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(71) Applicant (for all designated States except US): **THE JOHNS HOPKINS UNIVERSITY** [US/US]; 3400 North Charles Street, Baltimore, MD 21218 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **KALLOO, Anthony, N.** [US/US]; 1244 Dockside Circle, Baltimore, MD 21224 (US). **KHASHAB, Mouen, A.** [LB/US]; 960 Southerly Road, Apartment 249, Towson, MD 21204 (US).

(74) Agent: **TAYLOR, Stacy, L.**; Dla Piper LLP (US), 4365 Executive Drive, Suite 1100, San Diego, CA 92121-2133 (US).

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(54) Title: VISUALIZATION BALLOON AND METHOD OF USE THEREOF

(57) Abstract: The present invention utilizes a device and method for visualization of a bodily lumen. The invention provides a device and method for visualization and inspection of a bodily lumen via deployment of a dual lumen balloon including an optical sensor, the balloon configured to smooth folded tissue upon deployment as well as maintain the surface of the balloon free from debris for optimal visualization of the bodily lumen.



VISUALIZATION BALLOON AND METHOD OF USE THEREOF

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

[0001] The present invention relates generally to medical devices and more specifically to a device and method for visualizing a bodily lumen of a subject.

BACKGROUND INFORMATION

[0002] Colorectal cancer is the fourth most common form of cancer in the United States and the third leading cause of cancer-related death in the Western world. Colorectal cancer arises from adenomatous polyps in the colon.

[0003] Colonoscopy is the most prevalent screening tool for colorectal cancer. Colonoscopy protects against death from colon cancer because it allows detection and resection of precancerous polyps and, thus, prevents their transformation into colon cancer. In addition, colonoscopy allows detection of early-stage (asymptomatic) cancers.

[0004] However, colonoscopy is not perfect and interval cancers still occur. Its effectiveness is subject to the degree to which the entire colon is visualized during an exam. There are several factors that may contribute to incomplete viewing of the entire colonic wall. These include particulate matter in the colon, subject discomfort/motion, physician attention, the speed at which the endoscope is withdrawn, and complex colonic morphology.

[0005] Interval cancers are defined as cancers diagnosed within 3 years of colonoscopy. Among the most common causes of interval cancers are missed lesions. Many lesions are hard to detect because they are located behind colonic folds.

[0006] There is, therefore, a continuing need for methods and devices for enhancing the visualization of the colon during colonoscopy. For example, a device that helps flatten the folds may improve detection of colonic cancerous and precancerous lesions.

SUMMARY OF THE INVENTION

[0007] The present invention provides a device and method for visualization of a bodily

lumen.

[0008] Accordingly, in one aspect, the present invention provides a device for visualization of a bodily lumen. The device includes: a) a shaft defining a longitudinal lumen extending from a distal end of the shaft to a proximal end of the shaft; b) an optically transmissive deployable balloon disposed within the lumen of the shaft; and c) an optical sensor deployable within the inner lumen of the balloon for visualization of the bodily lumen. The balloon has an inner lumen and an outer lumen such that in a deployed state, (i) the inner lumen of the balloon is inflated to an expanded state and protrudes beyond the distal end of the shaft through a hole disposed at the distal end of the shaft, and (ii) fluid is introduced into the outer lumen of the balloon, the outer lumen including pores for flow of the fluid from the outer lumen into the bodily lumen. In embodiments, the device includes a second longitudinal lumen in fluid communication with the bodily lumen operative to withdraw the fluid introduced into the bodily lumen through the outer lumen of the expanded balloon.

[0009] In another aspect, the invention provides a method for visualizing a bodily lumen using the device of the present invention. The method includes: a) advancing the device of the present invention into the bodily lumen of a subject; b) deploying the balloon by expanding the inner lumen of the balloon; c) introducing a fluid into the outer lumen of the balloon; and d) visualizing the bodily lumen via the optical sensor.

[0010] In embodiments of the invention, the bodily lumen is a body space having interior surfaces that may develop cancers, lesions or polyps, i.e., the gastrointestinal tract. In one embodiment, the bodily lumen is a region of the colon, such as the cecum.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Figure 1 is a longitudinal cross-sectional diagram showing a shaft of a device having proximal (**A**) and distal (**B**) ends along with central lumen (**50**) in one embodiment of the invention.

[0012] Figure 2 is a longitudinal cross-sectional diagram showing a device having a distally (**B**) disposed balloon (**20**) in an un-deployed state in one embodiment of the invention.

[0013] Figure 3 is a longitudinal cross-sectional diagram showing a device having a distally (B) disposed balloon (20) in a deployed state in one embodiment of the invention.

[0014] Figure 4 is a distal (B) side view along the longitudinal axis of a deployed device showing an expanded balloon (20) in one embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0015] The present invention provides a device and method for visualization of a bodily lumen. As discussed herein, the device utilizes an optically transmissive dual lumen balloon, which when deployed allows improved visualization by flattening out tissue folds present within the bodily lumen by the expanded balloon such that the tissue may be better viewed and inspected. Additionally, the unique dual lumen structure of the balloon (in which an inner inflation lumen is disposed within an outer lumen designed to flush debris from the balloon surface) allows for better visualization of surrounding tissue of the bodily lumen via an optical sensor within the inner lumen of the balloon. The device is ideally adapted for inspection and visualization of regions of the gastrointestinal tract. For example, the device may be used for improved detection and visualization of colonic lesions within the cecum which is a region that includes many colonic folds as well as surrounding debris, stool and blood which may hamper visualization.

[0016] The device provides means to allow visualization and inspection of a bodily lumen via endoscopy and/or laparoscopy procedures. The device of the present invention is feasible to manufacture and the method of its use allows for effective, efficacious, and safe visualization of bodily tissue as well as detection and inspection of cancerous lesions and ulcers.

[0017] Before the present device and method are described, it is to be understood that this invention is not limited to particular device and methodology described. It is also to be understood that the terminology used herein is for purposes of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only in the appended claims.

[0018] As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural references unless the context clearly dictates otherwise. Thus, for

example, references to “the method” includes one or more methods, and/or steps of the type described herein which will become apparent to those persons skilled in the art upon reading this disclosure and so forth.

[0019] Unless defined otherwise, 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 invention, the preferred methods and materials are now described.

[0020] The device of the present invention generally includes: a) a shaft defining a longitudinal lumen extending from a distal end of the shaft to a proximal end of the shaft; b) an optically transmissive deployable balloon disposed within the lumen of the shaft; and c) an optical sensor deployable within an inner lumen of the balloon for visualization of the bodily lumen. The balloon has an inner lumen and an outer lumen, the outer lumen partially or entirely surrounding the inner lumen.

[0021] The balloon is deployed in a bodily lumen of a subject by inflating the inner lumen to an expanded state such that the balloon protrudes from a hole in the distal tip of the shaft and expands to fill a bodily lumen. Fluid is introduced into the outer lumen of the balloon which includes pores in its surface for flow of the fluid from the outer lumen into the bodily lumen so as to clean or flush debris from the balloon surface to enhance visualization via the optical sensor within the inner lumen of the balloon. The device includes a second longitudinal lumen in fluid communication with the bodily lumen operative to withdraw the fluid introduced into the bodily lumen via the outer lumen of the balloon.

[0022] By way of illustration, Figure 1 generally depicts a longitudinal cross-section of a shaft (15) of a device (10) of the present invention having proximal (A) and distal (B) ends. The device further includes at least one longitudinal lumen (50) extending between the proximal and distal ends. In preferred embodiments of the invention, shaft (15) is configured as an invasive scope, such as an endoscope or laparoscope having at least one lumen therethrough.

[0023] Figure 2 is a longitudinal cross-section of the distal (B) end of the device. Disposed with the distal lumen of the device, a balloon (20) is shown in an un-deployed state.

When un-deployed, the balloon (20) is in an un-inflated state within the lumen (50).

[0024] Figure 3 is a longitudinal cross-section of the distal end (B) of a device of the present invention. In Figure 3, balloon (20) is shown in the deployed state in which the balloon (20) is expanded via introduction of a fluid into the inner lumen (30) of the balloon (20). The balloon (20) may be affixed within the distal end (B) of the shaft (15) or be advanced to the distal end (B) of the shaft (15) for deployment (for example, by deployment via coupling to a catheter, through lumen (50) to move balloon (20) distally and, in certain embodiments, to retract it proximally following visualization).

[0025] Upon expansion of balloon (20), fluid is introduced into the outer lumen (40) of the balloon. The outer lumen (40) includes one or more pores (60) through its surface to allow for fluid flow from the outer lumen (40) into the bodily lumen. Also shown in Figure 4 is an optical sensor (70) which is disposed within the inner lumen (40) of the balloon. The optical sensor may be may be affixed within the distal end (B) of the shaft (15) or be advanced to the distal end (B) of the shaft (15) for deployment (for example, by deployment via coupling to a catheter, through lumen (50) to move balloon (20) and optical sensor (70) distally and, in certain embodiments, to retract them proximally following visualization).

[0026] Flow of fluid within and out of the outer lumen (40) of the balloon allows for cleaning and/or flushing of any debris on or around the balloon surfaces to enhance visualization via the optical sensor (70) within the inner lumen (30) of the balloon. The device may also include a second longitudinal lumen (80) in fluid communication with the bodily lumen operative to withdraw the fluid introduced into the bodily lumen. The device may include multiple additional lumens for withdrawal of the fluid which may be disposed at any location distally.

[0027] Accordingly, when un-deployed, the balloon (20) is within the lumen (50). Additionally, when deployed, the balloon (20) protrudes out of the distal end (B) of the lumen (50) and expands to contact surrounding tissue surfaces.

[0028] In the deployed state, the balloon (20) may be configured to have a number of geometric shapes that facilitate unfolding and smoothing out of the surfaces of the bodily lumen. For example, Figure 4 is distal side view along the longitudinal axis of the lumen (50) which shows an embodiment in which the balloon is configured to expand into a shape

having four asymmetrical bulges, the bulges designed to expand and smooth folded tissue.

[0029] One skilled in the art would understand that the balloon may be configured to take any number of geometric shapes upon deployment that facilitates unfolding of surrounding tissue within the bodily lumen. Illustrations of additional shapes include generally cylindrical, round, elliptical, and ovoid shapes.

[0030] In various embodiments, the balloon radially expands upon inflation of inner or outer lumens. As is known in the art, the increase in diameter will be dependent upon the properties of the material used as well as the amount of inflation fluid introduced into the balloon, but typically the balloon is configured to increasing in diameter by a factor of at least 1, 1.5, 2, 2.5 or 3 times the diameter of lumen (50). In various embodiments, the balloon may have a major expanded diameter of about 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15 or 20 cm or even greater.

[0031] Accordingly, in practice, the device (10) is advanced into a bodily lumen of a subject. The balloon (20) is deployed through a hole in the distal end of the shaft (15) thereby allowing contact of the balloon (20) with surfaces of the bodily lumen. Contact of the balloon (20) with the surface of the bodily lumen allows for unfolding of tissue to facilitate optimal visualization and inspection of the tissue surfaces. Introduction of fluid into the outer lumen (40) of the balloon and into the surrounding bodily lumen allows for cleaning or flushing of the balloon surface to further facilitate optimal visualization.

[0032] The balloon may be deflated and retracted into lumen (50) of the shaft (15) and withdrawn from the body following visualization of tissue surfaces within the bodily lumen.

[0033] One skilled in the art would appreciate that the entire device, or any components thereof may be constructed of optically transmissive material, i.e., material that allows light to pass through, to facilitate visualization via the optical sensor. For example, the balloon is optically transmissible, as well as any fluid or gas used to inflate the inner or outer lumens of the balloon. Further, all or portions of the balloon may be optically transmissible.

[0034] The balloon may be made of a compliant material which resiliently deforms under radial pressure. Examples of suitable compliant materials are generally known in the art and include materials such as, but not limited to polyethylene (PE), polyurethane (PU), nylon,

silicone, low density polyethylene (LDPE), polyether block amides (PEBAX), and the like. The balloon may also be made of a semi- or non-compliant material. For example, the balloon may include an inelastic fiber layer and/or sleeve. The inelastic fibers are of high-strength and typically made of a high-strength polymeric material. Examples of suitable materials are generally known in the art and include materials such as, but not limited to Kevlar®, Vectran®, Spectra®, Dacron®, Dyneema®, Terlon® (PBT), Zylon® (PBO), polyimides (PIM), other ultra high molecular weight polyethylene (UHMWPE), aramids, and the like.

[0035] To facilitate inflation of the balloon (20) the device may include any number of inflation lumens disposed within lumen (50) which are in fluid communication with the balloon (20), or lumens thereof, whereby fluid or gas can be infused and withdrawn to inflate and to deflate the balloon. Fluid or gas may be infused or withdrawn through any number of accessory ports in fluid communication with the one or more inflation lumens which may be adapted to couple with a syringe, external pump, or the like.

[0036] One skilled in the art would understand that the device may include any number of additional balloons or other expandable elements disposed along the elongated shaft (15). For example, 1, 2, 3, 4 or more balloons or other elements may be disposed along the shaft (15).

[0037] In various embodiments, the device may further include a radiopaque material to allow for detection of the position of the device. A number of radiopaque materials and coatings are well known in the art which may be incorporated onto the surface of the device or otherwise integrated into the device. For example, well known radiopaque material include powdered tungsten, gold, iridium, platinum, barium, bismuth, iodine, iron and the like.

[0038] In various embodiments, the radiopaque materials may be incorporated over the entire device or in discrete regions in any number of patterns to allow for detection. In one embodiment, all or part of the balloon (20) may include radiopaque materials. In some embodiments the distal tip of the device includes radiopaque materials.

[0039] The device may conveniently be configured as an endoscope, laparoscope or other invasive scope device.

[0040] The term “subject” as used herein refers to any individual or patient to which the subject methods are performed. Generally the subject is human, although as will be appreciated by those in the art, the subject may be an animal. Thus other animals, including mammals such as rodents (including mice, rats, hamsters and guinea pigs), cats, dogs, rabbits, farm animals including cows, horses, goats, sheep, pigs, etc., and primates (including monkeys, chimpanzees, orangutans and gorillas) are included within the definition of subject.

[0041] The methodology and device of the present invention may be deployed to visualize and inspect tissue within any bodily lumen or cavity. Generally, the device is deployed to a bodily lumen, such as a hollow organ of the body, for example the gastrointestinal tract. As such, the term “bodily lumen”, “body cavity” or “tissue cavity” is intended to refer to internal surfaces and spaces of the body. In exemplary embodiments, the device is deployed to a region of the gastrointestinal tract, such as the cecum.

[0042] Although the invention has been described with reference to the above example, it will be understood that modifications and variations are encompassed within the spirit and scope of the invention. Accordingly, the invention is limited only by the following claims.

What is claimed is:

1. A device for visualization of a bodily lumen, comprising:
 - a) a shaft defining a longitudinal lumen extending from a distal end of the shaft to a proximal end of the shaft;
 - b) an optically transmissive deployable balloon disposed within the lumen of the shaft, the balloon having an inner lumen and an outer lumen, wherein in a deployed state, (i) the inner lumen of the balloon is inflated to an expanded state and protrudes beyond the distal end of the shaft through a hole disposed at the distal end of the shaft, and (ii) fluid is introduced into the outer lumen of the balloon, the outer lumen comprising pores for flow of the fluid from the outer lumen into the bodily lumen; and
 - c) an optical sensor deployable within the inner lumen of the balloon for visualization of the bodily lumen.
2. The device of claim 1, further comprising a second longitudinal lumen in fluid communication with the bodily lumen operative to withdraw the fluid introduced into the bodily lumen through the outer lumen.
3. The device of claim 1, wherein the shaft is configured as an endoscope, a laparoscope, or an overtube.
4. The device of claim 1, wherein the pores are disposed circumferentially or longitudinally on the outer lumen.
5. The device of claim 1, wherein when in the deployed state, the expanded balloon comprises one or more expanded protrusions adapted for flattening or smoothing folds of the bodily lumen.
6. The device of claim 1, wherein the bodily lumen is a region of gastrointestinal tract.
7. The device of claim 6, wherein the region is cecum.
8. The device of claim 1, wherein the fluid introduced into the outer lumen is optically transmissive.

9. The device of claim 8, wherein the fluid is water or saline solution.
10. The device of claim 1, wherein the inner and outer lumens of the balloon are each in fluid communication with one or more inflation lumens whereby fluid or gas can be infused and withdrawn to inflate and to deflate the lumens.
11. The device of claim 1, further comprising a light source.
12. The device of claim 11, wherein the light source is operatively coupled to the optical sensor.
13. The device of claim 12, wherein the optical sensor is operatively coupled to a visual display to allow for visualization of the bodily lumen.
14. The device of claim 1, further comprises a radiopaque material.
15. The device of claim 1, wherein the outer lumen is disposed over all or a portion of the inner lumen of the balloon.
16. The device of claim 1, further comprising one or more additional inflation balloons operatively coupled to the shaft.
17. A method for visualization of a bodily lumen, comprising:
 - a) advancing the device of claim 1 into the bodily lumen of a subject;
 - b) deploying the balloon by expanding the inner lumen of the balloon;
 - c) introducing a fluid into the outer lumen of the balloon; and
 - d) visualizing the bodily lumen via the optical sensor.
18. The method of claim 17, further comprising withdrawing the fluid from the bodily lumen.
19. The method of claim 17, wherein the bodily lumen is a region of gastrointestinal tract.
20. The method of claim 19, wherein the region is cecum.

21. The method of claim 17, wherein the shaft of the device is configured as endoscope, a laparoscope or an overtube.

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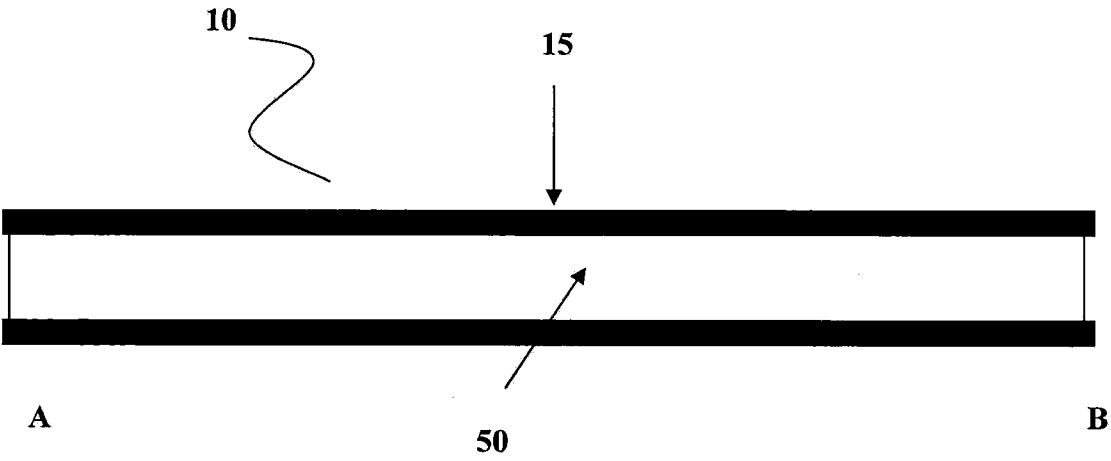


FIG. 1

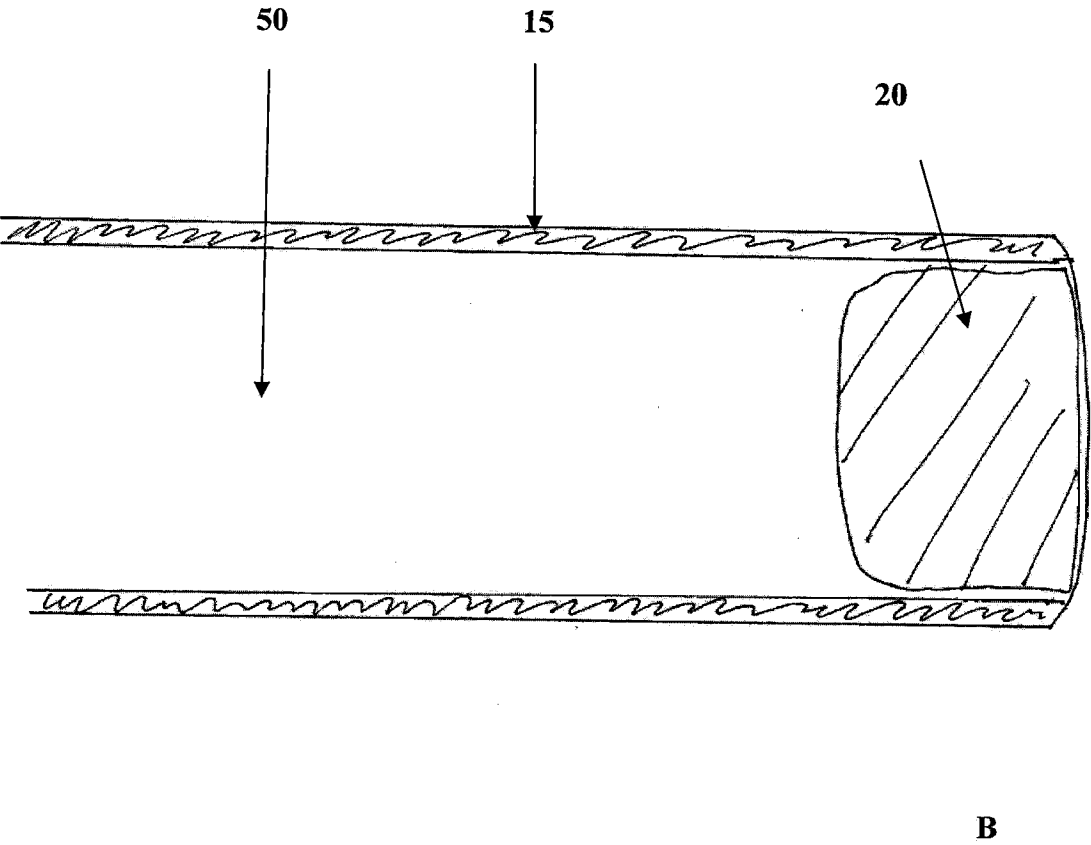


FIG. 2

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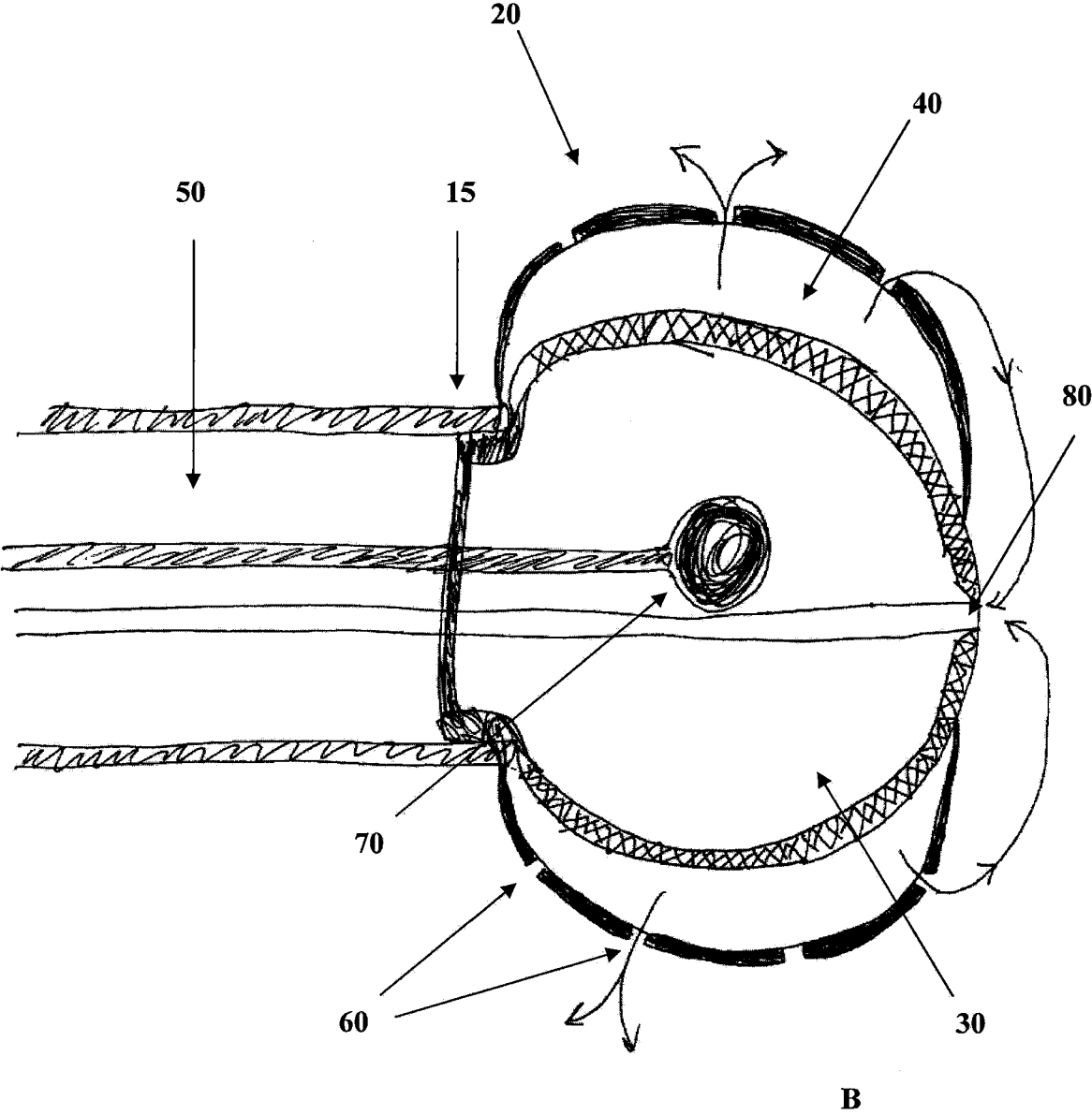


FIG. 3

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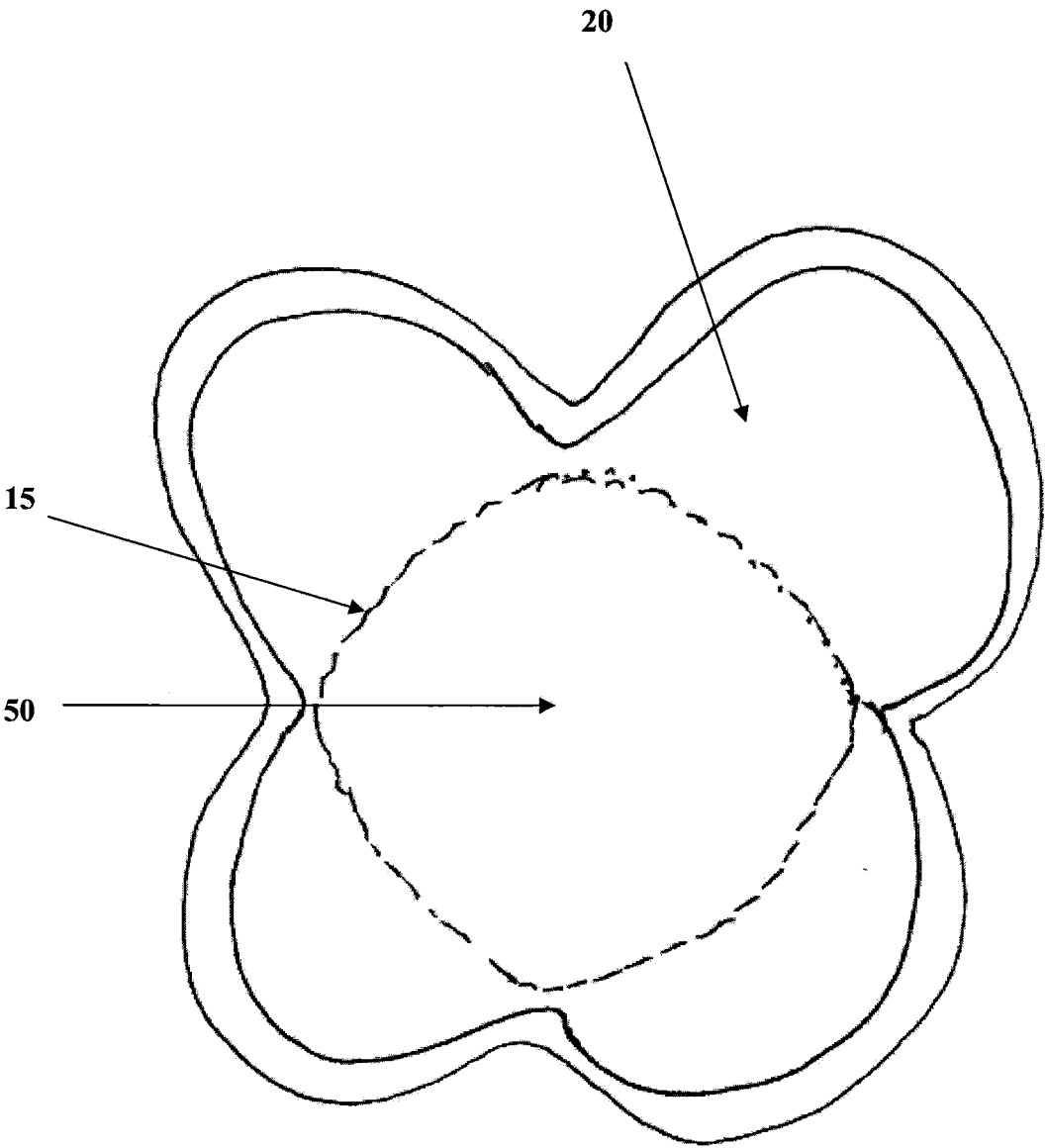


FIG. 4