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(54) BIOLOGICAL NAVIGATION DEVICE

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Related U.S. Application Data

(63) Continuation of application No. 12/512,878, filed on Jul. 30, 2009, now abandoned, which is a continuation of application No. PCT/US2008/052535, filed on Jan. 30, 2008.

(60) Provisional application No. 60/949,219, filed on Jul. 11, 2007, provisional application No. 60/887,319, filed on Jan. 30, 2007, provisional application No. 60/887,323, filed on Jan. 30, 2007.

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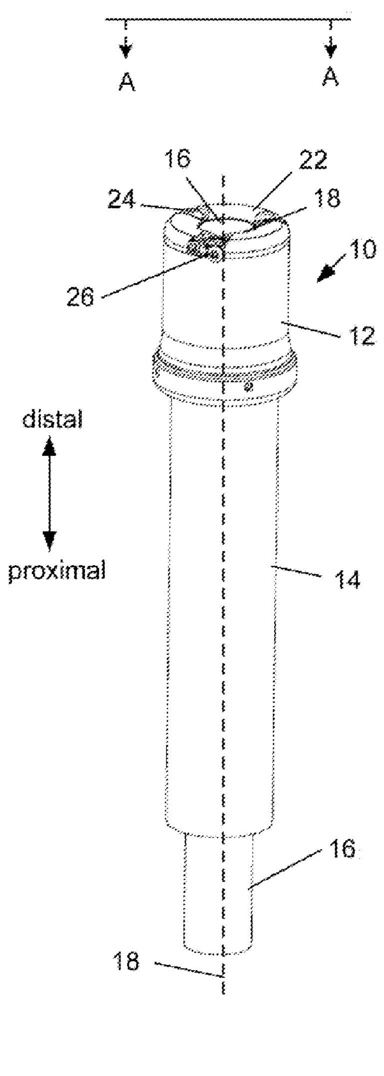
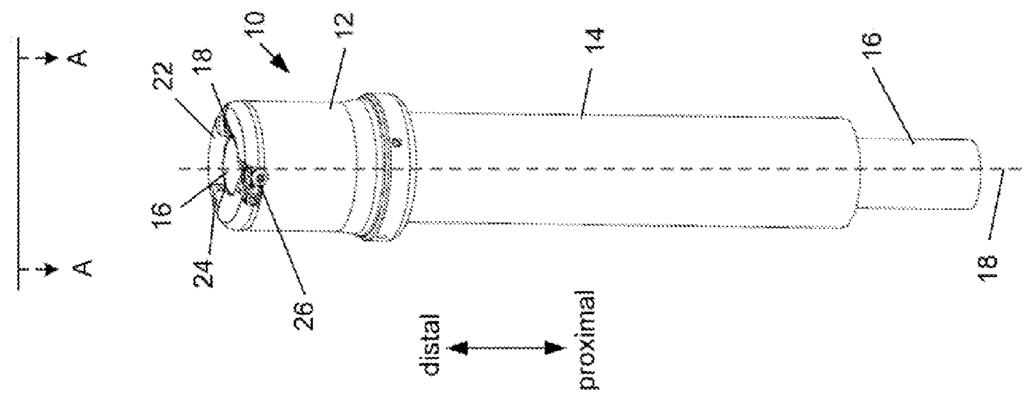
CPC *A61B 1/00151* (2013.01)

(57) **ABSTRACT**

Biological navigation devices and methods are disclosed. The devices can be used as or to support colonoscopies or endoscopes. The devices can have one or more releasable, and/or everting, and/or pressurized tubes. The devices can be removably attached to elongated elements, such as colonoscopes or other endoscopes.





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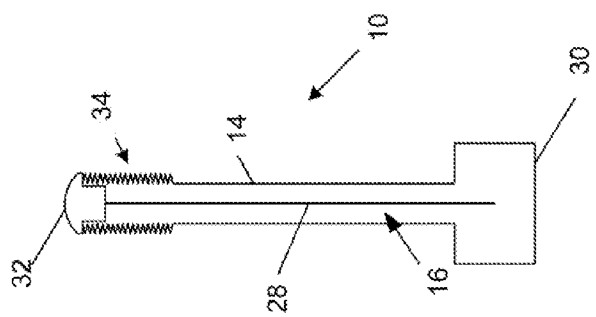

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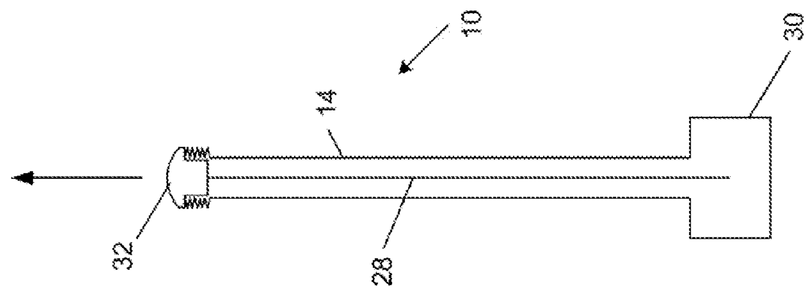


Fig. 2b

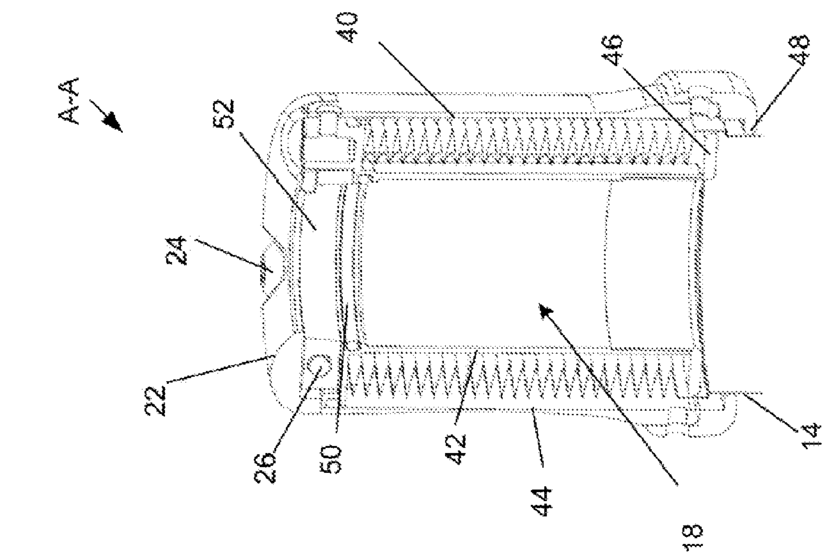
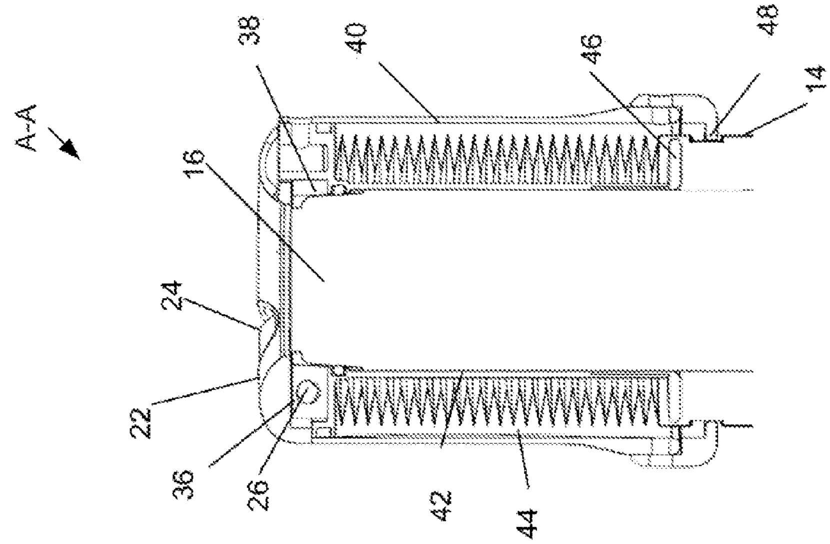


Fig. 3c



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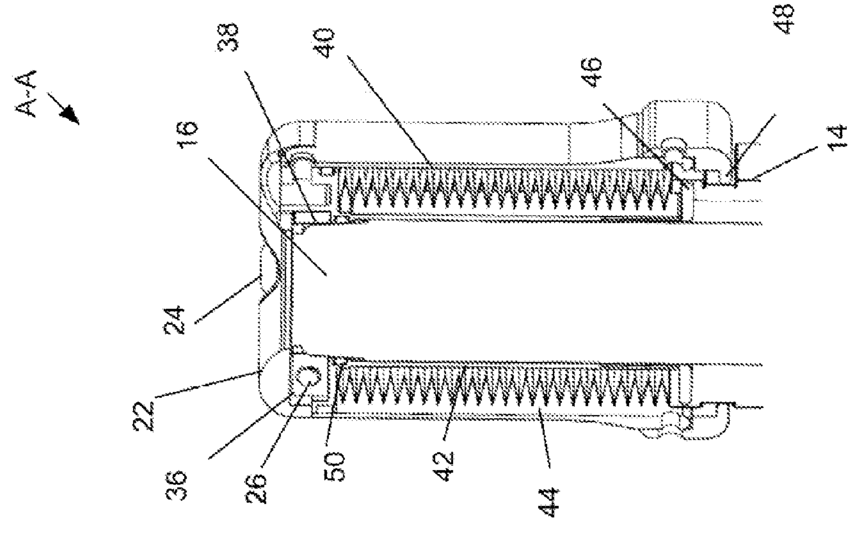

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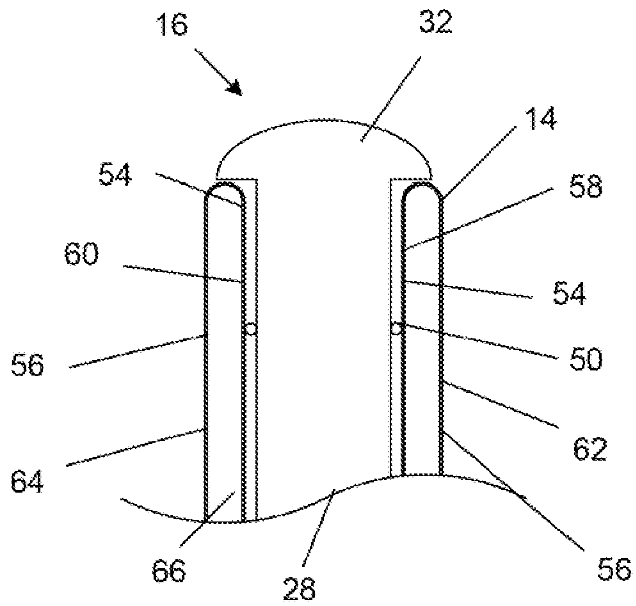
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Fig. 4a

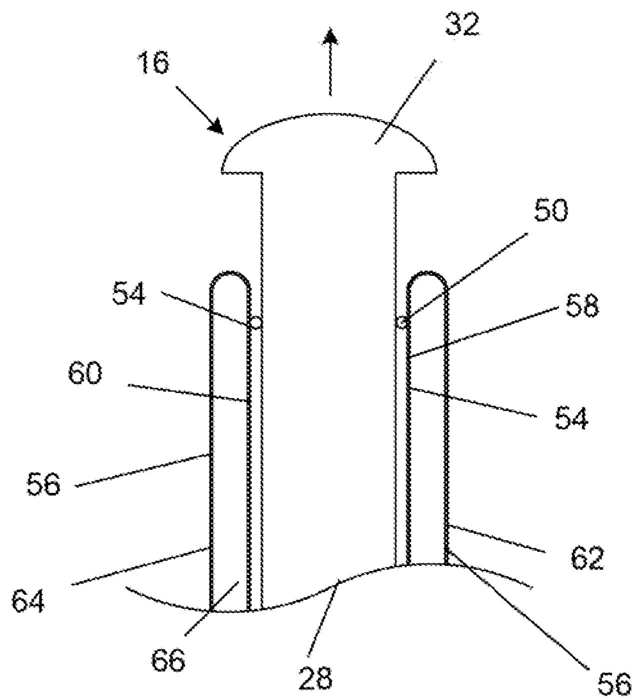
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Fig. 4b

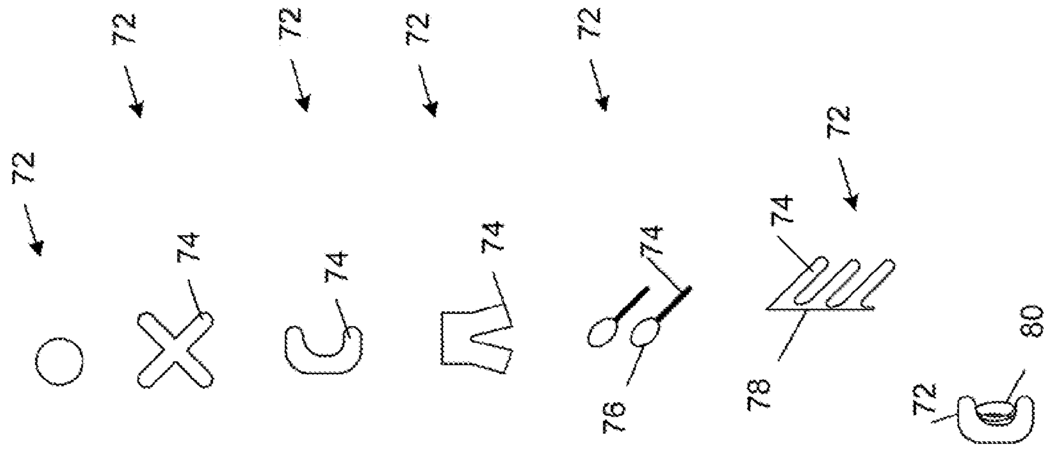


Fig. 6a

Fig. 6b

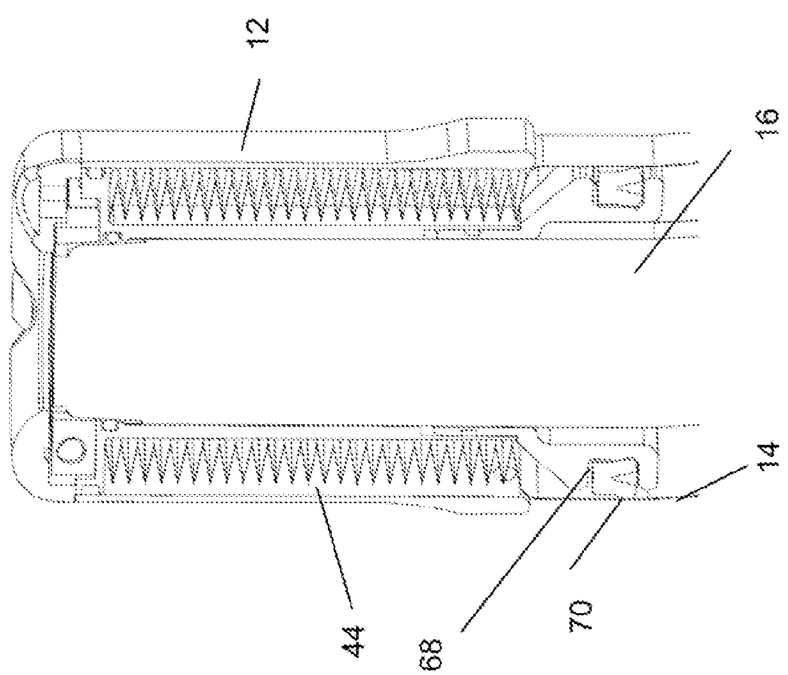
Fig. 6c

Fig. 6d

Fig. 6e

Fig. 6f

Fig. 6g



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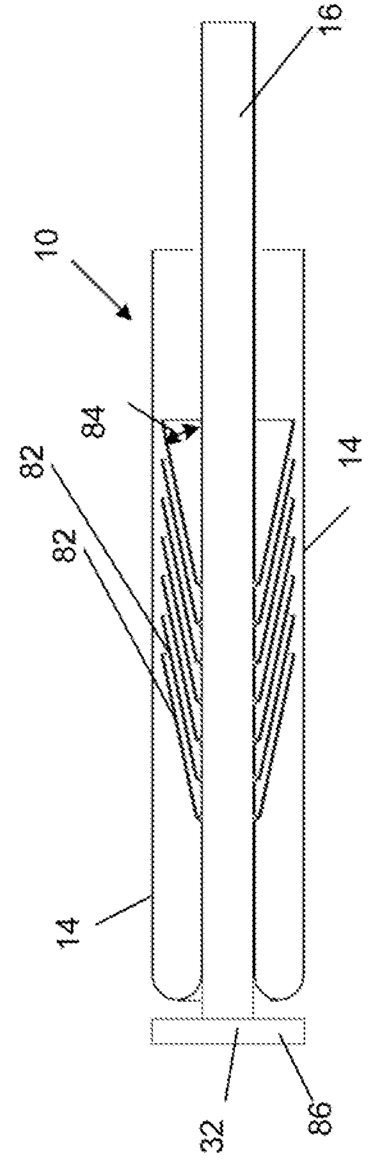

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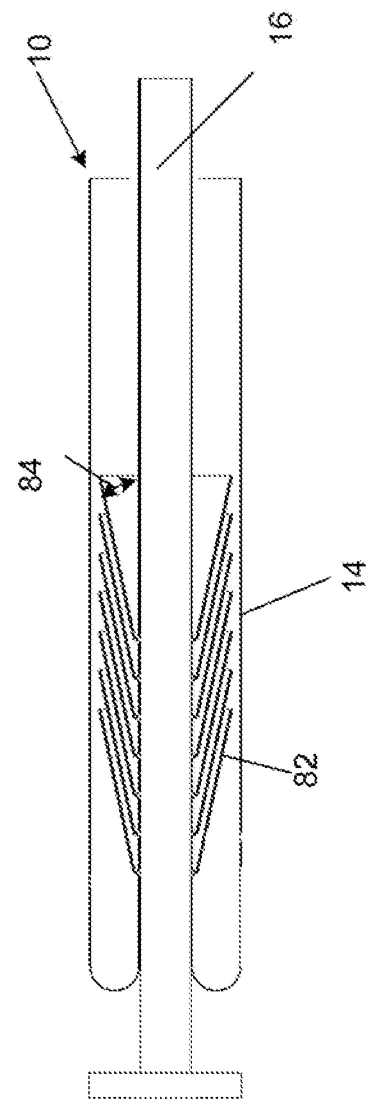

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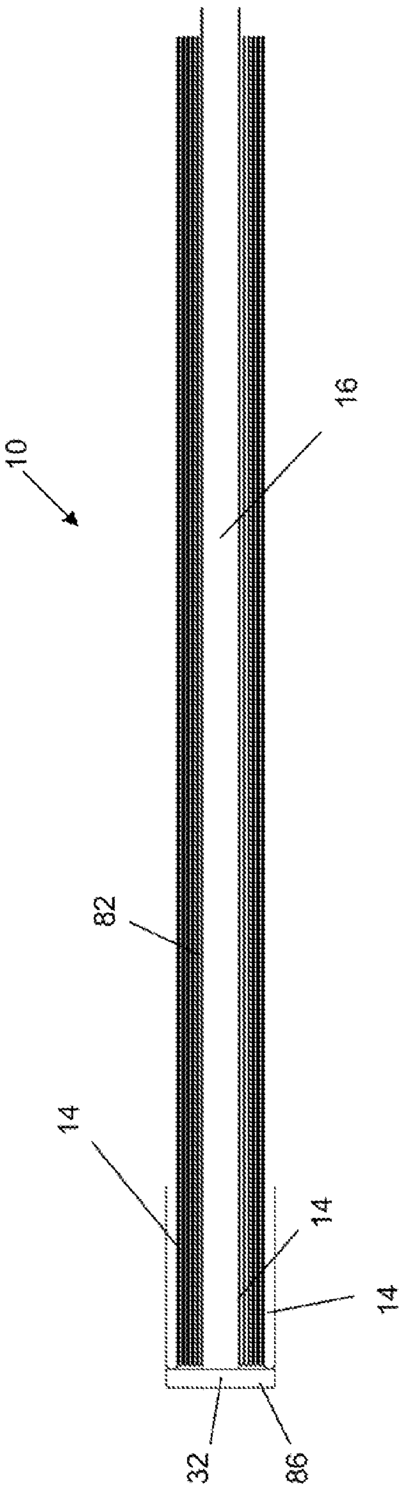

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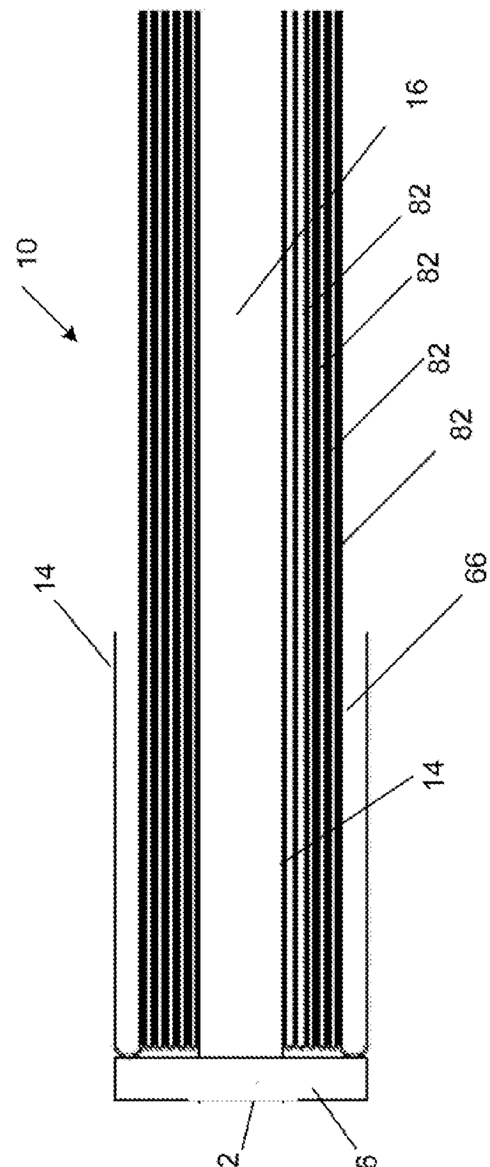

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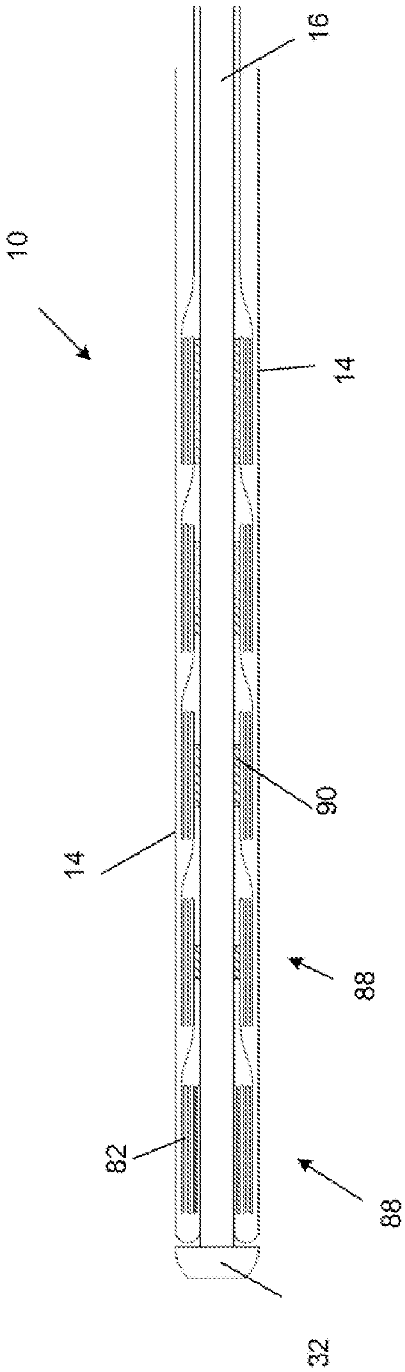

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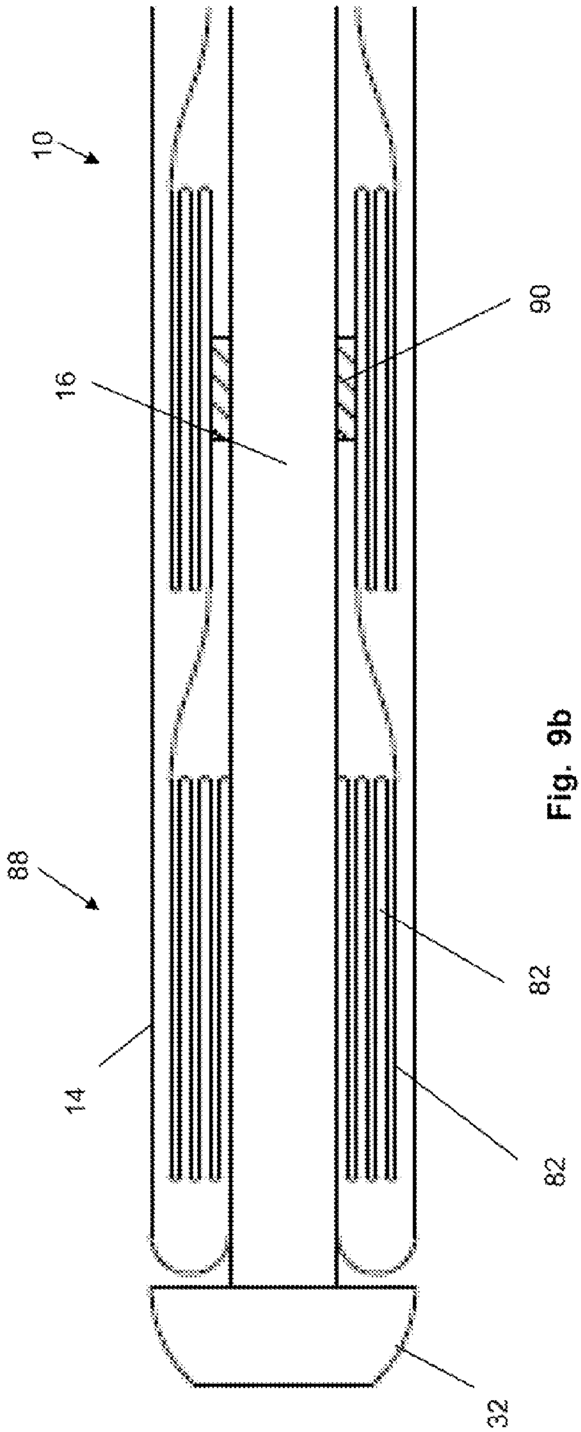

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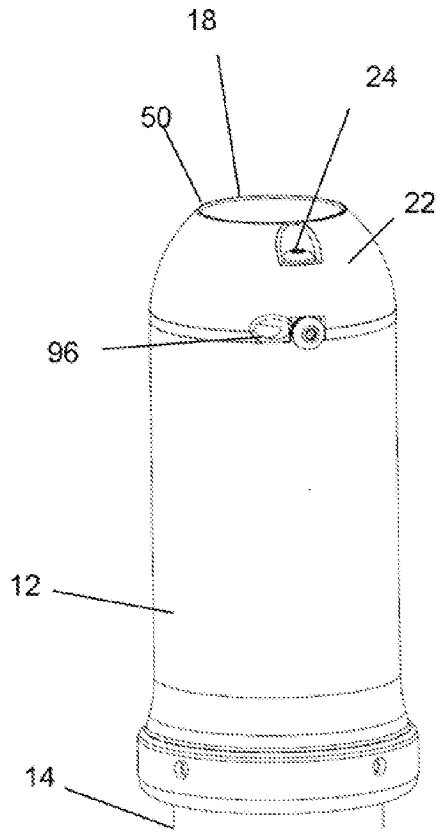

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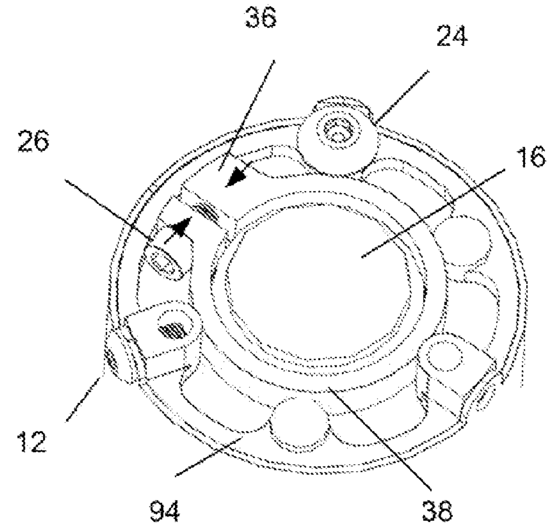

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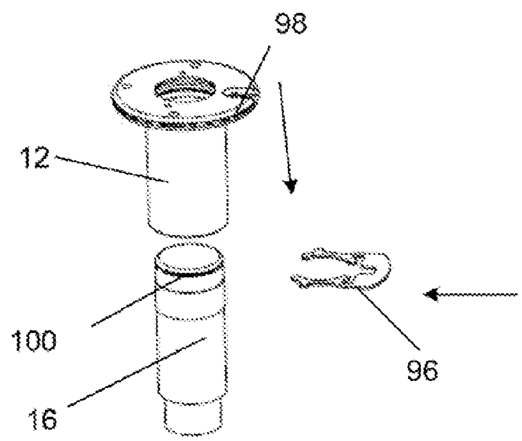

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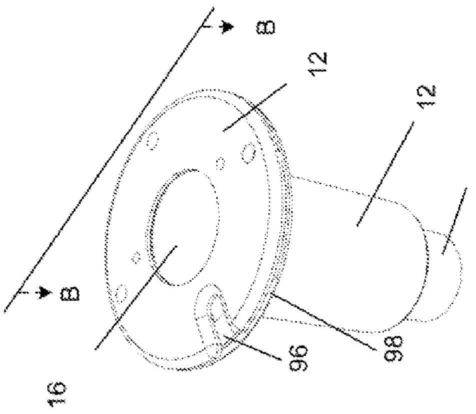

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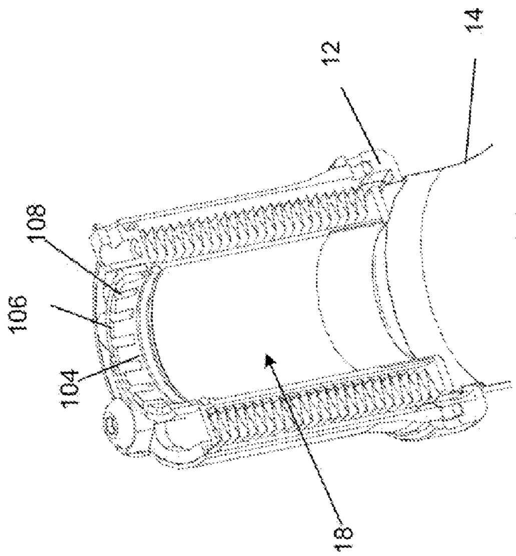

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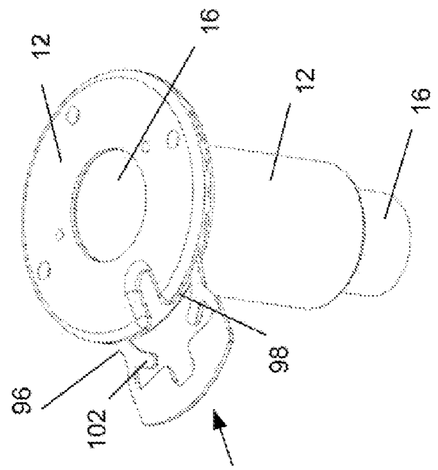

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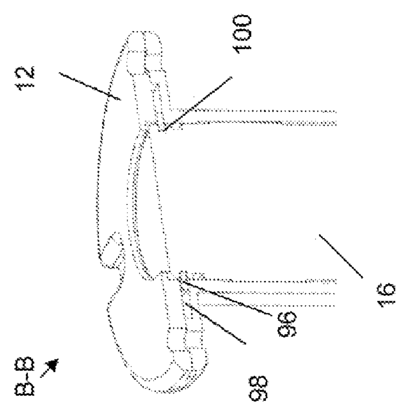

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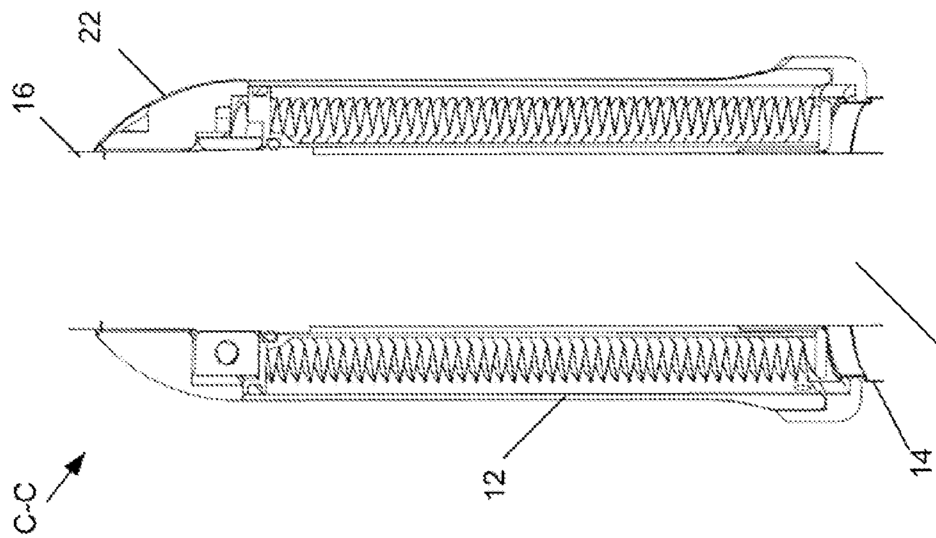

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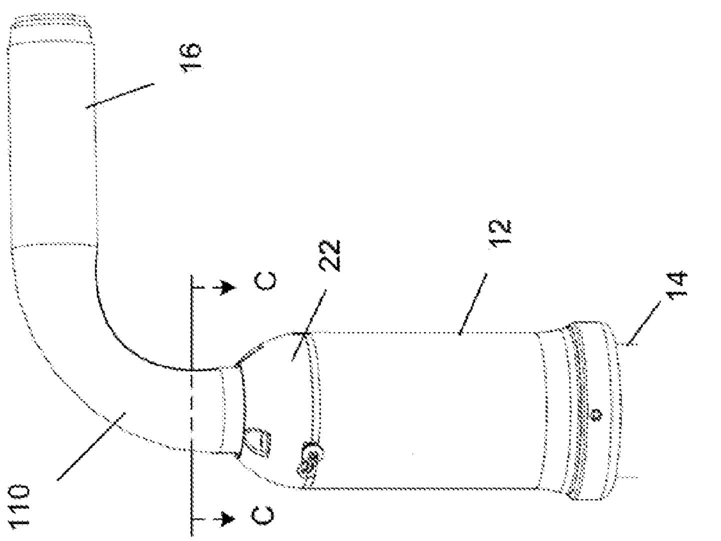

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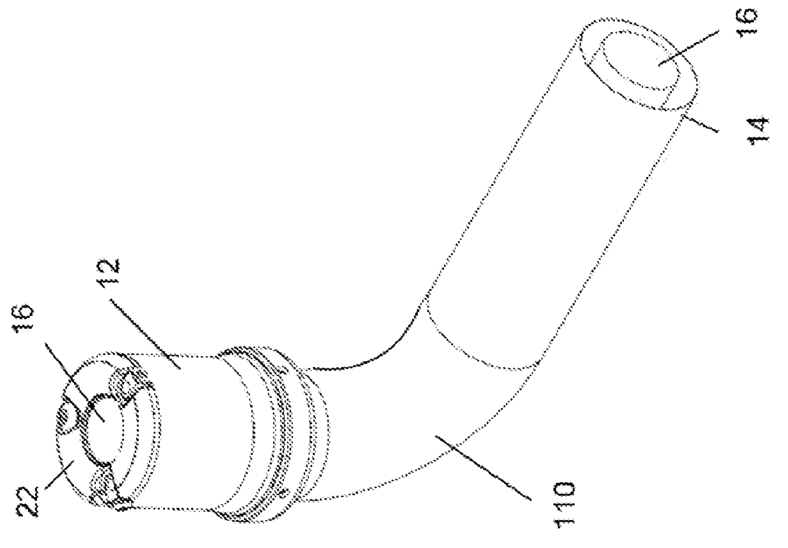

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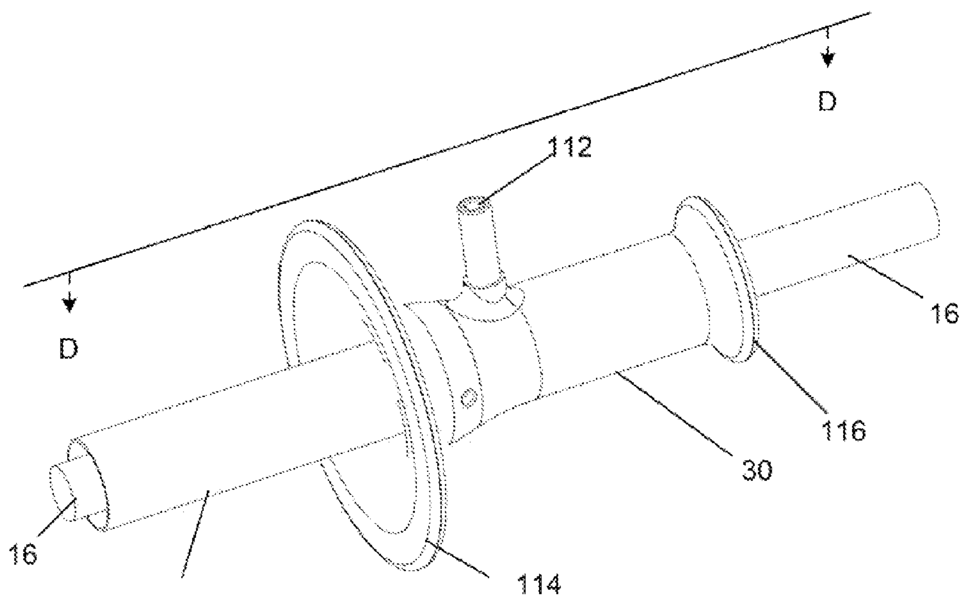

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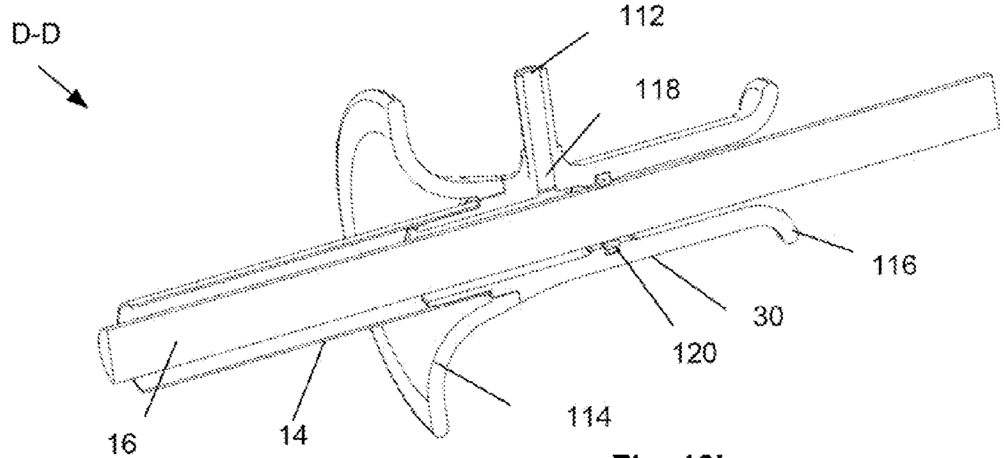

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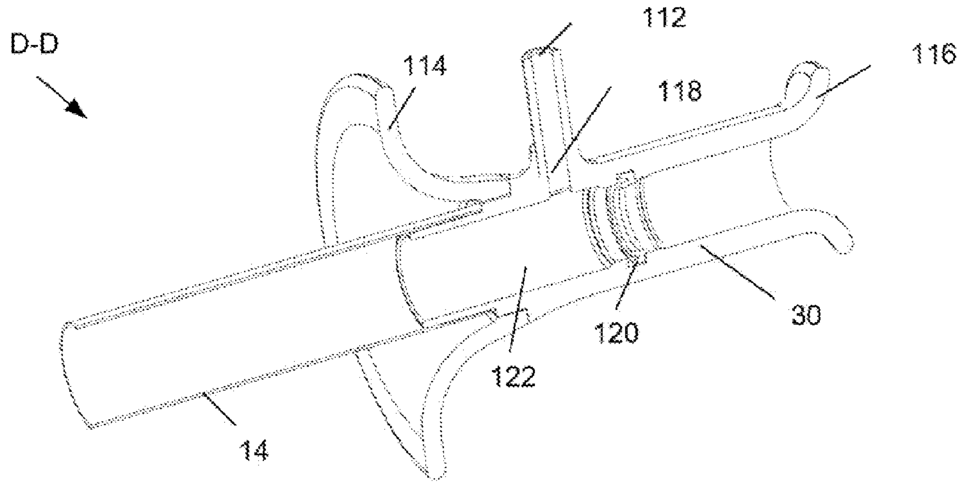

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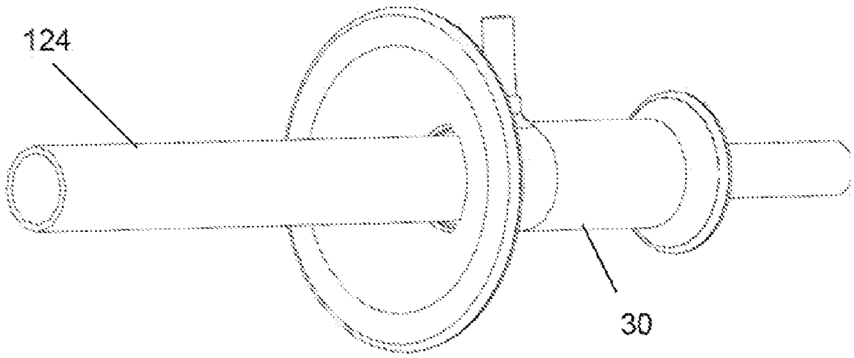

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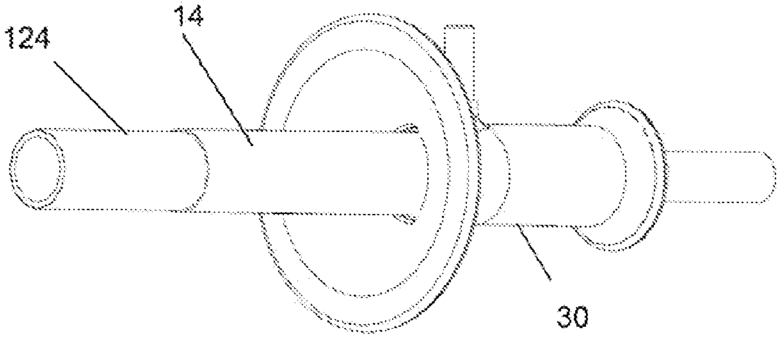

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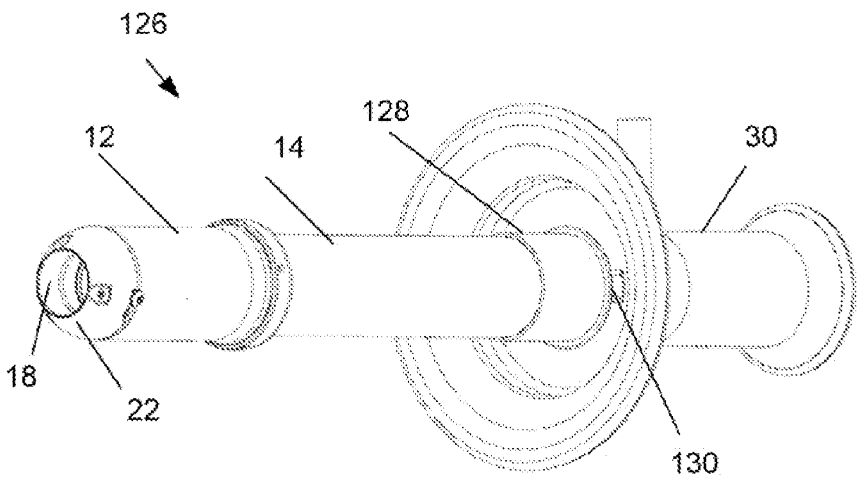

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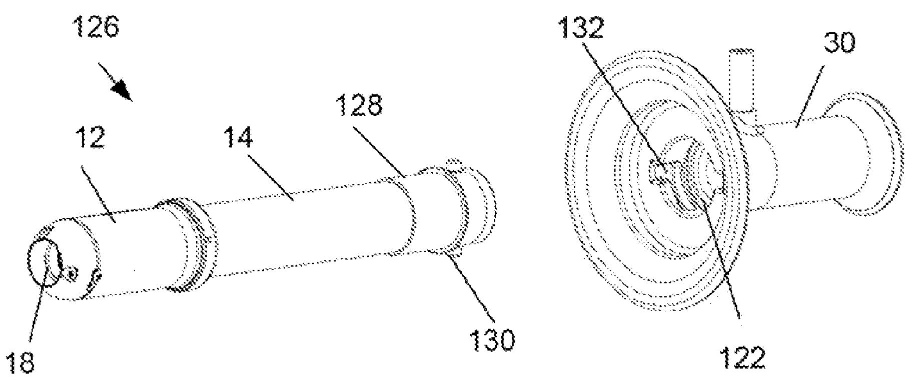

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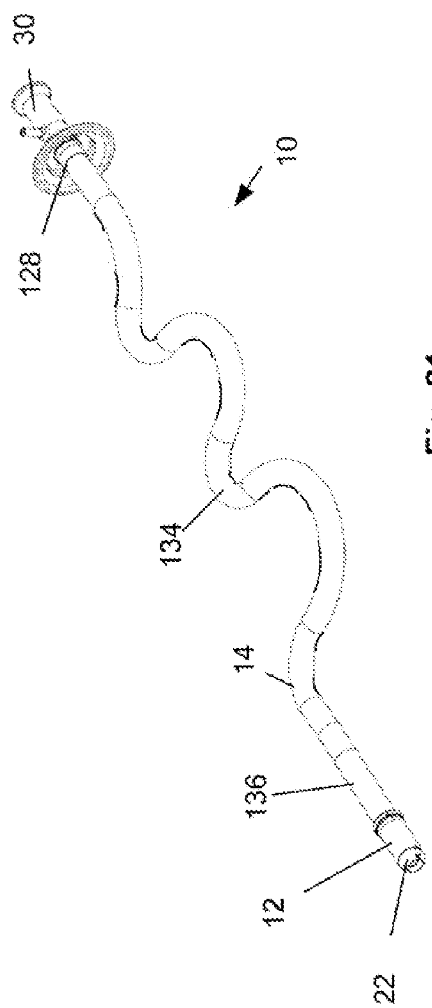

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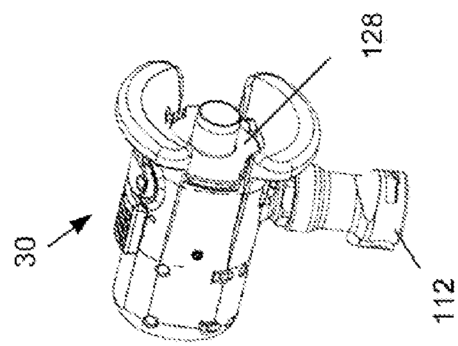

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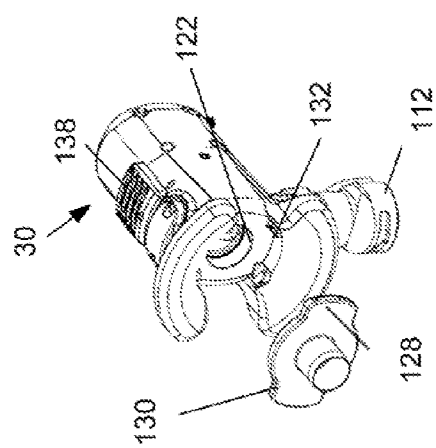

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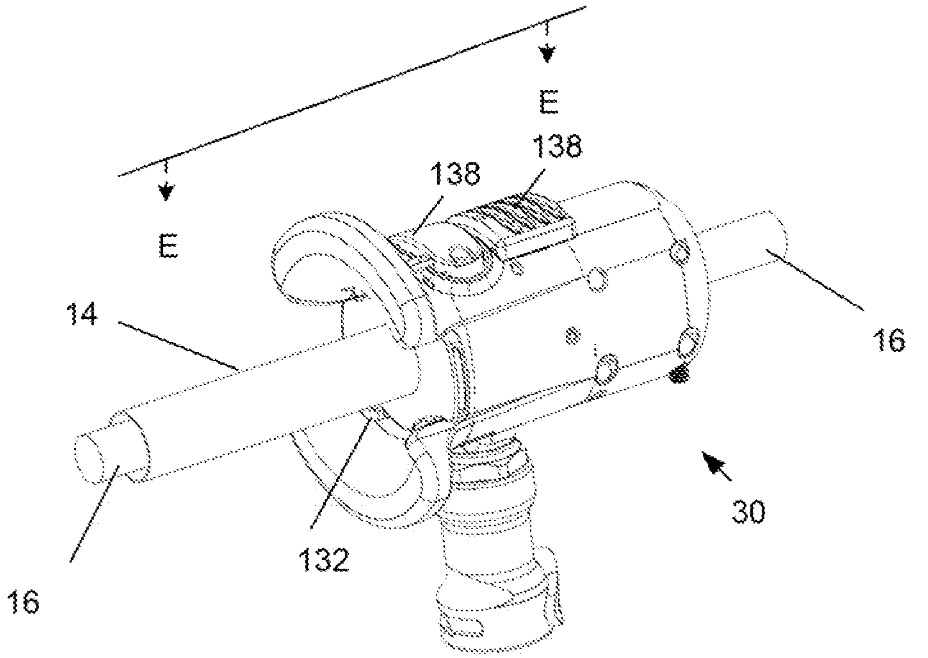

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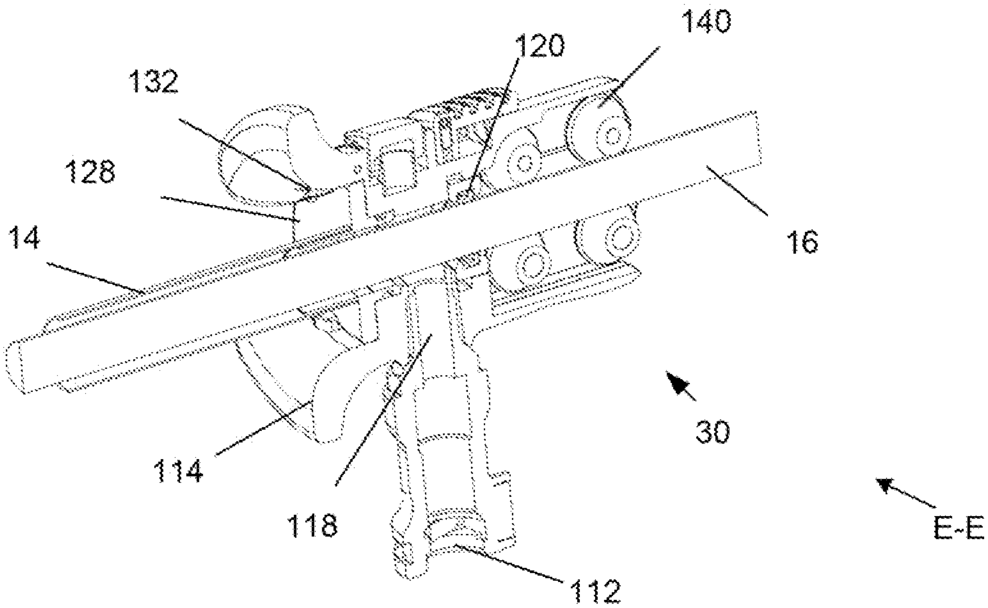

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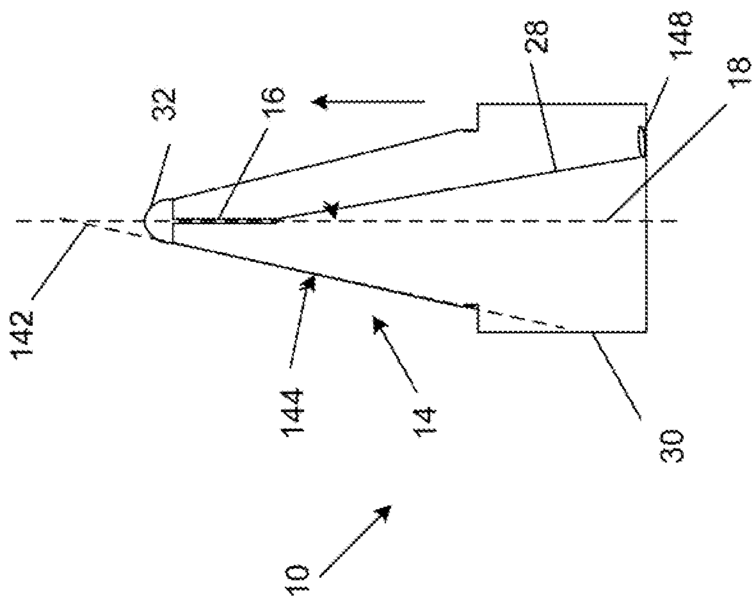

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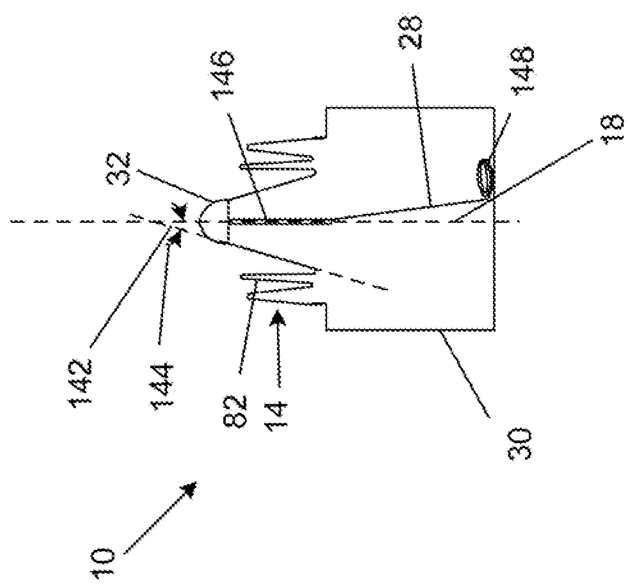

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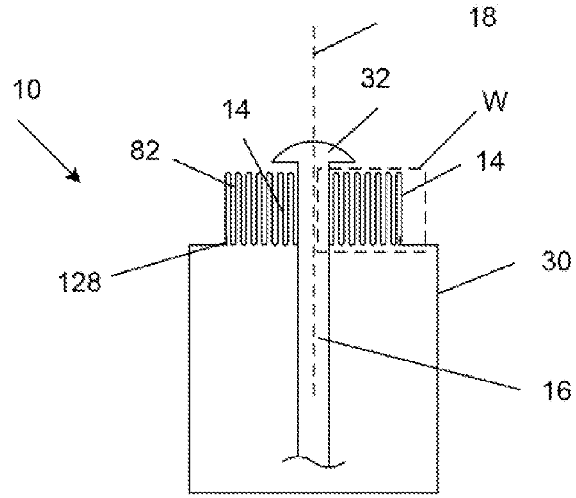

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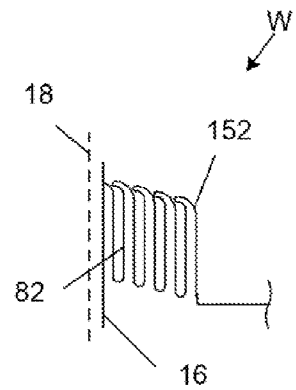

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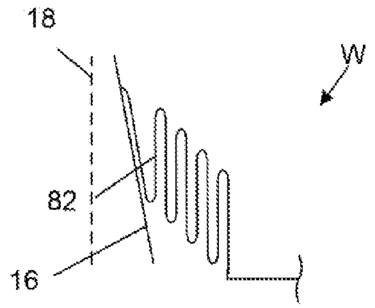

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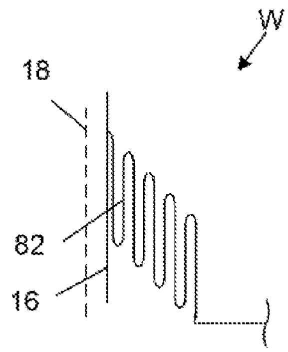

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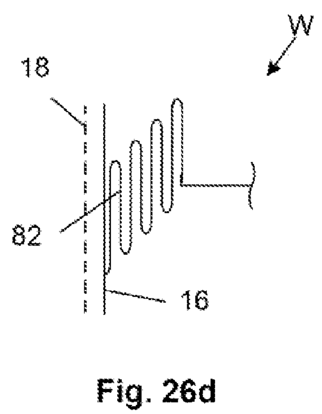

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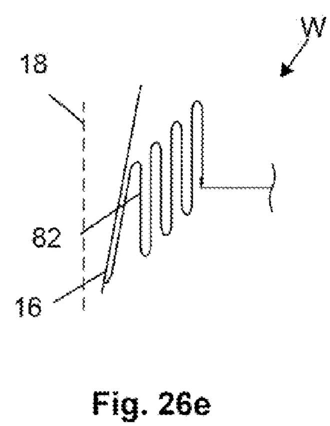

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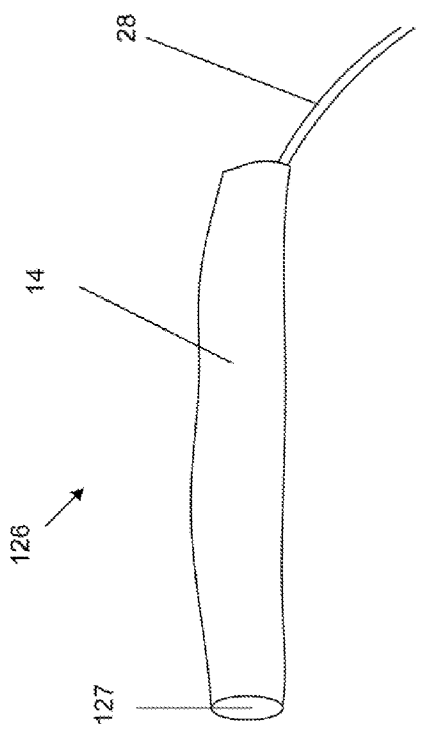

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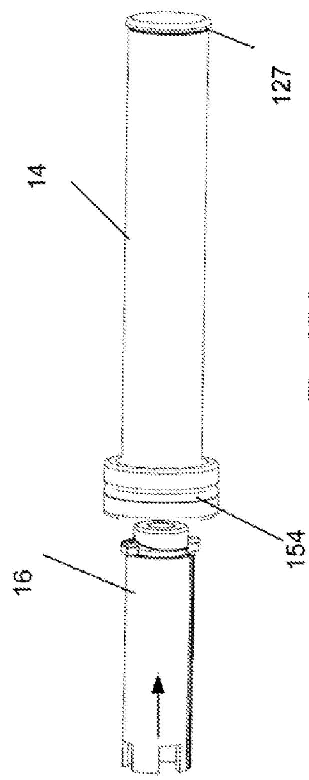

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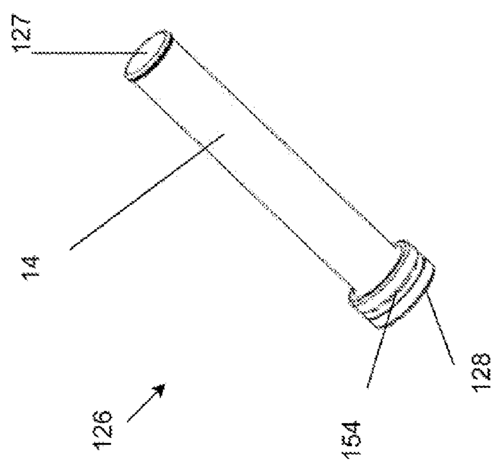

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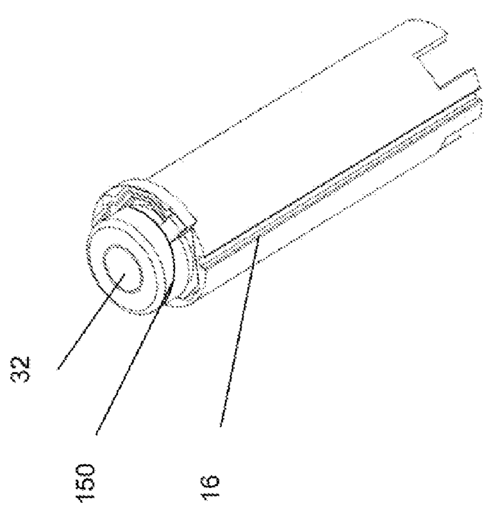

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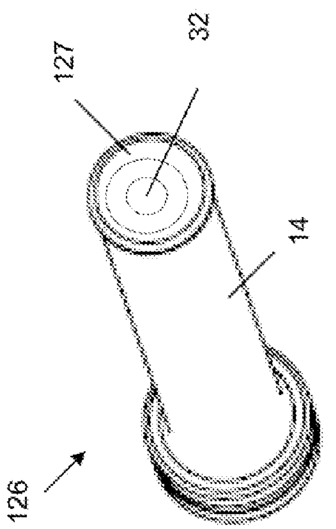

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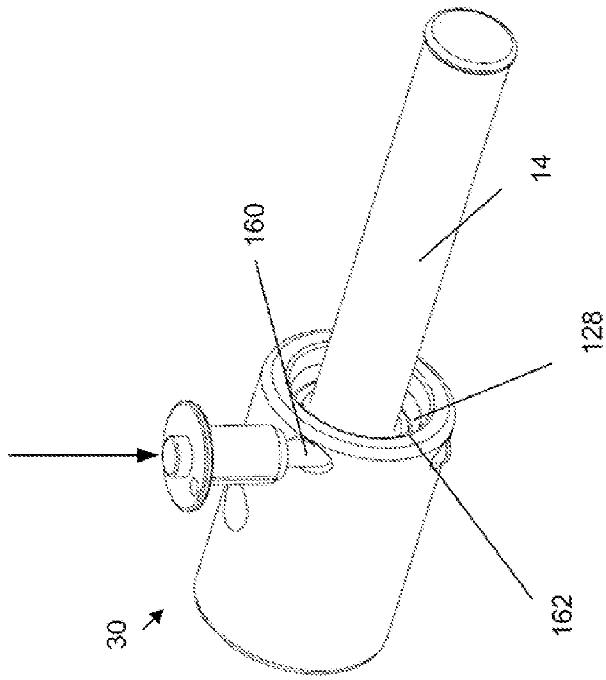

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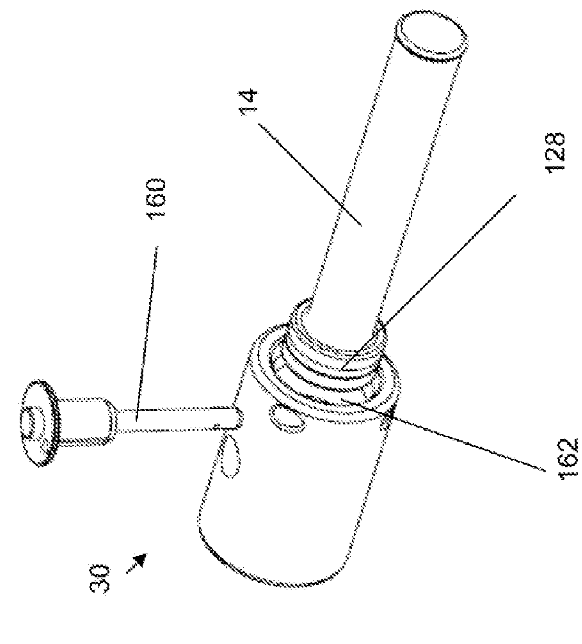

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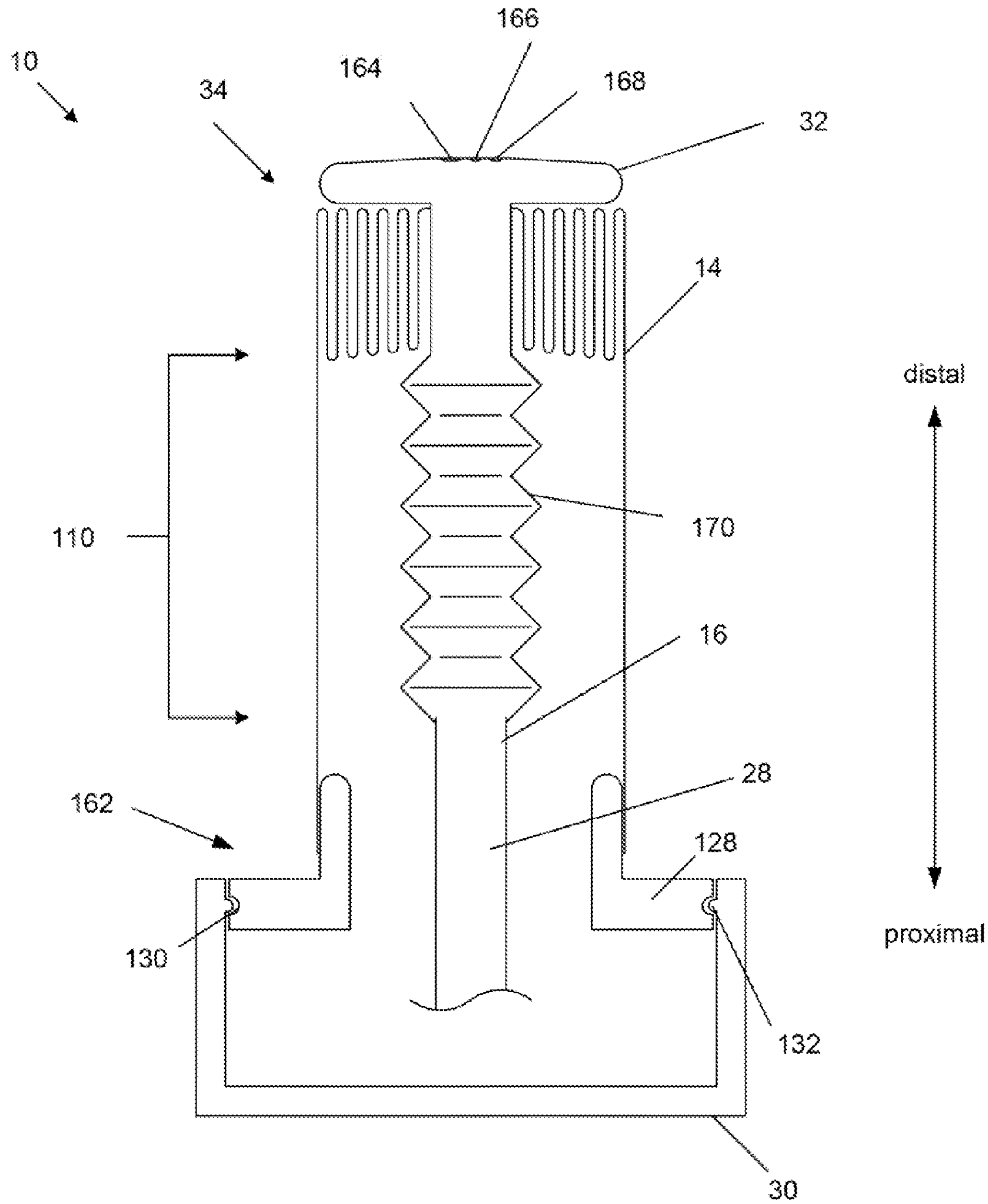
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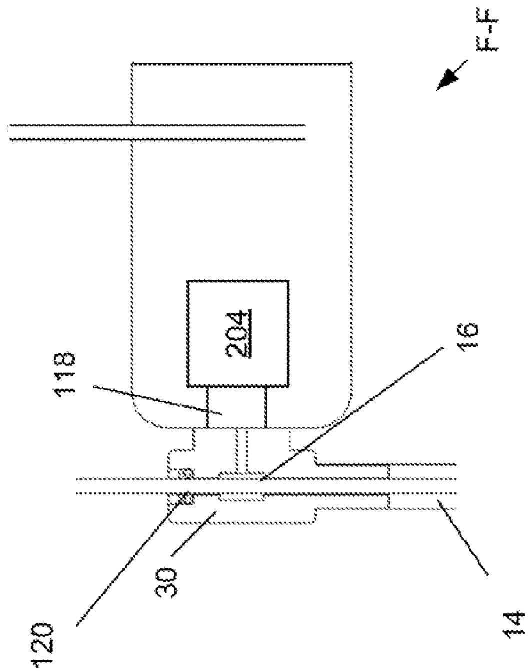
Fig. 27f



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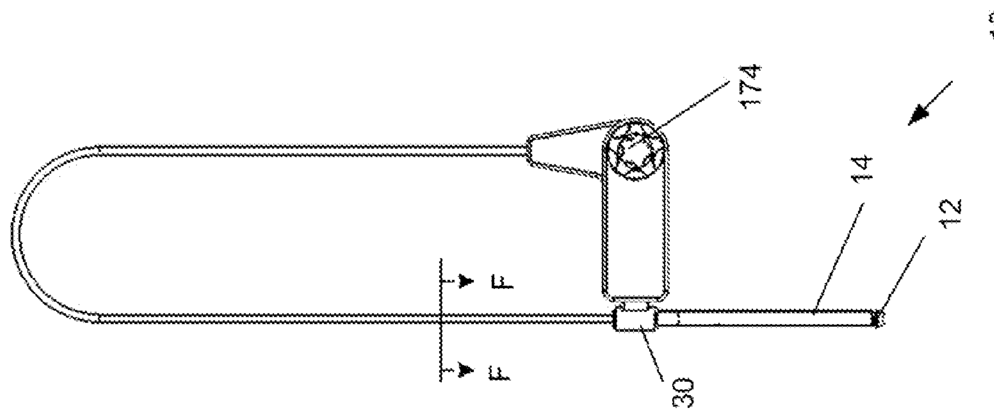

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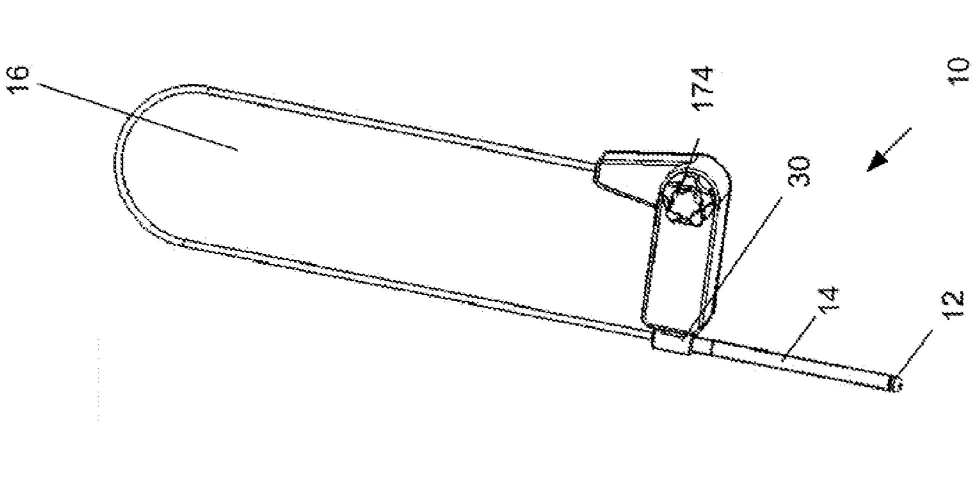

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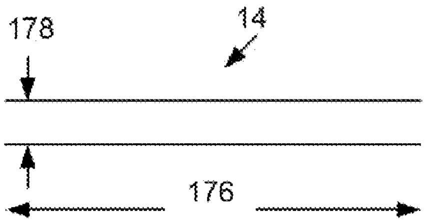

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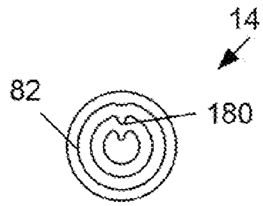

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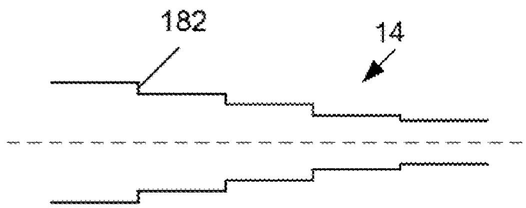

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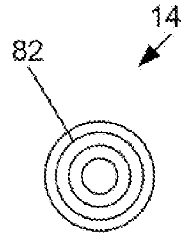

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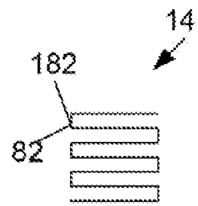

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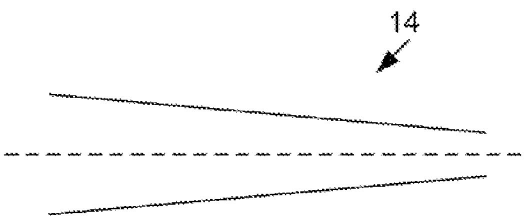
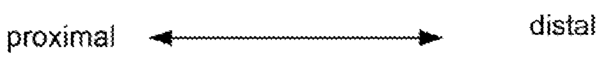
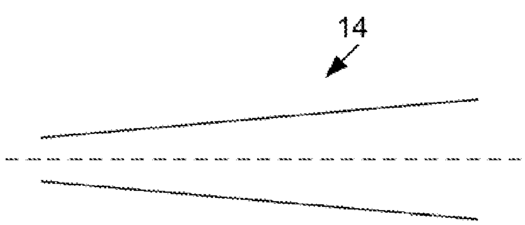


Fig. 34a





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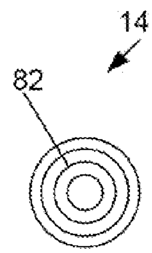

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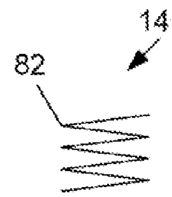

Fig. 34d

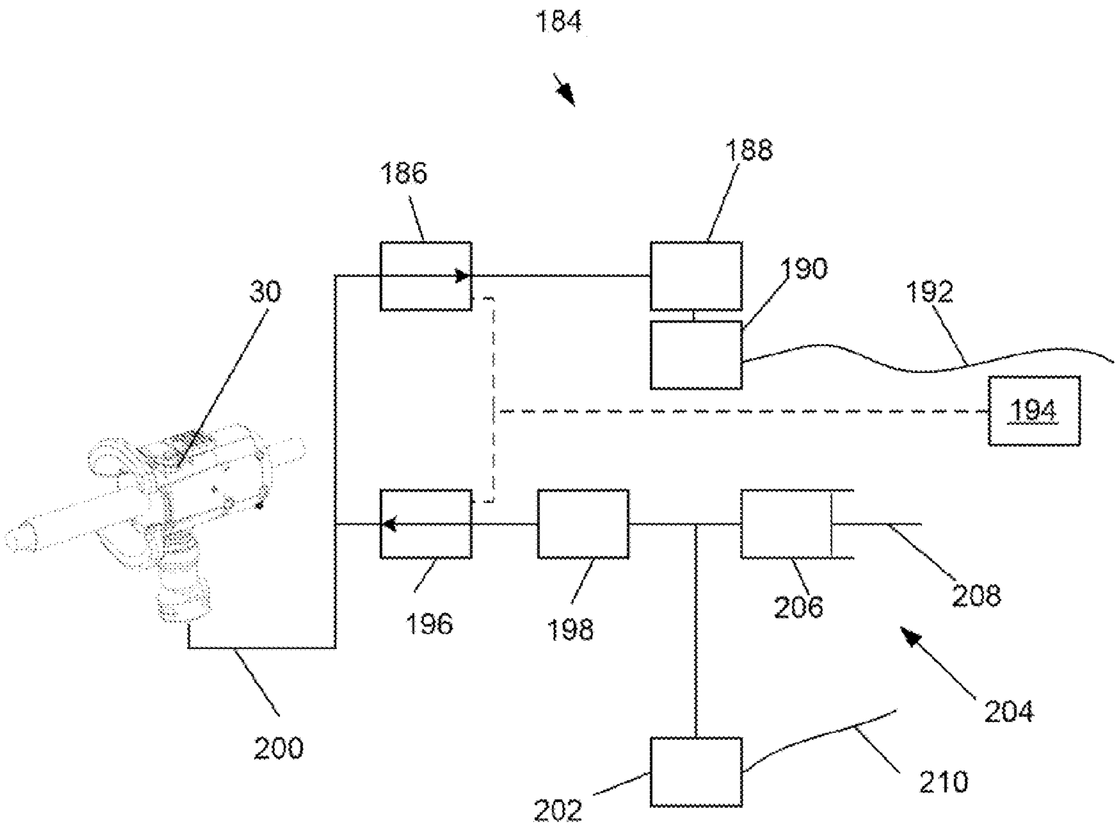

Fig. 35

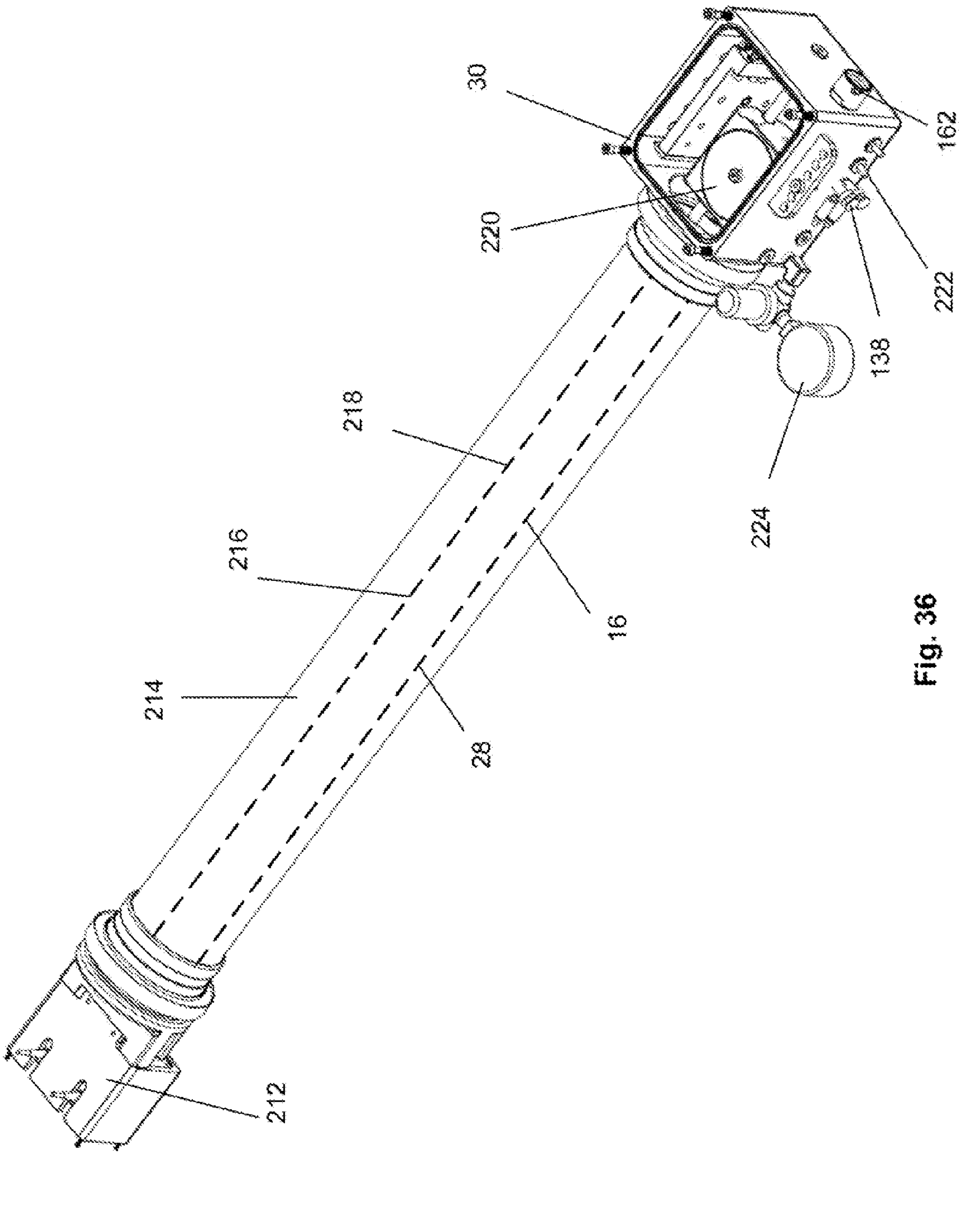

Fig. 36

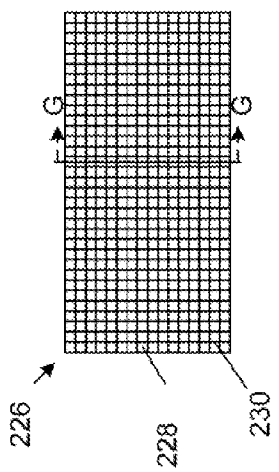

Fig. 37

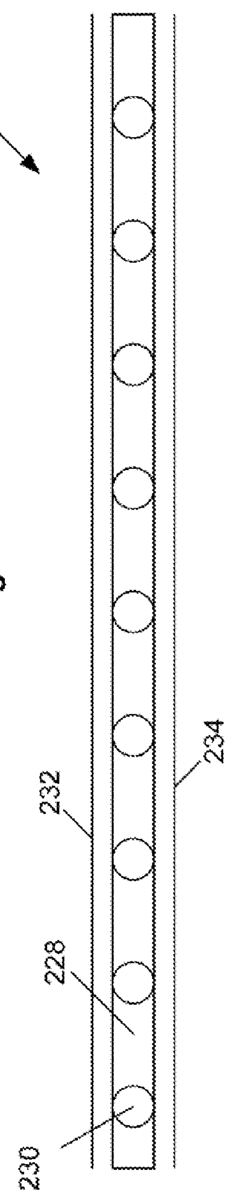

Fig. 38a

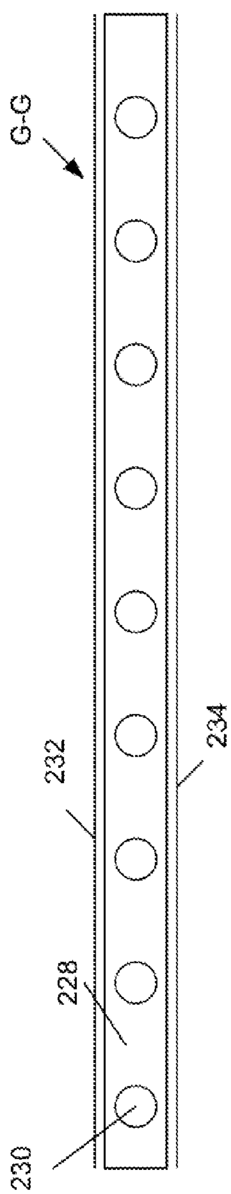

Fig. 38b

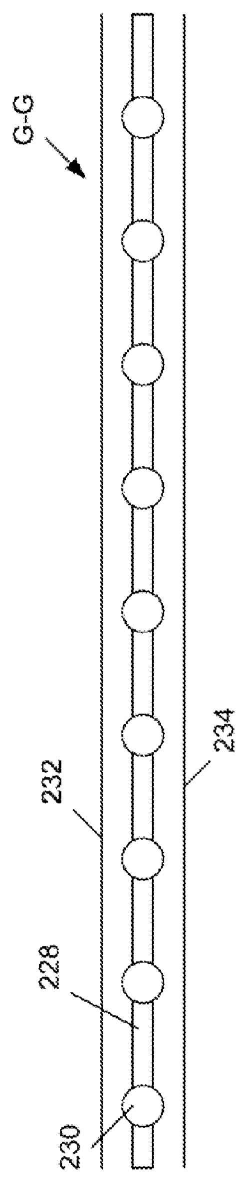

Fig. 38c

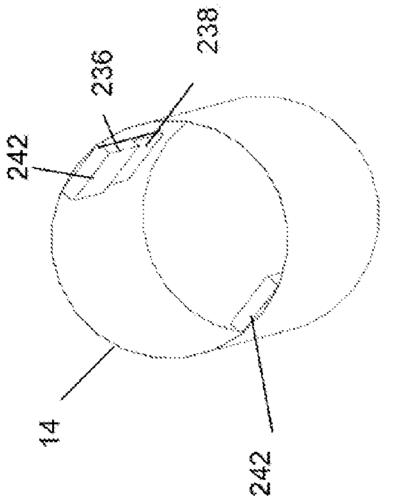

Fig. 40

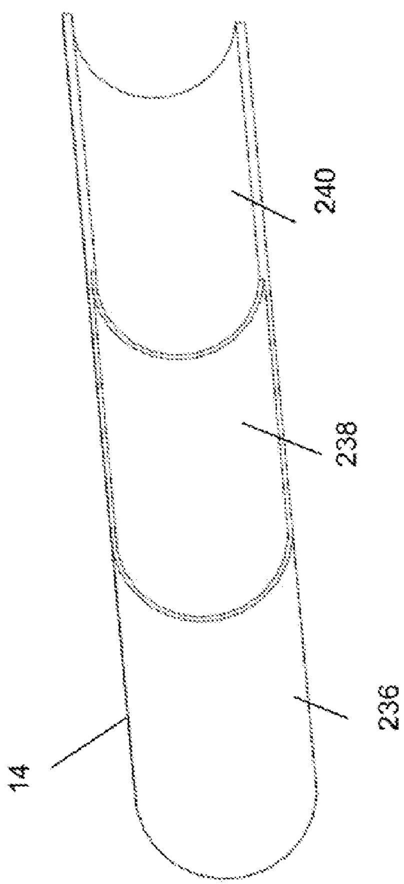

Fig. 39

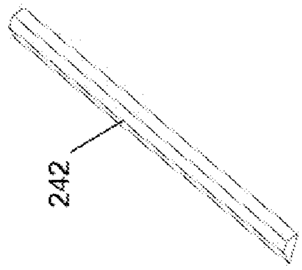

Fig. 41d

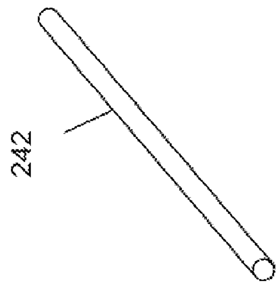

Fig. 41c

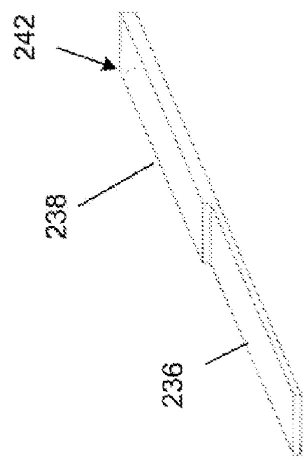

Fig. 41b

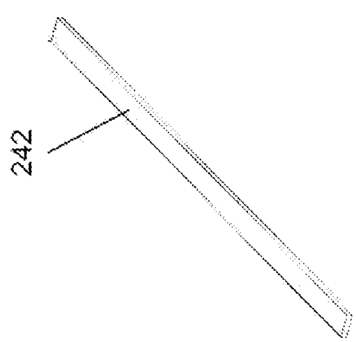

Fig. 41a

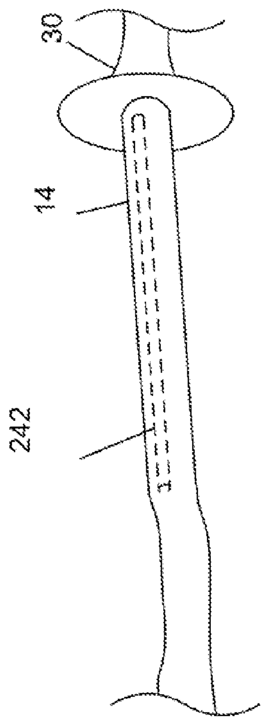

Fig. 42a

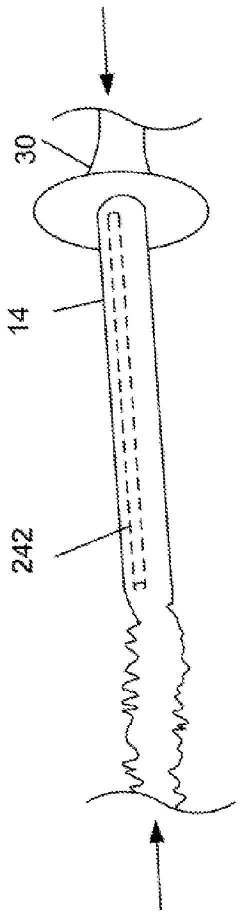

Fig. 42b

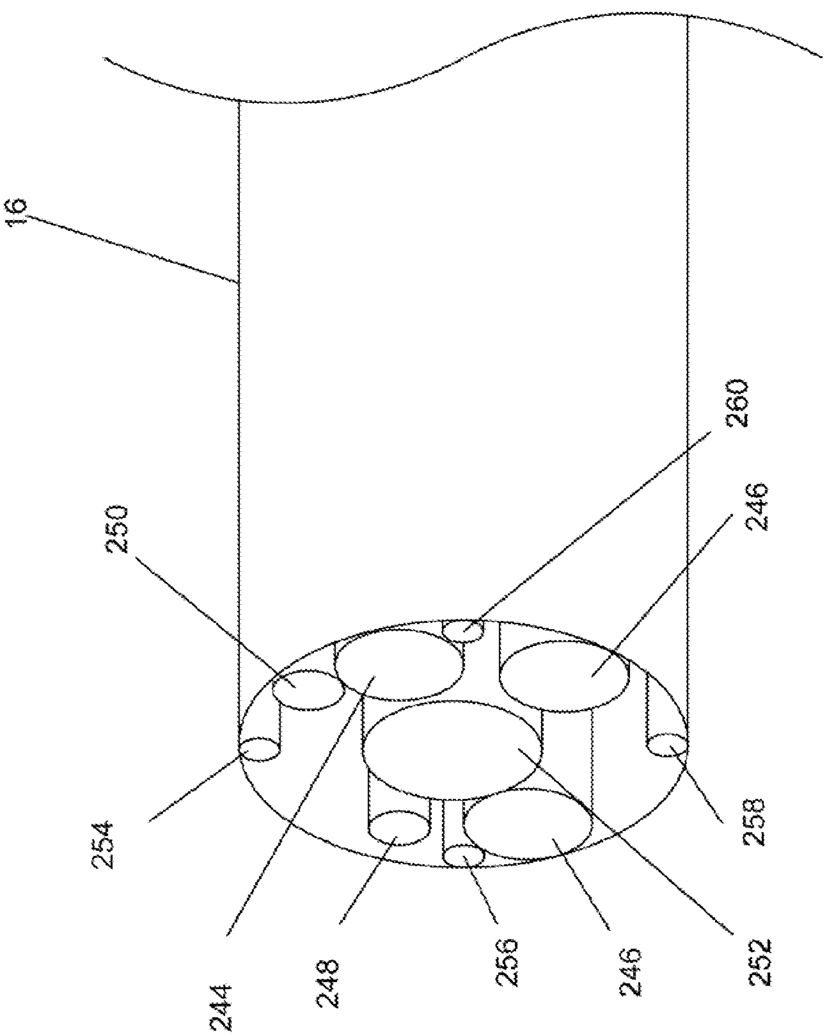

Fig. 43

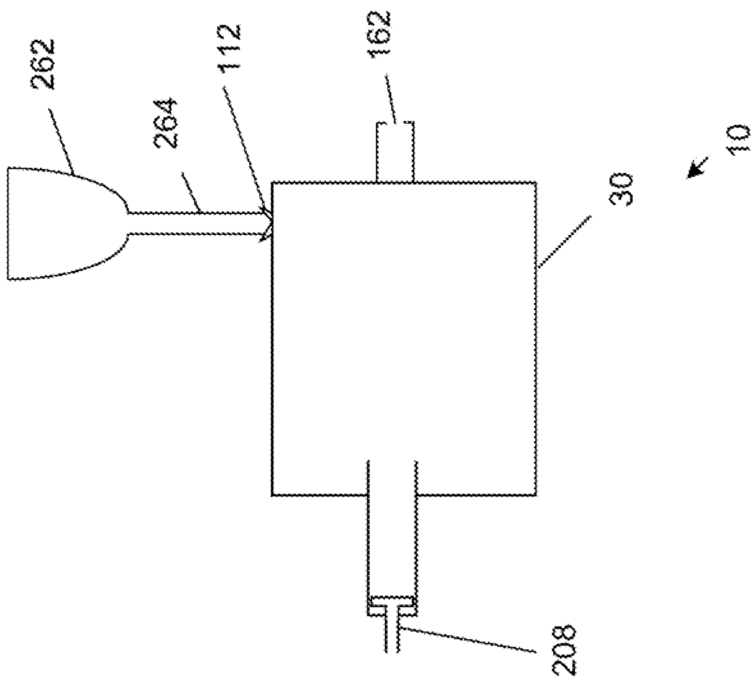

Fig. 44

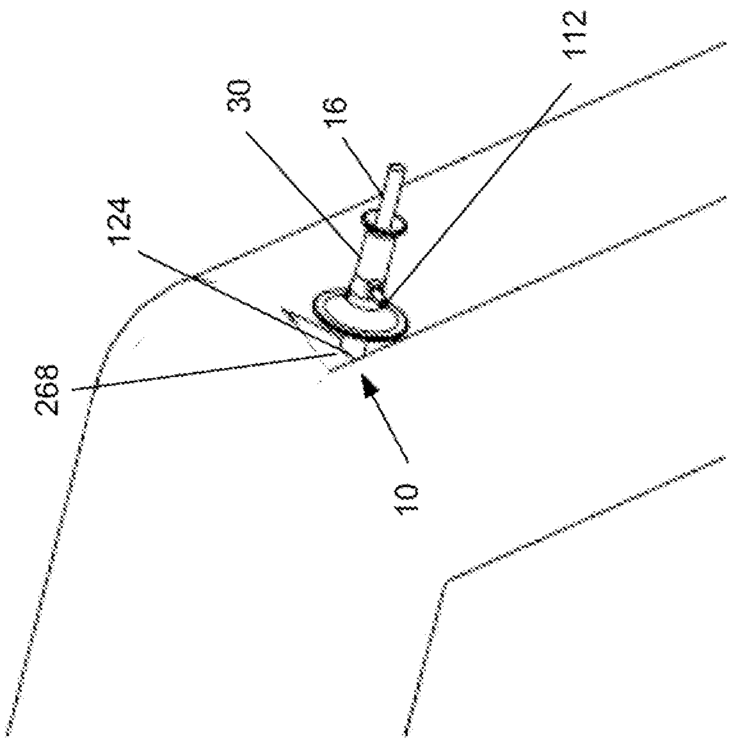

Fig. 45

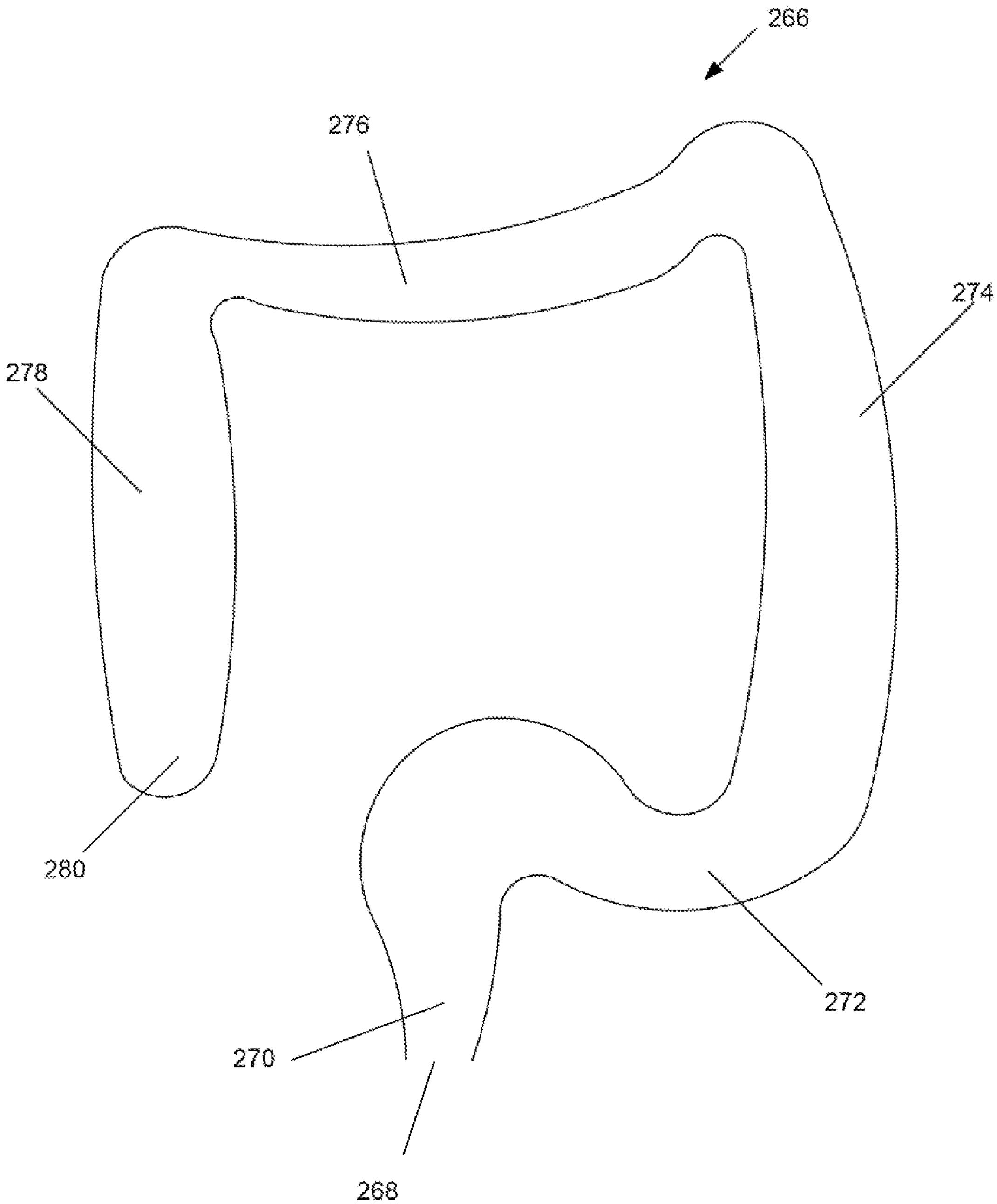

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Fig. 46

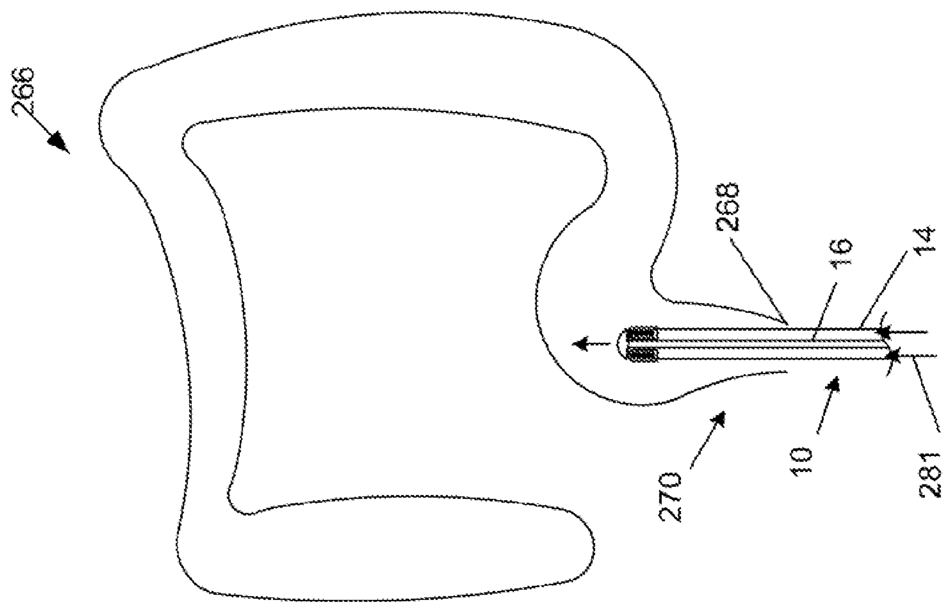

Fig. 47b

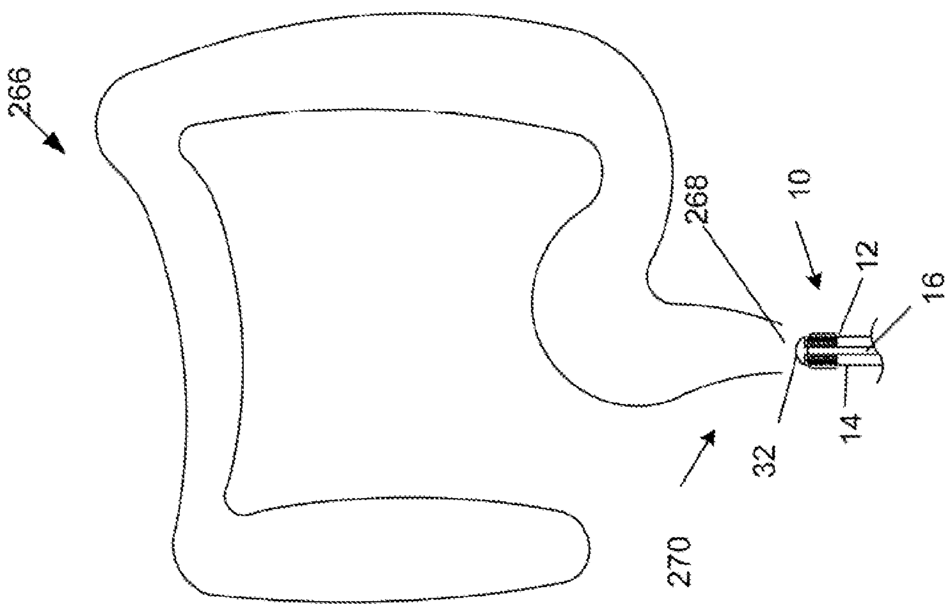

Fig. 47a

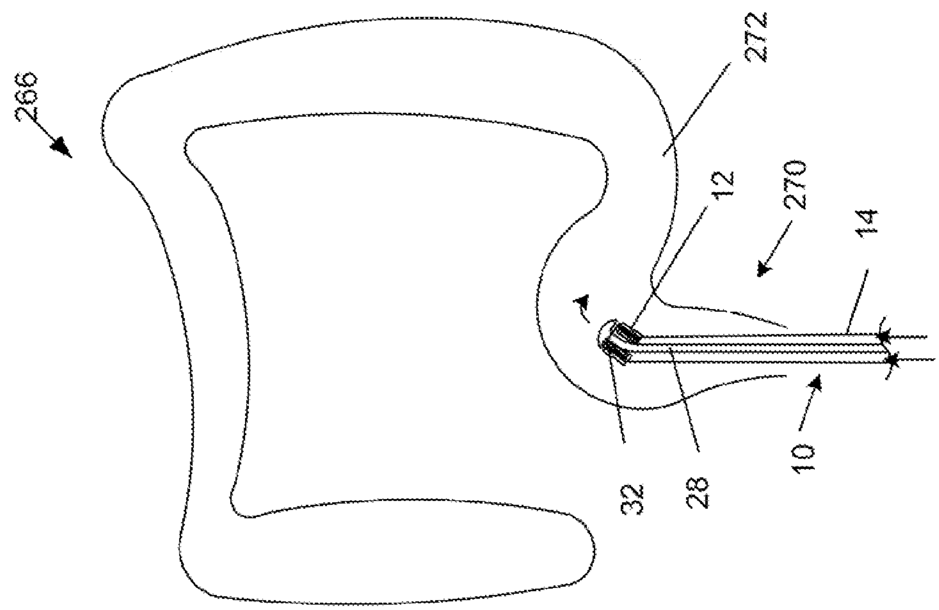

Fig. 47c

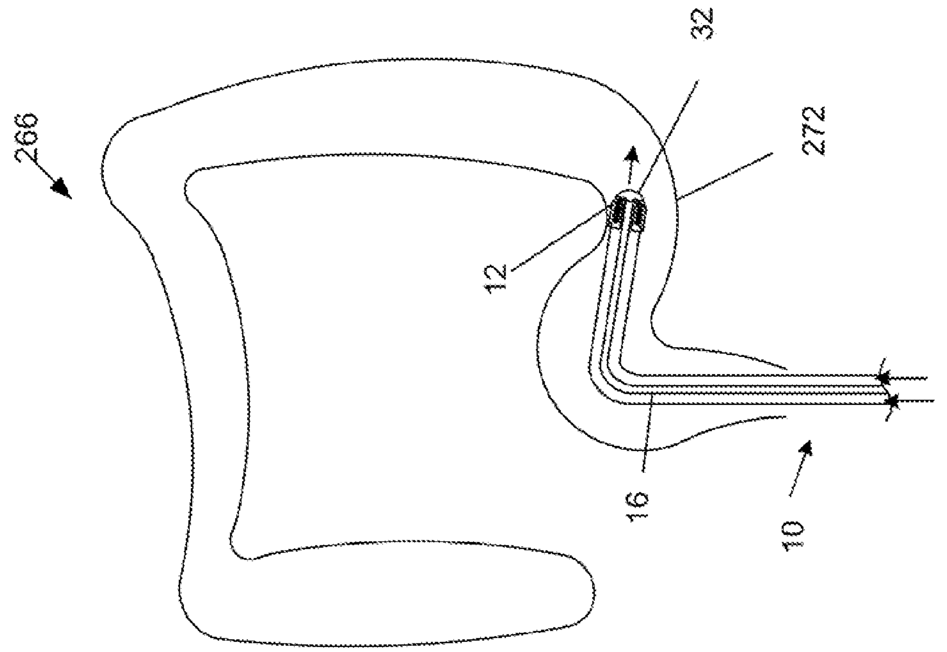

Fig. 47d

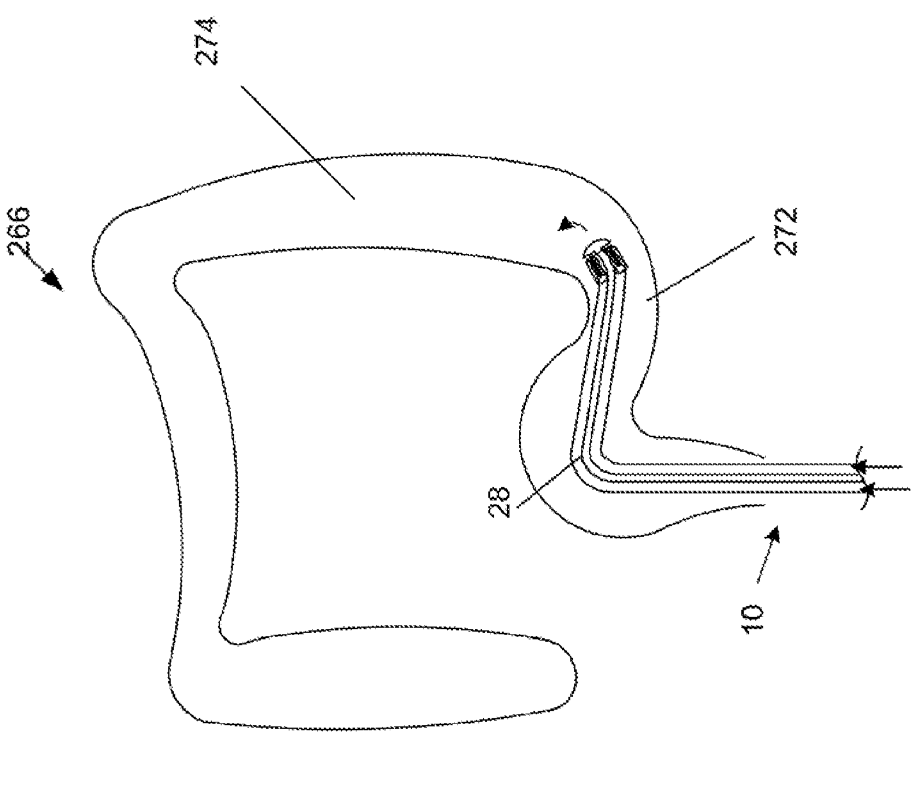

Fig. 47e

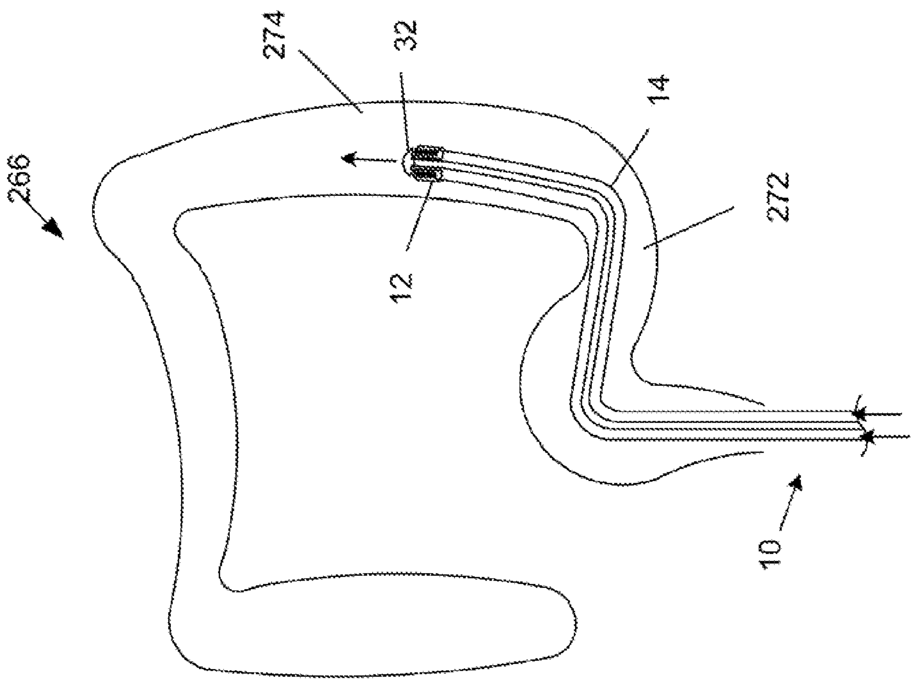

Fig. 47f

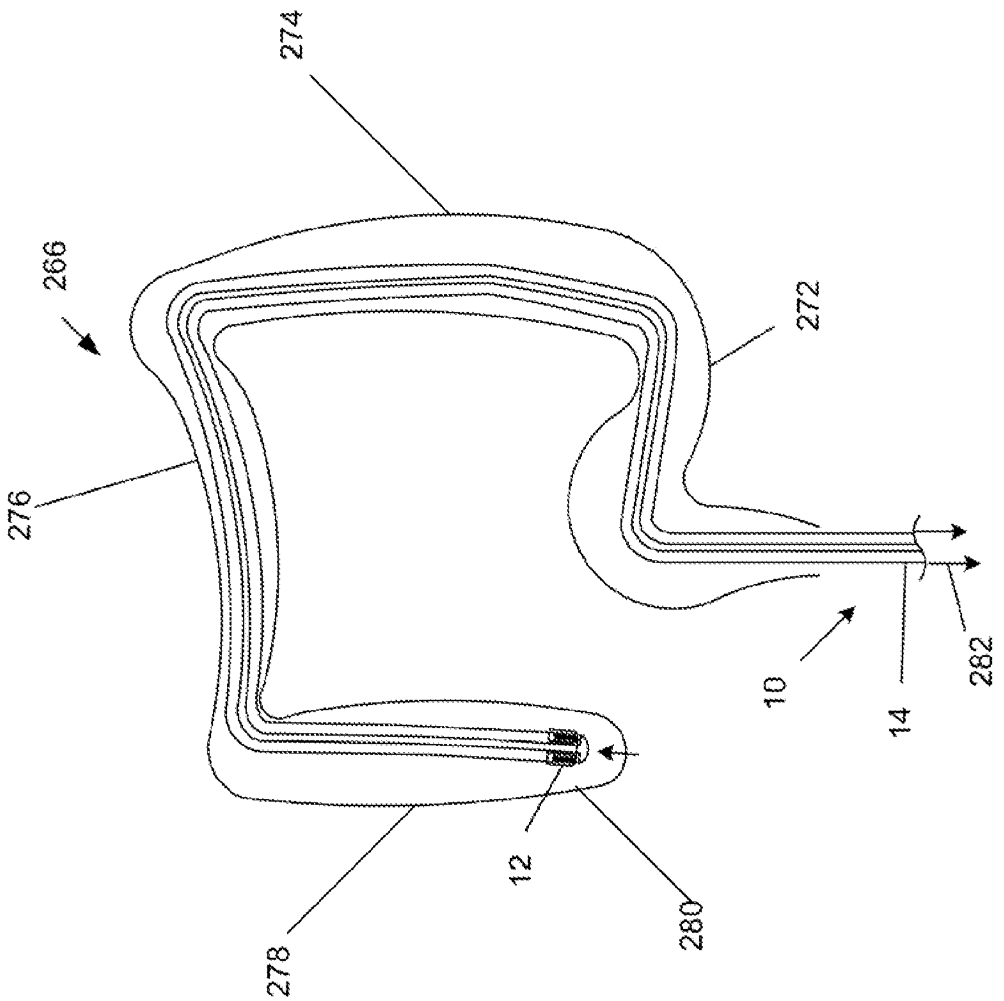

Fig. 47g

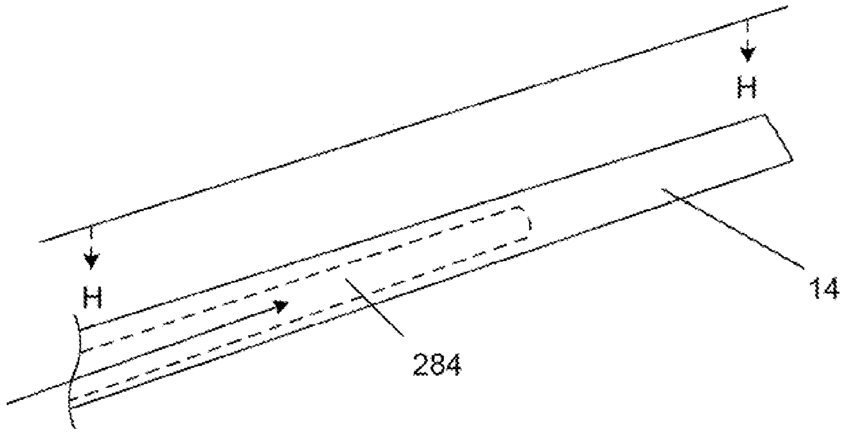

Fig. 48a

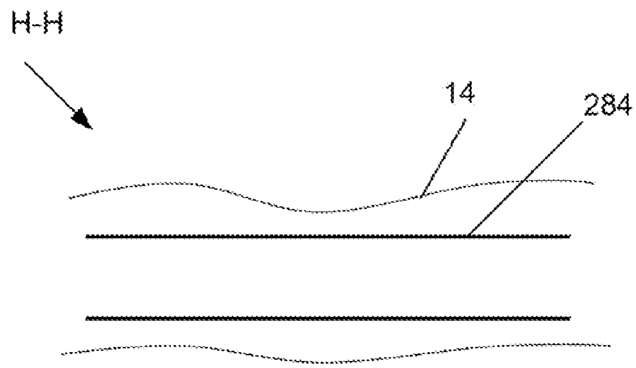

Fig. 48b

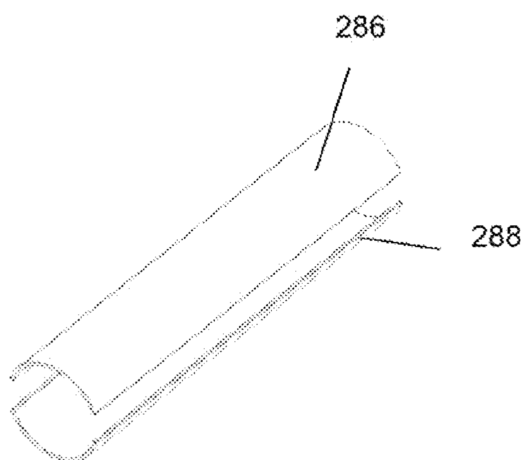

Fig. 48c

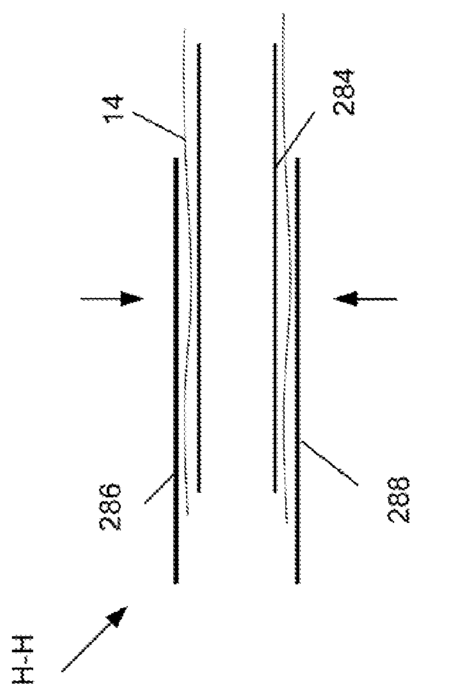

Fig. 48d

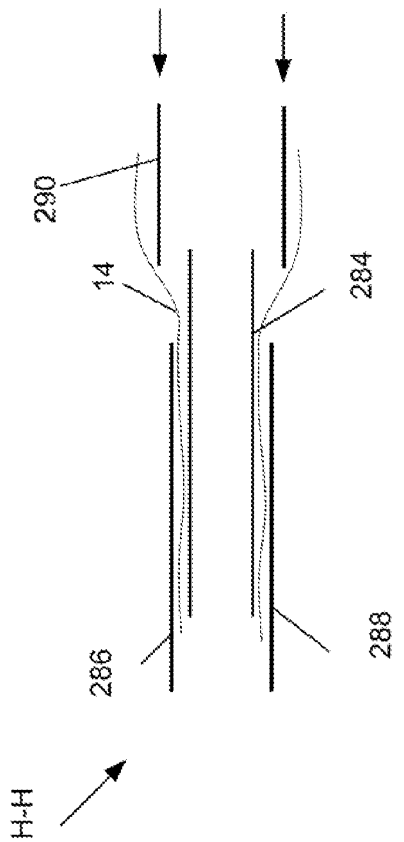

Fig. 48e

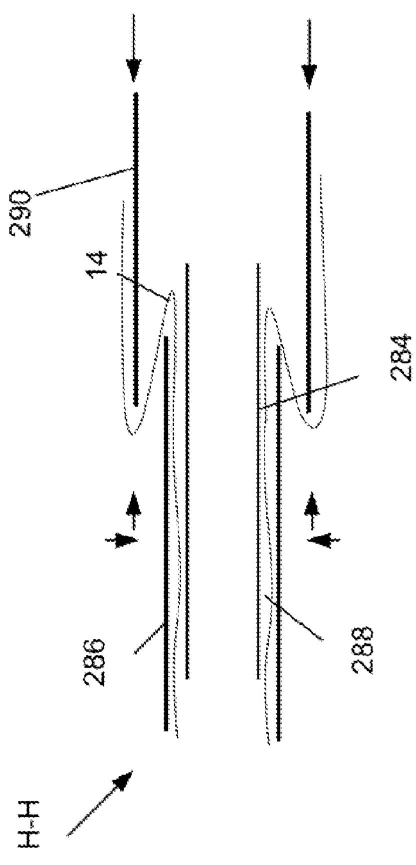

Fig. 48f

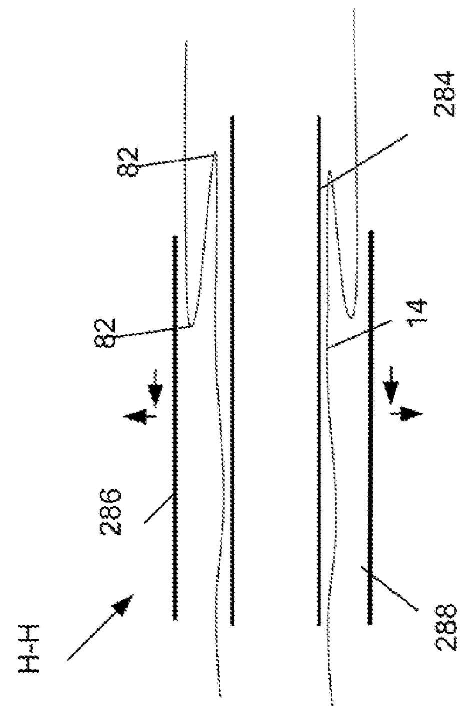

Fig. 48g

BIOLOGICAL NAVIGATION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of prior PCT Application No. PCT/US2008/052535 filed 30 Jan. 2008, which claims priority to U.S. Provisional Application Ser. Nos. 60/887,319, filed 30 Jan. 2007; 60/887,323, filed 30 Jan. 2007; and 60/949,219, filed 11 Jul. 2007, which are all incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The presented invention relates generally to devices for the exploration of luminal cavities. One such device example is an endoscope, which can be used to explore body passages. Such passages typically include, but are not limited to, the GI tract, the pulmonary and gynecological systems, urological tracts, and the coronary vasculature. One application is directed towards the exploration of the lower part of the GI tract, for example the large intestine or colon.

[0004] 2. Description of the Related Art

[0005] Colonoscopy is a diagnostic and sometimes therapeutic procedure used in the prevention, diagnosis and treatment of colon cancer, among other pathologies. With colonoscopy, polyps can be harvested before they metastasize and spread. With regular colonoscopies, the incidence of colon cancer can be substantially reduced.

[0006] The anus can provide entry into the colon for a colonoscopy. The colon extends from the rectum to the cecum and has sigmoid, descending, transverse and ascending portions. The sigmoid colon is the s-shaped portion of the colon between the descending colon and the rectum.

[0007] Colonoscopy typically involves the anal insertion of a semi-flexible shaft. To typically navigate the colon, the forward few inches of tip are flexed or articulated as the shaft is alternately pushed, pulled, and twisted in a highly skill-based attempt to advance to the end of the colon: the cecum. The medical professional imparts these motions in close proximity to the anus, where the device enters. Tip flexure has typically been accomplished by rotating wheels—one that controls cables that move the tip right-left, and one that controls cables that move the tip up-down.

[0008] Colonoscopes typically utilize various conduits or channels. The conduits or channels often contain elements that enable vision (e.g., fiber optics, CCD cameras, CMOS camera chips) and lighting (e.g., fiber optic light sources, high power LEDs (Light Emitting Diodes)). They have conduits that provide suction or pressurization, fluid irrigation, the delivery of instruments (e.g., for cutting, coagulation, polyp removal, tissue sampling) and lens cleaning elements (typically a right angle orifice that exits near the camera, such that a fluid flush provides a cleansing wash).

[0009] Colonoscopes include articulating sections at their tip, which allow the user to position the tip. These articulating sections have rigid link bodies that rotate relative to each other through the use of pins at their connecting joints. As tensile cables pull from the periphery of the articulating sections, they impart torques, which rotate the link sections on their pins, articulating the tip section. The links are usually rotated by two or four tensile cables.

[0010] Typical commercially available colonoscopes are currently reusable. However, as disposable and other lower-cost colonoscopes are developed, these articulatable sections are no longer practical. Their high part count creates total costs that are exorbitant for a lower cost, disposable device. The pivot pins can also fall out, which can create a patient danger. Their design geometries, while suited for long life, high cost, high strength metals elements, don't readily suit themselves to the design goals of lower-cost and more readily mass-produced parts.

[0011] Suction can be utilized to remove debris or fluid. The colon can be pressurized to reconfigure the coloninto an expanded cross-section to enhance visualization.

[0012] During advancement of the colonoscope through the colon, landmarks are noted and an attempt is made to visualize a significant portion of the colon's inside wall. Therapeutic actions can occur at any time, but are typically performed during withdrawal.

[0013] Navigating the long, small diameter colonoscope shaft in compression through the colon—a circuitous route with highly irregular anatomy—can be very difficult. Studies have shown a learning curve for doctors performing colonoscopies of greater than two-hundred cases. Even with the achievement of such a practice milestone, the cecum is often not reached, thereby denying the patient the potential for a full diagnosis.

[0014] During colonoscopy, significant patient pain can result. This is typically not the result of colon wall contact or of anal entry. The primary cause of pain is thought to be stretching and gross distortion of the mesocolon (the mesentery that attaches the colon to other internal organs). This is commonly referred to as 'looping' and is a result of trying to push a long, small diameter shaft in compression as the clinician attempts to navigate a torturous colon. While attempting to advance the tip by pushing on the scope, often all that occurs is that intermediate locations are significantly stretched and grossly distorted. Due to this pain, various forms of anesthesia are typically given to the patient. Anesthesia delivery results in the direct cost of the anesthesia, the cost to professionally administer, the costs associated with the capital equipment and its facility layouts, and the costs associated with longer procedure time (e.g., prep, aesthesia administration, post-procedure monitoring, and the need to have someone else drive the patient home). It has been estimated that forty percent of the cost of a colonoscopy can be attributed to the procedure's need for anesthesia.

[0015] Cleaning of colonoscopes is also an issue. Cleaning is time consuming, and lack of cleaning can result in disease transmission. Cleaning can utilize noxious chemicals and requires back-up scopes (some in use while others being cleaned). Cleaning also creates significant wear-and-tear of the device, which can lead to the need for more servicing.

[0016] It would therefore be desirable to create a system that is less painful—possibly not even requiring anesthesia—is significantly easier to use, and does not require cleaning.

[0017] Evening tube systems have been proposed for use as colonoscopes. However, multiple challenges exist for evening systems. One typical challenge is the differential speed between the center lumen and the tip. For example, as the typical everting tube is advanced, the center lumen of the colonoscope advances 2" for every 1" of eversion front advancement. When the center advances it moves only itself, whereas tip movement advances material on both sides. Because there is this dual wall material requirement for tip advancement, two times as much material is required, so it inherently must travel at half the rate.

[0018] Anything that is in the center of the typical everting tube is 'pressure clamped,' as the tube's inner diameter collapses to no cross sectional area as the tube is pressurized. This can make it difficult to try to solve the 2:1 problem in a typical everting tube by sliding elements in the inner diameter or central region.

[0019] This 2:1 advancement issue and the pressure clamping can make it difficult to locate traditional colonoscope tip elements at the everting tip's leading edge. Given that the tube is often long and pressurized, it therefore often precludes the ability to create a functioning center working channel.

[0020] Another issue is internal drag. Material (e.g., tube wall) fed to the tip can cause increased capstan drag, for example the overall system advance force can be retarded to the point of stopping extension.

[0021] Optimal material selection is a highly significant challenge. The desired structure must have a rare combination of features: softness, strength, radial stiffness, low thickness, freedom from leaks, flex-crack resistance, puncture resistance, appropriate coefficient of friction, the potential for modifiable geometry as a function of length, and appropriate manufacturability and cost. Monolithic materials have proven insufficient at providing the variety of requisite specifications.

[0022] It can be difficult to create a system that is of adequately low stiffness. Larger diameters create higher propulsive forces, but they also do not typically readily conform to the colon in a lumen-centric manner and can be overly stiff.

[0023] Historically, several solutions have been suggested. One involves periodically depressurizing the system then withdrawing elements so that their leading edges match. This is time consuming and creates an undesirably non-continuous and geometrically interrupted procedure. It is also very difficult to create 'correct' undesirable relative motion to a deflated structure that essentially is no longer a structure. Another approach involves driving the inner lumen (typically with a special, thicker, anti-buckle wall). Because it is driven in compression rather than through pressure, the everting front can be inflated to a lower pressure such that its pressure clamping forces are less significant. This approach, augmented by the significant infusion of liberal amounts of interluminal lubricants, should enable advance. However, it has yet to be commercialized, it is very complicated, creates an undesirably larger diameter instrument, has lubrication leakage issues, and breaks down at longer advance lengths.

[0024] Additionally, colonoscopic devices have found it notably challenging to create methods to steer through torturous geometries, particularly without undue colon wall stresses and subsequent mesocolon stretch. Steering kinematics have been an ongoing challenge—certainly for existing colonoscopes (which result in 'looping'), but also to more effective next-generation devices.

[0025] Numerous driven tubes have been proposed for colonoscopy. Some utilize tube inlaid elements driven in compression. Others utilize tubes that are pressure driven, with their tubes being of multiple varieties, including the bellows variety, or everting types, or other stored material varieties, including scrunch, fold, or spooled versions.

[0026] The systems proposed to-date have geometries that create suboptimal steering efficacies. When a propulsion tube section's leading edge then has a steering section more distal, with typically a camera, lighting source, and working channel exit at the tip, the steering is less than effective when going around a corner: A situation is created in which the tip is retroflexed and is pointing in one desired direction of advance, but the system's advance is in an exactly opposite direction. The driven section presumes a vector—typically an axial manner—with the steering tip only having efficacy as it relates to its interaction with luminal walls. In a colonoscopy, this wall interaction is undesirable—it creates unnecessary wall stress and trauma, and can be a significant contributor to gross wall distortion, known as looping.

[0027] It would therefore be desirable to have system designs that enable more lumen-centric steering as the unit is advanced through colon curvature. Other improvements are also desired.

[0028] Additionally, during colonoscopy, a common kinematic procedure is called 'reduction' or 'reducing.' In this maneuver, the colonoscope shaft is withdrawn such that there is a reduced amount of colonoscope shaft for a given colon length. For example, before reducing the sigmoid colon, there can be fifteen inches of colonoscope shall threaded through this portion of the patient's anatomy. After reduction, the same portion of colon can be threaded with only a few inches of colonoscope shaft length. This reduction procedure is an important maneuver that allows the endoscopist to straighten out and maneuver though what was previously circuitous colon.

[0029] When this procedure is done in conjunction with a system that utilizes a pressure sleeve, the pressure sleeve is put into compression. During some reduction maneuvers, the reduced length of pressure sleeve for a given colonoscope shaft length can be upwards of twelve inches. As a result, the pressure sleeve is compressed and, when subsequently repressurized or otherwise again moved forward, it tends to propel itself forward from these compressed or buckled regions. Given that these regions tend to occur in regions close to the anus, the end effect is subsequent propulsion that is anus-based, rather than colonoscope tip-based. This effect compromises subsequent kinematics and the desired tip-based propulsion, which can lead to undesirable affects such as looping. Pressure sleeve wall thicknesses are typically only a few thousandths of an inch thick. When the through-center colonoscope shaft is withdrawn in tension, the pressure sleeve walls are loaded in compression, and they may buckle.

[0030] It would therefore be desirable to have pressure sleeve system elements that preferentially buckled, so that the reduced or compressed pressure sleeve regions were most typically located more distal than the anus and moved closer to the system's tip.

SUMMARY OF THE INVENTION

[0031] A device for navigating biological lumen is disclosed. The device can be used for treatment and/or diagnosis. For example, the device can have or be attached to a visualization element and can be used as a colonoscope and/or an endoscope. The device can also have a biopsy element. The device can also resect tissue and/or deliver drugs or other agents.

[0032] The device can have a removable cartridge. The cartridge can have a pressurizable tube at least partially stored in a head. The cartridge can be attached to a base through which an elongated element can be deployed.

[0033] The device can have one or more pressurizable tubes. The tubes can be 'scrunched' or folded at the front. The tube material can all be located distal or proximal to an ariculatable steering section on the elongated element. The tube material can be partially located distal to the tip steering section. The tube material can be entirely located proximal to the tip steering section. The tubes can be sequentially staggered. After each lengthwise portion, the tube can have a sudden step-wise reduction in diameter, including equivalent to the previous section's diameter minus the walls thicknesses. This could create a steadily sequentially smaller diameter tube that packs well. The tubes can have tapered segments coupled with other elements, including staggers or straight sections. The tube can be configured to minimize creasing and have high packing densities during tube storage.

[0034] These cartridges can be attached via the head to the tip of an elongated element. The tube can then be pressurized to be propelled. The base or manifold can deliver pressure into the tube. The base can seal between the tube and the elongated element. The head can seal between the tube and the elongated element.

[0035] High pressure fluid can be delivered to the base. The fluid can be water or saline. The fluid can be delivered via a pump. The fluid can be delivered by a piston that is moved by an actuator; this method serves to minimize stored system energy. As the piston is driven, it can increase pressure which, when released to the tube can lead to the extension of the pressure tube. When the piston is withdrawn, it can create a vacuum that serves to evacuate a significant portion of the fluid in the tube.

[0036] The development of disposable cartridges can reduce or eliminate cleaning costs, cleaning trouble, and the risk inherent to reused devices. The risk of a poorly cleaned elongated element can be reduced because the elongated element can be substantially covered by the pressurizable tube.

[0037] The disclosed system, device or elements thereof can be used as elements that are combined into dedicated systems, as portions of dedicated systems (portions that can be reusable and portions that can be separable on a case-by-case basis, with some reused and some disposed of, sometimes referred to as 'semisposables' or 'resposables'), or as additive elements to existing systems (i.e., retrofit device). Disposable systems only need to function for limited life, and they do not have to interface with other components again and again. Semisposable varieties can utilize a very high-quality, higher-cost core device portion, and lower cost, single-use portions. The single use portions can negate the need for most of the typical cleaning, for example for the sheath exposed portions. Adding to existing systems can leverage large installed bases, methods, and usage patterns.

SUMMARY OF THE FIGURES

[0038] FIG. **1** illustrates a distal end of variation of the biological navigation device and an elongated element.

[0039] FIGS. **2***a* and **2***b* illustrate a variation for deploying the biological navigation device having a locally, tip-based bunched or scrunched tube.

[0040] FIG. **3***a* is a perspective view of cross-section A-A of a variation of the device and the elongated element of FIG. **1**.

[0041] FIG. **3***b* is a side view of cross-section A-A of the variation of the device and the elongated element of FIG. **3***a*.

[0042] FIG. **3***c* is a perspective view of cross-section A-A of the variation of the device of FIG. **3***a*.

[0043] FIG. **4***a* illustrates a cross-section of a variation of the biological navigation device.

[0044] FIG. **4***b* illustrates cross-section a variation of a method for using the biological navigation device of FIG. **4***a*.

[0045] FIG. **5** illustrates is a perspective view of cross-section A-A of a variation of the biological navigation device and the elongated element of FIG. **1**.

[0046] FIGS. **6***a* through **6***g* illustrate transverse cross-sections of variations of shaft seals.

[0047] FIGS. **7***a* and **7***b* illustrate a longitudinal cross-section of a variation of the biological navigation device and the elongated element in first and second configurations, respectively.

[0048] FIG. **8***a* illustrates a longitudinal cross-section of a variation of the biological navigation device and the elongated element.

[0049] FIG. **8***b* illustrates a close-up of the distal end of the biological navigation device and elongated element of FIG. **8***a*.

[0050] FIG. **9***a* illustrates a longitudinal cross-section of a variation of the biological navigation device and the elongated element.

[0051] FIG. **9***b* illustrates a close-up of the distal end of the colonoscope of FIG. **9***a*.

[0052] FIG. **10** illustrates a variation of the head and cap.

[0053] FIG. **11** illustrates a perspective view of a variation of the clamp on the head.

[0054] FIG. **12** illustrates a variation of a method of assembling the head with a shear clip and an elongated element.

[0055] FIG. **13***a* illustrates a variation of a method of assembling the head with a shear clip and an elongated element.

[0056] FIG. **13***b* illustrates the head, shear clip and elongated element of FIG. **13***a* in an assembled configuration.

[0057] FIG. **13***c* is a variation of cross-section B-B of FIG. **13***b*.

[0058] FIG. **14** is a perspective view of cross-section A-A of a variation of the biological navigation device of FIG. **1**

[0059] FIGS. **15** and **16** illustrate variations of the biological navigation device and elongated element.

[0060] FIG. **17** is a variation of cross-section C-C of FIG. **16**.

[0061] FIG. **18***a* illustrates a variation of the base, the tube and the elongated element.

[0062] FIG. **18***b* is a variation of cross-section D-D of FIG. **18***a*.

[0063] FIG. **18***c* is a variation of cross-section D-D of FIG. **18***a* without the elongated element.

[0064] FIG. **19***a* illustrates a variation of the base and the elongated element.

[0065] FIG. **19***b* illustrates the variation of the base and the elongated element from FIG. **19***b* with the tube.

[0066] FIG. **20***a* illustrates a variation of the biological navigation device in an assembled configuration

[0067] FIG. **20***b* illustrates the biological navigation device of FIG. **20***a* in a disassembled configuration.

[0068] FIG. **21** illustrates a variation of the biological variation device of FIG. **20***a* in an elongated configuration.

[0069] FIG. **22***a* is a perspective view of a variation of the base with the tube connector.

[0070] FIG. **22***b* is a top perspective view of the base of FIG. **22***a*.

[0071] FIG. **23***a* illustrates a variation of the base with the tube and the elongated element.

[0072] FIG. **23***b* is a variation of cross-section E-E of FIG. **23***a*.

[0073] FIG. **24***a* is a partial cross-section of a variation of the biological navigation device in a retracted configuration.

[0074] FIG. **24***b* is a cross-section of the variation of the biological navigation device of FIG. **24***a* in an extended configuration.

[0075] FIG. **25** illustrates a cross-sectional view of a variation of a biological navigation device system.

[0076] FIGS. **26***a* through **26***e* are close-up views of variations of section W of FIG. **25**.

[0077] FIG. **27***a* illustrates a variation of a cartridge or cassette.

[0078] FIG. **27***b* illustrates a variation of a cartridge or cassette with a working channel sleeve.

[0079] FIG. **27***c* illustrates a variation of the threaded tip of the elongated element.

[0080] FIG. **27***d* illustrates a variation of a method for assembling the elongated element and the cartridge.

[0081] FIG. **27***e* is a perspective distal end view of the cartridge and elongated element in an assembled configuration.

[0082] FIG. **27***f* illustrates a cross-section of a variation of the biological navigation device.

[0083] FIG. **28***a* illustrates a variation of a method for fitting the female exit port and the tube connector.

[0084] FIG. **28***b* illustrates a variation of a method for locking the tube connector in the female exit port with a quick-release shear pin.

[0085] FIGS. **29** and **30** illustrate a variation of the biological navigation device and the elongated element.

[0086] FIG. **31** illustrates a variation of cross-section F-F of FIG. **30**.

[0087] FIG. **32***a* illustrates a longitudinal cross-section of a variation of the tube in a longitudinally elongated configuration.

[0088] FIG. **32***b* is an end view of a variation of the tube in a longitudinally contracted configuration.

[0089] FIG. **33***a* illustrates a longitudinal cross-section of a variation of the tube in a longitudinally elongated configuration.

[0090] FIG. **33***b* is an end view of the tube of FIG. **33***a* in a longitudinally contracted configuration

[0091] FIG. **33***c* is a longitudinal cross-section of half of a variation of the tube of FIG. **33***a* longitudinally contracted configuration

[0092] FIG. **34***a* illustrates a longitudinal cross-section of a variation of the tube in a longitudinally elongated configuration.

[0093] FIG. **34***b* illustrates a longitudinal cross-section of a variation of the tube in a longitudinally elongated configuration.

[0094] FIG. **34***c* is an end view of the tube of FIG. **34***a* or **34***b* in a longitudinally contracted configuration.

[0095] FIG. **34***d* is a longitudinal cross-section of half of a variation of the tube of FIG. **34***a* or **34***b* in a longitudinally contracted configuration.

[0096] FIG. **35** is a schematic view of a variation of the base and a fluid system.

[0097] FIG. **36** illustrates a variation of the system base station capital equipment.

[0098] FIG. **37** illustrates a variation of the sheet that comprises the tube.

[0099] FIGS. **38***a* through **38***c* are variations of cross-section G-G of the sheet of FIG. **37**.

[0100] FIG. **39** is a longitudinal cross-section of a variation of the tube.

[0101] FIG. **40** is an end view of a variation of the tube.

[0102] FIGS. **41***a* through **41***d* illustrate variations of reinforcing members.

[0103] FIG. **42***a* illustrates a section of the base and length of the tube in a first configuration.

[0104] FIG. **42***b* illustrates the section of the base and length of the tube of FIG. **42***a* in a compressed configuration.

[0105] FIG. **43** illustrates a variation of a perspective view of a transverse cross-section of an elongated element.

[0106] FIG. **44** illustrates a variation of a method for using the base.

[0107] FIG. **45** illustrates a method for using the biological navigation device in a patient.

[0108] FIG. **46** is not the invention and illustrates a colon.

[0109] FIGS. **47***a* through **47***g* illustrate a variation of a method for using the biological navigation device.

[0110] FIGS. **48***a* through **48***g* illustrate a method of folding the tube.

DETAILED DESCRIPTION

[0111] FIG. **1** illustrates a biological navigation device **10**. The device can be used for navigation through a biological anatomy, such as a biological lumen, for example any or all of the GI tract (e.g., colon, stomach, esophagus) or cardiovascular vessels (e.g., arteries, veins, heart chambers).

[0112] The navigation device can be removably attached or integrated (e.g., permanently fixed, welded, glued, fused, or otherwise substantially permanently fixed) with an elongated element. The elongated element can be, for example, an endoscope or colonoscope. For example, the elongated element can be a CF-Q160 series, PCF-160 series, or CF-2T160 series colonoscope (from Olympus America, Inc., Center Valley, Pa.), a Pentax EC-series colonoscope (from Pentax of America, Inc., Montvale, N.J.), a Fujinon HD Super CCD colonoscope, or a G-5 endoscope (from Fujinon Inc., Wayne, N.J.).

[0113] The biological navigation device **10** can have a head **12**, a tube **14** or a combination thereof. The head **12** can have a cap **22**. The cap **22** can be attached to the remainder of the head **12**, for example with cap screws **24**. The cap **22** can be atraumatic (as shown) or traumatic (e.g., with a sharp edge). The cap **22** can have a hemi-toroidal configuration, as shown. The cap **22** can be attached to the remainder of the head **12** with one or more cap screws **24**.

[0114] The head **12** can have a longitudinal axis **18**. The head **12** can have a head channel **20** passing through the head **12**, for example along the longitudinal axis **18**. The head channel **20** can have a cylindrical configuration. The head channel **20** can be configured to fixed or releasably attach to or integrate with the elongated element **16**.

[0115] The head channel **20** can be adjacent to or surrounded by an attachment element, such as an adjustable or non-adjustable clamp **52**. The attachment element can be configured to attach the head **12** to the elongated element **16**. The attachment element can be adjustable, for example, by one or more clamp screws.

[0116] The distal end of the tube **14** can be attached to or loosely enclosed in the head **12**. The tube **14** can extend out of the proximal end of the head **12**. The tube **14** can be flexible. The tube **14** can be resilient or non-resilient. The tube **14** can be made from a sheet of fiber-reinforced substrate. The tube **14** can be non-porous. The tube **14** can be substantially fluid impermeable. The tube **14** can have an engineered coefficient of friction (COF) on both its inner and outer surfaces. The tube **14** can be pressurizable. The tube **14** can have a tube channel through the center of the tube **14** configured to receive the elongated element **16**.

[0117] FIGS. **2***a* and **2***b* illustrate that the tube **14** can be stored or stowed (e.g., rolled, bunched, scrunched, pleated) in a compressed configuration at or near the distal end of the tube **14**. The tube **14** can be stowed in the head **12** (not shown in FIGS. **2***a* and **2***b*) or not in the head **12** (e.g., the head **12** can be absent). Bunched tube configurations can include scrunched configurations, for example can include transverse and irregular folding and compaction of the wall of the tube **14**. The tube **14** can be passively or actively longitudinally distributed as the colonoscope longitudinally extends or advances, as shown by arrow in FIG. **2***b*. The tube **14** can have elements that serve to recapture parts of the tube **14** as the colonoscope is used for a reduction of the colon. The elongated element **16** can have a distal component **32** attached to or integrated with the distal end of a umbilical **28**. The distal component **32** can have therapeutic and/or diagnostic instrumentation (e.g., CMOS camera, one or more other sensors, ablation elements). The umbilical **28** can be flexible. The umbilical **28** can have conduits for power or data electricity, fluids, elongated tools, mechanical control lines or combinations thereof.

[0118] FIGS. **3***a* through **3***c* illustrate that a length of the distal end of the tube **14** can be stored in a head chamber **44** in the head **12**. The head chamber **44** can be substantially defined by a head inner wall **42** and a head outer wall **40**. The chamber-side of the head inner wall **42** and/or head outer wall **40** can be coated by a lubricant and/or a low friction material, such as Teflon.

[0119] The space in the head chamber **44** between the tube **14** and the head outer wall **40** can be vented to the atmospheric pressure outside the head **12**.

[0120] The tube **14** can be foldable. A foldable tube **14** can be, for example, folded to have a minimum of about five about 180 degree folds **82**. A foldable tube **14** can also have a wall thickness, for example, of less than about 0.2 mm (0.007 in.). The tube **14** can have folds **82** or scrunches that can be regular (as shown for illustrative purposes) or irregularly shaped. The folds **82** can be parallel, perpendicular, or randomly oriented with respect to the longitudinal axis **18**.

[0121] The attachment element, such as a clamp **52**, can be in the head **12**. The clamp **52** can have a clamp ring **38** substantially surrounding the head channel **20**. The clamp **52** can have a clamp head **36** configured to receive a clamp screw **26** for adjusting the tension of the clamp **52**. The clamp **52** can be tightened (e.g., the clamp screw **26** can be turned) to attach the head **12** to the elongated element **16**, for example when the elongated element **16** is in the head channel **20** and is longitudinally concurrent or even with the clamp **52**. The clamp screw **26** can be loosened to detach the head **12** from the elongated element **16**.

[0122] The radially inner side of the head inner wall **42** can have an elongated element seal **50** configured to seal between the head inner wall **42** and the elongated element **16**. The elongated element seal **50** can prevent or minimize pressure loss from within the tube **14** during pressurization of the tube **14**. The elongated element seal **50** can be one or more gaskets or o-rings surrounding the head channel **20**.

[0123] When the tube **14** is pressurized, the head **12** can be pressurizably advanced through a target site. Pressurizably advancing systems and devices can be configured to deliver at least a majority of the force causing advancement of the head **12** due to the fluid pressure in the tube **14**.

[0124] The head **12** can have a labyrinth geometry having a circularizer **46** and/or a fold restrictor **48**, for example to control egress of the tube **14** from the head chamber **44**. The circularizer **46** can extend radially outwardly from the head inner wall **42** proximal to the head chamber **44**. The circularizer **46** can be configured to prevent or minimize premature and/or undesired release of tube material from the head chamber **44**. The fold restrictor **48** can extend radially inwardly from the head outer wall **40** proximal to the circularizer **46**. The fold restrictor **48** can be configured to shape the tube **14** as the tube **14** extends proximal to the fold restrictor **48**.

[0125] FIG. **4***a* illustrates that the tube **14** can be an everting tube. The evening tube can have an evening element inner section **54** and an everting element outer section **56**, and an everting element cavity **66** therebetween. The tube **14** can have a separatable sheath lining the evening element inner section **54**. The separatable sheath can split at the distal end of the tube **14** from having a separatable sheath first inner section **58** attached to a second inner section **60** into a sheath first outer section **62** separated from a sheath second outer section **64**. The sheath first and second outer sections **62** and **64** can line the evening element outer section. The separatable sheath can have a low friction surface.

[0126] The tube **14** can have the elongated element seal **50** between the evening element inner section **54** and the tip body **146**. The elongated element seal **50** can be on either side of the separatable sheath inner sections **58** and/or **60**. The elongated element seal **50** can be a low friction interface between the umbilical **28** and the everting element inner section **54**. The elongated element seal **50** can fluidly seal between the tube **14** and the umbilical **28**.

[0127] FIG. **4***b* illustrates that the elongated element **16** can be translated distally (and proximally) with respect to the tube **14**. A distal force can be applied to the elongated element **16** relative to the tube **14**, resulting in distal translation, as shown by arrow, of the elongated element **16** and distal component **32**. The elongated element seal **50** can roll or slide between the tube **14** and the elongated element **16** when the umbilical **28** is translated with respect to the tube **14**.

[0128] FIG. **5** illustrates that the head **12** can have a head seal **70** in a head seal seat **68** proximal of the head chamber **44**. The head seal **70** can be configured to create a fluid-tight seal between the head **12** and the inside of the tube **14** as the tube **14** exits the head chamber **44**. The head seal **70** can create two regions that can be pressurized to different pressures. The seal can be a two-way seal or a substantially one-way seal, for example allowing movement of the tube **14** out of the head chamber **44**.

[0129] FIGS. **6***a* through **6***g* illustrate cross-sections of variations of shaft seals **72**. FIG. **6***a* illustrates a seal having a substantially circular cross-section. FIG. **6***b* illustrates a seal having a substantially x-shaped cross-section. The seal can have four cantilever arms **74** extending therefrom. FIG. **6***c* illustrates a seal having a substantially C-shaped cross-section. The seal can have two cantilever arms **74** extending therefrom.

[0130] FIG. **6***d* illustrates that the seal **72** can be a cup seal. Cup seals can have cantilevered sealing surfaces, which can be lower drag and more compliant against irregular surfaces than o-ring (compression) seals.

[0131] FIG. **6***e* illustrates that the seal **72** can have one or more separate seal heads **76** with a single cantilever arm extending from the seal head **76**. The cantilever arms **74** can all be unidirectional. FIG. **6***f* illustrates that the seal **72** can have a number of unidirectional cantilever arms **74** extending from a single backing **78**. FIG. **6***g* illustrates that the seal **72** can have a seal spring **80** inserted into the seal **72** to pressurize the cantilever arms **74** outward.

[0132] Seal designs can be modulated to reduce the seal drag for the head **12** and/or base seals **72**. The seal durometer, material surface friction, squeeze pressure, size, pressure area, and combinations thereof can be varied to modulate desired seal drag. Seal materials can be low durometer to be more compliant and seal with lower forces and lower drag. The seals **72** can have in-seal lubricants. Fluid lubrication can be applied to the seal **72**. The seal **72** can have a geometry that limits directional variation, such as a cup seal. Lubricants or other low friction elements can be added to the seals **72**, to the elongated element **16**, or to the pressurization fluid or media.

[0133] FIGS. **7***a* and **7***b* illustrate that the tube **14** (everting—as shown—or directly releasing, as shown in FIGS. **1-3** inter alia) can have one or more folds **82** extending at a fold angle **84** or pitch from the head channel **20** or umbilical **28**. The fold angle **84** can be obtuse, acute, or right. The folds **82** can be stowed to hold additional, pre-loaded length of the tube **14**. The folds **82** can overlap each other. The folds **82** can unfold and distally extend the tube **14**, for example, as pressure is increased in the tube **14**. The folds **82** can unfold sequentially when pressure is increased in the tube **14**.

[0134] The tube material can be stowed along the length of the head **12**. When then released in this manner it can substantially enables a 1:1 ratio of motion of the elongated element **16** to the tube advancement. The tube material can be stowed in the form of folds **82** that are staggered by varying angles.

[0135] The distal component **32** can have one or more shoulders **86**, for example, to prevent excessive release of the folds. The shoulder **86** can be configured to prevent overextension of the tube **14** during deployment. The shoulder **86** can have a larger outer diameter than the outer diameter of the inflated tube **14**. The shoulder **86** can be a fender washer or other geometric abutment.

[0136] FIGS. **8***a* and **8***b* illustrate that the folds **82** can extend from the distal end **34** of the tube **14**. The tube **14** can be stowed along the length of the tube **14**, then released in a manner that substantially enables a 1:1 ratio of advancement of the distal end **34** of the tube **14** and the elongated element **16**. The tube **14** can be stowed in the form of non or minimally staggered folds **82**. The folds **82** can have substantially no pitch. The folds **82** can lay substantially parallel with the longitudinal axis of the elongated element **16** and/or the tube **14**. The terminal end of the radial outermost fold **82** of the tube **14** can be fixed and sealed to a deployment mechanism (e.g., pressurizer, such as a pressure box) not shown. The other terminal end of the tube **14** (radial innermost) can be fixed and sealed to the umbilical **28** or other portion of the elongated element **16**, for example minimally proximal to the termination of the fold's proximal edge.

[0137] FIGS. **9***a* and **9***b* illustrate that the folds **82** can be stacked in one or more fold series. The tube **14** can be stowed along the length of the elongated element **16** and/or tube **14**, then released in a manner that substantially enables a 1:1 ratio of advancement of the distal end **34** of the tube **14** and the elongated element **16**. The tube **14** can be stowed in the form of non or minimally staggered series of folds **82** that are connected sequentially to other fold series **88**. The fold series **88** can be between the radially outermost portion of the tube **14** and the elongated element **16**. The fold series **88** can unfold sequentially from most distal to most proximal. The fold series **88** can be slidably or fixedly attached to the elongated element **16** at fold mounts **90**. The fold mounts **90** can have low friction. More proximal fold mounts **90** can have higher friction (e.g., equal frictional coefficients with more surface area, or larger frictional coefficients with equal surface area) against the fold series **88** than more distal fold mounts **90**, for example to sequentially release the fold series **88**.

[0138] FIG. **10** illustrates that the cap **22** can have a bulleted atraumatic configuration. The head **12** can have a clamp screw port **92**. The clamp screw port **92** can be configured to allow access by a tool to the clamp screw **26** contained inside of the head **12**. For example, the clamp screw port **92** can be configured to receive an Allen wrench. The head channel **20** can have an elongated element seal **50** at the distal end of the cap **22**.

[0139] FIG. **11** illustrates that the clamp **52** can be seated in a clamp frame **94** in the head **12**. The clamp **52** can be a split clamp. The clamp screw **26** can pull the separate sides of the clamp head **36** together, as shown by arrows. Although the cap **22** is not shown in FIG. **11**, the cap **22** can be over the clamp **52**.

[0140] FIG. **12***a* illustrates the distal end of the elongated element **16** with a shear clip **96** and the head **12**. The shear clip **96** can be configured to use shear resistance to attach at least two elements. The head **12** can be slid, as shown by arrow, onto the elongated element **16** and the shear clip **96** can be inserted, as shown by arrow, through a corresponding clip seat **98** and shear groove **100** on the head **12** and the elongated element **16**, respectively.

[0141] FIGS. **13***a* through **13***c* illustrate a variation of the clip **96** being inserted into a clip seats **98** on the head **12** and a corresponding shear groove **100** in the elongated element **16**. The clip **96** can have internal reinforcing struts **102**.

[0142] FIG. **13***b* illustrates the elongated element **16**, shear clip **96** and head **12** in an assembled configuration. The elements of FIG. **13***b* can be ready for pressurization of the tube (not shown for illustrative purposes). The shear clip **96** can mechanically join the head **12** to the elongated element **16**, and enable simultaneous motion of the head **12** and the elongated element **16**.

[0143] The head **12** can be lowered onto the elongated element **16** and can seal radially or over the entire face. Sealing over the face can increase the effective pressure area and therefore the effective propulsion force, because its pressure area is the full cross sectional area. Though it creates a smaller propulsion area (a substantially annular pressure area), sealing radially can be advantageous in that it can enable therapeutic or diagnostic elements of the elongated element **16** to exit the distal end of the elongated element **16** without any significant modification. The elongated element seal **50** (e.g., o-rings, cup-seals, boss seals, face seals) can help seal the head **12** to the elongated element **16**.

[0144] As the tube **14** is pressurized, the stored tube **14** in the head **12** can naturally exert a force load pushing the elongated element **16** along as the load is transferred through the attached structure.

[0145] During or after use, the clip **96** can be removed and the head **12** can be removed from the elongated element **16**.

[0146] The head **12** can join the elongated element **16** by friction, bonding, shear, or combinations thereof. For example, the attachment elements used to join the head **12** to the elongated element **16** can be a bayonet, threads (parts threading together or set screws from the side), shear wire, a snap ring, metal lateral shear clips **96** (as shown in FIGS. **12** through **13**). The attachment elements can be high-strength, predictable, and reliable. Threads create material in shear. Tabs can create material in shear. A head installation and/or removal tool (e.g., an allen wrench) can be used.

[0147] The elongated element seal **50** can be one or more o-rings. The elongated element seal **50** can be a radial seal, a face seal, an o-ring boss type seal, or combinations thereof.

[0148] The head **12** can be configured to encompass the full distal face of the elongated element **16**. Fully encompassing the distal face can create a complete pressure area and higher propulsion forces (at any given cross section). The head **12** can partially encompass the distal face of the elongated element (not shown). Partially encompassing the face can leave vision and working channels of the elongated element **16** unimpeded.

[0149] FIG. **14** illustrates that the attachment element can be a collet **104**. The collet **104** can have collet panels **106** or tabs oriented radially inward. The collet panels **106** can be separated by collet slots **108** to allow flexing of the collet panels **106** when an elongated element **16** is inserted into the head channel **20**. The collet panels **106** can squeeze against the elongated element **16**, friction fitting the elongated element **16** to the head **12**. The elongated element **16** can have slots to attachably engage the collet panels **106**.

[0150] FIG. **15** illustrates that the elongated element **16** can have an articulating length **110** proximal to the head **12**. The tube **14** can passively articulate with the elongated element **16**. The elongated element **16** can not extend distal to the head **12**.

[0151] FIG. **16** illustrates that the elongated element **16** can extend distal to the head **12**. The elongated element can have an articulating length **110** distal to the head **12**. FIGS. **16** and **17** illustrate that the bullet-shaped cap **22** can be used when the elongated element **16** extends beyond the head **12**. Any configuration of cap **22** can be used with an elongated element **16** extends distal to, or does not extend distal to the head **12**.

[0152] FIGS. **18*a*** through **18*c*** illustrates that the base **30** can be ergonomically configured to be of low mass and volume. In this configuration the base **30** can rest by itself in anal proximity, or the base **30** can be hand held. For example, the base **30** can have a generally cylindrical outer case sized to fit into a hand.

[0153] The base **30** can have a base channel **122** passing through the base **30**. The base channel **122** can be configured to slidably receive the elongated element **16**. The tube **14** can be permanently or removably attached or integrated to the distal end of the base **30** surrounding the base channel **122**.

[0154] The base **30** can have a base distal flange **114** and/or a base proximal flange **116**. The base flanges **114** and/or **116** can be trumpeted to guide the elongated element **16** into the base channel **122** when the elongated element **16** is inserted into the base **30** from either end. The base distal flange **114** can be configured to comfortably stop against the patient before getting to the anus **268**.

[0155] The base **30** can have a base pressure port **112** configured to attach to a pressure source or sources. The base pressure port **112** can be in communication with a base pressure channel (s) **118**. The base pressure channel(s) **118** can be configured to deliver pressure from the pressure source into the base channel **122**. During use the pressure can pressurize the tube **14**.

[0156] The base **30** can have a base seal **120** configured to seal between the wall of the base channel **122** and the elongated element **16**. The base seal **120** can be any of the seals **72** shown supra (shown as a cup seal). The base seal **120** can be located proximal to where the base pressure channel **118** enters the base channel **122**.

[0157] FIG. **19*a*** illustrates that the base **30** can have a rigid or flexible proximal stiffener extending distally from the distal end of the base **30**. The proximal stiffener can be configured to enter the anus **268**. The proximal stiffener **124** can provide the tube **14** with an increased rigidity, for example at the proximal end of the tube **14**. The proximal stiffener **124** can deliver force to introduce the tube **14** and the head **12** into the anus **268**. FIG. **19*b*** illustrates that the tube **14** can slide over the proximal stiffener.

[0158] FIGS. **20*a*** and **20*b*** illustrate that the proximal end of the tube **14** can be fixed to a tube connector **128**. The tube connector **128** can be removably attached to the base **30**. The tube connector **128** can have one or more tube connector interlocks **130**, such as keys or pegs (i.e., a bayonet connector). The base **30** can have one or more base interlocks **132**, such as slots or channels. The tube connector interlocks **130** can be configured to removably attach to the base interlocks **132**.

[0159] The tube **14**, head **12** and tube connector **128** can form a cartridge or cassette. The cartridge can be quickly removed from the base **30** and replaced with another cartridge. The cartridge can seal to the base **30** with a fluid seal that is located in either the base unit or in the cartridge or cassette.

[0160] The head channel **20** can be aligned with a channel (not shown) in the tube **14** and the base channel **122**.

[0161] FIG. **21** illustrates that the tube **14** in an expanded configuration can actively (i.e., designed to form the specific shape) or passively (i.e., designed to flexibly fit the surrounding shape) form tube straights **136** and tube curves **134**. For example, the tube **14** can be sufficiently flexible to accommodate various anatomical configurations.

[0162] The base **30** can have an attached cartridge (shown only as the tube connector **128** for illustrative purposes). FIG. **22*a*** illustrates the cartridge separated from the hand manifold. The tube connector interlocks **130** can be one or more wings or panels extending radially from the tube connector **128**. The tube connector **128** can mount and seal against the distal face of the base **30**. The base interlock **132** can be retractable pegs or shear prongs or shear pins configured to hold the tube connector **128**. The base **30** can have one or more controls for releasing the tube connector **128** and/or for controlling the fluid pressure through the base pressure channel **118**.

[0163] FIG. **22*b*** illustrates that as the control is activated (i.e., the button is depressed), the base interlocks **132** can be actuated and released. The base interlocks **132** can release the tube connector **128**. During pressurization the shear prongs can keep the tube connector **128** in the base **30** and leak-free.

[0164] The cartridge for the biological navigation device **10** can be replaced with a new cartridge for each patient. All or part of the base **30** can be reusable and cleanable or disposable—for example minimizing the need for the cartridge to be released, as the cartridge can be fixedly attached to the base **30** and be thrown away, with the base **30**, after use.

[0165] FIGS. **23*a*** and **23*b*** illustrate that the base **30** can have sets of one or more rollers **140** above and below the elongated element **16**. The elongated element **16** can have seal drag against the base seal **120**.

[0166] The base **30** can have guide wheels or rollers **140**. The rollers **140** can be used to guide the elongated element **16** on a straight path to the base seal **120**, for example to minimize drag between the elongated element **16** and the base seal **120**. The rollers **140** can be powered friction wheels, to help move the elongated element **16** forward or backward. The rollers **140** can provide base-delivered propulsive of the elongated element **16**. The base-delivered propulsion or braking or reversing can be used in combination or separately from the propulsion of the elongated element **16** due to fluid pressurization. Alternately, the wheels can have sensors which pick up on forward or reverse motion to trigger an event, such a change in system pressure.

[0167] The base **30** can have more than one control **138**. The controls **138** can be, for example, press buttons and/or slides. The controls **138** can control the base interlocks **132**, the roller speed (e.g., including locking the rollers **140** and allowing the rollers **140** to roll freely), pressure through the base pressure channel **118**, and combinations thereof.

[0168] FIGS. **24***a* and **24***b* illustrate that the tube **14** can be tapered, for example, the tube **14** can have a conical configuration when extended. The tube **14** can utilize a locally tip stowed material on a tapered eversion tube. This version utilizes locally folded material. In a longitudinally contracted configuration, the tube **14** can be folded into folds **82**. For example, a six foot long tube could have six folds **82**, each fold at about six inches in each direction. The tube **14** can have from about five to about twenty folds **82**, for example about six folds **82**.

[0169] The tube **14** can be tapered at a taper angle **144**. The taper angle **144** can be measured between the taper axis **142** and the longitudinal axis **18**. The taper angle can be more than about 0° and less than about 90°. For example, the tube **14** can have a taper of about $3/16^{th}$ of an inch of diameter over six feet of length. This taper can reduce or eliminate the creases that can be created during a stowage or folding process. Other varying cross section geometries can have locally repeating bulbous features **152** that serve to control fold unfurling sequencing.

[0170] The elongated element **16** can have the umbilical(s) **28** that extends therefrom. A control wire in the umbilical **28** can communicate data and/or power and/or fluid. The control wire can be attached, for example, to a controller. Excess length of undeployed umbilical **28** can be stored on a spool **148**.

[0171] As shown in FIG. **24***b*, the tube **14** can be extended, translating the tube distally, thereby towing the umbilical **28** and distal component **32**. The umbilical(s) **128** can be stowed in either a substantially linear or a substantially rotary manner on the spool **148**. The tube **14** can be extended, for example by the base **30** pressurizing the tube **14**.

[0172] FIG. **25** illustrates the colonoscopy system that can have a folded tube **14**. The tube **14** can be attached or integral with the elongated element **16**, for example along the umbilical **28**, the distal component **32**, or combinations thereof.

[0173] FIG. **26***a* illustrates that the folds **82** can have bulbous portions **152**, for example one or more or less bulbous portions **152** per fold **82**. The bulbous portions **152** can extend radially inward toward the longitudinal axis **18**.

[0174] FIG. **26***b* illustrates that the folds **82** can be staggered distally. The elongated element **16** can be tapered. FIG. **26***c* illustrates that the folds **82** can be staggered distally as radius increases. The folds **82** and the tip body **146** can be substantially parallel with the longitudinal axis **18**. FIG. **26***d* illustrates that the folds **82** can be staggered proximally as radius increases. FIG. **26***e* illustrates that the elongated element **16** can be tapered radially outward with respect to the longitudinal axis **18**. The folds **82** can be staggered proximally as radius increases.

[0175] FIG. **27***a* illustrates a variation of a cassette or cartridge **126** (cassette and cartridge are terms used interchangeably herein). The cartridge **126** can have an exit fitting, a pressure sleeve with multiple folds **82**, or tube sliding receptacle (not shown, but can be located underneath the tube **14**), a cassette seal **154** and a clear cassette tip **156**. For example, the cassette or cartridge **126** can be used for a semisposable system, in which some system portions have a life that can be used for multiple times before it is disposed of, while other system portions have a substantially disposable product life. The cassette or cartridge **126** can have a thin shell upon which the extensible pressure sleeve can be mounted. The cassette or cartridge **126** can include a tip **156** or cap region. The tip **156** or cap region can cover the tip of the elongated element **16**, or radially encompass tip of the elongated element **16** (e.g., radially, with an open center area for the through passage of scope elements to exit).

[0176] Through the use of the cartridge **126**, for example, an elongated element **16** can be coupled and the elongated element **16** could be pulled along with what serves as a propulsive element. As the propulsive elements stowed material is pressurized and spent out from its stored location, the elongated element **16** is pulled along. After the procedure is complete, this cartridge **126** could then be disposed of. This cartridge **126** also serves to protect the elongated element **16** from contamination, including potentially the use of working channel sleeves.

[0177] FIG. **27***b* illustrates that the cassette can have a sleeve for working channel(s) and/or to enable tip washing and/or for pressurization of the working channel sleeves and/or biological anatomy. The cassette can be loaded and attached to a base region. The base region can be fixed in space, or go over a colonoscope shaft to enable reciprocating motion. As the tube **14** is inflated, the tube **14** can utilize pneumatic or hydraulic pressure to linearly expand, thereby applying a load (typically at or near the tip) that can serves to propel the scope forward.

[0178] FIG. **27***c* illustrates that the elongated element **16** can have a threaded elongated element connector **158**. The elongated element distal component **32** can have lighting (e.g., one or more LEDs) and a camera lens. The elongated element **16** can be attached to the cassette, for example, by screwing the elongated element connector **158** into a threaded receptacle in the tube **14**.

[0179] FIG. **27***d* illustrates a method for entering the elongated element **16** into the cartridge **126**. FIG. **27***e* illustrates that the distal component **32** (e.g., camera lens and LED) can show through the clear tip.

[0180] FIG. **27***f* illustrates that the device can have or be attached to (e.g., in the elongated element **16**) a steerable section, for example articulating links **170** or an otherwise articulatable section **110**. A distal end of the biological navigation device **10** can be distal to all or a substantial portion of the steerable section. Alternatively, the distal end of the biological navigation device **10** can be proximal to all or a substantial portion of the steerable section.

[0181] The articulatable links **170** can be individually and/or concurrently articulatable. The tube **14** can be configured to be an everting tube. The tube **14** can have stowed tube material at a distal end **34** of the tube **14**. For example, the stowed material can be scrunched, bunched or folded. The folds **82** can be substantially parallel (as shown) or perpendicular to the longitudinal axis of the tube **14**. The proximal end of the tube **14** can be attached to or integral with a tube connector **128**.

[0182] The device can have a base **30**. The base **30** can have an exit port **162**. The tube connector **128** can be removably attachable to the base **30** at the exit port **162**. For example, the tube connector **128** can have a tube connector interlock **130** that can removably attach to a base interlock **132** on the base. The interlocks **132** can be a peg, rail, hole or other receiver, snap, thread, or combinations thereof. The tube **14** and tube connector **128** can form a cartridge **126**. The cartridge **126** can seal to a base unit with a fluid seal that is located in either the base unit or in the cartridge **126** or cassette (e.g., along the tube connector **128**, for example at the tube connector interlock **130** and/or base interlock **132**). The cartridge **126** can have a substantially disposable product life.

[0183] The base **30** can controllably deliver fluid pressure to the inside of the tube **14**. For example, the base **30** can controllably deliver pressure independently to the different fluid channels of the device. The base **30** can control the articulating links **170**, for example via one or more control leads, wires, cables, or combinations thereof.

[0184] The distal component **32** of the elongated element **16** can have a camera or other visualization element **166**. The distal component **32** can have one or more elements that enable vision (e.g., fiber optics, CCD cameras, CMOS camera chips) and/or lighting **168** (e.g., fiber optic light sources, high power LEDs (Light Emitting Diodes)). The distal component **32** can have the working channel port **164**, for example to provide suction or pressurization, fluid irrigation, the delivery of instruments (e.g., for cutting, coagulation, polyp removal, tissue sampling) and lens cleaning elements (typically a right angle tool or orifice that can exit near the camera, such that a fluid flush provides a cleansing wash).

[0185] In an exemplary variation, the elements, in order from the proximal end of the device to the distal end of the device (including the elongated element **16**), can include: the base **30**, the tube **14**, the steering mechanism, the distal end of the tube **14**, and the distal component **32**, for example, including lighting and vision and working channel exit.

[0186] FIG. **28***a* illustrates that the tube connector **128** can be attached to or integral with the tube **14**. The umbilical **28** can pass through the tube connector **128**. The base **30** can have a female exit port **162** configured to receive the tube connector **128**. The female exit port **162** can be fit on the tube connector **128**.

[0187] FIG. **28***b* illustrates a method for locking the exit fitting in the female exit port **162** with a separable base interlock **132**, such as a quick-release shear pin **160**.

[0188] FIGS. **29** through **31** illustrate that the elongated element **16** have a base or other component configured to translate the elongated element **16**. The elongated element **16** can enter the base directly (straight), or it can be looped in a U-shape (as shown). Through the use of a sliding shaft seal against the elongated element's shaft, the system can be advanced without the need for full volume pressurization of the elongated element **16**.

[0189] The tube **14** can be pressurized locally, for example to enable a design for the system that is smaller and more compact. The pump **204** can be in or directly attached to the base. The pump **204** can be in fluid communication with the base via the base pressure channel **118**. The navigation device can be substantially entirely contained a hand-held unit (e.g., the base or a component attached to or separate from the base).

[0190] FIGS. **32***a* through **34***d* illustrate variations of tube packing configurations. Tube layout (i.e., tube packing configuration) can affect the kinematics, size, stability, and aesthetics of the biological navigation device **10**.

[0191] FIG. **32***a* illustrates that the tube **14** can be straight in cross section. The tube **14** can have a tube length **176** and a tube outer diameter **178**. The tube length **176** can be about 1.0 m (40 in.) to about 2.0 m (79 in.), for example about 1.6 m (63 in.). The tube outer diameter **178** can be from about 18 mm (0.71 in.) to about 23 mm (0.91 in.).

[0192] FIG. **32***b* illustrates that as the straight tube **14** is folded into itself, folds **82** are formed. The tube **14** also has compressive deformations **180** to allow for the shrinking radius of the folds **82**. The sheet forming the tube **14** can be configured (e.g., by altering the reinforcement fibers accordingly or weakening the sheet at those points) so that the compressive deformations **180** are aligned at a single angle.

[0193] FIGS. **33***a*, **34***a* and **34***b* illustrate that the tube **14** can be tapered. FIG. **33***a* illustrates that the tube **14** can have steps **182** or discrete changes in radius along the length.

[0194] FIG. **33***b* illustrates that the folded tube **14** with steps **182** can have no compressive deformations. FIG. **33***c* illustrates that the tube **14** can fold at the location of the steps **182**.

[0195] FIGS. **34***a* and **34***b* illustrate that the tube **14** can be tapered. The tube **14** can have a larger diameter at the proximal end of the tube **14** and a smaller diameter at the distal end of the tube **14**. FIG. **34***b* illustrates that the tube **14** can have a smaller diameter at the proximal end of the tube **14** and a larger diameter at the distal end of the tube **14**. FIGS. **34***c* and **34***d* illustrate that the tapered tubes can be folded multiple times without compressive deformation.

[0196] The longer the elongated element **16** extends through the tube **14**, the larger the capstan drag. The tube **14** can be tapered to create an increasingly higher or lower capstan drag force with distance or extension of the elongated element **16** and biological navigation device **10** through the anatomy (e.g., colon).

[0197] FIG. **35** illustrates that the base can be in fluid communication with a fluid control system **184**. The base, for example at the base pressure port **112**, can be connected to a pressure delivery line **200**. The pressure delivery line **200** can be connected to an outgoing second valve **196** and/or an incoming first valve **186**.

[0198] The first valve **186** can be configured to open manually and/or automatically. The rust valve **186** can open when the tube pressure exceeds a maximum desired tube pressure. The first valve **186** can be connected to a vacuum pump **188**. The vacuum pump **188** can be activated to deflate the tube **14** and withdraw the tube **14** or reduce the tube pressure. The vacuum pump **188** can be attached to an exhaust tank **190** and/or directly to a bleed or drain line **192**. The exhaust tank **190** can be connected to the drain line **192**, for example to exhaust overflow from the exhaust tank **190**.

[0199] Controls **194** can be in data communication with the first valve **186** and the second valve **196**. The controls **194** can be on the base (e.g., a button or switch on the base).

[0200] The second valve **196** can be attached to a pump **204**, for example a cylinder **206** with a displacement component **208**, such as a piston. A pressure regulator **198** can be in the flow path between the pump **204** and the second valve **196**. The pressure regulator **198** and/or the first valve **186** can open and release pressure from the pump **204** when the tube pressure exceeds a maximum desired tube pressure.

[0201] An intake tank **202** can be fed in line (as shown) or through the pump **204** to the second valve **196**, for example through the pressure regulator **198**. The fluid in the intake tank **202** can be fed into the pressurized tube **14**. The intake tank **202** can have a fill line **210** for filling the intake tank **202** with fluid. The fill line **210** can be fed directly to the second valve **196**, pressure regulator **198** or pump **204** without the intake tank **202**.

[0202] The biological navigation device **10** can have capital equipment which can provide utility to the remainder of the device. The capital equipment can include, for example, the elements in the fluid control system **184**. The fluid control system **184** can have a fluid source (e.g., the intake tank **202** and/or fill line **210**), a pressurize source such as the pump **204**, a conduit for delivery of the pressurization media (e.g., the pressure delivery line **200**), controls **194**, system monitoring elements (e.g., can be in the controls). The capital equipment can reduce the profile of the tube **14**, for example, in which tools can be inserted. The integrated tools can create elements that reduce waste, thereby allowing for higher value capture and less refuse.

[0203] The fluid pressurization can be controlled by a variety of user inputs, for example a button on the elongated element **16** or base, voice commands, foot pedals, or combinations thereof.

[0204] FIG. **36** illustrates that the base can have an elongated element feeder **220**. The elongated element feeder **220** or linearized system can have a linearizing extender that can travel back and forth to linearly control umbilical extension. The linear travel of the elongated element feeder **220** can be controlled by a motor that can turn a lead screw **216** and/or drive shaft **218** connected to the elongated element feeder **220**. Before being deployed, the umbilical **28** can be substantially straight in a pressure chamber **214**, for example to reduce capstan drag in the elongated element **16** (as compared to a spooled configuration). As the elongated element feeder **220** is moved linearly, it can provide control of the device in one direction, with pressurization providing a force in the opposing direction. The pressure chamber **214** can be sealed with the base and pressurized. The base is shown without a top for illustrative purposes. A pressure gauge **224** can be attached to the pressure chamber **214** and/or the base and can sense and display pressure therein.

[0205] Steering controls can include one, two or more motors **212** thereby allowing an electronic input interface (e.g., joystick, buttons, paddles, pedals) to control the deployment of the elongated element **16**. Another motor can provide axial movement for actuation of the distal component **32** of the elongated element **16**, for actuation of tools at the distal component **32** and/or for steering and other motion (e.g., vibration, rotation, drilling) of the distal component **32** itself. The base can have feed through ports **222** for example to feed tools such as electronics and/or mechanical devices through the elongated element **16**. The feed through ports **222** can be configured so the tools can be transitioned to or from a pressurized region from or to a non-pressurized (e.g., outside) region without pressure leakage. The feed through ports **222** can negate the need for a base seal around the elongated element shall, but a base seal can still be used in addition to the feed through ports **222**.

[0206] FIG. **37** illustrates a flat panel of a sheet **226** that can be used to make the tube **14**. The sheet **226** can be made from a composite including thin films, resins, and fibers **230**. The thin films can include PET, nylon, or any other material disclosed herein, or combinations thereof. The sheet **226** can be reinforced, such as by integral metal filaments or fibers **230**, or an integral metal mesh.

[0207] The sheet **226** can be a laminate as describe in U.S. Pat. No. 5,333,568 or 5,470,632, both of which are herein incorporated by reference in their entireties. The sheet **226** can have a substrate **228** and fibers **230** in the substrate **228**. The fibers **230** can be oriented to desired relative angles, with one or more layers of tape (i.e., unidirectionally oriented fiber array in each layer), weave, braid, matte (i.e., randomly oriented fibers), or combinations thereof.

[0208] One or more films can be applied to either and/or both sides of the fibers **230**, with a resultant thin laminate that can be formed. The fibers **230** can be embedded in a resin polymer matrix.

[0209] The sheet **226** can be configured to contain at least about 6 psi (48 kPa) in a 0.80" diameter configuration, more narrowly at least about 7 psi (48 kPa), yet more narrowly, at least about 100 psi (690 kPa) even in a very thin wall configuration (e.g., 0.002 in.), even yet more narrowly at least about 200 psi (1380 kPa).

[0210] The sheet **226** can have one or more reinforcement fibers **230**. The fibers **230** can be high strength and low elasticity. The low elasticity fibers **230** can be very flexible and have very low radial compliance. The fibers **230** can be made from, for example, Kevlar, Vectran (spun from Liquid Crystal Polymer (LCP)), Spectra, Dacron, Twaron, Pentex, Technora, Dyneema, Teflon (PBT), Zylon (PBO), Polyimide (PIM), Boron/ceramic boron, Nylon, fiberglass, carbon, graphite, polyester, extended chain polyethylenes, or hybrids or combinations thereof

[0211] The substrate **228** can be made from a flexible resin matrix.

[0212] The sheet **226** can be thinner than about 0.1 mm (0.004 in.), yet more narrowly thinner than about 0.05 mm (0.002 in.).

[0213] The sheet **226** can have a sheet coefficient of friction on either or both sides equal to or greater than about 0.3, more narrowly equal to or greater than about 0.4. The sheet coefficient of friction can be equal to or lower than about 0.2, more narrowly equal to or lower than about 0.15. The sheet coefficient of friction can be equal to or greater than about is greater than 0.1 and equal to or less than about 0.6. The sheet coefficient of friction can be equal to or greater than about a coefficient of friction to maintain a deformed expanded configuration of the tube **14**.

[0214] The sheet strength can result in the tube **14** having a radial stiffness equal to or lower than about a 0.05% change in diameter per 1 psi, more narrowly radial stiffness equal to or lower than about a 0.01% change in diameter per 1 psi, even when these values are observed from a tube **14** of very low wall thickness (e.g., less than about 0.002 in.).

[0215] The sheet strength can result in a tube **14** delivering a propulsive force of up to about 4 N (1 lbs.) or, for example, up to about 9 N (2 lbs.), for example, or for example, up to about 18 N (4 lbs.), or for example, up to about 27 N (6 lbs.), with these values typically taken from an annular pressure area design with an o.d. of approximately 0.8".

[0216] FIG. **38***a* illustrates that the reinforcing fiber can have a substantially equivalent diameter to the thickness of the substrate **228** (a single layer is shown, but the sheet **226** can also have multiple layers). The sheet **226** can have a top film **232** and/or a bottom film **234**. The films can be made from, for example, PET and/or Nylon. The films can be attached to or integrated with the substrate **228** and/or the fiber **230**. FIG. **38***b* illustrates that the fiber can have a substantially smaller diameter to the thickness of the substrate **228**. FIG. **38***c* illustrates that the fiber can have a substantially larger diameter than the thickness of the substrate **228**

[0217] FIG. **39** illustrates that the tube **14** can have variable wall thicknesses along the length of the tube **14**. For example, the tube **14** can have a first length **236** adjacent to a second length adjacent to a third length **240**. The tube wall along the first length **236** can have the smallest thickness of the lengths. The tube wall along the second length **238** can have a larger wall thickness than the tube wall along the first length **236**. The tube wall along the third length **240** can have a larger wall thickness than the wall along the second length **238**. The differential of the wall thicknesses between the lengths can be discrete or gradual.

[0218] FIG. **40** illustrates that the inner surface of the tube **14** can have an attached or integral reinforcing member **242** along all or part of the length of the tube **14**.

[0219] FIG. **41***a* illustrates that the reinforcing member **242** can have a rectangular transverse cross-section.

[0220] FIG. **41***b* illustrates that the reinforcing member **242** can have a variable transverse cross-section along the length of the reinforcing member.

[0221] FIG. **41***c* illustrates that the reinforcing member **242** can have a circular transverse cross-section. For example, the reinforcing member **242** can be a rod. FIG. **41** *d* illustrates that the reinforcing member **242** can have a trapezoidal transverse cross-section.

[0222] By adding geometric and or modulus-enhancing reinforcing elements to local portions of the pressure sleeve, the sleeve's local resistance to buckling can be enhanced.

[0223] Attaching the reinforcing members to the tube **14** can decrease the buckling of the tube **14**.

[0224] The reinforcing members can have tube, rod, rectangular, trapezoidal configurations, or combinations thereof. The reinforcing members can be bonded or otherwise attached to the tube wall. One, two, three, four or more local reinforcements, for example radially spaced, can be attached to the tube **14**. Alternatively, reinforcing members can be added to the entirety of the tube wall.

[0225] The reinforcing members can be made by extrusion, injection molding, or additional laminates of pressure sleeve material. The reinforcing member **242** can be configured to not substantially change the tube's inflated bending properties, yet enhance the tube's local buckling resistance. The enhanced buckling resistance can be designed into a variety of locations on the tube **14**. The locations of higher buckling resistance in the tube **14** can be located near the patient's anus **268**. The pressure sleeve can buckle more distally than the anus **268**, for example, to reduce looping in more proximal regions, including the sigmoid.

[0226] The selectively enhanced buckling resistance regions along the tube **14** can be fixed to the tube **14**, or the enhanced buckling resistance regions can move relative to the tube **14**. The enhanced buckling resistance regions can follow a few inches behind the distal tip or head **12** of the device. For example, any tube wall buckling can be shifted to occur close to the distal tip or head **12** of the device. After retraction, once the device is driven forward, the propulsion can be more closely tip-based (e.g., due to the buckling near the distal tip due to the enhanced buckling resistance farther away from the distal tip). For example, a small diameter rod can be pulled along by tensile members attached to the distal end of the device or the head **12**. The tensile members can be in pockets on either side of the tube **14**. During a reducing maneuver, the tensile members can be vacuumed in their pockets, providing enhanced buckling resistance where the tensile members' pockets are located, and preferentially low buckling resistance where the pockets are not located (e.g., near the distal tip or head **12**). This ability to reduce proximal buckling in favor of more distal tube wall buckling serves to minimize looping after a reduction procedure.

[0227] FIG. **42***a* illustrates that the reinforcing member **242** can be attached to the radial inside to the proximal end of the tube **14**. For example, the reinforcing member **242** can be adjacent to the base.

[0228] FIG. **42***b* illustrates that when the tube **14** is subject to longitudinal compressive forces, as shown by arrows, a length of the tube **14** distal to the reinforcing member **242** can buckle before the length of the tube **14** with the reinforcing member **242** buckles.

[0229] FIG. **43** illustrates a cross-section of an elongated element **16**, such as a tool, for example a colonoscope. Colonoscopes can have various conduits or working channels. The conduits or channels can contain elements that enable vision (e.g., fiber optics, CCD cameras, CMOS camera chips) and lighting (e.g., fiber optic light sources, high power LEDs (Light Emitting Diodes)), such as energy delivery conduits **244** and **246**. The colonoscopies can have conduits that can provide suction or pressurization, fluid irrigation, the delivery of instruments (e.g., for cutting, coagulation, polyp removal, tissue sampling) and lens cleaning elements (typically a right angle orifice that exits near the camera, such that a fluid flush provides a cleansing wash), such as conduits **248**, **250**, **252**, **254**, **256**, **258** and **260**.

[0230] Suction can be utilized to remove debris or fluid. The colon can be pressurized to reconfigure the colon into a more circular cross-section to enhance visualization.

[0231] During advancement of the colonoscope through the colon, landmarks can be noted and a significant portion of the colon's inside wall can be visualized. Therapeutic actions can occur at any time, for example during withdrawal of the colonoscope.

[0232] FIG. **44** illustrates that a pump **204** having an extensible displacement component **208**, such as a piston, can be used to pressurize the base. The piston or otherwise extensible displacement component **208** can be manipulated to control load volume to exert a corresponding pressure out of the exit port **162** and into the pressurizable tube **14** of the navigation device. A fluid supply **262** can be attached to the base pressure port **112**, for example via connecting tubing **264**. The inlet port can have a one-way (i.e., check) valve preventing backflow. The exit port **162** can have a one-way (i.e., check) valve preventing backflow. The fluid supply **262** can be filled with fluid. The fluid can be delivered to the deployment system under no pressure or positive pressure. The fluid can be air, saline, water, carbon dioxide, nitrogen, or combinations thereof. The pump **204** can be separate from or attached to the base pressure port **112**. For example, the fluid supply **262** can be routed through the pump **204** before or after passing through the base pressure port **112** and into the base.

[0233] FIG. **45** illustrates that the proximal stiffener of the base can be inserted into the anus **268**. The base pressure port **112** can be connected to a pressure source before or after inserting the proximal stiffener.

[0234] A simplified typical large intestine or colon **266** is shown in FIG. **46**. The anus **268** can provide entry into the colon **266** for a colonoscopy. The colon **266** extends from the rectum **270** to the cecum **280** and has sigmoid, descending, transverse and ascending portions. The sigmoid colon **272** is the s-shaped portion of the colon **266** between the descending colon **274** and the rectum **270**.

[0235] A colonoscopy can include inserting the proximal stiffener and/or elongated element **16** into the anus **268**. To navigate the colon **266**, the forward few inches of the proximal stiffener or the elongated element **16** can be flexed or steered and alternately pushed, pulled, and twisted. Once inserted, the biological navigation device **10** can navigate to the end of the colon **266**: the cecum **280**.

[0236] FIG. **47***a* illustrates that the biological navigation device **10** (i.e., colonoscope) can be positioned before entry into the colon **266**, for example via the rectum **270** after passing the anus **268**. FIG. **47***b* illustrates that the pressure in the tube **14** can be increased and/or the biological navigation device **10** can be otherwise deployed. The biological navigation device **10** can translate, as shown by arrow, into the rectum **270**, attached to the elongated element **16**.

[0237] The biological navigation device **10** is shown having an outer diameter smaller than the inner diameter of the colon **266** for exemplary purposes. The biological navigation device **10** can have an outer diameter about equal to the inner diameter of the colon **266**. For example, the tube **14** can flexibly expand to substantially fill the cross-section of the length of the colon **266** occupied by the biological navigation device **10**.

[0238] FIG. **47***c* illustrates that the distal end of the biological navigation device **10** can actively or passively flex in a 'cone of motion', with one portion of that plane of motion depicted by the arrow. The distal end of the biological navigation device **10** can actively rotate, for example by actuation of control wires and/or actuators in or attached to the distal component **32** or head **12**.

[0239] The distal end of the biological navigation device **10** can passively rotate, for example if the biological navigation device **10** (e.g., the tube **14** and/or the head **12**) contacts a wall of the colon **266** (e.g., the superior wall of the rectum **270**), the biological navigation device **10** can then track to the wall of the colon **266**.

[0240] FIG. **47***d* illustrates that after making a turn in the rectum **270**, the distal end of the biological navigation device **10** can be further extended, as shown by arrow, or translated into and through the sigmoid colon **272**, for example as the tube **14** continues to release from the head **12**.

[0241] FIG. **47***e* illustrates that the biological navigation device **10** can make a turn, as shown by arrow, for example as the biological navigation device **10** passes from the sigmoid colon **272** to the descending colon **274**. FIG. **47***f* illustrates that the biological navigation device **10** can be further advanced, extended or translated, as shown by arrow, for example by everting the everting element, through the descending colon **274** after the biological navigation device **10** has made two previous turns.

[0242] The biological navigation device **10** can be repeatedly turned and advanced, for example by inflating the tube **14** and/or controlling the head **12** and/or the elongated element **16**, to extend as far along the colon **266** as desired.

[0243] At any length in the colon **266**, the biological navigation device **10** or elongated element **16**, for example at the distal component **32** of the elongated element **16**, can gather diagnostic (e.g., sensing) data, such as data for visualization, tissue inductance, RF absorption or combinations thereof. The biological navigation device **10** and/or elongated element **16** can also gather tissue samples (e.g., by performing a biopsy or removing a polyp). At any length in the colon **266**, the biological navigation device **10** and/or elongated element **16**, for example at the distal component **32**, can perform treatment or therapy, such as delivery of a drug onto or into tissue, tissue removal (e.g., polyp or tumor removal), or combinations thereof.

[0244] FIG. **47***g* illustrates that the biological navigation device **10** can be advanced along the entire colon **266**, passing through the rectum **270**, sigmoid colon **272**, descending colon **274**, transverse colon **276**, ascending colon **278**, and having the tip distal end in the cecum **280**. The biological navigation device **10** can be withdrawn, as shown by arrows, from the colon **266**, for example by applying a tensile force against the tube **14** and/or elongated element **16**, as shown by arrows **282**. The biological navigation device **10** can be withdrawn, as shown by arrows, from the colon **266**, for example by applying a tensile force to the umbilical(s) **28**.

[0245] FIGS. **48***a* and **48***b* illustrate that for a method of constructing the folded tube **14**, an inner construction cylinder **284** can be inserted, as shown by arrow, into the tube **14**.

[0246] FIG. **48***c* illustrates a first split sleeve or grip half **286** and a second split sleeve or grip half **288**. The first and second grip halves **286** and **288** can be configured in a partially or completely cylindrical shape when adjacent.

[0247] FIG. **48***d* illustrates that the grip halves **286** and **288** can be placed, as shown by arrows, around the tube **14** on the inner construction cylinder **284**.

[0248] FIG. **48***e* illustrates that a tapered outer construction cylinder **290** can be translated, as shown by arrow, on top of the inner construction cylinder **284** and under the tube **14**. The outer construction cylinder **290** can be positioned to end from about 10 in. to about 20 in., for example about 12 in., from the end of the tube **14**. The inner construction cylinder **284** can be positioned to end from about 5 in. to about 10 in., for example about 6 in., from the end of the tube **14**.

[0249] FIG. **48***f* illustrates that two semi-cylindrical grip halves **286** and **288** can be diametrically oppositely compressed, as shown by arrows, onto the tube **14** on the inner construction cylinder **284**. The grip halves **286** and **288** can then be translated, as shown by arrow, toward the outer construction cylinder **290**, for example, until the grip halves **286** and **288** abut the outer construction cylinder **290**. The wrinkles in the tube **14** can be removed during translation of the grip halves **286** and **288**. The inner construction cylinder **284** and/or the tube **14** can have one or more markings to provide guidance for translation lengths.

[0250] FIG. **48***g* illustrates that the outer construction cylinder **290** and the grip halves **286** and **288** can then be removed once the set of folds **82** are properly formed. The tube **14** can then be repositioned with respect to the inner and outer construction cylinders **284** and **290**.

[0251] The inner and outer construction cylinders **284** and **290** can be removed from the folded tube **14** when the desired number of folds **82** are formed.

[0252] The systems, devices, elements and methods disclosed herein can be used in conjunction or substituted with any of the systems, devices, elements and methods disclosed in Provisional Patent Application Ser. Nos. 60/887,319, filed 30 Jan. 2007; 60/887,323, filed 30 Jan. 2007; and 60/949,219, filed 11 Jul. 2007; U.S. patent application Ser. No. titled "Biological Navigation Device", attorney docket number LMVSNZ00200, filed concurrently herewith; and PCT Application titled "Biological Navigation Device", attorney docket number LMVSNZ00600WO, filed concurrently herewith, which are all incorporated herein by reference in their entireties. The everting element can be merely representative of any pressurized tube **14**, including those disclosed in the references incorporated, supra.

[0253] The term colonoscope is used for exemplary purposes and can be any deployable elongated element **16** for use in a body lumen, such as an endoscope. The pressurizer can be the deployment system. The terms tip, tool tip, tip distal end, and tool head can be used interchangeably herein.

[0254] The tube **14** can have wide medical applicability, including, but not limited to, endoscopy and the dilation of anatomical structures. One such dilation application is for use in the field of interventional cardiology, where they can be used for lesion dilation, as a stand-alone procedure, for prestent deployment ('pre-dia'), for post-stent deployment, as part of a stent-expansion inflatable structure used as a stent delivery system, or combinations thereof.

[0255] Any elements described herein as singular can be pluralized (i.e., anything described as "one" can be more than one). Any species element of a genus element can have the characteristics or elements of any other species element of that genus. The above-described configurations, elements or complete assemblies and methods and their elements for carrying out the invention, and variations of aspects of the invention can be combined and modified with each other in any combination.

We claim:

1. A device for navigation through biological anatomy comprising:

an everting tube comprising a tube wall with a plurality of folds configured to be pressurizably unfolded; and

a tube channel in the everting tube, wherein the tube channel is configured to receive an elongated element such that the elongated element can be pressurizably advanced when the plurality of folds are pressurizably unfolded.

2. The device of claim **1**, wherein the tube is configured to contain a fluid pressure of about 6 psi to about 200 psi.

3. The device of claim **1**, wherein the tube wall comprises a sheet integrated with reinforcement fibers.

4. The device of claim **3**, wherein at least some of the reinforcement fibers comprise a unidirectional fiber array.

5. The device of claim **3**, wherein the reinforcement fibers are arranged in the tube such that the tube has a radial stiffness that results in equal to or lower than a 0.05% change in diameter per psi of fluid pressure in the tube.

6. The device of claim **3**, wherein the reinforcement fibers are arranged in the sheet such that the tube has a strength that allows a distal propulsive force of about 4N to about 27N to be delivered.

7. The device of claim **1**, wherein the sheet has a coefficient of friction that is equal to or greater than 0.1 and equal to or less than 0.6.

8. The device of claim **1**, wherein a first length of tube entering at least one fold the plurality of folds and wherein a second length of tube exiting the at least one fold are substantially parallel with the long axis of the tube.

9. The device of claim **1**, wherein the everting tube includes an inner section and an outer section, and wherein the plurality of folds is included in the inner section.

10. The device of claim **1**, wherein the plurality of folds comprises a first set of folds and a second set of folds, and wherein the first set of folds are separated from the second set of folds by a non-folded section of the tube wall.

11. A device for navigation through biological anatomy comprising:

a pressurazably everting tube including a tube wall with inner section and an outer section, said tube wall including a plurality of folds; and

a channel within the tube, wherein the channel is configured to receive an elongated element such that the elongated element can be advanced distally when the plurality of folds are unfolded;

wherein each of the plurality of folds extends at a fold angle with respect to a longitudinal axis of the tube.

12. The device of claim **11**, wherein the plurality of folds are included in the inner section of the tube wall.

13. The device of claim **11**, wherein the fold angle is acute.

14. The device of claim **11**, wherein the plurality of folds overlap one another.

15. A device for navigation through biological anatomy comprising:

a pressurazably everting tube including a tube wall with inner section and an outer section, said tube wall including a plurality of folds;

a channel within the tube, wherein the channel is configured to receive an elongated element such that the elongated element can be advanced distally when the plurality of folds are unfolded; and

at least one fold mount for providing a frictional engagement between at least one of the plurality of folds and the elongated element for sequentially releasing the plurality of folds.

16. The device of claim **15**, wherein the at least one fold mount comprises first and second fold mounts adapted to frictionally engage first and second folds, respectively.

17. The device of claim **16**, wherein the first fold mount is adapted to provide a first level of friction between the first fold and the elongated element and the second fold mount is adapted to provide a second level of friction between the second fold and the elongated element, and wherein the first level of friction is less than the second level of friction.

18. The device of claim **16**, wherein the first fold mount has a smaller surface area than the second fold mount.

19. The device of claim **16**, wherein the first fold mount has a lower coefficient of friction than the second fold mount.

20. The device of claim **16**, wherein the plurality of folds includes a first and a second fold series separated by a non-folded portion of the tube wall, and wherein the first fold mount is associated with the first fold series and the second fold mount is associated with the second fold series.

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