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- (71) Applicant (for all designated States except US): UNITED STATES ENDOSCOPY GROUP, INC. [US/US]; 5976 Heisley Road, Mentor, Ohio 44060 (US).
- (72) Inventor; and
- (71) Applicant : REYDEL, Boris [US/US]; 8 Woodland Road, West Caldwell, New Jersey 07006 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): SECREST, Dean [US/US]; 10433 Johnnycake Ridge Road, Concord, Ohio

44077 (US). WALES, Kenneth, S. [US/US]; 9675 Swan Place, Mason, Ohio 45040 (US).

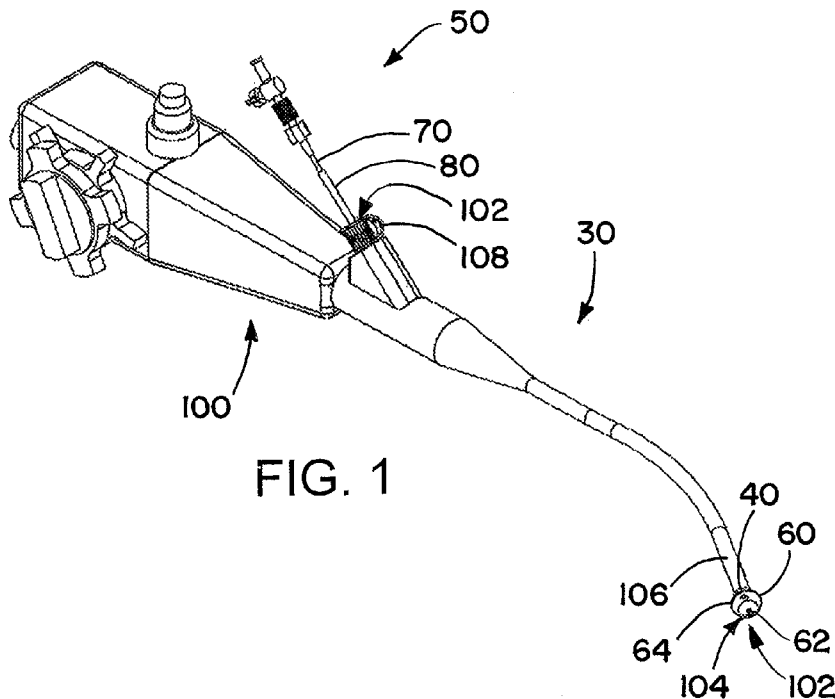
(74) Agent: TUCKER, Todd, R.; Renner, Otto, Boisselle & Sklar, LLP, 1621 Euclid Avenue, Nineteenth Floor, Cleveland, Ohio 44115 (US).

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(54) Title: BALLOON ACCESS DEVICE FOR ENDOSCOPE



(57) Abstract: Provided is a balloon access device having a cap coupleable to an endoscope and a balloon for sealing with the cap when expanded. The balloon access device allows a physician to both separate collapsed tissue and visualize the path of the endoscope without administering insufflation gas to the collapsed area of a patient.



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BALLOON ACCESS DEVICE FOR ENDOSCOPE

Related Applications

This application claims the benefit of U.S. Provisional Application No.
5 61/471,957 filed April 5, 2011, which is hereby incorporated herein by reference.

Field of Invention

The present apparatus embodied relates, in general, to medical devices
and in particular, to access balloons used in combination with endoscopes.

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Background

Endoscopes are well-known in the art and are flexible devices that are
inserted into a natural body orifice such as the mouth or anus to provide visual
and surgical access to portions of the upper and lower Gastro Intestinal (GI)
15 tract. Endoscope accessible portions of the lower GI tract extend from the anus
to the small intestine, and during this journey, the flexible endoscope must
traverse a torturous convoluted path through the anus, the rectum, and through
the large intestine to the ileocecal opening of the small intestine. The torturous
path includes an "S" shaped passage through the rectosigmoid junction and the
20 sigmoid colon, and around several larger than right angled bends of the splenic
flexure and hepatic flexure. Additionally, in small bowel enteroscopy, an
endoscope must traverse a large torturous convoluted path having multiple "S"
shaped passages.

Before insertion of the endoscope, the patient is given drugs to purge
25 fecal matter from the lower GI tract. Once emptied, the tubular walls of the large
intestine can flatten or collapse together into a flattened tubular configuration.
The collapsed intestines may inhibit passage of the flat face of the distal end of
the endoscope, and the collapsed tissue can inhibit visualization by pressing
against or near to a camera mounted within the flat face. To enhance the
30 passage of the endoscope through the collapsed lower GI tract and to improve
visualization, insufflation gas is routinely pumped into the patient's lower GI tract
to expand and distend the collapsed tubular tissues. The expanded walls may
improve visualization and reduce tissue contact with the flat face of the
endoscope as it is pushed farther and farther into the insufflated lower GI tract.

The distal portion of the endoscope is steerable, and the insufflated tissue can provide room for the surgeon to visually steer the endoscope through the path ahead.

The administration of insufflation gas to the lower GI tract can induce abdominal discomfort, and this has led to the common practice of using professional anesthesia providers to induce anesthesia to “knock-out” the patient. Additionally, insufflation gas may cause lengthening of anatomy and spontaneous perforation. Post surgical recovery times are provided to allow the patient to purge insufflation gas and to awaken from the anesthesia. CO₂ gas control systems, CO₂ tanks, and CO₂ gas heaters have found their way into the operating room to provide CO₂ as a insufflation gas. The CO₂ gas is more readily absorbed through the patient’s intestinal wall to reduce the post operative recovery time.

Summary of Invention

The present invention provides a balloon access device having a cap coupleable to an endoscope and a balloon for sealing along with the cap when expanded. The balloon access device allows a physician to both separate collapsed tissue and visualize the path of the endoscope without administering insufflation gas to the collapsed area of a patient.

In one embodiment, the balloon access device includes a balloon expandable from a deflated shape to an inflated shape, the balloon having a proximal end and a distal end, wherein a dome portion is formed on the distal end of the balloon, and a cap having a proximal end configured to be coupled to a distal end of an endoscope and a distal end for sealing with the proximal end of the balloon when the balloon is expanded.

In another embodiment, the inflated shape includes a non-pressurized shape and a fully inflated shape.

In still another embodiment, the proximal end of the balloon includes a proximal collar configured to couple to a distal end of a catheter and a sealing surface configured to seal with the cap.

In yet another embodiment, the cap includes an endoscope receptacle extending into the cap through the proximal end of the cap for receiving the distal end of the endoscope.

5 In a further embodiment, the cap includes a stop that engages a front face of the endoscope when the endoscope is received within the cap, and wherein an opening is provided through the stop to distally expose at least one of a light, opening, optics or operative channel on the front face of the endoscope.

10 In another embodiment, the cap includes a balloon sealing portion proximate the distal end of the cap, the balloon sealing portion including a circular groove that retains and seals with a circular rib of the balloon.

In still another embodiment, the cap includes an outwardly flaring balloon sealing portion that is flexible outwardly relative to a body of the cap to create a seal with the balloon.

15 In yet another embodiment, the outwardly flaring balloon sealing portion prevents the balloon from being unseated from the cap.

In a further embodiment, the cap includes a rib on an interior portion of the cap, and wherein the sealing surface of the balloon nests and seals with a receptacle of a balloon sealing portion and the rib.

20 In another embodiment, the dome portion is hemispherical or ellipsoidal in shape.

In still another embodiment, the balloon is non-concentrically disposed relative to the endoscope.

25 In yet another embodiment, the balloon includes a distally located guide tip on a distal portion of the dome portion for guiding an operator in parting and spreading non-insufflated gastrointestinal tissue during operation.

In a further embodiment, the balloon is a transparent hollow balloon.

In another embodiment, the balloon access device includes a lock mechanism for securing a catheter relative to the endoscope to maintain a sealing contact between the balloon and the cap.

30 In still another embodiment, the lock mechanism includes a releasably lockable clamp mechanism that contacts and grips the catheter.

In yet another embodiment, the balloon access device includes a lock mechanism including a balloon insertion tube for receiving the balloon when the

balloon is in the deflated state, the tube having a length greater than a y-portion of an operative channel within the endoscope to guide the balloon into and beyond the y-portion, and a clamp for securing a catheter relative to the endoscope to maintain a sealing contact between the balloon and the cap.

5 In a further embodiment, the balloon access device includes a balloon insertion tube for receiving the balloon when the balloon is in the deflated state, the balloon insertion tube having a length greater than a y-portion of an operative channel within the endoscope to guide the balloon into and beyond the y-portion.

10 In another embodiment, the balloon access device is in combination with a catheter, wherein the proximal end of the balloon is coupled to a distal end of the catheter.

In still another embodiment, the balloon access device is in combination with an endoscope, wherein the proximal end of the cap is coupled to the distal end of the endoscope.

15 In yet another embodiment, the cap is integral with the endoscope.

According to another aspect of the invention, a balloon access device for use with an endoscope is provided. The device includes a balloon expandable from a deflated shape to an inflated shape, the balloon having a proximal end and a distal end, wherein a dome portion is formed on the distal end of the balloon, a cap having a proximal end configured to be coupled to a distal end of an endoscope and a distal end for sealing with the proximal end of the balloon when the balloon is passed through the cap and expanded to the inflated shape, and a balloon insertion tube for receiving the balloon when the balloon is in the deflated state, the balloon insertion tube having a length greater than a y-portion of an operative channel within the endoscope to guide the balloon into and beyond the y-portion.

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According to still another aspect of the invention, a method of creating a seal between a balloon and a cap is provided, the balloon having a proximal end having a sealing surface and proximal collar coupled to a distal end of a catheter, and the cap having a proximal end coupled to a distal end of an endoscope, the method including advancing the catheter and balloon through an operative channel of the endoscope until the balloon is positioned distal the distal end of the cap, expanding the balloon from a deflated shape to at least a

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partially inflated shape, and moving the balloon proximally towards the cap so that the sealing surface (66) abuts a distal end of the cap to create a seal between the cap and the balloon.

According to yet another aspect of the invention, a method of performing a gastrointestinal procedure on a patient having gastrointestinal tissue in a non-insufflated state using an endoscope and balloon access device installed upon the endoscope is provided, the balloon access device including a cap coupled to a distal end of the endoscope and an at least partially inflated balloon coupled to a distal end of a catheter received in an operative channel of the endoscope, the method including advance the endoscope through the gastrointestinal tissue, guiding the endoscope using a camera on a distal end of the endoscope and a guide tip on a distal end of the balloon, and spreading the tissue using a body of the balloon and the guide tip, wherein the balloon is transparent so that an operator can view the tissue through the balloon using the camera and the operator can center the guide tip in a gastrointestinal tract.

In one embodiment, the method includes retracting the endoscope from the gastrointestinal tissue, wherein during the retracting a balloon sealing portion of the cap flattens a luminal fold in the tissue.

The foregoing and other features of the invention are hereinafter described in greater detail with reference to the accompanying drawings.

Brief Description of the Drawings

FIG. 1 is an isometric view of an embodiment of a transparent balloon access device deployed on an endoscope.

FIG. 2 is an isometric view of the balloon access device with the transparent balloon shown in a normal unexpanded dome shape.

FIG. 3 is an isometric exploded view of the balloon access device

FIG. 4 is an isometric view of the balloon access device with the balloon shown collapsed by drawing a vacuum prior to being inserted into an adjacent balloon insertion tube.

FIG. 5 is an isometric view of the balloon access device with a balloon seal cap placed on a distal end of the scope and with a dashed line illustrating a

path where the balloon access device can enter an open instrument channel which exits within the attached balloon seal cap.

FIG. 6 is a side section view of the flexible shaft of the endoscope with an un-inflated balloon being pushed longitudinally along an instrument passage of the endoscope.

FIG. 7 is a side view showing the balloon after emerging from a distal end of the endoscope.

FIG. 8 is a side view showing the balloon inflated after emerging from a distal end of the endoscope.

FIG. 9 shows an exploded cross sectional view of an embodiment of the balloon and balloon seal cap.

FIG. 10 shows an exploded cross sectional view of an embodiment of the balloon and balloon seal cap.

FIG. 11 shows an exploded cross sectional view of an embodiment of the balloon and balloon seal cap.

FIG. 12 shows an exploded cross sectional view of an embodiment of the balloon and balloon seal cap.

FIG. 13 shows the balloon of FIG 12 in a normal un-inflated shape wherein the inner air pressure is the same as the outside atmospheric pressure.

FIG. 14 shows the balloon of FIG 12 in an inflated shape where about 2.5 ml of air have been placed into the balloon and cannula.

FIG. 15 shows the balloon of FIG 12 in an inflated shape where about 3.5 ml of air have been placed into the balloon and cannula.

FIG. 16 shows the balloon of FIG 12 in an inflated shape where about 5 ml of air have been placed into the balloon and cannula.

FIG. 17 is a side cross sectional view of the balloon access device installed upon an endoscope as the balloon access device spreads tissue to burrow through non-insufflated and collapsed luminal tissue.

FIG. 18 is an enlarged side cross sectional view of the balloon access device of FIG. 17 showing spreading forces on the collapsed luminal tissue.

FIG. 19 is a view through the camera lens of the endoscope showing a guide tip of the balloon moved to a centered position in a collapsed tissue lumen

opening to ensure passage of the balloon and endoscope down a center of the lumen.

FIG. 20 is a cross sectional view of a blow molding dies that is configured to make the balloon of FIG. 12.

5 FIG. 21 is an isometric view of a clamp mechanism to clamp or lock the tensioned cannula relative to the endoscope to maintain a sealing contact between balloon and seal cap.

FIG. 22 is an alternate a clamp mechanism.

FIG. 23 is a front view of a distal end of an endoscope.

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Detailed Description

The following description of certain examples of the medical apparatus should not be used to limit the scope of the medical apparatus. Other examples, features, aspects, embodiments, and advantages of the medical apparatus will
15 become apparent to those skilled in the art from the following description, which is by way of illustration, one of the best modes contemplated for carrying out the medical apparatus. As will be realized, the medical apparatus is capable of other different and obvious aspects, all without departing from the spirit of the medical apparatus. Accordingly, the drawings and descriptions should be
20 regarded as illustrative in nature and not restrictive.

It should be appreciated that any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated material does not
25 conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or
30 other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

FIG. 1 is an isometric view of one embodiment of a balloon access device 30 installed upon an endoscope 100. The balloon access device 30 is

configured to fit within an operative channel 102 of the endoscope 100 when undeployed, and to deploy a transparent hollow balloon 60 across a distal face 104 of the endoscope 100. The balloon 60 is transparent so that scope optics can view GI tissue there through, and balloon 60 can be dome shaped on at least a distal end. A distally located guide tip 62 is supported solely on a distal end of the dome shape by a membrane wall 65 of the balloon 60. The configuration of the deployed guide tip 62 and balloon 60 on the endoscope 100 is such that non-insufflated GI tissue can be parted and spread with the tip 62 and the balloon 60 in response to pushing with the endoscope 100. The balloon access device 30 and endoscope 100 as configured can rapidly burrow along a non-insufflated and at least partially pinched GI tract such as the non-insufflated lower GI tract, or can pass through an expanded or insufflated portion of the GI tract. As will be described in detail later, the deployed transparent guide tip 62 can be visually aimed at a center of the collapsed lumen of the non-insufflated GI tract by articulating a distal end 106 of the endoscope 100. When the guide tip 62 is aimed, pushing the endoscope 100 initiates the spreading and parting of the collapsed tissue walls with the balloon access device 30, thereby enabling passage of the endoscope 100 along a center of the non-insufflated lumen of the GI tract.

As shown in FIG. 1, the balloon access device 30 is shown inserted into an operative channel 102 of the endoscope 100 and comprises a proximal handle portion 50 extending from a proximal opening of the instrument channel 102. A biopsy valve 108 is provided on the proximal opening of the instrument channel 102 and a hollow cannula 70 extends from the proximal handle portion 50, through the biopsy valve 108, and into the instrument channel 102. A distal end of the cannula 70 is secured to a proximal end of the transparent balloon 60 shown extending across a distally located front face 104 of the endoscope 100.

A balloon seal cap 40 of the balloon access device 30 is removably secured to the distal end 106 of the endoscope 100 and forms a fluid tight seal with at least one surface on a proximal end of the balloon 60. Alternatively, it will be appreciated that the cap 40 may be integral with the endoscope. The seal cap 40 may be any suitable shape, such as cylindrically shaped. The sealing interaction of the seal cap 40 with the endoscope 100, and the balloon 60 with

the seal cap 40, can create a sealed volume across the front face 104 of the endoscope 100 to prevent the egress of unwanted fluids across the optical lens 105 of an endoscope camera located on the front face 104 (see FIG. 17).

Additionally, once the seal is formed, the balloon 60 can be further secured to the seal cap 40 by applying a vacuum to the instrument channel 102 to draw the balloon 60 into further engagement with the seal cap 40. Alternately, a vacuum port (not shown) in the endoscope 100 can be used to draw the balloon 100 against the front face 104 of the endoscope. The balloon device 30 can be rapidly deployed and inflated into place on the endoscope 100 for advancement, and rapidly deflated and withdrawn from the instrument channel 102 of the endoscope 100 for the insertion and deployment of another surgical instrument from the instrument channel 102 into the lower GI tract. An example of such another surgical instrument can be, but is not limited thereto, a snare or tissue biopsy device to retrieve a tissue sample from a suspect site.

FIG. 2 shows an isometric view of the balloon access device 30. The handle or proximal handle portion 50 includes a hollow passage 72 that extends longitudinally through the handle portion 50, through the hollow cannula 70, and operatively connects to an inner volume of the balloon 60. Handle portion 50 includes a proximal luer lock 52 to removably engage hollow passage 72 with compressed gas and/or vacuum lines and or fluid lines, a valve 54 to control the flow of gas and vacuum to the distal balloon 60, a grip 56, and orientation wings 58. Hollow cannula 70 can be configured to have sufficient length to work with an endoscope 100 as described above, or long enough to work with a variety of endoscopes 100 with differing lengths.

In FIGS. 2 and 3, the transparent balloon 60 is shown in the normal unpressurized or "as manufactured" shape wherein the hollow balloon 60 can have a distal dome 64 and at least one sealing surface 66 on a proximal side. The balloon 60 is configured to be symmetrical and concentric about a longitudinal axis of the balloon 60 and a longitudinal axis of the cannula 70, and the distal dome 64 can be hemispherical or elliptical in shape about the axis. A proximal collar 68 securely seals the balloon 60 to the catheter 70 via an attachment method such as but not limited thereto, by an adhesive or a shrink fit as described later. Proximal collar 68 can be cylindrical and can include a

conical or curved portion for engaging with or sealing with the instrument passage 102 of endoscope 100. The guide tip 62 can be a separate piece that can be secured to the dome of the balloon 60 in the exemplary manner. As best shown in FIG. 3, the guide tip 62 has a rounded distal tip and a stepped proximal post 69 that can be adhesively secured into a distal collar 67 formed from the balloon membrane 65. Alternately, the guide tip could be a rounded bump formed from the balloon membrane 65, or an injection of sealing material into the distal collar 67 such as a gob of silicone placed inside the distal collar 67. The guide tip 62 can be transparent for visualization therethrough, or can be opaque or translucent. As shown, guide tip 62 is supported by only the balloon membrane 65 which can provide some freedom of motion of the tip 62 relative to the endoscope 100. This freedom of motion can be beneficial when navigating through collapsed tissue. A hollow balloon insertion tube 80 is shown distal to the guide tip 62 may be provided to receive and store the balloon 60 and tip 62 within when the balloon is deflated by drawing a vacuum prior to being inserted into an adjacent balloon insertion tube 80, and tube 80 can have a length sufficient to guide the balloon 60 and tip 62 into and beyond a "Y" portion of the operative channel 102 within the endoscope 100. A deflated balloon 60 is shown in FIG. 4 just prior to insertion within a hollow of the balloon insertion tube 80. Before insertion, balloon 60 may have one or more deflation folds of the balloon 60 wrapped or twisted about a longitudinal axis of the balloon (not shown) to create a more compact and organized deflated balloon 60.

FIG. 5 shows the access device 30 ready for installation onto the endoscope 100. In this view, the cylindrical seal cap 40 is positioned for placement onto the distal end 106 of the endoscope 100. The balloon 60 is fully deflated as shown in FIG. 4, and resides within the balloon insertion tube 80. A dashed line is provided to show how the balloon insertion tube 80 of the access device 30 can be inserted into the proximal opening of the instrument channel 102 of endoscope 100, and if a biopsy valve 108 is provided, through the biopsy valve 108. The balloon insertion tube 80 can be configured to feed the balloon 60 directly into the instrument channel 102 through the balloon insertion tube 108 with the guide tip 62 leading the collapsed balloon. Balloon insertion tube 80 can be the length as shown, or can be longer to guide the collapsed balloon

past a “Y” within instrument channel 102. Balloon insertion tube 80 can be constructed from a slick or lubricious plastic such as PTFE, or can be lubricated to reduce egress of the collapsed balloon 60 into or out of the tube 80. FIG. 1 shows how the balloon insertion tube 80 can be retracted proximally around the
5 cannula 72 to a position adjacent to the handle portion 50 after the full insertion of the access device 30 into the instrument channel 102.

FIG. 6 shows the fully deflated balloon as it is being pushed down channel 102 of the endoscope 100 prior to emergence of the balloon 60 from the distal face 40 of the endoscope 100. The guide tip 62 can be configured with a tip
10 diameter that is close to the inner diameter of the instrument channel 102 of the endoscope 100, and an appropriate length so that the tip 62 will not cock and jam within the instrument channel 102 of the scope 100. The tip of the guide tip 62 can be any shape that is conducive to steering the guide tip along the instrument channel 102 such as the rounded tip 62 shown, or any other guiding
15 shape such as but not limited to a cone.

FIG. 7 shows the balloon 60 after emerging from the distal end 106 of the endoscope 100. Once the balloon 60 is extended from the endoscope 60 and beyond the seal cap 40, atmospheric air may be induced through the hollow passage 72 to allow the balloon 60 to expand into the non-pressurized shape as
20 shown. Once the balloon 60 is fully inflated with a fluid, such as air, to an operating pressure or volume, the balloon 60 is pulled proximally in the direction of the arrow to engage the balloon 60 with the seal tip 40. This pulling of the balloon 60 to seal against the seal tip 40 can be accomplished by pulling on the catheter 70 or the handle portion 50 outside of the patient. If required, the
25 balloon 60 is free to pivot somewhat about the attachment point to the cannula 70 to center itself in the seal cap 40.

FIG. 8 shows the fully inflated balloon 60 pulled against the seal cap 40 at the distal end 106 of the endoscope 100. In this view, it can be seen that the inflation of the balloon 60 has changed the at least one proximal sealing surface
30 66 into a rounded dome that has maintained a fluid-tight seal with the seal cap 40. The rounding of the at least one proximal sealing surface 66 has moved the distal dome 64 distally, and the distal dome 64 has expanded both in diameter and longitudinally as shown. The inflation of the balloon 60 can be

accomplished prior to insertion of the endoscope 100 into the patient, or after insertion of the endoscope 100 into the natural orifice such as the anus of the patient.

FIGS. 9 through 12 shows exploded cross sectional views of alternate
5 exemplary embodiments of the balloon 60, and balloon seal cap 40 of the
present apparatus. The guide tip 62 is also depicted. The exemplary and
previously described embodiment of balloon 60 and seal collar 90 is best shown
in FIGS. 2, and 3, and is shown in cross section in FIG. 11. The reader is
advised to note that the balloon access device 30 is not limited to the previously
10 described embodiment of FIG. 11, nor to the alternate embodiments of FIGS. 9-
10 and 12, nor to any of the materials or manufacturing techniques described.
Since many of the embodiments of the balloons and seal caps have features that
perform the same function, like numbers are identified with sub-identifiers and
are meant to correspond to like features on alternate embodiments. For
15 example, a balloon 60 in one embodiment may become a balloon 60a in another
alternate embodiment. If differences in functions exist between like numbers
such as sealing surfaces 66 and 66a, the description associated with the number
and sub-identifier will prevail for that embodiment. All embodiments described
below have a balloon 60, 60a, 60b, 60c and a seal cap 40, 40a, 40b, 40c.

20 The embodiment of FIG. 11 comprises the hollow balloon 60, the balloon
seal cap 40 and the guide tip 62. This embodiment uses a ring-in-groove seal
between the balloon and seal cap 40. The balloon 60 comprises the previously
described distal dome 64, the membrane 65, and the at least one sealing
surface 66. With this embodiment of the balloon 60, the at least one sealing
25 surface 66 of the balloon comprises two distinct portions. The first portion
comprises a circular rib 61 that rings the longitudinal axis of the balloon 60 and is
configured to engage with and seal with the circular groove 41 in the seal cap
40. The second portion of the at least one sealing surface 66 is a dish shaped
portion that extends substantially radially inwardly between the largest diameter
30 of distal dome 64 to the circular rib portion. The dish shaped portion can be
configured to seal against at least a distalmost surface 48 of the cap 40. The
distal collar 67 of balloon 60 extends distally from the dome 64 and is configured
to seal with the distal tip 62. The proximal collar 68 extends proximally from the

at least one sealing surface 66 and is configured to seal with the hollow cannula 70 (see FIGS. 2 and 3).

The balloon seal cap 40 of FIG. 11 comprises a hollow cylinder having an endoscope receptacle 42 extending into a proximal end of the seal cap 40 to receive and seal with the distal end 106 of the endoscope 100. A circular rib 45 can be provided at a distal end of the endoscope receptacle 42 to act as a stop that engages the front face 104 of the endoscope 100 once the scope 100 is fully received within the seal cap 40. An opening 46 is provided through the rib 45 to distally expose the optics, lights, and openings on the endoscope front face 104. A balloon sealing portion 44 extends distally from the rib 45 and includes the previously described circular groove 41 to retain and seal with the circular rib 61 of the balloon 60. The distalmost surface 48 of the balloon sealing portion 44 can seal with the balloon 60. As shown, the receptacle 42, the opening 46, and the balloon sealing portion 44 comprise the open hollow of the cylindrical seal cap 40.

The embodiment of FIG. 9 comprises a balloon 60a and a seal cap 40a and is configured to provide a ball-in-socket type of sealing. The balloon 60a has a substantially curved at least one sealing surface 66a that nests within and seals with an outwardly flaring cuplike balloon sealing portion 44a of the seal cap 40a. Seal cap 40a can be configured to flare outward to provide a larger support for the balloon 60a and can exceed the diameter of the endoscope 100. Seal cap 40a is a hollow cylinder that further comprises an endoscope sealing receptacle 42a, circular rib 45a, opening 46a, as well as the previously described balloon sealing portion 44a. Balloon 60a includes a distal dome 64a, a membrane 65a, a distal collar 67a, and a proximal collar 68a. Cuplike balloon sealing portion 44a of the seal cap 40a can also be used to flatten luminal folds, for example to discern pathologies behind the luminal folds.

The embodiment of FIG. 10 comprises a balloon 60b and a seal cap 40b and uses a peg-in-hole arrangement for sealing. In this embodiment, the balloon 60b is sized to have about the same radial diameter as the distal end 106 of the endoscope and the balloon 60b nests and seals with a receptacle of a cylindrical balloon sealing portion 44a. Mushroom shaped balloon 60a comprises a distal dome 64 with at least one sealing surface 66a that is

substantially flat and circular. Balloon 60b is configured to fit snugly in the cylindrical balloon sealing portion 44a and to seal the at least one sealing surface 66a against a rib 45b. Cylindrically shaped cap 40b further comprises an endoscope sealing receptacle 42b, and an opening 46b extending through rib 5 45b. Balloon 60b includes a distal dome 64b, a membrane 65b, a distal collar 67b, and a proximal collar 68b.

The embodiment of FIG. 12 comprises a balloon 60c and seal cap 40c that is configured to provide a flat-to flat seal as the balloon 60c is pulled against a distalmost surface 48c of seal cap 40c. As the inflating balloon 60c changes 10 shape from the mushroom shape to a rounded elliptical ball shape, the seal can move to a beveled portion of a distal balloon sealing portion 44c. Balloon 60c may be substantially mushroom shaped with a substantially flat at least one sealing surface 66c adjacent to a dome 64c. Unlike the embodiment of FIG. 10, the balloon 60c is larger than an outer diameter of a seal cap 40c and overhangs 15 the seal cap 40c. Cylindrically shaped cap 40c further comprises an endoscope sealing receptacle 42c, circular rib 45c, and opening 46c. Balloon 60a further comprises a distal dome 64a, a membrane 65a, a distal collar 67a, and a proximal collar 68a.

The balloons 60, 60a, 60b, and 60c are transparent and can be 20 constructed from a substantially rigid balloon material or an elastomeric material. Substantially rigid cannot expand greatly beyond the normal "as made" shape when inflated and many such materials are well known in the art for use as expansion balloons for cardiac stent deployment products. Elastomeric balloons are expandable, and can comprise material such as, for example, some grades 25 or durometers of elastomers such as polyurethane, latex, natural rubbers, silicones and the like.

The seal caps 40, 40a, 40b, and 40c can comprise a substantially rigid material such as a thermoform plastic, a thermoset plastic, or a metal. With rigid 30 embodiments of the caps, it is the deformation of the balloon 60, 60a, 60b, and 60c against the rigid cap that creates the seal. In yet another embodiment, the seal caps 40, 40a, 40b, and 40c can comprise an elastomeric material such as but not limited to a polyurethane, a polyethylene, silicone, rubber and the like. As such, the elastomeric properties of this embodiment can have sufficient

rigidity to generally support the balloon against normal surgical operating forces, yet provide atraumatic characteristics, should substantial resistance be encountered. Rigidity of the elastomeric material could be altered by changing a durometer of the material during manufacturing.

5 Alternately, the distal balloon sealing portion 44, 44a, 44b, 44c of the caps 40, 40a, 40b, and 40c could be rigid or elastomeric and can further comprise one or more deformable gasket materials to create a seal such as but not limited to: an elastomeric lip seal, an o-ring, an over-molded elastomer, or a foam seal (not shown). Such seals can seal with the balloon 40, the endoscope 100 or
10 both.

The distal guide tip 62 can be used with any balloon embodiments such as 60, 60a, 60b, and 60c. The distal guide tip 62 can include the stepped proximal post 69 which is configured to fit within the distal collar 67, 67a, 67b, or 67c to create a smooth exterior when mated with the balloon 60, 60a, 60b, or
15 60c (see at least FIGS. 1&2). The guide tip 66 and cannula 70 can be adhered to the balloon 60, 60a, 60b, or 60c with adhesives such as but not limited to polyurethanes or cyanoacrylates. Or, alternate fastening techniques can be used with distal guide tip 62 and cannula 70 such as but not limited to heat staking, ultrasonically welding, or laser welding. Whereas these fastening
20 techniques are described for the attachment of the distal guide tip 62, they can be used for all other embodiments of the apparatus such as elements of the handle portion 50 or attachment of the proximal collar 68 to the cannula 80.

FIGS. 13-16 are side views that detail the inflation of the distal portion of the balloon access device 30 on the endoscope 30. The mushroom shaped
25 balloon 60c and cap 40c are the embodiments shown in cross section in FIG. 12. For this inflation description, only the embodiment of FIG. 12 will be described, and the description is based on physical measurements of an actual balloon 60c and cap 40c as the balloon 60c is inflated.

FIG. 13 shows balloon 60c in a normal un-inflated normal shape wherein
30 the inner air pressure is the same as the outside atmospheric pressure and the balloon 60c has assumed the "as manufactured" mushroom shape. As shown, the normal shape of balloon 60c is substantially mushroom shaped, and comprises the distal dome 64c attached to the proximal at least one sealing

surface 66c. The at least one sealing surface 66c is substantially flat and has been pulled back (via catheter 70) to seal against a ring of contact with the ring shaped distalmost surface 48c of the seal cap 40. With atmospheric pressure within balloon 60c, and the valve 54 of the handle portion 50 closed, the balloon
5 62 is very flaccid and the guide tip 62 is substantially supported by only the membrane 65c. Pushing the guide tip 62 towards the cannula 70 creates a large indentation crater with the tip 62 standing proud within as the tip 62 is completely pushed into the dome 64c. Measurements of the balloon 60c of FIG 13 show an
10 outer dimension D1 of about 18mm at the widest diameter, and the sum of longitudinal lengths A1 and B1 equal about 11 mm. The balloon 60c and cannula 70 of the actual test balloon 60c required about 2-2.1 ml of air to arrive at the flaccid shape of FIG. 13.

FIG. 14 is another side view of the access device 30 on the endoscope 30 where about 2.5 ml of air have been placed into the balloon 60c and cannula 70.
15 At this air volume, the distal dome 64c maintained substantially the same shape, but the at least one sealing surface 66c domed slightly and pushed the distal dome 64c and guide tip 62 in the distal direction. This increased the sum of longitudinal lengths A1 and A2 to about 11.7 mm without an appreciable change in D2. It is visually seen that the majority of the .7 mm balloon longitudinal length
20 change occurred in the doming of the at least one sealing surface 66c which increased dimension B2. Pushing on the distal guide tip 62 so that it is embedded within the balloon created a slightly smaller dish shaped indent with the guide tip 62 standing proud in the indent. The increased volume of fill also increased the resistance to movement of the tip 62. The balloon 60c did not
25 appear to move longitudinally from pushing on the guide tip 62 but expanded radially when filled with 2.5 ml of air.

FIG. 15 is another side view of the access device 30 on the endoscope 30 where about 3.5 ml of air have been placed into the balloon 60c and cannula 70. Once again, the distal dome 64c maintained substantially the same shape and
30 the at least one sealing surface 66c continued to move towards a dome shape. The longitudinal length (sum of A1 and B1) increased to about 12.2 mm with the majority of the .5 mm additional length increase coming from additional doming of the at least one sealing surface 66c. The dimension D2 increased slightly to

18.73 mm. When the guide tip 62 was pushed distally into the balloon 60c, the distal guide tip 62 had substantial resistance. Pushing on the distal guide tip 62 so that it is embedded within the balloon created a noticeably smaller dish shaped indent with the guide tip 62 standing proud in the indent. As the guide tip
5 62 was embedded into the balloon 60c, the balloon 60c also moved distally as some of the distal movement of the guide tip 62 was transferred to the balloon 60c. Visually, it appears that there is about the same amount of distal longitudinal movement of the balloon 60c as there is distal embedding of the guide tip 62. The distal movement of the balloon 60c is primarily in the at least
10 one sealing surface 66c.

FIG. 16 is another side view of the access device 30 on the endoscope 100 where about 5 ml of air have been placed into the balloon 60c and cannula 70. The diameter D1 reduced back to the original 18mm diameter and the longitudinal length (sum of A1 and B1) increased to about 14.75 mm. Once
15 again, the majority of the additional length increase (2.55 mm) appears to be coming from additional doming of the at least one sealing surface 66c. There was some additional rounding of the distal dome 64c which may account for some of the reduction in overall diameter D1 and some of the length change. With respect to pushing distally on the guide tip 62 with 5ml of air, the guide tip
20 62 has substantial resistance and the combination of balloon geometry (mushroom shape), fill volume (ml) balloon membrane 65c thickness and material durometer have combined to provide an unexpected shift in load transfer that seems to prevent the guide tip 62 from creating much of a dish indent in the balloon. With this fill volume, a substantial portion of the movement
25 of the guide tip 62 towards the cannula 70 comes from a longitudinal compression of the balloon 60c to a different elliptical shape, and not from dishing the guide tip 62 into the balloon 60. This effect may be advantageous to tunneling through non-insufflated tissue lumens to maintain the distalmost positioning of the guide tip 62 during airless burrowing of the access device 30
30 and the endoscope 100. It is the distalmost position of the guide tip 62 which can enable the guide tip 62 to initiate separation of the collapsed luminal tissue. Once the initial separation occurs, the collapsed tissue separation may then be

transferred to the outer surface of the balloon 60c as the access device 30 and endoscope 100 advances along the GI tract.

FIGS. 17 and 18 are side cross sectional views of the balloon access device 30 installed upon an endoscope 100 as it burrows through non-insufflated luminal tissue of the GI tract. FIG 18 is an enlarged view of a portion of the cross sectional view of FIG. 17. As shown, the luminal tissue has collapsed, and the balloon access device 30 is providing both a visualization pocket and a tissue separator for the operator of the endoscope 100 so that the endoscope 100 can be easily advanced farther into the patient. An arrow is provided to indicate the direction of movement of the balloon access device 30 and endoscope 100. In this cross section, the collapsed luminal tissue 200 is partially spread by the balloon access device 30 and endoscope 100 as it burrows towards a bend in the tissue 200. The endoscope 100 is shown in cross section and has the instrument channel 102 and front face 104 shown. Front face 104 of the scope 100 further comprises a lens 105 that views tissue through the transparent balloon 60. A viewing angle of the lens 105 is shown as dashed lines extending from the lens 105 (see FIG. 18). To prevent reduction of the viewing angle, the cap 40 may protrude above the front face 104 of the scope between about .5mm to about 6mm. Alternately, the cap 40 may protrude above the front face 104 of the scope between about 1mm to about 3mm. If desired, the vacuum in the endoscope 100 can be used to draw the balloon 100 against the front face 104 and the lens 105 of the endoscope 100. The hollow catheter 70 extends longitudinally along the instrument channel 102 and is attached to the balloon 60 which is inflated (via the catheter 70) an amount that substantially restricts the embedding of the guide tip 62 into the balloon as described previously. The cap 40 is sealed against the endoscope and the balloon 60 is sealed within the cap 40 to seal the front face 104 of the endoscope 100 from fluids, mucous, and residual natural materials normally found within the luminal structure. As shown, ring 61 of the balloon is embedded in the groove 41 in the seal cap 40 to create a seal.

FIG 18 is an enlarged side cross sectional view of FIG 17. In this view, the spreading of the collapsed opening 204 of the tissue 200 can be seen through the transparent balloon 60. The lens 105 of the endoscope can be seen

with dashed lines indicating a field of view through the balloon access device 30. Arrows show how a spreading force F1 is applied from the guide tip 62 onto the tissue 200. The guide force F1 is perpendicular or normal to the point of contact on the tissue. A second spreading force F2 is exerted on the tissue by the inflated balloon 60. Once again, the spreading force F2 is perpendicular or normal to the point of contact of the membrane 65 of the balloon 60 on the tissue.

FIG. 19 is a view through the lens 105 of the camera of the endoscope 100 looking at collapsed tissue through the transparent balloon 60 and guide tip 62. In this view, the surgeon has steered the guide tip 62 of the balloon 60 to a centered position of the collapsed tissue opening 204 of the tissue 200. Since the tissue guide 200 is transparent, tissue 200 can be seen therethrough. Once the guide tip 62 of the balloon 60 is centered, the surgeon is confident that the balloon access device 30 and endoscope 100 are aimed at the center of the collapsed lumen, and that the balloon access device 30 and endoscope 100 can now be pushed down a center of the lumen such as the large intestine. During testing of the device in actual tissue, several of the medical professional operators were surprised at the depth of penetration of the balloon access device 30 equipped endoscope 100 in such a short time.

FIG. 20 is a cross sectional view of a blow molding dies that is configured to make the balloon of FIG. 12. As shown, the blow molding die 210 has a piece of expandable polyethylene tubing 220 placed along a longitudinal axis of the balloon shape of the die 210. Once the tubing 220 is heated, warm compressed air can be blown to expand the polyethylene tubing 220 against the cooler inner walls of the mold 210 which can be held slightly below the melting temperature of the polyethylene tubing 220. When the flow of warm expansion air is shut off, the tubing 220 has expanded against the walls of the mold 210 and sets in the net or normal "as manufactured" shape. Then the molded balloon 60 can be extracted by opening the die 210 to release the balloon 60. The dashed lines show the expansion stages of the polyethylene tubing 220 as it expands towards the mold walls 210. The natural tendency of the hot tubing 220 is to expand as a sphere until the expanding material contacts the walls of the die 210. As a consequence, different portions of the balloon membrane 65 (see Fig. 2) will be

thinner than others and may taper between the thick and thin portions. For example, the portions of the tubing 220 that form the proximal collar 68 and distal collar 67 will expand not at all or very slightly and will be thicker than the balloon membrane 65 at the points of largest expansion away from the

5 longitudinal axis. The shape of the balloon can affect the location of the thick and thin membrane 65 portions and a stiffened disk may be found near the proximal and distal collars 67, 68 which can affect the manner in which the balloon 60 expands (see FIGS 13-16). This thickening could affect or restrict the displacement of the guide tip 62 from tissue contact by creating a more rigid

10 "island" of membrane 65 around the distal tip 62 that may explain the deflection behavior described previously. In an alternate embodiment, the balloon 60 can be further stiffened in local areas by a dipping process to build up the balloon wall thickness. For example, the same material as the balloon membrane 65 can be used (such as polyurethane), or alternate dipping material may be used.

15 With some embodiments of the balloon such as that found in FIG. 12, a tension or pulling force may be applied to the cannula 70 to pull the balloon 60c into contact with the seal cap 40c to create a seal. It may be further desirable to include a lock or clamp mechanism 250 to hold the cannula 70 relative to the endoscope to ensure that the fluid tight seal is maintained in all tissue contacting

20 situations. FIG. 21 illustrates an embodiment of a clamp mechanism 250 that can be used to clamp or lock the tensioned cannula 70 relative to the endoscope 100 to maintain a sealing contact between balloon 60c and seal cap 40c. Clamp mechanism 250 comprises a releasably lockable clamp mechanism that contacts and grips cannula 70 and is actuated and released via a pull member 252 to

25 clamp the cannula 70. Alternate clamp mechanisms such as clamp mechanism 260 can surround the cannula 70 and retain it in place via frictional contact. One example of clamp member 260 would be a biopsy valve 108 or an adaptation thereof wherein the biopsy valve 108 grips the endoscope 100 and the cannula 70 with an elastomeric material. And, in yet another embodiment of a clamp

30 mechanism, the proximal sleeve 68 of the balloon may be configured to expand within the operative channel 102 of the endoscope 100 to lock the inflated balloon to the end of the endoscope. When the balloon is deflated, the proximal sleeve 68 unlocks from the operative channel 102.

FIG 22 shows an alternate embodiment of a clamping mechanism 270 that could be configured to replace the previously described hollow balloon insertion tube 80 with a clamping mechanism 270 that combines a hollow balloon insertion tube 280 with a user actuated clamp 282. The clamping

5 mechanism 270 has a longitudinal hollow that would slide freely over the cannula 70 and the collapsed balloon 60c could reside within (not shown). The hollow balloon insertion tube 280 can be configured to fit within the operative channel 102 of the endoscope and the biopsy valve 108 (if provided). The hollow balloon insertion tube 280 may be sized to be inserted into the operative channel 102 to

10 a position past a "Y" branch of the channel 102. The collapsed balloon 60c can then be introduced into the instrument passage 102 of the endoscope 100 without direct contact with the "Y". Once the balloon 60c was extended from the scope and inflated, the clamping mechanism 270 could be pushed inward to bring a stop collar 288 into contact with the proximal opening of the instrument

15 passage, or the biopsy valve 108 (if present). Pulling on the handle 50 or the cannula 70 while pushing on the clamping mechanism 270 can ensure a seal between the balloon 60c and the seal cap 40c (not shown). Locking the user actuated clamp 282 ensures the seal is locked and maintained between balloon 60c and the seal cap 40c. As shown in FIG. 22 but not limited thereto, the user

20 actuated clamp 282 can comprise a deflectable cantilever beam 284 that can, when deflected, simultaneously clamp on the cannula 70 and lock with a clamp arm 286. The clamp arm 286 can also be a cantilever, and can be deflected to release the deflectable cantilever beam 284 to unlock the user actuated clamp 282, and to release the cannula 70. Stop collar 288 can be used to contact and

25 push against the endoscope or the biopsy valve 108 to maintain tension on the cannula 70.

Turning now to FIG. 23, a front view of the front face 104 of the endoscope is shown. The operative channel 102 of the endoscope is non-concentrically disposed in the endoscope, and accordingly the catheter 70 and

30 balloon are non-concentrically disposed relative to a central axis of the endoscope. As described previously, when the cap 40 and balloon 60 are installed on the endoscope, pulling on the catheter seals the balloon 60 against the cap 40 and the non-concentrically disposed balloon 60 is free to pivot

somewhat about the attachment point to the cannula 70 to center itself in the seal cap 40.

During operation, as the balloon 60 pushes tangentially against the intestinal wall, the force attempts to unseat the balloon from the cap. The flaring portions of the cap, shown in FIG. 9 for example, seat the balloon to prevent the seal between the balloon and the cap from being broken or otherwise compromised. Additionally or alternatively, the cap, for example the cap shown in Figs. 9-12, may include one or more longitudinal cuts in a portion of the cap protruding past the distal end 106 of the endoscope to prevent the balloon from being unseated from the cap when the balloon pushes against the intestinal wall. Alternatively, the portion of the cap protruding past the distal end 106 of the endoscope may have portions of varying heights to seal with the balloon.

While the present medical apparatus has been illustrated by description of several embodiments, additional advantages and modifications may readily appear to those skilled in the art. For example, in embodiments, the seal cap 40 can be configured to grip the balloon 60 and the endoscope 100, thereby securing the balloon 60 to the endoscope 100.

Although the invention has been shown and described with respect to a certain embodiment or embodiments, it is obvious that equivalent alterations and modifications will occur to others skilled in the art upon the reading and understanding of this specification and the annexed drawings. In particular regard to the various functions performed by the above described elements (components, assemblies, devices, compositions, etc.), the terms (including a reference to a "means") used to describe such elements are intended to correspond, unless otherwise indicated, to any element which performs the specified function of the described element (i.e., that is functionally equivalent), even though not structurally equivalent to the disclosed structure which performs the function in the herein illustrated exemplary embodiment or embodiments of the invention. In addition, while a particular feature of the invention may have been described above with respect to only one or more of several illustrated embodiments, such feature may be combined with one or more other features of the other embodiments, as may be desired and advantageous for any given or particular application.

Claims

What is claimed is:

1. A balloon access device for use with an endoscope, the device
5 including:
 - a balloon (60, 60a, 60b, 60c) expandable from a deflated shape to an inflated shape, the balloon having a proximal end and a distal end, wherein a dome portion (64, 64a, 64b, 64c) is formed on the distal end of the balloon; and
 - 10 a cap (40, 40a, 40b, 40c) having a proximal end configured to be coupled to a distal end (106) of an endoscope (100) and a distal end for sealing with the proximal end of the balloon when the balloon is expanded to the inflated shape.
2. The balloon access device according to claim 1, wherein the
15 inflated shape includes a non-pressurized shape and a fully inflated shape.
3. The balloon access device according to claim 1 or 2, wherein the proximal end of the balloon includes a proximal collar (68) configured to couple to a distal end of a catheter (70) and a sealing surface (66) configured to seal with the cap.
- 20 4. The balloon access device according to any preceding claim, wherein the cap includes an endoscope receptacle (42) extending into the cap through the proximal end of the cap for receiving the distal end (106) of the endoscope (100).
- 25 5. The balloon access device according to any preceding claim, wherein the cap includes a stop that engages a front face (104) of the endoscope (100) when the endoscope is received within the cap, and wherein an opening is provided through the stop to distally expose at least one of a light,
30 opening, optics or operative channel on the front face (104) of the endoscope (100).

6. The balloon access device according to any preceding claim, wherein the cap includes a balloon sealing portion (44) proximate the distal end of the cap, the balloon sealing portion including a circular groove (41) that retains and seals with a circular rib (61) of the balloon.

5

7. The balloon access device according to any one of claims 1-4, wherein the cap includes an outwardly flaring balloon sealing portion (44a) that is flexible outwardly relative to a body of the cap to create a seal with the balloon.

10 8. The balloon access device according to claim 7, wherein the outwardly flaring balloon sealing portion prevents the balloon from being unseated from the cap.

15 9. The balloon access device according to any one of claims 1-4, wherein the cap includes a rib (45b) on an interior portion of the cap, and wherein the sealing surface (66b) of the balloon nests and seals with a receptacle of a balloon sealing portion (44b) and the rib (45b).

20 10. The balloon access device according to any preceding claim, wherein the dome portion is hemispherical or ellipsoidal in shape.

11. The balloon access device according to any preceding claim, wherein the balloon is non-concentrically disposed in the endoscope.

25 12. The balloon access device according to any preceding claim, wherein the balloon includes a distally located guide tip (62) on a distal portion of the dome portion (64) for guiding an operator in parting and spreading non-insufflated gastrointestinal tissue during operation.

30 13. The balloon access device according to any preceding claim, wherein the balloon is a transparent hollow balloon.

14. The balloon access device according to any preceding claim, further including a lock mechanism (250) for securing a catheter (70) relative to the endoscope (100) to maintain a sealing contact between the balloon and the cap.

5

15. The balloon access device according to claim 14, wherein the lock mechanism includes a releasably lockable clamp mechanism that contacts and grips the catheter.

10 16. The balloon access device according to any one of claims 1-13, further including a lock mechanism (270), the lock mechanism including:
a balloon insertion tube (280) for receiving the balloon when the balloon is in the deflated state, the tube having a length greater than a y-portion of an operative channel (102) within the endoscope (100) to guide the balloon into and
15 beyond the y-portion; and
a clamp (282) for securing a catheter (70) relative to the endoscope (100) to maintain a sealing contact between the balloon and the cap.

17. The balloon access device according to any one of claims 1-15,
20 further including a balloon insertion tube (80) for receiving the balloon when the balloon is in the deflated state, the balloon insertion tube having a length greater than a y-portion of an operative channel (102) within the endoscope (100) to guide the balloon into and beyond the y-portion.

25 18. The balloon access device according to any preceding claim in combination with a catheter (70), wherein the proximal end of the balloon is coupled to a distal end of the catheter (70).

19. The balloon access device according to any preceding claim in
30 combination with an endoscope (100), wherein the proximal end of the cap is coupled to the distal end (106) of the endoscope (100).

20. The balloon access device according to any of claims 1-18, wherein the cap is integral with the endoscope.

21. A balloon access device for use with an endoscope, the device
5 including:

a balloon (60, 60a, 60b, 60c) expandable from a deflated shape to an inflated shape, the balloon having a proximal end and a distal end, wherein a dome portion (64, 64a, 64b, 64c) is formed on the distal end of the balloon;

10 a cap (40, 40a, 40b, 40c) having a proximal end configured to be coupled to a distal end (106) of an endoscope (100) and a distal end for sealing with the proximal end of the balloon when the balloon is passed through the cap and expanded to the inflated shape; and

15 a balloon insertion tube (80) for receiving the balloon when the balloon is in the deflated state, the balloon insertion tube having a length greater than a y-portion of an operative channel (102) within the endoscope (100) to guide the balloon into and beyond the y-portion.

22. A method of creating a seal between a balloon and a cap, the balloon having a proximal end having a sealing surface (66) and proximal collar
20 (68) coupled to a distal end of a catheter (70), and the cap having a proximal end coupled to a distal end (106) of an endoscope (100), the method including:

advancing the catheter and balloon through an operative channel (102) of the endoscope until the balloon is positioned distal the distal end of the cap;

25 expanding the balloon from a deflated shape to at least a partially inflated shape; and

moving the balloon proximally towards the cap so that the sealing surface (66) abuts a distal end of the cap to create a seal between the cap and the balloon.

30 23. A method of performing a gastrointestinal procedure on a patient having gastrointestinal tissue in a non-insufflated state using an endoscope (100) and balloon access device (30) installed upon the endoscope, the balloon access device including a cap (40) coupled to a distal end (106) of the

endoscope and an at least partially inflated balloon (60) coupled to a distal end of a catheter (70) received in an operative channel (102) of the endoscope, the method including:

- advance the endoscope through the gastrointestinal tissue;
- 5 guiding the endoscope using a camera on a distal end of the endoscope and a guide tip (62) on a distal end of the balloon; and
- spreading the tissue using a body of the balloon and the guide tip (62);
- wherein the balloon is transparent so that an operator can view the tissue through the balloon using the camera and the operator can center the guide tip
- 10 in a gastrointestinal tract.

24. The method according to claim 23, further including retracting the endoscope from the gastrointestinal tissue, wherein during the retracting a balloon sealing portion of the cap flattens a luminal fold in the tissue.

15

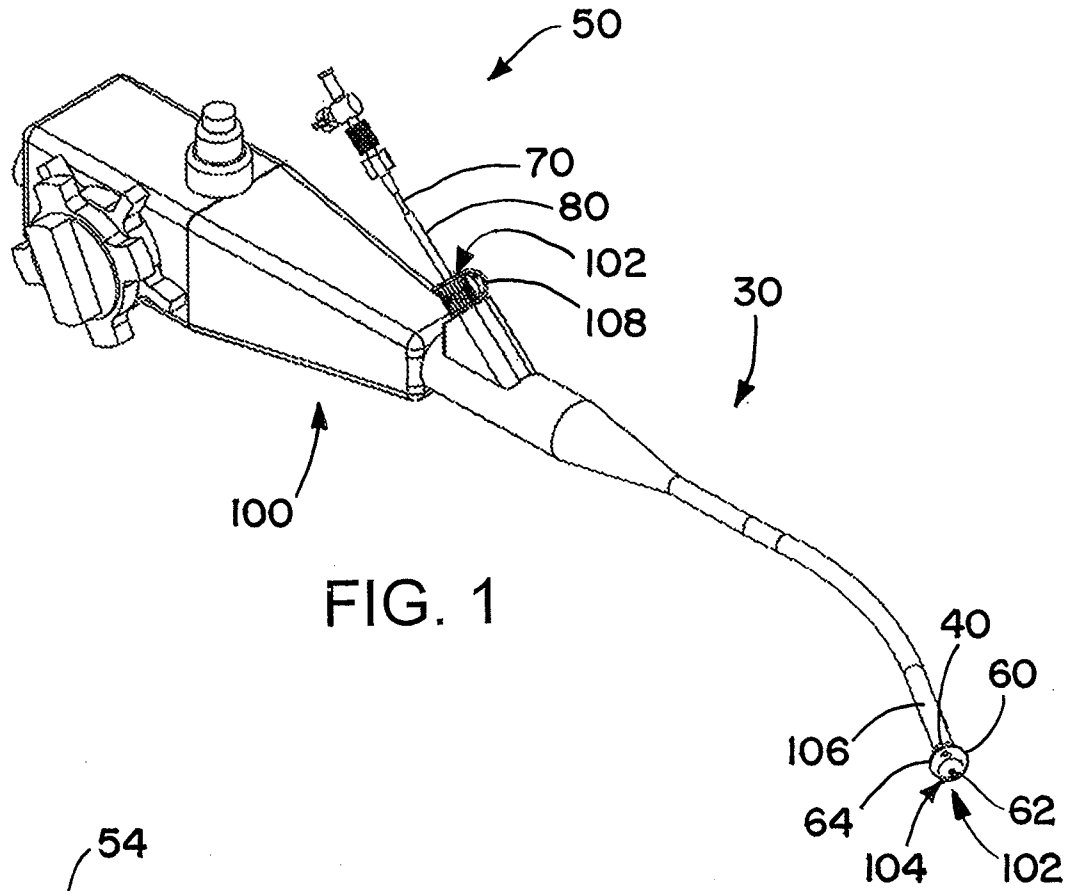


FIG. 1

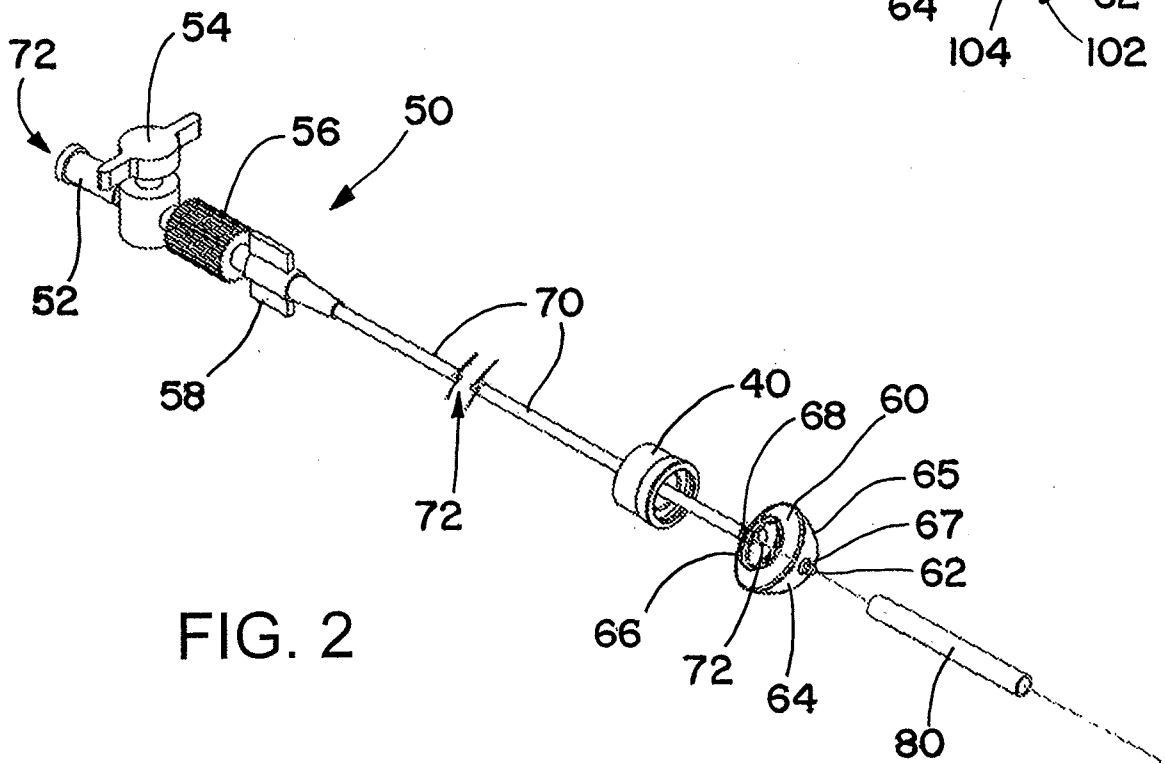


FIG. 2

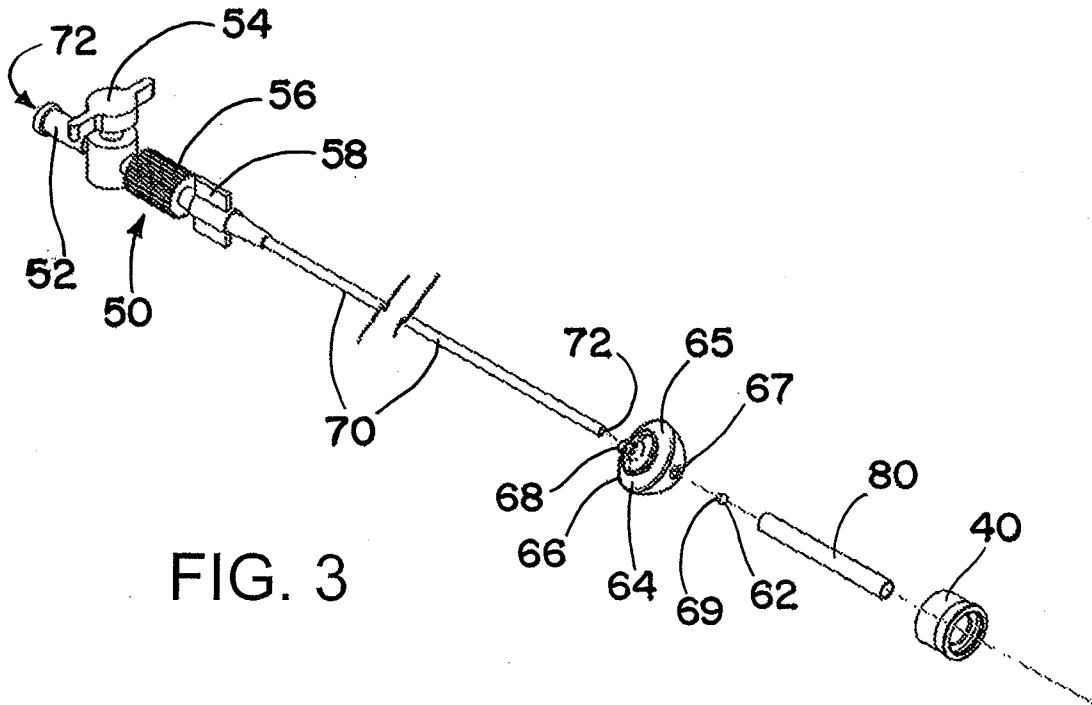


FIG. 3

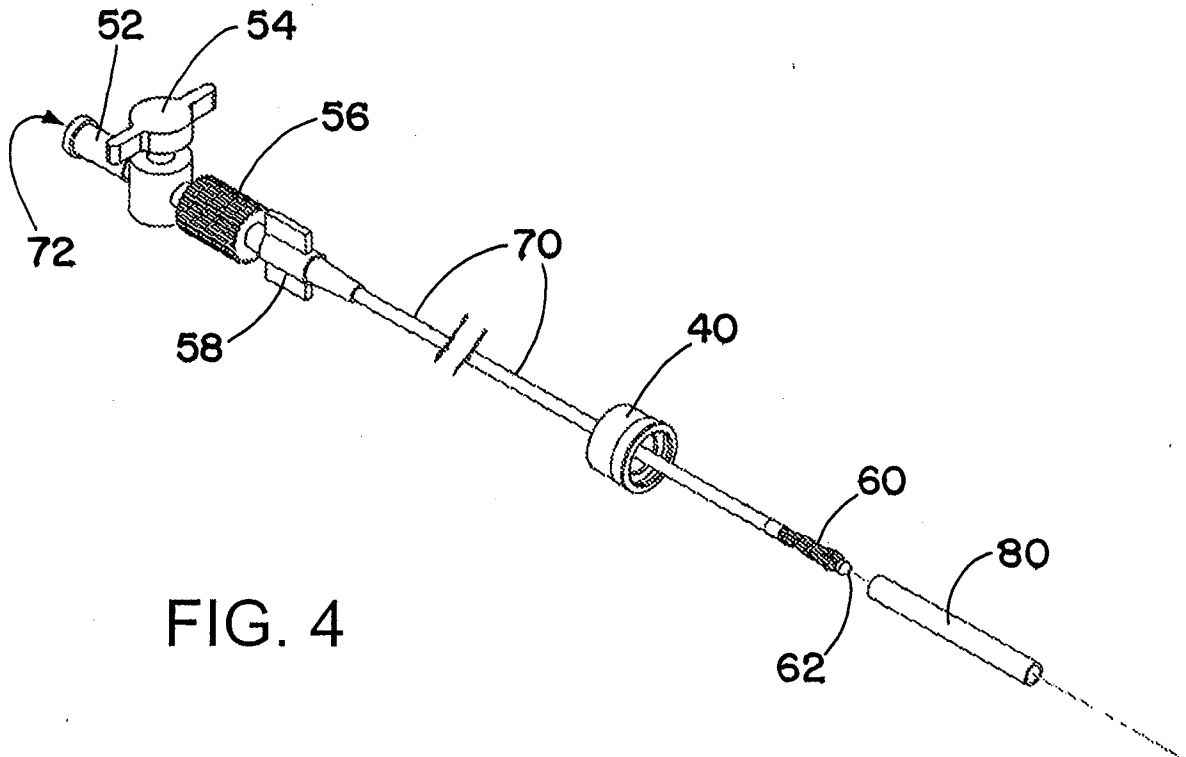
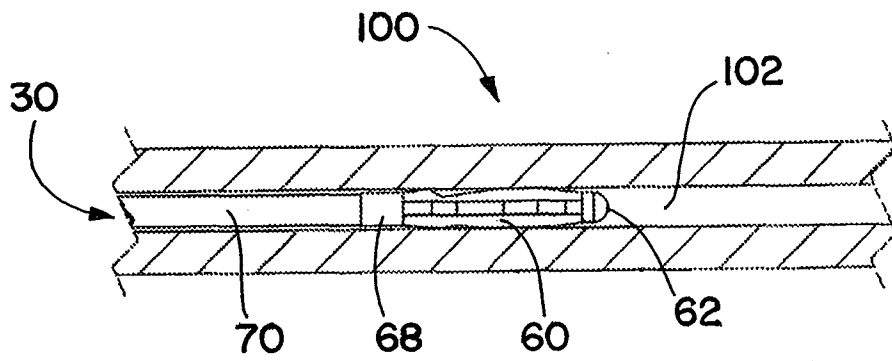
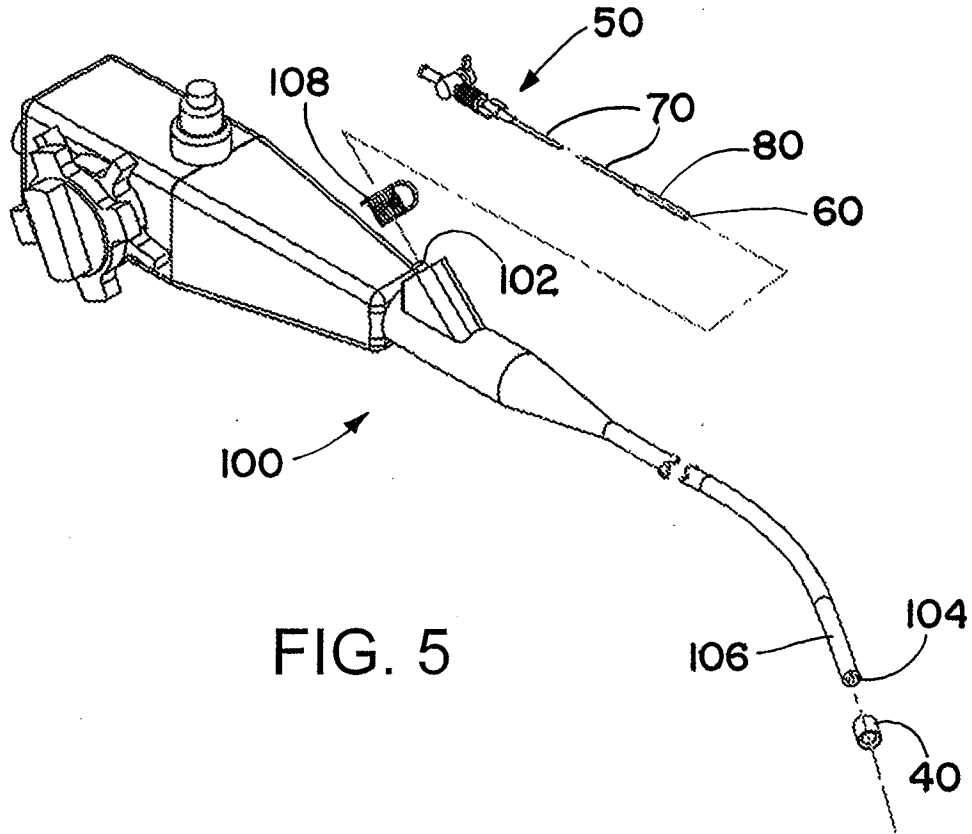


FIG. 4

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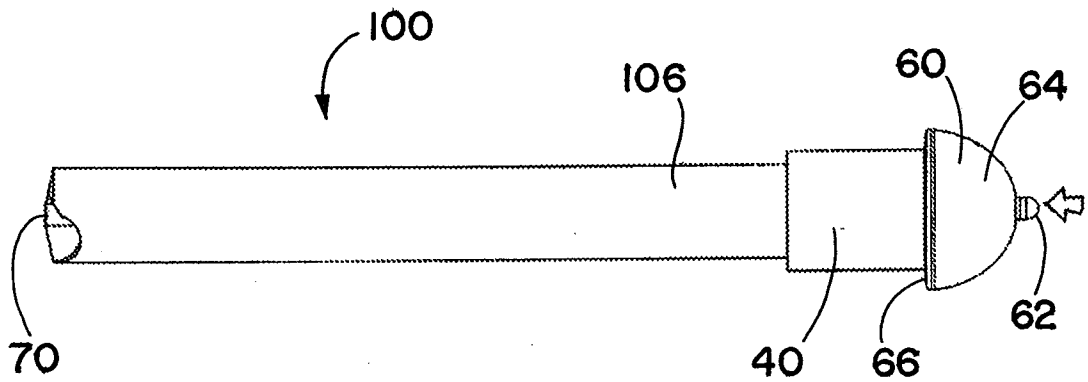


FIG. 7

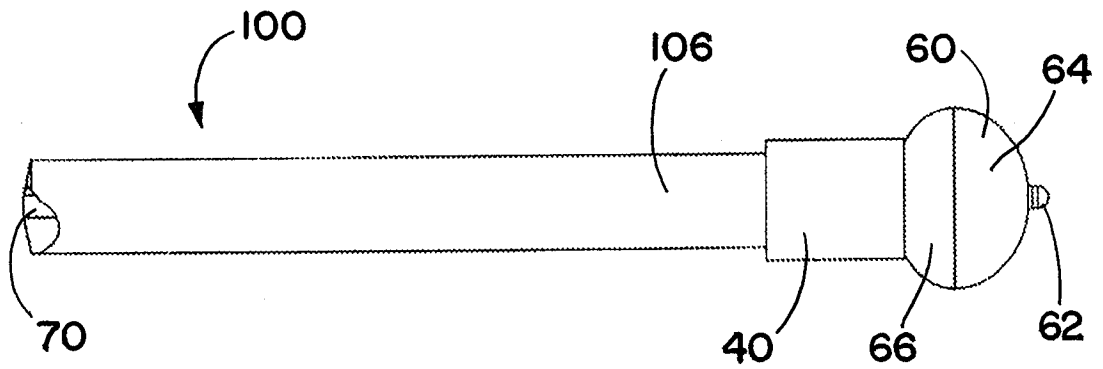
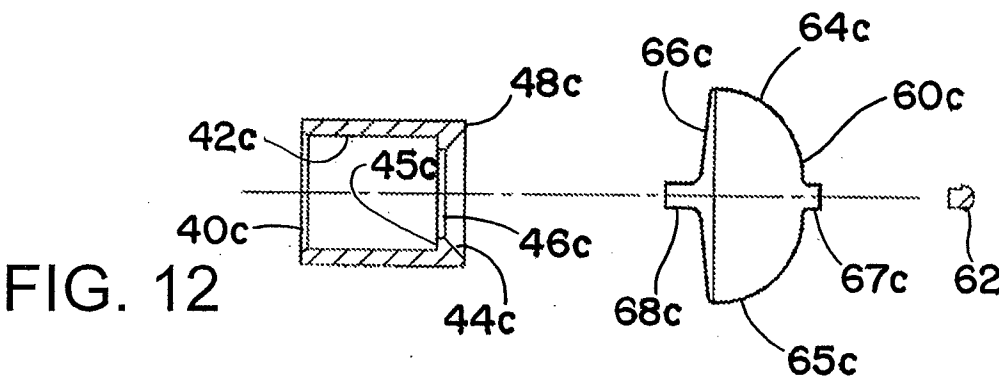
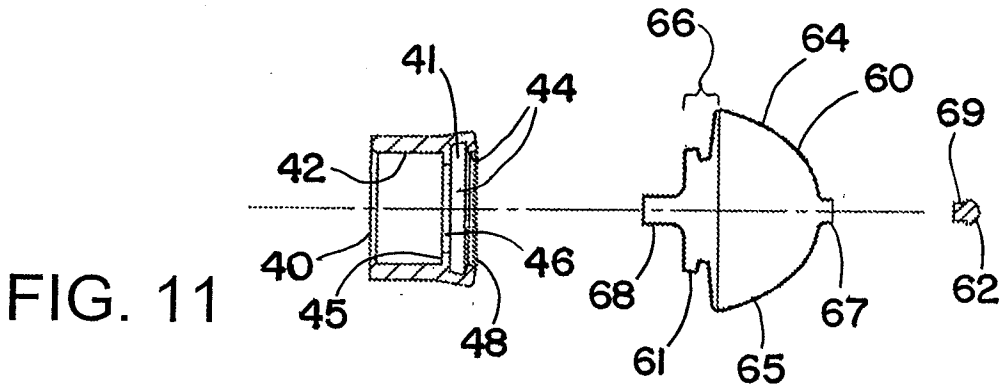
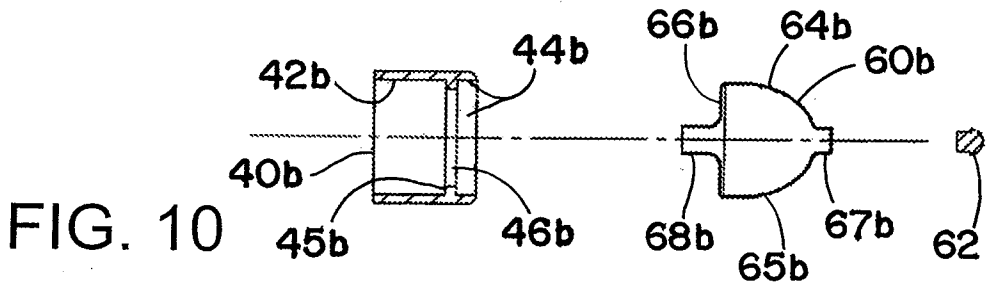
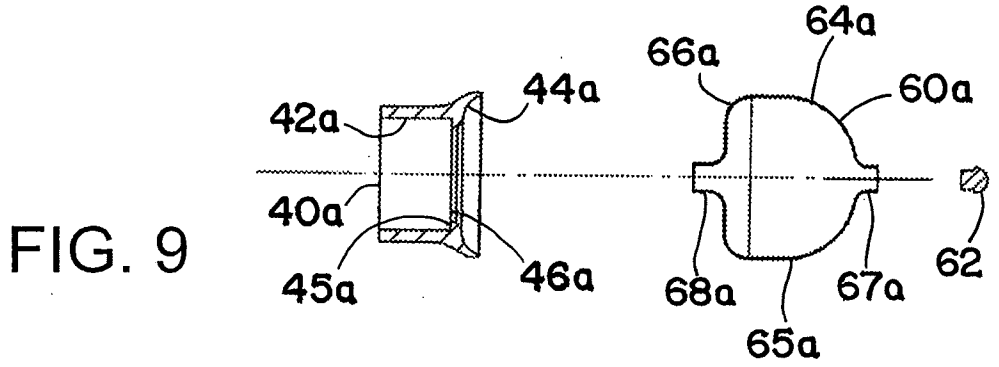


FIG. 8



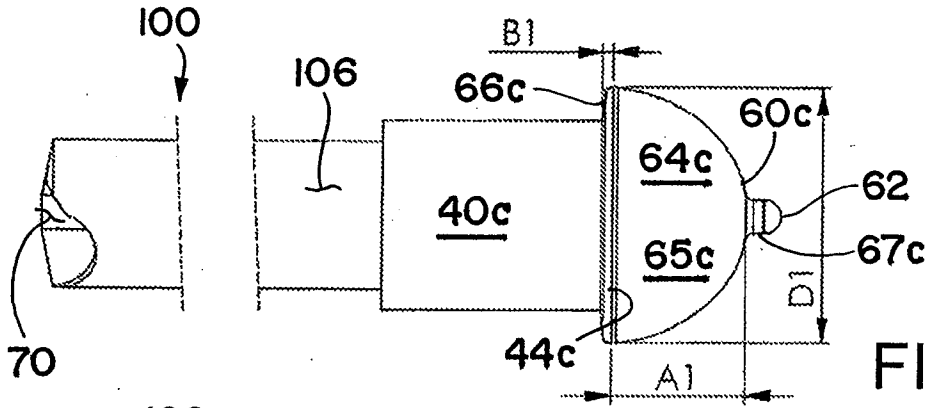


FIG. 13

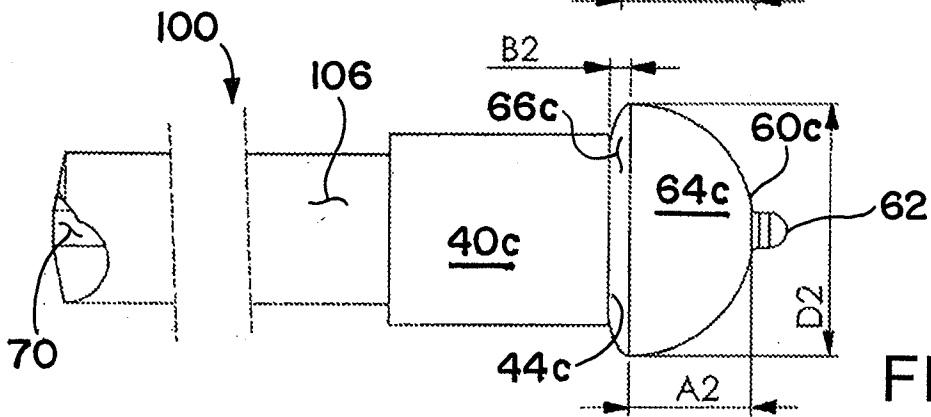


FIG. 14

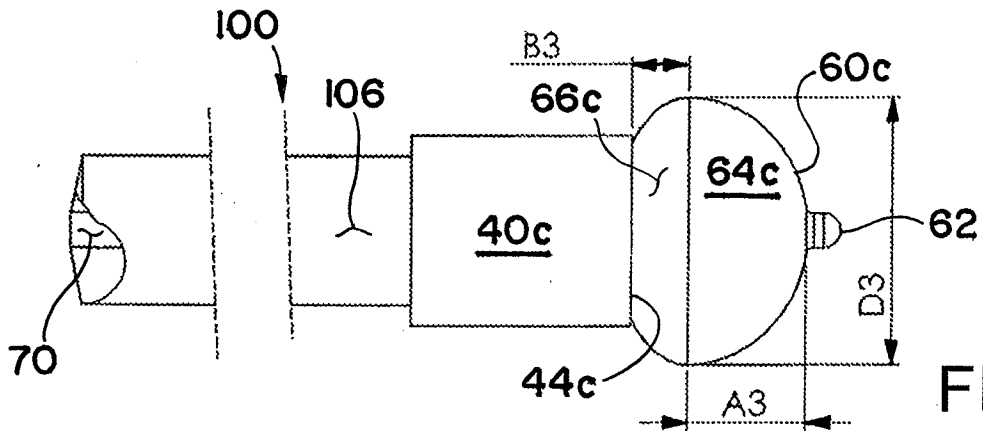


FIG. 15

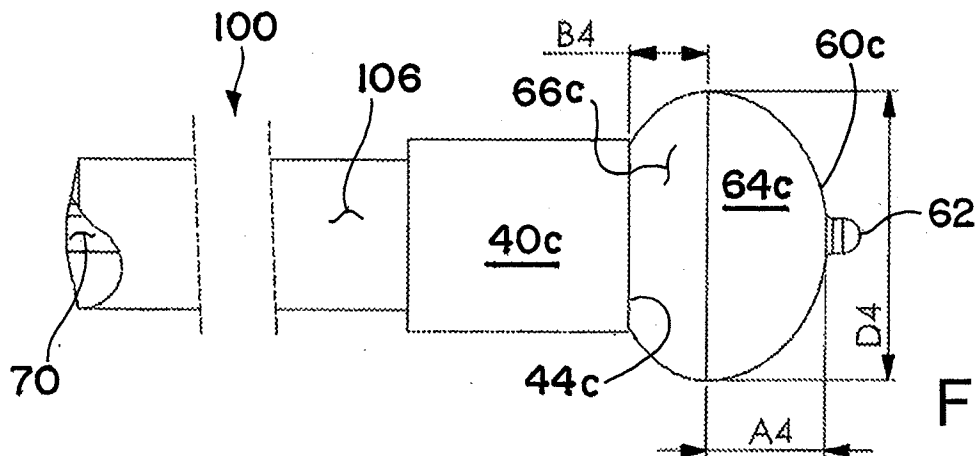


FIG. 16

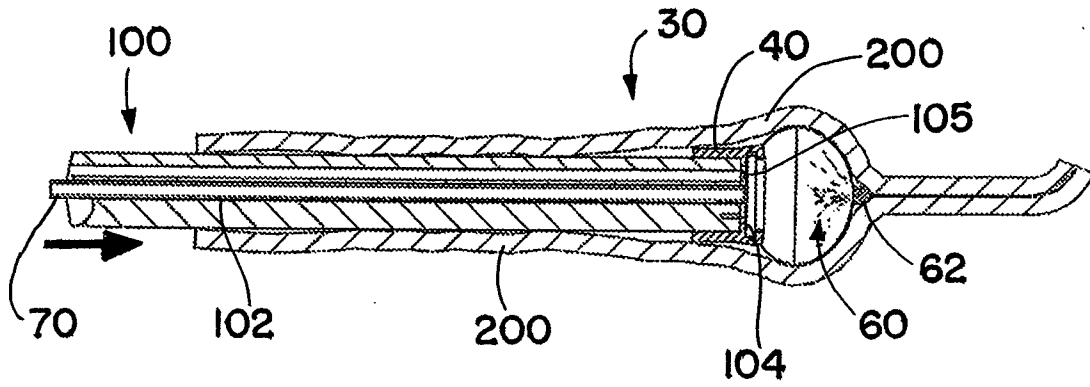


FIG. 17

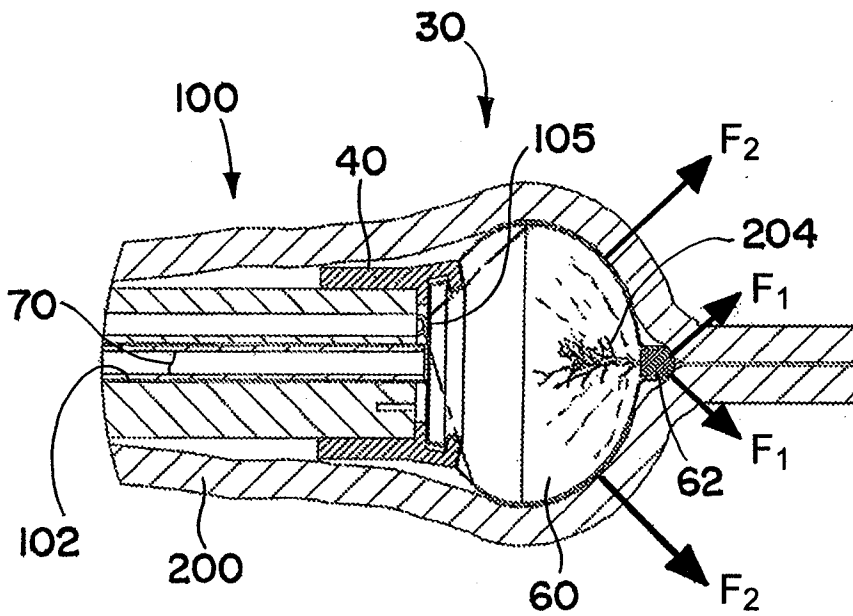


FIG. 18

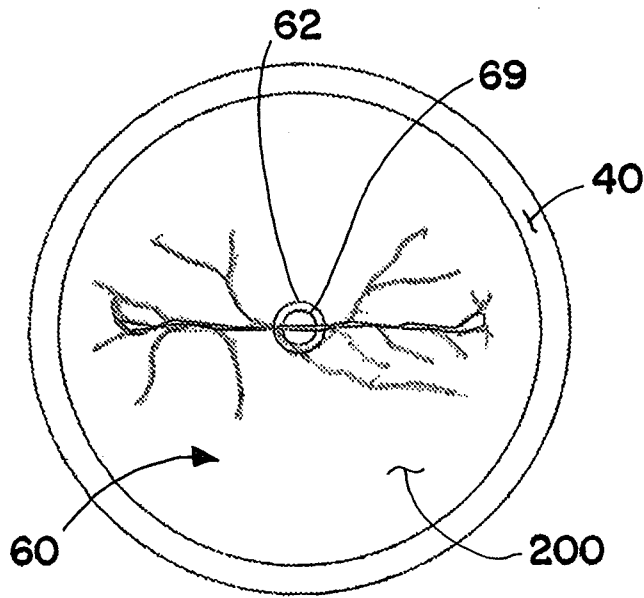


FIG. 19

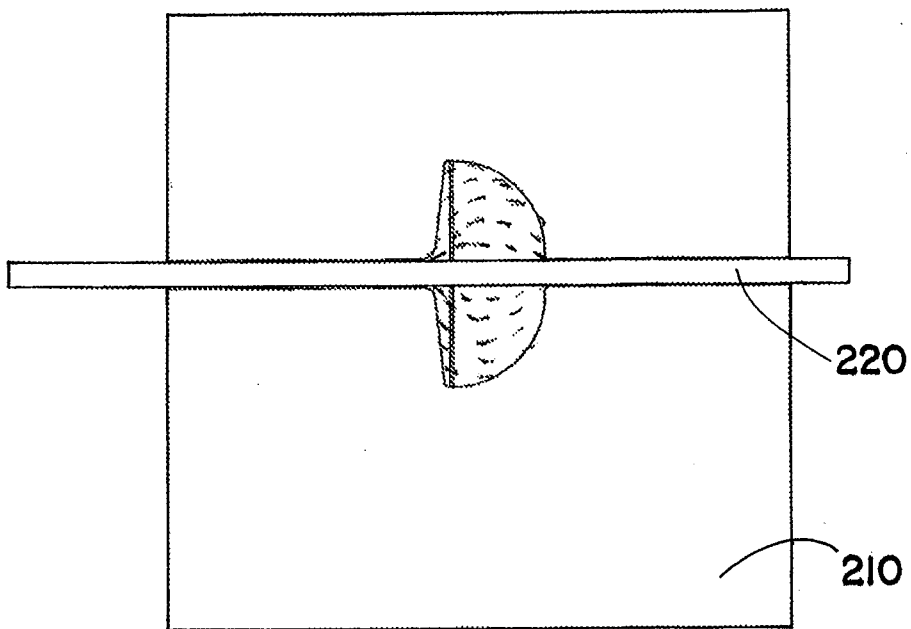


FIG. 20

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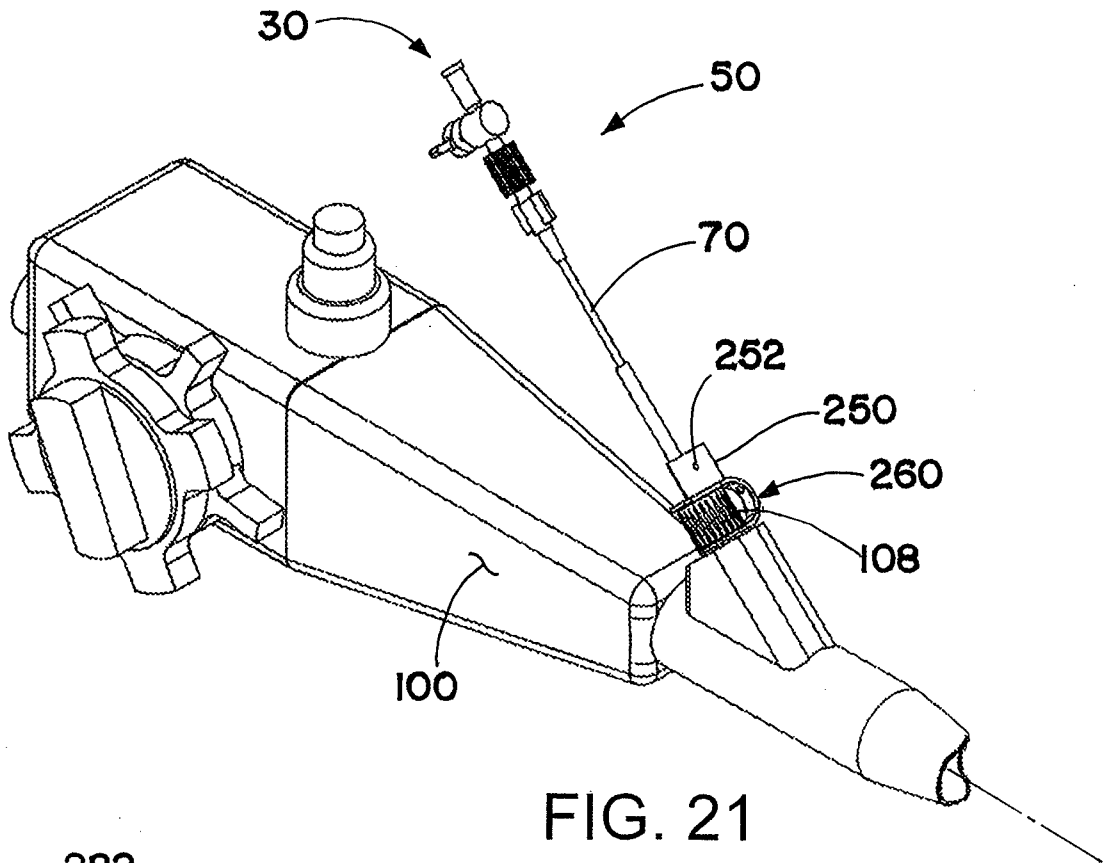


FIG. 21

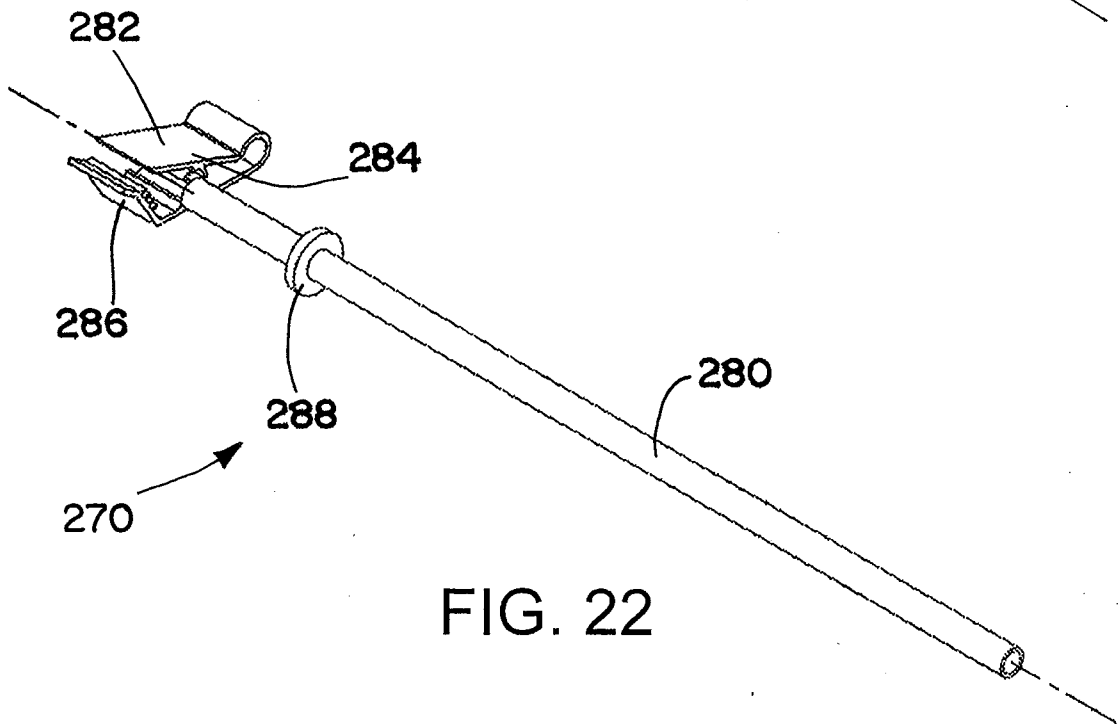


FIG. 22

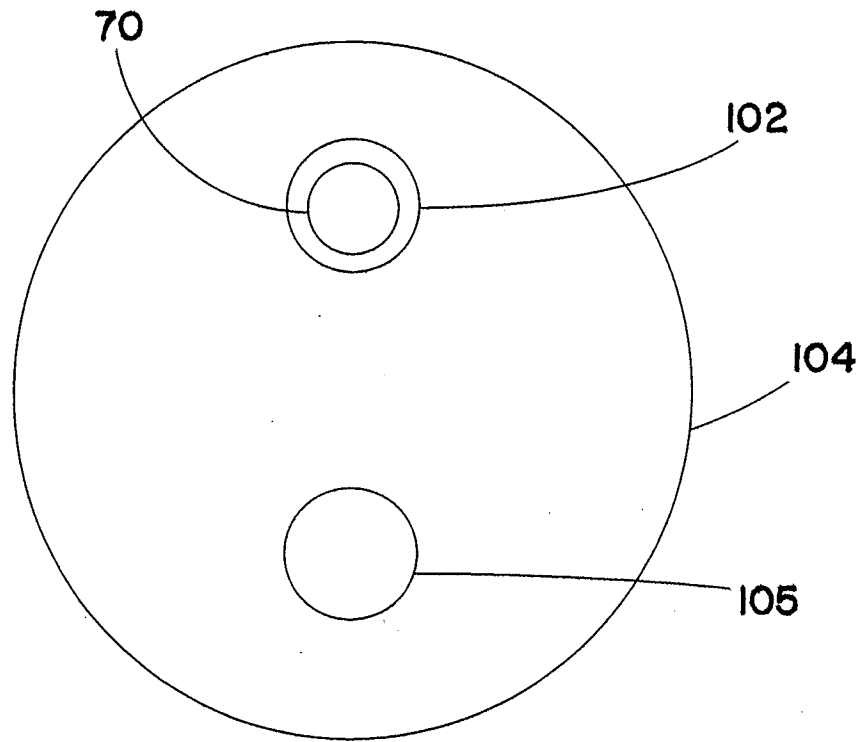


FIG. 23

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/032248

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61B1/00 A61B1/32 A61M25/10
 ADD.

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)
 A61B A61M

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)
 EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/082626 A1 (ICHIMURA HIRONOBU [JP] ET AL) 26 March 2009 (2009-03-26) paragraphs [0006], [0031] - [0032], [0039] - [0043], [0057], [0060] figures 1-4,8 -----	1-21
X	US 6 059 719 A (YAMAMOTO TETSUYA [JP] ET AL) 9 May 2000 (2000-05-09) column 18, line 64 - column 20, line 22 figures 27-29 -----	1-21
A	US 4 961 738 A (MACKIN ROBERT A [US]) 9 October 1990 (1990-10-09) the whole document -----	1-21
A	US 5 002 556 A (ISHIDA TOSHINOBU [JP] ET AL) 26 March 1991 (1991-03-26) the whole document -----	1-21

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"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</p> <p>"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</p> <p>"&" document member of the same patent family</p>
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Date of the actual completion of the international search 20 June 2012	Date of mailing of the international search report 02/07/2012
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Faymann, Juan
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/032248

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

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

1. Claims Nos.: **22-24**
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 22-24

Claims 22-24 relate to subject-matter considered by this authority to be covered by the provisions of Rule 39.1(iv) PCT. Claim 22 disclose a method of creating a seal between a balloon and a cap, comprising the steps of introducing the balloon beyond the tip of an endoscope ("the balloon is positioned distal the distal end of the cap") and inflating the balloon ("expanding the balloon") beyond the tip of the endoscope. Since the method does not exclude performing these steps within a living human or animal body, the steps constitute surgical steps since they imply movements and manipulation of the device within a living body. Thus, claim 22 is a method of treatment by surgery. Claim 23 discloses a method of performing a gastro-intestinal procedure. As such the method constitutes either a method of treatment by surgery or a method of treatment by therapy. Claim 24, as a dependent of claim 23, also falls under the provisions of Rule 39.1(iv) PCT.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/032248

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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