Development of an Endoscope Propulsion System to Aid in the Colonoscopy Procedure

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Masters of Science
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ABSTRACT

Colorectal cancer is the third most common form of cancer, and is the number two cancer-related death in the United States. Receiving regular colonoscopies can reduce the average person's risk of dying from colon cancer by 90%. However, only 54% if adults over the age of 50 get regular colonoscopies. This low percentage can be attributed to the exam's poor availability, severe discomfort, high cost, and the risk of procedural complications. The Endoscope Propulsion System, or EPS, will assist in the colonoscopy procedure. This device will enable a lesser skilled physician to effectively perform the colonoscopy, thus increasing the procedure's availability. In addition to requiring less skill, the assistive nature of the EPS will also decrease the chance of complications due to colon perforation. The EPS will greatly reduce the discomfort cause by the colonoscope, which will eliminate the need for anesthesia and recovery, therefore greatly reducing the cost of the procedure. The Endoscope Propulsion System design described in this paper is an update to the device outlined in Dr. M. Jonathan Bern's patent application (20060270901). The criteria and requirements of the design are discussed along with the final design and analysis. Finally, a prototype was built to ensure the validity of the proposed invention.

Acknowledgments

This thesis, as well as my undergraduate and graduate career would not have been possible without the following individuals. First and foremost, I would like to thank my mother, father, sister, girlfriend, and friends for their support through the years. Knowing I would have constant love, enthusiasm, and encouragement no matter which choices I made, granted me the freedom to pursue various paths, eventually ending up where I am today.

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Chapter 1

Introduction

1.1 Motivation

The motivation behind the design and implementation of this colonoscopy-assisting device is to decrease the number of colorectal cancer deaths. Colon cancer is the third most common form of cancer, and is the number two cancer death in the United States. Over 60,000 people die each year in the U.S. and more than 650,000 people die from colon cancer worldwide [8]. Malignant polyps form on the colon walls, leading to colon cancer. However, these polyps can be detected and removed through a procedure called a colonoscopy. Approximately 90% of colorectal cancers are completely curable if detected early. About 75% of the adults in the United States with colon cancer are over the age of 50, and have no other risk factors. Getting regular colonoscopies can reduce the average person's risk of dying from colon cancer by 90%. If all Americans received regular screenings, 25,000 lives would be saved in the U.S. every year [4].

1.2 Research Goals

The primary objective of this research is to create a more readily available, and a more appealing colonoscopy procedure. While colon cancer is easily treatable, it requires early detection, and early detection means patients need to receive regular colonoscopies. However, according to the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, in 2004, only 53.9% of adults 50 years and older

received colonoscopies [17]. The main reasons for this low percentage are poor availability, severe discomfort, the high cost of the procedure, and most importantly the risk, although very small, of damaging the colon wall using the current colonoscopy procedure.

After 22 years of performing colonoscopies, a Salem, Virginia Gastroenterologist by the name of Doctor M. Jonathan Bern, came up with the idea that a self propelled endoscope would improve the current method of performing a colonoscopy. Dr. Bern has been a doctor for 25 years and has been in practice as a gastroenterologist for 20 years. He has performed more than 35,000 colonoscopy exams, and with much experience and background knowledge, has developed a colonoscopy-assisting device. The Endoscope Propulsion System, or EPS, was developed and designed from this initial idea to enable a safer, more effective colonoscopy procedure. The propulsion unit is designed to mount onto currently available endoscopes, and can be disposed of after use. The assisted colonoscopy will allow the endoscope to easily navigate the colon without stretching or potentially tearing the luminal walls. The EPS will also eliminate any colonic looping associated with the current manually driven scope. This equates to a more comfortable procedure with minimal risk of complication. The logical assumption is that making the procedure safer and more comfortable will alleviate some of the patient anxiety, and will increase the percentage of adults receiving colonoscopies. Also, less discomfort means that there is no longer a need for heavy sedation. The Endoscope Propulsion System will negate the need for an anesthesiologist, and therefore will allow the colonoscopy to be performed in a physician's office. These comfort and safety factors are expected to lower the cost of the procedure by 66% [1]. In addition, the skill level required to effectively maneuver the scope will drastically decrease because of the self-propelling nature of the EPS, which eliminates the external pushing force required by currently used endoscopes. This enables the doctor to focus on navigating the scope and detecting any irregularities. Combining an increase in safety and effectiveness, with a decrease in discomfort and cost, equates to a procedure that people will be more likely to receive, thus increasing the chance of detecting cancerous polyps early enough for treatment.

Chapter 2

Literature Review

2.1 The Large Intestine

The Endoscopic Propulsion System was specifically designed to accommodate the large intestine. This working environment is described in the following: The large intestine is a sacculated organ comprised of the cecum, the colon, the rectum, and the anal canal that measures 4 to 5 feet in length. The cecum is considered the beginning of the large intestine. It connects the large intestine to the small intestine, via the colic valve. It is described as a pouch, averaging 6.25cm (2.46in) in length and 7.5cm (3in) in width. The cecum lies upright in the body, with the bulbous end pointing down, and its opening directed up. The cecum sits rather freely and can move a considerable amount within the abdomen. It is usually completely surrounded by peritoneum, which is the serous membrane covering the abdominal cavity.

The colon is separated into the ascending, transverse, descending, and sigmoid colon. The ascending colon connects to the cecum as its base, narrows, and extends upwards to join the transverse colon at the right colic (hepatic) flexure. The ascending colon sits in the colic impression, and is attached to the abdominal wall by the peritoneum; as a result, possessing less mobility than the cecum.

The right colic flexure makes a sudden forward, then leftward turn that connects the ascending colon to the transverse colon. As its name implies, the transverse colon

spans the horizontal distance between the ascending and descending colon. The transverse colon is the longest and most unrestricted part of the colon, and displays a reverse arch concavity as it extends across the abdomen. It is also completely enveloped in peritoneum, but with little confinement. The transverse colon connects to the descending colon at the left colic (splenic) flexure.

The left colic flexure consists of an extremely acute rearward then downward turn that typically results in contact between the transverse and descending colon. The left colic flexure is attached to the diaphragm and helps support the lower end of the spleen.

From the left colic flexure, the descending colon continues down to the sigmoid colon. The descending colon is covered by the peritoneum on its sides and anterior surface, but is connected to the left kidney on its posterior surface. While similar to the ascending colon in orientation, the descending colon has a smaller diameter and its mobility is more constrained.

At its base, the descending colon connects the final part of the colon, the sigmoid colon. The sigmoid colon forms a loop measuring 40cm (15.75in) long. The sigmoid colon carries a large range of motion, which can cause displacement from within the pelvis to the abdominal cavity. It is completely covered in peritoneum, whose length is greatest at the middle section of the sigmoid colon, and tapers as it reaches the descending colon and rectum at either end. This means the sigmoid is more stable at its ends, and is most flexible in the middle. The sigmoid region concludes the colon, and connects it to the rectum.

The rectum connects the sigmoid colon to the anal canal. The rectum measures 12cm (4.72in) in length, and contains two curves. The upper curve is convex backwards, while the lower curve is convex forwards. The rectum is not sacculated like the colon, but does contain several longitudinally folded layers. These folds mostly only exist when the rectum is contracted. There also exist three or four permanent 12mm folds that run transversely to the rectum. These folds overlap when the large intestine is empty, making them difficult to maneuver.

The terminal section of the large intestine is the anal canal. The anal canal averages between 2.5 and 4 cm (1- 1.57in) in length, and connects to the rectum at an angle. While it is not covered by the peritoneum, it is wrapped by the Sphincter and

supported by the Levatores. The anal lumen contains several vertical folds, which is caused by the mucous membrane folding over itself [13]. A diagram of the large intestine is shown below in Figure 2.1.

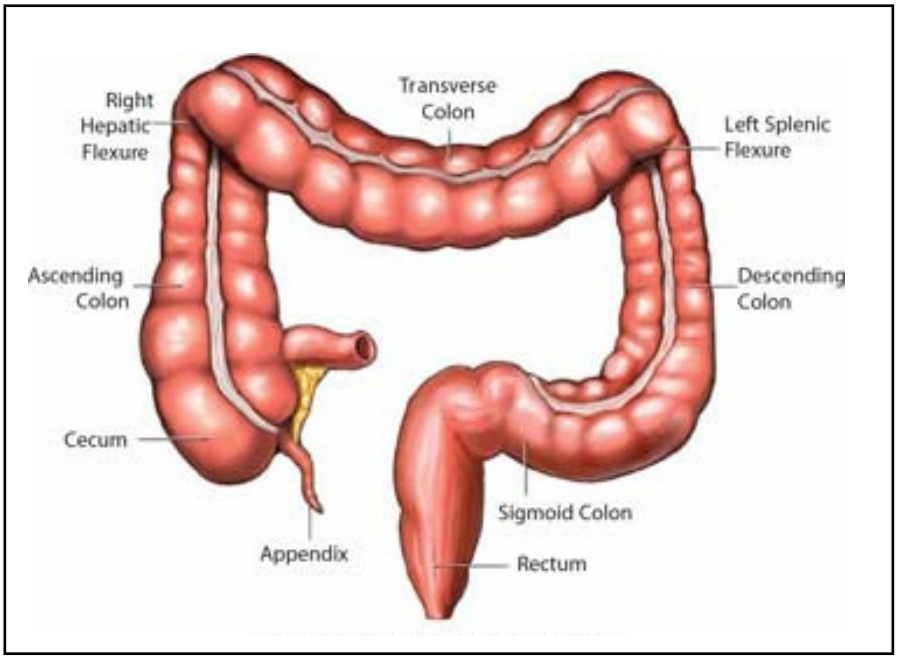

Figure 2.1. Anatomy of the Large Intestine [The Colon & Rectal Clinic of Ft. Lauderdale].

Radially, the large intestine is comprised of four coats, or layers: the serosa, the muscularis externa, the submucosa, and the mucosa. The outer most layer, the serosa, is derived from the peritoneum. The thickness of the serosa varies with each section of the large intestine. The cecum and transverse colon are completely covered by the serosa, while the ascending and descending colon are covered on their sides and front, but not on the majority of their posterior. The rectum has the serosa membrane only on its front side, but the anal canal does not possess the serosa layer at all.

The layer inside the serosa is the muscular layer, or muscularis externa. This layer can be described as muscular fibers that are situated longitudinally on the outer diameter of the layer and circularly on the inner diameter. In the cecum and colon, the longitudinal fibers measure 12mm and are separated into three flat bands, one on the back border of the large intestine, one on the front of the transverse colon, and one that runs along the sides of the ascending and descending colon, and under the transverse colon.

These bands are shorter in length than the other intestinal coats, and as a result, are responsible for the saccular contours that are present in the cecum and colon. These longitudinal muscular fibers are more spread out in the sigmoid colon, and completely envelope the rectum. To compliment the longitudinal fibers, the circular fibers, fill in the spaces created between each sacculi of the cecum and colon, which helps creates a smooth outer surface. These fibers form a thicker layer in the rectum, and make up the Sphincter in the anal canal.

The next layer, the submucosa, is responsible for holding the muscularis to the inner most layer, the mucosa. The mucosa layer is pale in color and smooth in texture, organized into many folds corresponding to the sacculi of the colon. In the rectum, the mucosa is darker in color and is connected more loosely by the submucosa. This mucosa also appears more vascular [13]. The open center of the colon is referred to as the lumen, and averages about 2 inches in diameter, but can vary anywhere from 1 to 3 inches. A diagram of the different intestinal layers, or coats, is shown in Figure 2.2.

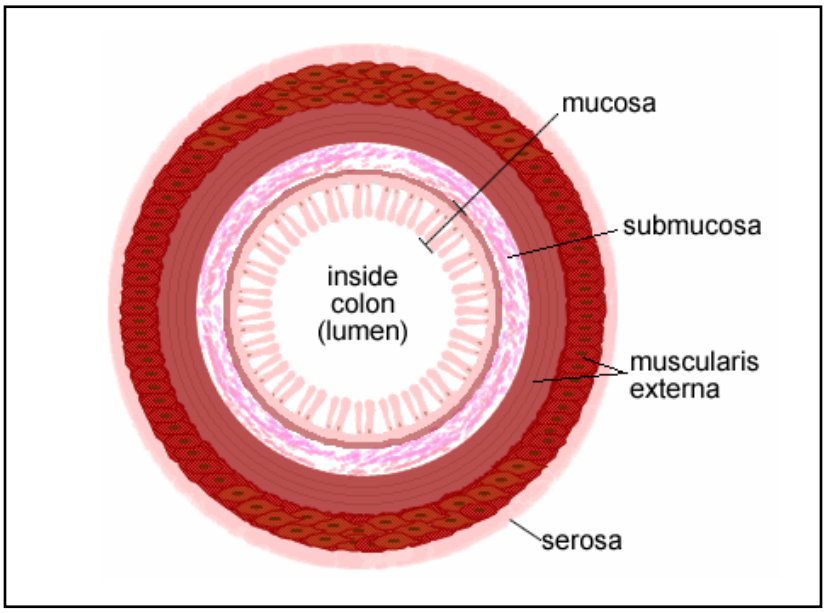

Figure 2.2. Coats of the large intestine [Myers, Donna].

2.1.1 Colorectal (Colon) Cancer

Colorectal cancer, or colon cancer, is caused by cancerous tumors that develop inside the large intestine. These tumors are mushroom-like growths, called polyps that form on the colon walls. These growths are usually benign, but can become malignant over time. Colon cancer occurs mostly in people over the age of 60, but a family history of the cancer can cause earlier development. There are many other risk factors that increase the chances of developing colon cancer: As with any type of cancer, having a history of cancer increases the chances of having it again. Individuals who have been previously diagnosed with colon cancer, as well as, women who have had ovarian cancer, breast cancer, or cancer in their uterus, have a high risk of developing colon cancer. One's heredity is also influential to the development of the disease. A higher chance of colon cancer is found when a family member has been diagnosed, especially when the disease was contracted before the age of 55. Studies show that individuals with FAP, or familial adenomatous polyposis, have a 100% chance of contracting colorectal cancer by the age of 40, if this inherited condition is left untreated. Lastly, those who smoke, have a poor diet, or do not exercise regularly, have shown an in increased risk of developing colon cancer. Colon cancer shows no noticeable symptoms in the early stages, making it very difficult to detect unless the proper screening tests are routinely performed [8].

2.2 Colorectal Screening Tests

There are various methods to screen for colorectal cancer, including the sigmoidoscopy, the fecal occult blood test (FOBT), the CT Colonography (Virtual Colonoscopy), and the colonoscopy. Colorectal screenings are the only way to detect and prevent colon cancer.

2.2.1 Sigmoidoscopy

The sigmoidoscopy uses a semi-rigid scope to explore only the sigmoid colon, about 60cm into the colon. The scope is equipped with a light, an instrument channel, a camera, and water/air injection tubes. This procedure induces moderate discomfort to the

patient, and can be performed in a physician's office. However, a sigmoidoscopy does not search the entire colon, missing approximately 50% of colon cancers. The scope is advanced through the colon by hand pushing the semi-rigid scope. The scope rubbing against the colon walls causes the colon to stretch and/or loop, inducing a range of visceral pain. The mobility of the sigmoid colon lends itself to looping as the scope is inserted. This looping is responsible for the majority of the pain felt during the exam. In addition to the discomfort cause by the scope, if the procedure is performed by an inexperienced doctor, the stretching and looping of the colon can increase the chances, though very low, of colon perforation, which requires immediate surgery for correction [1].

2.2.2 Fecal Occult Blood Test

The FOBT is a blood stool test, in which the patient can use an in-home kit to test for the existence of blood in the stool. If there is blood in the stool, however, this can mean that the tumors have already grown large, and a complete recovery is less likely. If any irregularities are found, a more invasive procedure will be required for further diagnosis. Also, only about 30% of colorectal cancer is detected by FOBT [1].

2.2.3 CT Colonography

The CT colonography, or Virtual colonoscopy, is a method in which the colon is expanded with pumped air, and x-rays are taken, giving a virtual image of the colon walls. While this technique is less invasive than a traditional colonoscopy, it is not as accurate as a colonoscopy and does not allow for therapeutic treatment, should a polyp be detected [2]. Virtual colonoscopies can miss up to 25% of large polyps (raised 10mm), and up to 90% of small polyps (raised less than 5mm) [4].

2.2.4 Colonoscopy

A colonoscopy is a procedure, similar to the sigmoidoscopy, in which a semi-rigid, cylindrical endoscope is inserted into the large intestine, via the anus. Like a sigmoid scope, a colonoscope is equipped with lights, a video camera, fluid supply tubes,

and an instrument tube, which provides a channel to insert various medical tools into the colon. These tools are used to perform biopsies, remove polyps, or inject solutions [3]. The scopes used for colonoscopies measure 1690mm (5.5ft) of working length, and are 11.5mm (0.45in) in diameter. The distal portion of the scope is flexible, with a bending capability of 180 degrees in the up/down direction, and 160 degrees in the left/right direction. The camera has an observation range between 3 and 100mm. The before-mentioned instrument channel measures 3.8mm (0.15in) in diameter [7]. A diagram of the front of an endoscope is shown in Figure 2.3.

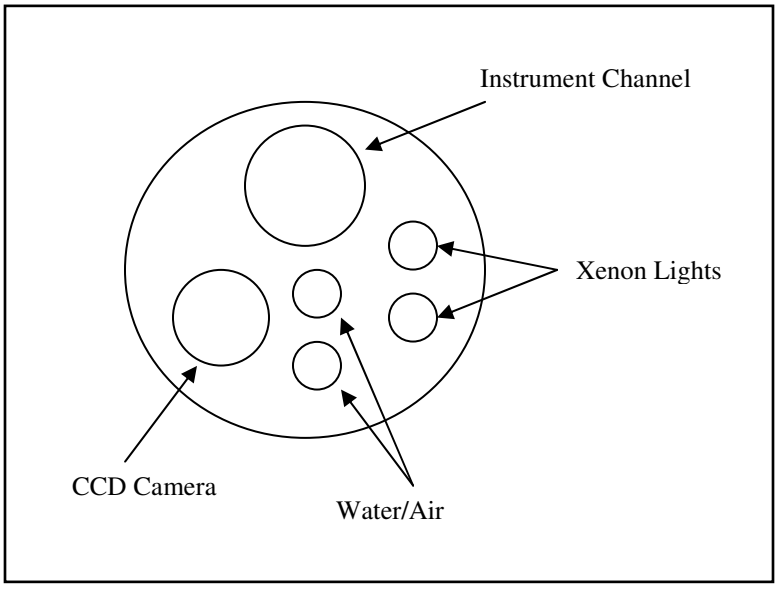

Figure 2.3. Front view of an endoscope.

A colonoscopy uses the described colonoscope to maneuver through the colon. The CCD camera is used to look for polyps growing on the colon walls. If a polyp is seen, a polypectomy is performed. Polypectomy snares are used to loop a wire around the polyp. Electricity is then applied to the wire, causing electrocautery, which simultaneously cuts through the polyp and cauterize the area. The polyp is then sucked out through the instrument channel for biopsy. Other therapeutic procedures can be performed during the colonoscopy, including tissue biopsies and fluid injections. Aside from polyps, colonoscopies are also used to detect colitis, a constant inflammation of the

colon, diverticulitis, pockets that form along the colon wall, bleeding lesions, and other bowel discomforts [3].

As with a sigmoidoscopy, similar drawbacks are encountered regarding the strain on the colon walls, and the need for sedation due to pain. The majority of the pain felt during the colonoscopy occurs in the sigmoid region of the colon, and is typically caused by either the force of the scope stretching the colon wall through looping, or distention, which is the result of air insufflation used to open any collapsed portions of the colon [10]. Looping is when the tip of the endoscope stalls, while the tail end of the scope continues to be fed into the body, causing the scope to curl over itself, bending the colon with it. This curling puts extra force on the colon wall. Depending on doctor and/or patient preference; various levels of sedation or general anesthesia are used.

While there is little information about the exact forces and pressure experienced during a colonoscopy, there is some experimental data available. To study the forces that exist between the scope and the colon walls, an endoscope was fitted with several piezoresistive force sensors prior to *in-vitro* experimentation. Electromagnetic imaging was used in conjunction with the force sensor to see how the position of the scope in the colon relates to the forces experienced. It was found that the maximum forces occurred in when the tip of the scope was stuck, causing the rest of the scope to loop. The looping of the bowels created larger forces. This looping most often occurs in the sigmoid and transverse section of the colon because of their length and pliability. The maximum force between any sections of the scope against the colon wall observed during the *in-vitro* experimentation was 12.73N, but all other peak values were less than 10N [10].

A separate experiment was performed on porcine bowel tissue to find the perforation force. The material property difference between porcine bowel tissue and human bowel tissue is negligible. The tissue was pinched between two 1.5mm hemispheres. The hemispheres were wired to measure the electrical resistance between them. Force was then applied to the tissue via the spheres until the resistance reached zero, indicating a perforation. The average perforation force of the large intestine of a pig is 13.5 ± 3.7N [11].

In addition to perforation of the colon by force, excessive pressure can also puncture the colon. To find the perforation pressure of the colon, young pigs were given

air and hydrostatic enemas. The pressure of the enema was increased until a perforation was detected via fluoroscopy. Fluoroscopy uses x-rays to produce an image on a fluorescent screen of internal body parts. Hydrostatic perforations occurred at 120mm Hg (2.32Psi), and air perforations occurred at 108mm Hg (2.09Psi) without the Valsalva maneuver and at 145mm Hg (2.8Psi) with the Valsalva maneuver [12].

The possibility of these complications lends the need for a skilled gastroenterologist to perform the exam. The chance of perforation during the procedure can range from 0.01% - 0.03% [18]. With the necessity of sedation for discomfort and a skilled gastroenterologist to perform the colonoscopy, the procedure can get expensive. According to *Thompson Medstat*, in 2004 the average price for a colonoscopy was $557, but ranged from $150-$1112 [9]. These prices have been greatly reduced by Medicare, and with inflation, the current prices are on the order of three times greater. In addition, the price can further increase should the patient require an extended hospital stay as a result of complications, or just the effects of the anesthesia. A summary of the prices for the various screening methods is given in Table 2.1.

Table 2.1. The Average Private-Sector Costs of Colon Cancer Screenings [9].

Screening Technique	Average Price per Procedure	Recommended Number of Over a 10-Year Period	Average Price Over a 10-year Interval
Colonoscopy	$557 (range $150 to $1,112)*	1	$557 (range $150 to $1,112)*
Flexible sigmoidoscopy; requires a follow-up colonoscopy if polyps are found	$174 (range $54 to $392)*	2	$348 (range $108 to $784)*
Double-contrast barium enema; may require follow-up colonoscopy	$126 (range $38 to $399)*	2	$252 (range $76 to $798)*
Fecal occult blood test (FOBT); may require follow-up colonoscopy	$7 (range $2 to $16)*	10	$70 (range $20 to $160)*
Combination of flexible sigmoidoscopy and FOBT	$181 (range $56 to $408)*	2/10	$418 (range $128 to $944)*

2.3 The assisted colonoscopy

There are many patented ideas for the development of the assisted colonoscopy. An assisted colonoscopy involves some type of robotic assistance, either externally pushing or pulling the scope through the colon, or internally transporting the scope through the colon. Many of these robotic devices require complex mechanisms or kinematically redundant designs for proper control. Below is a summary of the related patents with more detail into their design.

Device and method for advancing an endoscope through a body passage
***Meiri*, (4,207,872)**

Meiri uses an annular device to assist in moving the endoscope through a body lumen. The annular chamber is covered in small pockets. Fluid is then pushed into the chamber, causing the pockets to fill, and protrude out rearward. These rearward protrusions cause the device to move forward. As the fluid pressure is reduced, the protrusions retract. This process of increasing and decreasing the fluid pressure causes the protrusions to pulsate, creating a massaging motion with the annularly distributed protrusions [19]. Several views of the endoscope advancing device are shown in Figure 2.4.

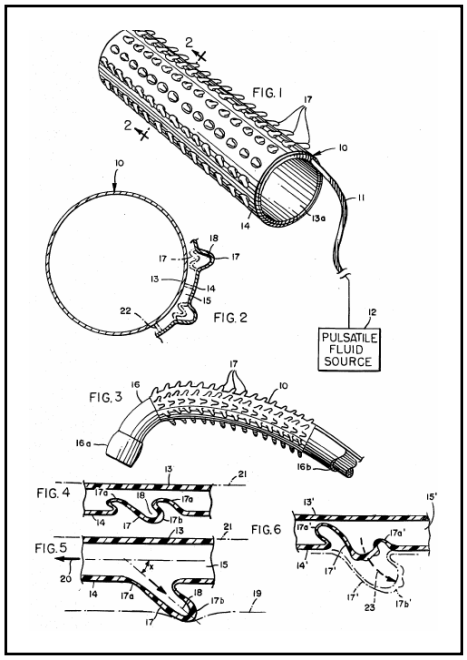

Figure 2.4. Endoscope advancing device [Meiri, et al].

Everting tube device with relative advance control
Leighton, (4,321,915)

Leighton has developed an apparatus capable of safely and effectively inserting and removing a flexible tube and/or endoscope into various body cavities. The device operates using everted tubes. The tubes are initially retracted inside a housing, external to the body. The tube is then extended by applying pressure to the housing chamber. As the tube extends, it carries the flexible tube, or scope, with it. By applying pressure, or by creating a vacuum, the scope can be extended or contracted. This allows sensitive control of the scope as it is guided through the body cavity [20]. A side view of the device is shown in Figure 2.5.

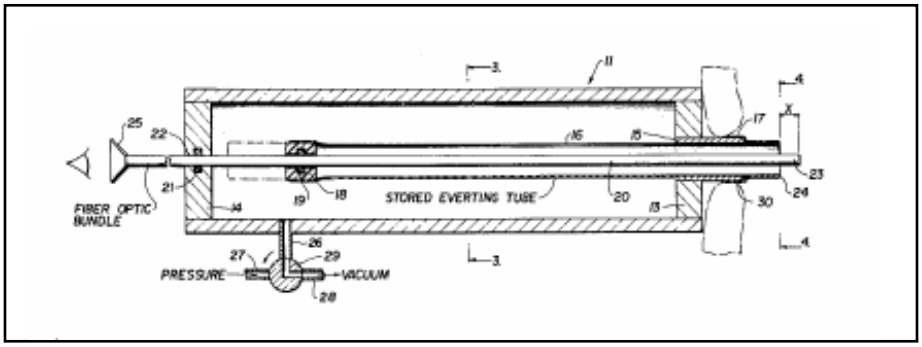

Figure 2.5. Side view of everting tube device [Leighton, et al].

Self-propelled colonoscope and cleaning process thereof
***Takada*, (4,561,427), (5,562,601), (6,224,544)**

Takada uses an endless belt design to move the colonoscope through the colon. A multitude of endless belts are positioned inside a flexible tube. The flexible tube is inserted into the colon, and gears engage the endless belts. The belts rotate, moving the colonoscope through the colon. One of the main problems with this design is the large number of rollers, guide pipes, and belts that have to be cleaned after every use. This design is both complex and costly [21]. A section view of the apparatus is shown in Figure 2.6.

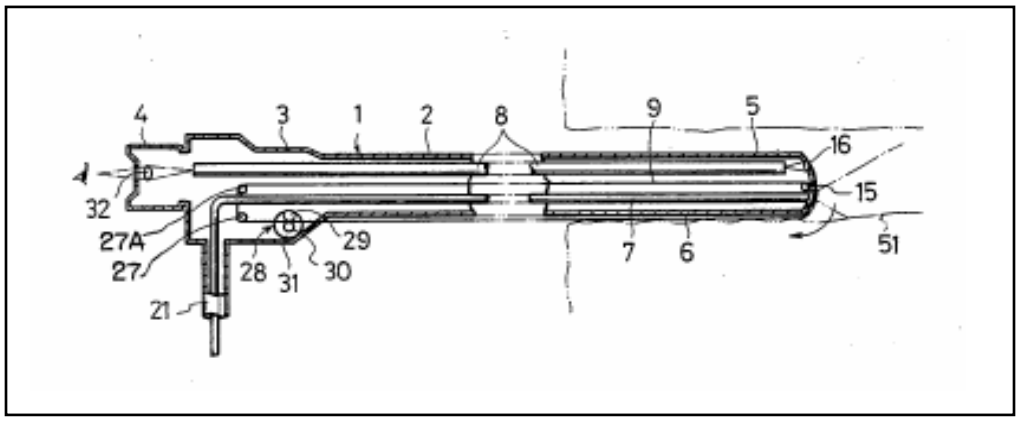

Figure 2.6. Section view of the self-propelled colonoscope [Takada, et al].

Medical instruments with aid to introduction
***Kramann*, (4,615,331)**

Kramann has designed an elongating instrument used to examine body cavities. The device uses a flexible inverting, tubular structure positioned inside a pipe. The endoscope fits in the middle of these folding tubular layers. The inverted tubes are extended through pressure connectors fitted on the sides of the pipe. Fluid is pushed through the pressure connectors inside the pipe, causing the folds to invert, and therefore, extend. The extending tubes push the scope forward, inserting it into the body cavities [22]. A side view of the design is shown in Figure 2.7.

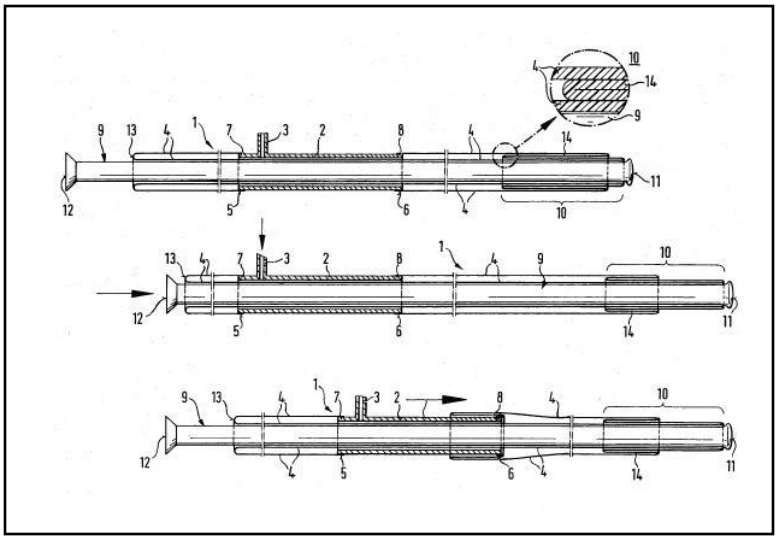

Figure 2.7. Side view of the inverted tube device [Kramann, et al].

Medical apparatus having inflatable cuffs and a middle expandable section
***Krasner*, (4,676,228)**

Krasner describes a device comprised of a flexible sheath that fits coaxially on an endoscopic instrument. The ends of the device consist of cuffs which slide axially over the scope and are capable of inflating, deflating, and clamping to the endoscope. The middle section of the device can extend and retract. The movement created by the cuffs is similar to that of an inchworm; first, the proximal cuff clamps to the scope and the distal cuff inflates to contact the lumen. The middle section now retracts, pulling the proximal cuff toward the distal cuff, moving the scope with it. Now, the proximal cuff inflates to contact the lumen, while the distal cuff clamps to the scope. The middle section extends, pushing the distal cuff and the scope away for the proximal clamp. This process repeats, moving the scope through the lumen [23]. A drawing of the device is shown in Figure 2.8.

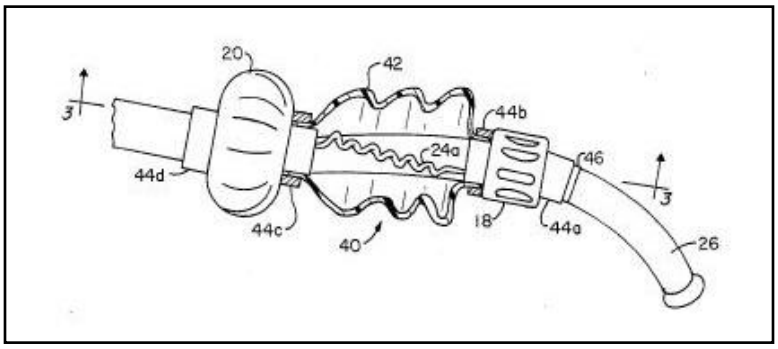

Figure 2.8. Inflatable Cuff Apparatus [Krasner, et al].

Lumen traversing device
Ortiz, (5,398,670)

Ortiz introduces another inchworm-like design, similar to that of Krasner, with the main difference being that the endoscopic instrument is built into Ortiz's device. In this way, there is no clamping to an axially central tube. Instead, the distal clamp engages the lumen wall, and the middle section retracts, pulling the proximal clamp forward. Then the proximal end engages the lumen wall, while the distal clamp disengages the lumen wall. The middle section extends, pushing the distal portion forward, further into the lumen. This process repeats to move the device through the

lumen. The distal portion is equipped with the means to deliver a fluid, i.e. water or air, as well as administer therapy in the form of light, acoustic, electric, medication, etc. This combines the scope and means of conveyance into one apparatus [24]. A sketch of the design is shown in Figure 2.9.

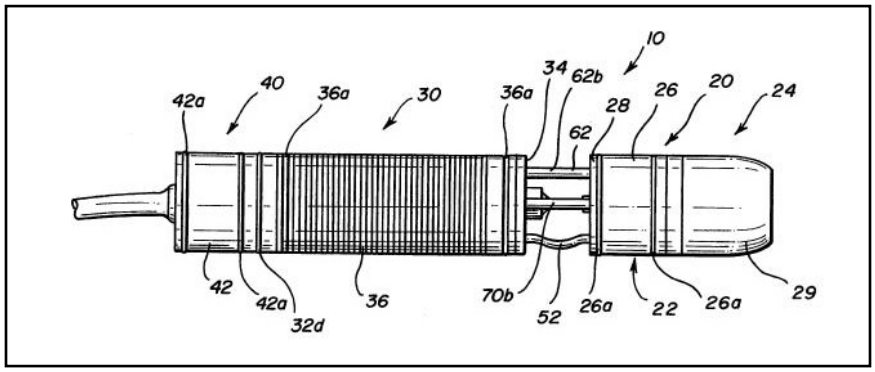

Figure 2.9. Lumen traversing device [Ortiz, et al].

Robotic endoscopy
***Grundfest*, (5,337,732), (5,662,587)**

Grundfest uses a kinematically redundant device to induce movement similar to that of an inchworm, snake, or combination of the two. The segments are angularly and axially actuated in conjunction with an engaging and disengaging of the lumen walls, creating a wave-like motion, to produce forward movement. The lead segment includes the capabilities of an endoscope, so no additional scope is necessary [25]. A drawing of the robot is shown in Figure 2.10.

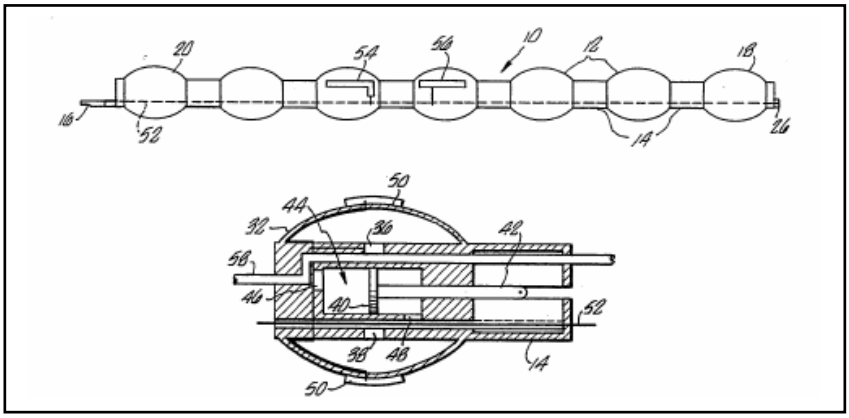

Figure 2.10. Robotic endoscopy [Grundfest, et al].

Inflatable member for an endoscope sheath
Oneda, Katsumi*, (*20020143237)

For this device, a sheath is positioned over an insertion tube, forming a toroidal shape. There are at least two flexible, radially expandable pockets attached to the sheath. These pockets are inflated and deflated methodically through the inner tube producing a peristaltic movement of the device. The insertion tube has an inner lumen, which houses the endoscope during operation [26]. A sketch of this device is shown in Figure 2.11. The top image illustrates the pocket that forms within the sheath, and the bottom image provides a close-up of the pocket.

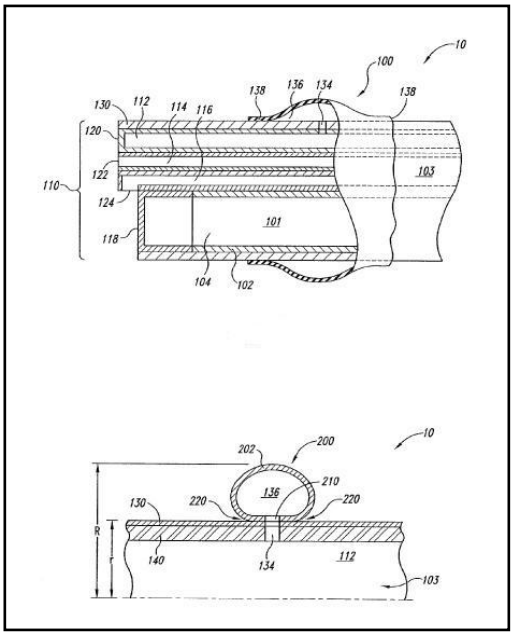

Figure 2.11. Section view of inflatable member device [Oneda, Katsumi, et al].

Chapter 3

Design

3.1 Requirements

To achieve the research goals described in Chapter 1, several design requirements must be met. The main purpose for the Endoscopic Propulsion System is to provide an assistive locomotion for a colonoscope. In addition to the primary propulsion goal, safety, effectiveness, ease of use, and affordability must also coexist.

Most importantly, the EPS needs to be safe. One of the safety concerns with the unassisted colonoscopy is the strain that the scope puts on the colon walls while being pushed through the lumen, specifically, around corners. The EPS is designed to contact the lumen around its entire circumference to enable constant, equally distributed force to be applied to the luminal walls as the EPS moves through the colon. The colon walls will not experience a greater force in one area over another, eliminating the possibility of damaging the colon, and greatly decreasing the discomfort felt from the colonoscope pushing into and/or rubbing against the colon walls either directly or via looping. The forces of the EPS against the colon will not exceed 10N, and the pressure will not exceed 2psi. Aside from the procedural safety, the EPS will be made out of non-immunogenic materials to ensure that the body does not have any immune responses to the foreign object, further decreasing any complications during the procedure.

The EPS will provide the proper assistance needed to guide the colonoscope through the colon. The EPS will maintain constant traction against the colon walls,

providing a smooth observation process via the CCD camera. If the observation process is more controlled, there is little chance of the scope jumping sections due to any stretch induced recoil of the lining, thus decreasing observational deficiencies.

Another important requirement to enable any physician to perform the procedure is the user interface. The safety and effectiveness of the device have already been covered, so the last part is to facilitate easy operation. The EPS will be easily controllable in both the forward and reverse direction. This control will work in conjunction with the 4in flexible tip of the scope to improve steering and navigation, thus simplifying the maneuverability of the colonoscope.

One of the main reasons colon screening is neglected among Americans, is the high cost of the procedure. So far, this cost has been greatly reduced by making the procedure more comfortable, eliminating the need for the sedation, as well as; removing the need for highly skilled gastroenterologists to navigate the scope through the colon. The final variable to the cost equation is the ease of manufacturability. The EPS will have as few parts as possible to enable easy production out of inexpensive materials, as the EPS will be disposable. Making the EPS disposable saves on the expensive cleaning process of intricate parts, and making the manufacturability less expensive encourages this disposability. In addition, the EPS will attach directly to existing colonoscopes so that there is no extra cost in the design and purchase of compatible scopes.

3.2 Constraints

The geometry of the colon requires that specific design constraints be set. The maximum diameter of the rectum is approximately 2.5cm (1.1in). The diameter once inside the sigmoid colon expands to about 5cm (2in), and then varies between 2 and 3 inches in the remaining sections of the colon. As explained in Chapter 2, the colon contains four turns of at least 90 degrees, though the flexibility of the colon dulls the severity of the turns.

To accommodate these physical characteristics, the EPS is constrained to 2.5cm in diameter during insertion, but with expansion capabilities to no more than 7cm (2.75in) once inserted. These dimensions will allow for easy insertion and constant

traction post-insertion. The controllable, flexible segment of a colonoscope, which guides the scope around turns, measures 10cm. Using the length of the controllable tip as a guide, the EPS will measure no more than 10cm (3.9in) in total length. The EPS will be completely flexible except for a 2.5cm rigid section in the middle. To ensure compatibility with existing scopes, the lumen diameter of the device will measure 1.25cm (~0.5in). The EPS will mount just behind the directionally controllable segment of the colonoscope. The EPS will fasten to the scope in a manner that enables a quick and easy connect and disconnect.

To ensure there is no chance of colon perforation by applying too much pressure, the maximum pressure between the EPS and the colon walls will not exceed 2psi. The maximum force between the EPS and the colon will be less than 10N, eliminating the possibility of perforation due to excessive force.

3.3 Initial Design

The initial design for the Endoscopic Propulsion System stems from patent application 20060270901, by gastroenterologist, Dr. M. Jonathan Bern, November 30, 2006. In this document, the preliminary design for the EPS is explain along with several detailed drawings.

The motivation behind this initial design was to simplify the existing robotic endoscopes. As described by the patents of previous colonoscopy robots, the majority of the designs involve: multiple interacting segments, a complex array of sensors requiring intricate controls, and are expensive to manufacture. This initial design chooses to concentrate on minimum parts, easy manufacturability, and simple controls. The EPS is also designed to be disposable, to save on cleaning costs.

Dr. Jonathan Bern's patented EPS design includes descriptions of many possible variations. Here, the focus is on the version that best meets the customer needs and design requirements for this project. The complete text of the patent application is available in Appendix A.

The EPS uses an external motor to provide variable torque to the EPS robot to control the speed and direction of the device. The motor is connected to a drive shaft, which is sheathed to the endoscope, runs its length, and is attached to the EPS. This drive

shaft is connected to a smaller drive gear, which contacts a larger drive gear, both of which are located within the EPS assembly.

The large drive gear engages a cylinder with a helical groove that spans the length of the EPS. This helical groove then interacts with an annular invaginating balloon that also runs the length of the EPS. The balloon is equipped with four rows of "T" shaped protrusions spaced 90 degrees apart. The motion of the helix will cause a rotation of the balloon about a circular axis. After insertion into an organ lumen, the balloon can be inflated by means of a cannula with a pressure-sensing device and a syringe. This inflation will ensure maximum surface area contact between the organ walls and the balloon. The inflation and deflations is based on either a predetermined volume, or a predetermined pressure. Once the balloon is at its proper inflation, the cannula and pressure-sensing bulb are removed, and a self-sealing valve is used to maintain the volume/pressure of the balloon.

The interaction between the balloon and the luminal side of the organ wall is similar to that of a rolling tire or tank tread. As the worm rotates, it engages the "T-shaped" protrusions, which invaginates the balloon, producing the dynamic rolling motion to move the endoscope through the organ lumen.

This initial design provided an excellent model of the desired concept of the device; however, there were several limitations that needed to be addressed. The flexibility of this design was limited as the rigid internal drive mechanisms ran the entire length of the EPS, which restricted its ability to maneuver turns. Also, while the number of parts were minimized, they were difficult to manufacture. To create the invaginating balloon, an injection molding process needed to be used. Also, the body of the balloon and the protrusions were to be made out of different materials. In addition, the concept of whole skin locomotion did not allow for a continuously controlled internal pressure. In this initial design, the balloon would inflate after insertion into the colon, and then the inflation device was removed, so the balloon could roll. The volume of the balloon could no longer be adjusted to conform to the varying diameters of the colon. After several revisions, the design was modified to better incorporate all of the desired design requirements.

3.4 Final Design

After much iteration, a final design for the device was developed. This design encompasses all the requirements and constraints previously set to ensure a safe, effective, and affordable colonoscopy assisting device. The Endoscopic Propulsion System is designed with a simple drive mechanism, and very few total parts. The final EPS is a 4 inch long, 1 to +2 inch diameter cylindrical ellipsoid. The details into the design and operation of the EPS will be discussed.

The final design description begins with an inner cylinder. The inner cylinder of the device has a 0.5 inch lumen, which will accommodate most modern colonosopes, and runs the length of the rigid internal section of the EPS. An isometric drawing of the inner cylinder is shown in Figure 3.1.

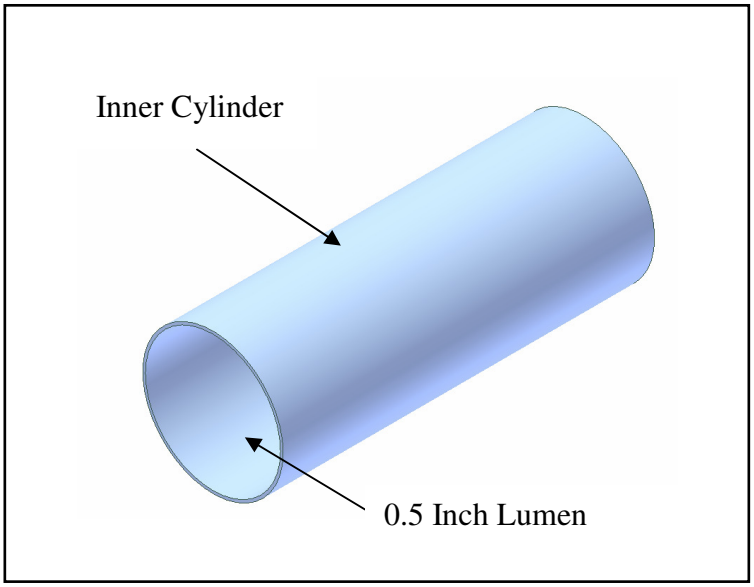

Figure 3.1. Isometric drawing of inner cylinder.

A central worm rotates about the inner cylinder. The worm is a single-start, helical gear that translates axial rotational into rotation that is transverse to the neutral axis of the worm. The proximal end of the worm has a built-in spur gear, called the worm spur. This worm spur is power by a smaller drive gear that is mounted on the outer edge of the worm. The drive gear is connected to a flexible drive shaft, and the torque applied to the drive shaft is controlled by an external motor. The motor has forward and

reverse control, and operates at a very low speed. The drive shaft runs from the drive gear, along the length of the scope, to the external motor. The worm and drive train are shown in Figure 3.2.

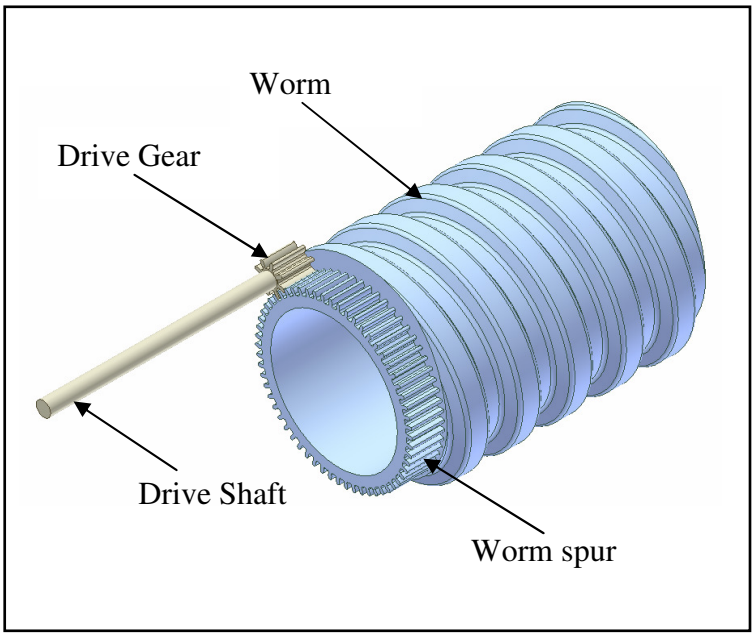

Figure 3.2. Isometric drawing of worm with drive train.

As the worm rotates, it engages the four drive belts, causing them to rotate simultaneously, thus giving locomotion to the device. The belts are singled-sided, and have trapezoid shaped teeth. The EPS is equipped with four belts, spaced 90 degrees apart. Each belt rotates longitudinally around a cylindrical shell giving equal driving force on all sides of the EPS. The cylindrical shell is a semi-rigid feature used to guide the belts about the EPS. The shell attaches to the outside of an outer cylinder, but extends past the cylinder at both ends, making the shell three times longer than the outer cylinder. The outer cylinder is further explained later in the chapter. Inside the shell is a small balloon that can be inflated and deflated. This balloon attached to the exterior surface of the outer cylinder at its middle, and does not extend past the ends of the cylinder. When inflated, the balloon expands, increasing the diameter of the cylindrical shell to the operating shape of the EPS. The belts, balloon, and cylindrical shell are shown in Figure 3.3.

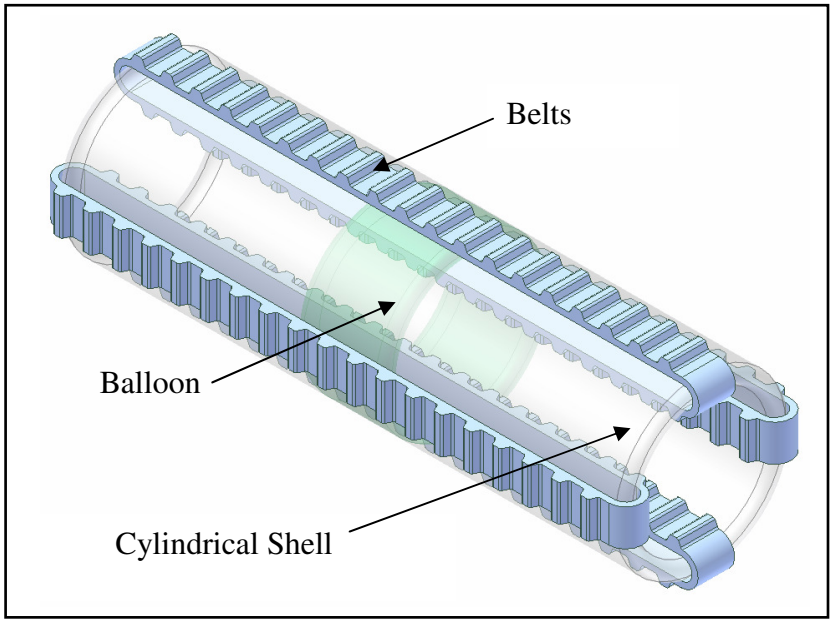

Figure 3.3. Isometric drawing of shell and balloon with drive belts.

The belts engage the worm from within the outer cylinder. The outer cylinder fits around the outside of the worm, and within the lumen of the balloon and shell. Recesses in the interior of the cylinder guide the belts in a straight path through the cylinder as they are engaged by the worm. In addition to the worm, the outer cylinder also houses the worm spur and the drive gear. There is a semi-circular cutout in the interior surface of the cylinder to give the drive gear more space to spin. This keeps the entire drive mechanism of the EPS secured in a compact area. The outer cylinder is equipped with a fluid supply channel. The channel leads from the proximal end of the cylinder, to the middle of the cylinder where it opens on the exterior surface, directing the fluid into the attached balloon. A fluid supply tube connects an external fluid source to the channel on the cylinder. Fluid can then be injected or aspirated, causing the balloon to inflate or deflate as needed. This allows for the diameter of the EPS to continuously be adjusted to the changing diameters of the colon, maintaining constant contact between the drive belts and the colon walls. Figure 3.4 shows the outer cylinder integrated with the internal parts.

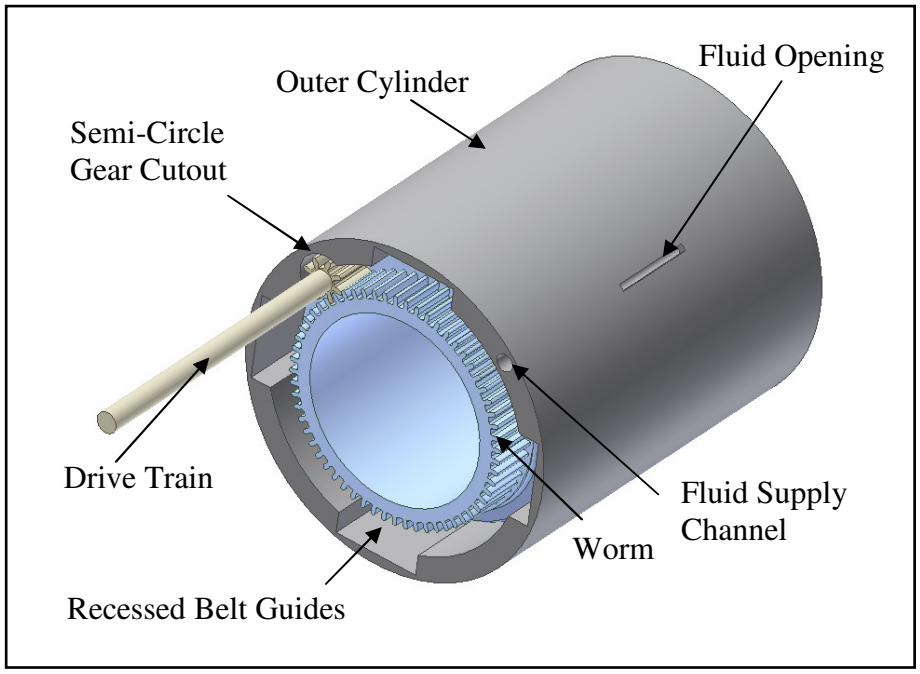

Figure 3.4. Isometric drawing of the outer cylinder and internal parts.

The EPS attaches to the colonoscope, just behind the manually controllable tip of the scope. Two clamps at either end of the EPS hold the device to the scope. The designs of the clamps are identical, except that the proximal clamp has holes cut out for the drive shaft and the fluid supply tube. The clamps also have four cut-outs at 90 degree intervals so that once secured to the outer cylinder, the drive belts can pass through them. 3-D isometric models of the proximal and distal EPS clamps are shown in Figure 3.5.

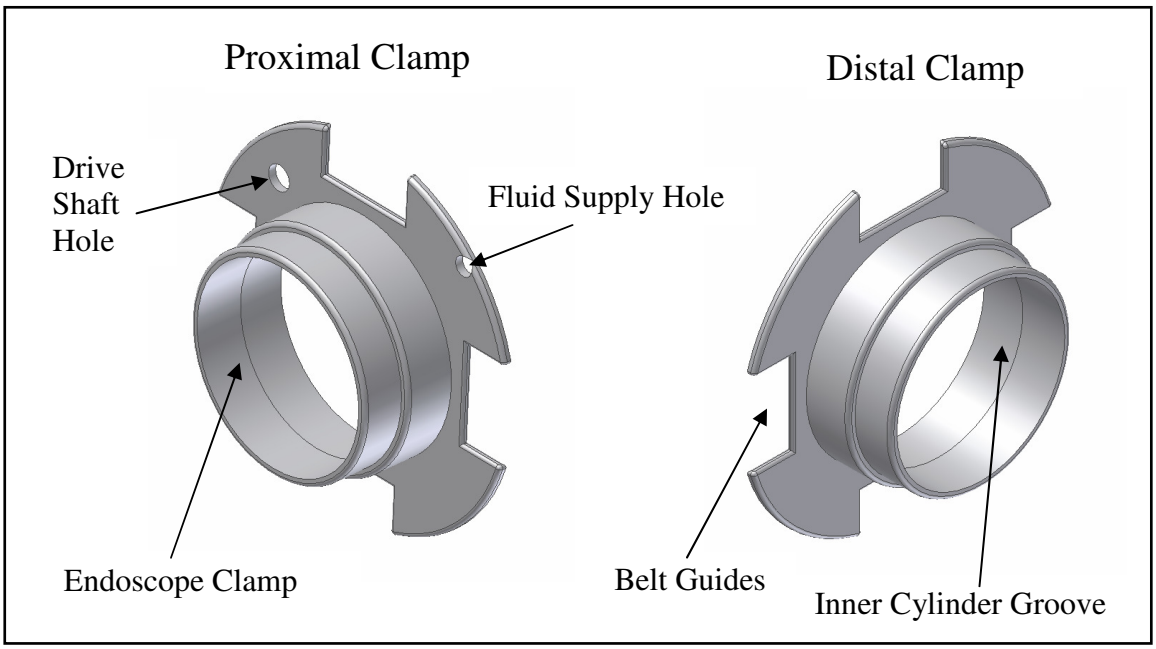

Figure 3.5. The proximal and distal EPS clamps.

In addition to securing the EPS to the scope, the clamps are also designed to hold the entire EPS together. The length of the inner cylinder is designed in conjunction with the end clamps to provide accurate spacing between the parts internal to the outer cylinder. The inner cylinder extends beyond the worm and outer cylinder at either side. The exposed ends slide into recesses on either clamp. The clamps then butt up against the outer cylinder, holding the inner cylinder, outer cylinder, worm, and drive train securely between them. A CAD model showing the integration of these parts is shown in Figure 3.6.

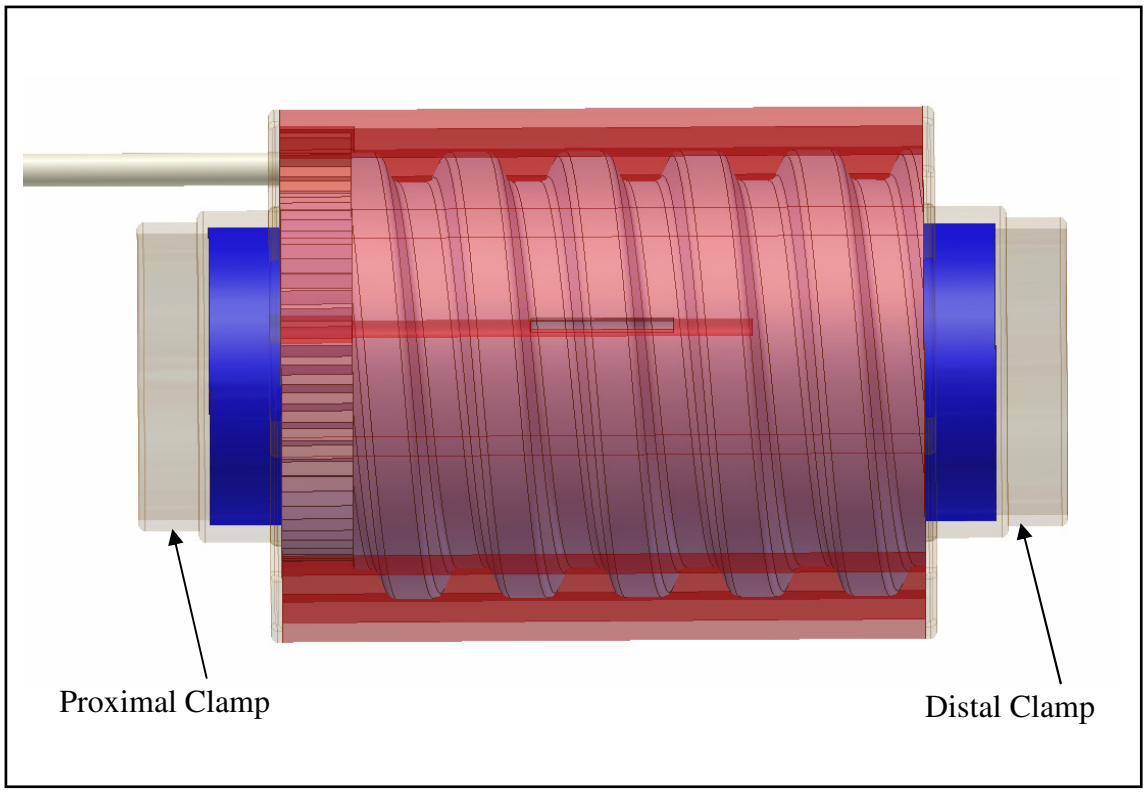

Figure 3.6. This is a side view of the rigid portion of the EPS. The outer cylinder, proximal, and distal clamps are shown transparent so the internal interaction between each of the parts can be viewed.

There are two tethers that run from the EPS down the length of the scope; one is a fluid supply tube, and the other is a drive shaft. Both the supply tube and the drive shaft are flexible and can bend with the endoscope. They are tightly sheathed to the scope, so as not to interfere with their environment. CAD drawings of the final design depicted in its semi-deflated state are shown in the figures below. First, an isometric view of the EPS is given in Figure 3.7.

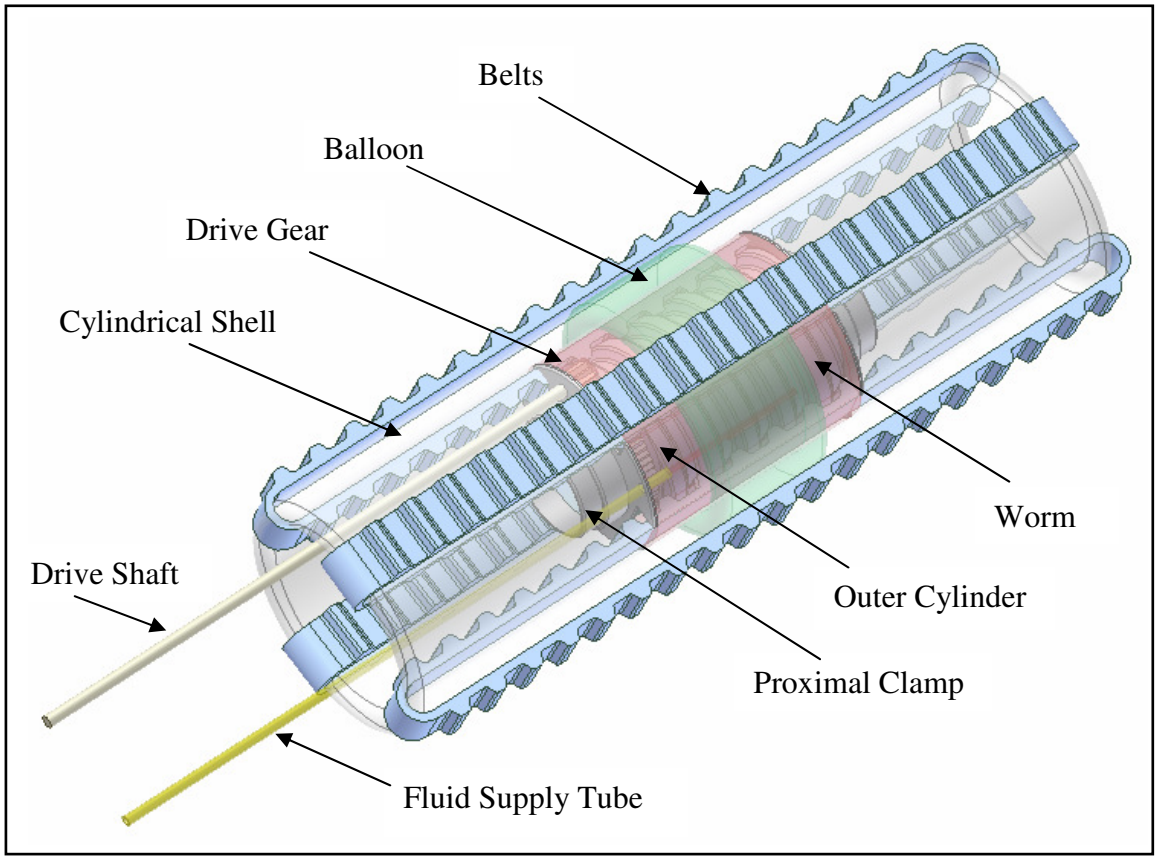

Figure 3.7. Isometric view of the deflated Endoscope Propulsion System.

Next, a front view of the EPS shows how the parts fit concentrically together. In this case the proximal clamp is shown as a transparent material so the gears are viewable. This view shows the EPS in a semi-deflated state. When completely deflated, the belts are flush with the outside of the outer cylinder. Also, from the front view, the balloon and the cylindrical shell are indistinguishable. This front view is shown below in Figure 3.8.

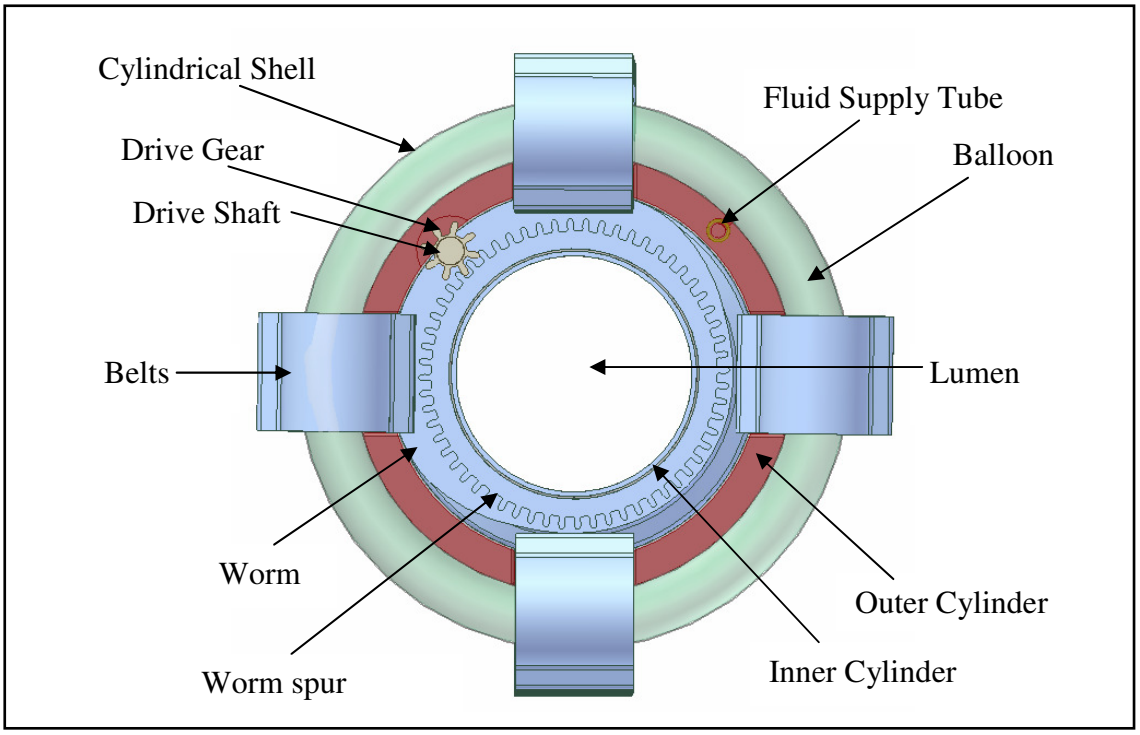

Figure 3.8. Front view of deflated Endoscopic Propulsion System.

Finally, the side view of the EPS shows how the belt teeth interact with the worm. The valve that allows the fluid to enter the balloon can also be seen, and length proportions of the different parts are viewable, as well. The side view of the Endoscopic Propulsion System is shown in Figure 3.9. Finally, an exploded view of the EPS is shown in Figure 3.10. This figure uses an isometric view to show how each of the parts fit together. In this case, the shell, balloon, and drive belts are shown already together.

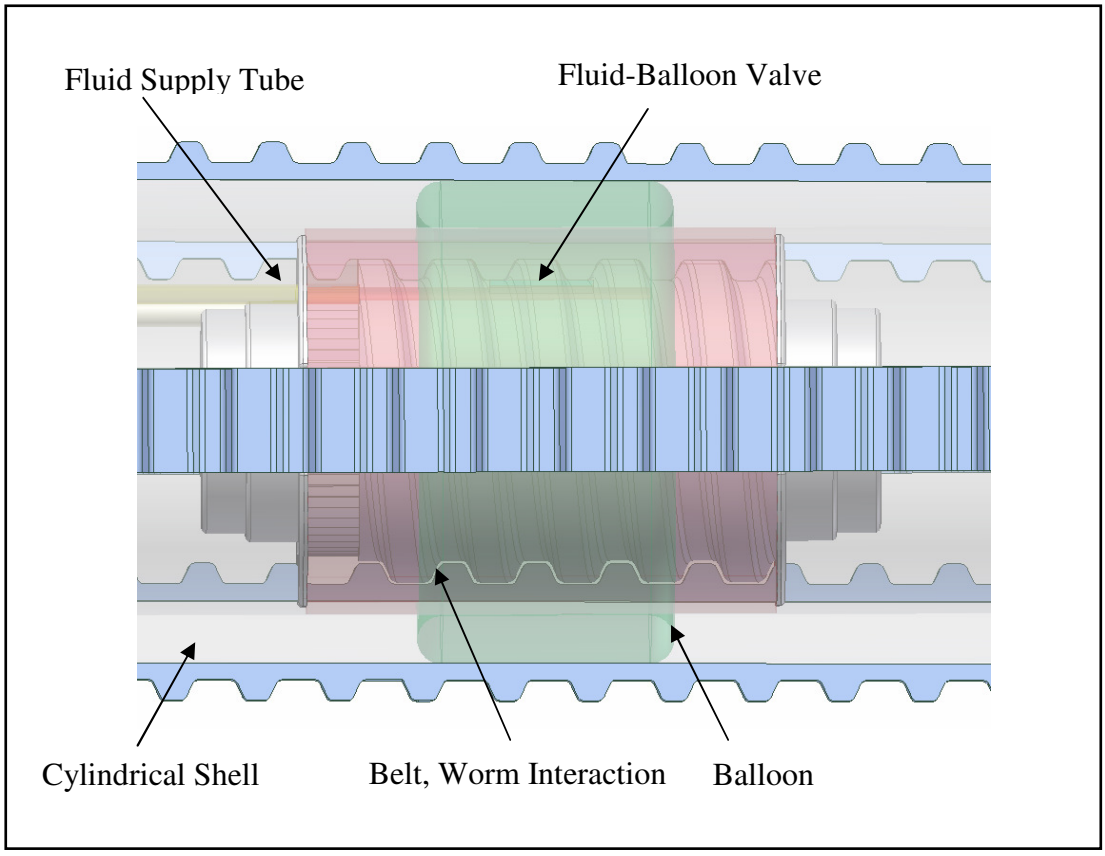

Figure 3.9. Side view of deflated Endoscopic Propulsion System.

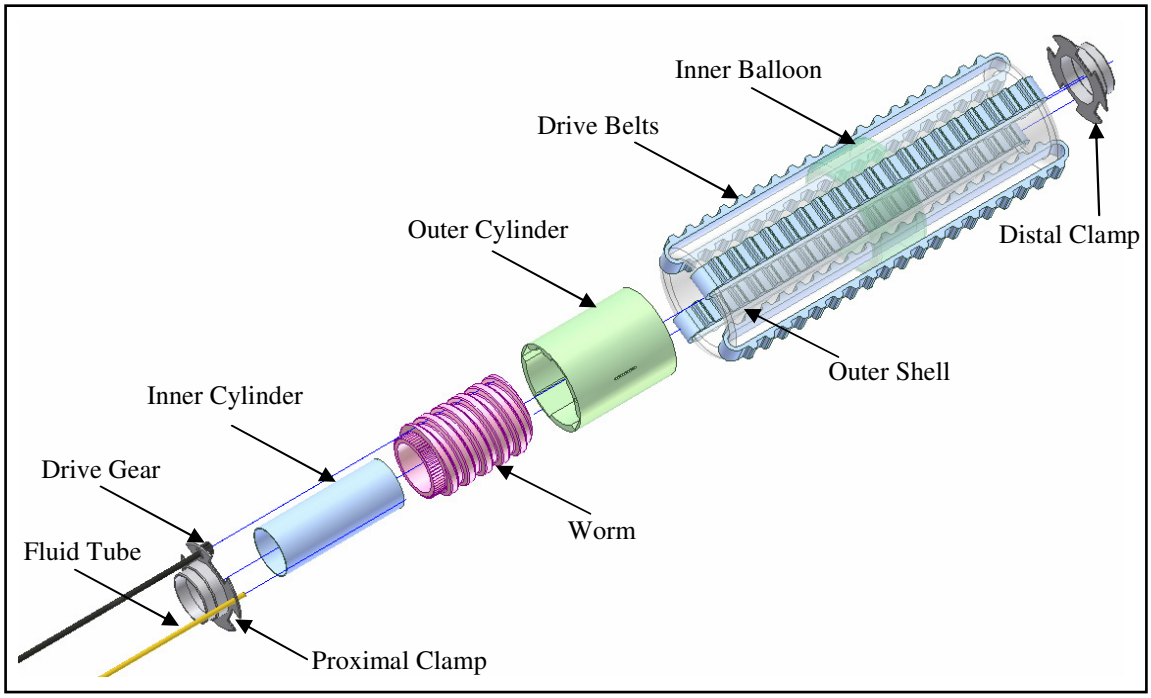

Figure 3.10. Exploded view of deflated Endoscopic Propulsion System.

3.4.1 Parts with Dimensions

The EPS can be broken up into nine main parts: the inner cylinder, the worm, the drive gear, the outer cylinder, the balloon, the cylindrical shell, the belts, the proximal clamp, and the distal clamp. The design details and dimensions of each part are explained the following section.

The inner cylinder of the EPS measures 1.375 inches long, has an inner diameter of 0.5 inches, and has an outer diameter of 0.52 inches. It is made out of a plastic polymer to reduce weight and cost, as well as, provide an FDA approved material for insertion into the body. The main function of the inner cylinder is to provide a central axel for the worm to rotate about. The inner cylinder also creates the necessary spacing between the proximal and distal clamps, which will be explained in further detail later. A part drawing with dimensions of the inner cylinder is shown in Figure 3.11.

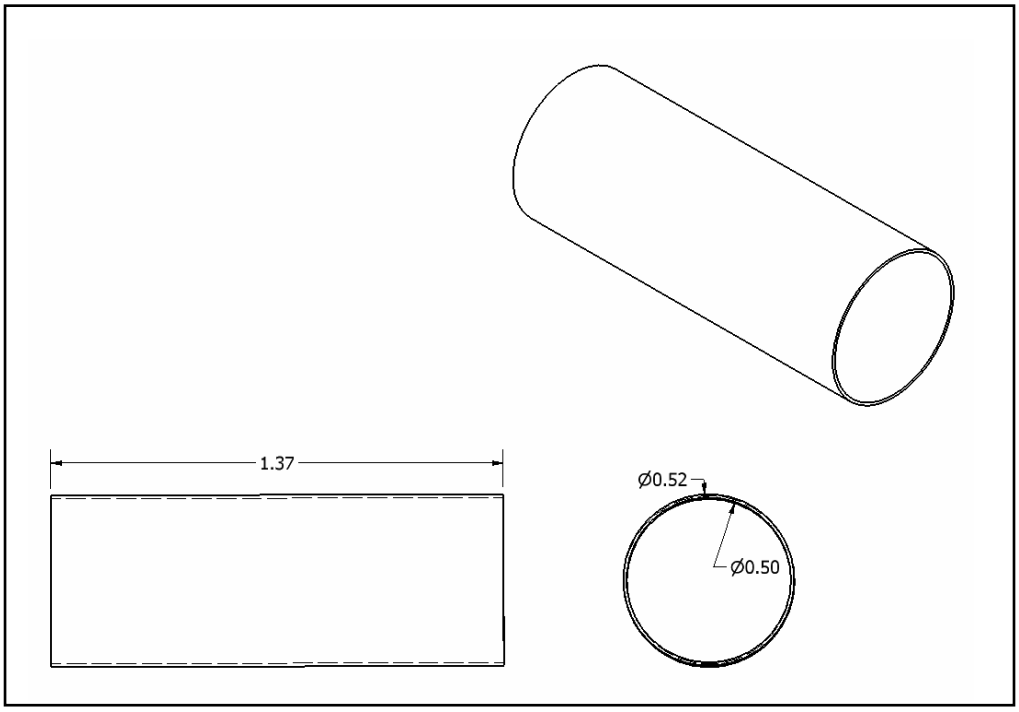

Figure 3.11. Part drawing of the inner cylinder.

The worm is the central helical gear in the EPS. It engages the drive belts, which propel the system. The worm has an inner diameter of 0.53 inches, slightly larger than the outer diameter of the inner cylinder, allowing it to use the cylinder as an axel. The

outer diameter of the worm is 0.79 inches, and is 1 inch in length. The worm has a single-start thread with a 0.2 inch pitch, and a depth of 0.53 inches designed to engage the trapezoid teeth of the drive belts. At the proximal end of the worm is a spur gear, which will be referred to as the worm spur. The worm spur has a diametral pitch of 96, with 60 teeth. The outside diameter of the worm spur is 0.655 inches, and the inner diameter is the same as that of the worm at 0.53 inches. The width of the gear is 0.125 inches, making the total length of this part 1.125 inches. The worm is made of the same light-weight, low friction coefficient, plastic polymer as the inner cylinder. A part drawing with dimensions of the worm with the integrated spur gear is shown below in Figure 3.12.

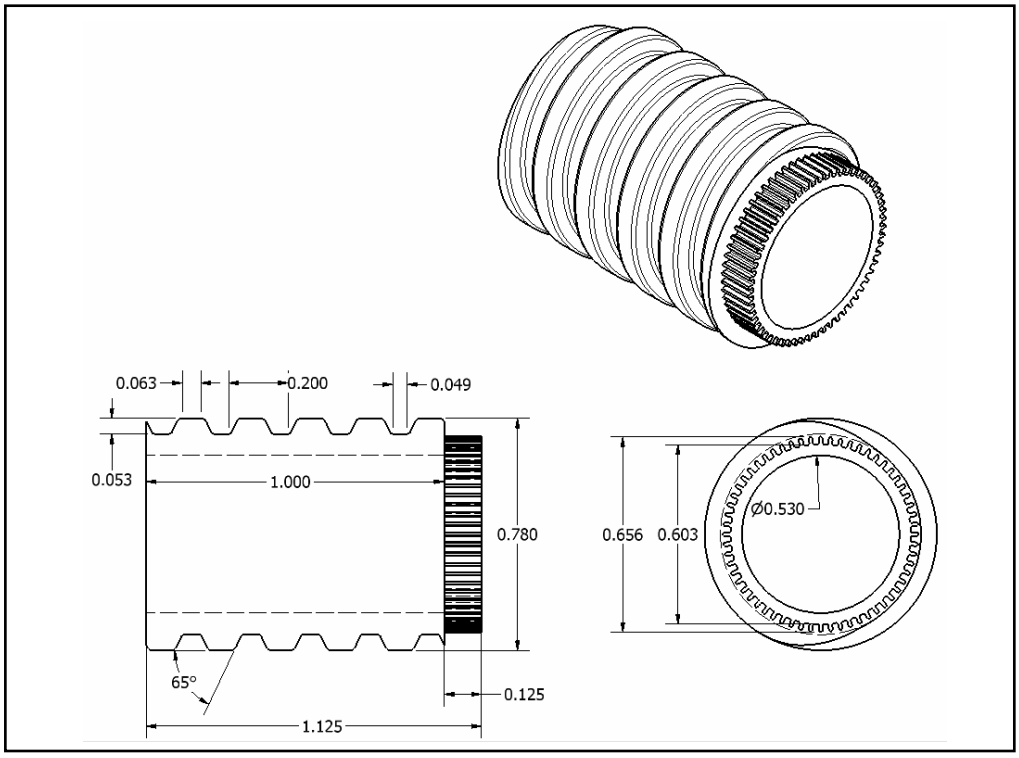

Figure 3.12. Part drawing of the worm and worm spur.

The worm is powered by a drive gear that interacts with the worm spur. The drive gear has a diametral pitch of 96, with 10 teeth. The outer and inner diameters of the drive gear are 0.125 inches and 0.06 inches, respectively, with a width of 0.125 inches. The gear must be small enough to fit between the outside of the worm spur and the inside of the outer cylinder. The drive gear is powered by a flexible drive shaft. The flexible

drive shaft has an outer diameter of 0.06 inches, and runs the length of the scope to attach to an external motor. A part drawing with dimensions of the drive gear is given in Figure 3.13.

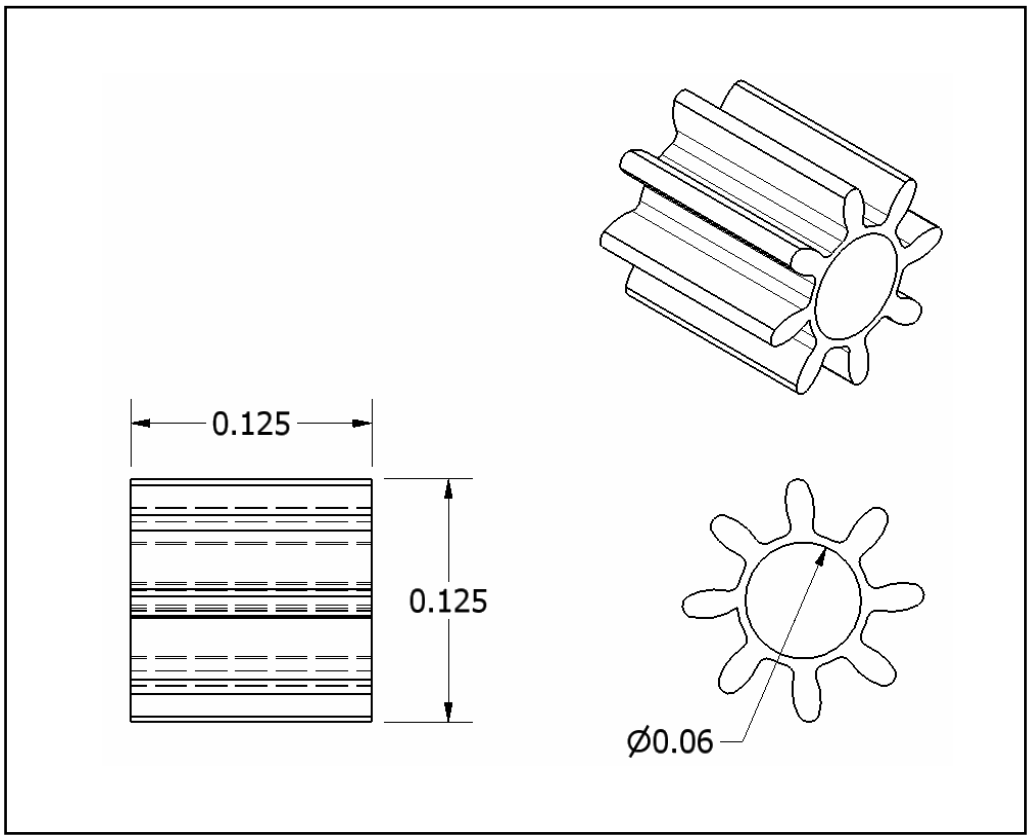

Figure 3.13. Part drawing of the drive gear.

The outer cylinder of the EPS has many functions. The interior surface has four recessed belts tracks, which guide the belts through the center portion of the EPS as they are engaged by the worm. These belt tracks extend the length of the cylinder, and the recessions measure 0.25 inches wide, and are 0.04 inches deep. The outer cylinder is also equipped with an air channel in the outer rim that attaches to the fluid supply tube. The entrance of air channel is 0.05 inch diameter and 0.125 inch long, but then reduces to a diameter of 0.03125 inches. Half way down the length of the cylinder, there is a 0.25 by 0.02 inch rectangular opening. This opening feeds the fluid from the supply tube to the inner balloon. The inner rim of the cylinder has a semi-circular cut out to give space for the drive gear to turn. The cylinder has an inner diameter of 0.79 inches, allowing the

worm to fit just inside. This close fit is essential to keeping the belts in their guides, while being properly engaged by the worm. The total required diameter of the EPS is 1.125 inches deflated. The outer diameter of the cylinder is 0.93 inches, leaving 0.0975 inches on all sides for the thickness of the balloon and the belts. A part drawing with dimensions of the outer cylinder is given in Figure 3.14.

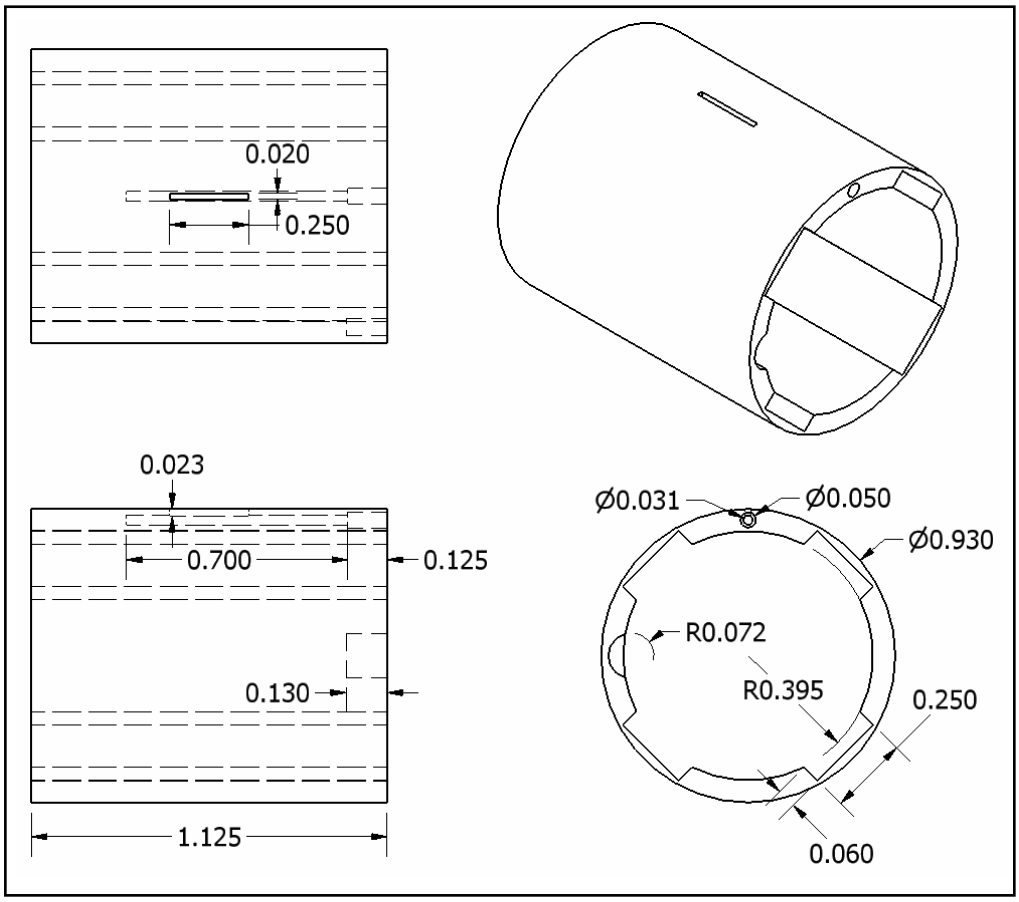

Figure 3.14. Part drawing of the outer cylinder.

The next embodiment outside of the outer cylinder is the EPS balloon. This balloon has a cylindrical shape and is attached to the outer edge of the outer cylinder. The balloon has an initial diameter of 0.94 inch, but can be inflated to +2 inches. The balloon measures 0.75 inches in length, and is secured to the cylinder at its edges with adhesive and compression bands. The balloon is made out of a thin, medical grade PVC. This material is safe for entry into the body, while still providing a flexible and expandable alternative to natural rubber.

External to the balloon, is a semi-rigid, cylindrical ellipsoid shell. The shell fits just over the balloon, but extends out approximately 1.4 inch on either end of the outer cylinder. The shell is made of a thin, semi-rigid material. This is what gives the EPS its characteristic cylindrical-ellipsoid shape. The shell provides a tracked surface for the drive belts to rotate about, and ensures that the belts are in constant contact with the colon walls for the entire length of the EPS. The semi-rigid structure of the shell gives support for the belts, while still providing the necessary flexibility for the EPS to bend around turns. The cylindrical shell attaches to the outside of the outer cylinder, around the balloon. The semi-elastic characteristics of the shell allow it to expand with the balloon to the ~2 inch working diameter of the EPS.

Woven through the interior of the outer cylinder and wrapped around the outside of the balloon are four drive belts. These four belts are situated at 90 degree intervals. The EPS is design so that all four belts maintain constant contact with the colon. The belts have a pitch of 0.2 inches and are 0.25 inches wide. The tooth thickness is 0.05 inches and the total belt thickness is 0.09 inches. The belts measure 8 inches in circumference. This means that about 4 inches of each belt is contacting the colon walls. By the spreading the applied force felt by the colon over a larger surface area, there is less chance of colon perforation, and much less discomfort felt by the patient. The belts are made out of a material that can provide a strong, flexible, and non-immunogenic alternative to rubber, such as nitrile rubber. A part drawing of the belt is shown below in Figure 3.15.

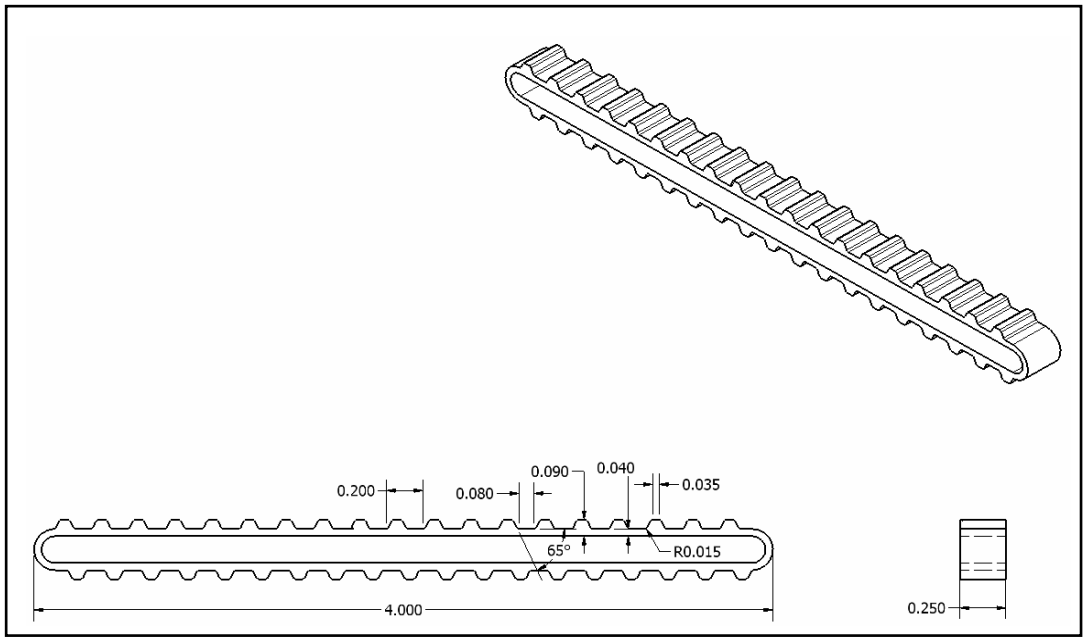

Figure 3.15. Part drawing of the drive belt.

The parts that hold the EPS together and attach it to the scope are the end clamps. There is a proximal clamp and a distal clamp. The clamps are identical, except that the proximal clamp has two additional holes to accept the fluid supply line and the drive shaft. The clamps are designed with two concentric cylinders joined end-to-end. The smaller cylinder, located towards the outside of the clamp, has an inner diameter of 0.5 inches and is 0.105 inches long, which allows the clamp to secure itself to the endoscope. The inner diameter then increase to 0.53 inches for a length of 0.145 inches, comprising the second cylinder. This increased diameter is designed to accept the inner cylinder, thus securing the cylinder at both ends. The inside edges of the clamps, where they contact the ends of the outer cylinder, have an outer diameter of 0.93 inches, allowing them to sandwich the outer cylinder. Each clamp has four grooves cut out at 90 degree intervals for the belts to rotate through. The clamps, like the other internal parts, are made of a plastic polymer. Part drawings of the proximal and distal clamps are given in Figures 3.16 and 3.17, respectively.

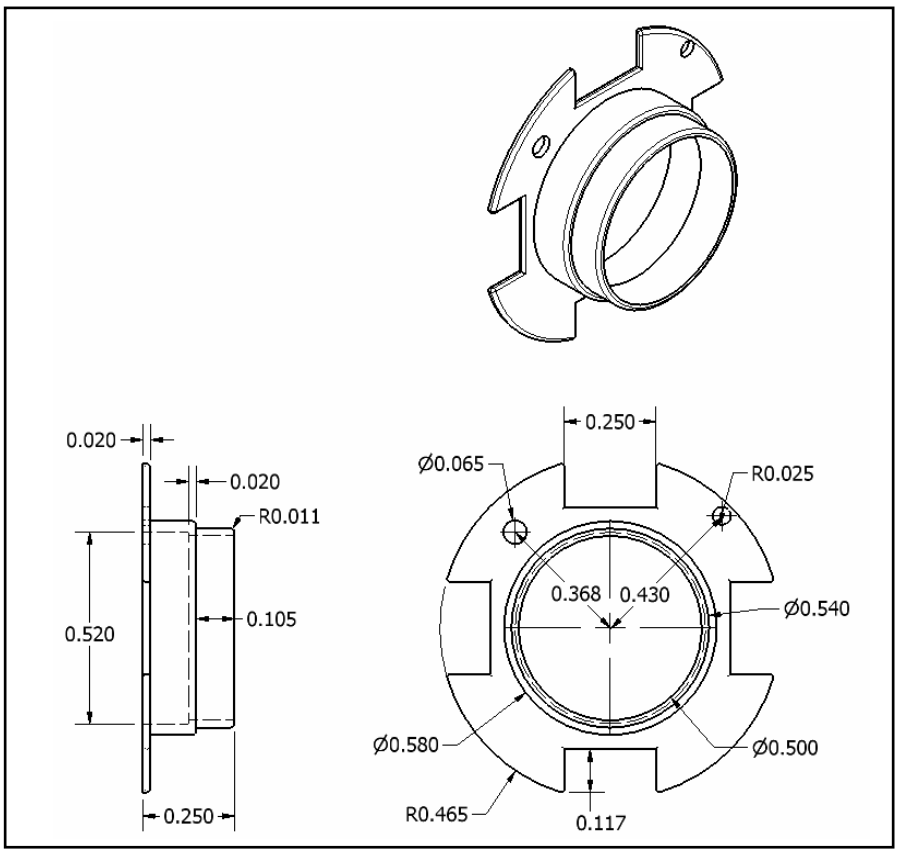

Figure 3.16. Part drawing of the proximal clamp.

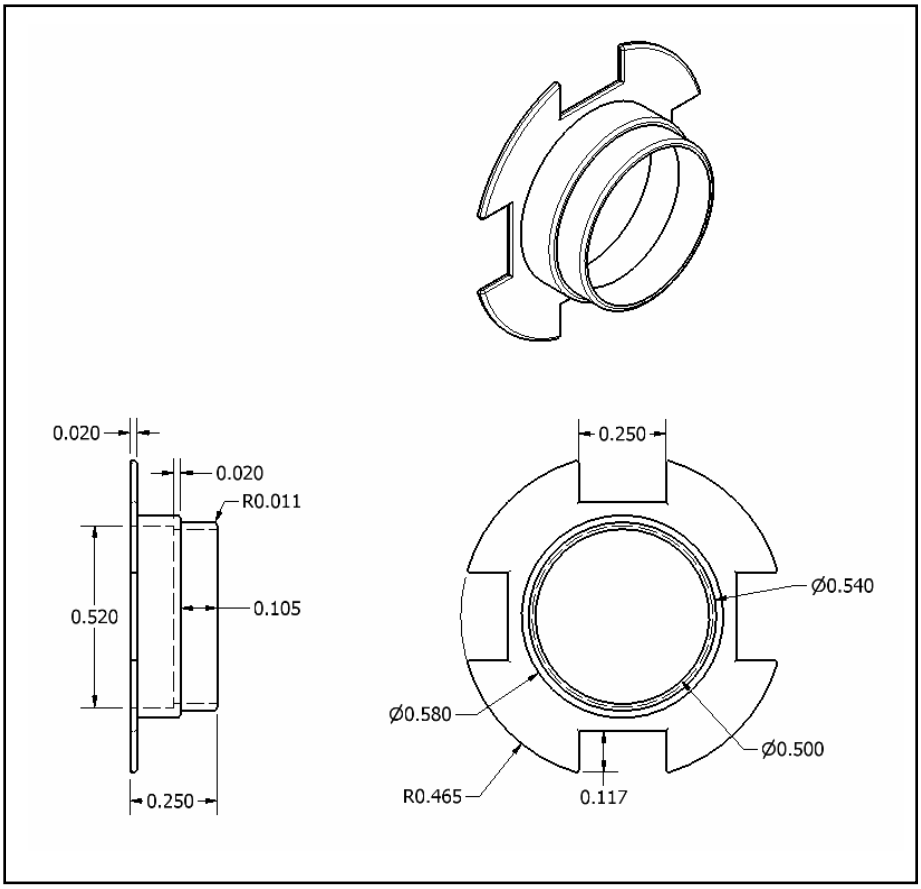

Figure 3.17. Part drawing of the distal clamp.

3.4.2 Overview of the Device Function

The final Endoscope Propulsion System design provides the required assistance to the traditional colonoscopy. This section will detail how the EPS can be used with a modern colonoscope to perform a safer and more effective colonoscopy. The description includes some of the future work that has not yet been fully developed.

The colonoscope, with the attached EPS, is inserted into the anus. During insertion, the EPS holds an outer diameter of <1.125 inches. Once the EPS passes through the anus and into the sigmoid section of the colon, fluid is injected through the fluid supply tube, and into the inner balloon of the EPS. As the balloon inflates, it expands the cylindrical shell, increasing the diameter of the device to approximately 2 inches, or until sufficient contact with the luminal walls is made. A piezoelectric pressure sensor on the balloon will ensure that the pressure of the EPS against the colon

walls will not exceed 2psi. An automated pump, linked to the feedback of the pressure sensor, is used to continuously increase and decrease the fluid pressure as the EPS navigates the varying diameters of the colon. Once the EPS is inflated to the proper pressure, ensuring an adequate working diameter to equally distribute the contact forces between the drive belts and the luminal walls of the colon, the drive mechanism is engaged. The external motor applies a controlled torque to the drive shaft, which in turn, rotates the drive gear. The drive gear engages the worm spur, which causes the worm to rotate. As the worm revolves, it engages the teeth on the four drive belts, and simultaneously rotates them around the cylindrical shell. The belts apply constant, equally distributed force on the colon wall at 90 degree intervals for the entire working length of the EPS. These rotating belts drive the EPS, and in turn guide the colonoscope through the colon.

This added assistance greatly improves the traditional colonoscopy. With this self-propelled feature, the scope applies a minimal force and pressure to the colon walls. The EPS also eliminates any looping, which occurs when the scope is manually fed into the body while the tip of the scope is blocked, causing the scope to curl over itself. This curling motion creates a strong radial force on colon wall, which causes severe pain, and could result in perforation. Any looping tendencies of the scope and colon are overcome by the EPS, since it provides a propulsion force at the head of the colonoscope, pulling the scope, rather than pushing it through the large intestine. This exponentially increased comfort and safety of the procedure are a direct effect of the EPS. Also, the slow and methodic movement of the device through the colon will increase the accuracy of the exam. The camera on the scope will now be able to view the entire colon without the chance of skipping segments due to looping or bunching within the colon.

The majority of polyp detections occur as the scope is being pulled out of the colon. Once the scope reaches the end of the large intestine, the drive system on the EPS is switched to reverse, and the scope is gently pulled out. The reverse drive during the removal of the scope will ensure that when in motion, the scope is being removed at a steady, controlled pace. This will allow for a more meticulous and effective polyp detection process.

3.5 Prototype

To further evaluate the final design of the EPS, a prototype was manufactured. The main purpose of the prototype is to give a hands-on feel to a concept that previously existed only through CAD. The prototype is scaled up to approximately three times the actual size of the EPS. This larger scale model will make the parts easier to work with as different experiments are conducted. With a working prototype, previously unforeseen problems are brought to light, leading to more efficient iterations. Another outcome of building a prototype is to make contacts with various manufacturing companies, whose services can be requested once the final EPS is in the production phase. The prototype will also give hands on practice with various part materials. It is one thing to know a material via its spec sheet, and quite another to actually feel, and work with the material. The remainder of this section will discuss the different parts of the EPS, their corresponding materials, and approximate dimensions. Lastly, the manufacturing process of the prototype will be covered to give an additional design aspect to the EPS.

3.5.1 Prototype Parts

The prototype parts are similar to that of the final design, with the exception of dimensions, tolerances, and possible material choices. In building this prototype, a lower budget was maintained. To do this, many of the parts were designed around 'off-the-shelf' items. This decreased the cost and increased the availability of many of the pieces. The prototype design began by choosing the drive belts and the drive gears, as these were the easiest to find without custom manufacturing. Once these were selected, the remaining parts were custom made.

The drive belts were ordered from Mcmastercarr.com, part number 1840K5. These belts have a 0.5in pitch and a 0.75in width, approximately three times the size of the drive belts in the final design. They are single-sided, urethane belts with trapezoid teeth. The drive belts were ordered open-ended, so that their length could be adjusted as needed once assembled.

The drive gear and worm spur were the next off-the-shelf items to be sized. Initially, a semi-custom gear was designed to better meet the 3x scale of the prototype.

However, the quote received from www.rushgears.com priced the parts at over $1,000 per gear, which was well above the desired budget of this project. Since the number of teeth and diametral pitch of the gear had little effect on the design of the EPS prototype, the dimensions were the limiting factors. From www.robotobjects.com , suitable gears were found at less than $2 per gear. This more reasonable price, allowed for multiple orders, and more experimentation with the gears. The gears are made from high quality Delrin®, which is a DuPont designed plastic polymer used as a substitute for metal. Delrin is lightweight and has a very low friction coefficient. The drive gear selected has a diametral pitch of 48, with 16 teeth, but most importantly, has an outside diameter of 0.375 inches. While a high diametral pitch was desired, the outside diameter was the limiting dimension, as the gear had to fit within the outer cylinder.

The final EPS design will be manufactured with the worm spur and the worm as a single part. For the prototype, however, the worm spur and the worm were separate so that a worm spur compatible with the non-custom drive gear could be used. The worm spur was also from www.robotobjects.com , and was just as affordable. This spur gear has a diametral pitch of 48, with 84 teeth. The limiting factors of the gear were the outer and inner diameters. The outer diameter had to be small enough to fit adjacent to the drive gear, inside the outer cylinder, while the inner diameter had to be large enough to spin freely around the inner cylinder. The outer and inner diameters of the worm spur are 0.25in and 0.125in, respectively. Again, these gears were chosen first, so that the dimensions of the inner cylinder, the worm, and the outer cylinder could be designed around them.

Once the drive belts and the drive gears were selected, the inner cylinder, the worm, the outer cylinder, and the end clamps were designed. Using Inventor, these parts were modeled so that the dimensions were approximately three times the size of the final design parts, while still accommodating the previously selected, off-the-shelf parts. The CAD parts were then sent to ProtoCam for rapid prototyping. To obtain custom parts while staying within budget, ProtoCam offered a 50% student discount for an allowed lead time of one week and a Level 1 finish. The Level 1 finish meant that the parts had a "strip and ship" finish, which increased the dimension tolerance. These custom parts were designed to accommodate a tolerance of $\pm$ 0.01", which the 3x scale allowed. The

parts were rapid prototyped using stereolithography. Stereolithography is a process that turns 3D CAD drawings into solid objects by using an ultra-violet laser to cure a photopolymer resin. The UV laser traces the cross-sectional pattern of the part onto a container of liquid resin. The laser causes the resin to harden, and each time it traces the pattern, another layer hardens and adheres to the previous layer. The laser continues to retrace the pattern until the part is completed [15]. The EPS parts were rapid prototyped using Accura 25 resin, which looks and feels like molded polypropylene. This material can be machined, painted, and is robust enough to manufacture functional prototype parts. The rapid prototyped parts are shown in Figure 3.18.

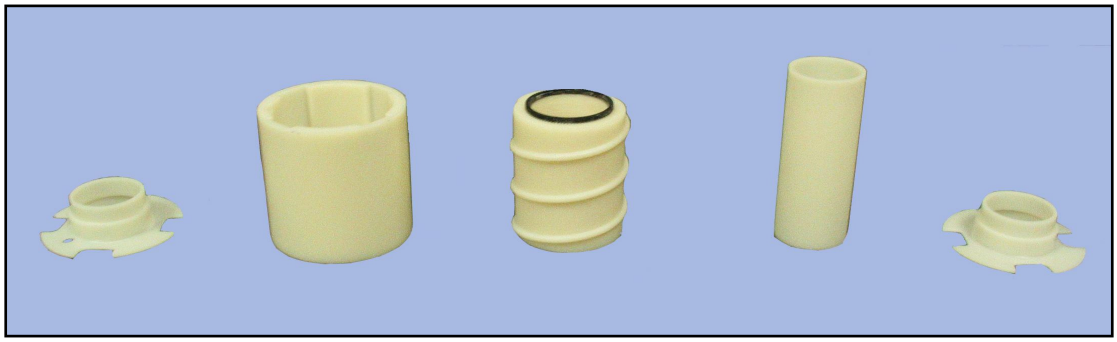

Figure 3.18. Rapid prototype parts.

One of the major components of the EPS is the balloon, which was a challenge to manufacture for the prototype. The balloon requires a custom shape, so several companies specializing in customized inflatable devices were contacted. In addition to its shape, the balloon must also be made out of a non-immunogenic material. Researching medical materials led to two main options, medical grade PVC or nitrile rubber. Unfortunately, the companies that could make custom shapes out of these materials could not create a balloon to match the large scale size requirement. This means the balloon must be manufactured by hand, from the raw material. Several trials were run using thin sheets of medical PVC and nitrile rubber. The prototyped medical PVC balloon is a hand-fashioned toroidally shaped inflatable designed to fit outside of the outer cylinder and inflate to an outer diameter between 3 and 6 inches.

The cylindrical shell used to guide the belts was modified for more simple operation for the prototype. Instead of a shell, four independent plastic tracks were bent

in a semi-elliptical shape. The tracks attach to the outside of the outer cylinder at the same locations as the interior recessed belt guides, and bend around in a semi-elliptical shape from one end of the outer cylinder to the other. The tracks are thin pieces of plastic, with metal U-shaped clips used to keep the drive belts from slipping off the tracks. The plastic is flexible enough to expand from an initially compressed position to an operating position as the balloon is inflated. Small metal sections were used where the tracks attach to the outer cylinder to give the tracks a semi-elliptical shape. Using independent tracks in place of the cylindrical shell increases the ease of manufacturability, while maintaining the functionality of the part.

3.5.2 Prototype Assembly

The EPS is designed to be assembled in a specific sequence. The assembly of the prototype will be reviewed to serve as a guide for the assembly process of the final product. As a general rule, the EPS is assembled from the outside in. The first step is to mount the balloon to the outer cylinder. To do this, the outer cylinder was inserted into the inner balloon lumen. The balloon was designed to slide over the cylinder, and was then secured at either end. A plastic epoxy was used to attach the balloon at either end to give an air tight seal between the balloon and the outside of the outer cylinder. To prevent any fluid leaks from the internal pressure of the balloon, compression bands were used to further secure the sealed area of the balloon to the cylinder.

After the balloon was attached, the plastic belt tracks were added. One end of each track was secured to the outer cylinder using a plastic epoxy. The tracks were then looped around the outside of the balloon, and attached to the other side of the outer cylinder. This process is repeated with each track until all four are in place.

Once the balloon and the tracks were mounted to the outer cylinder, the drive belts were added. Each of the four drive belts were fed through the lumen of the outer cylinder, and then around the outside of the metal tracks. Once the belts were fed through the cylinder and looped around the tracks, the ends of each belt were fused together using an adhesive, and a heat gun, to complete the shape of the drive belt. The

drive belts should fit tight enough so as to not fall out of the guide tracks, but loose enough to easily rotate about the tracks.

As previously mentioned, for the actual EPS the worm and the worm spur are one piece. For the prototype however, they are two separate pieces, which were attached using a plastic epoxy. For the rest of the assembly instructions, the 'worm' will include both the worm and the worm spur. After these two parts were secured, the next step was to insert the worm into the outer cylinder. This can be achieved in one of two ways; either the worm can be rotated to avoid engaging the drive belts, or the drive belts can be rotated, allowing the worm to slide into place. Ideally, the coefficient of friction between the balloon and belts is low enough to allow the worm to easily slide in, however, the use of a lubricant may be necessary to achieve this.

Once the worm has been properly set, the inner cylinder was inserted into the worm lumen. The inner cylinder was positioned so that an equal length was exposed on either end of the worm. This is important because the inner cylinder provides the necessary spacing for the propulsion mechanism; however, the position of the inner cylinder will self-adjust during the addition of the final parts.

The last step of the assembly process was to slide the proximal and distal clamps onto the inner cylinder. As specified in the part descriptions, both clamps have an internal diameter recess to accept the inner cylinder, which repositioned the cylinder to its proper place, once the clamps were in position.

Before adding the proximal clamp, there was some sub-assembly required. This clamp was designed to accommodate the fluid supply tube and the drive shaft, both of which need to be added prior to placing the proximal clamp on the EPS. First, the drive shaft was inserted into the drive shaft hole on the clamp. During insertion, the clamp was positioned so that the free end of the drive shaft was exposed on the inner side of the clamp. Next, the drive gear was attached to the drive shaft and then inserted into the drive shaft hole on the clamp. This hole contains a small Timken® bearing for drive gear to rotate in. If the previous step was followed correctly, the gear will be on the inside of the proximal clamp. After the drive train was assembled, the fluid supply tube was fed through its designated hole on the proximal clamp, and then inserted into the fluid supply hole on the face of the outer cylinder. The fluid supply hole is only on one side of the

outer cylinder, thus guaranteeing the proximal clamp has been installed on the proximal side of the EPS.

Once the sub-assembly was completed, the proximal clamp was slid over the inner cylinder until the clamp contacted the outer cylinder. The inner cylinder was inserted as far is it would go into the proximal clamp. The proximal clamp was then secured to the outer cylinder with small button-head screws. With this complete, the distal clamp could be slid over the other side of the inner cylinder, again, until the clamp was in contact with the outer cylinder. The clamp was then secured to the outer cylinder with the button-head screws. The prototype assembly is shown without the belt tracks below in Figure 3.19.

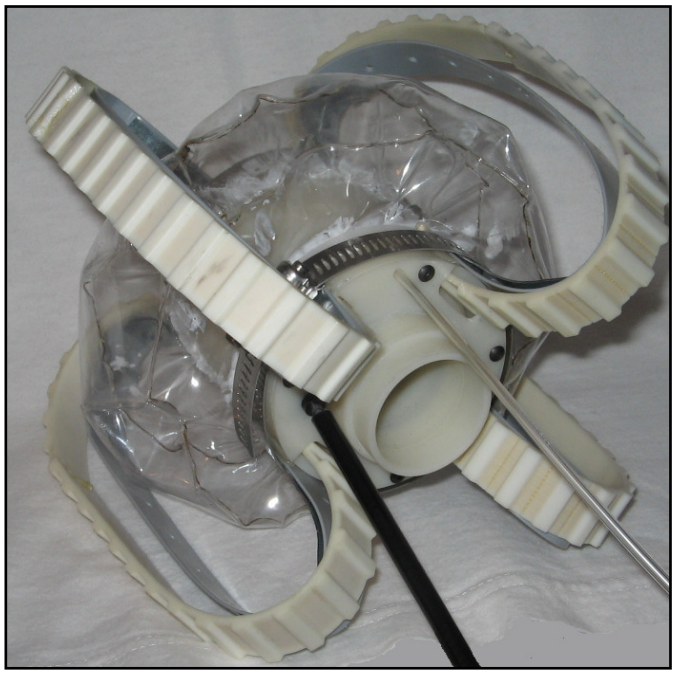

Figure 3.19. The prototype assembly, shown without belt tracks.

Chapter 4

Analysis

To effectively measure the ability of the Endoscope Propulsion System to meet and exceed the specified design goals, several analyses need to be conducted. These analyses will examine the mechanical, the safety, and the propulsion characteristics of the device. Also, a sample calculation is provided, to give an analytical model for this device, as well as, for future iterations.

4.1 Mechanical Analysis

The mechanical analysis of the EPS will investigate the force output, as required for propulsion. Here, the required torque of the worm will be addressed, along with, the corresponding tangential forces of the drive belts against the luminal walls of the colon. To give an accurate estimation of the necessary propulsion forces, the various coefficients of frictions present during operation will also be investigated.

4.1.1 Coefficient of Friction (CoF)

There are two types of coefficient of friction; static and dynamic. For this analysis, the static friction coefficient is of most interest. The static coefficient of friction can be defined as the ratio of tangential force to the normal force between two surfaces.

When the tangential force applied to an object exceeds the friction force between the object and a surface, the object will begin to slide on the surface. A free-body diagram of these forces is shown in Figure 31.

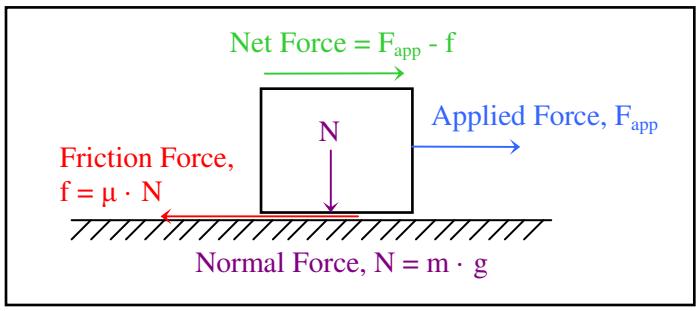

Figure 4.1. The free body diagram of the fiction forces acting on an object [Roymech].

The friction forces between the object and the surface can be modeled using the equation,

$$\mu = \frac{F}{N} \ , \tag{1}$$

where μ is the static coefficient of friction, F is the tangential force applied to the object, and N is the normal force exhibited between the object and the surface [14].

The coefficient of friction between the drive belts and the mucosa layer of the colon will have a significant impact on the mobility of the EPS. This will determine that amount of shear force, or tangential force, necessary to achieve forward and reverse motion of the EPS. There is little known about the material properties of the colon, and further experimentation is necessary. For a more accurate analysis, an experiment should be performed to determine the coefficient of friction between various materials and the mucosa layer. This is discussed further in Chapter 5.

The CoF of the colon tissue can also be adjusted by applying a mucalytic. A mucalytic is a substance that dissolves the natural mucus coat of the colon wall. By removing this lubrication, the CoF between the drive belts and the mucosa will increase. This ability grants added freedom in the propulsion analysis.

In addition to the coefficients of friction between the belts and mucosa, the CoF between the belts and the worm and the belts and the balloon must also be found. The various belts materials that should be tested are nitrile rubber, nylon, and silicon, as these

are the most viable non-immunogenic materials that will be used to manufacture the EPS. Ideally, the coefficient of friction between the belts and the mucosa should be high, while the coefficient of friction between the belts and the balloon and the belts and the worm should be very low. This will enable the belts to easily slide over the balloon and through the worm, while providing enough friction on the colon walls to propel the device. There are several design variations that can influence these values in the desired direction. The application of a mucalytic on the colon was already discussed, but other changes include adding lubrication to the underside of the belts, the outer surface of the balloon, and on the outer surface of the worm. The correct additive will help safely lower the coefficient of friction to very low, very desirable value.

4.1.2 Worm Output Force

The worm output force is determined from the amount of torque applied to the worm via the drive shaft. A clutch on the external drive assembly will limit the amount of torque applied to the drive gear. This mechanism will ensure that the worm output force will not exceed a maximum allowable value, to limit the shear force experienced by the luminal wall of the colon. Several calculations can be performed to estimate the output force of the worm, and furthermore, the tangential force of the drive belts against the colon. First, the tangential force on the worm, or the axial force on the drive belts is found using the equation,

$$F_{wt} = F_{ga} = 2M_1 / d_1 \ , \tag{2}$$

where F_{wt} is the tangential force on the worm, F_{ga} is the axial force on the drive belt, M_1 is the torque applied to the worm, and d_1 is the pitch diameter of the worm. From this value, the axial force on the worm, or the tangential force on the drive belt can be derived using the equation,

$$F_{wa} = F_{gt} = F_{wt}\left(\frac{(\cos\alpha_n)(\sin\gamma) + \mu\cos\gamma}{(\cos\alpha_n)(\cos\gamma) - \mu\sin\gamma}\right) , \tag{3}$$

where F_{wa} is the axial force on the worm, F_{gt} is the tangential force of the drive belt, F_{wt} is the previously calculated tangential force on the worm, α_n is the normal pressure angle of

the drive belt, γ is the lead angle of the worm, and μ is the coefficient of friction between the worm and the drive belt.

With the tangential force on the drive belt now known, the output torque of the drive belt can be calculated using the equation,

$$M_2 = \frac{F_{gt} \cdot d_2}{2} \ , \tag{4}$$

where M_2 is the output torque of the drive belt, F_{gt} is the tangential force of the drive belt, and d_2 is the pitch diameter of the drive belt. To find d_2, model the drive belts as circular spur gears, and use the equation,

$$d_2 = \frac{OD \cdot N}{N + 2} \ , \tag{5}$$

where OD is the outside diameter of the belts and N is the number of teeth on the belts.

To find the amount of shear force, or tangential force applied by the drive belt, Equations 2 and 3 can be reversed solved to find the corresponding output torque of the external motor. This value will equate to the limiting force on the worm. Substituting Equation 3 into Equation 2, and back solving for the worm torque, will result in equation,

$$M_1 = \left(\frac{d_1(\cos\alpha_n)(\cos\gamma) - \mu \sin\gamma}{2(\cos\alpha_n)(\sin\gamma) + \mu\cos\gamma} \right) F_{gt} \ , \tag{6}$$

where a relationship between the input torque and the output force has been derived. The bracketed portion of Equation 6 is based on the geometry, and the material properties of the worm and drive belts. This expression will be referred to as the worm coefficient, λ. The worm coefficient relates the input and output parameters, and simplifies Equation 5 to,

$$M_1 = \lambda F_{gt} \ or \ F_{gt} = \frac{M_1}{\lambda} \ . \tag{7}$$

4.2 Safety Analysis

As with any design, safety is the most important design criterion. For the EPS, there are several safety constraints. As previously discussed, one of the most dangerous

parts of the colonoscopy procedure, is colon perforation, which requires immediate surgical attention. From experimentation, it has been found that the maximum forces experienced between the colon walls and the colonoscope occur due to looping in the sigmoid colon. Looping is when the tip of the endoscope stalls, while the tail end of the scope continues to be fed into the body, causing the scope to curl over itself, bending the colon with it. This curling puts extra force on the colon wall. The design and purpose of the EPS eliminates any stalling of the tip, thus disallowing the scope to loop over itself, and negates the potential of the scope administering a maximum force, or for the colon to bend into uncomfortable and/or dangerous positions. This means the majority of the force exerted on the colon walls is by the colonoscope tip, which is directly related to the tangential force of the drive belts, as applied by the EPS. The average perforation force of a porcine colon is 13.5 $\pm$ 3.7N. Porcine colon is very similar to human colon, so these numbers are accurate for the human colon as well. From these values, the minimum force it took to perforate the colon was 9.8N. The mobility of the colon lends itself to absorb a large portion of the force applied by the scope tip, which gives further leniency to the max force of the EPS. Regardless, the maximum allowable force of the EPS will be X Newtons, as found through future experimentation. This gives a factor of safety of 9.8/X, as determined from the equation,

$$FOS = \frac{Minimum\ Perforation\ Force}{Maximum\ EPS\ Force} \quad . \tag{8}$$

In addition to the perforation force, the perforation pressure must also be considered during the safety analysis of the EPS. For this design, the perforation pressure is a greater limiting factor than the perforation force. Experiments were conducted using air-filled and liquid-filled enemas to find the perforation pressure of the large intestine of young pigs. The results gave an average perforation pressure of 2.09psi. Adapting Equation 9 to apply to the pressure yields a factor of safety equation,

$$FOS = \frac{Perforation\ \mathrm{Pr}essure}{Maximum\ EPS\ \mathrm{Pr}essure}. \tag{9}$$

The EPS is rated to inflate to an internal pressure of no more than Y psi, as found through future experimentation, which gives a factor of safety equal to 2.09/Y.

4.3 Propulsion Analysis

To create locomotion, the tangential force applied to the luminal walls of the colon by the drive belts must less than the applied normal force by a factor greater than the coefficient of friction between the two surfaces. If the drive belt force is greater, it will overcome the friction forces between the belts and the colon wall, causing the belt to slip. This concept can be expressed by rearranging Equation 1,

$$F < \mu N \,, \tag{10}$$

again, where F is the tangential force, μ is the coefficient of friction, and N is the applied normal force.

From the design constraints, the applied normal force cannot be more than 9.8N, and the internal pressure of the EPS balloon must be less than 1.5psi. With this in mind, an applied torque interval can be calculated that will ensure propulsion without exceeding any safety specification. First, the surface area of the drive belts that will contact the luminal wall must be found using the equation,

$$A_s = l \cdot w \quad , \tag{11}$$

where l is the belt length and w is the belt width. From this, the applied normal force can be calculated by,

$$N = p \cdot A_s \,, \tag{12}$$

where N is the normal force, p is the internal pressure of the EPS balloon and A_s is the contacting surface area of the drive belt. Next, through experimentation, the coefficient of friction between the drive belts and the colon mucosa must be determined. For this analysis, the CoF value will be $\mu = x$. Plugging this information into Equation 10 gives

$$F_{gt} < x \cdot N \,. \tag{13}$$

The tangential perforation force of the colon must also be found experimentally. This value will be known as F_p. From the input torque relationship derived in Equation 7, and the perforation force expression of Equation 13, a locomotion equality can be created.

$$M_i < F_{gt} \cdot \lambda < F_p \cdot \lambda \,, \tag{14}$$

where F_{gt} is the applied tangential force, λ is the worm coefficient, M_i is the input torque, and F_p is the tangential perforation force. The input torque must be less than the product of the tangential force and the worm coefficient for the EPS to achieve propulsion, and the tangential force must be less than the perforation force for the EPS to operate safely.

Sample Calculation

A sample calculation will be used as a model for the EPS analysis. First, the geometry and material properties values are assigned. The normal pressure angle of the teeth on the belts, α_n, is 25° and the lead angle of the worm, γ, is 25°. The pitch diameter of the worm, d_1, is approximately 0.725 inches. The coefficient of friction between the belts and the worm will be estimated assuming the worm is made out of Delrin, the belt is made of urethane, and a KY lubricant is used. Under these conditions, the assumption is made that the CoF will be approximately 0.05. Plugging these values into

$$\lambda = \left(\frac{d_1(\cos\alpha_n)(\cos\gamma) - \mu\sin\gamma}{2(\cos\alpha_n)(\sin\gamma) + \mu\cos\gamma} \right) , \tag{15}$$

yields a worm coefficient of,

$$\lambda = \left(\frac{0.725(\cos 25)(\cos 25) - 0.05\sin 25}{2(\cos 25)(\sin 25) + 0.05\cos 25} \right) = 0.708in .$$

Substituting this value into Equation 7 gives,

$$M_i = 0.708F_{gt} \; or \; F_{gt} = \frac{M_i}{0.708} ,$$

which represents the input torque, output tangential belt force relationship for the specified geometric constraints and material properties of the EPS. Plotting this relationship gives a linear curve that estimates the amount of force that will be applied to the luminal walls of the colon based on the torque applied to the drive train. This plot is shown below in Figure 4.2.

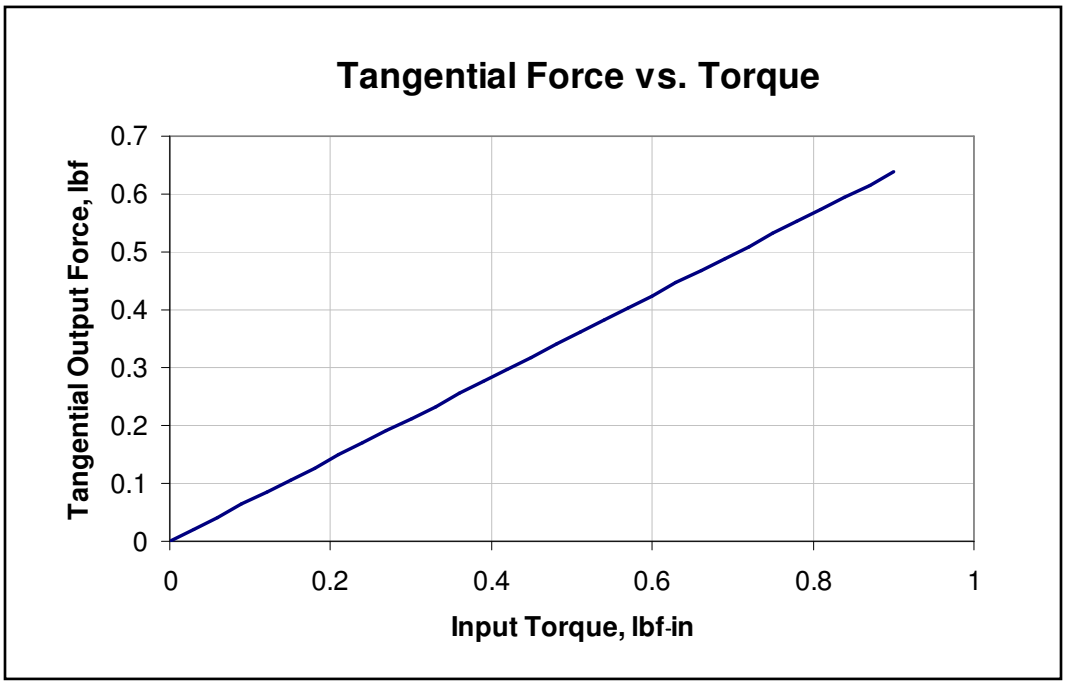

Figure 4.2. Linear relationship between input torque and tangential output force.

From this equation, the analysis can be expanded to include the propulsion forces of the EPS. The sample calculation will be continued with the applied normal forces of the drive belts against the lumens wall. The surface area can be found from Equation 11,

$$A_s = w \cdot l = 0.25 \cdot 3.77 = 0.942\, in^2 / belt \ .$$

The normal force can then be calculated using Equation 12,

$$N = p \cdot A_s = 1.5\, psi \cdot 0.94 in^2 = 1.41 lbf / belt \ .$$

For this sample calculation, the coefficient of friction between the colon mucosa and the drive belts will be estimated at 0.1. Using this parameter, the amount of tangential force necessary to overcome the friction forces is calculated using Equation 13,

$$F_{gt} < x \cdot N < 0.1 \cdot 1.41 \rightarrow F_{gt} < 0.141 lbf / belt \ .$$

This shows that the tangential force of the belts must be less than 0.141lbf/belt, or the EPS will not achieve either forward or reverse motion.

To take into account the safety requirements, the tangential force, F_{gt}, must be less than the experimentally determined tangential perforation force, F_p. Letting F_p = 5N

(1.124lbf), and applying this to the interval of the previously calculated input torque, M_i, generates the operating equality,

$$M_i < 0.099\,lbf \cdot in < 0.796\,lbf \cdot in\,.$$

This torque interval can then be applied to the plot previously shown in Figure 4.2 to illustrate the operating boundary for safe, effective propulsion. These boundaries are added to the graph as shown below in Figure 4.3.

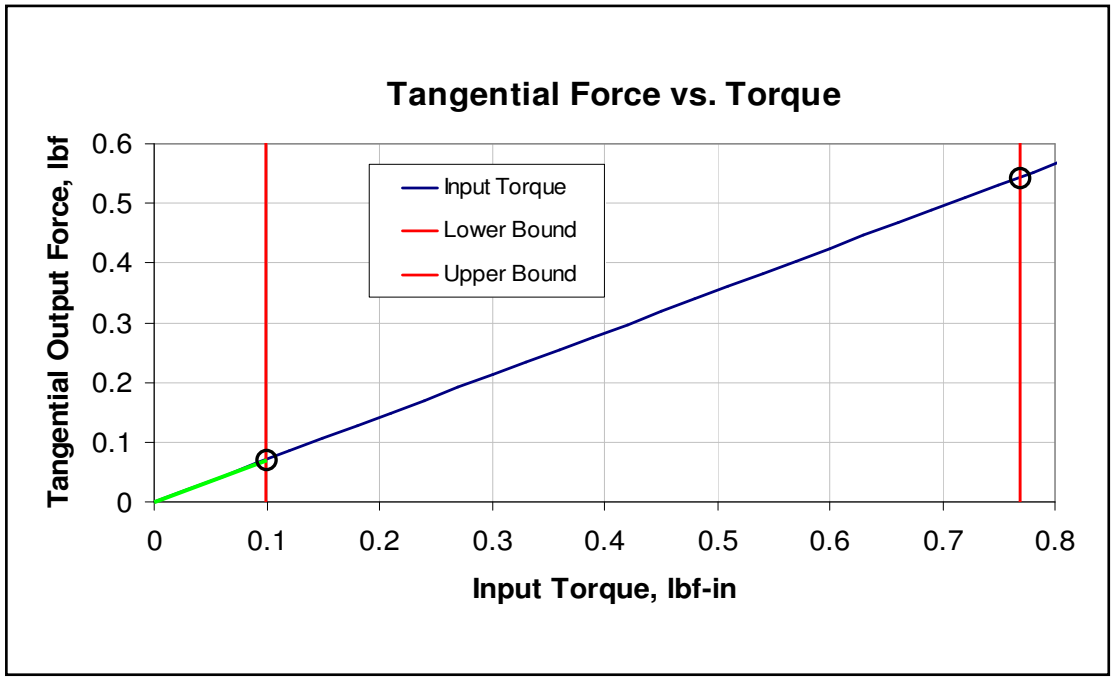

Figure 4.3. Input torque and tangential output force relationship with operating intervals.

The red lines show the upper and lower bounds of the torque interval. If the input torque exceeds 0.769lbf·in then the tangential force of the EPS drive belts could potentially perforate the colon. If the input torque is greater than 0.009lbf·in, then the tangential force of the drive belts will overcome the normal and friction forces between the belts and the colon wall, which means there is no propulsion. The green line overlaid on the input torque relationship on the graph represents the preferred input torque, which will provide the necessary propulsion while maintaining the desired level of safety.

Chapter 5

Future Work

The Endoscope Propulsion System is in a young design stage, and there is much work that can be done to further improve the operation of the device to prepare it for *in-vivo* experimentation and operation. First, many experiments can be run to better understand the device materials, as well as, the environment that the EPS will be operating in. Second, as mentioned in Chapter 3, the current prototype is three times the size of the actual EPS, and can maneuver large PVC pipes. This prototype was built with "off-the-shelf" parts and non FDA approved materials. The next step is to develop an actual size prototype out of applicable materials. Once this is done, a more thorough analysis can be performed to obtain real quantifiable values for the various input and output forces. As the device approaches a more finalized prototype, the EPS will be tested *in-vitro*, then eventually *ex-vivo,* and finally *in-vivo*. The *ex-vivo* and *in-vivo* experimentation will be performed on pigs until the device is approved safe for human experimentation.

As the testing phase progresses, several updates will be made, including the development of a user interface to interact with the drive motor to provide the forward and reverse propulsion control, and a real time internal pressure feedback control unit. Another future design adaptation can be implemented that would allow the EPS to navigate the small intestine, in addition to the colon. This alternate design includes a more complex, but more controllable drive mechanism.

5.1 Experimentation

As previously mentioned, much experimentation is needed to better understand the material properties, to further clarify the mechanical and safety analysis, and to better quantify the prototype functionality. A few test setups will be discussed to complete the respective objectives.

Material Experimentation

To utilize the proper EPS materials, further experimentation is necessary. The mechanical properties of the colon must be examined, specifically the coefficient of friction, CoF, between the drive belts and the luminal walls of the colon (the mucosa). In addition, the coefficient of friction between the worm and the belt teeth and the balloon and the back side of the drive belts must be analyzed. For the most efficient performance, the CoF between the mucosa and the drive belts should be high, and the CoF between the worm and teeth and belts and balloon must be low. The most accurate method for experimental measurement of these coefficients of friction is to use a coefficient of friction tester. International Equipments produces a digital static and dynamic coefficient of friction tester, which is shown below in Figure 5.1.

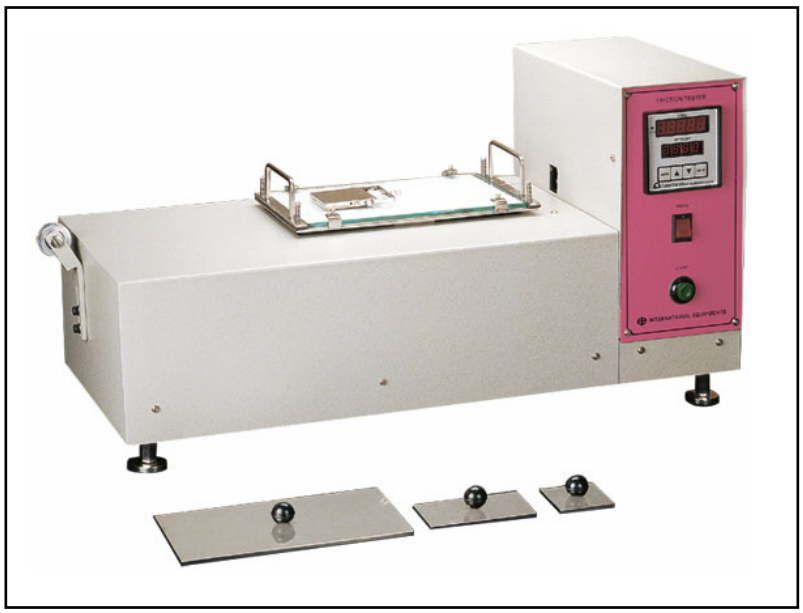

Figure 5.1. Digital Static and Kinetic Coefficient of Friction Tester [International Equipments].

This CoF tester works by placing the two materials of interest in contact with each other inside the tester. The machine then slides the two materials against each other and records the necessary force to overcome the normal and frictional forces, thus allowing sliding, and then records the force necessary to continue this sliding. These two measurements give the static and dynamic coefficients of friction, respectively, between the two materials.

In addition to using this test apparatus, additional variables must be controlled to accurately test the CoF of the colon. A specific test environment must be preserved to properly model the natural material properties of the colon. The colon tissue must be maintained at the correct temperature and humidity to ensure an accurate test environment. With these mechanical properties known, a more accurate theoretical analysis can be performed, thus allowing the utilization of the chosen EPS materials.

Another method for determining the coefficient of friction between two materials is to use an incline plane. Place one material on an incline plane, and then place the other material on top. Then, increase the angle of the incline until the second material begins to slide. Once the material slides, the friction coefficient can be found by dividing the height of the inclined plane by its length. A diagram of this friction test is shown in Figure 5.2.

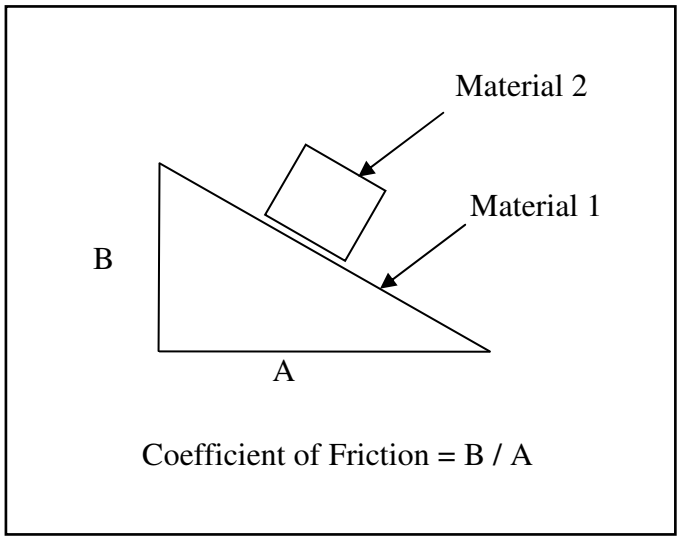

Figure 5.2. Diagram of coefficient of friction test.

Prototype Experimentation

The current prototype is a large scale model of the EPS that can maneuver its way through 6 inch pipe with 45° bends. A future prototype will be manufacture to the actual EPS dimensions. Once built, the prototype will be initially tested on flexible tubing with diameter changes from 1 to 2 inches. The working environment will completely mimic that of the large intestine. With this setup, the necessary tangential output forces and internal pressures can be evaluated to more accurately analyze the mechanical and safety aspects of the design. After further analysis, the next step in prototype experimentation is *ex-vivo* followed by *in-vivo* experimentation on pigs. The final experiment will be performed on a sedated pig with equipment to internally evaluate the EPS performance. As future iterations of the EPS come into fruition, several updates will occur, which include a developed pressure control system, and a marketable user interface.

5.2 Pressure Control

As discussed in Chapter 3, the internal pressure of the balloon needs to be continuously monitored and adjusted to apply a consistent operation force to the colon walls. This can be achieve in a variety of ways, however, the two that best meet this application are to either use a piezoelectric pressure transducer external to the body with wires running to the EPS, or use an internal pressure transducer mounted directly to the balloon. The piezoelectric pressure transducer consists of a small chip with a nozzle that mounts to a printed circuit board, or PCB. The PCB is in a pressure control module external to the body. Within this module are the pressure transducer, pressure feedback logic, and a fluid pump. The piezo-pressure transducer works by converting an output pressure into an electric signal. This would require a separate pressure feedback tube in addition to the fluid supply tube on the EPS. The fluid supply tube would connect to the fluid pump, while the pressure feedback tube would connect to the PZT pressure transducer. The feedback logic is then designed to provide an “intelligent” link between the pump and the transducer, in which the converted electric signal from the transducer will allow a real time decision from the pump. This configuration will enable the EPS to maintain a consistent pressure between the drive belts and the luminal walls of the colon.

This will improve the mechanical drive efficiency of the belts, while also preventing the existence of any unsafe internal pressures due to rapid constricting of the colon diameter.

5.3 User Interface

The ideal user interface for the Endoscope Propulsion System will allow the user to operate the device with little or no effort, so that the primary focus can be on observation. A foot pedal will be used to control the forward and reverse speed, so that the doctor can manipulate the tip of the scope in the usual fashion, while effortlessly controlling the motion of the EPS with his or her foot.

In addition to the mobile operation of the EPS, interfacing the previously discussed pressure monitoring system will exist through a small self-contained unit equipped with a real-time digital display of the internal pressures of the EPS.

5.4 Alternate Drive Mechanism

The current drive mechanism is designed to balance effectiveness with simplicity and cost; however, this simplicity can limit the maneuverability of the EPS. The use of a central worm to drive the EPS on all four sides eliminates the possibility of steering. If testing shows that steering is necessary to negotiate the sharper turn of the colon, the effectiveness/simplicity balance of the design will become lopsided. To increase effectiveness and maintain this balance, the simplicity of the device would need some adjustment. The easiest way to integrate this extra maneuverability is through differentially driven belts. The use of separate motors to independently drive the belts can be incorporated. This design can be implemented in one of two ways; either the motors are small enough to be internal to the body, or the motors are external and control separate drive shafts that are attached to each individual drive gear. As technology advances, very small, battery powered, radio controlled motors can be implemented. This will eliminate any extra tethers to the EPS, while enabling differential steering. The use of integrated circuit board will then be used to control the motors to provide effective steering ability, via joystick or other user interface. A CAD model of this future design is shown in Figures 5.2 and 5.3.

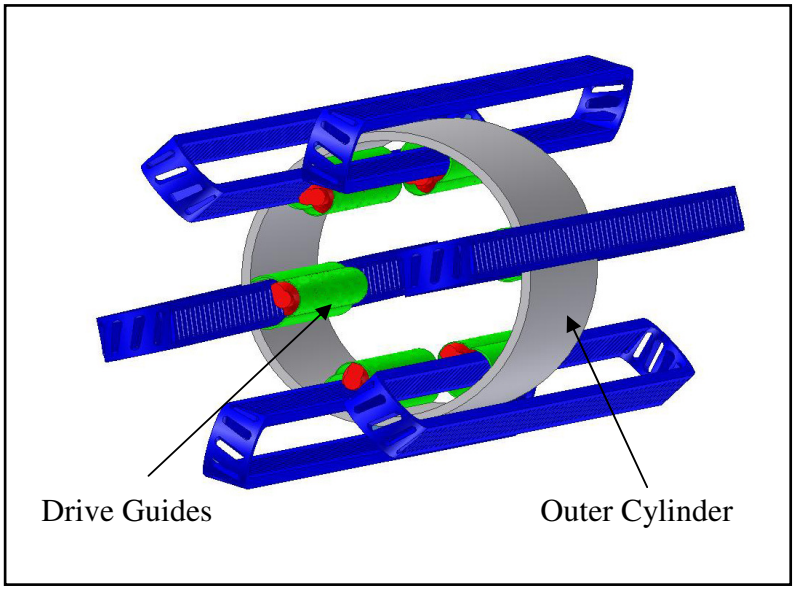

Figure 5.3. Isometric view of future design drive mechanism.

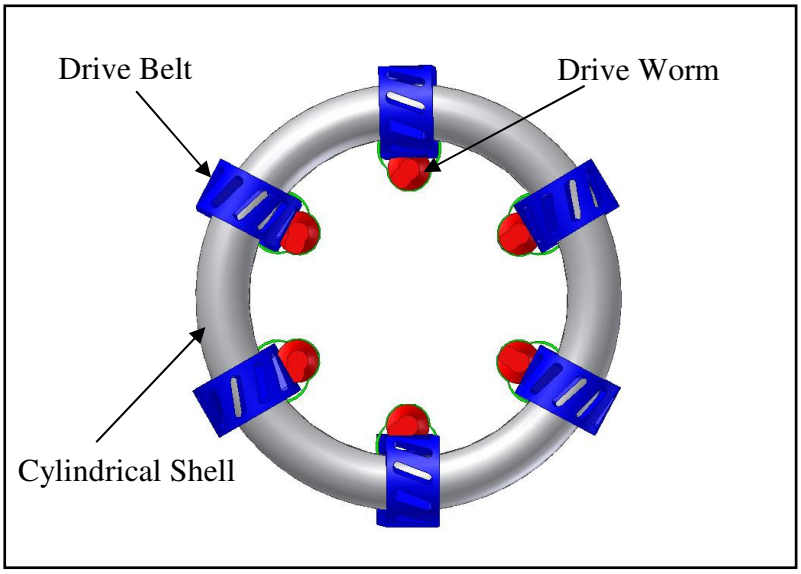

Figure 5.4. Front view of future design drive mechanism.

Chapter 6

Conclusion

6.1 Summary

Colorectal cancer is the third most common form of cancer, and is the number two cancer-related death in the United States. Receiving regular colonoscopies can reduce the average person's risk of dying from colon cancer by 90%. However, only 54% if adults over the age of 50 get regular colonoscopies. This low percentage can be attributed to poor availability, severe discomfort, high cost, and the risk of procedural complications. The Endoscope Propulsion System, or EPS, will assist in the colonoscopy procedure. This device will enable a lesser skilled physician to effectively perform the colonoscopy, thus increasing the procedure's availability. In addition to requiring less skill, the assistive nature of the EPS will also decrease the chance of complications due to colon perforation. The EPS will greatly reduce the discomfort cause by the colonoscope, which will eliminate the need for anesthesia and recovery, therefore greatly reducing the cost of the procedure. The initial Endoscope Propulsion System design is outlined in Dr. M. Jonathan Bern's patent application (20060270901). The criteria and requirements of the design were reevaluated, and after several iterations, a finalized EPS came into fruition. A working prototype was built and tested to ensure the validity of the proposed invention.

6.2 Summary of Design

The initial design of the Endoscope Propulsion System consisted of a 4in long rigid internal drive mechanism, which engaged an invaginating, cylindrical balloon. This balloon had integrated teeth that interacted with a central, rotating, helical groove. While this preliminary design provided a basic drive mechanism, several of the device requirements were not met. The varying diameter of the colon requires a device whose operating diameter can also change to retain constant contact with the colon walls. The invaginating motion of the balloon only allows an initial inflation. Once inflated, the working diameter of the balloon could no longer be adjusted, which lessens the effectiveness of the device propulsion. Also, the 4in rigid section could not maneuver the sharp turns of the colon as easily as was desired. Finally, the necessity of the balloon to act as both the main drive mechanism and the inflation device placed added complexity on its manufacturability; as well as, a higher demand on the balloon material. After several design iterations, a final design was developed to meet all of the EPS requirements.

While the overall design of the internal drive mechanism remained unchanged, the internal rigid section, the balloon, and the propulsion method evolved. Rather than having the rigid section extends the entire length of the EPS, it was shortened from 4in to just over 1.5in. This gives the EPS added flexibility, which increases its maneuverability. The balloon in the initial design served two main purposes; to inflate, giving the EPS its operating diameter, and to engage the worm and invaginate, providing the necessary propulsion to move the EPS. However, this dual action neglected two main design requirements; continuous inflation and deflation of the balloon, and simple, cost-effective manufacturing. To improve this, the responsibility of the balloon was limited only to providing the proper diameter for the EPS to operate. Rather than having a cylindrical ellipsoid shape, the shape was simplified to something that resembles a cylindrical toroid. The balloon no longer invaginates, and instead attaches securely to the outer cylinder. With its now stationary position, the balloon can be continuously inflated and deflated in real-time to adjust the diameter of the device to the varying diameters of the colon wall. The propulsion of the EPS is now provided by four drive belts, spaced at 90 degree

intervals around the outer cylinder and balloon. These drive belts have trapezoid teeth which interact with the worm, causing them to rotate, and thus propel the device.

With the drive belts and balloon separated into two different components, a third component was required to maintain a semi-rigid shape to guide the drive belts about their rotation. To do this, a semi-rigid, cylindrical ellipsoid shell was added. This shell is positioned outside of the balloon, but within the drive belts. Its semi-rigidity allows for the necessary flexibility for the EPS to maneuver, while still providing a stable surface for the drive belts to rotate about. While an added component may seem to complicate the design, it actually simplified the manufacturability of the before-mentioned parts, and also addressed the previously unmet design requirements.

With all the design requirements met, the EPS design with dimensions was finalized, so the analysis of this design could be performed. The final EPS part dimensions are summarized in Table 2.

Table 6.1. Summary of the EPS part dimensions.

Parts	Dimensions, in		
	Length	Inner Diameter	Outer Diameter
Inner Cylinder	1.370	0.500	0.520
Worm	1.125	0.530	0.780
Drive Gear	0.125	0.060	0.125
Outer Cylinder	1.125	0.790	0.930
Drive Belts	4.000	N/A	N/A
End Clamps	0.250	0.500	0.930
Overall (incl, balloon, shell, and drive belts)	4.000	0.500	1.100-2.100

6.3 Summary of Analysis

The analysis of the Endoscope Propulsion System examined its mechanical, safety, and propulsive characteristics. The mechanical analysis focused of the various coefficients of friction between the EPS parts, and between the parts and the operating environment, as well as, the output force generated by the worm by various input forces.

There is still work to be done in finalizing this analysis, but a model has been set up, once every aspect of the design is known.

The safety analysis discussed how the forces and pressures generated by the EPS compared to the forces and pressures at which colon perforation can occur. These perforation values were found in journal entries that appeared in the *Journal of Roentgenology,* and *Surgical Endoscopy.* These experiments were conducted on porcine colons to give an accurate estimation of the average and extreme values of force and pressure required to perforate the colon. From these values and the required operating values of the EPS, the factor of safety of the internal pressure and applied force of the EPS was determined to be greater than 1.4.

The propulsion forces generated by the Endoscope Propulsion System were the last to be analyzed. While there is still a lot of future work that needs to be performed to finalize this analysis, a model of the forces was generated. Specifically, the tangential output forces generated by the drive belts as a result of the input torque were looked at. An operating interval for the input torque was created, which ensured forward and reverse EPS motion, while eliminating the possibility of colon perforation as a result of the force of the drive belts against the colon walls. Again, further work is needed before this analysis can be finished.

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Appendix A

EPS Patent Application Document

United States Patent Application **20060270901**
Kind Code **A1**
Bern; M. Jonathan ; et al. **November 30, 2006**

Endoscope propulsion system and method

Abstract

A system and method provides active propulsion of endoscopes along 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. A rotatable toroidal wall, e.g. annular invaginated balloon, provides the propulsion. A drive assembly rotates the toroid while maintaining the toroid's position along the endoscope. The toroid is radially extended or inflated within the lumen to engage its outer surface to the lumen. The toroidal rotation tracks the lumen wall for propulsion. Stops maintain the rotating toroid's position on the endoscope. A helical screw within the toroid engages patterned protrusions around the toroid; screw rotation advances the protrusions to rotate the toroid wall. A fitted belt coupled to a groove in the toroid provides alternative actuation. Colonoscopy is substantially improved, reducing anesthesia and other requirements and costs, and improving safety.

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Claims

1-35. (canceled)

36. An endoscope propulsion device assembly, 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 and 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; and 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; and 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; and 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; and 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 and 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; and 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. A method for propelling an endoscope, comprising: 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; adjusting the toroidal wall from a radially collapsed condition to a radially extended condition, respectively, transverse to the longitudinal axis at the location; actuating the drive assembly 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; and substantially maintaining the toroidal wall at the location along the endoscope while imparting the toroidal rotation to the toroidal wall.

55. The method of claim 54, further comprising: inserting the endoscope and respectively coupled toroidal wall and drive assembly into a body lumen of a patient; engaging a lumen wall of the body lumen with the exterior surface of the toroidal wall in the radially extended condition; and propelling the toroidal wall and endoscope 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.

56. A method for performing endoscopy within a body lumen in a patient, comprising: inserting an endoscope assembly within the body lumen; engaging a substantial circumference of a body lumen wall of the body lumen surrounding the endoscope with a propulsion assembly coupled to the endoscope; providing an axial force against the body lumen wall and around the substantial circumference with the propulsion assembly; and propelling the endoscope along the body lumen at least in part using the axial force against the body lumen wall from the propulsion assembly.

Description

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not Applicable

INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC

[0003] Not Applicable

NOTICE OF MATERIAL SUBJECT TO COPYRIGHT PROTECTION

BACKGROUND OF THE INVENTION

[0005] 1. Field of the Invention

[0006] This present invention provides a system and method adapted to assist movement of devices through body spaces, and in particular body lumens. More specifically, it provides a system and method adapted to assist endoscope movement along body spaces such as lumens. Still more specifically, it provides a system and method adapted to assist movement of devices, and in particular endoscopes, through the colon and lower gastrointestinal tract.

[0007] 2. Description of Related Art

[0008] 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.

[0009] 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.

[0010] 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.

[0011] 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.

[0012] The purpose of the current invention is to develop a safe and effective low cost method for colon cancer screening. To achieve this end the inventors have developed an endoscopic propulsion unit that can attach to currently available colonoscopes. The endoscopic propulsion unit will advance a colonoscope in the colon lumen without stretching the colon wall; greatly reducing procedure-related pain. In addition, safety of colonoscopy will be improved by eliminating the risk of colon perforation. The endoscopic propulsion unit advances a colonoscope by pulling the distal end of the instrument. The invention that follows will allow relatively painless colonoscopy that can be performed safely in a physician's office. By removing the need for high level sedation, colonoscopy could be moved to a lower cost center such as a physician's office. This could result in a 66% savings in the total colonoscopy cost. It is hoped that this comfortable, effective, affordable and safe method for colon cancer screening will be widely used to reduce colon cancer mortality.

[0013] 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 previously disclosed 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. An examining physician has no direct control of the robotic endoscope. Furthermore the examining physician cannot 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.

[0014] 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.

[0015] 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 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.

[0016] 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.

[0017] The toroidal balloon(s) described in at least these two prior disclosures involves 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. This degree of organ wall distention may produce 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.

[0018] 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.

[0019] 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 may 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 may result in elevated potential for infectious disease transmission.

[0020] 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.

[0021] The disclosures of the following issued U.S. Patents are herein incorporated in their entirety 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.

[0022] The following U.S. Patent Application Publications are also herein incorporated in their entirety 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.

[0023] There is still a need for improved endoscope delivery, in particular relation to colonoscopy.

[0024] There is in particular still a need for 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.

[0025] There is also still a need for an improved system and method that modifies commercially available endoscopes for active propulsion along body lumens.

BRIEF SUMMARY OF THE INVENTION

[0026] 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.

[0027] 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.

[0028] 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.

[0029] Another aspect of the invention provides a delivery assembly that works in conjunction with endoscopes, such as for example currently available endoscopes.

[0030] Another aspect of the current invention provides a delivery assembly that attaches easily to currently available endoscopes without generally requiring modification of such endoscopes.

[0031] Another aspect of the current invention provides an endoscope delivery assembly that is easily used and requires minimal training of the endoscopist.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] According to another mode, the annular invaginating balloon is provided as a modification to the endoscope, such as to currently available devices.

[0036] 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.

[0037] 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.

[0038] 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.

[0039] 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.

[0040] Another aspect of the invention provides a colonoscopy system and method that incorporates a colonoscope delivery assembly.

[0041] According to one mode of this aspect, the colonoscope delivery assembly is adapted to allow enhanced patient comfort during colonoscopy with substantially limited sedation.

[0042] 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.

[0043] 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.

[0044] According to one mode of this aspect, the endoscope delivery system and method is adapted to move a commercially available endoscope in this manner.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] Another aspect of the invention provides an endoscope delivery assembly that is under substantial direct control of the endoscopist.

[0054] 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.

[0055] Another aspect of the invention provides an endoscope delivery assembly that incorporates a relatively simple machine with relatively few working parts.

[0056] 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.

[0057] Another aspect of the invention provides an endoscope delivery assembly that is manufacturable at sufficiently low a cost production so as to allow for a disposable product.

[0058] 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.

[0059] 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.

[0060] 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.

[0061] According to one mode of this aspect, the toroidal wall is provided in the form of a toroidal balloon. In a more detailed 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.

[0062] 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.

[0063] 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.

[0064] 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 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; whereas 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. 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 thereby continuously drive toroidal rotation of the toroidal balloon.

[0065] 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.

[0066] According to another further feature, four of such groups of protrusions are provided. In still a further highly beneficial feature, these may be spaced at 90 degree intervals around the circumference transverse to the longitudinal axis.

[0067] 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.

[0068] 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.

[0069] 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.

[0070] 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.

[0071] According to yet another mode, an endoscope is also provided in the system.

[0072] 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.

[0073] In another embodiment, the endoscope and toroidal wall are adapted to be releasably coupled to each other via the endoscope coupler assembly.

[0074] 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.

[0075] 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 translational motion to the exterior surface in the second direction to thereby provide toroidal rotation of the balloon.

[0076] 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.

[0077] 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.

[0078] 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.

[0079] 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.

[0080] Another aspect of the invention is a method for performing endoscopy within a body lumen in a patient as follows. An endoscope assembly 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.

[0081] 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.

[0082] 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 beneficial 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 ordinary skill in the art, are further considered independently beneficial and within the intended scope hereof.

[0083] Further aspects of the invention will be brought out in the following portions of the specification and accompanying claims below, wherein the detailed description is for the purpose of fully disclosing preferred embodiments of the invention without placing limitations thereon.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[0084] The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

[0085] FIG. 1 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 aspect of the invention.

[0086] FIG. 2 shows a perspective view of a schematic illustration of an operator assembly adapted for use in an endoscope delivery system of the invention.

[0087] FIG. 3 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.

[0088] FIG. 4 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.

[0089] FIG. 5A shows an end view of an annular invaginating balloon adapted for use in an endoscope delivery system of the invention.

[0090] FIG. 5B shows a cut away view of an annular invaginating balloon similar to that shown in FIG. 5A, and shows an attached inflation cannula, pressure sensor, and valve.

[0091] FIG. 5C shows another cut away view of an annular invaginating balloon similar to that shown in FIGS. 5A-B, and shows inner and outer balloon surfaces.

[0092] FIG. 6A 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.

[0093] FIG. 6B 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.

[0094] FIG. 6C 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.

[0095] FIG. 6D 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.

[0096] FIG. 7A shows a perspective view of an intermediate (helical) drive wheel

adapted for use in an endoscope delivery assembly of the invention.

[0097] FIG. 7B shows a perspective view of an outer drive wheel adapted for use in an endoscope delivery assembly of the invention.

[0098] FIG. 7C shows a perspective view of an inner drive wheel adapted for use in an endoscope delivery assembly of the invention.

[0099] FIG. 8A 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.

[0100] FIG. 8B 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.

[0101] FIG. 8C 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.

[0102] FIG. 9 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.

[0103] FIG. 10 shows a schematic side view of an endoscope.

[0104] FIG. 11 shows a schematic side view of the endoscope shown in FIG. 10 in a coupled arrangement with a carriage assembly according to a further embodiment of the invention.

[0105] FIG. 12 shows a side view of further detail of the carriage assembly shown schematically in FIG. 11 in coupled arrangement with a drive gear assembly.

[0106] FIG. 13 shows an end view of the carriage assembly and drive gear assembly taken along line 13-13 in FIG. 12.

[0107] FIG. 14A shows a side view of the carriage assembly and drive gear assembly shown in FIG. 12, with the additional feature of a slotted cowling.

[0108] FIG. 14B shows a schematic end view of the respectively coupled components shown in side view in FIG. 14A.

[0109] FIG. 15A shows a longitudinally cross-sectioned side view of an annular invaginated balloon as a further component adapted for coordinated use with the

variously coupled assemblies and components shown in FIGS. 11-14B.

[0110] FIG. 15B shows an end view of an annular invaginated balloon similar to that shown in FIG. 15A.

[0111] FIG. 16 shows a schematic transversely cross-sectioned view through a coupled assembly that includes the various components shown in FIGS. 11-15B.

[0112] FIGS. 17A and 17B show transversely cross-sectioned and longitudinal side views, respectively, of an assembly adapted for use in manufacturing the annular invaginated balloon shown in FIGS. 15A-16.

[0113] FIG. 18 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.

[0114] FIG. 19 shows a partially cross-sectioned side view of the embodiment shown in FIG. 18 in order to illustrate other functional details of the assembly.

DETAILED DESCRIPTION OF THE INVENTION

[0115] Referring more specifically to the drawings, for illustrative purposes the present invention is embodied in the apparatus generally shown in FIG. 1 through FIG. 19. 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.

[0116] The following provide certain clarifying descriptions of the definitions intended according to certain terms and phrases, which are provided for the purpose of providing a better general understanding of the various aspects of the invention herein described.

[0117] In one regard, 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.

[0118] In another regard, an "endoscope" is generally herein intended to mean an optical or video device for examining the lumen (internal opening) of an organ.

[0119] In another regard, a "fluid" 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).

[0120] In another regard, the term "gear" is herein 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).

[0121] In another regard, the terms "helical gear" are herein 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.)

[0122] In another regard, the term "motor" is herein intended to mean something that imparts or produces motion (Funk and Wagnalle, "Standard College Dictionary" Harcourt, Brace & World cw1968).

[0123] In still a further regard, the terms "pin coupling" are herein intended to mean a form of slip joint coupling to a shaft of a motor.

[0124] In yet another regard, the terms "pinion gear" are herein intended to mean a toothed wheel driving or driven by a larger cogwheel (Funk and Wagnalle, "Standard College Dictionary" Harcourt, Brace & World cw1968).

[0125] In yet still an additional regard, the terms "rolling traction" or "rotary traction" are herein 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.

[0126] The term "toroid" is herein 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).

[0127] One highly beneficial embodiment of an endoscopic propulsion device of the present invention is illustrated in FIGS. 1 and 2. FIGS. 1 and 2 represent longitudinal views that show the component parts of the endoscopic propulsion device. FIG. 1 generally shows an entire assembled device, and FIG. 2 shows the order of assembly of the endoscopic propulsion device.

[0128] FIG. 3 shows external drive unit 60 that is composed 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.

[0129] A drive shaft 40 (FIGS. 1-4) 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. 4. The drive shaft sheath prevents trauma to the organ as the drive shaft 40 turns. The drive shaft 40 enters the drive unit, transmission 25, via the proximal attachment bracket 50 and via the end support assembly 20.

[0130] In one embodiment, the drive unit or transmission 25 shown in FIG. 6C consists of 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, transmission 25. In the embodiment illustrated in FIG. 6A, each end support assembly 20 is composed 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. 6A-D, the drive shaft 40 is solidly attached to the inner drive wheel 28. The inner drive wheel 28 is a pinion gear in the preferred embodiment 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. 6D).

[0131] The inner drive wheel 28 is in contact with the intermediate drive wheel 26 with sufficient friction to transmit adequate torque (FIG. 6D). The drive shaft 40 is the axle for the inner drive wheel 28. The drive shaft 40 is positioned parallel to the log axis of the support tube 10 (FIG. 6D).

[0132] In the present embodiment, 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.

[0133] 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 the preferred embodiment, the outer drive wheels 24 are in contact with the intermediate drive wheel 26 in such a means as to allow transfer of rotational energy from the intermediate drive wheel 26 to the outer drive wheels 24 (FIG. 6B). In the present embodiment, rotational energy from the external drive wheels 24 is transmitted to the annular invaginating balloon 30 by friction.

[0134] Further to the present embodiment, such as illustrated in FIGS. 1, 5A, 6B, and 6D, an annular invaginating balloon 30 is positioned over the drive unit 25, as shown in particular in FIG. 6C. 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. 6B) 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. 1) and the long axis of the drive unit 25 (FIG. 6C).

[0135] The annular invaginating balloon 30 is composed of contiguous inner 35 and outer 36 surfaces, as shown in FIG. 5C. 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.

[0136] 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.

[0137] In one highly beneficial embodiment, the annular invaginating balloon 30 illustrated in FIGS. 5A-B has a detachable cannula 31 for fluid inflation, as shown in FIG. 5B. Such a balloon may be similar to a type that is currently commercially available. Manufacture of such a balloon would be 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.

[0138] In the present illustrative embodiment, the endoscopic propulsion device has a flexible support tube 10 with a lumen suitable for the passage and attachment of an endoscope. FIG. 2 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 end supports 50 and 51, as shown in FIG. 2.

[0139] 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.

[0140] 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. 2. As the drive shaft insertion nears completion, the operator will insert 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. 2. 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.

[0141] 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. 1. 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.

[0142] 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 highly beneficial 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.

[0143] The components of drive unit 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 beneficial 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.

[0144] In general with regard to one particular embodiment, 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 highly beneficial further 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.

[0145] An additional embodiment is shown in FIGS. 8A, 8B and 8C. 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 consist of 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. 8a). 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.

[0146] The additional embodiment is shown in FIG. 9 wherein 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.

[0147] It is to be appreciated that the foregoing embodiments herein shown and described by reference to FIGS. 1-9, 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. 10-19.

[0148] 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. 10.

[0149] One particular further beneficial embodiment is shown in various levels of detail in FIGS. 11-17B, which should be read together where appropriate for further understanding of the system and method described.

[0150] More specifically, as shown in FIG. 11, 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.

[0151] As shown in FIG. 12, 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.

[0152] 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.

[0153] As also further shown in the transverse partially cross-sectioned view in FIG. 13, 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.

[0154] As further shown in FIG. 14A, 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. 14B, 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 need.

[0155] FIG. 15A 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. 11-14B. 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. 15B.

[0156] As shown in FIG. 16, 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.

[0157] 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.

[0158] As shown in FIG. 17A and FIG. 17B 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.

[0159] It is to be appreciated, as shown in partial schematic cross-section in FIG. 18, 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. 18, 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.

[0160] It is to be appreciated that other drive mechanisms and relative coupling between components may be used to accomplish various objectives herein described.

[0161] In one particular further embodiment shown in FIG. 19, 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. 19. 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.

[0162] 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.

[0163] Additional modifications or improvements may be made by the embodiments shown and described herein without departing from the intended scope of the invention which is considered to be broadly beneficial according to various independent aspects described. For example, various modifications to or combinations with the present embodiments may be made in view of other available information to one of ordinary skill in the art upon review of this disclosure and remain within the intended scope of the invention.

[0164] Although the description above contains many details, these should not be

construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. Therefore, it will be appreciated that the scope of the present invention fully encompasses other embodiments which may become obvious to those skilled in the art, and that the scope of the present invention is accordingly to be limited by nothing other than the appended claims, in which reference to an element in the singular is not intended to mean "one and only one" unless explicitly so stated, but rather "one or more." All structural, chemical, and functional equivalents to the elements of the above-described preferred embodiment that are known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the present claims. Moreover, it is not necessary for a device or method to address each and every problem sought to be solved by the present invention, for it to be encompassed by the present claims. Furthermore, no element, component, or method step in the present disclosure is intended to be dedicated to the public regardless of whether the element, component, or method step is explicitly recited in the claims. No claim element herein is to be construed under the provisions of 35 U.S.C. 112, sixth paragraph, unless the element is expressly recited using the phrase "means for."

Appendix B

EPS Patent Application Images

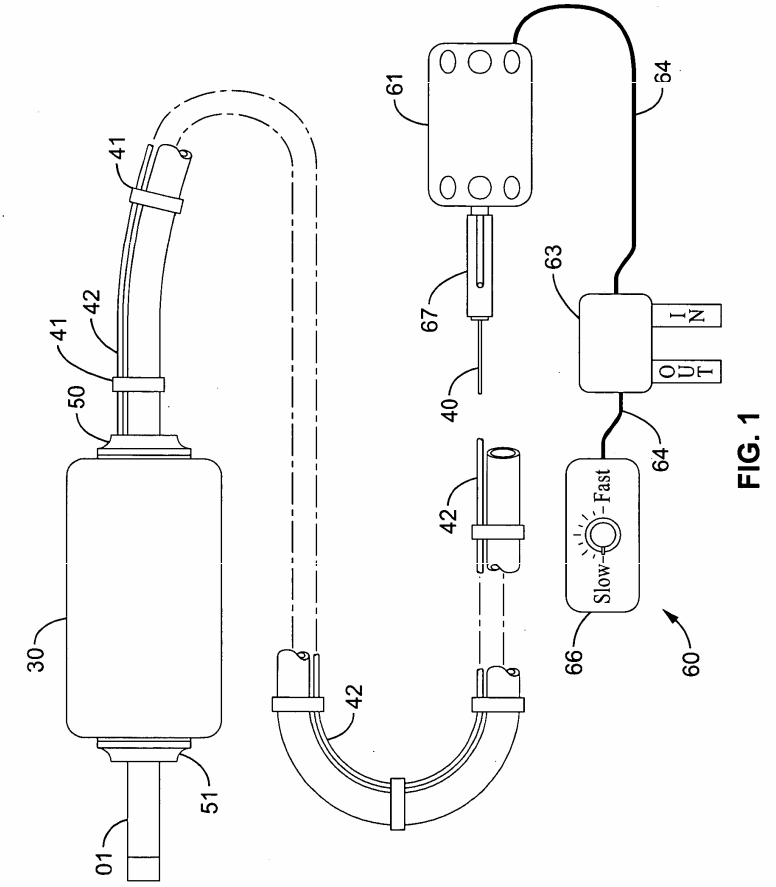

FIG. 1

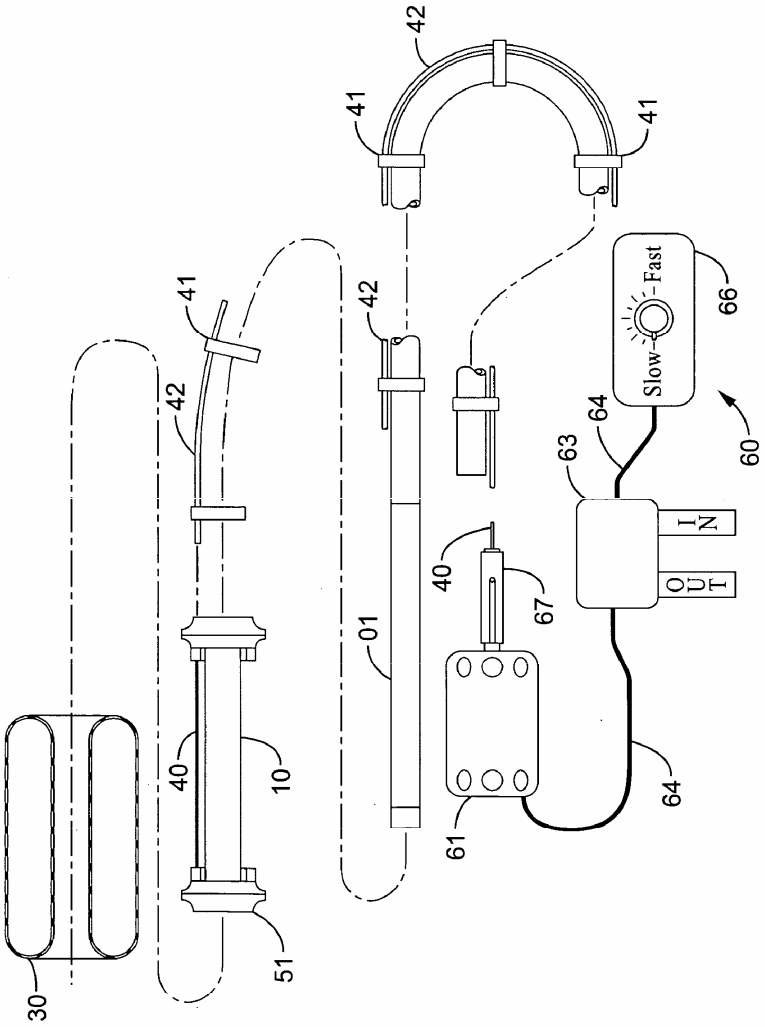
42
41
41
42
41
42
Slow
Fast
66
64
63
60
IN
OUT
40
67
01
40
10
61
64
51
30

FIG. 2

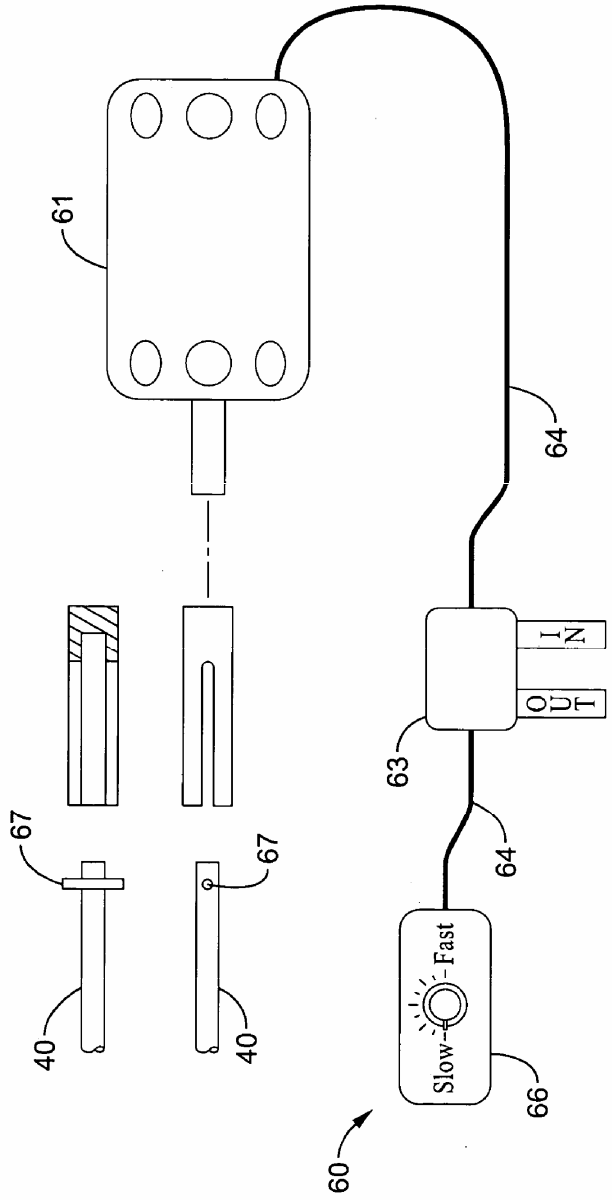

FIG. 3

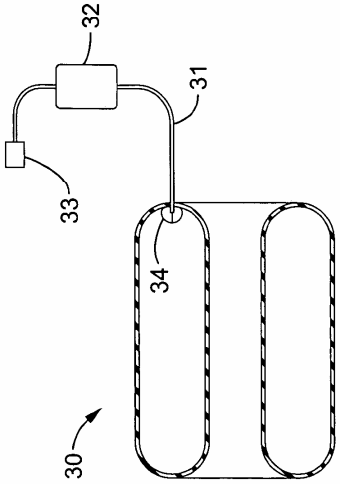

FIG. 5B

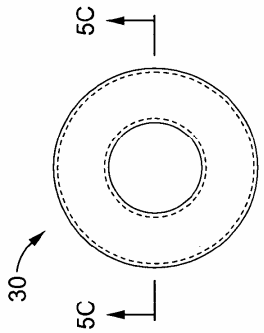

FIG. 5A

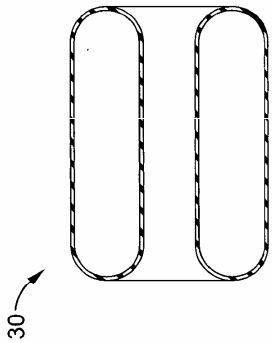

FIG. 5C

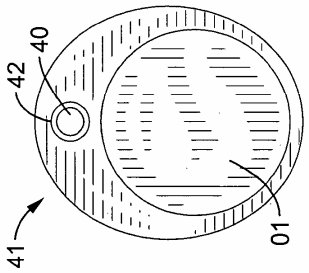

FIG. 4

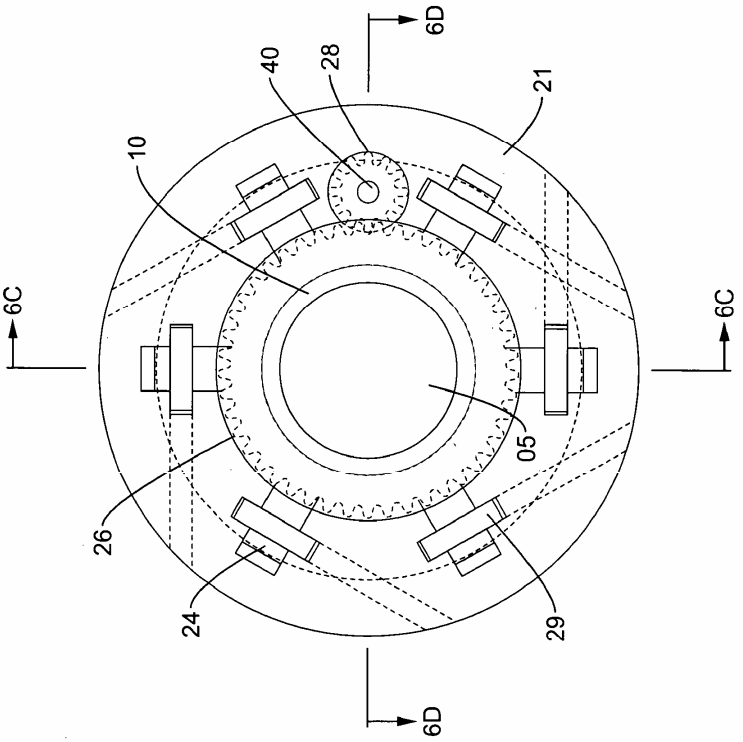

FIG. 6A

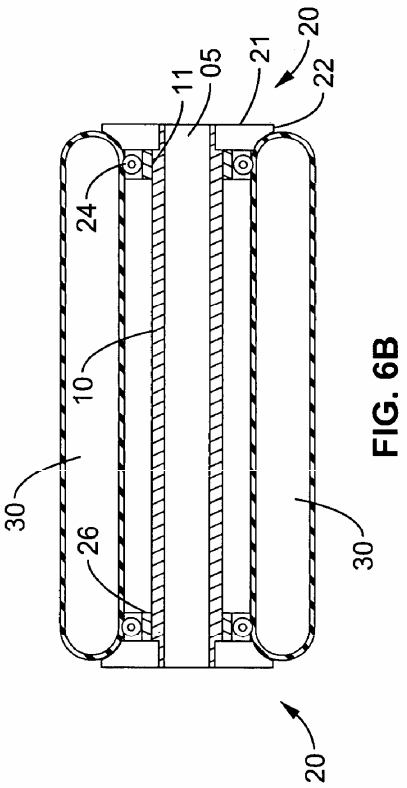

FIG. 6B

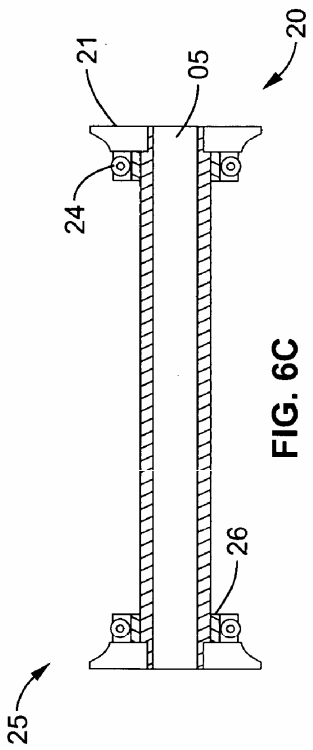

FIG. 6C

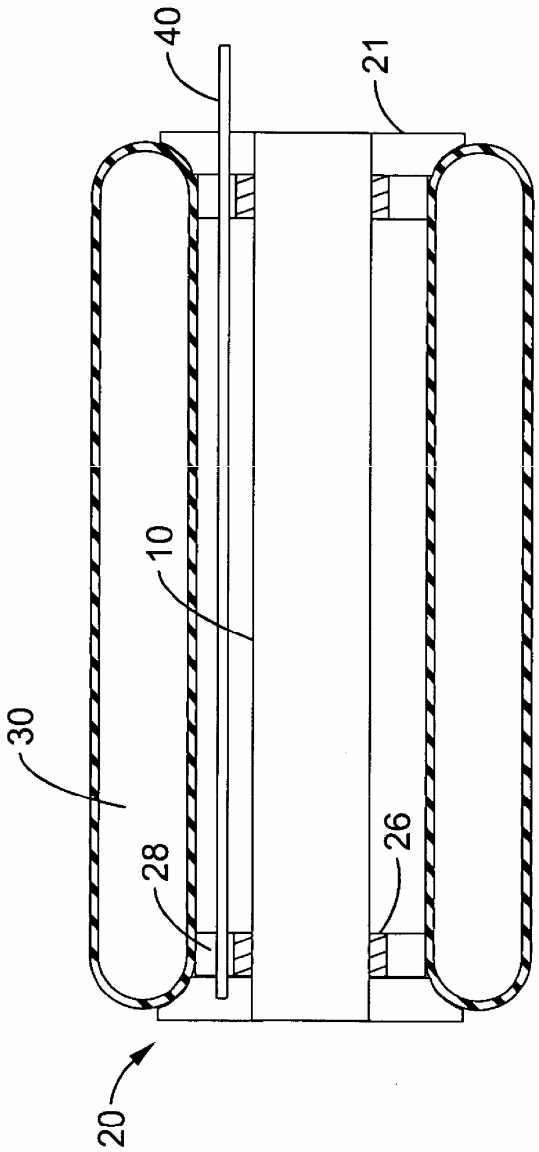

FIG. 6D

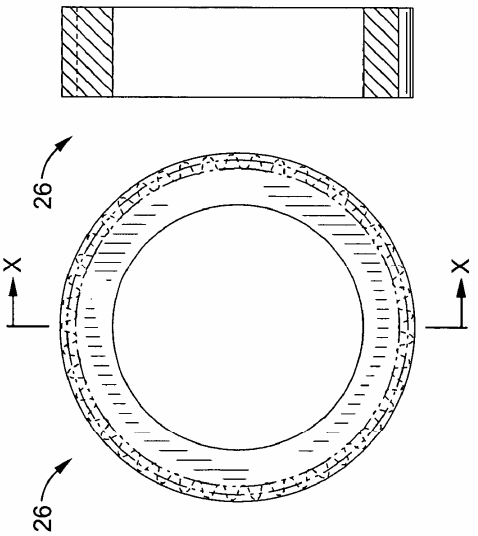

FIG. 7A

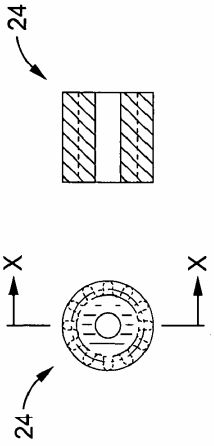

FIG. 7B

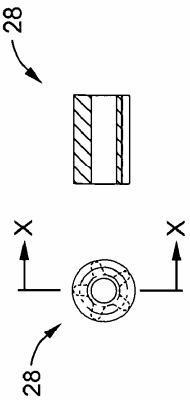

FIG. 7C

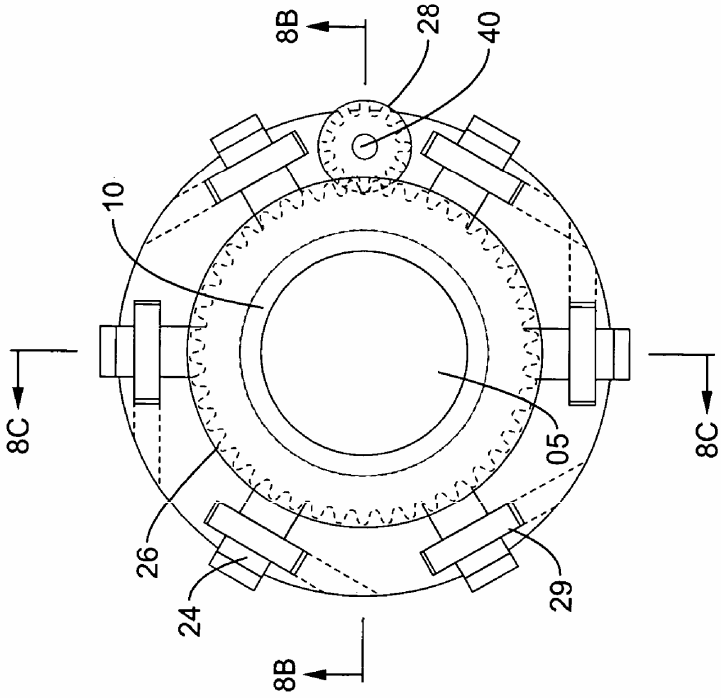

FIG. 8A

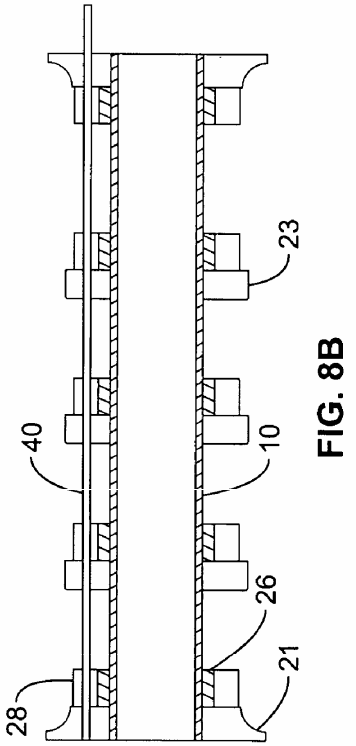

FIG. 8B

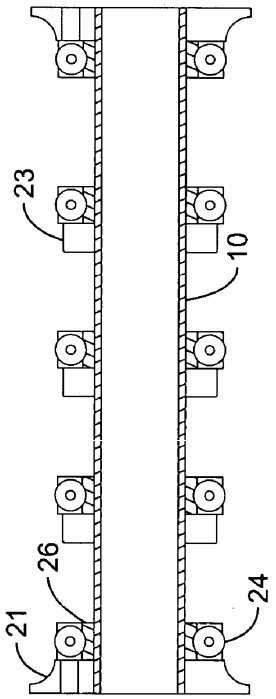

FIG. 8C

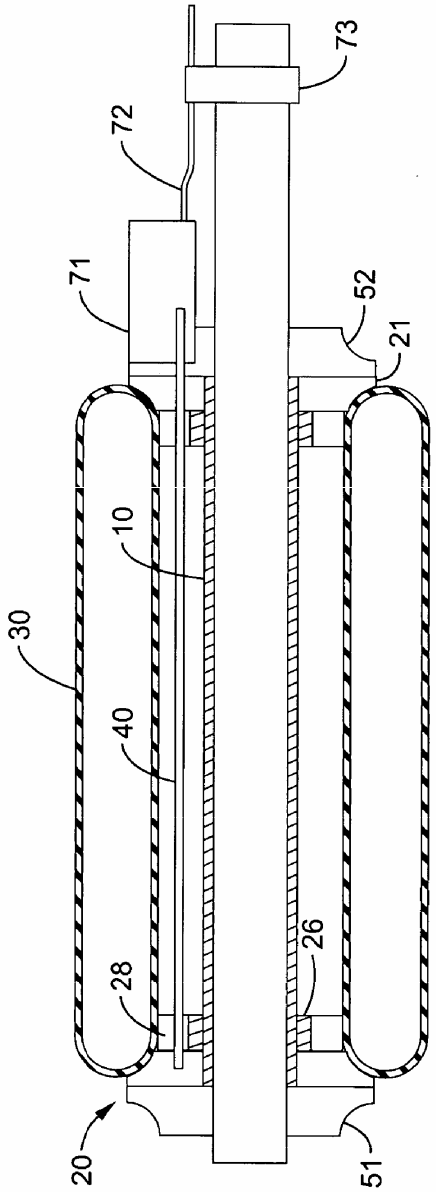

FIG. 9

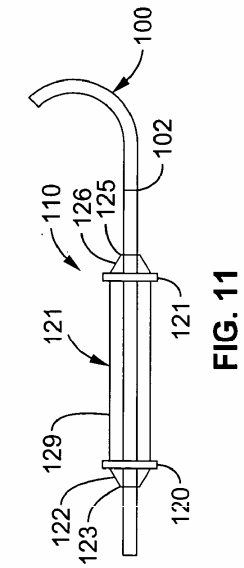

FIG. 11

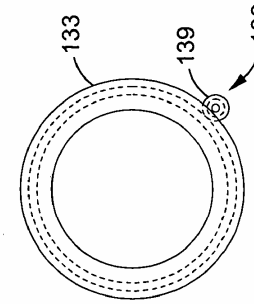

FIG. 13

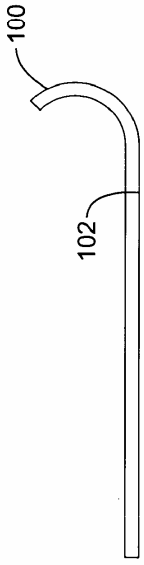

FIG. 10

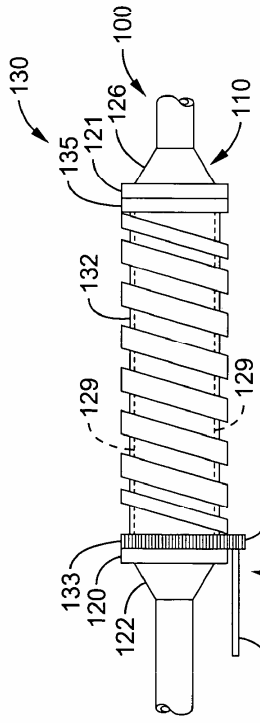

FIG. 12

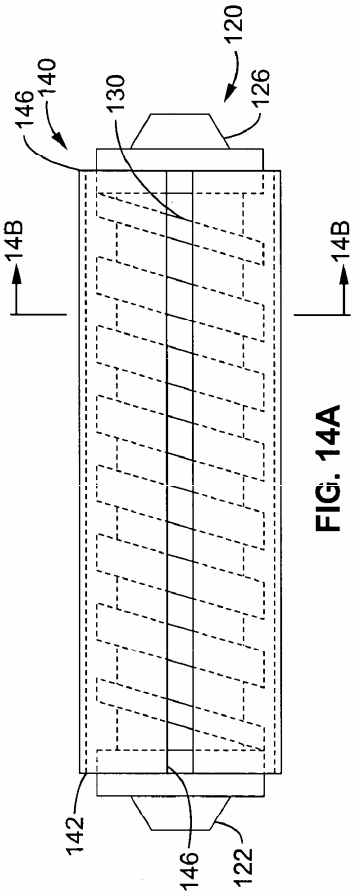

FIG. 14A

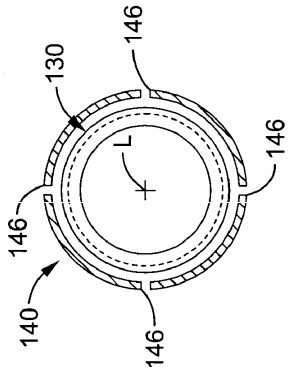

FIG. 14B

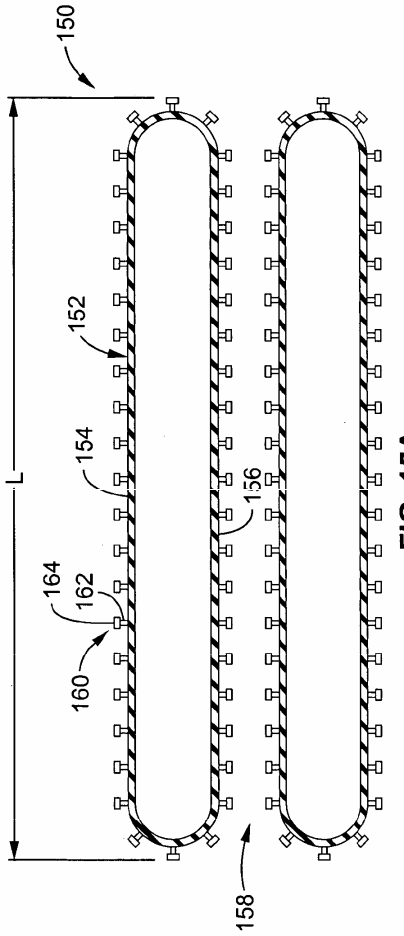

FIG. 15A

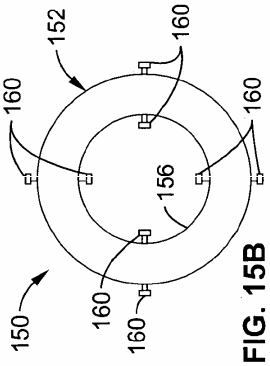

FIG. 15B

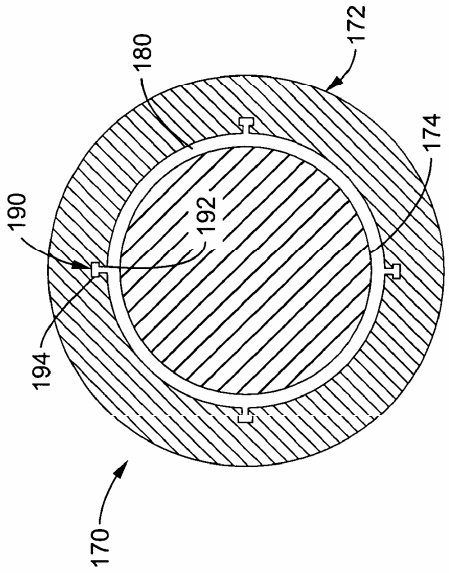

FIG. 17A

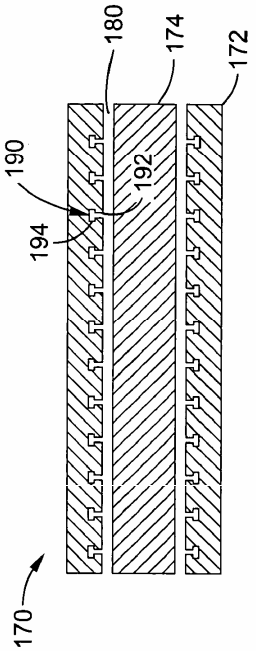

FIG. 17B

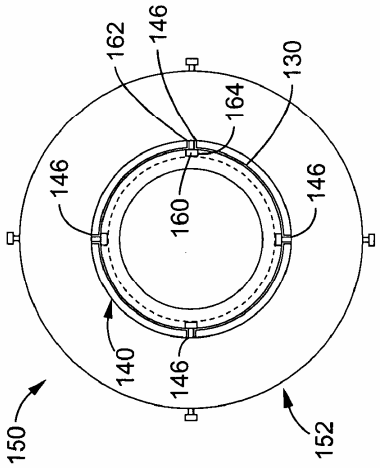

FIG. 16

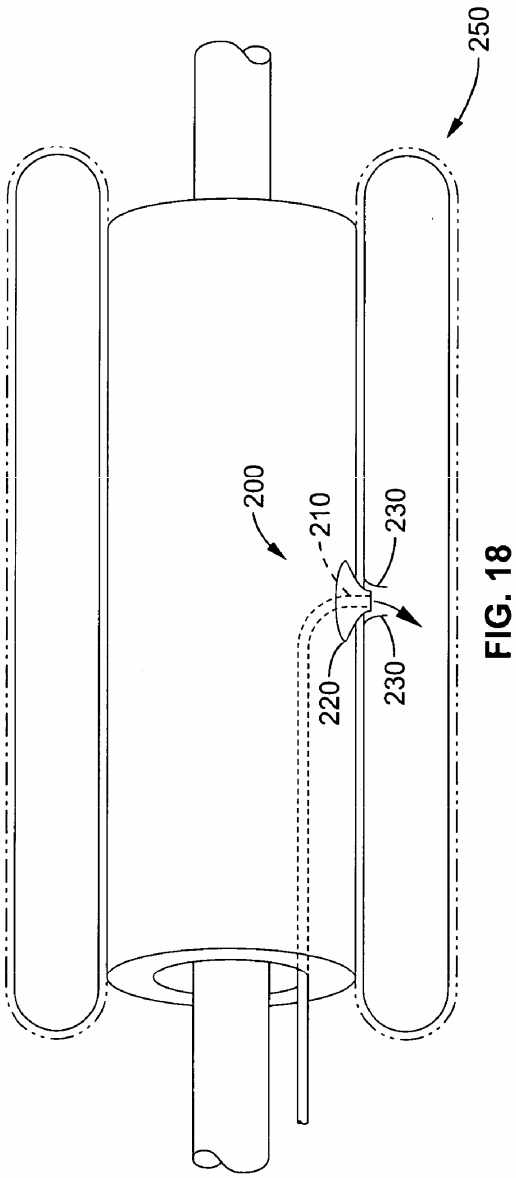

FIG. 18