



(51) International Patent Classification:

A61B 17/12 (2006.01) A61M 29/04 (2006.01)
A61M 29/02 (2006.01)

(21) International Application Number:

PCT/US2014/052785

(22) International Filing Date:

26 August 2014 (26.08.2014)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/870,566 27 August 2013 (27.08.2013) US

(71) Applicant (for all designated States except US): **UNIVERSITY OF SOUTH FLORIDA** [US/US]; 3802 Spectrum Blvd., Suite 100, Tampa, Florida 33612 (US).

(72) Inventors; and

(71) Applicants : **SANCHEZ, Jaime Eduardo** [US/US]; 4123 Saltwater Blvd., Tampa, Florida 33615 (US). **DOLBERG, Michael Eric** [US/US]; 15627 SW 53rd St., Miramar, Florida 33027 (US). **RASHEID, Sowsan Heidar** [US/US]; 1452 Yardley Dr., Wesley Chapel, Florida 33544 (US).

(74) Agent: **LAWSON, Michele L.**; 180 Pine Ave N., Oldsmar, Florida 34677 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: INTRALUMINAL OCCLUDING CATHETER

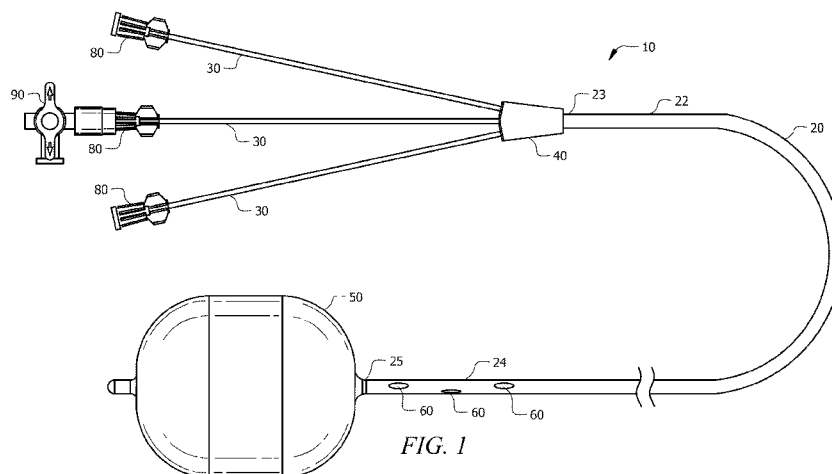


FIG. 1

(57) Abstract: An intraluminal occluding catheter and method for preventing the loss of gas insufflation from a physiological lumen during a medical procedure is presented. The intraluminal occluding catheter is generally comprised of a catheter shaft having a flexible balloon affixed on a distal intraluminal end and a plurality of independent channels extending through the catheter shaft from the external proximal end to the distal intraluminal end. Once inserted into a physiological lumen such as the bowel, the intraluminal occluding catheter controls the loss of insufflation proximally thereby improving the safety and efficiency of TAMIS as well as allowing for more controlled gas exchange to clear smoke or vapor.



5

INTRALUMINAL OCCLUDING CATHETER

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a nonprovisional of and claims priority to U.S. Provisional Patent Application No. 61/870,566, entitled "Intraluminal Bowel Occluding Catheter", filed August 27, 2013, the entire contents of which is herein incorporated into this disclosure.

FIELD OF INVENTION

This invention relates to catheters. More specifically, the invention relates to an intraluminal catheter capable of preventing the loss of insufflation when performing laparoendoscopic procedures.

15 BACKGROUND OF THE INVENTION

Transanal excision of rectal neoplasms has until recently been essentially limited to tumors of the low rectum. However, transanal endoscopic microsurgery (TEM) allowed access to higher rectal tumors through the use of specialized equipment in order to avoid unnecessary proctectomy (Buess G, Theiss R, Gunther M, Hutterer F, Pichlmaier H. Transanal endoscopic microsurgery. Leber Magen Darm 1985; 15:271-279; Buess G, Kipfmuller K, Hack D, Grussner R, Heintz A, Junginger T. Technique of transanal endoscopic microsurgery. Surg Endosc 1988; 2:71-75; Buess G. Review: transanal endoscopic microsurgery (TEM). J R Coll Surg Edinb 1993; 38:239-245).

A more recent advancement hybridizing the concept of TEM with single-incision laparoscopy has led to the creation of transanal minimally invasive surgery (TAMIS) (Atallah S, Albert M, Larach S. Transanal minimally invasive surgery: a giant leap forward. Surg Endosc 2010; 24:2200-2205). This innovative approach is seeing increasing popularity as a safe, feasible and cost-effective alternative to TEM, providing the benefits at reduced cost with a possibly shorter learning curve (Walensi M, Kaser SA, Theodorou P, Bassotti G, Cathomas G, Maurer CA. Transanal endoscopic microsurgery (TEM) facilitated by video-assistance and anal insertion of a single-incision laparoscopic surgery (SILS®)-port: preliminary experience. World J Surg 2014; 38:505-511; Khoo RE. Transanal excision of a rectal adenoma using single-access laparoscopic port. Dis Colon Rectum 2010; 53:1078-1079; Slack T, Wong S, Muhlmann M. Transanal minimally invasive surgery: an initial experience. ANZ J Surg 2014; 84:177-180; Lee TG, Lee SJ. Transanal single-port microsurgery for rectal tumors: minimal invasive surgery under spinal anesthesia. Surg Endosc 2014; 28:271-280).

TAMIS is generally easier to set up, and provides a viewing quality comparable to traditional laparoscopy. Additionally, single-incision laparoscopic ports allow greater instrument

- 5 maneuverability, and have been shown to cause less anorectal trauma (Walensi M, Kaser SA, Theodorou P, Bassotti G, Cathomas G, Maurer CA. Transanal endoscopic microsurgery (TEM) facilitated by video-assistance and anal insertion of a single-incision laparoscopic surgery (SILS®)-port: preliminary experience. *World J Surg* 2014; 38:505-511; Slack T, Wong S, Muhlmann M. Transanal minimally invasive surgery: an initial experience. *ANZ J Surg* 2014; 84:177-180; Barendse RM, Doornebosch PG, Bemelman WA, Fockens P, Dekker E, de Graaf EJ. Transanal employment of single access ports is feasible for rectal surgery. *Ann Surg* 2012; 256:1030-1033; Hayashi S, Takayama T, Yamagata M, Matsuda M, Masuda H. Single-incision laparoscopic surgery used to perform transanal endoscopic microsurgery (SILSTEM) for T1 rectal cancer under spinal anesthesia: report of a case. *Surg Today* 2013; 43:325-328; Canda AE, Terzi C, Sagol O, Sarioglu S, Obuz F, Fuzun M. Transanal single-port access microsurgery (TSPAM). *Surg Laparosc Endosc Percutan Tech* 2012; 22:349-353).

Despite its multiple advantages over traditional transanal excision techniques, TAMIS does have its limitations. Single port procedures can be expensive, and have an inherent tendency for instrument clash (Sehgal R, Cahill RA. Advanced laparoscopic surgery for colorectal disease: NOTES/NOSE or single port? *Best Pract Res Clin Gastroenterol.* 2014; 28:81-96). Rectal insufflation can be lost through the trocar seals when torque forces on the instruments are extreme, or it can also be lost passively into the proximal bowel (Atallah SB, Albert MR, deBeche-Adams TH, Larach SW. Robotic transanal minimally invasive surgery in a cadaveric model. *Tech Coloproctol* 2011; 15:461-464). Additionally, the cost-effectiveness of TAMIS may be limited by the need for an assistant surgeon to manage the camera (Barendse RM, Doornebosch PG, Bemelman WA, Fockens P, Dekker E, de Graaf EJ. Transanal employment of single access ports is feasible for rectal surgery. *Ann Surg* 2012; 256:1030-1033; Rimonda R, Arezzo A, Arolfo S, Salvai A, Morino M. TransAnal Minimally Invasive Surgery (TAMIS) with SILS™ port versus Transanal Endoscopic Microsurgery (TEM): a comparative experimental study. *Surg Endosc* 2013; 27:3762-3768). TAMIS has also been reported to have longer operative times than TEM (; Rimonda R, Arezzo A, Arolfo S, Salvai A, Morino M. TransAnal Minimally Invasive Surgery (TAMIS) with SILS™ port versus Transanal Endoscopic Microsurgery (TEM): a comparative experimental study. *Surg Endosc* 2013; 27:3762-3768).

Colon and rectal surgeons have commonly encountered some major time-consuming and technical obstacles to performing safe and efficient TAMIS procedures such as fluctuation of pneumorectum as insufflation gas escapes proximally into the bowel, causing repeated collapse of the rectal lumen as well as dense smoke created from electrocautery devices obscuring the visual field.

The instant invention alleviates the above obstacles encountered during TAMIS procedures and in addition can be used for any sort of endoscopic procedure to ensure a clear visual field during the procedure.

5 SUMMARY OF INVENTION

The intraluminal occluding catheter presented herein addresses the loss of gas insufflation from the lumen of a body cavity such as the bowel when performing medical procedures. When gas is used to insufflate the bowel, in order to distend the walls and provide sufficient working space, it is often lost from the area of interest due to passage within the lumen causing collapse of the working space. This has become a particularly important problem with the development of advanced techniques that allow complex procedures to be performed within the lumen of the bowel instead of more morbid abdominal or pelvic operations.

Specifically, this invention is particularly useful to prevent the loss of insufflation with either gas or fluid when performing endoscopic procedures in a body cavity such as in the rectum or colon as with a colonoscopy as well as when performing laparoendoscopic procedures within the rectum such as the transanal minimally invasive surgery (TAMIS) technique. The invention can also be used in other body cavities such as the bowel, esophagus, stomach, colon and small intestine.

The intraluminal occluding catheter is generally comprised of a catheter shaft, a flexible balloon affixed at one end of the catheter shaft and a plurality of independent channels that extend the length of the catheter shaft and into the balloon. The catheter shaft may have an exterior surface; an interior surface defining an inner lumen; a distal section terminating at an intraluminal end; a plurality of orifices disposed in the distal section of the catheter shaft; and a proximal section terminating at an external end. The flexible balloon may be affixed to the intraluminal end. Preferably the balloon is capable of conforming to a size and shape of a physiological lumen when filled with gas or fluid. The plurality of independent channels have proximal and distal ends and extend through the inner lumen of the catheter shaft with the distal end of each channel having an aperture disposed therein that may be positioned substantially in alignment with the corresponding orifice in the catheter shaft.

In some embodiments, the intraluminal occluding catheter may also have a flow control device positioned at the proximal end of each channel to open or occlude each channel. This flow control device may be a valve or stopcock.

In an alternative embodiment, an adapter is positioned between the flow control device and the proximal end of each channel.

The device may be further comprised of a sleeve attached to the external end of the catheter shaft with the plurality of independent channels extending through the sleeve and into the inner lumen of the catheter shaft.

Further, a removable wire may be inserted into one of the plurality of channels to provide rigidity when inserting the catheter into a patient.

5 A method of preventing the loss of gas insufflation in a physiological lumen during a medical procedure is also presented. The method comprises inserting the intraluminal occluding catheter into the physiological lumen, positioning the catheter so that it is proximal to the area having the medical procedure, inflating the balloon, performing the medical procedure, deflating the balloon and removing the catheter. If smoke or vapor is created during the medical
10 procedure, it may be evacuated passively through one of the open channels or a smoke removal apparatus or system may be attached to one of the channels to remove the smoke/vapor to allow for a clear viewing field.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the invention, reference should be made to the following detailed
15 description, taken in connection with the accompanying drawings, in which:

Figure 1 is a perspective image of the intraluminal occluding catheter.

Figure 2 is a perspective image of the intraluminal occluding catheter.

Figure 3 is a magnified image of the proximal section of the catheter shaft illustrating the connection of the catheter shaft to the sleeve as well as the channels extending through the
20 catheter shaft and the distal section of the catheter shaft illustrating the connection of the catheter shaft to the balloon as well as the orifices in the catheter shaft. As shown in the image, one channel has apertures at the distal end which is within the balloon to allow for inflation of the balloon. The other channels may have apertures outside the balloon. Apertures close to the balloon, but not within the balloon are used for evacuation of smoke, vapor and gas toward
25 the balloon and thus away from the operative site. Apertures slightly farther from the balloon allow insufflation gas to enter the lumen of the bowel.

Figure 4 is an exploded image of the intraluminal occluding catheter.

Figure 5 is a perspective image of a portion of the proximal section of the intraluminal occluding catheter.

30 **Figure 6** is a front view of the proximal section of the intraluminal occluding catheter illustrating the wire extending through the middle channel.

Figure 7 is a transparent view of the sleeve showing the individual channels extending through sleeve and into catheter shaft.

Figure 8 is a front view of the distal section of the intraluminal occluding catheter showing the
35 distal section of the catheter shaft extending into the balloon. Orifices are also shown in the catheter shaft.

- 5 **Figures 9A-B** are a series of images depicting the balloon as attached to the catheter shaft. **A)** balloon deflated and **B)** balloon inflated. As shown in the image, the balloon can take any shape as long it is capable of conforming to the physiological lumen into which it is placed.

Figures 10 is an exploded image showing a cross section of the catheter shaft with the individual channels extending therethrough.

- 10 **Figure 11** is a cross sectional image of the intraluminal occluding catheter positioned for use in a woman's rectum.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

- In the following detailed description of the preferred embodiments, reference is made to the accompanying drawings, which form a part hereof, and within which are shown by way of illustration specific embodiments by which the invention may be practiced. It is to be understood that other embodiments by which the invention may be practiced. It is to be understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the invention.
- 15

Definitions

- 20 Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, some potential and preferred methods and materials are described herein. All publications mentioned herein are incorporated herein
- 25 by reference in their entirety to disclose and describe the methods and/or materials in connection with which the publications are cited. It is understood that the present disclosure supercedes any disclosure of an incorporated publication to the extent there is a contradiction.

As used in the specification and claims, the singular form "a", "an" and "the" include plural references unless the context clearly dictates otherwise.

- 30 "Substantially" as used herein refers to an amount greater than 50%. In an embodiment, "substantially" refers to a proportional relationship in which one element is largely aligned with or covers a large proportion of the surface of another element.

- "Adapter" as used herein refers to a device which connects different parts of an apparatus, particularly an adapter allows one part of the apparatus to be coupled to an otherwise incompatible device or system. In the instant case, the adapter may be used to connect a
- 35 channel with a flow control device or other device used in conjunction with the intraluminal occluding catheter described herein such as a smoke removal device, a light emitting device, an insufflator device, etc.

5 “Sleeve” as used herein refers to a single continuous structure with two open ends that fits over or around another structure. In the instant case, the plurality of channels are extended through one end of the sleeve and is used to gather the individual channels in a tighter space before they extend into the catheter shaft. At the opposite end, the sleeve fits around the external proximal end of the catheter shaft. In the figures the sleeve is funnel-shaped, however any
10 shape is contemplated as long as the catheter shaft is capable of being attached to one end and all channels are capable of extending through the opposite end into the catheter shaft.

“A plurality” as used herein refers to at least two of the indicated components.

“Flow control device” as used herein refers to any device that is capable of regulating, directing or controlling the flow of a medium such as a gas, liquid, fluidized solid or powder into or out of
15 a space by opening, closing or partially obstructing a passageway. Exemplary flow control devices that may be used in the instant invention include, but are not limited to, valves and stopcocks.

“Physiological lumen” as used herein refers to a cavity within a hollow organ in an animal, preferably a mammal, more preferably a human. Examples of physiological lumens include,
20 but are not limited to, the bowel, stomach, intestines, and esophagus.

“Inflation” as used herein refers to filling the balloon of a catheter with gas or fluid.

“Insufflation” as used herein refers to the act of blowing something, such as a gas, powder or vapor, into a body cavity. In TAMIS, insufflation is continued throughout the procedure to ensure the bowel lumen remains open.

25 TAMIS is a versatile operative technique seeing increased usage not only for the local resection of rectal neoplasms, but in even more complex operations as well. It has been described for use in total mesorectal excision (TAMIS-TME) procedures, transanal completion proctectomies, ligation of rectal Dieulafoy’s lesions, repair of rectourethral fistulas, and extraction of recto-sigmoid foreign bodies (Atallah S, Albert M, Debeche-Adams T, Larach S.
30 Transanal minimally invasive surgery (TAMIS): applications beyond local excision. Tech Coloproctol 2013; 17:239-243; Bak Y, Merriam M, Neff M, Berg DA. Novel approach to rectal foreign body extraction. JSLs 2013; 17:342-345).

TAMIS is seeing major advancements in both technological and technical aspects. The advent of robotic TAMIS is one such innovation that may also improve the technique. For example,
35 instrument clash while working in the tight confines of the rectum is a commonly encountered problem that may be reduced with the dexterity of the robot (Atallah SB, Albert MR, deBeche-Adams TH, Larach SW. Robotic transanal minimally invasive surgery in a cadaveric model. Tech Coloproctol 2011; 15:461-464; Bardakcioglu O. Robotic transanal access surgery. Surg Endosc 2013; 27:1407-1409; Mirnezami AH, Mirnezami R, Venkatasubramaniam AK,

- 5 Chandrakumaran K, Cecil TD, Moran BJ. Robotic colorectal surgery: hype or new hope? A systematic review of robotics in colorectal surgery. *Colorectal Dis* 2010; 12:1084-1093; Hompes R, Rauh SM, Hagen ME, Mortensen NJ. Preclinical cadaveric study of transanal endoscopic da Vinci ® surgery. *Br J Surg* 2012; 99:1144-1148). Additionally, the robot may also provide superior ergonomics and three-dimensional viewing (Atallah S, Nassif G, Polavarapu H, et al.
- 10 Robotic-assisted transanal surgery for total mesorectal excision (RATS-TME): a description of a novel surgical approach with video demonstration. *Tech Coloproctol* 2013; 17:441-447). Endoscopic visualization for TAMIS (eTAMIS) is another advancement, found to minimize instrument collision and provide enhanced visual clarity (McLemore EC, Coker A, Jacobsen G, Talamini MA, Horgan S. eTAMIS: endoscopic visualization for transanal minimally invasive
- 15 surgery. *Surg Endosc* 2013; 27:1842-1845).

With more widespread use, and as TAMIS progresses, it becomes increasingly important to find solutions to commonly encountered difficulties. Fluctuation of pneumorectum frequently obscures laparoscopic visualization, and may increase the risk of instrument collisions and accidental maneuvers. This can be is hazardous, as it may cause accidental lacerations,

20 perforations, and thermal damage to the bowel.

Smoke produced by electrocautery is also a factor that limits visualization, causing loss of precision and time. Ultrasonic shears, in contrast, produce a low-temperature vaporization of biologic material rather than smoke (Takahashi H, Yamasaki M, Hirota M, et al. Automatic smoke evacuation in laparoscopic surgery: a simplified method for objective evaluation. *Surg*

25 *Endosc* 2013; 27:2980-2987; Barrett WL, Garber SM. Surgical smoke: a review of the literature. Is this just a lot of hot air? *Surg Endosc* 2003; 17:979-987; Johnson GK, Robinson WS. Human immunodeficiency virus-1 (HIV-1) in the vapors of surgical power instruments. *J Med Virol* 1991; 33:47-50). Ultrasonic dissection compared to standard electrosurgery has also been found to cause significantly less intraoperative blood loss (140.8 mL vs 182.6 mL, $p = 0.032$) (20. Morino

30 M, Rimonda R, Allaix ME, Giraudo G, Garrone C. Ultrasonic versus standard electric dissection in laparoscopic colorectal surgery: a prospective randomized clinical trial. *Ann Surg* 2005; 242:897-901). Of note however, both types of dissectors become heated during use, with the potential to cause thermal injury to the rectum if inadvertently applied to tissues, especially in the case of obscured visualization.

35 TAMIS Procedure

The patient is placed in lithotomy position and the rectum is irrigated as desired. The perineum is draped in a sterile fashion. Gentle digital dilation of the anus is performed, and a transanal, single-incision, laparoscopic port is introduced. Insufflation is achieved using carbon dioxide instead of air to facilitate resorption of retained gas and improve postoperative patient comfort.

40 The rectal neoplasm is excised, and the resultant defect is repaired.

5 Maintenance of Pneumorectum

During conventional TAMIS procedures, there are considerable fluctuations in the degree of distention of the rectal lumen as well as collapse, which occur as gas escapes proximally into the colon. The frequency of this collapse depends on factors such as the angulation of rectosigmoid junction or the location of the rectal lesion where dissection is needed. To properly maintain pneumorectum (at the appropriate pressure of approximately 15-20cm of water) throughout the operation, the inventors developed an intraluminal occluding catheter to prevent loss of insufflation proximally. Once a port is placed in the anus, the catheter is introduced through the port, and with the intraluminal end of the catheter placed proximal to the lesion or at the rectosigmoid junction. One channel is used for inflation of the balloon which is performed under direct visualization. Full occlusion of the lumen is assured by cessation of flow from the laparoscopic insufflator at an appropriate pressure. The use of this device in the bowel is known as balloon occlusive transanal minimally invasive surgery.

Electrocautery Smoke

The use of electrocautery during TAMIS can create a significant amount of thick smoke, which is not readily evacuated from within the confined space of the lumen, obscuring the visual field and slowing progress of the operation. As well, loss of visualization can be unsafe during the critical portion of the operation when dissection is occurring. Use of an ultrasonic dissector, which produces vapor as a byproduct, instead of smoke, leads to improved visualization. Although gas exchange is still necessary to clear the vapor from the field of view, the problem is more easily managed. The instant invention is capable of removing the smoke or vapor caused by electrosurgical devices by allowing passive flow through, or attaching a smoke removal system to the proximal end of one of the channels. The smoke or vapor is drawn through orifices in one channel of the catheter shaft, out of the viewing area, and up the channel once the smoke removal system is operated.

As illustrated in Figures 1 and 2, catheter 10 is generally composed of semi-rigid catheter shaft 20 having an exterior and interior surface which defines inner lumen 26 through which a plurality of separate and independent channels 30 extend. Catheter shaft 20 is composed of proximal section 22 which terminates at external end 23 and distal section 24 which terminates at intraluminal end 25. Channels 30 extend through inner lumen 26 of catheter shaft 20 from proximal section 22 to distal section 24 where flexible balloon 50 is affixed. Catheter shaft 20, and correspondingly channels 30, extend into inner lumen of balloon 50.

Figure 3 is a transparent view of catheter 10. The proximal end (external end) of catheter 10 has multiple independent channels 30 that correspond to the individual internal channels 30 within inner lumen 22 of catheter shaft 20. As shown in the figure, channels 30 extend from proximal section 22 of catheter shaft 20 to distal section 24 of catheter shaft 20 to provide a

5 plurality of separate independent channels within inner lumen 26 of catheter shaft 20. While the number of channels shown in the figures is three, the number of channels may vary as long as they are capable of fitting within the inner lumen of the catheter shaft. In some embodiments channels 30 may have apertures 65 positioned at distal end to allow for removal of smoke/vapor from the potential space. Apertures 65 in channels 30 are substantially aligned with
10 corresponding orifices 60 in catheter shaft 20. As shown in Figure 3, one channel 30 has apertures 65 only within balloon 50 to allow for inflation of balloon 50. To inflate balloon 50, a syringe or other inflation device is attached to the proximal end of channel 30. A different channel 30 may have one or more apertures 65 near balloon 50, allowing for evacuation of smoke, vapor and gas toward balloon 50 and thus away from the camera and operative site.
15 Another different channel 30 may have one or more apertures 65 slightly farther from balloon 50 to allow insufflation gas to enter the lumen of the bowel and push the smoke toward balloon 50 and away from the camera and operative site. Channels 30 may be used for various purposes according to the needs of the physician including, but not limited to, inflation of the balloon with gas; insufflation of gas or instillation of fluid into the lumen of the bowel; evacuation
20 of gas, smoke or vapor from the lumen of the bowel; and internal lighting of the lumen.

Figure 4 is an exploded view of catheter 10. Adapter 80 is capable of attaching to proximal end of each channel 30. Flow control device 90 is shown as an example of a device that can be attached to adapter 80, however any device known in the art for use with catheters during endoscopic surgery may be attached to adapter 80. For example, instead of flow control device
25 90, a Plume-away™ smoke evacuation system device may be attached to adapter 80 to remove smoke from the visual field; a light emitting device may be placed directly through adapter to further illuminate the visual field; or a fluid irrigation device may be attached to adapter 80 to irrigate the site. Additionally, flow control device 90 can be attached to adapter 80 and an additional device may then be attached to flow control device 90 so that the channel
30 may be opened or closed according to the use of the device. For example, this device can be a smoke/vapor removal system described previously or an insufflator device to fill the bowel lumen with air or other gas. Channels 30 may be gathered and extend through sleeve 40 which can be attached to proximal section 22 of catheter shaft 20. Sleeve 40 allows channels 30 to be more easily inserted into proximal section 22 of catheter shaft 20. Balloon 50 is shown
35 as attaching to distal section 24 of catheter shaft 20.

Figure 5 illustrates a cut-away section of proximal section 22 of catheter shaft 20 showing channels 30 extending through sleeve 40. Figure 7 is a transparent view inside sleeve 40 and catheter shaft 20. As shown in the figures, channels 30 are gathered and positioned to extend through sleeve 40. Catheter shaft 20 is affixed to opposite end of sleeve 40 and channels 30
40 pass through sleeve 40 and into catheter shaft 20 to form a plurality of independent channels within inner lumen 26 of catheter shaft 20. The proximal end of each of channels 30 may have

5 adapter 80 onto which flow control device 90 is connected. Flow control device 90 is capable of occluding or opening an individual channel 30. Adapters 80 are shown as attached to proximal end of channels 30 with flow control device 90 shown as attaching to adapter 80 of one channel 30. Adapter 80 may be any type of adapter known in the art to be used to attach a flow control device or other medical instrument. An example of such adapter includes, but is
10 not limited to, a Luer Lock. Flow control device 90 may be any flow control device known in the art to be capable of opening or closing channel 30 such as a valve or stopcock.

As shown in Figures 6 and 10, one channel 30 may have removable wire 70 slideably disposed within inner lumen of channel 30. Wire 70 extends outwardly from proximal end of channel 30 and extends through inner lumen of channel 30 to distal end of channel 30 which is located in
15 balloon 50. (Figure 8) Wire 70 provides additional rigidity to catheter 10 and allows for catheter 10 to be more easily placed in the physiological lumen. Once catheter 10 is placed within the body of the patient, wire 70 may be easily removed allowing channel 30 to be used for another purpose such as inflation of balloon 50.

Figures 8 and 9 depict distal section 24 of catheter shaft 20 illustrating a plurality of orifices 60
20 disposed within distal section. Each orifice 60 in catheter shaft 20 corresponds to a similarly placed aperture 65 found in one or more channels 30. Corresponding orifice 60 and aperture 65 allows for inflation/deflation of balloon 50, insufflation of gas into the physiologic lumen, removal of smoke/vapor from the potential space, etc. Figure 9A depicts balloon 50 in a deflated state while Figure 9B depicts balloon in an inflated state. Figures 9A and B also
25 illustrate that any shape of balloon may be used as long as it is capable of conforming to the physiological lumen.

Balloon 50 is affixed to distal section 24 of catheter 20 by any means known to those in the art including, but not limited to, heat bonding or adhesive. Intraluminal end 25 of catheter 20 extends through the inner lumen of balloon 50 with proximal waist of balloon 50 being secured
30 to exterior surface of distal section 24 of catheter shaft 28. Balloon 50 is a flexible balloon capable of conforming to the size and shape of the bowel lumen, or any other lumen/cavity such as the esophagus, small intestine, colon or stomach, when filled with gas or fluid. Any type of balloon may be used as long as it has the ability to expand in size with inflation while attached to the catheter and completely occlude the given cavity, in this example the proximal
35 rectal lumen, without injury. An example of such balloon for use in the rectum is an anal manometry balloon.

In use, catheter 10 is capable of being inserted and guided into position within a physiological lumen such as the bowel. Figure 11 illustrates catheter 10 in use in the rectum of a patient. While use in the rectum is illustrated, catheter 10 is capable of use in any endoscopic procedure
40 and can be used to occlude any cavity such as the esophagus, small intestine, colon, or

5 stomach. As shown in Figure 11, a port is positioned within the opening of the physiological lumen, in this case, the port is inserted into the anus. There is a cap to the outside of the port to close the lumen off distally while the balloon closes the lumen proximally. The distal end (intraluminal end) of catheter 10 is inserted into the bowel through the port and positioned within
10 within the bowel, wire 70 may be removed and inflation of the balloon may be performed using a variety of methods such as, but not limited to, a syringe attached to one channel 30. Full occlusion of the bowel is assured by cessation of flow from the laparoscopic insufflator at an appropriate pressure. One channel 30 of the catheter 10 may have an endoscopic light extended therethrough to illuminate the visual field. Once occluded, the physician may excise
15 the lesion and any smoke/vapor that may impair the visual field can be removed through another channel 30 in the catheter 10 by passive flow or with the use of a smoke removal system that is attached to external channel 30 by adaptor 80 or flow control device 90.

Successful maintenance of pneumorectum using balloon occlusion and lessening of the smoke or vapor produced using electrosurgical dissection in conjunction with removal of gas using the
20 intraluminal catheter presented herein both allow for an obvious improvement in visualization and precision and along with facilitation of rectal defect closure may decrease total operative times. Better visualization, improved precision, decreased operative time, and lessened blood loss all improve surgical efficiency, safety, and postoperative outcomes.

The disclosures of all publications cited above are expressly incorporated herein by reference,
25 each in its entirety, to the same extent as if each were incorporated by reference individually.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the scope of the invention which, as a matter of language, might be said to fall there between. Now that the invention has been described,
30

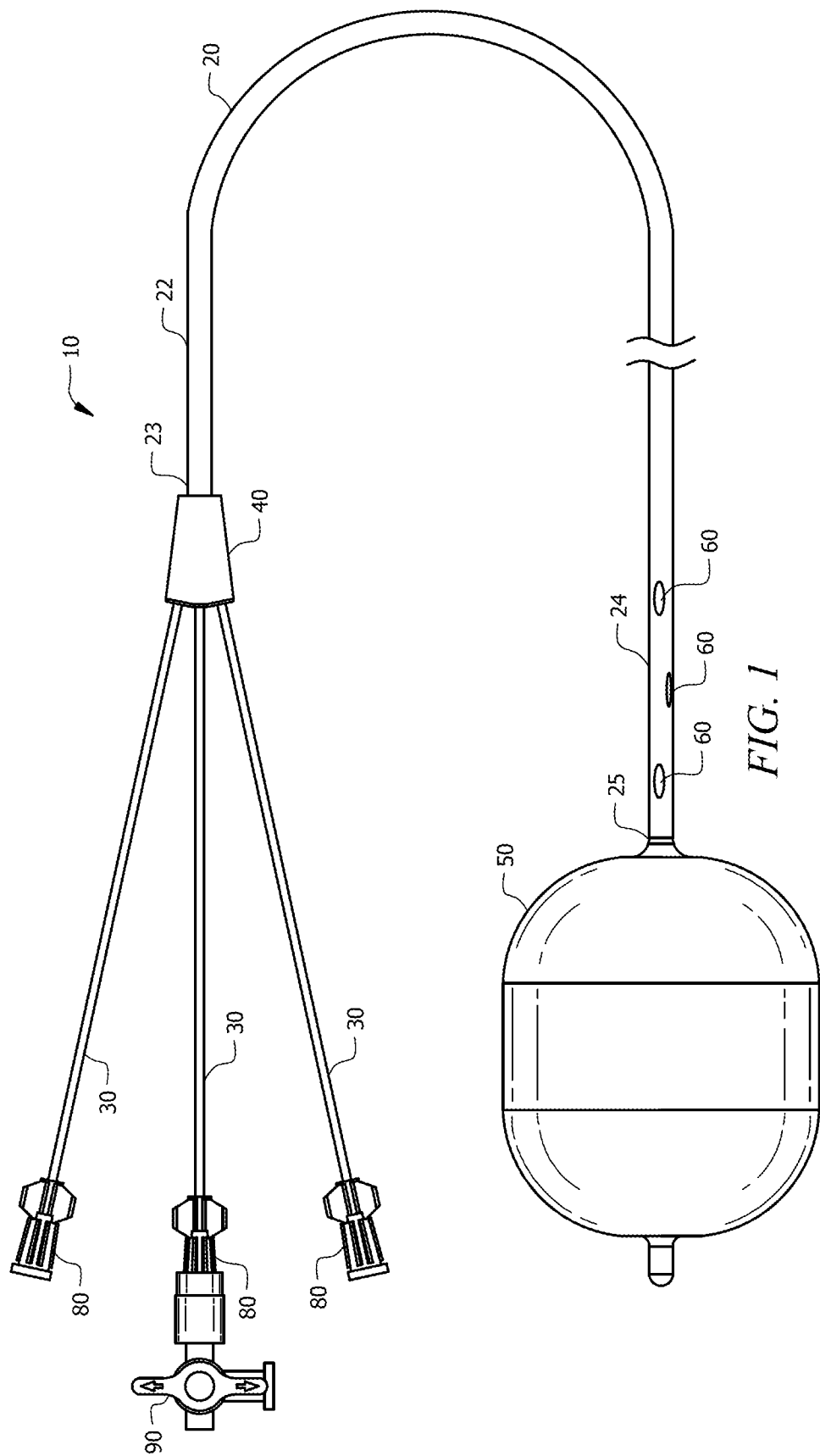
5 What is claimed is:

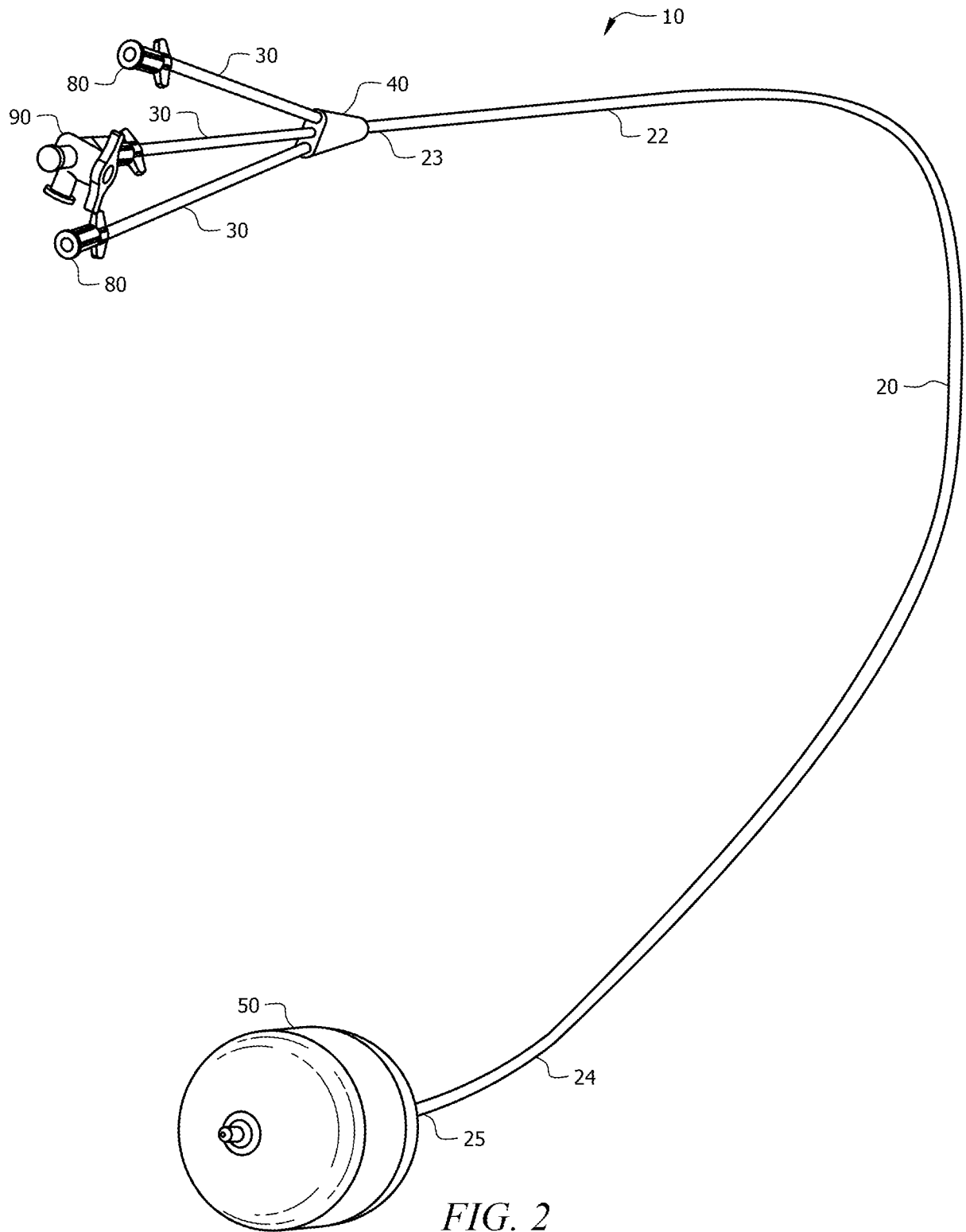
1. An intraluminal occluding catheter comprising:
 - a catheter shaft comprising
 - an exterior surface;
 - an interior surface defining an inner lumen;
 - 10 a distal section terminating at an intraluminal end;
 - a plurality of orifices disposed in the distal section of the catheter shaft; and
 - a proximal section terminating at an external end;
 - 15 a flexible balloon affixed to the intraluminal end whereby the balloon is capable of conforming to a size and shape of a physiological lumen when filled with gas or fluid; and
 - a plurality of independent channels having proximal and distal ends wherein the independent channels extend through the inner lumen of the catheter shaft;
 - 20 wherein the distal end of each channel has at least one aperture disposed therein;
 - wherein each aperture is substantially aligned with the corresponding orifice in the catheter shaft.
2. The catheter of claim 1, further comprising a flow control device positioned
 - 25 at the proximal end of each channel to open or occlude each channel.
3. The catheter of claim 2, wherein the flow control device is a valve or stopcock.
4. The catheter of claim 1, further comprising an adapter positioned between the flow control device and the proximal end of each channel.
5. The catheter of claim 1, further comprising a sleeve attached to the external
 - 30 end of the catheter shaft wherein the plurality of independent channels extend through the sleeve and into the inner lumen of the catheter shaft.
6. The catheter of claim 1, wherein the independent channels extend through the entire length of the inner lumen of the catheter shaft from the external
 - 35 end to the intraluminal end.

- 5 7. The catheter of claim 6, further comprising a removable wire inserted into one of the plurality of channels to provide rigidity when inserting the catheter into a patient.
8. The catheter of claim 6, wherein the apertures of one independent channel are disposed only within the distal end of the one independent channel
- 10 9. The catheter of claim 1, wherein the physiological lumen is selected from the group consisting of bowel, stomach, intestines, colon and esophagus.
10. An intraluminal occluding catheter comprising:
- 15 a catheter shaft having a distal section terminating in an intraluminal end, a proximal section, an inner lumen;
- a plurality of orifices disposed in the distal section of the catheter shaft;
- a flexible balloon affixed to the intraluminal end whereby the balloon is capable of conforming to a size and shape of the physiological
- 20 lumen when filled with gas or liquid;
- a plurality of independent channels having a distal end and a proximal end wherein the distal end of the plurality of independent channels extends through the inner lumen from the proximal section to the distal section of the catheter shaft;
- 25 an adapter having opposing ends wherein one end is positioned at the proximal end of each channel;
- a flow control device positioned at the opposing end of the adapter;
- wherein the distal end of each channel has at least one aperture disposed therein;
- 30 wherein the at least one aperture is substantially aligned with the corresponding orifice in the catheter shaft.
11. The catheter of claim 10, further comprising a sleeve attached to the external end of the catheter shaft wherein the plurality of independent channels extend through the sleeve and into the inner lumen of the catheter
- 35 shaft.

- 5 12. The catheter of claim 10, further comprising a removable wire inserted into one of the plurality of channels to provide rigidity when inserting the catheter into a patient.
13. The catheter of claim 10, wherein the apertures of one independent channel are disposed only within the distal end of the one independent channel
- 10 14. The catheter of claim 10, wherein the flow control device is a valve or stopcock.
15. The catheter of claim 10, wherein the physiological lumen is selected from the group consisting of bowel, stomach, intestines, colon and esophagus.
- 15 16. A method of preventing the loss of gas insufflation in a physiological lumen during a medical procedure comprising:
- inserting an intraluminal occluding catheter into the physiological lumen wherein the intraluminal occluding catheter is comprised of
- a catheter shaft having a distal section with a plurality of
- 20 orifices, a proximal section, an inner lumen;
- a plurality of independent channels having a distal end and a proximal end wherein the distal end of the plurality of independent channels extends through the inner lumen of the catheter shaft;
- 25 a flexible balloon capable of conforming to a size and shape of the physiological lumen when filled with gas or liquid;
- an adapter having opposing ends wherein one end is positioned at the proximal end of each channel;
- 30 a flow control device positioned at the opposing end of the adapter;
- wherein the distal end of each channel has at least one aperture disposed therein;
- wherein the at least one aperture is substantially aligned with the corresponding orifice in the catheter shaft.
- 35 inflating the balloon to occlude the physiological lumen;
- performing the medical procedure;

- 5 deflating the balloon; and
- removing the intraluminal occluding catheter from the physiological lumen.
- 10 17. The method of claim 16, further comprising removing smoke or vapor produced by the medical procedure by allowing passive flow of gas through the orifices in the catheter shaft and the corresponding apertures in one of the channels.
18. The method of claim 16, further comprising removing smoke or vapor produced by the medical procedure by attaching a smoke removal apparatus to the flow control device of the intraluminal occluding catheter.
- 15 19. The method of claim 16, wherein the intraluminal occluding catheter is further comprised of a removable wire inserted into one of the plurality of channels.
20. The method of claim 19, further comprising removing the wire from the channel after the intraluminal occluding catheter is inserted into the physiological lumen.
- 20





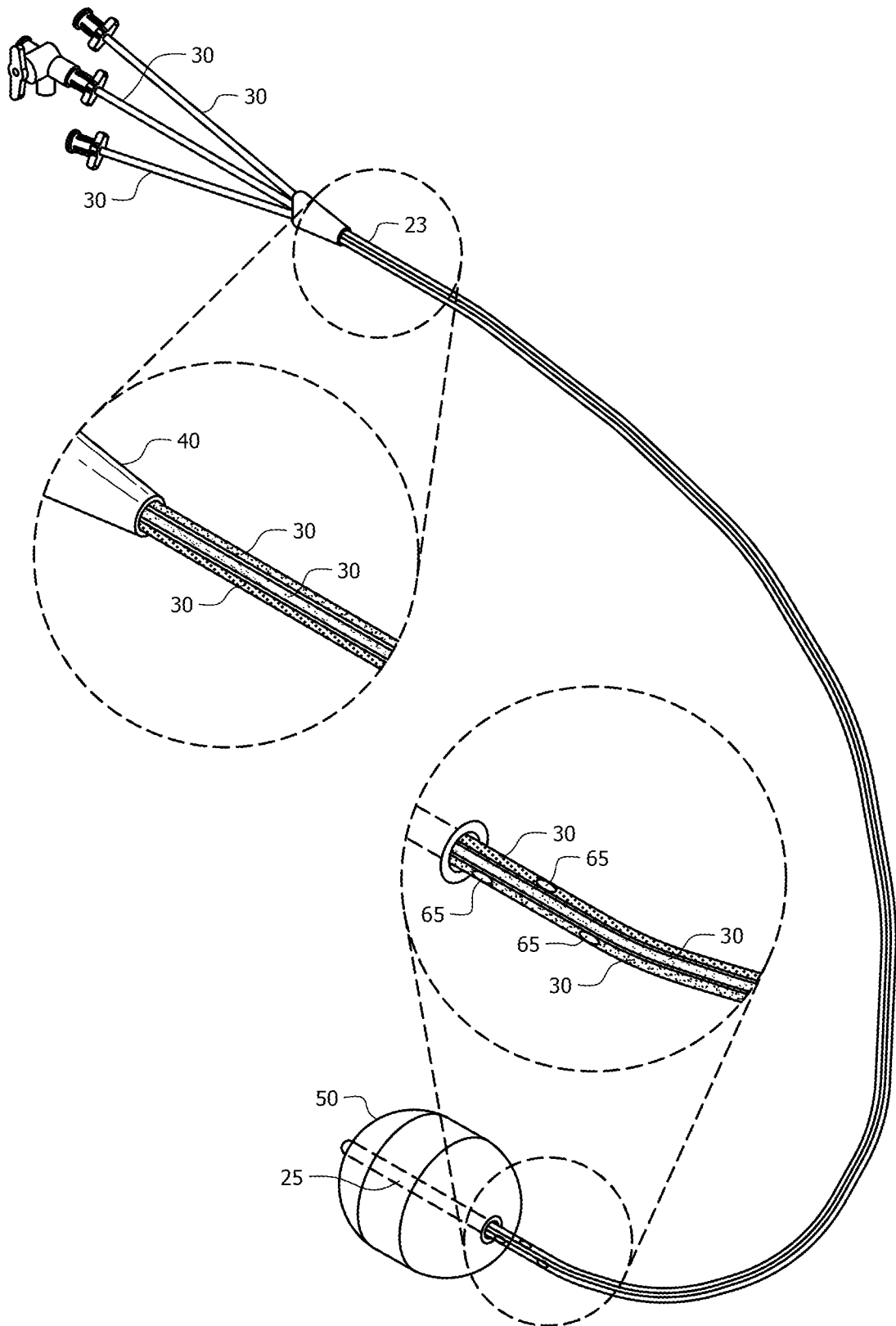
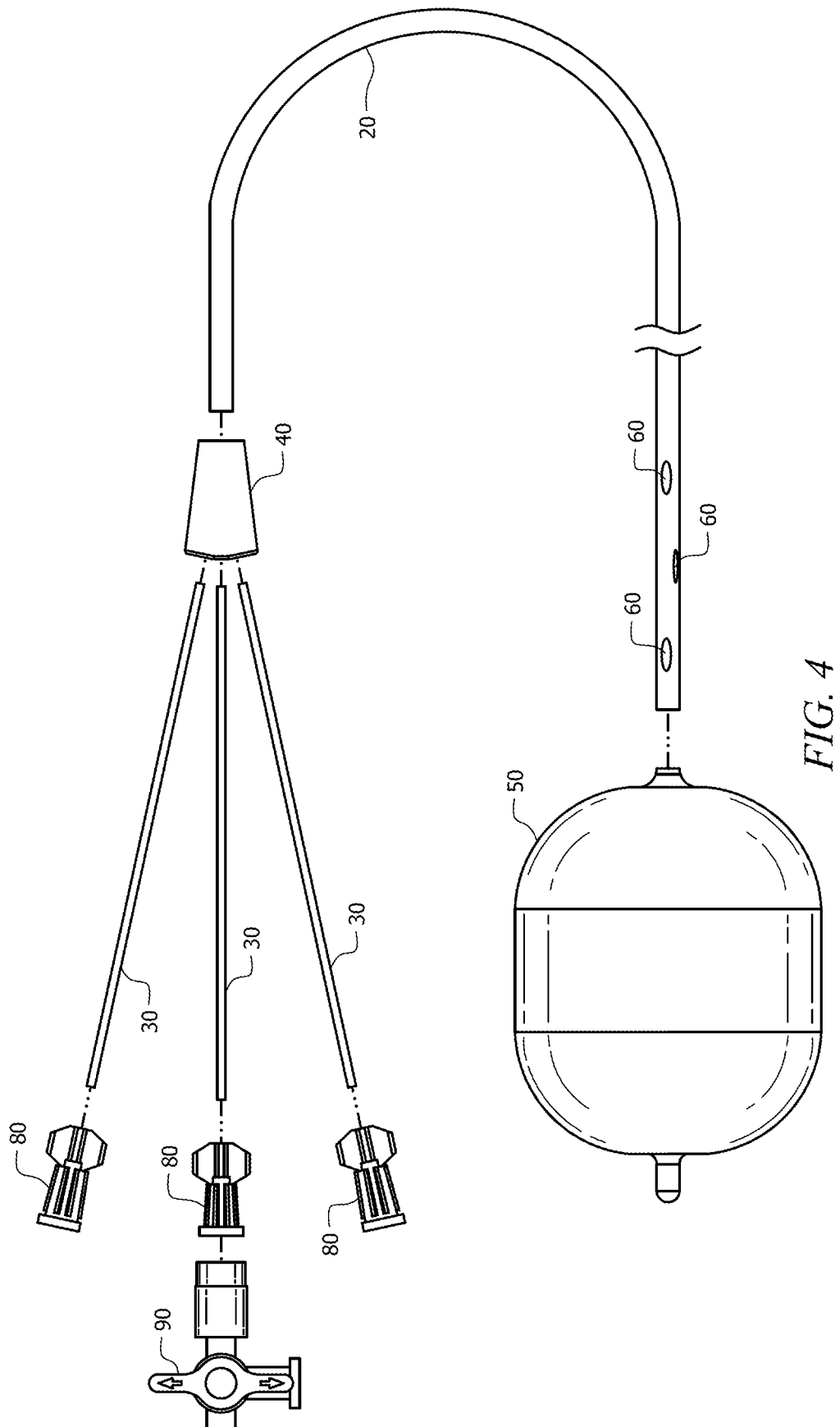
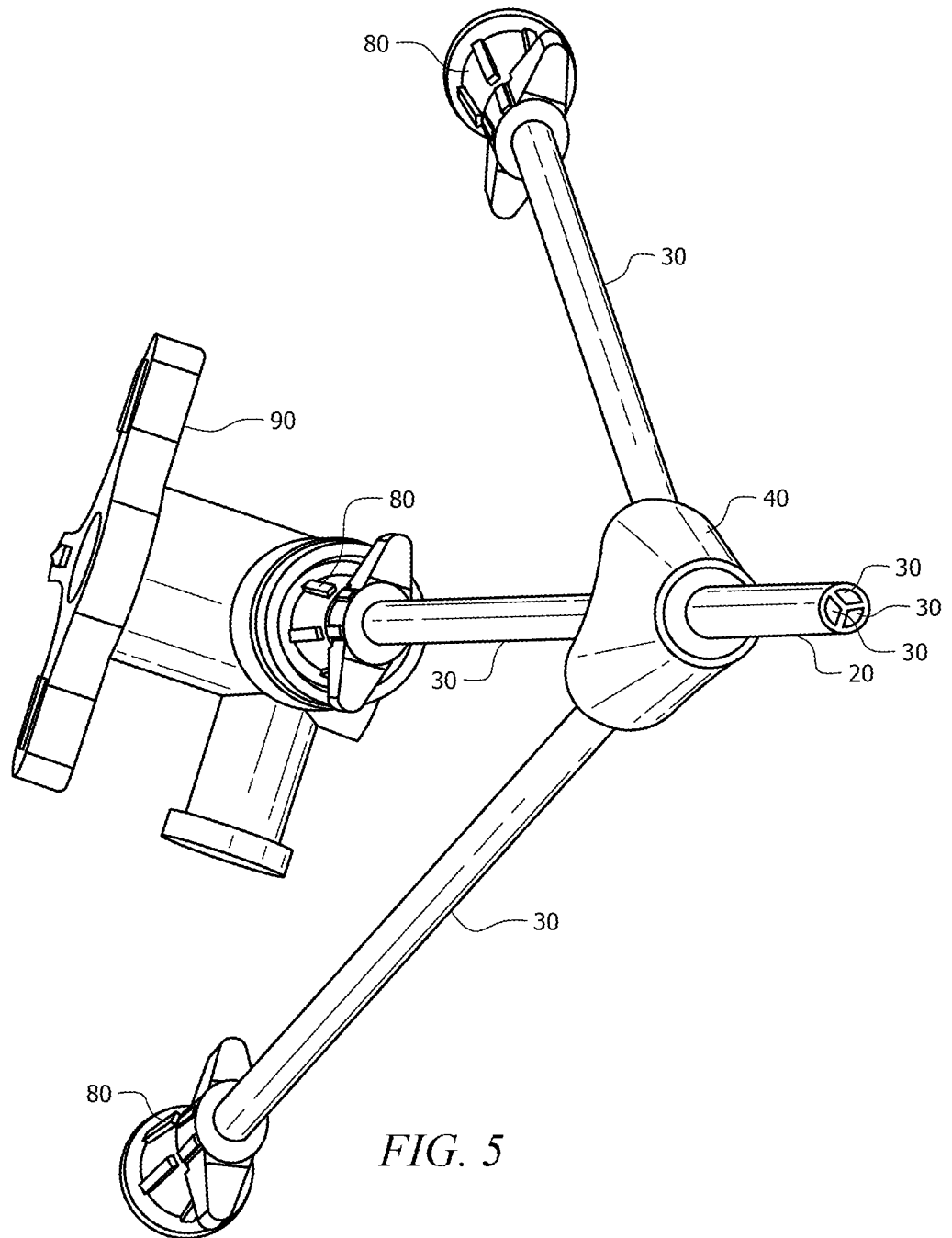


FIG. 3





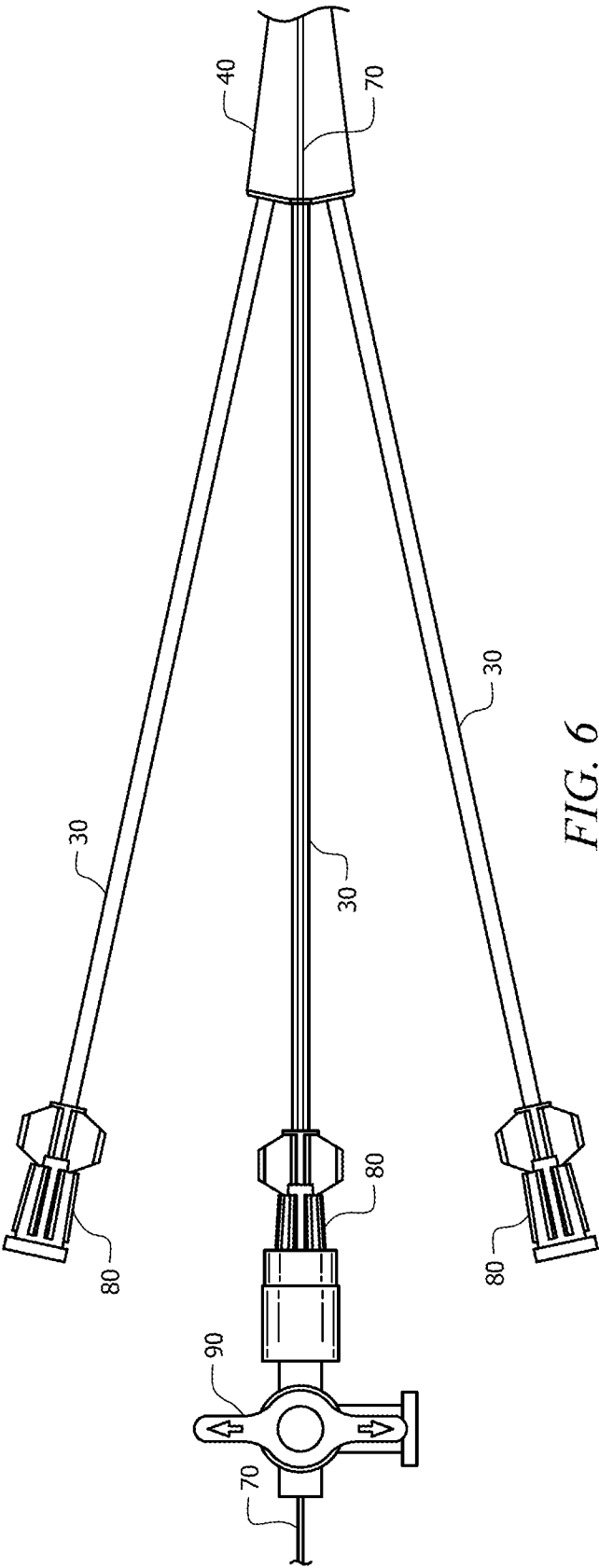


FIG. 6

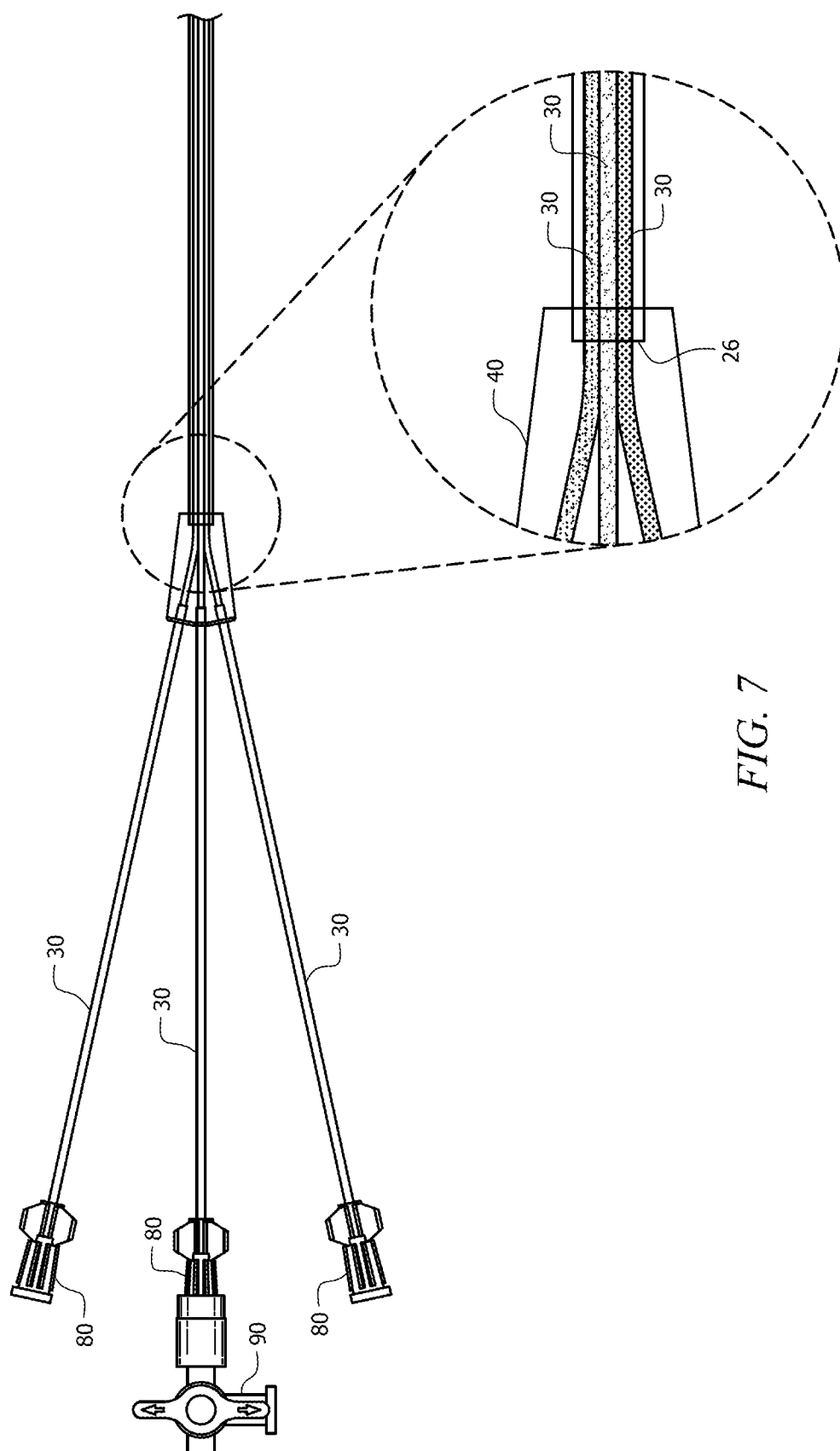


FIG. 7

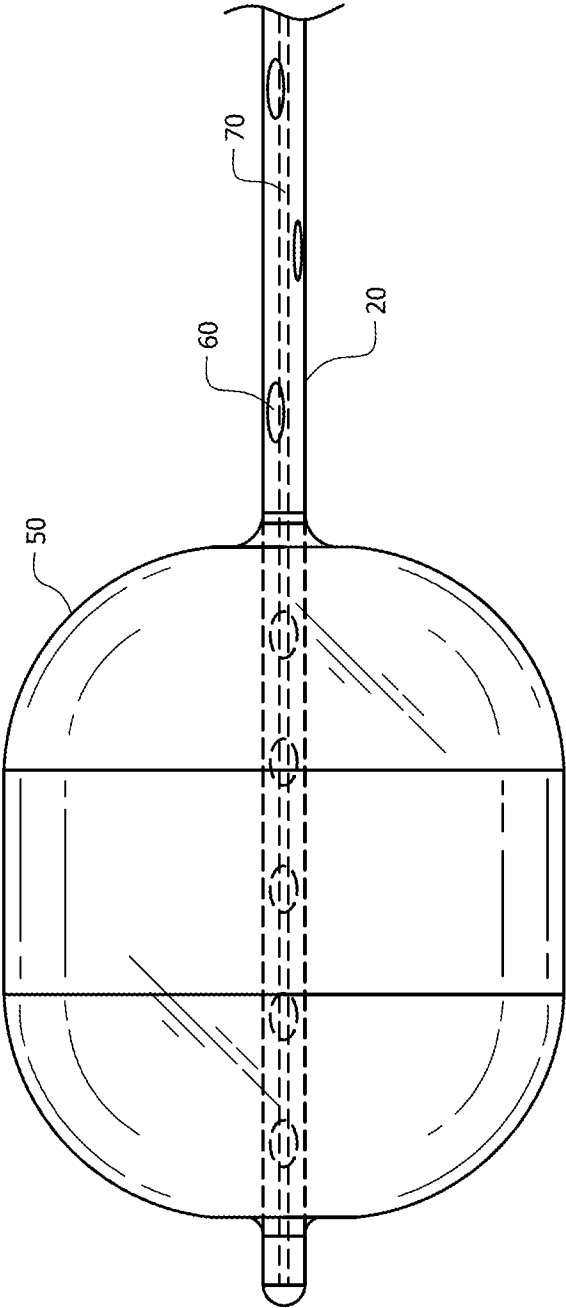
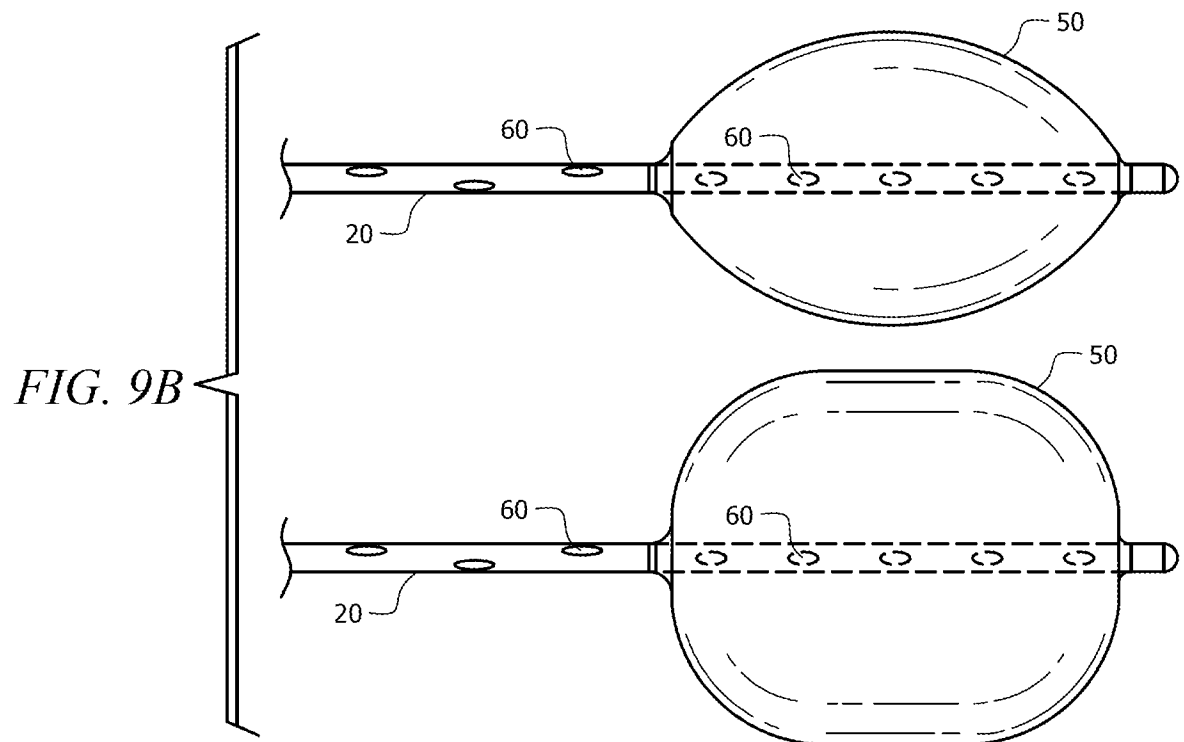
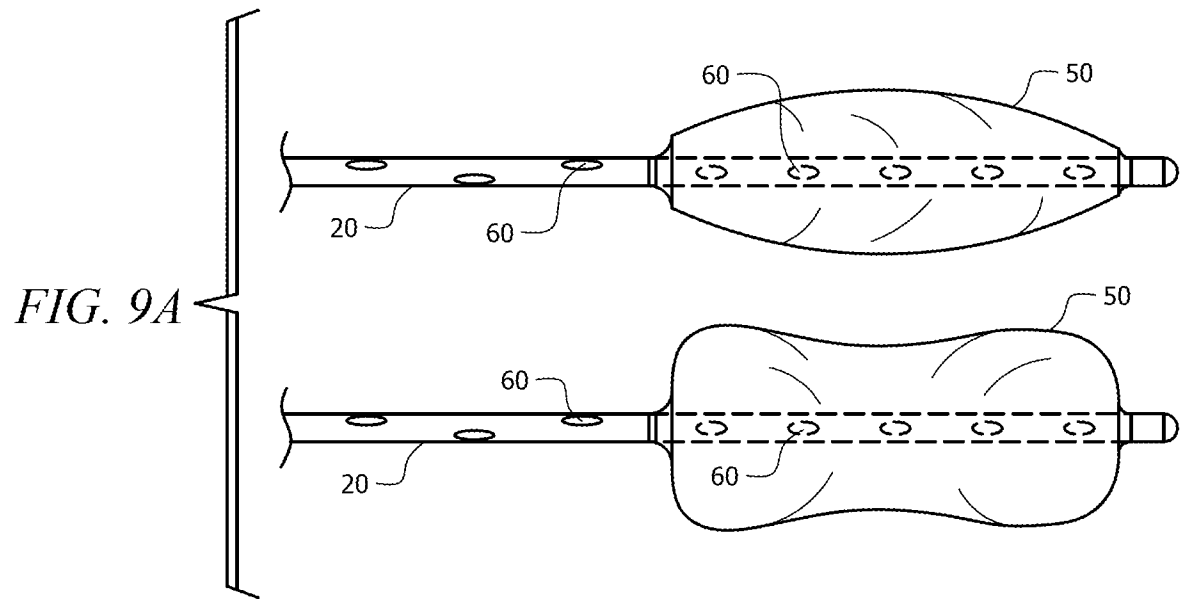
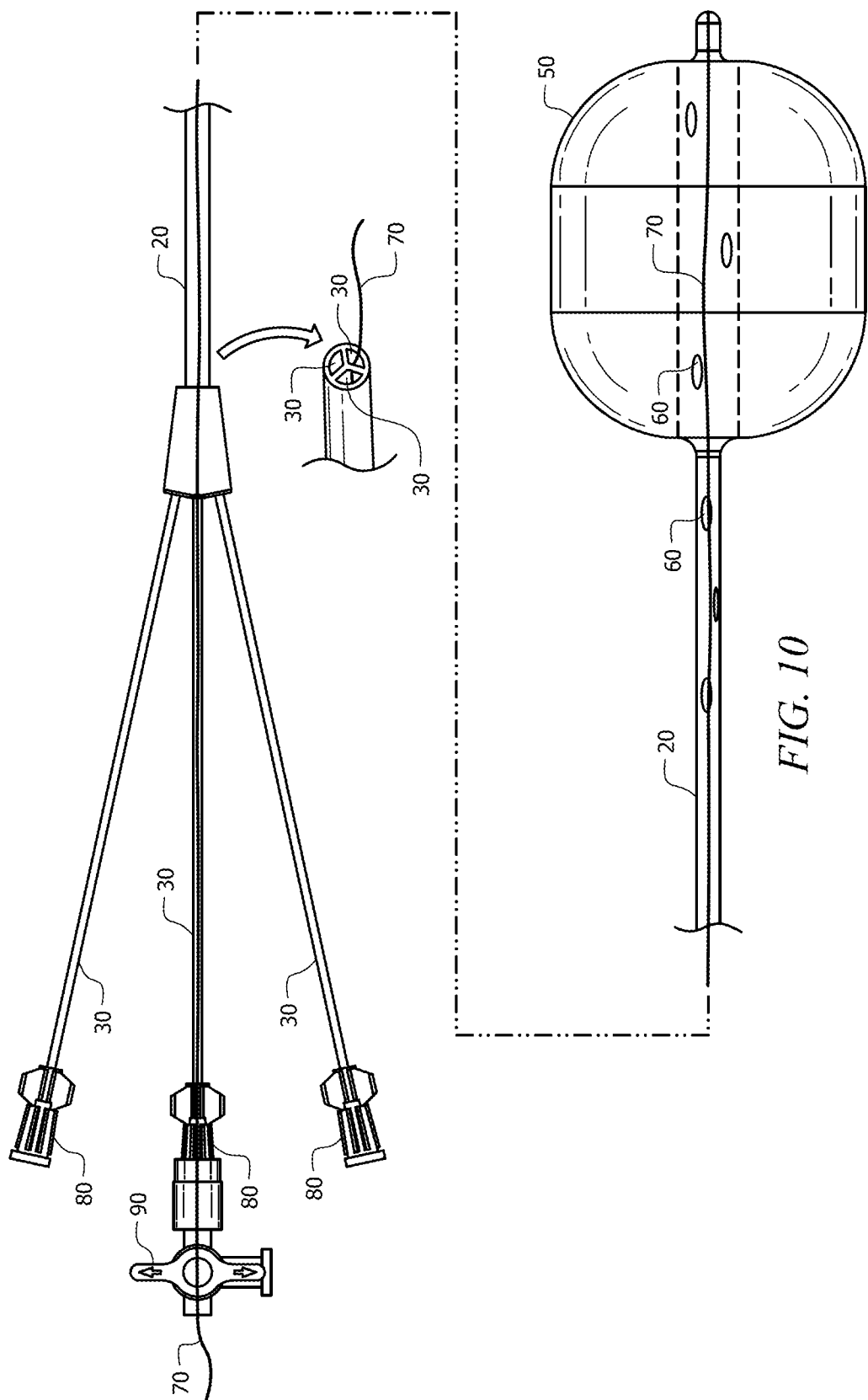
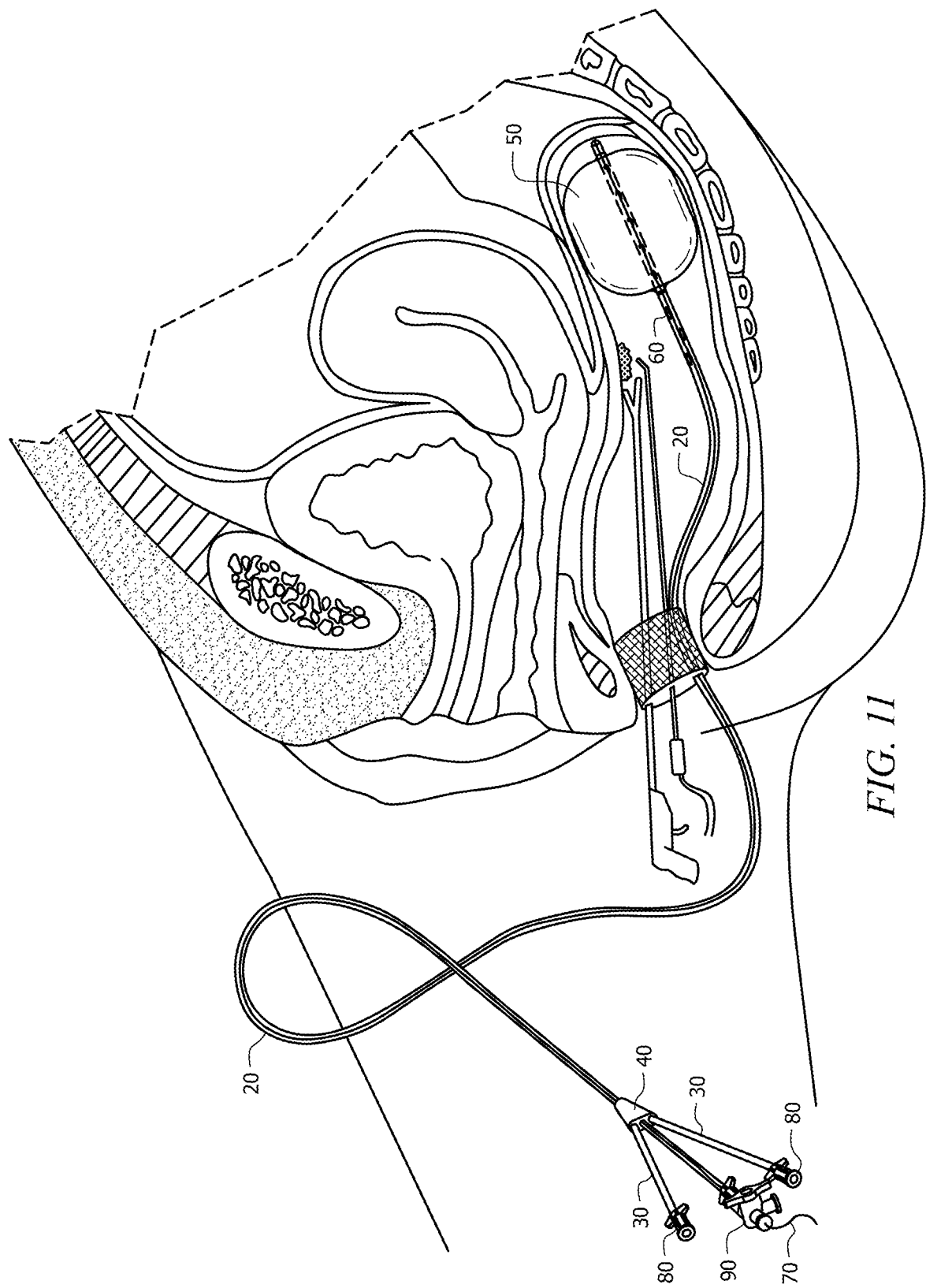


FIG. 8







INTERNATIONAL SEARCH REPORT

International application No.

PCT/US14/52785

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/12; A61M 29/02, 29/04 (2014.01)

CPC - A61B 17/12136; A61M 29/02, 2025/0681

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 17/12; A61M 29/02 29/04 (2014.01)

CPC - A61B 17/12136; A61M 29/02, 2025/0681; USPC - 604/26,104, 509

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

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

MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); Google/Google Scholar; Proquest; IP.com; intraluminal, occlude, occlusion, catheter, intraluminal occluding catheter, shaft, balloon, channel, lumen, duct, orifice, aperture, opening, luer, adapter, connector, valve, stopcock, wire, bowel, colon

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 8,409,166 B2 (WIENER, S. et al.) April 2, 2013; figures 4, 19, 15, 20A-20B, 35; column 19, lines 48-55; column 20, lines 17-19, 61-63	1-3, 9
X ----- Y	US 2011/0160648 A1 (HOEY, M.) June 30, 2011; figures 9, 12A-12C, 16C; paragraphs [0111], [0120]-[0121], [0125], [0127], [0129]	1, 4-6, 8, 10, 11, 13-18 ----- 7, 12, 19, 20
Y	US 5,429,597 A (DEMELLO, R. et al.) July 4, 1995; abstract; figure 2; column 2, lines 26-27; column 7, lines 39-42	7, 12, 19, 20
A	US 2004/0093007 A1 (SUSSMAN, A. et al.) May 13, 2004; entire document	1-20
A	US 2004/0260239 A1 (KUSLEIKA, R.) December 23, 2004; entire document	1-20
A	US 8,267,886 B2 (EWING, B. et al.) September 18, 2012; entire document	1-20

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


* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

22 November 2014 (22.11.2014)

Date of mailing of the international search report

02 JAN 2015

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Shane Thomas

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774