extending longitudinally therethrough, the medical device comprising: a stoma site protection device at the distal portion of the medical device.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention: a body having a proximal end, a distal end, an outer surface, an inner bearing surface, and a lumen extending longitudinally therethrough, the body comprising: a proximal collar having a collar width and defining a top opening; an indented portion extending distally from the proximal collar and having an indented portion width that is less than the collar width; and a non-rigid or semi-rigid plug extending distally from the indented portion and having an outer surface, an inner bearing surface, a bottom opening and a plug lumen, the plug lumen axially aligned and in fluid communication with the bottom opening and the top opening, the stoma site protection device being sized and dimensioned to prevent or minimize leakage of fluid from a stoma as claimed therein is not present in the invention of Groups II and III. The special technical feature of the Group II invention: a proximal adapter comprising one or more ports; a feeding tube extending distally from the proximal adapter; a first bumper disposed about the feeding tube below the proximal adapter; a second bumper disposed about the feeding tube below the first bumper; and a stoma site protection device comprising a non-rigid or semi-rigid plug disposed about the tube between the first bumper and the second bumper as claimed therein is not present in the invention of Groups I or III. The special technical feature of the Group III invention: a one-piece medical device having a proximal portion, a distal portion, and a lumen extending longitudinally therethrough, the medical device comprising: a stoma site protection device at the distal portion of the medical device and comprising: an inner portion having supporting ribs disposed about an outer surface of the inner portion; a tapered cup surrounding the inner portion and having a flexible outer surface; a proximal bumper that is above and integral with the stoma site protection device; and a bandage that is above and integral with the proximal bumper, the medical device being sterile as claimed therein is not present in the invention of Groups I or II.

Groups I, II and III lack unity of invention because even though the inventions of these groups require the technical feature of a stoma site protection device comprising a non-rigid or semi-rigid plug, the stoma site protection device being sterile, this technical feature is not a special technical feature as it does not make a contribution over the prior art.

Specifically, US 4,668,227 A to Kay teaches a stoma site protection device comprising a non-rigid or semi-rigid plug, the stoma site protection device being sterile (col.2, lines 30-46; col.4, lines 54-65).

Since none of the special technical features of the Group I, II or III inventions are found in more than one of the inventions, unity of invention is lacking.

It is noted that claim 21 is objected under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 21 is indefinite for the following reasons: Claim 21 is stated to depend from claim 21 itself and further refers to "bandage" which has antecedent basis in claim 20, Therefore, for the purposes of this opinion, claim 21 is best understood as depending from claim 20.