

(21) Application No: 0900788.1

(22) Date of Filing: 19.01.2009

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(51) INT CL:
A61B 1/32 (2006.01) **A61B 1/31** (2006.01)
A61B 1/303 (2006.01) **A61B 17/02** (2006.01)

(56) Documents Cited:
EP 1929959 A1 **WO 2006/127085 A1**
WO 2004/010858 A2 **US 6083241 A**
US 20020045906 A1

(58) Field of Search:
INT CL **A61B**
Other: **Online: WPI, EPODOC**

(54) Title of the Invention: **A speculum**
Abstract Title: **A self-retaining speculum**

(57) A speculum (100) having an elongate retractor (101), an annular retaining collar (103), a skirt (102) and an actuator (105) configured to operate the retaining collar (103) between an engaged and disengaged position. The speculum (100) is designed to be self retaining once inserted within an animal or human body cavity involving the radial extension of the retaining collar (103) and abutment with the internal walls of the body cavity. Examination of the internal cavity walls is possible via exposure through an elongate window (115) formed in the retractor side walls (118).

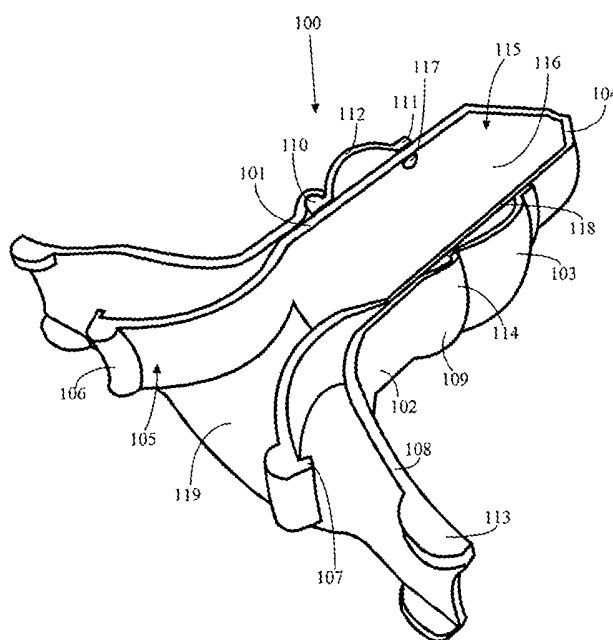


Fig. 1

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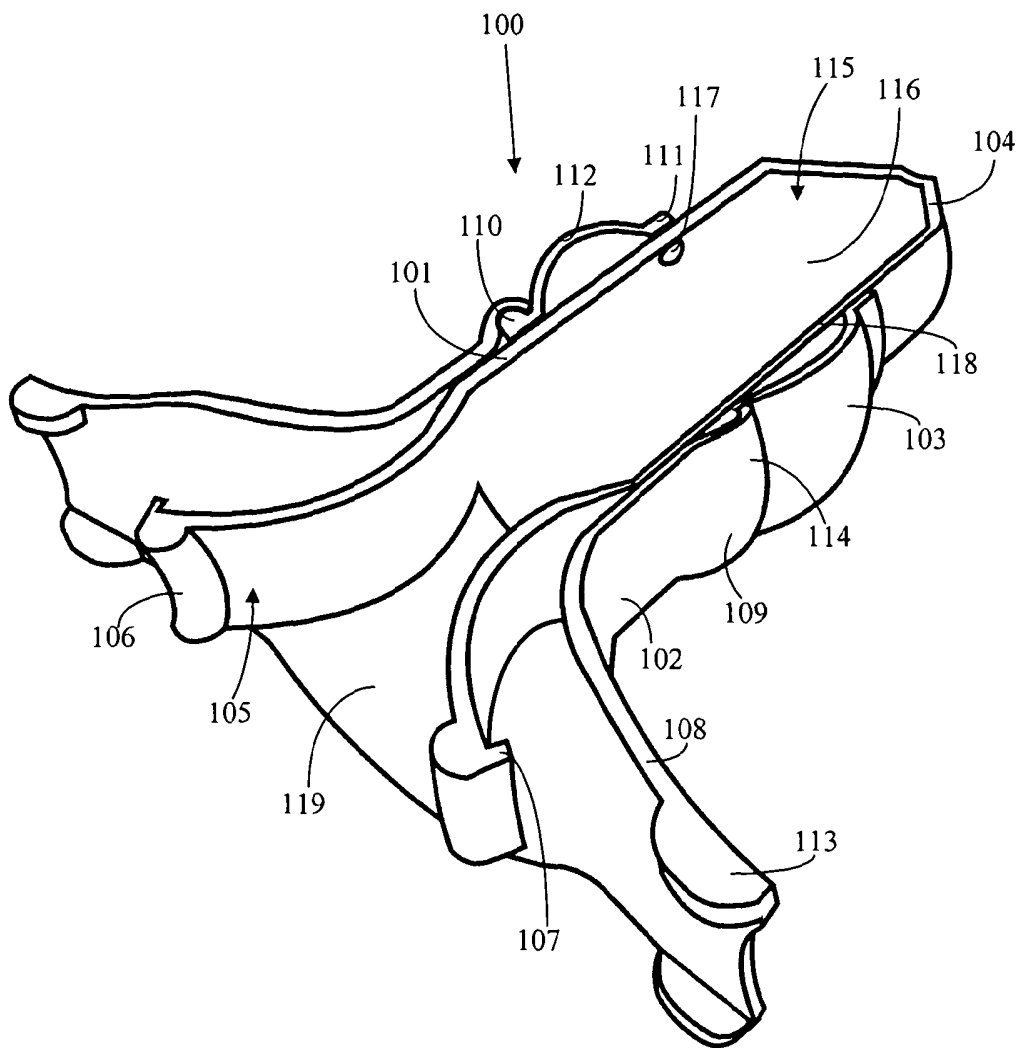


Fig. 1

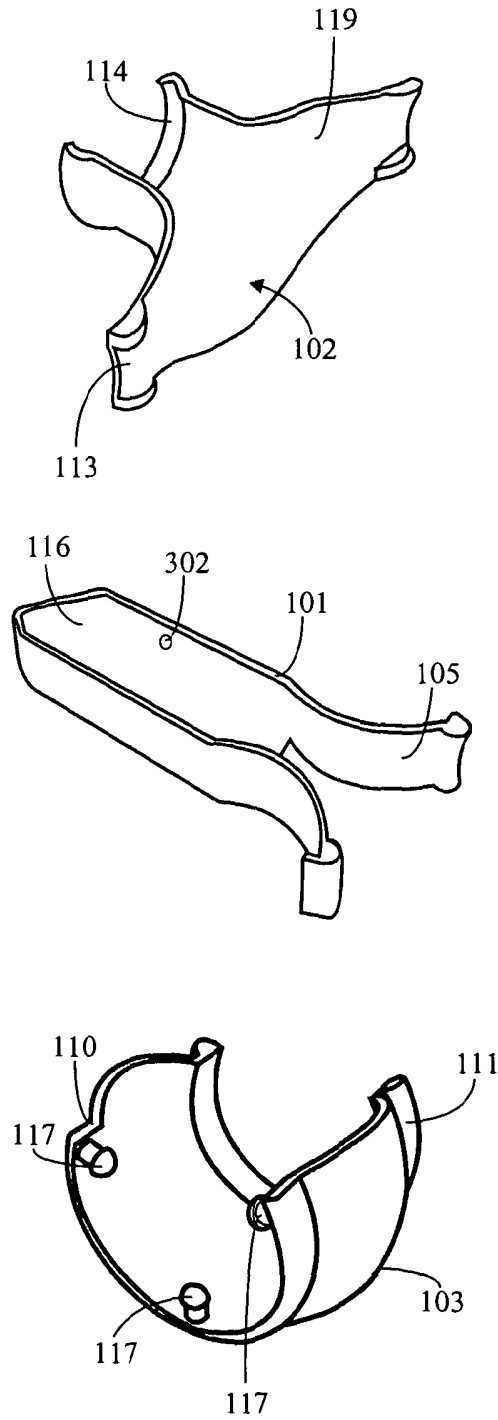


Fig. 2

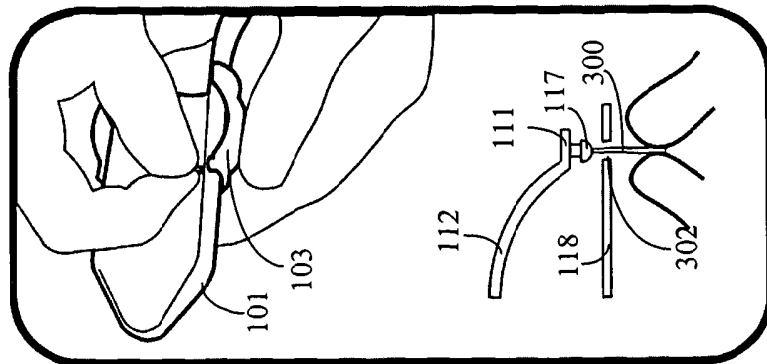


Fig. 3A

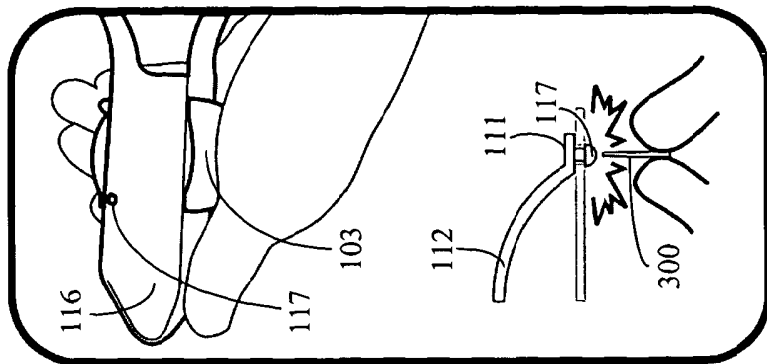


Fig. 3B

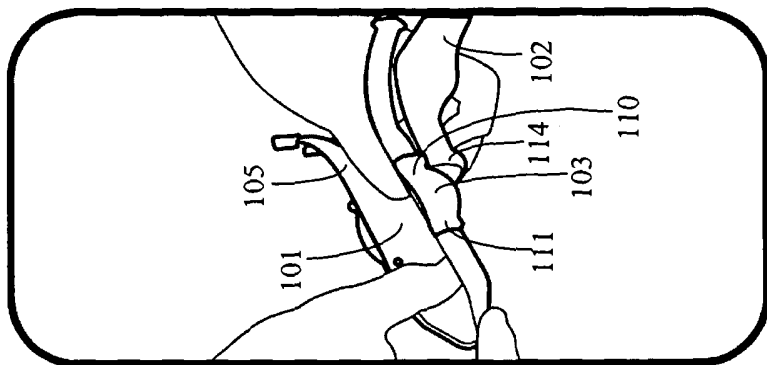


Fig. 3C

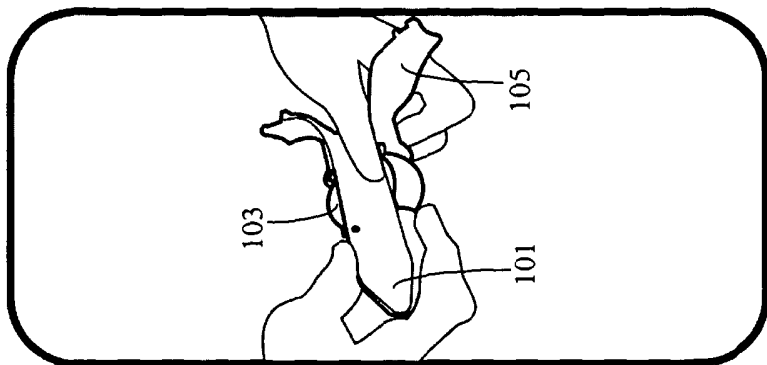


Fig. 3D

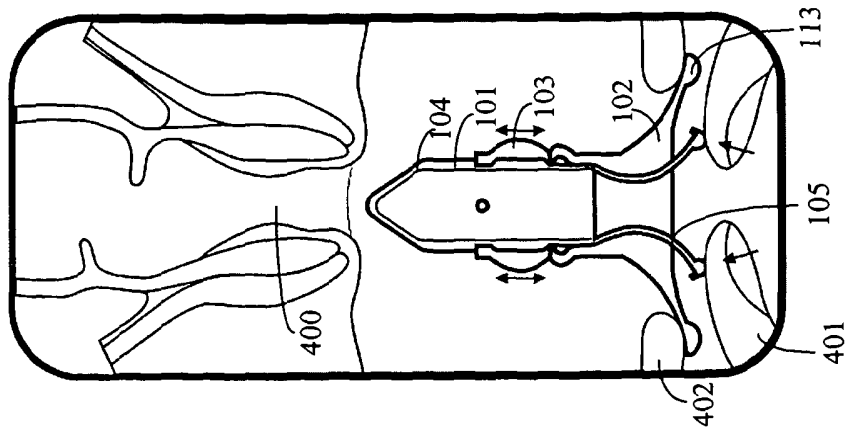


Fig. 4A

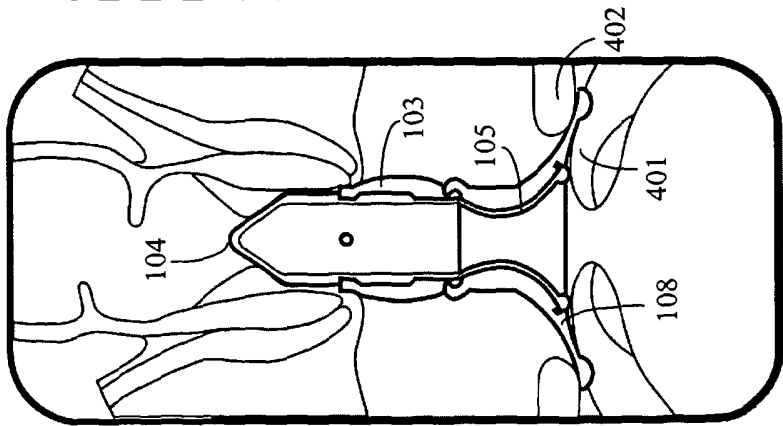


Fig. 4B

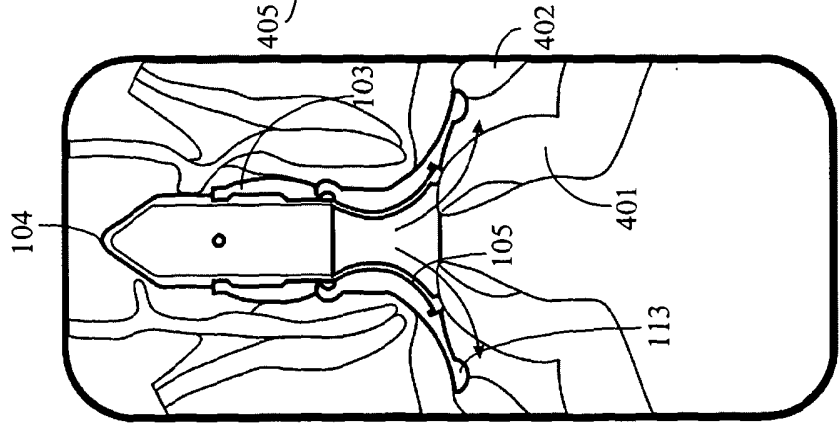


Fig. 4C

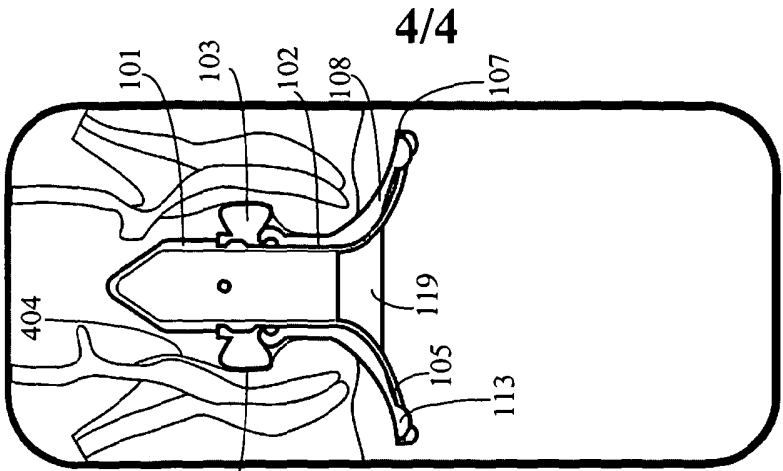


Fig. 4D

A Speculum

The present invention relates to a speculum, and in particular although not exclusively, to an anal speculum comprising means to inhibit undesired withdrawal of the speculum once
5 inserted.

Speculums, in particular anal speculums or retractors are used to dilate the anal canal for medical examination and to enable surgical procedures.

10 Over the years, a variety of different retractors have been proposed including for example the Barr, Sim's, Bodenheimer, Pratt, Cook's and Park's retractors. Most of these devices are scissor-like implements in which separating plates extend from one end of the scissor and are separated by opening the scissor arms to retract and open the anal canal.

15 More recently, US 6,083,241 discloses apparatus and method to capture and draw a haemorrhoid at the anal canal into an inner chamber of a stapling head assembly of a speculum for treatment of the haemorrhoidal tissue.

WO 01/43626 discloses an anal speculum for the surgical treatment of haemorrhoids in
20 which a hollow sleeve-like anal retractor is introduced into the anal canal using a bullet-shaped elongate member is temporarily inserted into a retractor sheath to facilitate insertion into the anus.

WO 2007/016946 discloses an insertable rectal sleeve with a window formed in the sleeve
25 to allow a surgeon to access the internal wall of the anal canal for examination and to perform surgical procedures.

WO 2007/116327 discloses an endoscope formed as a two piece system in which an elongate bullet-shaped front piece is inserted through a cylindrical sheath during insertion
30 into the anal canal. The endoscope is configured to be transparent and has a window to facilitate inspection and treatment of haemorrhoids. The endoscope may be rotated to access all quadrants of the rectum once inserted.

WO 2008/035384 discloses a device for examining and allowing surgery on human or animal body cavities. The device comprises or torpedo-shaped hollow body having a window through which the internal wall of the anus is exposed once the device is inserted and a channel extending over a region of the device to facilitate manoeuvring of diagnostic and surgical instruments within the device.

WO 2008/068106 discloses a three-piece speculum. An anal dilator, formed as an outer collar is positioned over and about an elongate hollow sleeve having an open end and a side wall window to allow examination and access to the anal walls. The device is inserted via use of an obturator temporarily inserted within the sleeve and surrounding collar-like anal dilator.

Common to all speculums is the requirement to maintain the retractor in position within the body cavity when inserted during use. To achieve this, some speculum devices necessitate a surgeon's assistant applying a constant force to the exposed end of speculum to avoid it withdrawing from the anal canal during surgical procedures. A lesser number of speculums, such as the Park's retractor are configured to be self retaining. However, due to the mechanisms by which these devices are held in the retracted positions, studies have shown that in a large number of cases, sphincter function is damaged in turn causing very undesirable complications such as faecal incontinence following anorectal surgery.

There is therefore a need for a speculum configured to be self retaining whilst not damaging the tissue in and around the body cavity.

Accordingly, the inventors provide a self retaining speculum suitable for use on a human or animal body cavity such as the anus and vagina which obviates the need for a surgeon or assistant to hold the device in place during use and is non-damaging to the body cavity.

According to a first aspect of the present invention there is provided a speculum comprising; an elongate retractor for at least partial insertion into the cavity of a human or animal body and configured to maintain the cavity in an open retracted position whilst inserted; a retainer positioned at a region along the length of the retractor and configured to

extend and contract radially relative to a longitudinal axis of the retractor; and an actuator operative to cause the retainer to extend and contract radially; wherein the retainer, in a radially extended position, is configured to inhibit the speculum from withdrawing out of the cavity.

5

Preferably, the speculum further comprises a skirt positioned about said retractor, the skirt being flared along its length, the retractor configured to move axially relative to the skirt. The skirt is flared so as to be easily grasped by a user and to provide a limiting means by which the speculum may be inserted axially into the cavity.

10

Preferably, the retainer is deformable and connected to the retractor and the skirt.

Preferably, the retainer is anchored to the retractor and is configured to abut against the skirt so as to be sandwiched between the retractor and skirt. Preferably, the retainer is releasably anchored at the retractor by way of, for example, a lug and hole type

15 arrangement or the like. The retainer is positioned between the retractor and skirt such that movement of the retractor in a longitudinal direction along its axis relative to the skirt causes the retainer to deform so as to bend outwardly from the longitudinal axis of the retractor.

20 Preferably, the speculum further comprises lock means to releasably lock the actuator and retainer in a fixed position when the retainer is radially extended relative to the retractor. Preferably, the lock means is provided between the actuator or retractor and the skirt so as to maintain the retainer in the radial extended position relative to the retractor.

25 Preferably, the retractor comprises a hollow elongate body having an elongate window formed in its side wall. In particular, the window may extend substantially the full length of the hollow elongate body to increase the area of exposure of the internal cavity wall to the interior of the hollow elongate retractor body. Optionally, at a cross section of the speculum, the hollow elongate body is substantially circular and the window extends over
30 an arc in the range 100° to 140° of the circumference of the retractor. Preferably, the window extends over an arc at an angle of substantially 120°.

Optionally, the actuator may be formed integrally with the retractor and comprises flexible arm extensions that may be manipulated by the fingers and thumb of a user. Alternatively, the actuator may be formed non-integrally with the retractor and may comprise any means configured to provide a mechanical actuating force to the retainer causing it to extend

5 outwardly from the retractor body to increase the cross sectional area of the speculum so as to inhibit the speculum from withdrawing from the cavity. According to further optional embodiments, the actuator may be a remote device and may comprise any mechanical, pneumatic, hydraulic or electrical device configured to provide the necessary mechanical actuation.

10

According to one embodiment, the actuator comprises barbs positioned at the arm extensions to realisably lock against the skirt. Optionally, the skirt comprises fins and the barbs are configured to realisably engage the fins to maintain the actuator and retainer in locked position.

15

According to specific implementations, the retainer may be configured to be disposable or suitable for reuse. According to one implementation, the retainer comprises silicone rubber or according to further implementations may comprise any resiliently deformable material, in particular any rubber based material. Preferably, the retractor and skirt are reusable and
20 comprise stainless steel. Alternatively, the retractor and skirt may be disposable and may comprise polyetheretherketone (PEEK) or polypropylene

According to a second aspect of the present invention there is provided a method of surgically retracting a human or animal body cavity using a speculum, the method
25 comprising: introducing an elongate retractor at least partially into the body cavity; maintaining a retainer, positioned at a region along the length of the retractor, in a radially contracted orientation relative to a longitudinal axis of the retractor as the retractor is inserted into the body cavity; introducing the retractor into the body cavity such that the retainer is fully inserted within the body cavity; causing the retainer to extend radially
30 relative to the longitudinal axis of the retractor and to abut against the internal walls of the body cavity using an actuator; and inhibiting withdrawal of the speculum from the cavity by maintaining the retainer in the radially extended position.

Preferably the method comprises maintaining the retainer in the radially extended position by realisably locking the actuator in a fixed position. Preferably, the actuator is locked in position so as to not obscure an internal hollow region of the retractor.

5

Once the examination or surgical procedure has been undertaken the speculum is then capable of being withdrawn from the body cavity by the method further comprising: causing the retainer to contract radially relative to the longitudinal axis using the actuator; and withdrawing the speculum from the body cavity.

10

Optionally, and according to a specific implementation, the method further comprises axially moving the retractor relative to the skirt positioned over at least part of the retractor to cause the retainer to extend radially relative to the longitudinal axis of the retractor by compressing the retainer between the retractor and the skirt.

15

Optionally, the retainer is anchored to the retractor and the retractor is moveable relative to the skirt positioned over at least a portion of the retractor, the method further comprising: moving the retractor relative to the skirt to cause the retainer to deform radially outward relative to the longitudinal axis of the retainer.

20

A specific implementation of the invention will now be described, by way of example only and with reference to the accompanying drawings, in which:

figure 1 is a perspective view of a speculum according to a specific implementation of the present invention;

25

figure 2 illustrates the three component parts of the speculum of figure 1 in a disassembled state;

figure 3A illustrates a first step of the assembly process of the three component parts of the speculum illustrated in figure 2;

figure 3B illustrates a second step of the assembly procedure of figure 3A;

30

figure 3C illustrates a third step of the assembly procedure of figure 3B;

figure 3D illustrates a fourth step of the assembly procedure of figure 3C;

figure 4A illustrates a first step of an operational procedure for insertion of the speculum of figures 1 to 3D according to a specific implementation;

figure 4B illustrates a second step of an operational procedure for insertion of the speculum of figure 4A;

5 figure 4C illustrates a third step of an operational procedure for insertion of the speculum of figure 4B; and

figure 4D illustrates a fourth step of an operational procedure for insertion of the speculum of figure 4C.

10 Referring to figures 1 and 2, the speculum 100 comprises an elongate retractor 101 comprising a main length having an elongate bullet-like configuration with substantially cylindrical side walls 118 terminating towards one end as a pointed dome 104. Two arm extensions 105 extend from a second end of the elongate retractor 101 opposed to domed end 104.

15 A deformable, part annular collar 103 is positioned over and about retractor 101 approximately mid-way between arm extensions 105 and domed end 104. Deformable collar 103 is held in place, in part, by a skirt 102 that is also positioned over and about retractor 101 towards the arm extension end of its main length opposed to domed end 104.

20 The substantially cylindrical section of retractor 101 comprises an elongate window 115 formed in side walls 118 of the retractor 101, window 115 extending from domed end 104 to the second end positioned at skirt 102. At a cross section aligned perpendicular to the longitudinal axis of the elongate retractor 101, window 115 extends over an arc of
25 approximately 120° of the circumference of the cylindrical retractor body 101. Accordingly, the internal walls 116 of retractor 101 are exposed via window 115 along the length of retractor 101.

Deformable collar 103 comprises a curved portion 112 extending between a first shoulder
30 110 and a second shoulder 111. Part annular shoulder 111 is positioned in contact with the outer surface of retractor 101. Two lugs 117 extend from opposed ends of annular shoulder 111 and are configured to be received and engaged in respective apertures (302 illustrated

in figure 3A) formed in side walls 118 of retractor 101. The first part-annular shoulder 110 of collar 103 is also positioned in contact with the outer surface of retractor 101 and is held in place by a part-annular flange 114 provided at one end 109 of skirt 101. Shoulder 110 is held in position at retractor 101 but is capable of sliding movement over the exterior
5 surface of retractor 101. In contrast, part annular shoulder 111 is anchored in fixed position at retractor 101 via lugs 117.

Arm extensions 105 are formed integrally with retractor body 101 and are curved along their length and comprise a thickness suitable to allow each arm 105 to flex in response to
10 a force applied to each end 106 of the arms 105. Each end 106 of arm 105 comprises a barb 107 configured to realisably engage a respective fin 113 provided at a second end of skirt 102 opposed to end 109.

The three piece speculum 100 comprising retractor 101, skirt 102 and flexible collar 103
15 are assembled to form modular speculum 100 according to the assembly procedure illustrated in figures 3A to 3D. Collar 103 is anchored in position at retractor 101 by inserting lugs 117 through apertures 302 formed in retractor walls 118. Lugs 117 are pulled through apertures 302 by respective tabs 300 attached to each lug 117. Accordingly shoulder 111 is brought into contact with the outer surface of retractor 101 as each tab 300
20 is pulled by the fingers and thumb 301 of a user. Referring to figure 3B, once collar 103 is anchored in position via lugs 117, each tab 300 breaks away from lug 117 by continued application of the pulling force applied by the fingers and thumb 301.

Referring to figures 3C and 3D, skirt 102 is housed in position over and about retractor 101
25 and annular shoulder 110 of collar 103. In particular, flange 114 is configured to engage over and about should 110 such that at least a portion (110) of collar 103 is sandwiched between skirt 102 and retractor 101.

In use, speculum 100 is grasped by the fingers and thumb 401, 402 ready for insertion into
30 an anal canal 400 illustrated in figure 4A. Speculum 101 is aligned such that domed end 104 is inserted first into anal canal 400 followed by collar 103 and ultimately skirt 102. Referring to figure 4B, during insertion a force is applied to arm extensions 105 via thumbs

104 pressing against arm extensions 105 via end portions 106. Pressing against arm extensions 105 actuates and displaces retractor 101, in an axial direction aligned with the longitudinal axis of the retractor 101, away from skirt 102 as the skirt 102 is held by fingers 402. Accordingly, as retractor 101 is pushed away from skirt 102, deformable
5 collar 103 elongates such that curved portion 112 becomes flattened against the outer surface of retractor 101 to effectively decrease the cross sectional area of the speculum 100 along its main length. This more streamlined configuration facilitates insertion into anal canal 400 as illustrated in figures 4B and 4C. Speculum 100 is fully inserted in position when skirt 102 is brought into contact with anal canal opening 403. At this stage, flexible
10 arm extensions 105 are bent outwardly against the inner surface 119 of skirt 102. A sliding pulling force is then applied to arm extensions 105 via thumbs 401 until end portions 106 are aligned substantially with fins 113 of skirt 102 as illustrated in figure 4D. The arm extensions 105 are then locked in position against skirt 102 as each barb 107 is clipped into locking engagement against each respective fin 113.

15
The action of withdrawing each arm extension 105 towards fins 113 causes retractor 101 to move in the axial direction aligned with the longitudinal axis of the speculum 100 but in the opposite direction to that referring to figure 4B. This axial movement of retractor 101 relative to skirt 102 causes collar 103 to deform radially outward from retractor 101 as the
20 two shoulders 110, 111 are brought together and collar 103 compressed between retractor 101 and skirt 102. An outer surface 405 of deformable collar 103 is then forced against the internal walls 404 of anal canal 400. In this configuration, with collar 103 radially extended, speculum 100 is held in position within cavity 400 by abutment with the soft tissue of the internal cavity walls 404.

25
Surgical examination or procedure is then undertaken at the cavity wall 404 exposed to the internal walls 116 of retractor 101 via window 115. Access to window 115 is not inhibited by arm extensions 115 as these are locked in position against internal walls 119 of skirt 102. The speculum 100, once inserted, as illustrated in figure 4D, may be rotated by
30 grasping fins 113 between fingers and thumb 401, 402 so as to access desired quadrants of anal cavity 400, 403.

To release speculum 100 from the inserted position of figure 4D, barbs 107 of arm extensions 105 are unlocked from the respective fins 113 and the retractor 101 moved axially away from skirt 102 so as to elongate collar 103 from the position illustrated in figure 4D to that of figure 4C. The insertion steps of figures 4A to 4C are then reversed.

5

Speculum 100 may then be disassembled by a reverse of the steps illustrated in figures 3A to 3D in order to clean the component parts and/or discard disposable components such as, for example, the deformable collar 103.

Claims:

1. A speculum comprising;
an elongate retractor for at least partial insertion into the cavity of a human or
5 animal body and configured to maintain the cavity in an open retracted position whilst
inserted;
a retainer positioned at a region along the length of the retractor and configured to
extend and contract radially relative to a longitudinal axis of the retractor; and
an actuator operative to cause the retainer to extend and contract radially;
10 wherein the retainer, in a radially extended position, is configured to inhibit the
speculum from withdrawing out of the cavity.
2. The speculum as claimed in claim 1 further comprising a skirt positioned about
said retractor, the skirt being flared along its length, the retractor configured to move
15 axially relative to the skirt.
3. The speculum as claimed in claim 2 wherein the retainer is deformable and
connected to the retractor and the skirt.
- 20 4. The speculum as claimed in claim 3 wherein the retainer is configured to deform
by axial movement of the retractor relative to the skirt.
5. The speculum as claimed in any one of claims 2 to 4 further comprising lock
means to releasibly lock the actuator and retainer in a fixed position when the retainer is
25 radially extended relative to the retractor.
6. The speculum as claimed in claim 4 comprising lock means to lock the actuator in
a fixed position at the skirt to maintain the retainer in the radially extended position
relative to the retractor.

7. The speculum as claimed in any one of claims 2 to 6 wherein the retractor comprises a hollow elongate body having an elongate window formed in a side wall of the elongate body.
- 5 8. The speculum as claimed in claim 7 wherein the window extends substantially the full length of the hollow elongate body.
9. The speculum as claimed in claim 7 or 8 wherein at a cross section of the speculum, the hollow elongate body is substantially circular and the window extends over
10 an arc in the range 100° to 140° of the circumference of the retractor.
10. The speculum as claimed in claim 9 wherein the window extends over an arc at an angle of substantially 120° .
- 15 11. The speculum as claimed in one of claims 2 to 10 wherein the actuator is formed integrally with the retractor and comprises flexible arm extensions that may be manipulated by the fingers and thumb of a user.
12. The speculum as claimed in any one of claims 2 to 11 wherein the actuator
20 comprises barbs positioned at the arm extensions to realisably lock against the skirt.
13. The speculum as claimed in claim 12 wherein the skirt comprises fins and the barbs are configured to realisably engage the fins to maintain the actuator and retainer in locked position.
25
14. The speculum as claimed in any preceding claim wherein the retainer comprises a rubber based material.
15. The speculum as claimed in claim 14 wherein the retainer comprises silicone
30 rubber.

16. The speculum as claimed in claims 1 or 2 wherein the retractor and skirt comprise polyetheretherketone (PEEK).
17. The speculum as claimed in claims 1 or 2 wherein the retractor and skirt comprise
5 stainless steel.
18. The speculum as claimed in claim 1 or 2 wherein the retractor and the skirt comprise polypropylene.
- 10 19. A method of surgically retracting a human or animal body cavity using a speculum, the method comprising:
introducing an elongate retractor at least partially into the body cavity;
maintaining a retainer, positioned at a region along the length of the retractor, in a
radially contracted orientation relative to a longitudinal axis of the retractor as the retractor
15 is inserted into the body cavity;
introducing the retractor into the body cavity such that the retainer is fully inserted within the body cavity;
causing the retainer to extend radially relative to the longitudinal axis of the
retractor and to abut against the internal walls of the body cavity using an actuator; and
20 inhibiting withdrawal of the speculum from the cavity by maintaining the retainer in the radially extended position.
20. The method as claimed in claim 19 comprising maintaining the retainer in the
radially extended position by realisably locking the actuator in a fixed position.
25
21. The method as claimed in claim 20 wherein the actuator is locked in position so as to not obscure an internal hollow region of the retractor.
22. The method as claimed in any one of claims 19 to 21 further comprising:
30 causing the retainer to contract radially relative to the longitudinal axis using the actuator; and
withdrawing the speculum from the body cavity.

23. The method as claimed in any of one claims 19 to 22 wherein the retainer comprises a deformable material, the method further comprising:

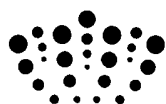
5 axially moving the retractor relative to a skirt positioned over at least part of the retractor to cause the retainer to extend radially relative to the longitudinal axis of the retractor by compressing the retainer between the retractor and the skirt.

24. The method as claimed in claim 23 further comprising locking the actuator against the skirt to maintain the retainer in the radially extended position.

10

25. The method as claimed in claim 19 wherein the retainer is anchored to the retractor and the retractor is moveable relative to a skirt positioned over at least a portion of the retractor, the method further comprising:

15 moving the retractor relative to the skirt to cause the retainer to deform radially outward relative to the longitudinal axis of the retainer.



Application No: GB0900788.1

Examiner: Emily Jones

Claims searched: 1-18

Date of search: 24 April 2009

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	X: 1, 2, 14 - 18	WO2004/010858 A2 (GROSS et al) Whole document relevant
X,Y	X: 1, 14 and 15 Y: 2, 16-18	WO2006/127085 A1 (RAUKER et al) Whole document relevant
X,Y	X: 1, 14-15 Y: 2, 16-18	US2002/045906 A1 (KELLY) Whole document relevant
Y	2, 16-18	US6083241 A (LONGO et al) Whole document relevant
A	-	EP1929959 A1 (LONGO et al) Whole document relevant

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

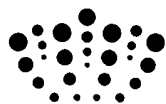
Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^X:

Worldwide search of patent documents classified in the following areas of the IPC
A61B
The following online and other databases have been used in the preparation of this search report
WPI, EPODOC

International Classification:

Subclass	Subgroup	Valid From
A61B	0001/32	01/01/2006



Subclass	Subgroup	Valid From
A61B	0001/31	01/01/2006
A61B	0001/303	01/01/2006
A61B	0017/02	01/01/2006