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(54) **ENDOSCOPE PROPULSION SYSTEM AND METHOD**

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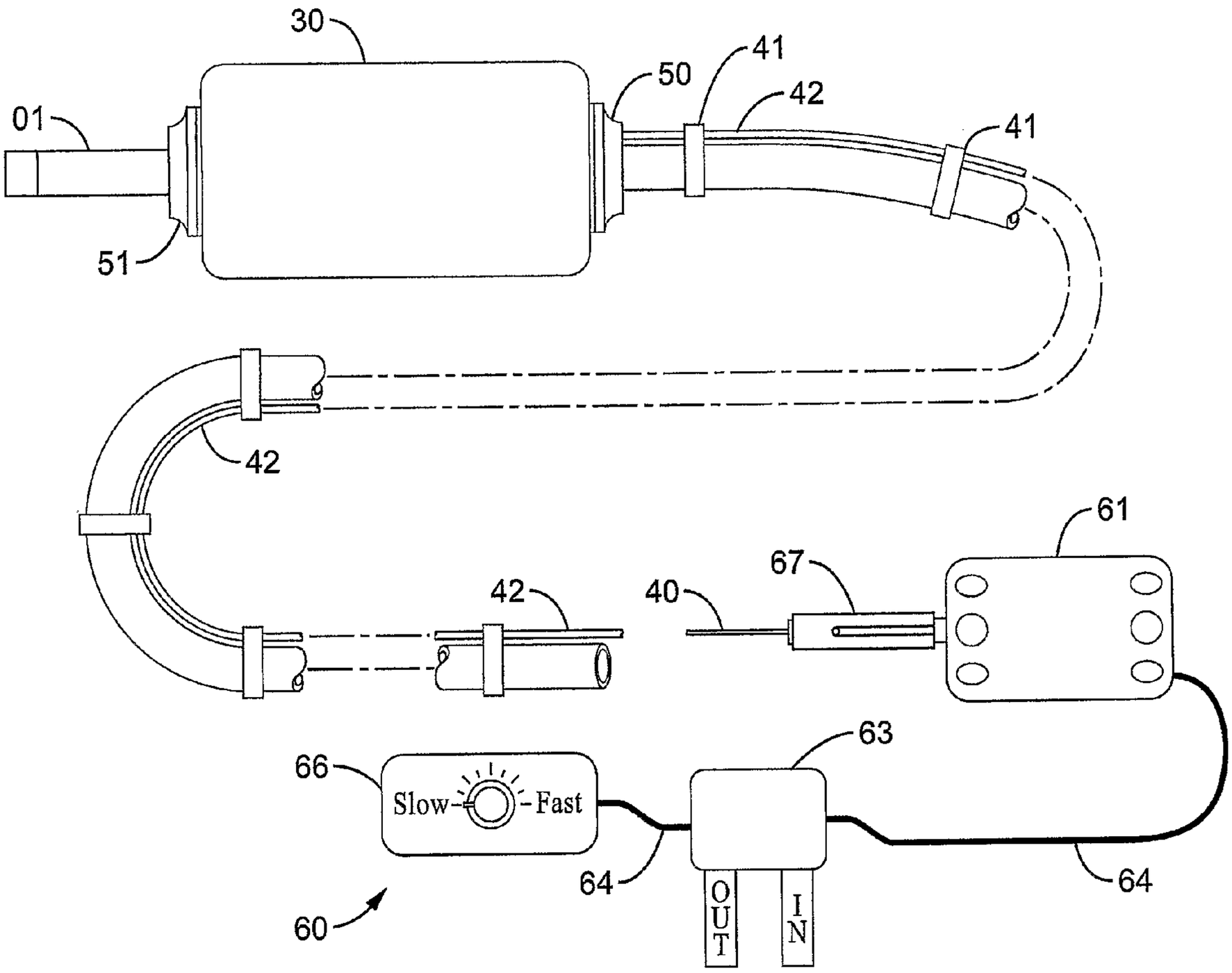
(57) **ABSTRACT**

The present invention provides a system and method for active propulsion of devices, such as endoscopes, along cavities, such as body lumens. The propulsion system can be attached to a commercially available endoscope, or be provide affixed together, and moves the endoscope in a lumen by pulling it forward. The present invention further provides a method of diagnosing diseases and disorders, and treatment of diseases and disorders, using a device according to the invention.



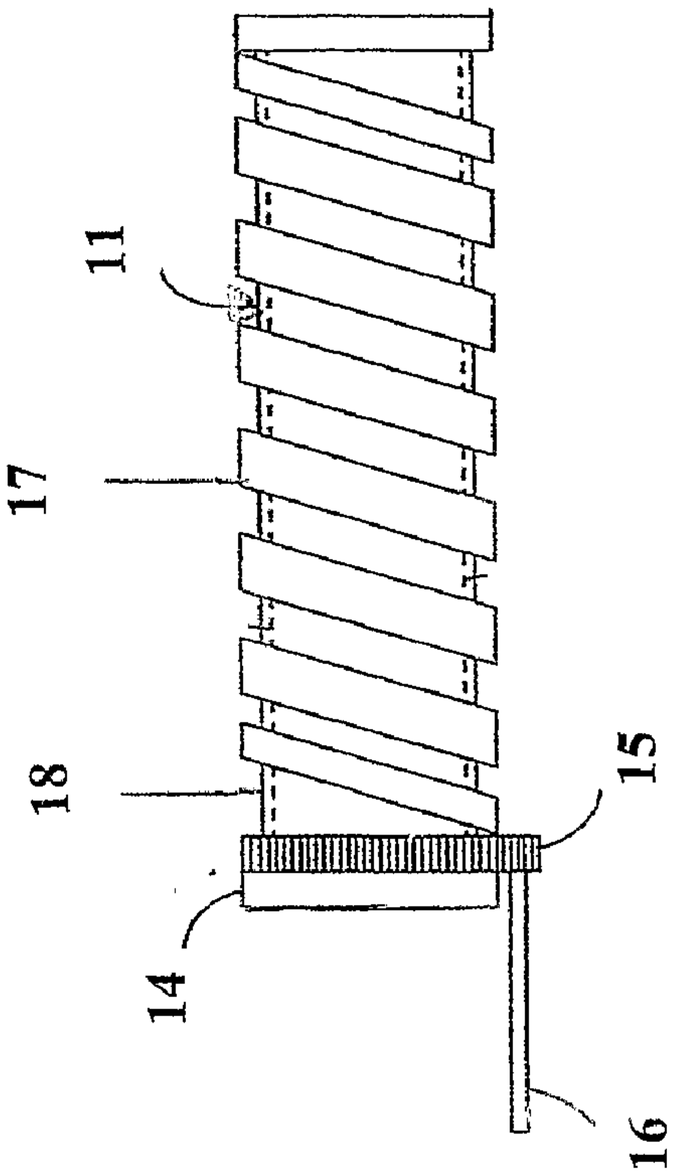


FIG. 2

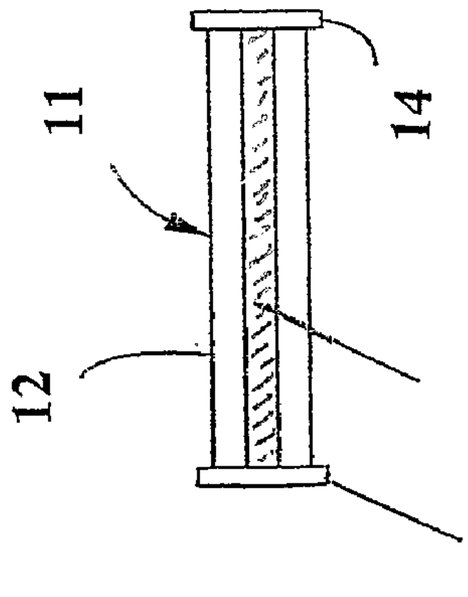


FIG. 1

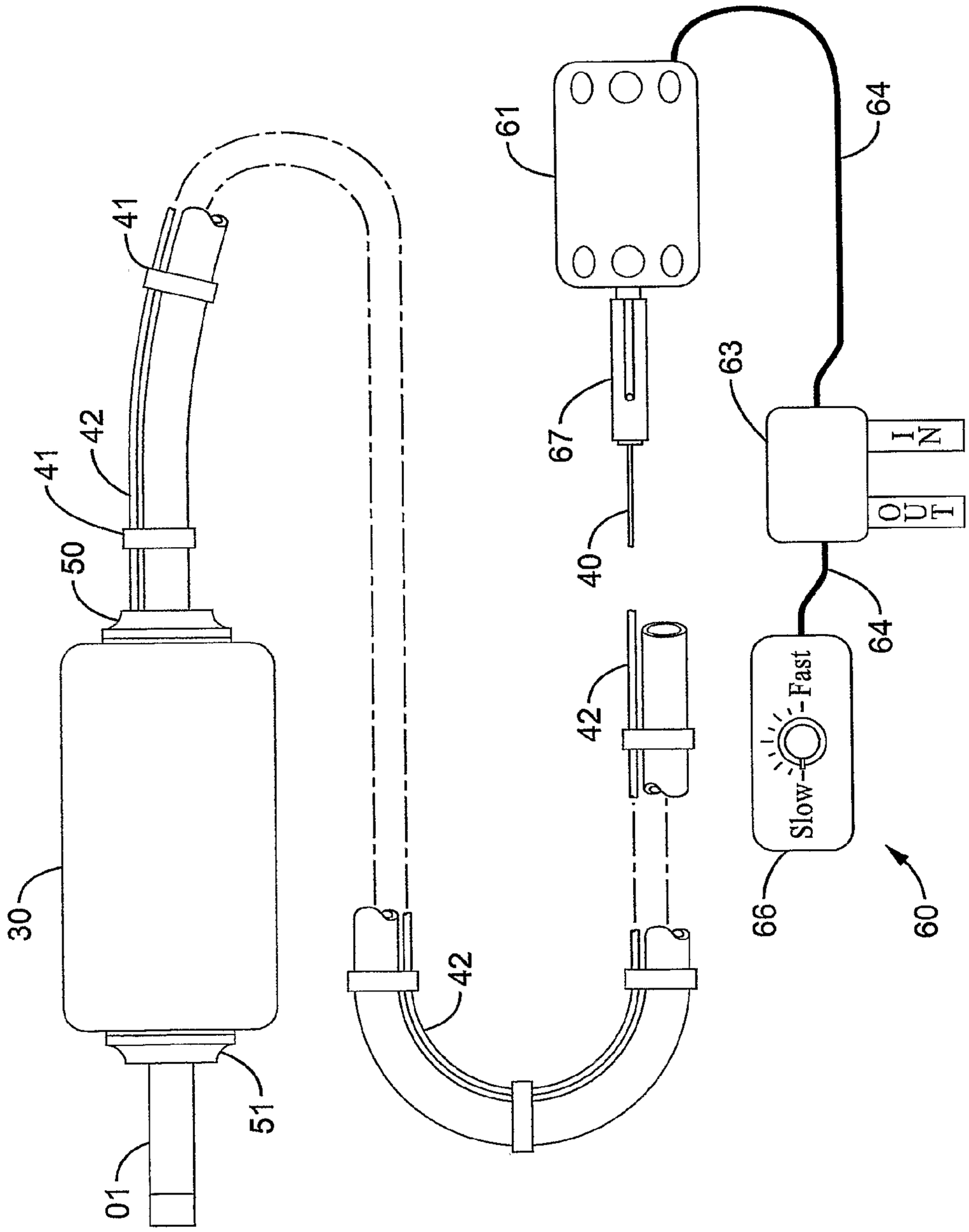


FIG. 3

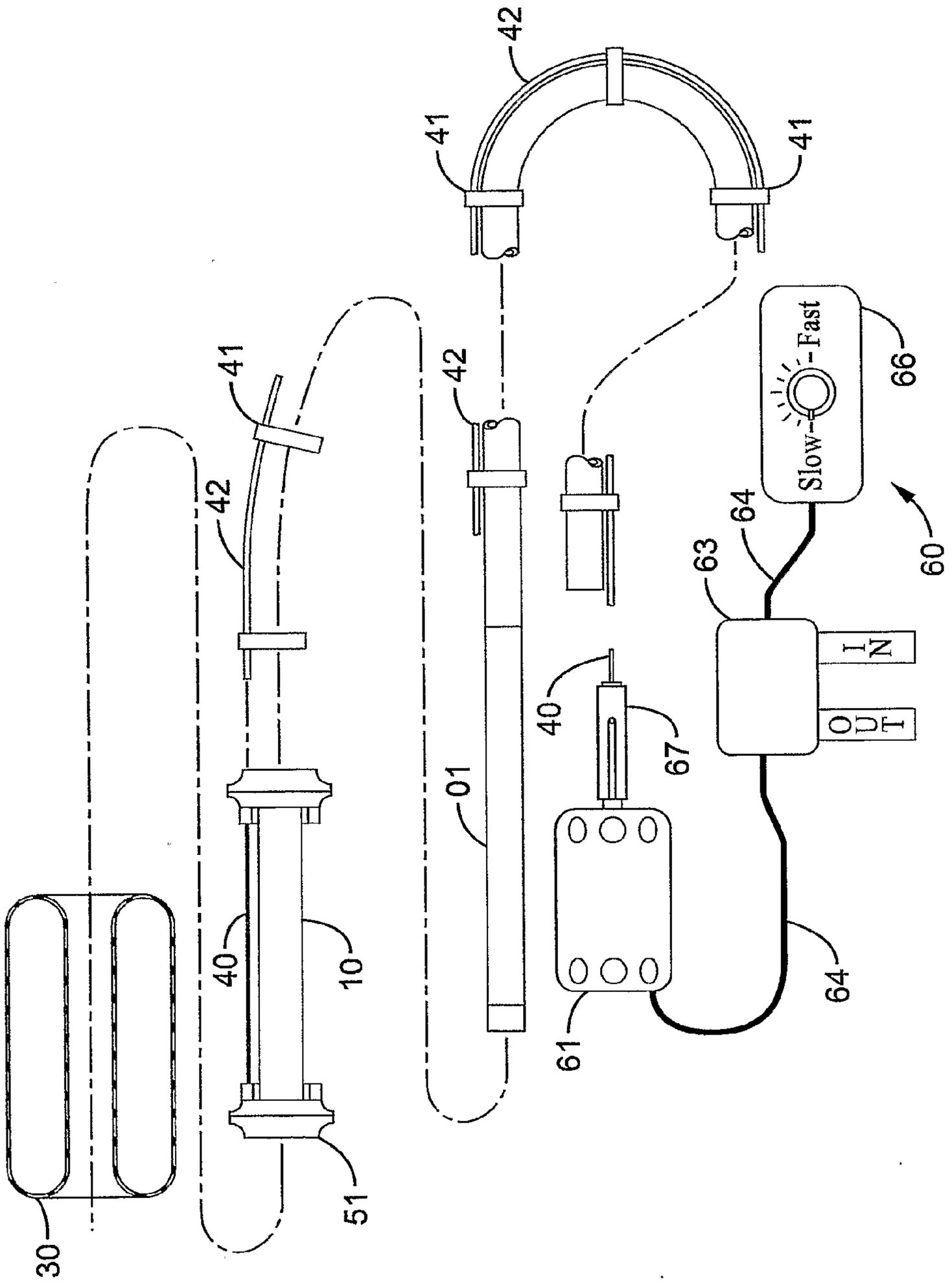

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FIG. 4

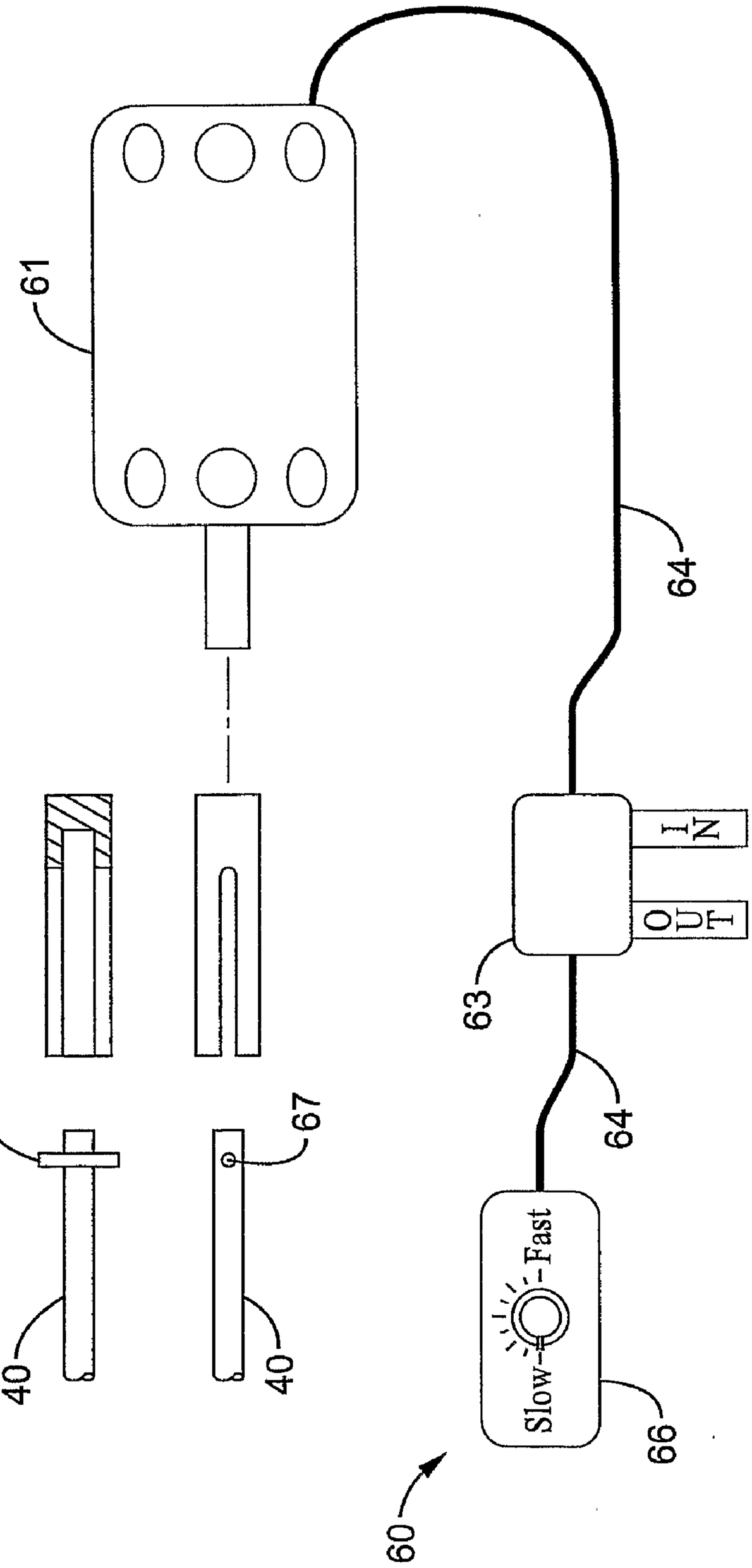

FIG. 5

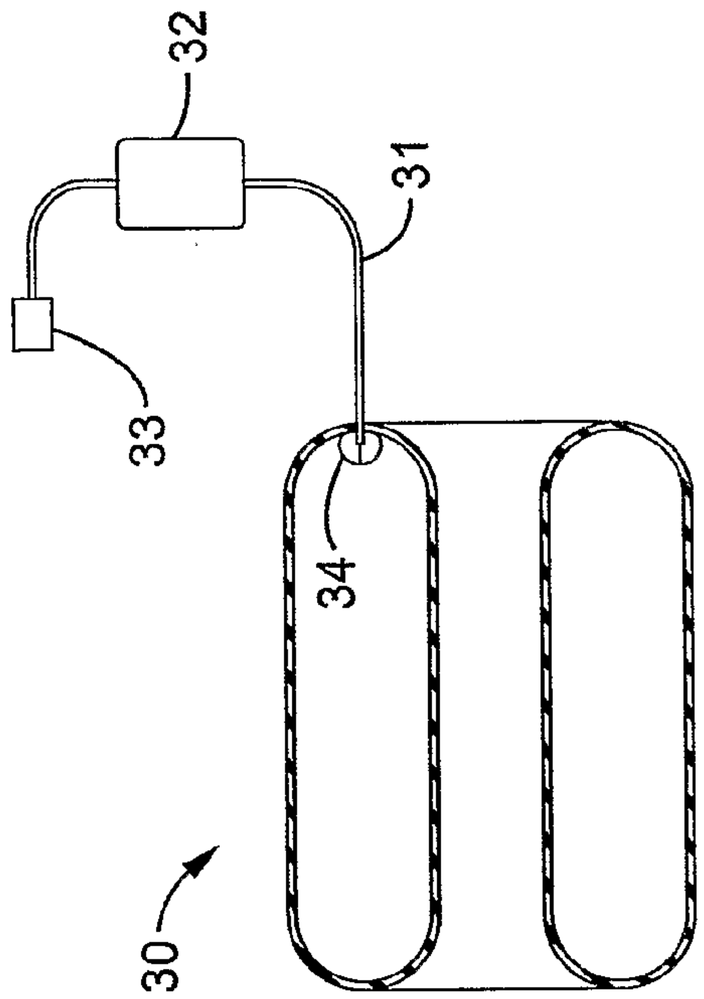

FIG. 7A

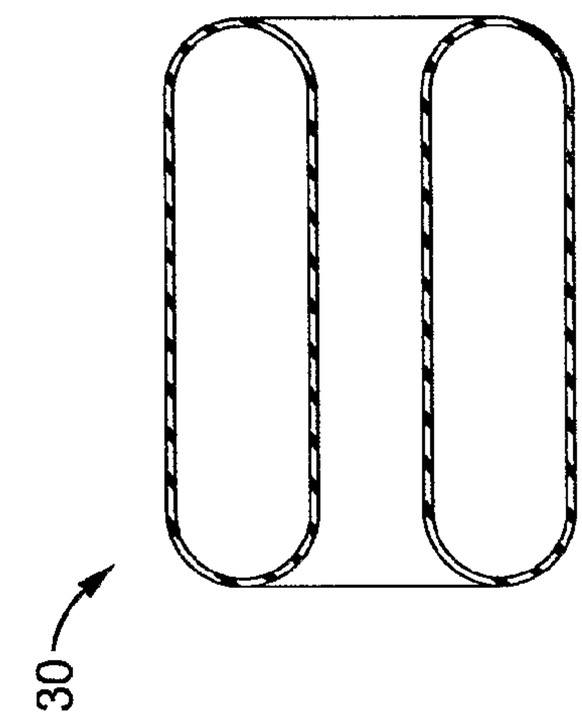

FIG. 7C

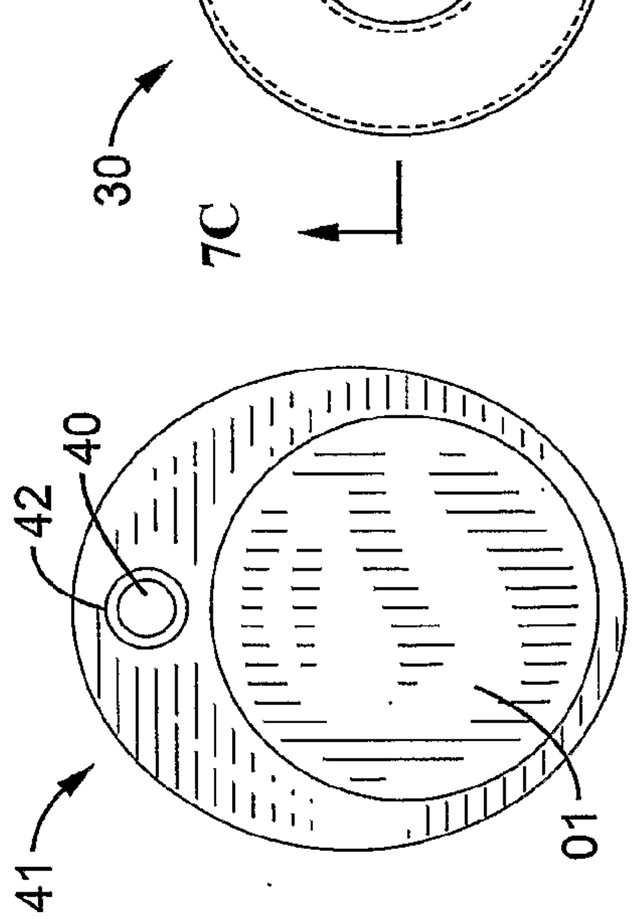

FIG. 6

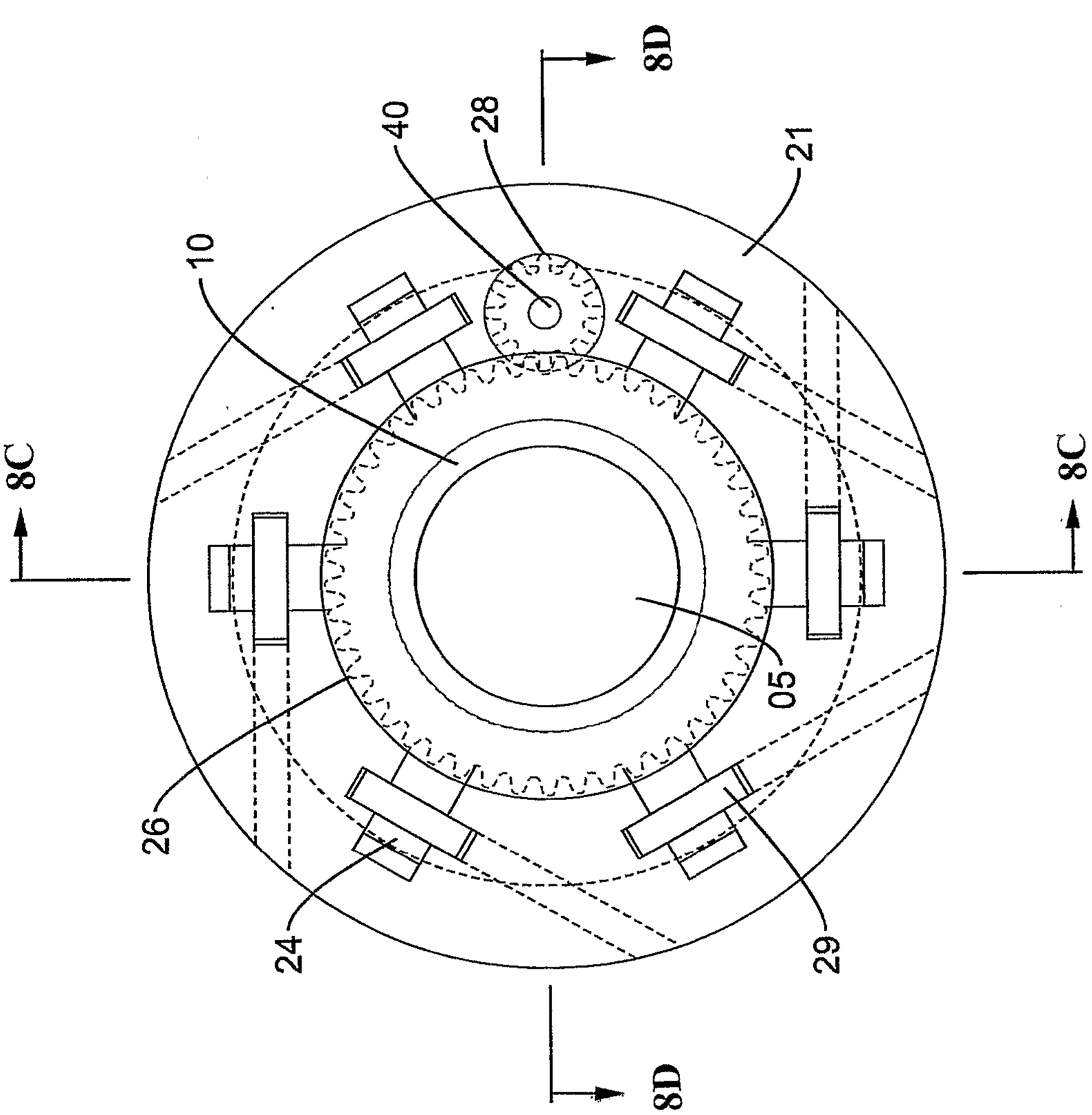

FIG. 8A

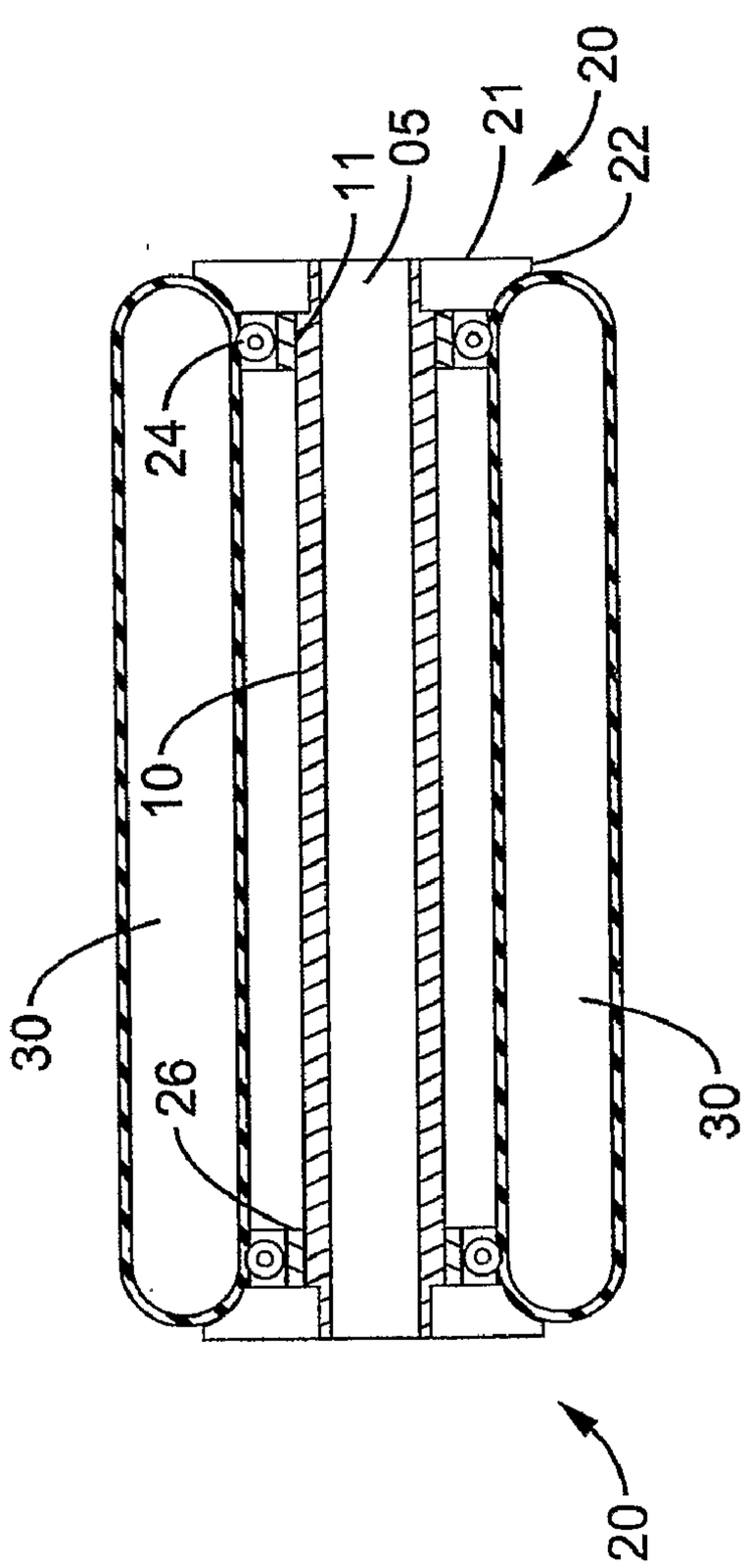

FIG. 8B

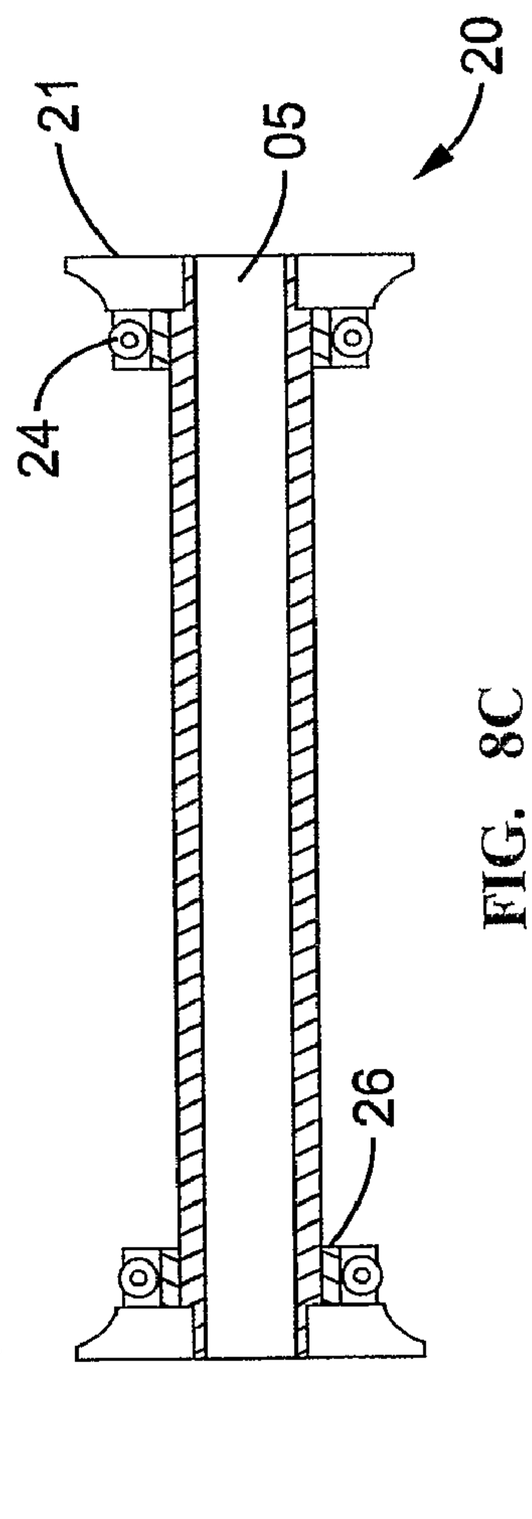

FIG. 8C

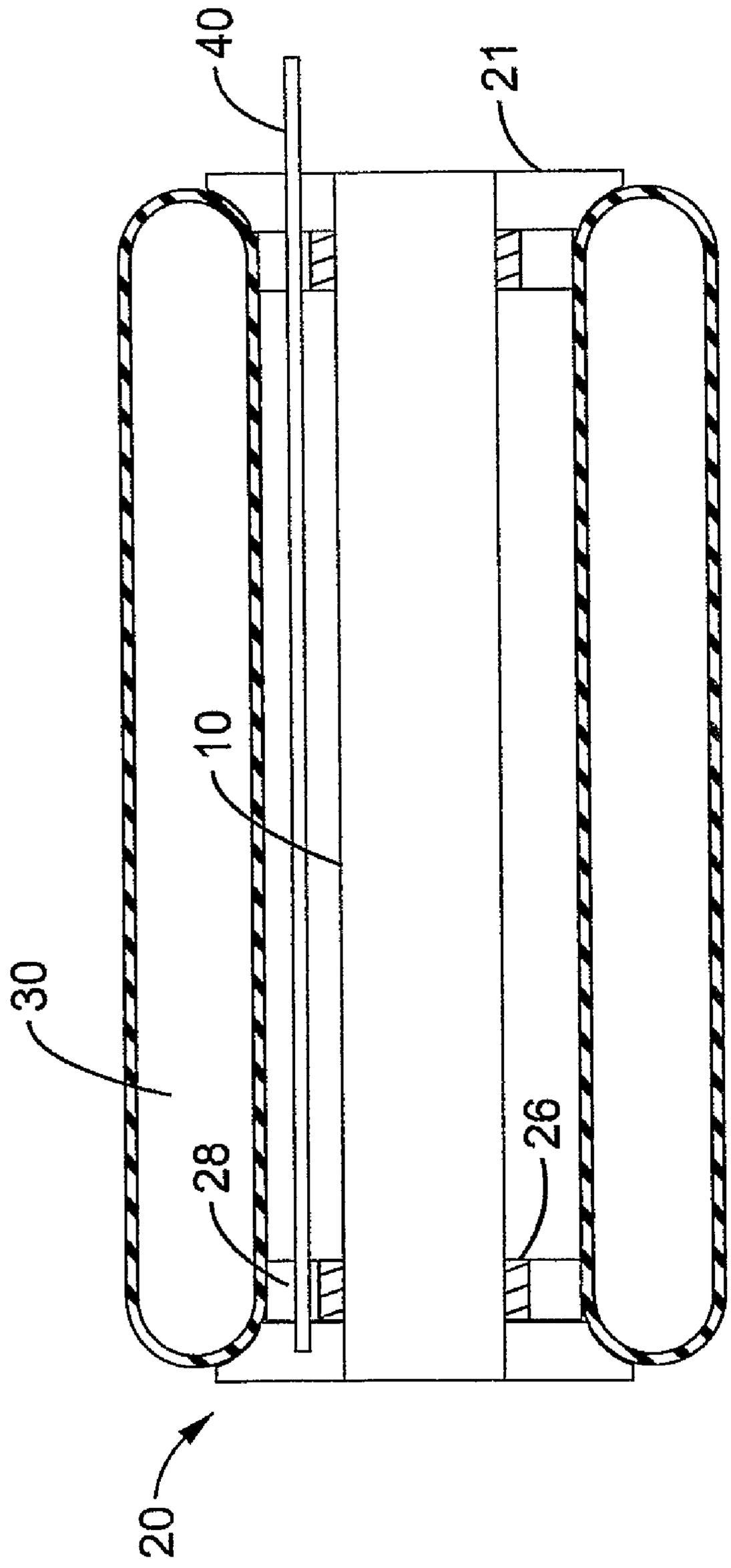

FIG 8D

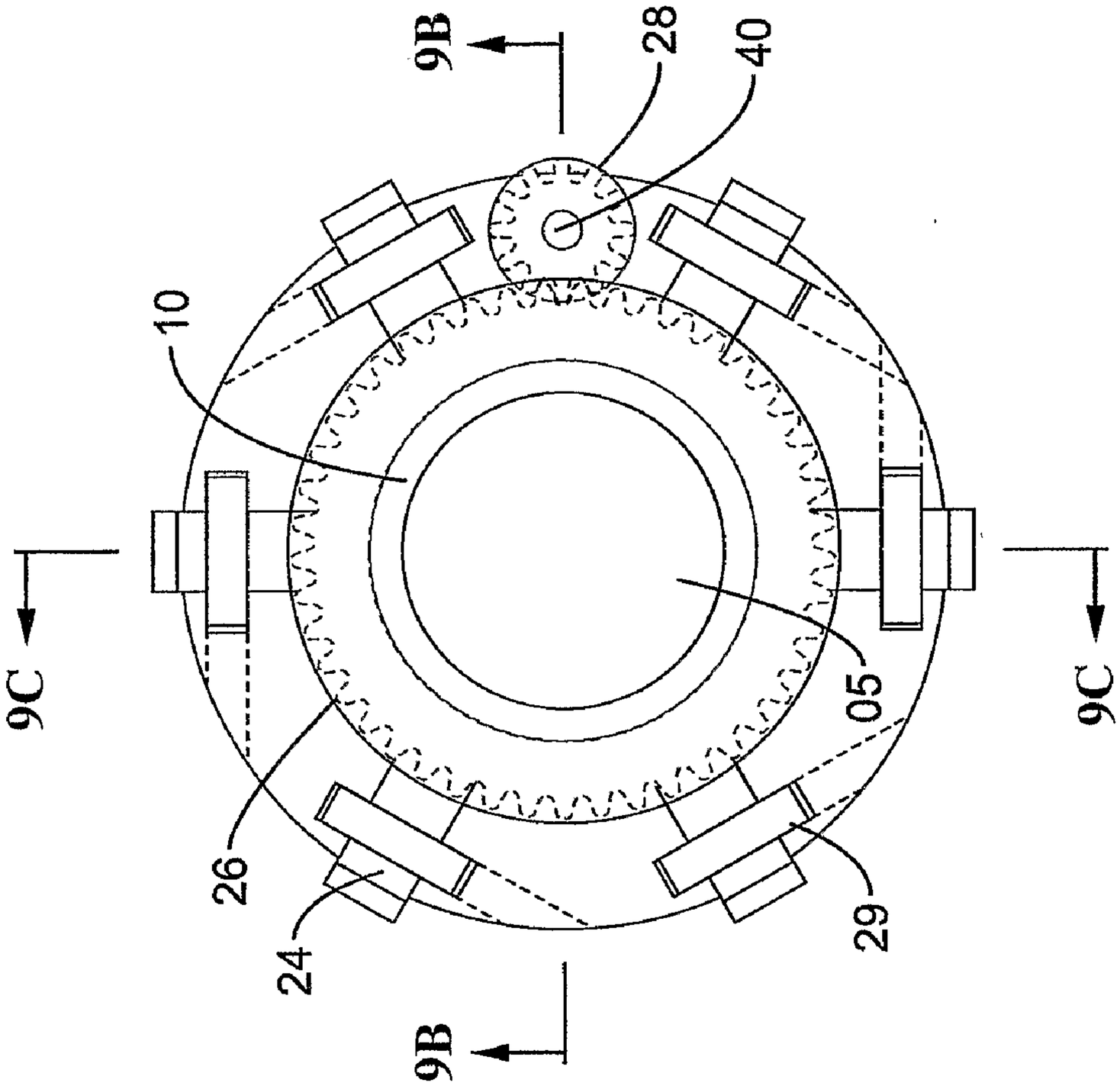

FIG. 9A

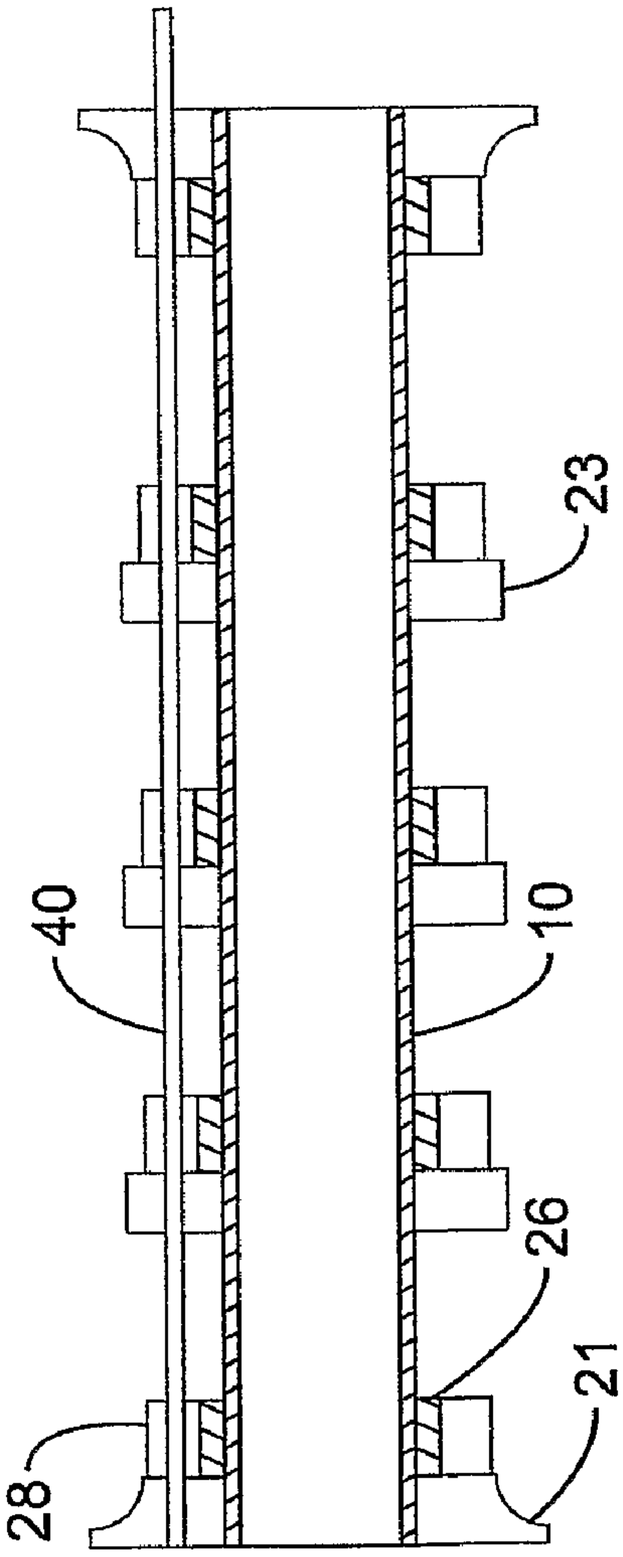

FIG. 9B

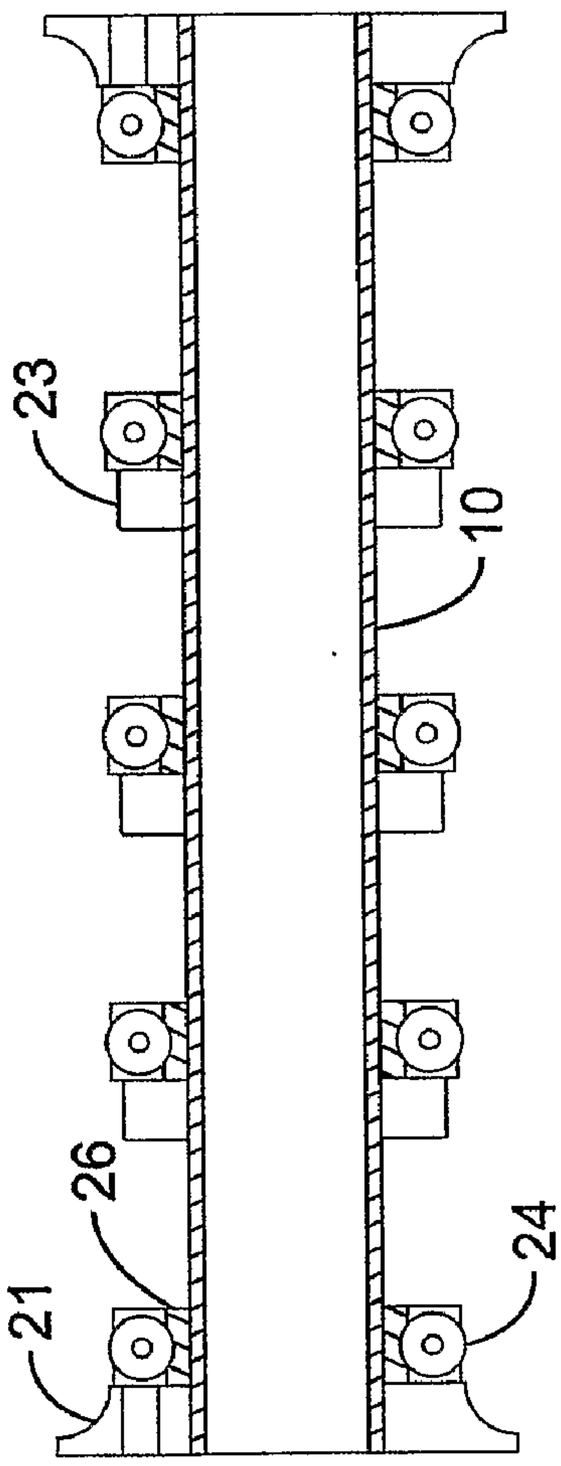

FIG. 9C

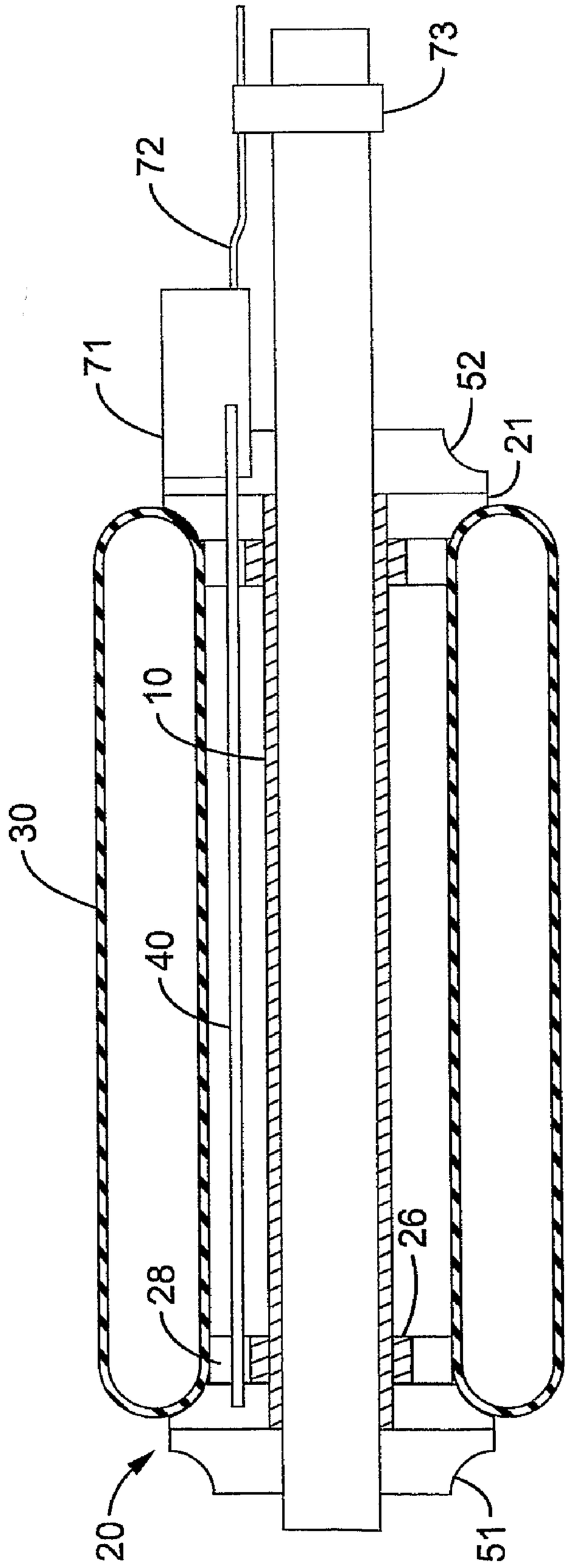

FIG. 10

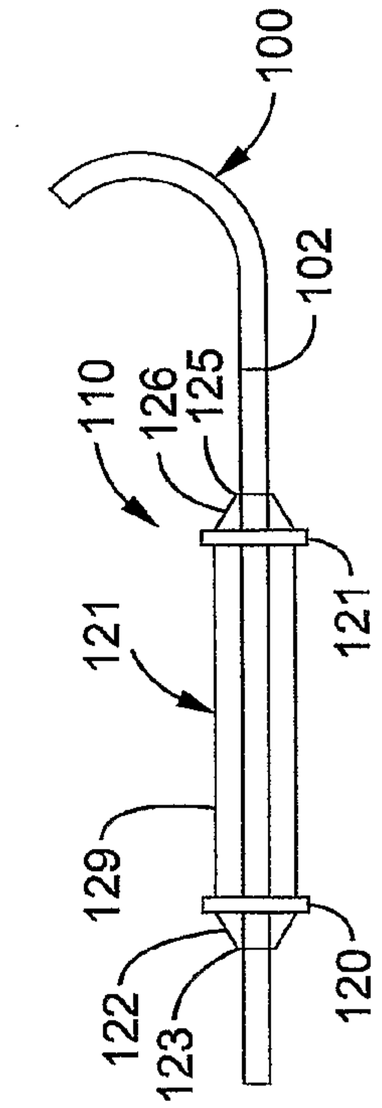

FIG. 12

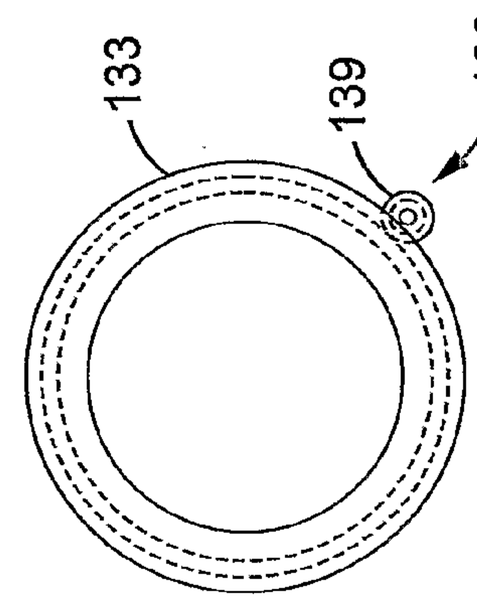

FIG. 14

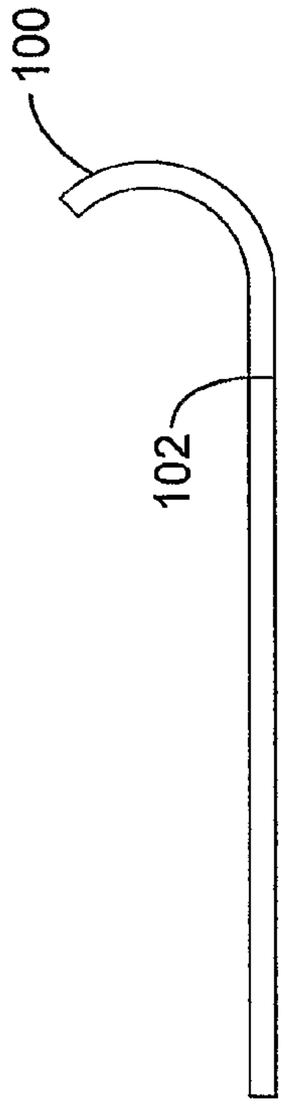

FIG. 11

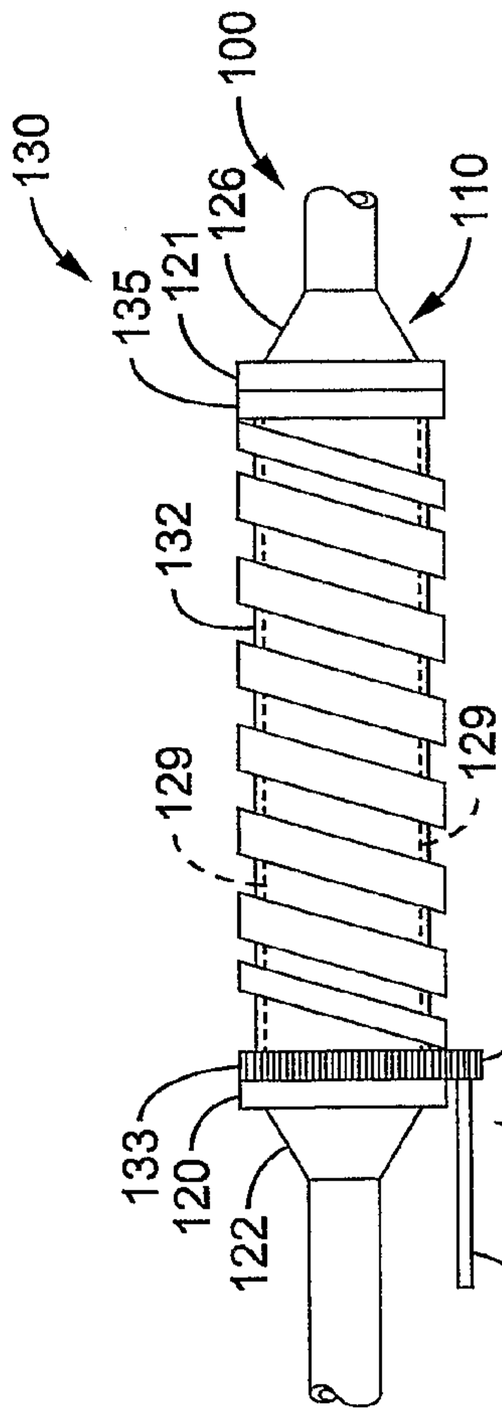

FIG. 13

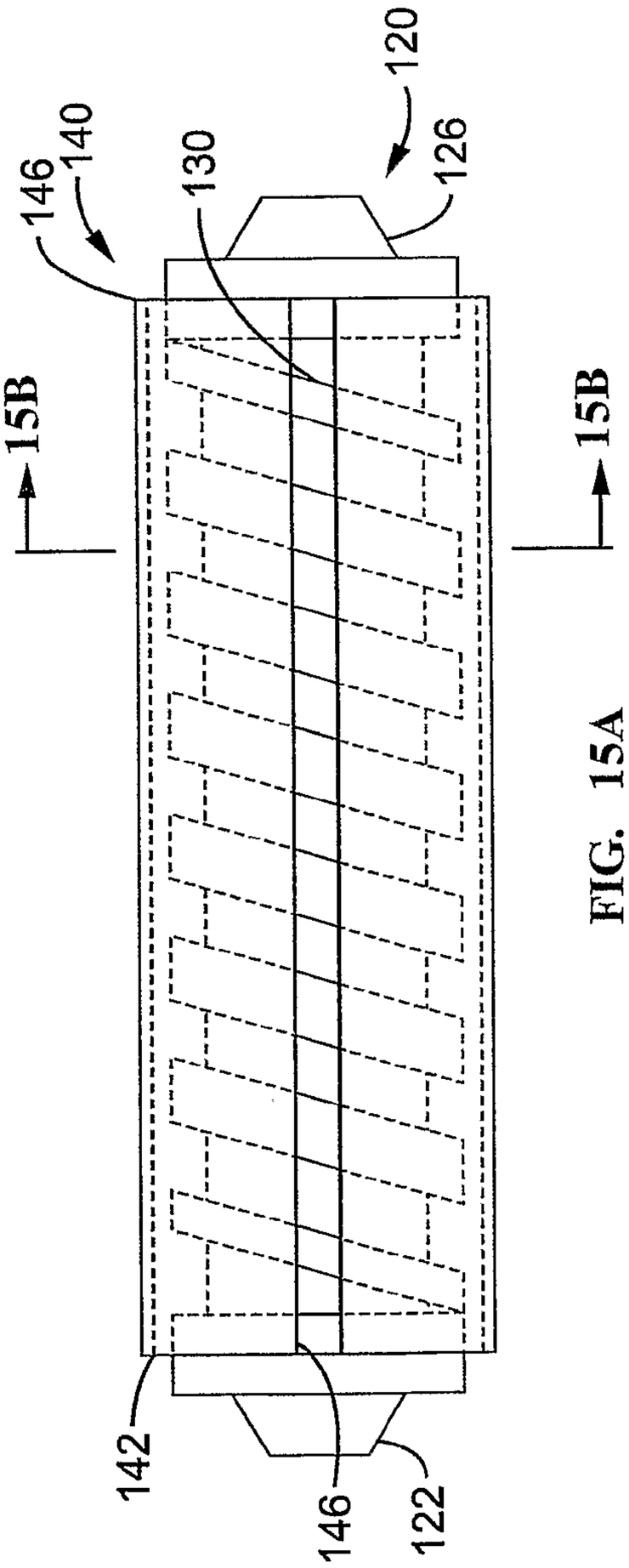

FIG. 15A

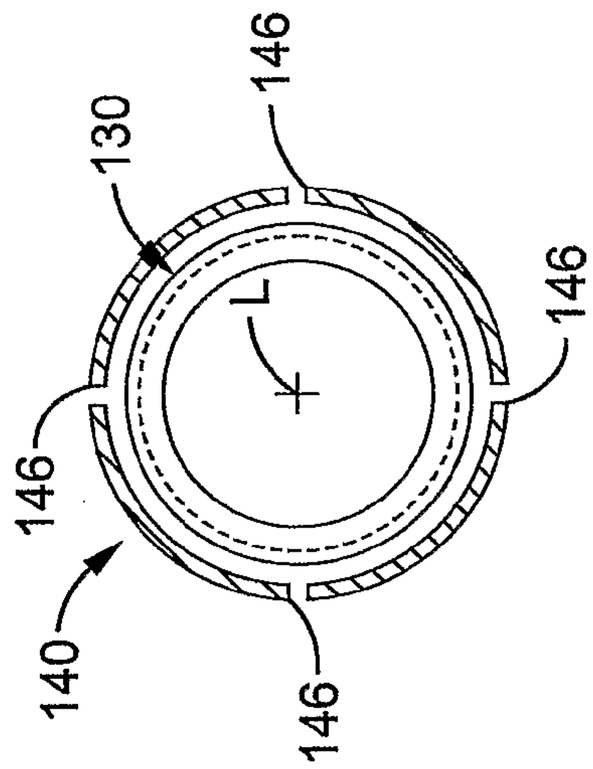

FIG. 15B

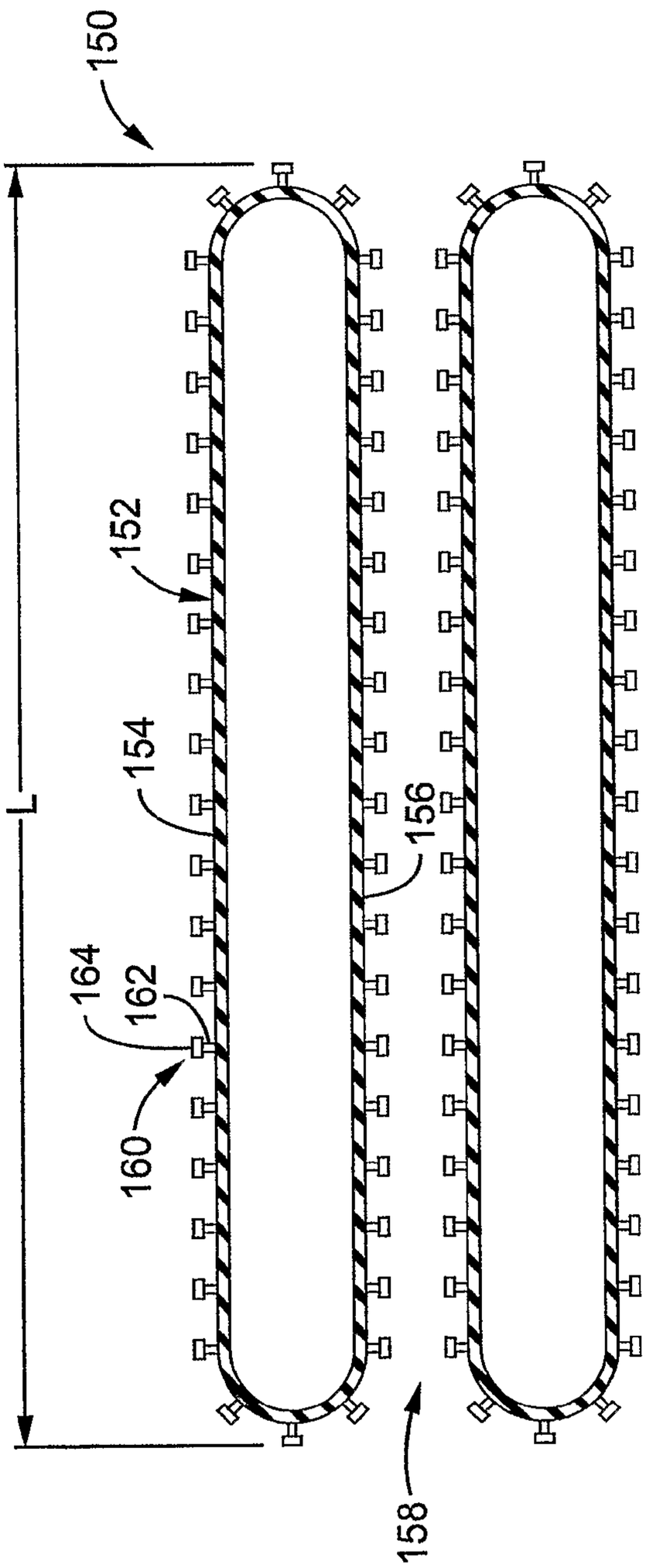

FIG. 16A

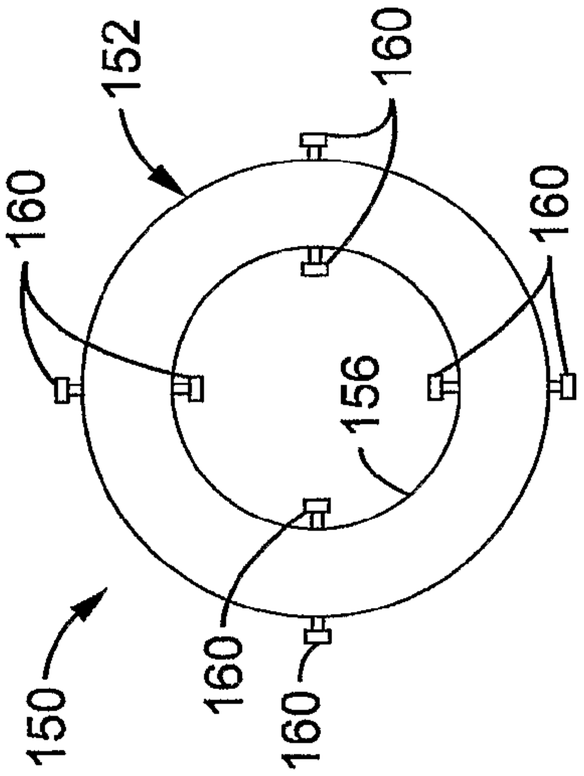

FIG. 16B

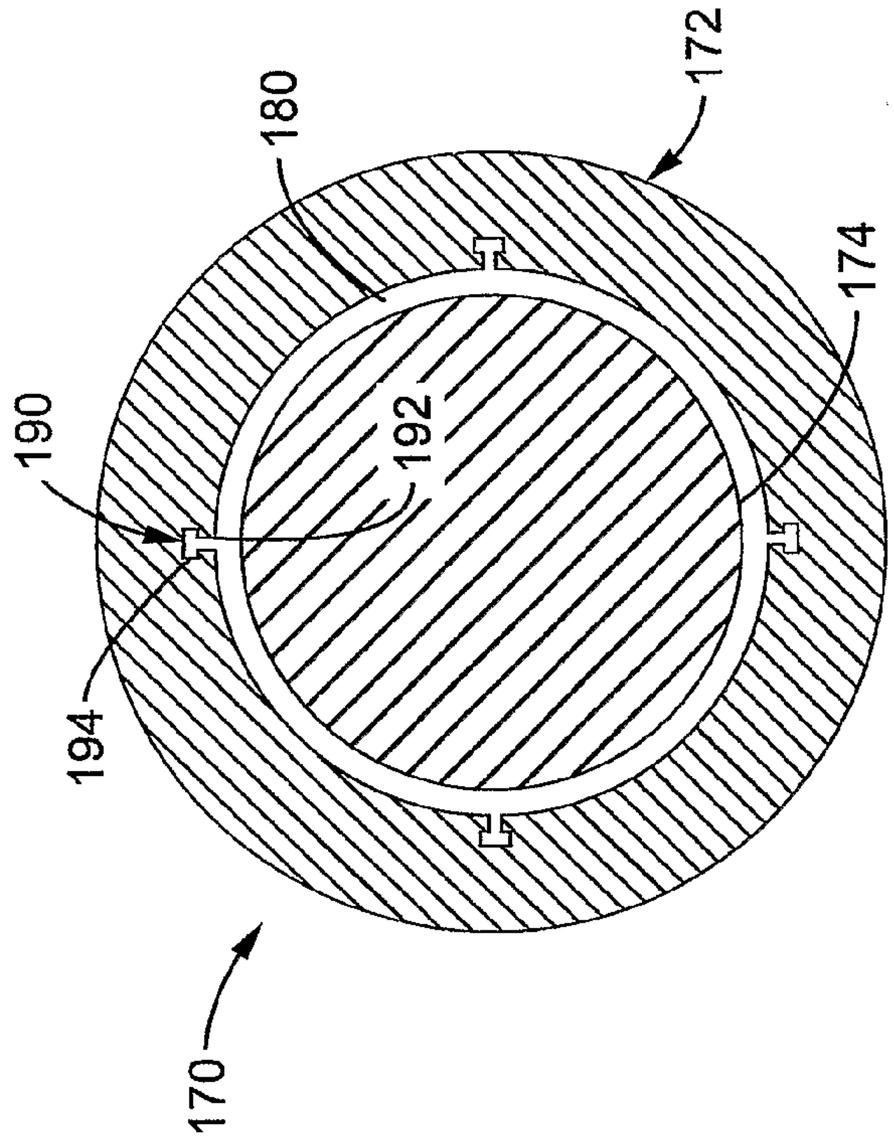

FIG. 18A

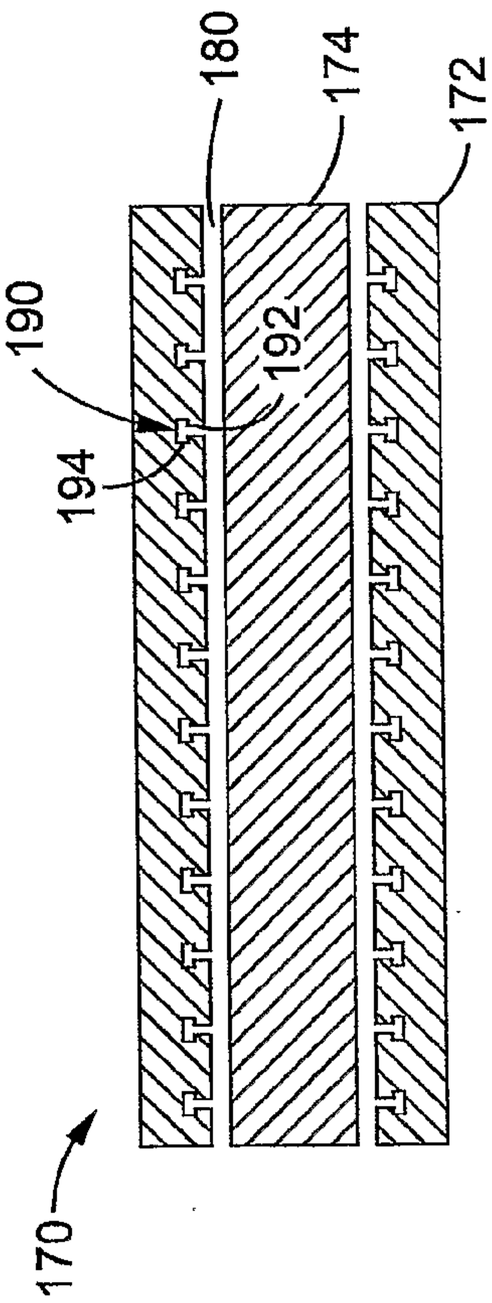

FIG. 18B

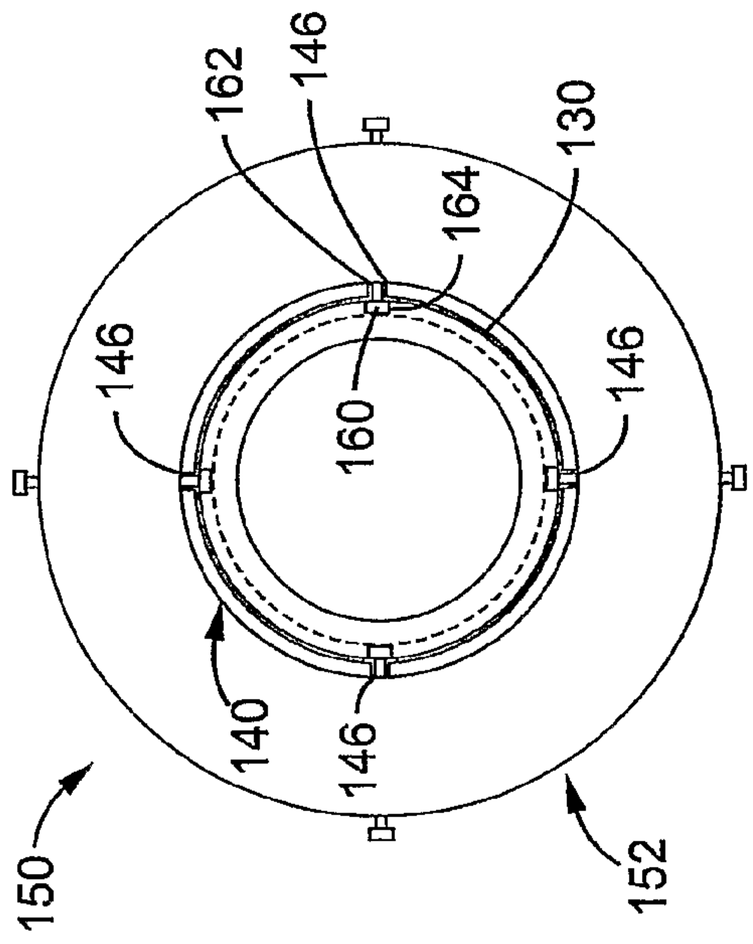

FIG. 17

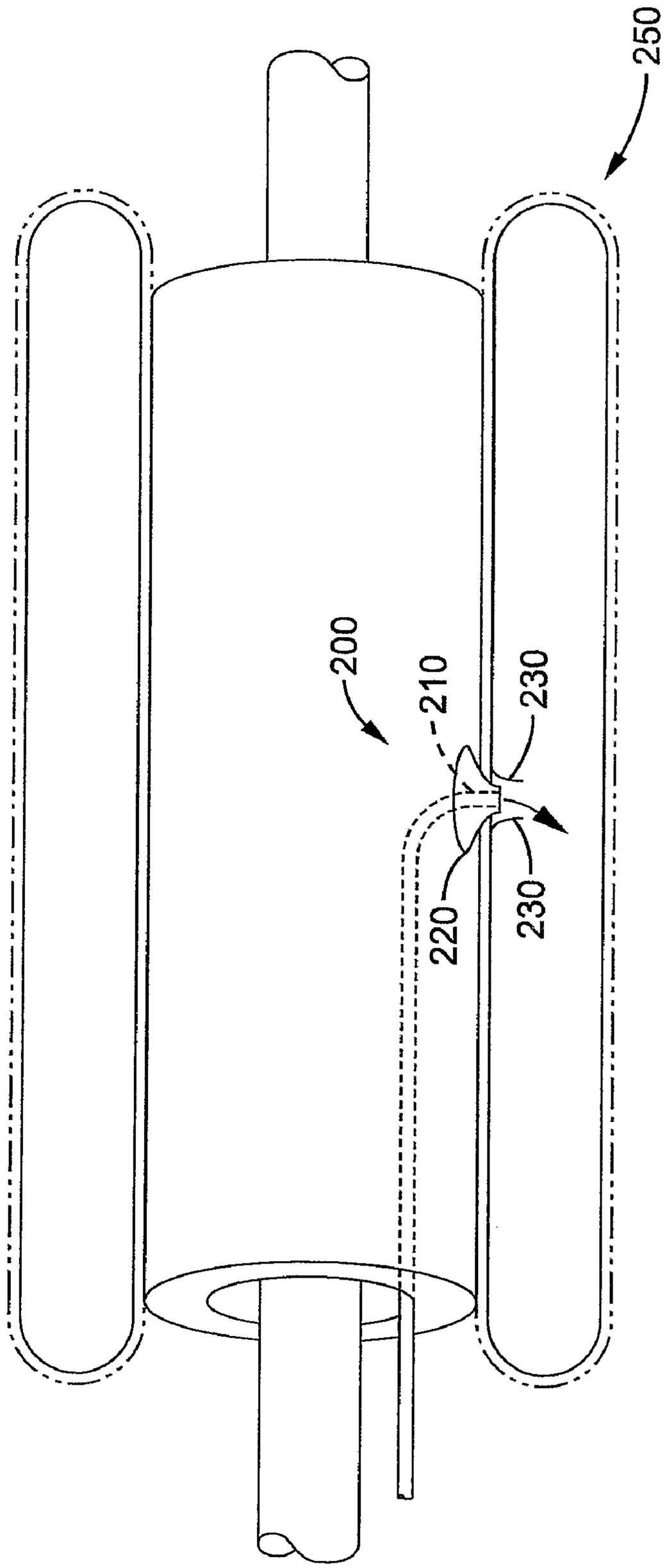

FIG. 19

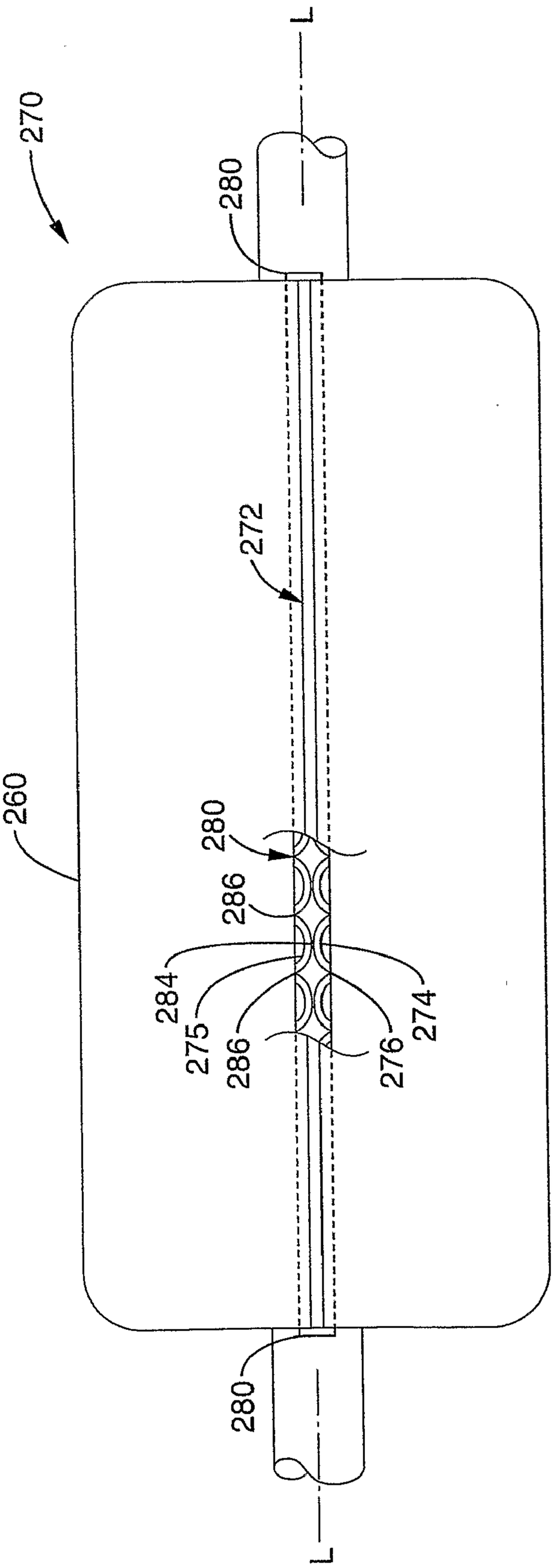

FIG. 20

ENDOSCOPE PROPULSION SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application relies on, and claims the benefit of the filing date of, U.S. patent application Ser. No. 11/140,595, filed 27 May 2005. Priority of the filing date of this application is claimed, and the disclosure of the application is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to the field of health care. More specifically, the invention relates to the field of endoscopy, and particularly to devices and methods for performing endoscopic examinations and surgeries.

[0004] 2. Description of Related Art

[0005] Each year, 60,000 Americans die from colon cancer, making colon cancer the second leading cause of cancer death in the United States. Early detection of the disease greatly improves survival. Furthermore, removal of pre-cancerous polyps can be achieved endoscopically, which prevents colon cancer altogether. Unfortunately early colon cancer and polyps are asymptotic. For this reason screening tests are needed to detect and prevent colon cancer. Currently available screening tests include fecal occult blood test, flexible sigmoidoscopy, and colonoscopy. In part because of the limitations of these tests, only about 10% of the United States population is currently screened for this common preventable cause of death.

[0006] Fecal occult blood testing detects blood in the stool that can not be seen on visual inspection of the stool. Unfortunately only about 30% of colon cancers can be detected by fecal occult blood testing, making this test too insensitive for effective screening.

[0007] Flexible sigmoidoscopy is a type of endoscopy that uses a semi-rigid tube with fiberoptic lenses to directly visualize the colon. The end of this semi-rigid tube has a flexible steering section to direct the instrument's tip. In an ideal patient, this test can visualize up to 60 centimeters of the distal colon (or approximately one-third of the entire colon). The limited extent of the flexible sigmoidoscopy exam misses approximately 50% of colon cancers. Although flexible sigmoidoscopy is insensitive, it is relatively inexpensive and can be performed as a screening test in a physician's office. Unfortunately flexible sigmoidoscopy is too uncomfortable for many patients to tolerate. Flexible sigmoidoscopy is painful because the scope is advanced in the colon by pushing the semi-rigid tube against the colon wall. As the tube is pushed against the colon wall, the colon is stretched. Stretching of the colon causes intense visceral pain. In addition to pain, stretching the colon too far can result in colon perforation, a potentially life threatening complication of flexible sigmoidoscopy.

[0008] Colonoscopy, like flexible sigmoidoscopy, is a type of endoscopy that utilizes a semi-rigid tube with either fiberoptic lenses or a video camera to directly visualize the colon. Currently available colonoscopes offer an excellent view of the colon. In a fashion similar to flexible sigmoidoscopy, the semi-rigid tube has a flexible steering section at the distal end of the instrument. Unlike the flexible sigmoidoscope, the colonoscope is long enough to visualize the entire colon. For this reason colonoscopy is ideal for colon cancer screening. If a pre-cancerous colon polyp is detected at the time of colonoscopy it can be removed through the scope's "working channel" using various endosurgical instruments (such as biopsy forceps and polypectomy snares). In a fashion similar to flexible sigmoidoscopy, pushing the semi-rigid tube against the colon wall advances the colonoscope. Unfortunately colonoscopy is far too uncomfortable to be performed without high level intravenous sedation or general anesthesia. The pain experienced during colonoscopy is related to stretching of the colon wall as the colonoscope is advanced. Colon perforation can occur as a result of pushing the semi-rigid tube too forcefully against the colon wall as the colonoscope is advanced. The high level of sedation needed for colonoscopy requires a highly monitored environment, such as an operating room. With the added operating room charges colonoscopy becomes quite costly. If colonoscopy were less expensive, it would be more widely accepted as a colon cancer-screening test.

[0009] Various robotic endoscopy devices and methods have been previously disclosed. Several such disclosures involve robotic endoscopes that are generally complex devices with multiple interacting segments. These robotic endoscopes generally involve a kinematically redundant robot, which generally has about seven or more internal degrees of freedom. These robotic endoscopes are also designed to function autonomously as a robot. That is, an examining physician has no direct control of the robotic endoscope. Furthermore, the examining physician can not directly assist in the movement of the scope in an organ lumen. The lack of direct physician control will markedly increase the risks of robotic endoscopy.

[0010] The previously disclosed robotic endoscopes also depend on a complicated interaction of a plurality of segments. At least one previously disclosure involves a robotic endoscope that relies on a complex array of pressure sensors, gripping devices, and expansion modules under the control of at least one computer. Even the slightest malfunction of the complex control mechanism could cause devastating complications for a patient.

[0011] More specifically, the prior robotic endoscope uses a proximal and a distal toroidal balloon in conjunction with an extensor module. The proximal toroidal balloon expands to statically grip the organ wall and thereby fix this segment of the robotic endoscope to the organ wall. After the proximal balloon has expanded, the extensor module expands, thus lengthening the robotic endoscope. The robotic endoscope depends primarily on the extensor module for movement. After the extensor module has lengthened the robotic endoscope, the distal toroidal balloon expands to fix this segment of the robotic endoscope to the organ lumen wall. After distal toroidal balloon inflation, the proximal toroidal balloon deflates and the extensor module contracts. This arrangement is said to produce an inch-worm-like movement in an organ lumen.

[0012] The toroidal balloon described in at least two such prior disclosures operates by means of static friction. This static friction is fundamental to the operation of the robotic endoscope. This static friction is between the balloon and organ wall. The only dynamic feature of the toroidal balloon's operation is expansion and contraction. Extension and contraction of the extensor module causes movement of the

robotic endoscope in an organ lumen. As such, the extensor module is the main dynamic component of the robotic endoscope.

[0013] The toroidal balloon(s) described in at least these two prior disclosures involve a relatively small surface area. Thus high inflation pressures may be required to grip and fix the toroidal balloon to the organ wall. A high inflation pressure used to fix the toroidal balloon to an organ wall may distend the organ wall. Depending on the degree of organ wall distention, the patient may experience intense visceral pain. Therefore, robotic endoscopy according to these prior devices and methods may often require high level sedation or general anesthesia to permit a comfortable examination. In this regard, robotic endoscopy according to these prior disclosures offers no additional benefits to currently available endoscopic procedures.

[0014] Furthermore, the extensor module of these prior robotic endoscope disclosures is constantly changing the axial length of the robotic endoscope. As the robotic endoscope is constantly changing length, currently available endosurgical devices, such as biopsy forceps or polypectomy snares, may be very difficult if not prevented from conjunctive use.

[0015] The mechanical complexity of this prior approach and the need for computer control systems generally relate to relatively high production cost for the robotic endoscope. And, as in many fields, high production cost could substantially limit the availability of robotic endoscopy for widespread clinical use, such as in colorectal cancer screening. Moreover, sufficiently high production cost might also prohibit disposal of the robotic endoscope after each use. As disposal would not be generally practical according to these prior approaches, sterilization of the robotic endoscope becomes a likely necessity. Furthermore, sterilizing such a complex device with multiple mechanical and electronic components would be still a further challenge of substantial difficulty. The difficulty in sterilizing these robotic endoscopes could result in elevated potential for infectious disease transmission.

[0016] Other medical devices have also been previously disclosed that operate, at least in part, in much the same fashion as the robotic endoscopes just described. At least one additional medical device has been disclosed that uses an expandable front and rear cuff section with an expandable center section to produce movement, sharing certain similarities, including various of the incumbent shortcomings and concerns, with the robotic endoscope noted above. Another lumen-traversing device has also been disclosed that also shares certain similar limitations as the robotic endoscopes noted.

[0017] The disclosures of the following issued U.S. patents are herein incorporated in their entireties by reference thereto: U.S. Pat. No. 4,117,847 to Clayton; U.S. Pat. No. 4,207,872 to Meiri et al.; U.S. Pat. No. 4,321,915 to Leighton et al.; U.S. Pat. No. 4,368,739 to Nelson, Jr.; U.S. Pat. No. 4,561,427 to Takada; U.S. Pat. No. 4,615,331 to Kramann; U.S. Pat. No. 4,676,228 to Krasner et al.; U.S. Pat. No. 4,776,845 to Davis; U.S. Pat. No. 5,236,423 to Mix et al.; U.S. Pat. No. 5,259,364 to Bob et al.; U.S. Pat. No. 5,331,975 to Bonutti; U.S. Pat. No. 5,337,732 to Grundfest et al.; U.S. Pat. No. 5,398,670 to Ortiz et al.; U.S. Pat. No. 5,562,601 to Takada; U.S. Pat. No. 5,586,968 to Grundl et al.; U.S. Pat. No. 5,662,587 to Grundfest et al.; U.S. Pat. No. 6,071,234 to Takada; U.S. Pat. No. 6,086,603 to Termin et al.; and U.S. Pat. No. 6,224,544 to Takada. The following U.S. patent application Publications are also herein incorporated in their entireties by reference thereto: US 2002/0143237 to Oneda et al.; US 2003/0225433 to Nakao; US 2004/0106976 to Bailey et al.; and US 2004/0138689 to Bonutti.

[0018] Although numerous approaches to developing and implementing endoscopic devices and methods, particularly for colon screening, have been proposed, there is still a need for improved endoscope delivery, in particular relation to colonoscopy. There is, in particular, still a need for an improved system and method that actively propels endoscopes within tortuous body lumens, and in particular the colon and lower GI tract, with improved control and substantially reduced wall trauma and pain. There is also still a need for an improved system and method that modifies commercially available endoscopes for active propulsion along body lumens.

SUMMARY OF THE INVENTION

[0019] This present invention provides a system and method adapted to assist movement of devices through body spaces, and in particular body lumens. In exemplary embodiments, it provides a system and method to assist endoscope movement along body spaces, such as lumens. For example, in some embodiments, it provides a system and method to assist movement of devices, and in particular endoscopes, through the colon and lower gastrointestinal tract.

[0020] One advantage provided by the present invention is a safe and effective low cost method for colon cancer screening. To achieve this end, the invention provides an endoscopic propulsion unit that can attach to currently available colonoscopes. The endoscopic propulsion unit can advance a colonoscope in the colon lumen without stretching the colon wall, greatly reducing procedure-related pain. An additional advantage provided by the invention relates to safety. For example, safety of colonoscopy is improved through the use of the present invention by reducing or eliminating the risk of colon perforation. In contrast to other propulsion units, the endoscopic propulsion unit of the present invention advances a colonoscope by pulling the distal end of the instrument. This reduces the likelihood of perforations, and reduces the amount of pain experienced by the patient. Furthermore, the present invention allows relatively painless colonoscopy that can be performed safely in a physician's office. By removing the need for high level sedation, colonoscopy can now be moved to a lower cost center, such as a physician's office or outpatient clinic. This movement away from hospital settings could result in a 66% or greater savings in the total colonoscopy cost. This comfortable, effective, affordable and safe method for colon cancer screening provided by the present invention can be widely used to reduce colon cancer mortality. Other advantages will be realized through consideration of the following disclosure and practice of the invention.

[0021] In a first aspect, the invention provides a device, such as one for use with a medical instrument. The device is capable of self-propelled motion through cavities defined by one or more walls, such as pipes and tubes, and such as body spaces, cavities, lumens, etc. (used interchangeably herein to denote an area within an animal, including human, body that is defined and bordered by a wall). When attached to another instrument, such as a medical instrument, provides the instrument with the ability to move through the cavities, such as body spaces, substantially without propulsive force provided by a human, or with relatively little human force. In general,

the device comprises a drive unit or transmission for converting rotational energy from a drive shaft into longitudinal (i.e., forward or backward) movement of the device along a cavity. The drive unit comprises means for receiving one or more drive shafts, such as a drive shaft receptacle; means for converting rotational force provided by the drive shaft to longitudinal force, such as a radial gear, a series of interconnecting gears, or a worm gear; means for providing the longitudinal force of the drive unit to an exterior surface of the drive unit to cause the drive unit to move longitudinally, such as a rotatable rod or band comprising a suitable surface; and means for translating the longitudinal force of the drive unit to longitudinal force exerted against a cavity surface to cause the drive unit to move longitudinally along the cavity, such as a membranous element comprising a surface that releasably contacts the means for providing longitudinal force to a surface of the drive unit and releasably contacts the cavity surface. As can be seen, the device of the invention comprises two subparts that can be provided separately but combined to function together. That is, the drive unit may be provided with or without the means for translating longitudinal force from the drive unit to the cavity surface; where the two are provided separately, they can be combined to provide a unitary device.

[0022] In embodiments where the drive unit is adapted to connect to another instrument, such as a medical instrument, for example an endoscope, the drive unit comprises means for connecting to the instrument, such as a support tube traversing the length of the drive unit, typically located in the center of the drive unit when viewed on cross-section from one end or the other. Furthermore, the drive unit can comprise means for assisting in the attachment and release of the means for translating force from the drive unit to the body cavity surface, such as one or more support assemblies that can support a membranous element and guide it during attachment and/or release from the drive unit.

[0023] In a second aspect, the invention provides an article of manufacture for use with a drive unit of the invention, and preferably with another instrument, such as a medical instrument. The article provides the instrument with the ability to move through cavities, such as body spaces, and thus can be a means for translating longitudinal force from the drive unit to the cavity surface. In general, the article comprises a membrane that is generally toroidal in shape, having a single surface defining an inner surface, an outer surface, and front and back surfaces, all defined with respect to a mechanical device in conjunction with which the article is used. The article of manufacture of this aspect of the invention finds particular use in combination with the drive unit described herein. However, it may find uses in other devices, including medical devices in which self-movement of medical equipment (e.g., colonoscopes) through body cavities is desired. Indeed, when used in combination with the device of the first aspect of the invention, the article of manufacture of this aspect of the invention is particularly well suited for use in many fields, including, but not limited to engineering, fluid transfer technologies (e.g., inspection/repair of underground pipes, fuel lines, aircraft or other internal combustion engine-driven machinery parts), and medical (e.g., endoscopy). In general, in embodiments, the article of manufacture is fabricated in conjunction with a medical device, and thus its size, general shape, and composition can vary. However, in general, it is limited in size by its use in medical equipment and in its shape and fabrication by its function in the context of medical equipment for use inside a human or animal body cavity. Where used in non-medical settings, the size will be dependent on the size of the cavity, tube, line, pipe, etc. in which the device is to be used.

[0024] In a third aspect, the invention provides a medical device for performing diagnostics or surgery. The medical device according to this aspect of the invention comprises a combination of the device of the first aspect of the invention and the article of manufacture of the second aspect of the invention. The medical device is capable of traveling longitudinally along a body space defined by a wall using a propulsion mechanism that does not rely on human strength. It is thus a self-propelled medical device for traversing body cavities.

[0025] In another aspect, the invention provides an endoscope comprising an element that permits the endoscope to travel longitudinally using a propulsion mechanism, which is not force provided by human strength. The endoscope generally comprises a standard endoscope unit to which is attached, either fixedly or removable, a self-propelled device comprising a drive unit that is functionally linked to a membranous element. The endoscope is capable of self-propulsion through a body cavity through the action of the self-propelled device, which couples rotational movement of a drive shaft to backward and/or forward movement of the device by way of linkage of the drive shaft to the membranous element.

[0026] In a further aspect, the invention provides an endoscope comprising one or more drive shafts for connection to a drive unit that provides self-propelled movement through a body cavity. The drive shaft(s) are physically connected to the endoscope and a means for controlling movement of the endoscope when physically attached to a drive unit of the invention, such as an external drive unit and/or speed controller. In some embodiments, the endoscope further comprises one or more means for coupling the endoscope to a drive unit, such as one or more collars that releasably connect a drive unit to the endoscope.

[0027] In yet another aspect, the invention provides a method of diagnosis of a disease or disorder. In general, the method comprises inserting a device according to the present invention into a body cavity of a subject, and determining if one or more symptoms of a disease or disorder is evident in that body cavity. In certain embodiments, the method further comprises moving the device, via self-propulsion, longitudinally through the body cavity to observe some, most, or all or essentially all of the body cavity, or to otherwise determine if one or more symptoms of a disease or disorder exists. In exemplary embodiments, the method is a method of visualizing one or more abnormal growths in or on the surface of a body cavity.

[0028] In a further aspect, the invention provides a method of treatment of a disease or disorder. In general, the method comprises inserting a device according to the present invention into a body cavity of a subject, determining if one or more symptoms of a disease or disorder is evident in that body cavity, and, if one or more symptoms exist, treating the symptom(s). In certain embodiments, the method further comprises moving the device, via self-propulsion, longitudinally through the body cavity to observe some, most, or all or essentially all of the body cavity, or to otherwise determine if one or more symptoms of a disease or disorder exists. In exemplary embodiments, the method is a method of using an endoscope, such as a colonoscope, comprising the drive unit of the invention to identify one or more abnormal growths,

such as polyps in or on the surface of a body cavity, such as the colon, and removing the abnormal growths.

[0029] Other aspects provide use of the devices, instruments, and articles in diagnosis and treatment of one or more diseases and/or disorders. The uses may be clinical and therapeutic. The uses may be experimental. The uses may be prophylactic, such as when a non-cancerous growth is removed from a body cavity under situations where it is known that the presence of the non-cancerous growth is highly correlated with a later development of a cancerous growth, such as in the case of polyps that are present in a colon. In yet other aspects, the invention provides for use of the devices, instruments, and articles in industrial and non-medical fields. The uses may be diagnostic, for example to determine if a fuel line is blocked or fractured, or may be reconstructive, for example by clearing a blocked line or pipe to restore function to it.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention, and together with the written description, serve to explain certain principles of the invention.

[0031] FIG. **1** shows a side view of one embodiment of the drive unit of the present invention.

[0032] FIG. **2** shows a side view of one embodiment of the drive unit of the present invention.

[0033] FIG. **3** shows a perspective view of a schematic illustration of an endoscope delivery system, including an endoscope delivery assembly and an external drive unit and external controls, according to one embodiment of the invention.

[0034] FIG. **4** shows a perspective view of a schematic illustration of an operator assembly adapted for use in an endoscope delivery system of the invention.

[0035] FIG. **5** shows a perspective view of a schematic illustration of an external drive unit including drive shaft coupling, external drive motor, and external controls, that is adapted for use in an endoscope delivery system according to the invention.

[0036] FIG. **6** shows a schematic illustration of the location of attachment brackets and the orientation of a drive shaft adapted for use in an endoscope delivery system of the invention.

[0037] FIG. **7**A shows an end view of an annular invaginating balloon adapted for use in an endoscope delivery system of the invention.

[0038] FIG. **7**B shows a cut away view of an annular invaginating balloon similar to that shown in FIG. **7**A, and shows an attached inflation cannula, pressure sensor, and valve.

[0039] FIG. **7**C shows another cut away view of an annular invaginating balloon similar to that shown in FIGS. **7**A-B, and shows inner and outer balloon surfaces.

[0040] FIG. **8**A shows a schematic illustration of an end support assembly adapted for use in an endoscope delivery assembly of the invention, and shows the placement of certain component parts.

[0041] FIG. **8**B shows a schematic illustration of a longitudinal mid-cross-section of an endoscope delivery assembly of the invention, and shows a longitudinal orientation of the support tube, end assemblies, a lumen for the endoscope, and an annular invaginating balloon.

[0042] FIG. **8**C shows a schematic illustration of a drive unit or transmission adapted for use with an endoscope delivery assembly of the invention, wherein the annular invaginating balloon has been omitted for clarity.

[0043] FIG. **8**D shows a schematic illustration of a longitudinal mid-cross-section of an endoscope delivery assembly of the invention along the axis of a drive shaft incorporated into the delivery system.

[0044] FIG. **9**A shows a schematic illustration of certain cross-sectional detail of an end view of an additional drive assembly adapted for use in an endoscope delivery assembly of the invention.

[0045] FIG. **9**B shows a schematic illustration, in a longitudinal view along the axis of a drive shaft, of certain detail of additional drive assemblies including inner drive wheels according to further aspects that are adapted for use in an endoscope delivery assembly of the invention.

[0046] FIG. **9**C shows a schematic illustration of additional drive assemblies placed along a length of a support tube in a plane to include outer drive wheels, which configuration is further adapted for use in an endoscope delivery assembly of the invention.

[0047] FIG. **10** shows a schematic illustration of certain aspects of another endoscope delivery system of the invention that includes an internal drive motor and an air motor attached to the drive unit.

[0048] FIG. **11** shows a schematic side view of an endoscope.

[0049] FIG. **12** shows a schematic side view of the endoscope shown in FIG. **11** in a coupled arrangement with a drive unit according to the embodiment of the invention depicted in FIG. **1**.

[0050] FIG. **13** shows a side view of further detail of the drive unit shown in FIG. **2** in coupled arrangement with a drive gear assembly and an endoscope.

[0051] FIG. **14** shows a cross-section view of the drive unit and drive gear assembly depicted in FIG. **13**.

[0052] FIG. **15**A shows a side view of the drive unit and drive gear assembly shown in FIG. **13**, with the additional feature of a slotted cowling.

[0053] FIG. **15**B shows a schematic end view of the respectively coupled components shown in side view in FIG. **15**A.

[0054] FIG. **16**A shows a longitudinally cross-sectioned side view of an annular invaginated balloon as a further component adapted for coordinated use with a drive unit of the invention.

[0055] FIG. **16**B shows an end view of an annular invaginated balloon similar to that shown in FIG. **16**A.

[0056] FIG. **17** shows a schematic transversely cross-sectioned view through a coupled assembly that includes the various components shown in FIGS. **12-16**B.

[0057] FIGS. **18**A and **18**B show transversely cross-sectioned and longitudinal side views, respectively, of an assembly adapted for use in manufacturing the annular invaginated balloon shown in FIGS. **16**A-**17**.

[0058] FIG. **19** shows a schematic longitudinal side view of a further embodiment, and includes various features in shadow to highlight certain functional details within an overall assembly.

[0059] FIG. **20** shows a partially cross-sectioned side view of the embodiment shown in FIG. **19** in order to illustrate other functional details of the assembly.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS OF THE INVENTION

[0060] Reference will now be made in detail to various exemplary embodiments of the invention, examples of which are illustrated in the accompanying drawings. The following detailed description is provided to detail various elements, combinations, and embodiments of the invention, and is not intended as a limitation of the invention to the particular elements, combinations, and embodiments exemplified.

[0061] In a first aspect, the invention provides a device, such as a medical device or a device for use in non-medical situations. The device may be used for diagnostic purposes and therapeutic purposes in its medical embodiments, and for diagnostic and reparative purposes in its non-medical embodiments. In its various embodiments, it is appropriately sized to fit and function within the particular cavity it is to be used in. Thus, in embodiments, it is sized to fit in a human cavity, such as a colon, vein, or the like. It also may be used in conjunction with another instrument of device, such as a medical device or medical instrument for diagnostics, repair, and/or therapeutics. The device of the invention is capable of self-propelled motion through cavities, such as body cavities, using little or no propulsive force provided by a human. When attached to a separate instrument, such as a medical instrument, the device of the invention provides the instrument with the ability to move through cavities, such as pipes, tunnels, tubes, and body spaces, substantially without propulsive force provided by a human.

[0062] In general, the device of the invention comprises a drive unit or transmission for converting rotational energy from a drive shaft into longitudinal (i.e., forward or backward) movement of the device along a cavity, such as a body space. The drive unit comprises means for receiving one or more drive shafts; optional means for converting rotational force provided by the drive shaft to longitudinal force; means for providing the longitudinal force of the drive unit to an exterior surface of the drive unit to enable the drive unit to move longitudinally; and means for translating the longitudinal force of the drive unit to longitudinal force exerted against a cavity surface to cause the drive unit to move longitudinally along the cavity.

[0063] According to the present invention, the means for receiving one or more drive shafts can be any suitable structure that permits an externally provided force to be converted to an internal force of the drive unit. It is often a physical element capable of providing rotational force to deliver that force to the drive unit of the invention. However, it can be air or other fluid pressure. While not so limited in structure or function, typically, the physical element that provides rotational force (referred to generally herein as a drive shaft) will be a wire, flexible rod, cable, or the like, which is connected on one end to a source of rotational energy and connected on the other end to the drive unit. While not necessary, typically the drive shaft will be encased in a protective sheath or coating, which will not rotate as the drive shaft rotates, to protect it and biological tissue or the like that it might contact from damage. Examples of means for receiving one or more drive shafts or the like include, but are not limited to, recesses or holes in an end support or collar of the drive unit, provided either within the general structure of the support or collar or as an additional element attached to a support or collar. Other examples include, but are not limited to, flanges or brackets attached to the drive unit, preferably at or near one end, but not necessarily so limited in placement. Thus, in embodiments, a drive shaft enters the drive unit through a hole in a surface of the drive unit.

[0064] According to the invention, the means for converting and external force (e.g., rotational force provided by a drive shaft) to longitudinal force can be any suitable element that is capable of converting the forces from one to the other. Non-limiting examples are one or more gears, cogs, sprockets, etc., or combinations of two or more of these in functional and physical contact. Various configurations of gears and the like are known in the art, and any suitable configuration is envisioned by the present invention. In exemplary embodiments, the means comprises at least one gear. In other exemplary embodiments, the means comprises a radial gear. Where desired, the drive unit may also comprise means for connecting a means for providing rotational force (e.g., drive shaft) to means for converting rotational force to longitudinal force. Thus, in embodiments, a drive shaft enters the drive unit through a hole in a surface of the drive unit; the drive shaft is physically connected to a first gear; and the gear is physically connected to a second gear, which causes a worm gear that traverses the length or essentially the length of the drive unit to turn.

[0065] According to the invention, the means for providing the longitudinal force of the drive unit to an exterior surface of the drive unit to enable the drive unit to move longitudinally can be any suitable physical element or combinations of elements. Non-limiting examples are worm gears that rotate along the long axis of the drive unit and have a surface that comprises one or more projections or troughs that spiral about the outer surface from one end to the other. Other non-limiting examples are bands or sheets of flexible material (e.g., rubber or other elastic material, nylon, cloth) that can be driven by gears to rotate longitudinally along a surface of the drive unit, similar to a treadmill tread, an escalator tread, or a moving sidewalk). The bands or sheets may be designed to comprise an outer surface that interacts with another complementary surface. For example, a flexible plastic band may comprise an outer surface that comprises hooks for mating with loops that are present on an outer surface of a means for translating longitudinal force to a body cavity surface. Alternatively, it may comprise a wave pattern that is complementary to a wave pattern on a means for translating longitudinal force to a body cavity surface. Additionally, it may comprise any number of other surface geometries and patters that cause it to releasably attach to a complementary surface of a means for translating longitudinal force to a body cavity. Any number of materials and geometries may be envisioned by those of skill in the art, and all suitable materials, geometries, and combinations are encompassed by the present invention. Thus, in embodiments, a drive shaft enters the drive unit through a hole in a surface of the drive unit; the drive shaft is physically connected to a first gear; and the gear is physically connected to a second gear, which causes a worm gear that traverses the length or essentially the length of the drive unit to turn. Turning of the worm gear causes projections on the surface of the gear, which are disposed on the surface in a manner to create spirals running from one end to the other, to rotate, providing longitudinal force for movement of the drive unit along a body cavity.

[0066] The drive unit of the invention may, in embodiments, comprise means for translating the longitudinal force of the drive unit to longitudinal force exerted against a cavity surface, such as a pipe or body cavity, to cause the drive unit to move longitudinally along the cavity. While the means can take any physical form, typically, the means will comprise a flexible material that can releasably attach to both the drive unit and a surface of a cavity. In essence, the means functions as a tread connecting the drive unit to the cavity surface. Non-limiting examples of this means include flexible balloon-like structures that can be provided in a small, deflated state, then inflated to obtain a larger, functional state. The surface of the means is preferably designed to be complementary or otherwise capable of attachment to the means for providing the longitudinal force of the drive unit to an exterior surface of the drive unit to enable the drive unit to move longitudinally. Accordingly, the surface may comprise loops, for use in a hook-and-loop combination. It likewise may comprise projections or troughs to accommodate troughs or projections on a complementary surface on the surface of the drive unit. It further may comprise any geometry or surface feature or characteristic that permits successful releasable attachment to a surface of interest, and in particular to a surface on the drive unit and to a surface on a cavity, such as a biological cavity. Thus, in embodiments, a drive shaft enters the drive unit through a hole in a surface of the drive unit; the drive shaft is physically connected to a first gear; and the gear is physically connected to a second gear, which causes a worm gear that traverses the length or essentially the length of the drive unit to turn. Turning of the worm gear causes troughs on the surface of the gear, which are disposed on the surface in a manner to create spirals running from one end to the other, to rotate. Projections on the surface of a membranous element, which are complementary to the troughs on the surface of the worm gear, engage the worm gear along the length of the drive unit. As the worm gear turns, projections at the rear of the gear are moved forward. This movement is translated to movement of the entire membranous element, part of which is releasably attached to a cavity surface, providing longitudinal force for movement of the drive unit along the cavity.

[0067] In certain embodiments, the drive unit comprises means for separating the means for providing longitudinal force to the drive unit and the means for translating the longitudinal force of the drive unit to longitudinal force exerted against a surface, such as a body cavity surface. The separating means may comprise any physical element that provides the stated function. Thus, it may be a simple physical separator positioned to split the two means from each other at an end of the drive unit. The shape and material of fabrication are not critical in providing the separating means. Thus, it may be any number of sizes, shapes, and materials. In embodiments, it is a flat plate connected to an end support or collar of the drive unit, positioned such that it lies in or near the plane of contact between the surfaces of a hook-and-loop complementary pair, one surface on the drive unit and the other on a membranous element that contacts the drive unit and the surface of a cavity. Thus, the separating means may be fabricated from one or more metals, metal alloys, plastics, and the like, and combinations of two or more of these. Those of skill in the art are well aware of suitable materials, shapes, and sizes to provide the separator function.

[0068] Furthermore, the drive unit can comprise means for assisting in the attachment and release of the means for translating force from the drive unit to the cavity surface, such as one or more support assemblies that can support a membranous element and guide it during attachment and/or release from the drive unit. This means may comprise the means for separating, as described above.

[0069] It should be evident that, in embodiments, the drive unit may comprise means for providing a force to the drive unit. In embodiments, the force is a rotational force. In other embodiments, the force is a longitudinal force, such as that provided by a fluid pressure, such as air pressure. The means may be any suitable physical element, including, but not limited to, a drive shaft, rod, wire, cable, or the like. For ease of reference, this element is referred to herein as a drive shaft. In embodiments, the device comprises multiple (e.g., two, three, four, five, or more) drive shafts, and, preferably, an equivalent number of means for accommodating them and functionally coupling them to the drive unit. It is to be noted that the use of two or more provides stability and control of the unit as it traverses cavities, such as biological cavities and man-made cavities. It is further to be noted that the use of three or more provides three-dimensional steering to the device, allowing the practitioner to guide the device in multiple directions within a cavity. Clearly, the more drive shafts and/or independently controllable means for providing the longitudinal force of the drive unit to an exterior surface of the drive unit to enable the drive unit to move longitudinally will provide increasing control over the device.

[0070] As can be seen, the device of the invention comprises at least two sub-parts that can be provided separately but combined to function together. That is, the drive unit may be provided with or without the means for translating longitudinal force from the drive unit to the cavity surface. Where the two are provided separately, they can be combined to provide a unitary device.

[0071] In some embodiments, the device is designed to be an autonomous unit for, among other things, diagnosis of a disease or disorder in an animal or human body, and diagnosis and optional repair of a man-made conduit, such as a tube, pipe, line, etc. Various examples of such embodiments are described above. In other embodiments, the device is designed to be used in conjunction with another device, for example a medical device, such as an endoscope. In such embodiments, it may be used, among other things, for diagnosis and treatment. In embodiments where the drive unit is adapted to connect to an instrument, such as a medical instrument, such as an endoscope, the drive unit comprises means for connecting it to the instrument. In general, the means will be some sort of indentation, invagination, cavity, or hole in the drive unit. In exemplary embodiments, the means is a hole traversing the longitudinal length of the drive unit. In particular embodiments, this through hole is referred to as a support tube, which, like other embodiments, comprises an inner and outer surface defining a cavity or space into which or through which another device, or a part thereof, may be disposed, either removably or permanently. The element may be fabricated in any shape and from any material. Typically, the means will traverse the length of the drive unit, and will typically be located in the center of the drive unit when viewed on cross-section from one end or the other.

[0072] As mentioned above, the invention provides a device for use with a medical instrument. The device provides the ability to move through body spaces in a human or animal without significant or essentially any force provided directly by a human. The device is thus a self-propelled drive unit that can be used in conjunction with other medical devices or

instruments and with one or more articles of manufacture to provide diagnostic and/or therapeutic treatments to subjects.

[0073] In view of its usefulness in conjunction with other devices or instruments, such as medical devices or instruments, in embodiments the device of the invention comprises a drive unit or transmission for converting rotational energy or force from a drive shaft into forward and/or backward movement of the device along a cavity, such as a tube or body space. In these embodiments, the drive unit comprises a support tube traversing the length of the drive unit and typically, but not always, located in the center of the drive unit when viewed on cross-section from one end or the other. While the support tube may provide numerous functions, in many embodiments, it serves as a conduit for a tube, such as an endoscope tube. As with all other elements of the device and article of manufacture of the present invention, the support tube may be fabricated out of any suitable material, including, but not limited to, plastics, polymeric, elastomeric, or other synthetic rigid, semi-rigid, or flexible materials; metals or metal alloys, such as steel, stainless steel, and aluminum; and composite materials, such as fiberglass and carbon composites; and the like. The selection of any particular material may be made by the practitioner without undue experimentation based on numerous considerations that are typical in the field, such as, but not limited to, size, cost, need for flexibility, whether the unit will be disposable or reusable, weight, availability of materials, and the like. Furthermore, while exemplary embodiments depict the support tube as having a round cross-section, it is to understood that the cross-section can take any shape, including, but not limited to, round, oval, elliptical, square, rectangular, hexagonal, octagonal, trapezoidal, and polygonal. The choice of shape may be made in consideration of many factors, including shape of the instrument to which the device will be connected, ease of manufacture, etc.

[0074] In addition to the support tube, the drive unit may further comprise one or more support assemblies, typically with one located at one or each end of the drive unit and attached to the support tube or the drive unit body. As with all elements that are attached to other elements, unless specifically noted otherwise for a particular embodiment, the support assemblies are attached to the support tube or drive unit body in any suitable fashion. Thus, they can be permanently (i.e., fixedly) attached, for example by way of chemical or mechanical fusion or welding; adhering, such as through the use of glue or other adhesives; or by use of any other type of permanent fastening means. Alternatively, they can be removably attached, for example, by way of one or more removable mechanical fasteners, such as by pinning; bolting; screwing; stapling; riveting; friction fitting; or by use of any other type of removable or reversible fastening means.

[0075] In some embodiments, each support assembly comprises or defines a hole that is identical or substantially similar in cross-sectional shape to the shape of the hole defined by the support tube. In their basic form, each support assembly comprises an end support comprising or forming the hole. The end support can take any shape, but is typically fashioned to comprise at least one exterior surface that faces away from the device, a mating surface that physically contacts the support tube or drive unit body, and at least one interior surface, which faces toward at least one other element of the device and which may be designed to comprise, at least over a portion of its length, a shape that guides moving elements of the device or devices or instruments for which it is a part. For example, where the interior face contacts a membranous element that functions in movement of the device along a body cavity wall, the interior face may be shaped in such a way as to receive the membranous element as it detaches from the cavity wall, and guide the membranous element toward one or more drive wheels, which contact the membranous element and cause it to move.

[0076] As should be evident, in some embodiments, the end support is designed to function in conjunction with a membranous element that contacts both the device and the wall of the body cavity in which the device is inserted. In these embodiments, the end support can have a height that varies according to the height of the membranous element. For example, in some embodiments, it has a height that approximates one-half or less of the height of the membranous element, from the point of contact of the membranous element with the device at the point closest to the support tube to the point of contact of the membranous element with the body cavity wall. In other embodiments, the end support extends one-half or more of the height. In certain embodiments, the end support extends at least about two-thirds (67%), three-fourths (75%), or four-fifths (80%) of the height. In other embodiments, it extends at least about 85%, 90%, 95%, 97%, or 99% of the height. In some embodiments, the end support extends greater than 99% of the height, such that it might make contact with the body cavity wall at certain times or continually during use of the device. The height of extension can be selected based on any number of considerations, including, but not limited to, the propensity of the membrane to adhere to the cavity wall, the composition and surface structure (e.g., smoothness, roughness) of the interior surface of the end support, and the composition and surface structure of the membranous element. Of course, in some embodiments, one, some, or all of the end supports are omitted.

[0077] Where the end support is used as a guide for the membranous element onto one or more drive mechanisms of the device (for example, an outer drive wheel), the interior surface may be generally curved from top to bottom, providing a curving ramp-like structure that guides the membranous element onto the drive mechanism(s). While an end support that does not guide the membranous element onto the drive mechanisms is envisioned, for obvious reasons, it is preferred that the end supports be shaped to provide at least some guidance for the membranous element.

[0078] It is to be noted that each end support may be designed independently of the other. Thus, in any one drive unit, multiple different end support, and thus multiple different support assemblies, may be present.

[0079] The support assembly may further comprise one or more outer drive wheels, which may be directly attached to the end support, the support tube, or both. Alternatively, each drive wheel may be independently attached via a mating groove to the support tube. In embodiments, the drive unit comprises two outer drive wheels, one located on each end of the unit, and attached as part of a support assembly, respectively. While not so limited, these outer drive wheels may function in conjunction with the end support to capture and move an attached membranous element, to assist in movement of the device along a cavity.

[0080] In some embodiments, one or more outer drive wheels are connected, physically and functionally, to a drive shaft via an intermediate drive wheel. The intermediate drive wheel may be physically connected to the support tube by way of a mating groove.

[0081] Within the drive unit, there also may be disposed one or more inner drive wheels. The inner drive wheel(s) can be provided to couple the rotational force of a drive shaft to the longitudinal force created by the intermediate drive wheel (s) and outer drive wheel(s). Thus, the inner drive wheels are physically connected to the intermediate drive wheels and to a drive shaft.

[0082] In view of the function of the device, in embodiments the drive unit comprises a drive shaft, which connects the drive unit to a power unit, which is typically located outside of the cavity in which the device is inserted and used. Although numerous configurations are possible, in a typical configuration, the drive shaft is connected to at least one inner drive wheel, serving as the axle for the wheel. As the drive shaft is connected to the inner drive wheel, and as this wheel is typically located within the interior spaces of the drive unit, in a typical configuration, the drive unit comprises a conduit, tube, through-hole, etc. to accommodate the drive shaft, which may or may not be encased in a protective sheath to isolate the rotational movement of the shaft from other elements of the device and from other materials, such as biological tissues. The through-hole may be disposed within the drive unit in any position, as long as the drive shaft is able to connect from the power unit to at least one inner drive wheel.

[0083] Within the drive unit, multiple outer drive wheels may be provided. Each may be provided associated with intermediate and inner drive wheels. Each may be disposed along the length of the support tube at any position. Exemplary embodiments depicted in the drawings show the presence of two outer drive wheels; however, it is to be understood that three or more wheels may be provided, for example to provide more support for a membranous element, to provide higher surface area for attachment of the device to a membranous element, or any other reason. Where multiple drive wheels are used, the height of each wheel, with respect to the support tube, may be selected independently to achieve any particular goal. For example, where a relatively tall toroidal shaped membrane is used, two end outer drive wheels may be provided, one at each end, and one central outer drive wheel may be provided. The two end outer drive wheels may be relatively tall with respect to the central outer drive wheel to ensure suitable contact with the membrane element as it traverses down one side of the drive unit to the bottom (at or near the central outer drive wheel) and then back up the other side.

[0084] The invention thus provides a device having means for driving, in a self-propelled manner, itself and other medical equipment and devices attached to it, through a cavity, such as a body cavity. The device comprises means for supporting one or more drive elements, which may also be a means for providing a through-passage for one or more elements of a medical instrument, such as an endoscope. Such a means may also simply be a structural framework or body for the device, fabricated in any suitable shape and of any suitable material. The device of the invention further has means for supporting an element that contacts the device and the wall of a cavity, which means may also provide guidance to the element as it enters and/or leaves the device. One or more means for driving the element across the length of the device are also provided.

[0085] As used herein, a subject or patient is a human or animal for whom medical treatment is intended. The subject can be any age or sex, and can show no, one, or multiple clinical signs of a disease or disorder. If an animal, the subject can be any animal, but will typically be one of commercial, medical, or scientific value, such as a farm animal, a companion animal, or a research animal. Non-limiting examples of animals include: dogs, cats, horses, cattle, sheep, pigs, rodents (e.g., rats, mice), and wild animals in captivity (e.g., elephants, tigers or other wild cats, monkeys, apes). Thus, the invention has applicability to both the human and veterinarian medical fields.

[0086] In a second aspect, the invention provides an article of manufacture for use with an instrument, such as a medical instrument. The article provides the instrument with the ability to move through cavities, such as body spaces, tubes, lines, pipes, and the like. In general, the article comprises a membrane (also referred to herein as a membranous element) that is toroidal in shape, having a single unitary surface defining an inner surface, an outer surface, and front and back surfaces, all defined with respect to a mechanical device in conjunction with which the article is used. The article may be air and/or water tight, and may be inflatable and deflatable. In this way, the article may be positioned within a cavity, inflated to create a contact with the cavity wall for use, then deflated for ease of removal upon completion of the desired task.

[0087] As used herein, the term "membrane" means any material that can be formed into a toroidal shape of a suitable size, strength, and flexibility to be used in conjunction with a drive unit according to the invention. It thus may be made from any material that can be provided in a thin sheet suitable for flexing about three dimensions without crimping, folding, cracking, or breaking. Suitable materials for such applications are known in the art and include, without limitation, materials such as or comprising latex or other natural or synthetic rubbers, nylon, polymeric materials, plastics, and fabrics (with man-made and/or natural fibers). As a general matter, preferred membranes have relatively low coefficients of friction with the interior surface of the end supports of the drive unit of the invention, but relatively high coefficients of friction with materials from which cavity walls are fabricated, such as, in the case of biological materials, walls of body cavities. In this way, the membrane slides relatively easily over the end supports of the device while adhering relatively strongly to the cavity wall, thus promoting movement of the device across and along the cavity. It is also preferred that the membrane have a relatively high coefficient of friction with regard to the drive wheels, again promoting movement of the device. As with all other components of the invention, as broadly described herein, preferably, the membrane is comprised of substances that can be sterilized by one or more means, such as by heat (e.g., autoclaving) or irradiation. In addition, as with all other components of the invention, in some embodiments, the membrane is sterile or has been sterilized.

[0088] The membrane may be fabricated in any suitable shape. It thus may have a long, low profile, when viewed in cross-section along its long axis (see, for example, FIGS. **7**, **16**, and **19**). Alternatively, it may have a short, high profile, when viewed in cross-section along its long axis (for example, in a donut shape). The shape may be selected without undue experimentation based on any number of parameters, including, but not limited to, relative friction coefficients for body cavity walls and end support interior surfaces, total surface area desired to be in contact with cavity walls, etc. In addition to the overall three-dimensional shape of the membrane, the membrane may be fabricated with any number of surfaces. For example, the membrane may be fabri-

cated with a smooth surface, a rough surface, or a surface comprising extensions, such as grooves, waves, bubbles, pins, spikes, rods, hooks, and loops, all of which can be aligned parallel to the line of motion, perpendicular to the line of motion, or randomly. Likewise, the individual characteristics (e.g., rough, wave, spike) can be used as the sole surface characteristic or in any combination, in any pattern (including random). The surface may be fabricated to advantageously interact or interconnect with the surface of one or more drive wheels of a drive unit of the present invention. Any modification to a smooth surface is contemplated by the present invention.

[0089] The membrane of this aspect of the invention finds particular use in medical devices, such as those used for movement of medical equipment (e.g., colonoscopes) through body cavities. When used in combination with the drive unit discussed above, the membrane is particularly well suited for use in endoscopy. It can be adapted to expand to fit any cavity of interest, providing good traction for the device without causing excessive extension of the body cavity, and producing associated pain.

[0090] In a third aspect, the invention provides a medical device for performing diagnostics or surgery. The medical device according to this aspect of the invention comprises the drive unit of the invention and, optionally, a combination of the drive unit and the membrane discussed above. According to the invention, the medical device is capable of traveling along a body space defined by a wall using a propulsion mechanism that does not rely directly on human strength. It is thus a self-propelled medical device for traversing body cavities. The medical device can advantageously be used, as compared to currently available technologies, as a self-propelled unit for diagnosis and/or therapy. In embodiments, it is used without connection to another device, such as an endoscope, and is used for diagnostic purposes only. In other embodiments, it is used in conjunction with a separate medical device, such as an endoscope, to provide diagnosis and/or treatment. The medical device is superior to similar devices in the field because it uses a gentle, self-propulsion mechanism to move the device (and any device connected to it) through a body cavity. When the device is connected to the distal end (i.e., tip) of a medical instrument, such as an endoscope, the movement caused by the device can be envisioned as pulling the device and instrument through the body cavity. This pulling action reduces the amount of pressure needed to move the device through the cavity, and reduces the likelihood of pain to the subject and perforation of the cavity wall due to excessive pressure being exerted to move a medical instrument through a body cavity. Preferably, the medical device is sterile, has been sterilized, or is comprised of materials that can withstand one or more means of sterilization.

[0091] In other aspects, the invention provides a device for performing diagnostics or repair of man-made structures, such as pipes, lines, tubes, conduits, and the like. The device according to this aspect of the invention comprises the drive unit of the invention and, optionally, a combination of the drive unit and the membrane discussed above. According to the invention, the device is capable of traveling along a man-made space defined by at least one wall using a propulsion mechanism that does not rely directly on human strength. It is thus a self-propelled device for traversing man-made cavities. The device can advantageously be used, as compared to currently available technologies, as a self-propelled unit for diagnosis and/or repair of man-made cavities. For example, it may be used to diagnose and optionally repair fuel lines (including underground piping and pipelines) or other fluid-transporting lines. In embodiments, it is used without connection to another device, such as a boring or drilling device, and is used for diagnostic purposes only. In other embodiments, it is used in conjunction with a separate device, such as a drilling or patching device, to provide diagnosis and/or repair of a man-made cavity. The device utilizes a self-propulsion mechanism to move the device (and any device connected to it) through the cavity, and thus requires little or no external propulsive force to move it through the cavity. As with the medical embodiments of the invention, when the device is connected to the distal end (i.e., tip) of another instrument, the movement caused by the device can be envisioned as pulling the device and instrument through the cavity, a mode of movement that is highly efficient. This pulling action reduces the amount of pressure needed to move the device through the cavity, and reduces the likelihood of damage to the cavity or the device due to excessive pressure being exerted to move the instrument through the cavity.

[0092] In another aspect, the invention provides an endoscope comprising an element that permits the endoscope to travel longitudinally through a body cavity using a propulsion mechanism other than force provided by human strength. The endoscope generally comprises a standard endoscope unit to which is attached, either fixedly or removable, a self-propelled device comprising a drive unit that is functionally linked to a membranous element. The endoscope is capable of self-propulsion through a body cavity through the action of the self-propelled device, which, in exemplary embodiments couples rotational movement of a drive shaft to backward and/or forward movement of the device by way of linkage of the drive shaft to the membranous element. In embodiments, the endoscope comprises a camera or other means for visualizing the interior of the body cavity in which the endoscope is placed. In embodiments, the endoscope comprises surgical instruments or other means for performing surgery in the body cavity. In embodiments, the invention provides a colonoscope. In preferred aspects and embodiments comprising an endoscope, some or all of the device components or the endoscope in total is sterile, has been sterilized, or is capable of withstanding one or more sterilization techniques without losing function.

[0093] In a further aspect, the invention provides an endoscope comprising one or more drive shafts for connection to a drive unit that provides self-propelled movement through a body cavity. The drive shaft(s) are physically connected to the endoscope and a means for controlling movement of the endoscope when physically attached to a drive unit of the invention, such as an external drive unit and/or speed controller. In some embodiments, the endoscope further comprises one or more means for coupling the endoscope to a drive unit, such as one or more collars that releasably connect a drive unit to the endoscope.

[0094] In yet another aspect, the invention provides a method of diagnosis of a disease or disorder. In embodiments, it is also a method of diagnosing the likelihood of a subject becoming a sufferer of a disease or disorder. In general, the method comprises inserting a device or medical instrument according to the present invention into a body cavity of a subject, and determining if the subject is suffering from one or more diseases or disorders, or is at high risk of suffering from one or more diseases or disorders. The step of determining can be accomplished by identifying one or more symptoms of

a disease or disorder in the body cavity. This can be done by visual observation of one or more symptoms, such as by visualization of one or more polyps on the colon wall of a patient, or by any other means that can provide the practitioner with a high level of confidence that a symptom exists.

[0095] In certain embodiments, the method further comprises moving the device, via self-propulsion or substantially by self-propulsion, through the body cavity to observe some, most, or all or essentially all of the body cavity, or to otherwise determine if one or more symptoms of a disease or disorder exists. In some embodiments, the device is attached to a medical instrument, such as an endoscope. In exemplary embodiments, the method is a method of using an endoscope, such as a colonoscope, to identify one or more abnormal growths in or on the surface of a body cavity. It is to be noted that the symptoms may be symptoms associated with a pre-disease state, which has a high correlation to a disease state. Accordingly, the invention may be a method of diagnosing a pre-condition for a disease, where the disease has not yet developed or is in a pre-clinical stage.

[0096] In a further aspect, the invention provides a method of treatment of a disease or disorder, or the treatment of a pre-clinical or pre-disease state of a patient. In general, the method comprises inserting a device or medical instrument according to the present invention into a body cavity of a subject, determining if one or more symptoms of a disease or disorder, or symptoms of a pre-clinical or pre-disease state, is evident in that body cavity, and, if one or more symptoms exist, treating the symptom(s) and/or the underlying cause(s) of the disease or disorder. In embodiments, the method further comprises treating the patient with one or more drugs or surgeries to reduce or eliminate the symptom(s) and/or underlying cause(s). Treatments may be repeated periodically as deemed advantageous by the practitioner or a medical consultant. Various treatment regimens for various diseases and disorders are known in the art and can be devised by medical practitioners without undue or excessive experimentation.

[0097] In certain embodiments, the method further comprises moving the device, via self-propulsion, through the body cavity to observe some, most, or all or essentially all of the body cavity, or to otherwise determine if one or more symptoms of a disease or disorder exists. In embodiments, the device is attached to a medical instrument, such as an endoscope. In exemplary embodiments, the method is a method of using an endoscope, such as a colonoscope, to identify one or more abnormal growths, such as polyps in or on the surface of a body cavity, such as the colon, and removing the abnormal growths.

[0098] Thus, one aspect of the present invention is a device and related method that is adapted to assist movement of a commercially available endoscope in an organ lumen. According to one mode, the device uses an external variable speed motor to provide torque. In one embodiment of this mode, an external control unit regulates rotational direction and speed. In a further embodiment, torque from the motor is transmitted to a flexible drive shaft that, according to one variation, runs through a slip coupling. In another further embodiment, the drive shaft is contained within a sheath that runs substantially along the length of the endoscope. In another further embodiment, the sheath is attached to the endoscope by brackets. In another further embodiment, the drive shaft is attached to an internal drive gear contained within a transmission.

[0099] In still a further transmission embodiment, the transmission comprises an internal drive gear, an intermediate gear, and an external drive gear, which are adapted to cooperate together, e.g., with various supports and couplings, necessary to allow for interaction and rotation of the individual gears. The internal drive gear turns an intermediate gear. According to one further feature, the intermediate gear may be held in position by bearing, which may include in one further embodiment a flexible tube. According to one variation of this feature, the flexible tube is coupled to the distal end of an endoscope, such as in one highly beneficial variation by attachment means that may include for example attachment brackets. Rotation of the intermediate drive gear causes rotation of external drive gears. The external drive gears are radially arrayed on the outside of the flexible tube. The external drive gears are in contact with the inner surface of an annular invaginating balloon. The annular invaginating balloon is donut shaped in cross-section with a length that may be adapted and varied in dimension to suit one or more particular applications. Interaction of the external drive gears with the annular invaginating balloon actuates rotation of the annular invaginating balloon along its long axis. The annular invaginating balloon is inflated after insertion into an organ lumen. This is accomplished in one particular variation by use of a cannula and a syringe. A sensor and/or indicator is provided that allows control of inflation to a desired parameter, such as for example pressure or volume. In one particular beneficial embodiment, a pressure sensor, which according to one variation may include a pressure-sensing bulb on the cannula, is adapted to allow control to an appropriate inflation pressure. After the annular invaginating balloon has been inflated to the appropriate pressure and/or other parameter such as volume, the cannula and pressure-sensing bulb (if provided) is removed. A valve, such as a self-sealing valve on the annular invaginating balloon, maintains pressure within the balloon. The annular invaginating balloon is in contact with the lumenal side of an organ wall. Interaction between the annular invaginating balloon and the lumenal wall produces dynamic rolling traction (like a tire or wheel). This rolling traction in turn moves the endoscope within the organ lumen.

[0100] Another aspect of the invention provides a delivery assembly that works in conjunction with endoscopes, such as for example currently available endoscopes. Another aspect of the current invention provides a delivery assembly that attaches easily to currently available endoscopes without generally requiring modification of such endoscopes. Another aspect of the current invention provides an endoscope delivery assembly that is easily used and requires minimal training of the endoscopist.

[0101] Another aspect of the current invention provides an endoscope delivery assembly with an annular invaginating balloon that is adapted to produce rolling traction along a luminal wall to move an endoscope in the lumen. According to one mode of this aspect, the invaginating balloon is adapted to be inflated with fluid to sufficiently low pressure such that trauma to the organ wall is substantially limited. According to another mode, the annular invaginating balloon has a sufficiently large surface area adapted to contact the luminal wall, thereby substantially limiting the required inflation pressure to provide traction along the wall and limiting the propensity for pressure-related trauma from the assembly. According to

another mode, the annular invaginating balloon is provided as a modification to the endoscope, such as to currently available devices.

[0102] Another aspect of the invention provides an endoscope delivery assembly that is adapted to move an endoscope along a lumen by pulling the distal end of the endoscope. According to one mode of this aspect, by pulling the distal end of the endoscope, the endoscopic delivery assembly substantially limits the stretching of the lumenal wall during delivery. According to another aspect, an endoscope delivery assembly and method is adapted to deliver an endoscope along a luminal wall with substantially limited risk of organ wall perforation. According to another aspect, an endoscope delivery assembly and method is provided that is adapted to substantially decrease procedure related pain. According to one mode of this aspect, the substantially decreased procedure-related pain is achieved by substantially reducing the extent to which the lumen wall is stretched during endoscope delivery.

[0103] Another aspect of the invention provides a colonoscopy system and method that incorporates a colonoscope delivery assembly. According to one mode of this aspect, the colonoscope delivery assembly is adapted to allow enhanced patient comfort during colonoscopy with substantially limited sedation.

[0104] Another aspect of the invention provides a colonoscopy system and method that is adapted to allow colonoscopy to be performed without substantial sedation. According to one mode of this aspect, such system and method is adapted to be used at lower cost facilities, such as for example a physician's office, than is generally accepted according to other conventional colonoscopy systems and methods.

[0105] Another aspect of the invention provides an endoscope delivery assembly and method that is adapted to move an endoscope along a body lumen without substantially changing the length of the endoscope. According to one mode of this aspect, the endoscope delivery system and method is adapted to move a commercially available endoscope in this manner. According to another mode of this aspect, as the length of the endoscope remains substantially fixed, one or more commercially available endosurgical devices, such as in certain beneficial embodiments polypectomy snares and biopsy forceps, are provided and/or used in conjunction with the system and method.

[0106] Another aspect of the invention provides an endoscope delivery assembly that is adapted to provide for the further combination and use of endosurgical devices and methods, including for example both diagnostic and therapeutic devices and related procedures. Another aspect of the invention provides an endoscope delivery assembly that is adapted to decrease procedure-related risk by decreasing the incidence of perforation during endoscopy. According to one mode, perforation is substantially reduced according to the assembly by pulling the endoscope at its distal end and by using an annular invaginating balloon as a tracking mechanism.

[0107] Another aspect of the invention provides an endoscope delivery assembly with an annular invaginating balloon that, in a radially collapsed configuration, has a first diameter that is sufficiently small to provide for introduction into a body lumen. After insertion, the annular invaginating balloon is inflated to a radially expanded configuration that is adapted to contact the luminal wall.

[0108] According to another aspect of the invention, an endoscope delivery assembly and method provides an invaginating balloon that has a removable inflation device. According to one mode, the removable inflation device comprises a cannula. According to another mode of this aspect, the balloon surface is sufficiently smooth so as to substantially limit risk of trauma to the lumen wall.

[0109] According to another aspect of the invention, an endoscope delivery assembly and method provides an annular invaginating balloon that circumscribes a longitudinal axis and has a cross-sectional profile substantially in the shape of a toroid. According to one highly beneficial mode of this aspect, the toroidal shape of the annular invaginating balloon has a length along the longitudinal axis that is larger than the cross-sectional diameter through a portion of the wall of the balloon in a radial axis transverse to the longitudinal axis, e.g., a length dimension that is longer than a simple toroid shaped balloon, thus forming an elongate tube with a lumen extending therethrough.

[0110] According to another aspect of the invention, an endoscope delivery assembly and method provides an annular invaginating balloon that rotates about its long axis while making contact with the respective lumen wall. In one highly beneficial mode of this aspect, the rotating annular invaginating balloon is adapted to provide for rolling traction of the assembly, and related assemblies coupled therewith, along the lumen wall. According to another mode, the annular invaginating balloon functions like a wheel in contact with the lumen wall. The annular invaginating balloon is a dynamic part of the endoscope delivery assembly and provides rolling traction along the wall, resulting in movement of the endoscope delivery assembly and respectively coupled components and assemblies, e.g., such as an endoscope shaft or endoscope delivery cannula coupled thereto, along the lumen.

[0111] Another aspect of the invention provides an endoscope delivery assembly that is under substantial direct control of the endoscopist. Additional aspects of the invention include various respective methods of operating the assemblies noted herein, which methods generally augment or replace various aspects of the endoscopic procedures and techniques previously available.

[0112] Another aspect of the invention provides an endoscope delivery assembly that incorporates a relatively simple machine with relatively few working parts. Another aspect of the invention provides an endoscope delivery assembly that is sufficiently simple so as to allow for a relatively low cost of production as compared to other endoscope delivery assemblies intended to augment traversal of various tortuous lumens, such as for example the colon. Another aspect of the invention provides an endoscope delivery assembly that can be manufactured at sufficiently low cost so as to allow for a disposable product. According to one mode of this aspect, providing the endoscope delivery assembly as a disposable product substantially reduces the risk of infectious disease transmission, such as for example from one patient to another as may occur with higher cost equipment that is thus re-used over multiple patients.

[0113] Another aspect of the invention provides an endoscope delivery assembly that includes an integral sheath and at least one attachment bracket insure ease of attachment to an endoscope and safety of operation. Another aspect of the invention is an endoscope propulsion device assembly with a toroidal wall, a drive assembly, and an endoscope coupler assembly as follows. The toroidal wall has an exterior surface

and an interior surface that circumscribes an interior passageway extending along a longitudinal axis, and with a length between a proximal end and a distal end relative to the longitudinal axis. The toroidal wall is adjustable from a radially collapsed condition to a radially extended condition, respectively, transverse to the longitudinal axis. The drive assembly is adapted to couple to the toroidal wall and to impart toroidal rotation onto the toroidal wall in the radially extended condition such that the interior surface translates in a first longitudinal direction and the exterior surface translates in a second opposite longitudinal direction along the longitudinal axis. The endoscope coupler assembly is adapted to couple the toroidal wall to an endoscope extending along the interior passageway such that the toroidal wall and endoscope are adapted to be propelled together in the first direction along a body lumen during toroidal rotation of the toroidal wall when the exterior surface is engaged to a wall of the body lumen with translating force against the wall. According to one mode of this aspect, the toroidal wall is provided in the form of a toroidal balloon. In another embodiment, this toroidal balloon has an annular invaginated balloon wall and is inflatable from the radially collapsed condition to the radially extended condition with a pressurized fluid. In another mode, the toroidal balloon includes a protrusion extending from the balloon wall along the interior surface and into the interior passageway. The drive assembly is provided with an elongate screw extending along the longitudinal axis within the interior passageway and with a helical groove extending helically around the longitudinal axis. This helical groove is adapted to receive the protrusion within the interior passageway such that rotation of the elongate screw advances the protrusion longitudinally in the first direction along the longitudinal axis. The helical groove is thus adapted to move the interior surface in the first direction along the longitudinal axis to impart toroidal rotation to the toroidal balloon along the longitudinal axis.

[0114] According to one further embodiment of this mode, the protrusion extends from the interior surface with a relatively narrow neck and terminates interiorly within the interior passageway with an enlarged head relative to the neck. According to another embodiment, a plurality of such protrusions are provided in a patterned group that are each spaced along a longitudinal pattern that circumscribes one lobe of the toroidal balloon along the longitudinal axis. Each protrusion of the group along the interior surface is engaged to a respective turn of the helical groove and translates longitudinally in the first direction along the rotating screw. Each protrusion of the group along the inner surface is released from the helical groove when it is translated in the first direction to a first end of the screw; whereas each protrusion of the group along the exterior surface translates in the second opposite direction and is adapted to rotate inwardly to the inner surface and to be engaged within the helical groove of the screw at a second end thereof. Accordingly, continuous rotation of the screw continuously releases and engages respective protrusions of the patterned group at the first and second ends of the screw, respectively, to continuously drive toroidal rotation of the toroidal balloon. According to one further feature that may also be provided according to this embodiment, a plurality of such groups of protrusions is provided in respectively patterned arrays. Each of the groups of protrusions is located at a unique respective position around a circumference of the toroidal balloon transverse to the longitudinal axis.

[0115] According to another further feature, four of such groups of protrusions are provided. In still a further feature, these may be spaced at 90 degree intervals around the circumference transverse to the longitudinal axis. In still another feature, a cowling with a substantially tubular body is located between the screw and the interior surface of the toroidal balloon and includes a longitudinal groove extending along the longitudinal axis between first and second ends of the screw. The protrusions are adapted to engage the helical groove of the screw through the longitudinal groove of the cowling. In another feature related to multiple groups of protrusions, a cowling with a substantially tubular body is located between the screw and the interior surface of the toroidal balloon and with a plurality of longitudinal grooves extending along the longitudinal axis between first and second ends of the screw. The protrusions of each group are adapted to engage the helical groove of the screw through a respective one of the plurality of longitudinal grooves of the cowling.

[0116] According to another embodiment related to inflatable toroidal balloon modes of this aspect, an expansion actuator is also provided that is adapted to couple to the toroidal wall and expand the toroidal wall from the radially collapsed condition to the radially extended condition. According to another mode, a motor is also provided that is adapted to couple to the drive assembly and to actuate the drive assembly coupled to the toroidal wall to impart toroidal rotation to the toroidal wall. According to yet another mode, an endoscope is also provided in the system. According to one embodiment of this mode, the endoscope and the toroidal wall are permanently secured in fixed position relative to each other via the endoscope coupler assembly. In another embodiment, the endoscope and toroidal wall are adapted to be releasably coupled to each other via the endoscope coupler assembly. According to another mode, the endoscope coupler assembly includes a base with a tubular member with an inner lumen extending along a length between first and second ends. The coupler assembly also includes first and second radial protrusion stops extending radially outwardly from the tubular member transverse to the longitudinal axis at each of the first and second ends, respectively. The base is adapted to be coupled to an endoscope extending along the inner lumen. The toroidal wall is adapted to be positioned at a location along the base with the tubular member located within the interior passageway and such that in the radially extended condition the toroidal wall has an inner diameter at the interior surface that is less than an outer diameter of the base at the first and second radial protrusion stops. The toroidal wall is adapted to undergo toroidal rotation at the position without substantially moving longitudinally along the base due to mechanical interference between the toroidal wall and the first and second radial protrusion stops.

[0117] According to another embodiment of the inflatable toroidal balloon mode, the drive assembly includes a belt that circumscribes one lobe of the toroidal balloon wall along the longitudinal axis and at a position around the circumference transverse to the longitudinal axis. The toroidal balloon wall includes a circumferential groove along the longitudinal axis and corresponding with the position. The belt is adapted to engage the circumferential groove along the exterior surface of the toroidal balloon wall at the position. The belt is also adapted to engage the drive assembly located within the interior passageway. The drive assembly is adapted to rotate the belt around the toroidal balloon and so as to impart transla-

tional motion to the exterior surface in the second direction to thereby provide toroidal rotation of the balloon.

[0118] In one further feature of this embodiment, the groove has a shaped interior surface with a plurality of spaced pairs of opposite protrusions into the groove to provide an alternating pattern of expanded and narrowed waste regions along the groove. The belt has a shaped outer surface with a plurality of enlargements separated by relatively narrowed waste regions. The belt and groove are adapted to couple along the exterior surface with the narrowed waste regions of the belt fitting into the narrowed waste regions of the groove. The belt is adapted to be released from the groove at first and second ends of the exterior surface along the balloon. According to another mode, the toroidal wall comprises an elongated toroidal wall such that the length is substantially greater than a profile diameter between the interior and exterior surfaces of the toroidal wall in the radially extended condition.

[0119] Another aspect of the invention is a method for propelling an endoscope. This method includes coupling a toroidal wall to an endoscope at a location along a distal end portion of the endoscope, coupling a drive assembly to the toroidal wall at the location, and adjusting the toroidal wall from a radially collapsed condition to a radially extended condition, respectively, transverse to the longitudinal axis at the location. The drive assembly is actuated to impart toroidal rotation onto the toroidal wall in the radially extended condition at the location such that the interior surface translates in a first longitudinal direction and the exterior surface translates in a second opposite longitudinal direction along the longitudinal axis. In addition, the toroidal wall is substantially maintained at the location along the endoscope while imparting the toroidal rotation to the toroidal wall. According to one mode of this aspect, the endoscope and respectively coupled toroidal wall and drive assembly are inserted into a body lumen of a patient. A lumen wall of the body lumen is engaged with the exterior surface of the toroidal wall in the radially extended condition. The toroidal wall and endoscope are propelled together in the first longitudinal direction along the body lumen by imparting the toroidal rotation to the toroidal wall and thereby translating the exterior surface with force in the second opposite direction against the respectively engaged body lumen wall.

[0120] Another aspect of the invention is a method for performing endoscopy within a body lumen in a patient as follows. An endoscope assembly, preferably sterile or having been sterilized, is inserted within the body lumen. A substantial circumference of a body lumen wall of the body lumen surrounding the endoscope is engaged with a propulsion assembly coupled to the endoscope. An axial force against the body lumen wall and around the substantial circumference is provided with the propulsion assembly. Accordingly, the endoscope is propelled along the body lumen at least in part using the axial force against the body lumen wall from the propulsion assembly.

[0121] According to further aspects of the invention, the various other aspects herein described for an endoscope delivery assembly, its construction, and the various related aspects and modes of method of operation, are suitably modified and applied to non-medical uses. In certain further modes of this aspect, such assemblies and methods are incorporated into devices and methods for visual inspection and manipulation of other tubular structures. It is also to be appreciated that each of the foregoing aspects, modes, embodiments, variations, features, or variants on such features is to be considered independently useful without necessarily requiring combination with the others unless expressly stated so. Notwithstanding the foregoing, it is also further appreciated that the various combinations and sub-combinations between them, as would be apparent to one of skill in the art, are further considered independently useful and within the intended scope hereof.

[0122] Turning now to the figures, which depict certain exemplary embodiments of the invention, for illustrative purposes, embodiments of the present invention are depicted in the apparatus generally shown in FIG. **1** through FIG. **9**. It will be appreciated that the apparatus may vary as to configuration and as to details of the parts, and that the method may vary as to the specific steps and sequence, without departing from the basic concepts as disclosed herein.

[0123] As used herein, an "annular invaginating balloon" is generally a balloon which has a cross-sectional profile that is donut shaped like a toroid. However, in contrast to a toroid, this variation has a length that is greater than its diameter. The balloon generally functions as an active, dynamic component of an endoscope delivery assembly, and in many instances an endoscopic propulsion device, and provides rolling traction like a wheel or tire. Where it is not specified, a membrane of the invention may be any toroidal shape, including, but not limited to an annular invaginating balloon.

[0124] As used herein, an "endoscope" is generally intended to mean an optical or video device for examining the lumen (internal opening) of an organ. A "fluid" according to the invention is a material that is capable of flowing, not solid of static shape and form; and may be liquid or gaseous (Funk and Wagnalle, "Standard College Dictionary" Harcourt, Brace & World cw1968). Further, the term "gear" is intended to mean a device adapted to interact in a mechanical assembly of interacting parts that serves to transmit motion or to change the rate or direction of motion (Funk and Wagnalle, "Standard College Dictionary" Harcourt, Brace & World cw1968). Term "helical gear" is intended to mean a gear having teeth arranged in the configuration of a helix. ("Machinery's Handbook" 25 ed., Industrial Press Inc. New York, 1996.) The term "motor" is intended to mean something that imparts or produces motion (Funk and Wagnalle, "Standard College Dictionary" Harcourt, Brace & World cw1968). The term "pin coupling" is intended to mean a form of slip joint coupling to a shaft of a motor. The term "pinion gear" is intended to mean a toothed wheel driving or driven by a larger cogwheel (Funk and Wagnalle, "Standard College Dictionary" Harcourt, Brace & World cw1968), while the term "rolling traction" or "rotary traction" is intended to mean the act of drawing, as by motive power over a surface using rolling or rotational movement, respectively, such as a wheel or tire. Finally, the term "toroid" is intended to mean a surface generated by the rotation of any closed plane curve about and axis lying in its plane but external to it (e.g. donut shaped) (Funk and Wagnalle, "Standard College Dictionary" Harcourt, Brace & World cw1968).

[0125] Two embodiments of a drive unit (also referred to herein as an endoscopic propulsion device) of the present invention is illustrated in FIGS. **1** and **2**. FIGS. **1** and **2** represent side views that show the external parts of embodiments of the endoscopic propulsion device. FIG. **1** generally shows a device **11** comprising an outer cowling **12**, longitudinal force providing bands **13** (only one shown), and end supports **14**. In this embodiment, bands **13** interconnect with

a membranous element (not depicted) to translate longitudinal force of the unit to longitudinal force exerted against a cavity wall (not depicted).

[0126] FIG. **2** depicts a device **11** comprising a worm gear **18** and a collar **14**. Connected to the worm gear **18** is a drive gear **15**, which engages a gear (not depicted) at the end of worm gear **13**. Drive gear **15** is connected to drive shaft **16** via gears at the end of drive shaft **16** and in a through hole (not depicted) in drive gear **15**. Rotational force provided by drive shaft **16** is translated to rotational force of worm gear **18**, which causes spiral projections **17** on worm gear **18** to rotate, providing longitudinal force for device **11**.

[0127] FIG. **3** depicts an entire assembled device comprising an endoscope. The various elements are described with reference to subsequent figures.

[0128] FIG. **4** shows the order of assembly of the endoscopic propulsion device, in which the various elements are described with reference to subsequent figures

[0129] FIG. **5** shows external drive unit **60** that is comprised of the external drive motor **61**, the control unit **63**, the control cables **64**, the speed controller **66**, and the pin coupling **67**. The external drive unit **60** couples to the drive shaft **40** by means of a pin coupling **67** that acts as a torque coupler and a slip joint. While a pin coupling is utilized in the present illustrative embodiment, other means and mechanisms of drive shaft coupling may be used.

[0130] A drive shaft **40** (FIGS. **1-6**) is enclosed within a drive shaft sheath **42** and is supported along the length of the endoscope by drive shaft attachment brackets **41** illustrated in FIG. **6**. The drive shaft sheath prevents trauma to the organ as the drive shaft **40** turns. The drive shaft **40** enters the drive unit **25**, via the proximal attachment bracket **50** and via the end support assembly **20**.

[0131] In one embodiment, the drive unit or transmission **25** shown in FIG. **8**C comprises two-end support assemblies **20**, each located and fixed to opposite ends of the support tube **10**. The end support assemblies **20** are sub-units of the drive unit **25**. In the embodiment illustrated in FIG. **8**A, each end support assembly **20** is comprised of the end support **21**, outer drive wheels **24**, an intermediate drive wheel **26**, an inner drive wheel **28**, and the pinion shafts **29**. In the embodiment shown in FIGS. **8**A-D, the drive shaft **40** is solidly attached to the inner drive wheel **28**. The inner drive wheel **28** is a pinion gear in embodiments that is held in place by the end supports **21** located on both ends of the end support tube **10** and by the drive shaft **40** (FIG. **8**D).

[0132] The inner drive wheel **28** is in contact with the intermediate drive wheel **26** with sufficient friction to transmit adequate torque (FIG. **8**D). The drive shaft **40** is the axle for the inner drive wheel **28**. The drive shaft **40** is positioned parallel to the long axis of the support tube **10** (FIG. **8**D).

[0133] In embodiments, the intermediate drive wheel **26** is a plastic helical gear. The intermediate drive wheel **26** is held in position on the support tube **10** by a mating groove **11** located on the external surface of the support tube **10**. This groove **11** serves as the bearing for the intermediate drive wheel **26**.

[0134] In embodiments, the outer drive wheels **24** are attached to the end support **21** in a radial array. The outer drive wheels **24** rotate in a direction parallel to the support tube **10**. In an embodiment, the outer drive wheels **24** are in contact with the intermediate drive wheel **26** in such a way as to allow transfer of rotational energy from the intermediate drive wheel **26** to the outer drive wheels **24** (FIG. **8**B). In embodiments, rotational energy from the external drive wheels **24** is transmitted to the annular invaginating balloon **30** by friction.

[0135] Further, embodiments of the invention such as illustrated in FIGS. **1**, **3**, **7**A, **8**B, and **8**D, an annular invaginating balloon **30** is positioned over the drive unit **25**, as shown in particular in FIG. **8**C. The annular invaginating balloon is held in position by the end support lips **22** located on each of the end supports **21**. The inner surface of the annular invaginating balloon **35** is in contact with the outer drive wheels **24** (FIG. **8**B) with sufficient friction so as to rotate the annular invaginating balloon about its long axis. The long axis of the annular invaginating balloon **30** is oriented parallel to the long axis of the endoscope **01** (FIG. **3**) and the long axis of the drive unit **25** (FIG. **8**C).

[0136] The annular invaginating balloon **30** is comprised of contiguous inner **35** and outer **36** surfaces, as shown in FIG. **7**C. The balloon **30** is constructed such that movement of the inner surface **35** translates into reactionary movement of the outer surface **36**. The inner surface of the annular invaginating balloon **35** moves in response to rotation of the external drive wheels **34**. This in turn moves the outer surface **36** of the annular invaginating balloon **30**.

[0137] In embodiments, friction between the outer surface **36** of the annular invaginating balloon **30** and the organ lumen wall results in movement of the entire drive unit **25** in the organ lumen. As the drive unit is firmly attached to the endoscope by the proximal **50** and distal **51** locking brackets, the endoscope moves in the organ lumen.

[0138] In embodiments, the annular invaginating balloon **30** illustrated in FIGS. **7**A-B has a detachable cannula **31** for fluid inflation, as shown in FIG. **7**B. Such a balloon may be similar to a type that is currently commercially available. Manufacture of such a balloon is, in embodiments, adapted to include an inflation assembly. Components **31**, **32**, **33**, and **34** provide such a means for balloon inflation as one illustrative example. The cannula **31** includes a connection **33** for an inflation device such as a syringe. The cannula **31** includes an inflation bulb **32** for manual detection of filling pressure. After insertion of the endoscopic propulsion device into an organ lumen, the annular invaginating balloon **30** is inflated with fluid. Once inflated, the cannula is detached from the annular invaginating balloon **30**. A self-sealing valve **34** maintains fluid pressure within the annular invaginating balloon **30** after the cannula **31** has been removed.

[0139] In embodiments, the endoscopic propulsion device has a flexible support tube **10** with a lumen suitable for the passage and attachment of an endoscope. FIG. **4** shows the insertion of a commercially available endoscope through the lumen of the support tube **10**. In one particular embodiment, the endoscopic propulsion device attaches near the distal end of the endoscope. The drive tube **10** has support areas for the attachment of an end supports **50** and **51**, as shown in FIG. **4**.

[0140] In embodiments, the endoscopic propulsion device according to various embodiments herein shown and described is adapted to enhance the capability of currently available endoscopes. The drive unit **25** and the annular invaginating balloon **30** attach near the distal end of the endoscope intended for endolumenal delivery within a body. One exemplary method and assembly is provided in further detail as follows in order to further illustrate various aspects of the present invention.

[0141] First, the operator attaches the drive shaft attachment brackets **41** with the integral sheath **42** along the length of the endoscope **01**. Next, the proximal locking bracket **50** is

attached to the endoscope. Next, the flexible drive shaft **40** is fed through the proximal locking bracket **50** and the sheath **42**, as shown in assembled view in FIG. **4**. As the drive shaft insertion nears completion, the operator inserts the endoscope through the support tube lumen **05** of the drive unit **25** to bring the drive unit **25** into its final location, as further illustrated in FIG. **4**. The drive unit **25** is fixed in place on the endoscope by attachment of the distal locking bracket **51**. The pin coupling **67** is attached to the end of the drive shaft and next attached to the external drive unit **60** via the pin coupling **67**.

[0142] Movement, direction and speed of the endoscopic propulsion device are controlled externally by the operator using controls attached to the external drive unit **60**, shown schematically in FIG. **3**. Torque created by the external drive unit couples directly to the drive shaft **40** via the pin coupling **67**. The direction of drive shaft rotation determines the movement direction for the endoscopic propulsion device.

[0143] Rotation of the drive shaft **40** rotates the internal drive wheel **28** that acts as a drive pinion to transmit torque to the intermediate drive wheel **26**. The intermediate drive wheel is a helical gear that rotates freely about the support tube **10**. Rotation of the intermediate drive wheel **26** transmits torque to the outer drive wheels **24** causing these wheels to rotate. In the present illustrative embodiment, the outer drive wheels **24** are pinion gears that are radially arrayed around the intermediate drive gear **26**. The radial array of outer drive wheels **24** supports the inner surface of the annular invaginating balloon **35**. The inner surface of the annular invaginating balloon **35** is in contact with the outer drive wheels **24** and the outer surface of the annular invaginating balloon **36**. The outer surface of the annular invaginating balloon **36** is in contact with the organ lumen wall. As the outer drive wheels **24** rotate, the inner surface of the annular invaginating balloon **35** moves. Movement of the inner surface of the annular invaginating balloon **35** results in movement of the outer surface **36** of the annular invaginating balloon **30**. The outer surface **36** of annular invaginating balloon **30** produces rolling traction in contact with the luminal surface of the organ wall. Movement of the inner surface **35** of the annular invaginating balloon **30** applies longitudinal forces to the end support lips **22**. The end support lips **22** are firmly fixed to the endoscope **01** by their associated end supports **21** and locking brackets **50**, **51**, respectively. As a result of this configuration, longitudinal force applied to the end support lip **22** moves the attached endoscope within the organ lumen.

[0144] As discussed above, the components of drive unit **25** can be made of any material having sufficient rigidity to hold the components in proper alignment. The materials generally are chosen to have sufficient durability to handle the necessary torque. In one particular embodiment, polyvinyl chloride (PVC) type of polymer or plastic is used. In addition or alternative to these, composite tubings or bodies may be employed, such as for example incorporating wire reinforcement fibers, winds, or braids, such as for example using stainless steel, nickel-titanium, or other wire mesh fibers laminated, embedded within, or otherwise coupled to a polymer wall or body.

[0145] In general with regard to certain embodiments, and as generally discussed above, the support tube may be made of any material having sufficient structural memory to substantially return to its native state once flexing and rotating forces are removed. In one embodiment, this material is nylon plastic. The drive shaft **40** is made of a nylon wire in the preferred embodiment but other flexible material such as multi-wire flexible steel cable may be used. The annular invaginating balloon **30** is typically made of a durable flexible material, such as plastic or rubber. PVC, latex, silicone, polyurethane, or other materials similar to these may be employed. Such balloons are currently commercially available.

[0146] An additional embodiment is shown in FIGS. **9**A, **9**B, and **9**C. This embodiment includes one or more additional intermediate drive assembly(s) placed on the tube **10** between the end support assemblies **20**. The additional intermediate drive assemblies comprise the intermediate drive support **23**, an inner drive wheel **28**, an intermediate drive wheel **26**, and outer drive wheels **24**. An intermediate drive assembly is similar in construction and function to the end drive assembly **20**. The intermediate drive support **23** consists of a durable material such as plastic, which may for example be of similar construction to the end support assembly **20**. The intermediate drive assembly contains the same radial array of outer drive wheels **24** (FIG. **8***a*). In addition, the intermediate drive assembly contains an intermediate drive wheel **26**, an inner drive wheel **28**, and the drive shaft **40**, as found in the end assembly **20**. The intermediate drive support **23** differs from the end support **21** by the absence of the end support lip **22** found on the end support **21**.

[0147] An additional embodiment is shown in FIG. **10**, where the external drive unit is replaced by an internal drive unit **70**. One such embodiment may include, in a further more detailed illustrative embodiment, the use of an air motor **71** to produce rotational energy as part of the internal drive unit **70** (FIG. **9**). In this embodiment, the drive shaft **40** is replaced by an air hose **72** to supply pressure to drive the air motor **71**.

[0148] It is to be appreciated that the foregoing embodiments herein shown and described by reference to FIGS. **1-10**, while highly beneficial, provide illustrative examples of certain specific features and components that are adapted to achieve the various broad aspects, modes, and objects of the invention also herein described. Other approaches than those specified for those particular embodiments are also contemplated. Certain further embodiments are thus provided for further illustration as follows and by reference to FIGS. **11-20**.

[0149] As explained above for the foregoing embodiments, the following further embodiments of the present invention also provide highly beneficial delivery assemblies that are particularly well suited to propel endoscopes through body lumens in highly beneficial and novel manners. Furthermore, as also elsewhere herein described, such delivery assemblies may be incorporated directly with endoscope assemblies in fixed or secured combination systems. Or, the delivery assemblies may be provided separately in a configuration that is adapted for cooperative engagement and use with endoscopes as separate, though cooperating, devices in an overall system. For the purpose of providing a thorough understanding, the following embodiments are herein shown and described in detail in the context of the latter configuration. In this context, for example, a delivery assembly is thus provided that is adapted for cooperative engagement and use with a separate endoscope **100** as shown schematically with regards to its working distal end portion **102** in FIG. **11**.

[0150] One particular further beneficial embodiment is shown in various levels of detail in FIGS. **12-18**B, which should be read together where appropriate for further understanding of the system and method described.

[0151] More specifically, as shown in FIG. **12**, the delivery assembly according to the present embodiment of the invention includes a carriage assembly **110** that includes a tubular body **121** that is adapted to be positioned coaxially over distal end portion **102** of endoscope **100**. Tubular body **121** includes a proximal end portion **122** and a distal end portion **126**, that are each shown to include tapered tips **123**, **125**, respectively in order to provide substantially smooth transition along endoscope **100**. An outer circumferential surface **129** extends between proximal and distal end portions **122**, **126**. In addition, proximal and distal stops **120**, **121**, respectively are also provided, and may be either integral with tubular body **121**, or assembled thereon.

[0152] As shown in FIG. **13**, a grooved drive assembly **130** is positioned coaxially around outer surface **129** in a manner allowing substantial rotation of drive assembly **130** while carriage assembly **110** remains substantially fixed along the rotational axis and on endoscope **100**. Grooved drive assembly **130** includes a helical groove **132** extending between its ends **133**, **135** that are positioned to correspond with proximal and distal end portions **122**, **126**, respectively, and in particular between proximal and distal stops **120**, **121**, respectively, of carriage assembly **110**. In order to provide such axially contained positioning, at least one of stops **120**, **121**, may be assembled onto tubular member **121** after first positioning grooved drive assembly **130** in the position shown.

[0153] A drive gear **136** is shown with a substantially flexible, yet substantially torqueable, drive shaft **137** that extends proximally from a distal coupler **139**. Distal coupler **139** is shown to be of a rotational toothed gear type and is adapted to be positioned at least in part within the slotted, toothed rotational gear surface shown at proximal end **133** of drive assembly **130**.

[0154] As also further shown in the transverse partially cross-sectioned view in FIG. **14**, the distal coupler **139** is constructed and geared to drive assembly **130** in a manner such that rotation of drive gear **136** translates into rotation of drive assembly **130** around carriage assembly **110**. It is to be appreciated that the interfacing and cooperation between drive gear **136** and drive assembly **130** is provided by means of certain structural supports in a housing assembly, not shown hear in order to provide sufficient view and detail of their functional inter-cooperation. However, such support structures may include, for example, a sheath positioned around drive gear **136** and extending to, and possibly coupled, engaged, or secured with, carriage assembly **110** or other connecting component(s). Or, these various components may be incorporated into the semi-flexible shaft of the related endoscope, such as for example various lumens provided therein, in such an integrated embodiment if so desired.

[0155] As further shown in FIG. **15**A, a longitudinally slotted cowling **140** is provided co-axially over grooved drive assembly **130**. Cowing **140** includes a plurality of longitudinal grooves **146** that extend between a proximal end **142** and a distal end **146** that are positioned to correspond with proximal and distal end portions **122**, **126** of carriage assembly **110**. As further shown in FIG. **15**B, four of these grooves **146** are provided in uniformly spaced, 90 degree separated positions around the longitudinal axis L of the assembly. It is to be appreciated that the embodiment herein shown and described in particular detail provides a highly beneficial arrangement, as will be explained in further detail below. However, other numbers, shapes, dimensions, or relative positioning between grooves may be employed to meet a particular desire.

[0156] FIG. **16**A shows a longitudinally cross-sectioned side view of an annular invaginated balloon **150** as a further component adapted for coordinated use with the variously coupled assemblies and components shown in FIGS. **12**-**15**B. More specifically, balloon **150** includes an outer wall with outer surface **154** surrounding an inner wall with inner surface **156**. A plurality of coupling feet **160** are provided in longitudinally patterned groups so as to provide a continuous array around a circumferential pattern extending along outer and inner surfaces **154**, **156**, respectively. The feet **160** include a neck **162** that is relatively more narrow than a head **164**. This allows for engaged coupling around neck **162** by a respective drive assembly whereas head **164** prevents mechanical disengagement from such coupling. Feet **160** that are located within lumen **158** surrounded by balloon **150** are coupled in this manner. One particular embodiment includes four such longitudinally and circumferentially spaced arrays of feet that are spaced 90 degrees apart, as shown in FIG. **16**B.

[0157] As shown in FIG. **17**, the spaced arrays of feet **160** of balloon **150** are oriented so as to couple with grooved drive assembly **130** as follows. Each head **164** is positioned within a groove of drive assembly **130** with neck **162** extending through slots **146** of cowling **140**. In this manner, rotation of grooved drive assembly **130** translates feet **160** longitudinally along grooves **146**, which translates inner wall **156** longitudinally in one direction, and conversely and responsively outer wall **154** translates longitudinally in the opposite direction.

[0158] Various methods and materials may be employed to manufacture these various components just described, including in particular balloon **150**. However, in order to provide further more detailed illustration for a complete and thorough understanding of the various aspects herein contemplated, one particular more detailed embodiment is provided as follows.

[0159] As shown in FIG. **18**A and FIG. **18**B in various cross-sections, a mold **170** may be used for injection molding a tubular member that includes feet as just described, which tubular member is inverted or everted onto itself such that by securing the opposite ends to each other the annular invaginated balloon such as balloon **150** may result. More specifically, an outer shell mold or die **172** includes an inner annular surface that defines an interior opening or passageway **180**. This inner surface includes a plurality of circumferentially and longitudinally spaced cavities **190** that form the negative impression of the intended feet **160**, including open neck **192** and head **194** that correspond with neck **162** and head **164** of the intended feet **160**. An additional interior mold member or mandrel **174** is positioned within passageway **180** within die **172** in a manner leaving a circumferential and longitudinal annular gap therebetween. The result provides a continuous space as a mold within which a thermoset, thermoplastic, or other polymer or injectable compound may be injected. Upon cooling or otherwise setting in the shape provided by this space, the desired tubing with external feet arrays results and may be inverted or everted to form the balloon as previously described above.

[0160] It is to be appreciated, as shown in partial schematic cross-section in FIG. **19**, that regardless of the particular drive assembly or coupling mechanism used to translate longitudinal motion of the annular tracking balloon, such balloon beneficially includes an inflation assembly. This is shown schematically in FIG. **19**, including an inflation assembly **200** with an inflation or injection needle **210** engaged within a

self-sealing valve **230** of balloon **250** via a coupler **220**. To deflate the balloon **250**, the self sealing valve **230** may be again registered with the coupler **220**, or balloon **250** may simply be "popped" by puncturing its wall with needle **210** or by other means for balloon rupture or deflation, as would be apparent to one of ordinary skill.

[0161] It is to be appreciated that other drive mechanisms and relative coupling between components may be used to accomplish various of the objectives herein described.

[0162] In one particular further embodiment shown in FIG. **20**, an endoscopic propulsion assembly **260** includes an annular invaginated balloon **270** that includes one or more circumferential grooves **272** extending along the longitudinal axis L of balloon **270**. Grooves **272** include an interior wall that is shaped with a series of paired, opposite inward protrusions **274**, **275** spaced at generally regular intervals to thus provide alternating gaps **276** between such paired protrusions. A belt assembly **280** is engaged within groove **272** and includes an array of longitudinally spaced enlargements **286** separated by relatively more narrow waist regions **284**. This shape for belt **280** is adapted to correspond with the shaped interior space of groove **272** as shown in FIG. **20**. Accordingly, by coupling belt assembly **280** to a drive assembly interiorly of the annular invaginated balloon, such as a grooved drive chassis as previously described above, belt **280** may be rotated longitudinally to thereby drive and translate balloon **270** into longitudinal rotational motion.

[0163] The annular invaginated balloon embodiments herein shown and described are hereby further defined as providing a "toroidal" shape in the sense that the balloon appears as a toroid in end-view, although including an extended length along the longitudinal axis encircled by that toroid. Moreover, the rotation imparted to such shape according to the various embodiments is defined as a "toroidal rotation", which is intended to mean the interior surface of the toroidal balloon translates in one longitudinal direction with the exterior surface translating in a second opposite longitudinal direction, thus the toroidal balloon rotates longitudinally around itself. Furthermore, a "side" or "lobe" of the toroidal balloon is intended to mean one circumferential location around the toroid when taken by reference to a transverse cross-section, whereas two opposite sides or lobes constitute two opposite circumferential locations relative to the cross-sectional reference plane transverse to the longitudinal axis encircled by the elongated toroid.

[0164] Of course, one or more of the various features of the embodiments and aspects discussed above may be combined with one or more other features discussed above with respect to other embodiments and aspects to achieve particular configurations that are advantageous for a particular use. The combinations specifically described above simply depict exemplary embodiments, while the invention encompasses all combinations of elements and method steps to achieve all of the purposes disclosed herein or envisioned by those of skill in the art. It will thus be apparent to those skilled in the art that various modifications and variations can be made in the practice of the present invention and in construction of the device and medical instruments comprising the device without departing from the scope or spirit of the invention. Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

1. A medical device comprising:
a drive unit comprising:
means for receiving a means for providing an external force to the drive unit;
means for converting the external force to an internal longitudinal force of the drive unit; and
means for translating the internal longitudinal force of the drive unit to an exterior surface of the drive unit.

2. The device of claim **1**, wherein the means for converting the external force to an internal longitudinal force and the means for translating the internal longitudinal force to an exterior surface of the drive unit is the same means.

3. The device of claim **1**, further comprising means for translating the internal longitudinal force of the drive unit to a body cavity surface that is external to the device.

4. The device of claim **1**, further comprising means for providing an external force.

5. The device of claim **1**, further comprising means for diagnosing an abnormal condition in a subject in which the device is placed.

6. The device of claim **1**, further comprising means for treating an abnormal condition in a subject in which the device is placed.

7. The device of claim **1**, comprising:
a drive unit comprising:
means for providing an external force to the drive unit;
means for receiving the means for providing an external force;
means for converting the external force to an internal longitudinal force of the drive unit;
means for translating the internal longitudinal force of the drive unit to an exterior surface of the drive unit;
means for translating the internal longitudinal force of the drive unit to a body cavity surface that is external to the device;
means for diagnosing an abnormal condition in a subject in which the device is placed; and
optionally, means for treating an abnormal condition in a subject in which the device is placed.

8. A medical device comprising:
a drive unit comprising:
at least one receptacle for at least one drive shaft;
a rotatable element that provides an internal longitudinal force for the drive unit; and
at least one gear that transfers force from the drive shaft to the rotatable element.

9. The device of claim **8**, further comprising a collar at one or both ends of the drive unit,
wherein the receptacle is a recess or hole in one of the collars, and
wherein connection of the drive shaft to the receptacle links rotational force supplied by the drive shaft to rotational movement of the rotatable element.

10. The device of claim **8**, wherein the rotatable element is a worm gear.

11. The device of claim **8**, wherein the rotatable element is a flexible band that is disposed within the drive unit to permit longitudinal rotation of the band along the long axis of the device.

12. The device of claim **8**, further comprising:
a membranous element that is releasably attached over at least a portion of its length to the rotatable element,
wherein the membranous element translates internal longitudinal energy of the drive unit to external movement of the unit along a body cavity.

13. The device of claim **12**, wherein the membranous element comprises a surface that comprises is complementary to a surface present on the rotatable element, whereby the two surfaces can interact to become attached to each other over at least a portion of their respective surfaces.

14. The device of claim **13**, wherein the membranous element comprises projections that releasably attach to invaginations on the surface of the rotatable element.

15. The device of claim **14**, wherein the rotatable element is a worm gear and wherein the membranous element comprises spikes that complement spiral troughs in the surface of the worm gear.

16. The device of claim **13**,
wherein the rotatable element is a flexible membrane having a surface populated by hooks of a hook-and-loop combination, and
wherein the membranous element has a surface populated by loops of a hook-and-loop combination.

17. The device of claim **8**, further comprising at least one drive shaft.

18. The device of claim **8**, further comprising an endoscope.

19. The device of claim **18**, wherein the endoscope is a colonoscope.

20.-**23**. (canceled)

24. An endoscope comprising:
an endoscope; and
a drive unit comprising:
at least one receptacle for at least one drive shaft;
a rotatable element that provides an internal longitudinal force for the drive unit; and
at least one gear that transfers force from the drive shaft to the rotatable element.

25. The endoscope of claim **24**, which is a colonoscope.

26.-**35**. (canceled)

36. An endoscope propulsion device assembly system comprising:
a toroidal wall having an exterior surface and an interior surface that circumscribes an interior passageway extending along a longitudinal axis, and with a length between a proximal end and a distal end relative to the longitudinal axis;
a drive assembly;
an endoscope coupler assembly;
wherein the toroidal wall is adjustable from a radially collapsed condition to a radially extended condition, respectively, transverse to the longitudinal axis;
wherein the drive assembly is adapted to couple to the toroidal wall and to impart toroidal rotation onto the toroidal wall in the radially extended condition such that the interior surface translates in a first longitudinal direction and the exterior surface translates in a second opposite longitudinal direction along the longitudinal axis; and
wherein the endoscope coupler assembly is adapted to couple the toroidal wall to an endoscope extending along the interior passageway such that the toroidal wall and endoscope are adapted to be propelled together in the first direction along a body lumen during toroidal rotation of the toroidal wall when the exterior surface is engaged to a wall of the body lumen with translating force against the wall.

37. The system of claim **36**, wherein the toroidal wall further comprises:
a toroidal balloon having an annular invaginated balloon wall that is inflatable from the radially collapsed condition to the radially extended condition with a pressurized fluid.

38. The system of claim **36**, wherein:
the toroidal balloon comprises a protrusion extending from the balloon wall along the interior surface and into the interior passageway;
the drive assembly comprises an elongate screw extending along the longitudinal axis within the interior passageway and with a helical groove extending helically around the longitudinal axis; and
the helical groove is adapted to receive the protrusion within the interior passageway such that rotation of the elongate screw advances the protrusion longitudinally in the first direction along the longitudinal axis, and thereby is adapted to move the interior surface in the first direction along the longitudinal axis to impart toroidal rotation to the toroidal balloon along the longitudinal axis.

39. The system of claim **38**, wherein the protrusion extends from the interior surface with a relatively narrow neck and terminates interiorly within the interior passageway with an enlarged head relative to the neck.

40. The system of claim **38**, further comprising:
a plurality of said protrusions in a patterned group that are each spaced along a longitudinal pattern that circumscribes one lobe of the toroidal balloon along the longitudinal axis;
wherein each protrusion of the group along the interior surface is engaged to a respective turn of the helical groove and translates longitudinally in the first direction along the rotating screw;
wherein each said protrusion of the group along the inner surface is released therefrom the helical groove when it is translated in the first direction to a first end of the screw;
wherein each said protrusion of the group along the exterior surface translates in the second opposite direction and is adapted to rotate inwardly to the inner surface and to be engaged within the helical groove of the screw at a second end thereof, and
wherein continuous rotation of the screw continuously releases and engages respective protrusions of the patterned group at the first and second ends of the screw, respectively, to thereby continuously drive toroidal rotation of the toroidal balloon.

41. The system of claim **40**, further comprising:
a plurality of said groups of protrusions in patterned arrays;
wherein each of the groups of protrusions is located at a unique respective position around a circumference of the toroidal balloon transverse to the longitudinal axis.

42. The system of claim **40**, further comprising:
four of said groups;
wherein the four groups are spaced at 90 degree intervals around the circumference transverse to the longitudinal axis.

43. The system of claim **40**, further comprising:

a cowling with a substantially tubular body located between the screw and the interior surface of the toroidal balloon and with a longitudinal groove extending along the longitudinal axis between first and second ends of the screw;

wherein the protrusions are adapted to engage the helical groove of the screw through the longitudinal groove of the cowling.

44. The system of claim **41**, further comprising:

a cowling with a substantially tubular body located between the screw and the interior surface of the toroidal balloon and with a plurality of longitudinal grooves extending along the longitudinal axis between first and second ends of the screw;

wherein the protrusions of each group are adapted to engage the helical groove of the screw through a respective one of the plurality of longitudinal grooves of the cowling.

45. The system of claim **37**, further comprising:

an expansion actuator that is adapted to couple to the toroidal wall and expand the toroidal wall from the radially collapsed condition to the radially extended condition.

46. The system of claim **36**, further comprising:

a motor that is adapted to couple to the drive assembly and to actuate the drive assembly coupled to the toroidal wall to impart toroidal rotation to the toroidal wall.

47. The system of claim **36**, further comprising an endoscope.

48. The system of claim **47**, wherein said endoscope and the toroidal wall are permanently secured in fixed position relative to each other via the endoscope coupler assembly.

49. The system of claim **47**, wherein said endoscope and toroidal wall are adapted to be releasably coupled to each other via the endoscope coupler assembly.

50. The system of claim **36**, wherein:

the endoscope coupler assembly comprises a base with a tubular member with an inner lumen extending along a length between first and second ends, and further comprises first and second radial protrusion stops extending radially outwardly from the tubular member transverse to the longitudinal axis at each of the first and second ends, respectively;

wherein the base is adapted to be coupled to an endoscope extending along the inner lumen;

wherein the toroidal wall is adapted to be positioned at a location along the base with the tubular member located within the interior passageway and such that in the radially extended condition the toroidal wall has an inner diameter at the interior surface that is less than an outer diameter of the base at the first and second radial protrusion stops; and

wherein the toroidal wall is adapted to undergo toroidal rotation at the position without substantially moving longitudinally along the base due to mechanical interference between the toroidal wall and the first and second radial protrusion stops.

51. The system of claim **37**, wherein:

the drive assembly comprises a belt that circumscribes one lobe of the toroidal balloon wall along the longitudinal axis and at a position around the circumference transverse to the longitudinal axis;

the toroidal balloon wall comprises a circumferential groove along the longitudinal axis and corresponding with the position;

the belt is adapted to engage the circumferential groove along the exterior surface of the toroidal balloon wall at the position;

the belt is also adapted to engage the drive assembly located within the interior passageway; and

the drive assembly is adapted to rotate the belt around the toroidal balloon and so as to impart translational motion to the exterior surface in the second direction to thereby provide toroidal rotation of the balloon.

52. The system of claim **51**, wherein:

the groove comprises a shaped interior surface with a plurality of spaced pairs of opposite protrusions into the groove to provide an alternating pattern of expanded and narrowed waste regions along the groove;

the belt comprises a shaped outer surface with a plurality of enlargements separated by relatively narrowed waste regions;

the belt and groove are adapted to couple along the exterior surface with the narrowed waste regions of the belt fitting into the narrowed waste regions of the groove; and

the belt is adapted to be released from the groove at first and second ends of the exterior surface along the balloon.

53. The system of claim **36**, wherein the toroidal wall comprises an elongated toroidal wall such that the length is substantially greater than a profile diameter between the interior and exterior surfaces of the toroidal wall in the radially extended condition.

54.-**56**. (canceled)

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