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(54) Title: EXAMINATION DEVICE

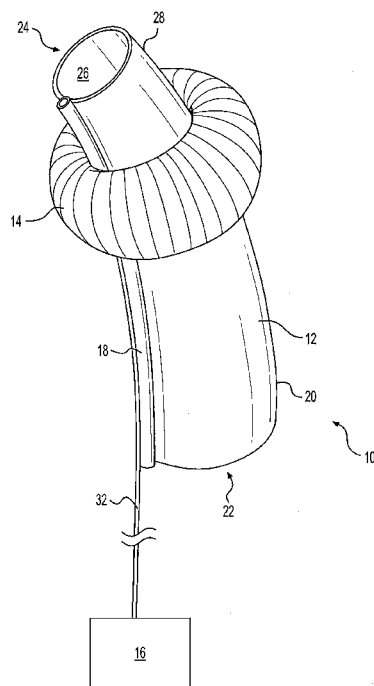


FIG. 1

(57) Abstract: Embodiments of the disclosure may include a natural body orifice examination device including a tubular member having an open proximal end, an open distal end, and a lumen connecting the proximal end and the distal end. An inflatable chamber may be included on an outer periphery of the tubular member. In addition, a pumping device may be located proximal to the tubular member and operationally coupled to the inflatable chamber. A method is also provided for using the examination device.

EXAMINATION DEVICE

DESCRIPTION

Field of the Disclosure

[001] Embodiments of the present disclosure include medical devices, and more particularly, devices for examination of and access to natural body orifices.

Background of the Disclosure

[002] A vaginal speculum is a medical device used for examination of the vagina and cervix. In order to gain access to the vaginal cavity, the speculum is inserted into the vagina to dilate it for examination. The speculum is inserted through the introitus with the hinged parts of the speculum folded together. Once in position, the hinged parts are opened by manipulation of an attached lever allowing visualization and access to the cervix and uterus.

[003] Problems exist, however, in the use of conventional speculums. For example, when opening the hinged parts of the speculum, it may unnecessarily distend the introitus causing pain and/or discomfort to the patient. Furthermore, finding the cervix can be difficult since the cervix can be positioned anteriorly, mid-position, or posteriorly in the vagina. Further, conventional speculums may provide limited vision within the vagina. The medical examination devices of the present disclosure are directed to improvements in the existing technology.

Summary of the Disclosure

[004] In accordance with this disclosure, a natural body orifice examination, diagnostic, or therapeutic device includes a tubular member having an open proximal end, an open distal end, and a lumen connecting the proximal end and the distal end. An inflatable chamber may be included on the tubular member. In addition, a

pumping device may be located proximal to the tubular member and operationally coupled to the inflatable chamber.

[005] Further in accordance with this disclosure, a natural body orifice examination, diagnostic, or therapeutic device includes a tubular member having an open proximal end, an open distal end, and a lumen connecting the proximal end and the distal end, an inflatable chamber on the tubular member, and a pumping device located proximal the tubular member and operationally coupled to the inflatable chamber. The tubular member includes a length between 50mm and 250mm, the open proximal end having a diameter between 25mm and 250mm, and the distal open end having a diameter of between 6mm and 150mm.

[006] Further in accordance with this disclosure, a method of examining a natural body orifice is provided. The method includes placing a tubular member on a finger, the tubular member having an open proximal end, an open distal end, and a lumen connecting the proximal end and the distal end, the placing including positioning the tubular member on the finger so that a tip of the finger extends distal to the distal open end. The method further includes locating a desired position within the natural body orifice with the tip of the finger extending distal the distal opening, inflating an inflatable chamber on the tubular member to secure the tubular member in position within the natural body orifice, and examining the natural body orifice through the lumen of the secured tubular member.

[007] The accompanying drawings illustrate certain exemplary embodiments of the present disclosure, and together with the description, serve to explain the principles of the present disclosure. As such, those skilled in the art will appreciate that the conception upon which this disclosure is based may readily be used as a basis for designing other structures, methods, and systems for carrying

out the several purposes of the present disclosure. It is important, therefore, to recognize that the claims should be regarded as including such equivalent constructions insofar as they do not depart from the spirit and scope of the present disclosure.

Brief Description of the Drawings

[008] Fig. 1 illustrates an exemplary natural body orifice examination device according to this disclosure.

[009] Fig. 2 illustrates a cross-section of the device of Fig. 1.

[010] Figs. 3A and 3B illustrate the device of Fig. 1 in an unexpanded and expanded configuration.

[011] Fig. 4 illustrates a natural body orifice examination device according to another embodiment of this disclosure.

[012] Fig. 5 is a flowchart of an exemplary method according to this disclosure.

Detailed Description

[013] Reference will now be made in detail to the exemplary embodiments of the present disclosure described above and illustrated in the accompanying drawings.

[014] The terms “proximal” and “distal” are used herein to refer to the relative positions of the components of an exemplary medical device. When used herein, “proximal” refers to a position relatively closer to the exterior of the body or closer to the physician, or other user, using the medical device. In contrast, “distal” refers to a position relatively further away from the physician, or other user, using the medical device or closer to the interior of the body.

[015] Fig. 1 illustrates an exemplary natural body orifice examination, diagnostic, or therapeutic device 10 according to this disclosure. Examination device 10 may include a tubular member 12, an inflatable chamber 14, and a pumping device 16. In addition, device 10 may include one or more longitudinal tubes 18 located on an outer or inner periphery 20, 36 of the tubular member 12.

[016] Tubular member 12 may include an open proximal end 22 and an open distal end 24 and a lumen 26 connecting the proximal end 22 and the distal end 24. The lumen 26 is sized to receive a finger therethrough so that a tip of the finger extends distally of the distal end 24. In particular, the tubular member 12 will be manufactured to ensue that the device is a comfortable fit in the appropriate natural body orifice. For example, the tubular member 12 may include a length between 50mm and 250mm, the open proximal end 22 may include a diameter between 25mm and 250mm, and the open distal end 24 may include a diameter between 6mm and 150mm. The tubular member may be formed of a material that provides sufficient stiffness to maintain its shape during use, while allowing for some flexing. Exemplary materials for the tubular member 12 include polymeric materials having a desired rigidity. The tubular member 12 may also be formed from a transparent or translucent material to assist in transmitting light to the surrounding structures. The tubular member 12 may be provided with one or more longitudinal or radial strips of supporting material to add stability and/or stiffness to the examination device 10.

[017] Tubular member 12 may be formed in a straight configuration or may include a longitudinal curvature similar to the curve of a finger and as shown in Figs. 1 and 2. Tubular member 12 may also include a tapering portion 28 extending at least from the inflatable chamber 14 to the open distal end 24. The tapering portion

28 allows a finger to fit snugly therein while allowing the finger to be withdrawn when the examination device 10 is ready to be secured in position. The tapering portion 28 provides for an area of the open proximal end 22 that is greater than the open distal end 24. Tubular member 12 may be provided with bellows (not shown) allowing the tubular member 12 to extend in length in order to accommodate longer fingers inserted through the lumen 26. The tubular member 12 may also include a mechanical structure within the tube material that will extend the diameter at the distal end of the tubular member 12. The mechanical structure open wider only the distal portion of the tubular member 12 allowing greater access for the surgeon.

[018] Referring to Figs. 1 and 2, inflatable chamber 14 may be located at a distal portion of the tubular member 12. For example, the inflatable chamber 14 may be located on a distal third of the tubular member 12. Figs. 1 and 2 illustrate the inflatable chamber 14 located on the outer periphery 20 of tubular member 12, but it is understood that the inflatable chamber 14 could alternatively be located on an inner periphery 36 of the tubular member 12. As best shown in Fig. 2, inflatable chamber 14 may be formed by fixing a portion of material 30 to the outer periphery 20 of tubular member 12. In such a configuration, a portion of the outer periphery 20 of the tubular member 12 forms an inner surface of the inflatable chamber 14. The fixing of the material 30 to the outer periphery 20 of the tubular member 12 can be achieved by any suitable attachment, such as adhesive or welding. Alternatively, inflatable chamber 14 may be a self contained element, separate from the tubular member 12, with a surface secured to the outer periphery 20 of the tubular member 12 by any suitable attachment, such as adhesive or welding. Even further, the inflatable chamber 14 and tubular member 12 may be a one-piece, molded structure.

[019] The portion of material 30 of the inflatable chamber 14 may be a different material from the material of tubular member 12. For example, the material of the tubular member 12 may have a greater stiffness than the material 30 of the inflatable chamber 14. Such a use of different materials may assist in maintaining lumen 26 fully open.

[020] Inflatable chamber 14 may include a rounded ring shape circumscribing the tubular member 12, or may take other shapes. In one example shown in Fig. 4, the inflatable chamber may be formed as a hollow cone 34 extending distally beyond the open distal end 24 of the tubular member 12. In another example (not shown), the inflatable chamber 14 may extend only partially around tubular member 12 and/or may be formed of more than one separate inflatable chamber. In addition, the inflatable chamber 14 may include ridges for structural support. Further, the tubular member 12 may include two or more circumferential inflatable chambers 14, for example two circumferential inflatable chambers 14 located on the distal half of the tubular member 12.

[021] As shown in Figs. 1 and 2, inflatable chamber 14 may be coupled to an inflation tube 32 that may be positioned inside or outside of the tubular member 12 and that extends proximally from the inflatable chamber 14 and proximal the open proximal end 22 of the tubular member 12. A proximal end of inflation tube 32 may be coupled to a pumping device 16, thus providing a fluid connection between the inflatable chamber 14 and the pumping device 16. The pumping device 16 may be any suitable pumping device, such as a pneumatic, hydraulic, or mechanical pumping component, e.g., a syringe, hand pump, or bulbous hand held device. The pumping device 16 may include a one-way valve, two-way valve, pressure limiting valve, and manual release valve, as is common in the art. For example, the

pumping device 16 may include a pressure limiting valve that ensures that the inflatable chamber does not extend to a diameter greater than is appropriate for the relevant body orifice. Further, it is understood that multiple pumping devices 16 may be used, for example, one pumping device 16 for each inflatable chamber 14.

[022] As noted above, natural body orifice examination device 10 may include one or more longitudinal tubes 18 extending the length of the tubular member 12. The one or more longitudinal tubes 18 may extend along the outer periphery 20 of the tubular member 12 as shown in Figs. 1 and 2, or alternatively could extend along an inner periphery 36 of the tubular member 12. The one or more longitudinal tubes 18 may be hollow for removably receiving one or more secondary devices. The secondary devices may include, for example, a tissue sampling device, an image capture device, an illumination fiber, or the one or more longitudinal tubes 18 could be coupled to an irrigation or suction supply. When the secondary device is an image capture device, the proximal end of the secondary device may be coupled to a computer, smartphone, or computer tablet for image processing and image displaying.

[023] As noted above, it is understood that more than one longitudinal tube 18 could be coupled to the outer or inner peripheries 20 and 36 of the tubular member 12, and the longitudinal tube 18 may extend less than the full length of the tubular member 12. Further, the longitudinal tube 18 could be replaced with the secondary device itself fixed to the length of the tubular member 12.

[024] Fig. 3A and 3B illustrates a schematic representation of the natural body orifice examination device 10 within a natural body orifice 38. In this case the natural body orifice 38 is a vaginal cavity. The natural body orifice 38 could be any other natural body orifice, such as the ear, nose, mouth, anus, etc. Fig. 3A illustrates

the examination device 10 during placement of the device with a finger extending through the lumen 26 of the tubular member 12, and the inflatable chamber 14 in an unexpanded configuration. Fig. 3B illustrates the examination device 10 after the device has been placed in the desired location and the inflatable chamber 14 has been inflated by the pumping device 16 to the expanded configuration. In the expanded configuration, the inflatable chamber 14 is secured in position by friction and pressure of the inflatable chamber 14 against the walls of the natural body orifice 38.

[025] Fig. 5 illustrates an exemplary method according to this disclosure. The method may include placing a tubular member 12 of the examination device 10 on a finger (step 50) and locating a desired position of the examination device within the natural body orifice 38 by feeling the location with the tip of the finger extending distal the distal opening 24 of the tubular member 12 (step 52). While the tubular member 12 may be delivered on a finger, it is understood that other support/delivery elements can be used to carry the tubular member 12 into a desired position, such as with an obturator (not shown). The examination device 10 is sized so that the open proximal end 22 of the tubular member 12 extends outside the natural body orifice 38. Once the examination device 10 has been placed in the desired position, the inflatable chamber 14 may be inflated with the inflation device 16 to secure and orient the tubular member 12 against the walls of the natural body orifice 38 (step 54). In particular, the expanded inflatable chamber 14 may serve to secure the examination device within the natural body cavity 38, expand the upper end of the natural body orifice 38, orient the tubular member 12 centrally within the natural body orifice 38, and even straighten the axis of the natural body orifice 38.

[026] Once secured, examination of the natural body orifice can take place through the lumen 26 of the tubular member 12 of the examination device 10 (step 56). Such examination can include placing one or more instruments through the lumen 26. Such instruments may include, for example, a tissue sampling device, an image capture device, an illumination fiber, a catheter, an endoscope (e.g., hysteroscope), and/or an irrigation or suction supply tube. In addition, or alternatively, one or more such instruments may be provided through one of the longitudinal tubes 18. Once the examination is complete, the inflatable chamber can be deflated and the examination device 10 removed from the natural body orifice (step 58).

[027] The examination device and method disclosed herein provide a comfortable yet practical access to a natural body orifice. Further, the device and method allow for the precise, comfortable, and proper placement of the device within the natural body orifice by the ease of feel by the operator (with the tip of a finger or other delivery element) without distending the natural body orifice. The device and method disclosed also provide visualization and access to a distal portion of the natural body orifice via the lumen 26 and/or longitudinal tube 18 of the examination device 10. Such access to the natural body orifice 38 will allow for, inter alia, illumination, irrigation, biopsy, insertion, and/or implantation. For example, the device may provide light illuminated naked eye or camera-based examination of the lower and upper genital tract. Finally, examination device 10 provides an inexpensive device for examining a natural body orifice, and thus can be disposable.

[028] Any aspect set forth in any embodiment may be used with any other embodiment set forth herein. Every device and apparatus set forth herein may be used in any suitable medical procedure, may be advanced through any suitable body

lumen and body cavity, and may be used for access to and diagnosis or treatment of any suitable body portion. The many features and advantages of the present disclosure are apparent from the detailed specification, and thus, it is intended by the appended claims to cover all such features and advantages of the present disclosure which fall within the true spirit and scope of the present disclosure. Further, since numerous modifications and variations will readily occur to those skilled in the art, it is not desired to limit the present disclosure to the exact construction and operation illustrated and described, and accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the present disclosure.

What is claimed is:

1. A natural body orifice examination, diagnostic, or therapeutic device, comprising:
 - a tubular member having an open proximal end, an open distal end, and a lumen connecting the proximal end and the distal end;
 - an inflatable chamber on the tubular member; and
 - a pumping device located proximal to the tubular member and operationally coupled to the inflatable chamber.
2. The natural body orifice device of claim 1, wherein the inflatable chamber is located on an outer periphery of the tubular member, and at a distal portion of the tubular member.
3. The natural body orifice device of claim 2, wherein the inflatable chamber circumscribes the tubular member.
4. The natural body orifice device of claim 3, wherein the tubular member is formed of a first material, and at least a portion of the inflatable chamber is formed of a second material.
5. The natural body orifice device of claim 4, wherein the first material has a greater stiffness than the second material.
6. The natural body orifice device of claim 3, wherein the inflatable chamber is located on a distal third of the tubular member.

7. The natural body orifice device of claim 3, wherein the inflatable chamber has a rounded ring shape.
8. The natural body orifice device of claim 3, wherein the inflatable chamber has a hollow cone shape extending distally beyond the open distal end of the tubular member.
9. The natural body orifice device of claim 3, wherein the tubular member includes a tapering end from the inflatable chamber to the open distal end.
10. The natural body orifice device of claim 3, wherein the tubular member includes a longitudinal curvature.
11. The natural body orifice device of claim 1, wherein the tubular member is one of transparent or translucent.
12. The natural body orifice device of claim 1, further including at least one longitudinal tube located on the tubular member and extending adjacent to the open distal end of the tubular member.
13. The natural body orifice device of claim 1, further including an image capture device coupled to the tubular member.

14. A natural body orifice examination, diagnostic, or therapeutic device, comprising:

a tubular member having an open proximal end, an open distal end, and a lumen connecting the proximal end and the distal end;

an inflatable chamber on the tubular member; and

a pumping device located proximal the tubular member and operationally coupled to the inflatable chamber;

the tubular member having a length between 50mm and 250mm, the open proximal end having a diameter of between 25mm and 50mm, and the distal open end having a diameter of between 6mm and 150mm.

15. The natural body orifice device of claim 14, wherein the inflatable chamber is located on an outer periphery of the tubular member and circumscribes the tubular member.

16. The natural body orifice device of claim 15, further including at least one longitudinal tube located on the tubular member and extending adjacent the open distal end of the tubular member.

17. The natural body orifice device of claim 16, wherein the tubular member includes a tapering end from the inflatable chamber to the open distal end.

18. A method of examining a natural body orifice, comprising:

placing a tubular member on a finger, the tubular member having an open proximal end, an open distal end, and a lumen connecting the proximal end and the distal end, the placing including positioning the tubular member on the finger so that a tip of the finger extends distal the distal open end;

locating a desired position within the natural body orifice with the tip of the finger extending distal the distal opening;

inflating an inflatable chamber on the tubular member to secure the tubular member in position within the natural body orifice; and

examining the natural body orifice through the lumen of the secured tubular member.

19. The method of examining a natural body orifice of claim 18, further including removing the finger from the tubular body after the tubular body is secured in position.

20. The method of examining a natural body orifice of claim 19, wherein the locating a desired position within the natural body orifice includes locating a cervix of a vaginal cavity.

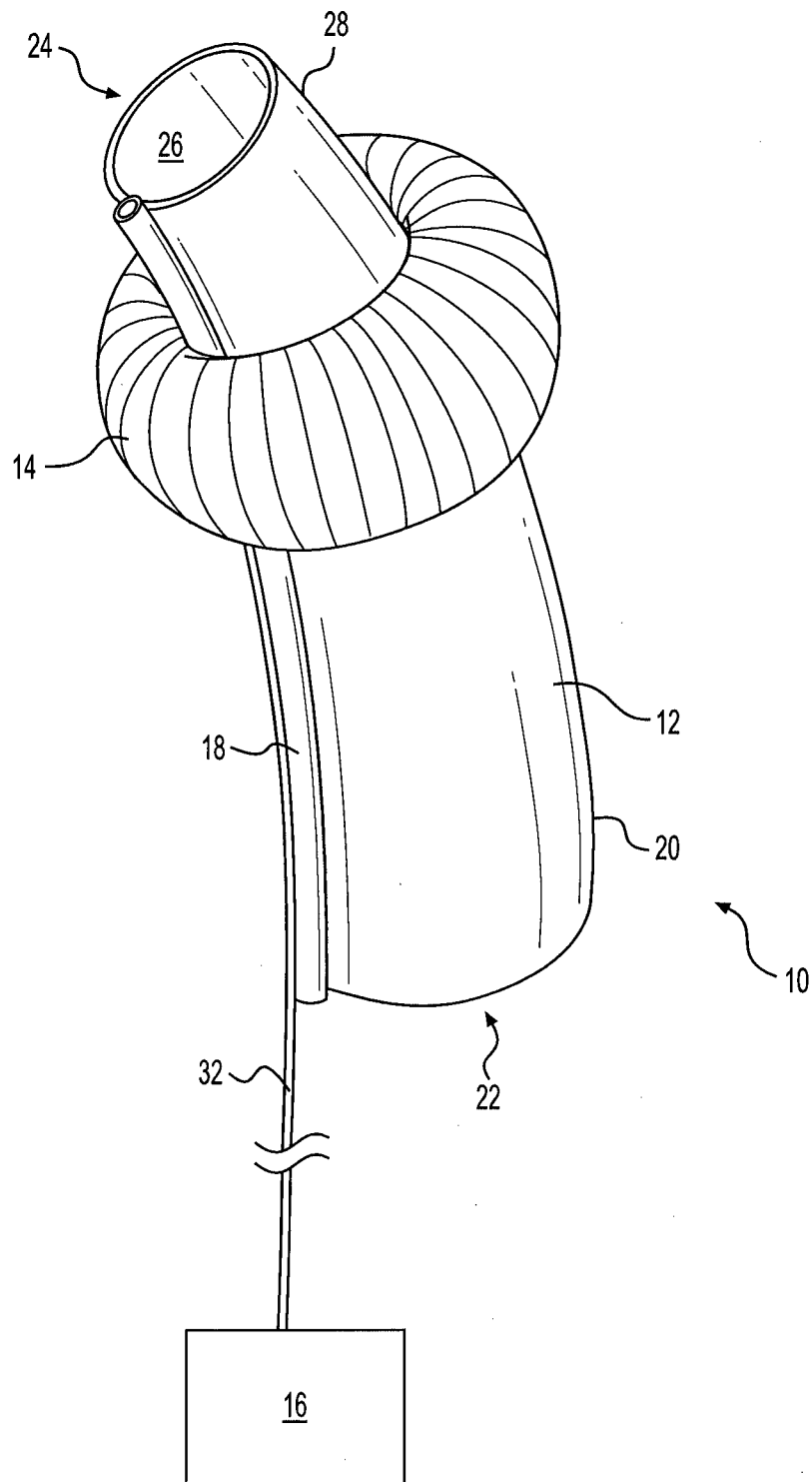


FIG. 1

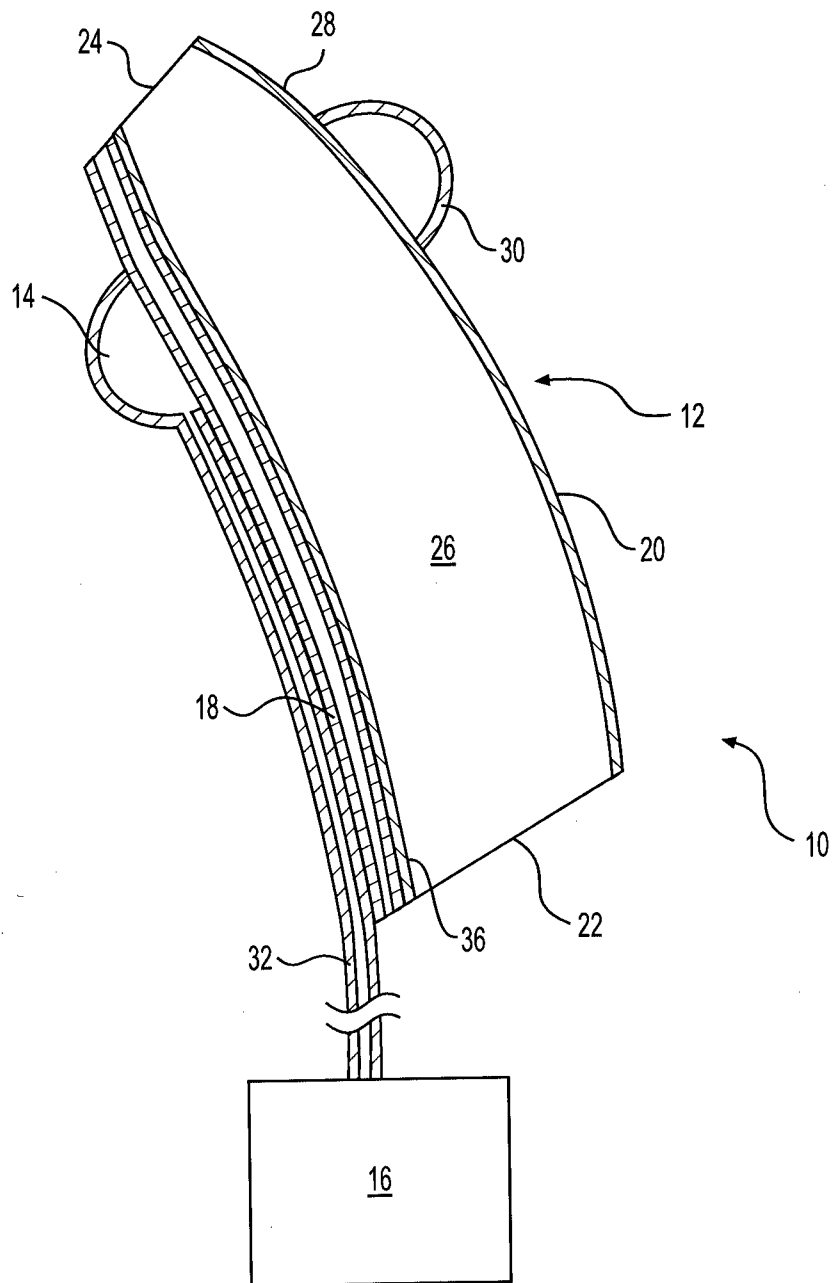


FIG. 2



FIG. 3A

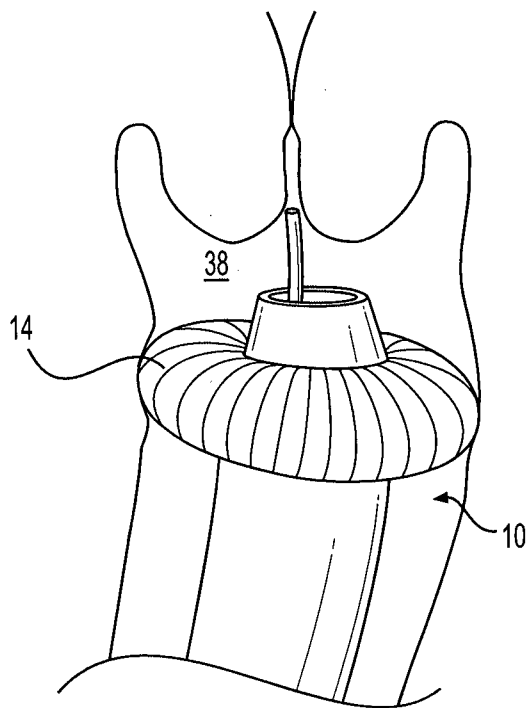


FIG. 3B

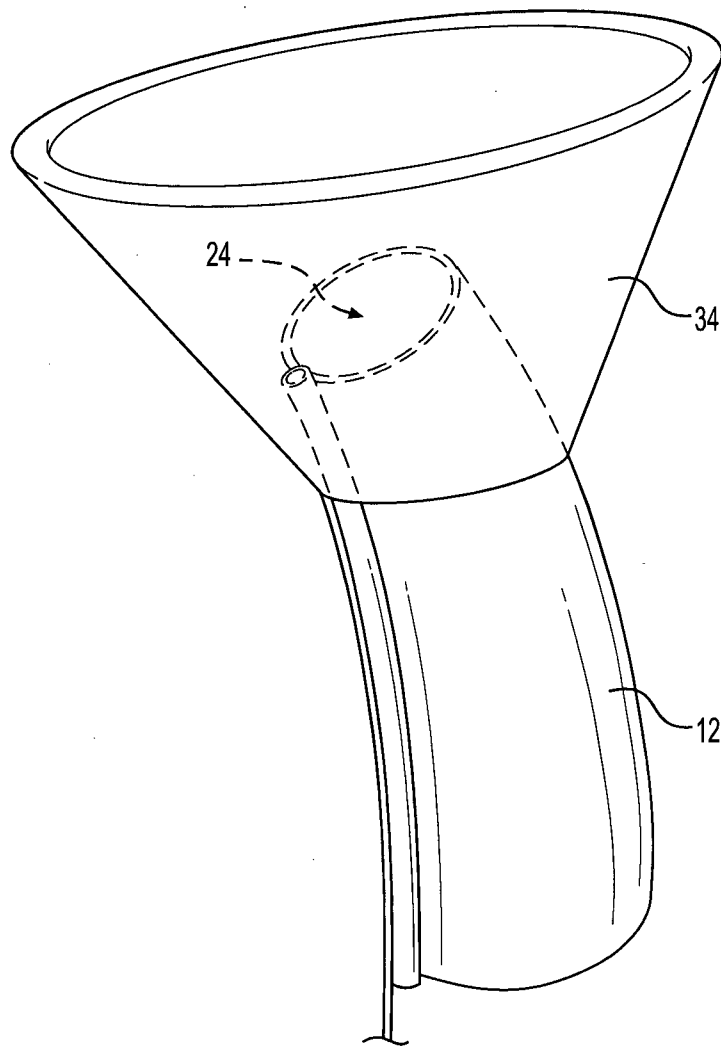
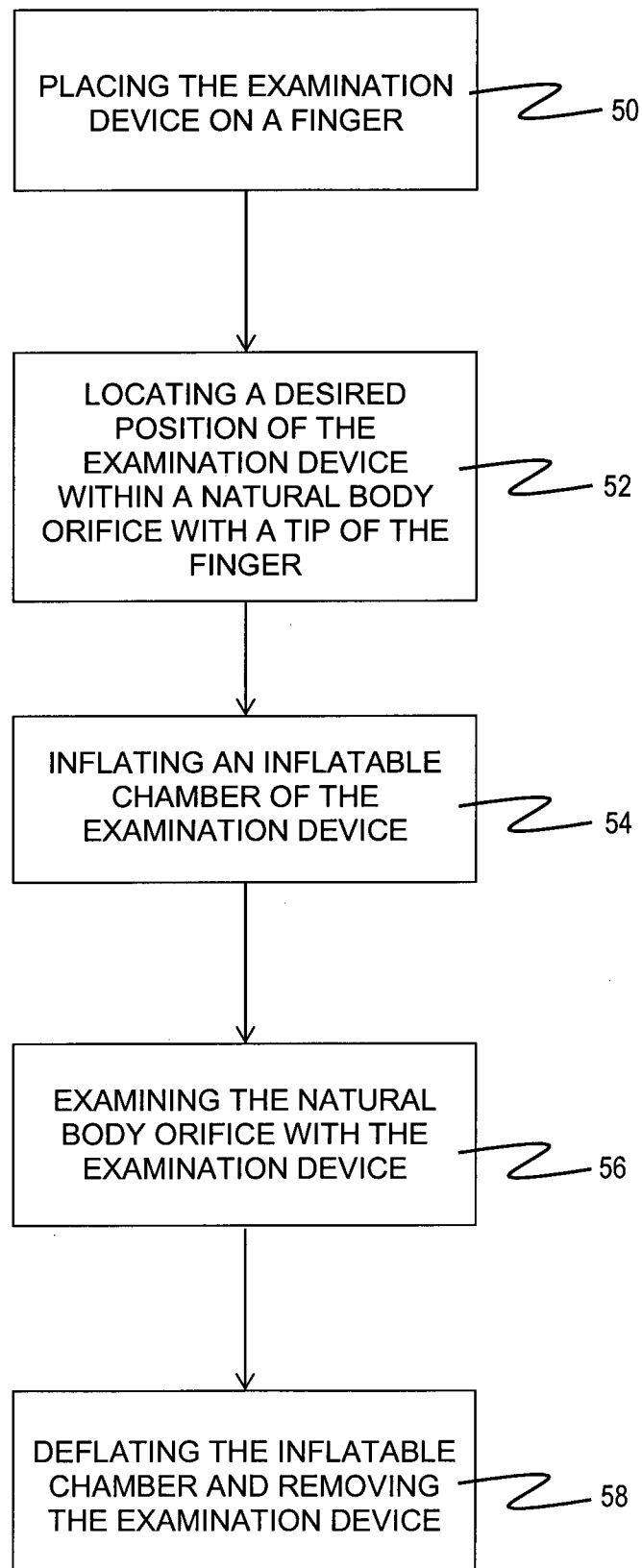


FIG. 4

**FIG. 5**

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2015/000942

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B1/00 A61B1/303 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)

EP0-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	WO 2009/029639 A1 (SPINE VIEW INC [US]; JANSEN LEX P [US]; TO JOHN T [US]; CHIN SINGFATT) 5 March 2009 (2009-03-05) the whole document -----	1-7, 10-13
X	US 2006/063973 A1 (MAKOWER JOSHUA [US] ET AL) 23 March 2006 (2006-03-23) paragraph [0190] -----	1-7
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

3 February 2016

Date of mailing of the international search report

12/02/2016

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2015/000942

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2014/105439 A1 (SANOVAS INC [US]) 3 July 2014 (2014-07-03) paragraph [0059] - paragraph [0080] -----	1-9, 13-17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2015/000942

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.: 18-20
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.: 18-20

Claims 18-20 relate to subject-matter mentioned in Rule 39.1(iv) PCT, in particular to a method of surgical treatment of the human body (the "method of examining a natural body orifice..." comprises the step locating the device at a desired position within the natural body orifice and therefore it is clearly an invasive method). Under terms of Art.17(2)(a)(i) an International Searching Authority is not required to carry out a search of such claims.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2015/000942

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