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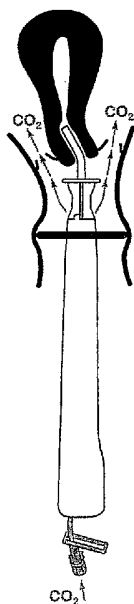
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(54) Title: SURGICAL APPARATUS AND THE USE THEREOF



(57) Abstract: Surgical apparatus for laparoscopic assisted vaginal hysterectomy. The apparatus has an elongate housing, having a handle end and a manipulator end; a diaphragm situated distal the handle end of the housing; a manipulator integral with a fitted in the manipulator end of the elongate housing; defining, the manipulator a tip extending distal of said housing and said handle end thereof, and a passage for passing gas from the handle end of the housing, to at least one exit in or adjacent to the manipulator and distal of the handle end beyond the diaphragm. The manipulator tip can be manipulated sufficiently by the handle end despite the gas sealing presence of the diaphragm to enable manipulation of the uterus.

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## SURGICAL APPARATUS AND THE USE THEREOF

### TECHNICAL FIELD

This invention relates to surgical apparatus and the use thereof.

5

### BACKGROUND ART

Hysterectomies have traditionally been performed by making a cut through the abdomen wall, freeing up the uterus and removing the uterus through the cut in the wall. In more recent times some hysterectomies have been able to be performed through the vaginal opening which consists in freeing up the uterus by using laparoscopic instruments and then removing the uterus through an opening made at the top of the vagina.

Laparoscopic procedures require the abdomen to be inflated with gas, to form a pneumoperitoneum, which enables the surgeon to see what needs to be done and easily move the instruments around and position them to make the necessary cuts, sutures, etc. Thus laparoscopically assisted vaginal hysterectomy (LAVH) is considered an advanced laparoscopic operative procedure.

One difficulty with LAVH procedures is that once the cut is made at the top of the vagina in order to allow the uterus to be removed, the gas in the abdomen escapes, making it difficult and time consuming to finally release the uterus from the abdomen (cut ligaments, etc) and remove it through the vaginal opening. Therefore although LAVH allows patient to avoid undergoing abdominal hysterectomy procedures, thus affording them a more rapid recovery, the vaginal portion of the operation can still be extremely difficult if there is little descent of the cervix, especially when the uterus is very large. In such circumstances the vaginal portion of the surgery can take almost as long as the laparoscopic portion and can cause great stress to the surgeon and lead to significant blood loss. The more dissection performed laparoscopically, the easier the vaginal component of the surgery. Therefore, the longer pneumoperitoneum can be maintained the more efficient the procedure becomes. Bleeding and/or damage to the uterine is also a significant problem. Formation of the "bladder flap" can be difficult and hazardous with perforation of the bladder on occasions occurring. However, the bladder has to be dissected off the lower segment of the uterus before the uterine arteries can be approached. In an attempt to make the "bladder flap" dissection easier,

the initial dissection has been performed vaginally without opening the peritoneal fold of the utero-vesical space. However, if the fold of the peritoneum is breached, then gas can escape from the abdomen into the vagina thus deflating the abdomen and making it impossible to continue the surgery. In order to minimise this problem saline packs have been placed into  
5 the vagina in an attempt to slow down gas leak, but rarely does this prove to be satisfactory.

In addition to this, in order for the hysterectomy procedure to be completed efficiently via the laparoscope, it is necessary to manipulate certain organs to obtain access to make the necessary cuts, sutures etc. For example, it may be necessary to push the uterus high up into the abdomen to free the ligaments for access by the surgeon.

10 A further difficulty occurs in forming the pneumoperitoneum as standard techniques usually involve the blind insertion of the gas used via a Verres needle. As this is blind insertion of the gas, the operator cannot have complete confidence in where the gas is being inserted.

To this end several types of device has been proposed as a means of overcoming these  
15 difficulties.

US 6,423,075; EP 0642766 A2 and Sabella et al in *Obstet. Gynecol.* 1996:87:465 proposed devices consisting of a handle, with a balloon cuff and manipulator at the distal end. By inflating the balloon the vagina can be occluded preventing the egress of gas thus allowing pneumoperitoneum to be maintained. However none of these devices provide means for  
20 producing pneumoperitoneum thus not overcoming the difficulty of the operator having to carry out blind insertion of the gas as previously described.

Similarly US 3,882,852 and US 6,174,317 proposed devices with balloon cuffs. However these devices do not include uterine manipulators or a means of inducing pneumoperitoneum. Thus these devices do not allow any of the previously discussed  
25 difficulties to be overcome.

Similarly US 6,572,631 proposes a device to occludes the vagina using a seal structure. The device allows pneumoperitoneum to be maintained however like the previous devices has no facility for introducing gas to create pneumoperitoneum.

US 5,704,372 proposed a device features an inflatable balloon cuff and a duct intended  
30 for producing pneumoperitoneum. However this device was not intended for vaginal use and hence no provision was made for a uterine manipulator. Hence this device offers no advantage when performing LAVH procedures.

US 5,643,285; US 5,487,377 and US 5,643,311 proposed inflatable cuff devices feature complex articulating, rotating or displaceable manipulators which add cost and complexity to the apparatus with no discernable gain in functionality. However none of these devices provide means for producing pneumoperitoneum thus not overcoming the difficulty  
5 of the operator having to carry out blind insertion of the gas as previously described.

US 6,235,037 proposed an inflatable cuff device featuring a rotating or displaceable manipulator which could be replaced. This device differed from those above in that it provided a means of producing pneumoperitoneum by passing gas through the handle of the device. However the inclusion of the rotating and displaceable manipulator adds cost and  
10 complexity to the apparatus with no discernable gain in functionality. The proposed device made no allowance for a fixed manipulator.

US 5,431,662; US 5,338,297; US 6,802,825 and US 5,935,098 proposed devices which provide occlusion of the uterus and manipulation of the uterus. However as these devices provide no means of achieving vaginal occlusion, pneumoperitoneum of the abdomen  
15 cannot be produced and thus these devices do not help overcome the previously detailed difficulties encountered when performing LAVH procedures.

The majority of the prior art discussed also utilises inflatable cuff devices to occlude the vaginal. The key deficiencies of inflatable cuff occluding devices are cost and complexity. In China it is estimated that 2.8 million hysterectomies are performed per year,  
20 and an estimated 2.3 million hysterectomies are performed per year in India. However in these countries cost is a principle factor in determining uptake and utilisation of a device. Therefore given the costs associated with inflatable cuff devices, these devices are unlikely to be used and thus treatment practices will revert to abdominal hysterectomy techniques which have a less favourable patient outcome.

25 There is therefore a need for a low cost device capable of maintaining a pneumoperitoneum throughout LAVH procedures, this device should provide means to manipulate the uterus as may be necessary during the LAVH procedure. The device should also have provision for improving the creation of a pneumoperitoneum during LAVH procedures.

30 In some situations the operator may choose to produce or maintain pneumoperitoneum by means other than that provided for by the present invention. Accordingly the device

should include a means to prevent the gas escaping via the mechanism to create pneumoperitoneum.

The field of surgery is also beginning to utilise mechanical means, such as robotic manipulation, for assisting surgeons in performing surgical procedures. This technology involves the surgeon directing the robotic mechanical manipulation means during the performance of a surgical procedure. In order for hysterectomies and other uterine procedures to be able to utilise this technology, it will be advantageous if not essential to provide a fixed fulcrum point about which and from which the manipulation device can be moved.

## 10 DISCLOSURE OF INVENTION

The invention consists in a surgical apparatus comprising or including:

- (a) an elongate housing, having a handle end and a manipulator end;
- (b) a diaphragm situated distal the handle end of the housing;
- (c) a manipulator integral with or fitted in the manipulator end of the elongate housing; defining, the manipulator a tip extending distal of said housing and said handle end thereof, and
- (d) a passage for passing gas from the handle end of the housing, to at least one exit in or adjacent to the manipulator and distal of the handle end beyond the diaphragm,

wherein the diaphragm can be positioned in the vaginal tract and either without further deployment or with further deployment (i.e. inflation or other activation) establish a sufficient seal to define a gas inflatable peritoneal and abdominal cavity in which a pneumoperitoneum can be established by the passage of gas and its egress from said exit,

**and therein** the manipulator tip can be manipulated sufficiently by the handle end despite the gas sealing presence of the diaphragm to enable manipulation of the uterus.

Preferred manipulation is either or both manipulation of the uterus from within the uterus prior to the vaginal cut and/or the manipulation of the uterus from outside the uterus after the vaginal cut.

In one option the diaphragm comprises a flat ring of fixed volume.

In another option the diaphragm comprises a ring of fixed volume, the majority of which, or all of which is, dished towards the distal end of the apparatus.

In still another option the diaphragm comprises a ring of fixed volume, the majority of which, or all of which is, dished away from the distal end of the apparatus.

5 In still another option the diaphragm may be mechanically deployed from a collapsed or relaxed state to an expanded less relaxed state.

In yet a further option the diaphragm may be thermally deployed, from a collapsed state to an expanded state.

10 In yet another option the diaphragm may be self deploying from a collapsed state to an expanded state.

Preferably the passage for passing gas to the distal end of the device has multiple exit points.

In a further aspect the invention consists in a method of laparoscopic assisted vaginal hysterectomy comprising or including the steps of:

- 15 (i) inserting apparatus comprising or including  
an elongate housing, having a handle end and a manipulator end;  
a diaphragm situated distal the handle end of the housing;  
a manipulator integral with or fitted in the manipulator end of the elongate housing;  
defining, the manipulator a tip extending distal of said housing and said handle end  
20 thereof, and  
a passage for passing gas from the handle end of the housing, to at least one exit in or adjacent to the manipulator and distal of the handle end beyond the diaphragm,  
into a vagina, and if necessary deploying the diaphragm, so as to have the diaphragm  
fix the apparatus in place and to provide a sealed peritoneal and abdominal cavity;
- 25 (ii) passing a gas through said passage and into the peritoneal and abdominal cavity to create pneumoperitoneum;
- (iii) utilising the manipulator tip to manipulate the uterus from within the uterus prior to vaginal cut; and

(iv) utilising the manipulator tip to manipulate the uterus from outside the uterus after vaginal cut.

The manipulator tip preferably does not affect the vaginal cut in any way. The vaginal cut is made either before the device is introduced using standard surgical methods (non laparoscopic), or alternatively, the vaginal cut may be made after the device is in place and pneumoperitoneum has been established. In this latter case the vaginal cut would typically be made laparoscopically. However the instruments do not need access via the device.

In an aspect, the invention relates to **a surgical apparatus** comprising or including an elongate housing, having a handle end and a manipulation end;

10 a diaphragm situated distal to the handle end of the housing which is adapted to expand and/or collapse and/or deform to occlude the vagina; and

a channel for passing a gas from the handle end of the apparatus, past the diaphragm, and having an exit in or adjacent to the manipulation end of the housing.

In still another aspect, the invention relates to **a method of laparoscopically assisted vaginal hysterectomy**, the method utilizing a surgical apparatus which includes a diaphragm adapted to expand and/or collapse and/or deform to occlude the vagina; the method comprising or including the steps of

15

inserting the apparatus with a diaphragm into a vagina;

utilising the diaphragm to occlude the vagina as required (i.e. of the apparatus) or a;

20 passing a gas through the gas channel and into a peritoneal and abdominal cavity to create a pneumoperitoneum;

utilizing the device to manipulate the uterus from within a uterus prior to the vaginal cut; and

utilizing the device to manipulate the uterus from outside the uterus after the vaginal cut.

25

The invention also comprises a surgical apparatus at least including:

a housing,

a diaphragm adapted to be substantially circumferentially around the housing,



manipulator tip which is connected to, or which forms an integral part of, the housing,  
and

a channel adapted to pass a gaseous substance.

Preferably a surgical apparatus has any one or more of:

5 an elongated housing,

a diaphragm capable of being expanded, collapsed or deformed to occlude the vagina,

a manipulator tip which is connected to, or which forms an integral part of, the  
housing, and

a channel adapted to pass a gaseous substance.

10 Preferably the diaphragm comprises a flat ring of fixed volume.

Preferably the gas channel extends along or through the housing and has an exit  
between the manipulation tip of the housing and the diaphragm.

In alternative configuration the gas channel may extend along or through the housing  
and have multiple exits between the manipulation tip and the diaphragm.

15 Preferably the gaseous substance is carbon dioxide.

The invention further comprises **a method of laparoscopically assisted vaginal  
hysterectomy** utilising a surgical apparatus which includes a diaphragm adapted to expand  
and/or collapse and/or deform as required to occlude the vagina, and manipulation means in  
the form of a tip extending from the housing;

20 the method comprising or including the steps of

inserting the apparatus with the diaphragm into the vagina,

expanding and/or collapsing and/or deforming the diaphragm as required to fix the  
apparatus in position and to seal the vagina,

25 utilising the manipulation tip to manipulate the uterus from within the uterus prior to  
the vaginal cut and to manipulate the uterus from outside the uterus after the vaginal cut.

The method preferably involves inserting the apparatus into the vagina, expanding  
and/or collapsing and/or deforming the diaphragm as required to fix the apparatus in position  
and to seal the vagina, passing a gas through the or a gas channel (preferably the gas channel  
of the apparatus) and into the peritoneal and abdominal cavity to create a pneumoperitoneum,

utilising the manipulation tip to manipulate the uterus from within the uterus prior to the vaginal cut and to manipulate the uterus from outside the uterus after the vaginal cut.

Preferably the method includes use of a mechanical means to manipulate the surgical apparatus during the course of the vaginal hysterectomy.

5 The invention further comprises a surgical apparatus comprising:

- (a) an elongated housing, having a handle end and a manipulator end;
- (b) a diaphragm situated distal the handle end of the housing;
- (c) a manipulator comprising a tip which extends from the manipulator end of the elongated housing; and
- 10 (d) a passage for passing gas from the handle end of the housing, to an exit in or adjacent to the manipulator end of the device.

Preferably the diaphragm comprises an expandable and/or collapsing and/or deforming device capable of occluding the vagina.

15 Preferably the diaphragm comprises a diaphragm adapted to be inflated and deflated substantially circumferentially from the elongated housing.

Preferably further comprising a passage extending from the handle end of the elongated housing to the diaphragm for inflating the diaphragm.

Preferably said passage includes means to prevent uncontrolled deflation of the diaphragm.

20 Preferably the diaphragm comprises a flat ring of fixed volume.

Preferably the diaphragm comprises a device of fixed dimensions which is sufficiently pliable that it is capable of deforming to occlude the vagina.

Preferably the diaphragm comprises a ring of fixed volume, the majority of which, or all of which is, dished towards the distal end of the apparatus.

25 Preferably the diaphragm may be thermally deployed from a collapsed state to an expanded state.

Preferably the diaphragm may be self deploying from a collapsed state to an expanded state.

Preferably the diaphragm may be manually deployed from a collapsed state to an expanded state and maintained and or controlled between either state.

Preferably the passage for passing gas to the distal end of the device has multiple exit points.

5 Preferably the passage for passing gas to the distal end of the device includes means to prevent egress of the gas used to create pneumoperitoneum.

The invention further comprises a method of laparoscopic assisted vaginal hysterectomy, the method utilising a surgical apparatus which includes a diaphragm, a gas channel, and a manipulator tip, the method comprising the steps of:

- 10 (a) inserting the apparatus into a vagina;
- (b) where applicable deploying the diaphragm to fix the apparatus in place and to seal the vagina;
- (c) passing a gas through a passage and into the peritoneal and adnominal cavity to create pneumoperitoneum;
- 15 (d) utilising the handle end of the apparatus to alter the position of the manipulator tip to effect manipulation of the uterus from within the uterus prior to vaginal cut; and
- (e) utilising the handle end of the apparatus to alter the position of the manipulator tip to effect manipulation of the uterus from outside the uterus after vaginal cut.

Preferably including manipulating the surgical apparatus by means of a robotic arm  
20 attached to the apparatus.

## BRIEF DESCRIPTION OF DRAWINGS

An embodiment of the present invention will now be described by way of example only with reference to the accompanying drawings in which:

25 **Figure 1** is a schematic representation of the medical instrument showing the instrument with a flat ring diaphragm, positioned in the vagina,

**Figure 1A** is a diagram of the device of Figure 1 showing preferred gas flows when deployed in use.

**Figure 2** is a schematic representation of the medical instrument showing the instrument with an inflatable diaphragm, positioned in a ballooning manner in the vagina,

**Figure 2A** is a diagram of the device of Figure 2 showing preferred gas flows when deployed in use.

5 **Figure 3** is a schematic representation of the medical instrument showing the instrument with a diaphragm dished towards the distal end of the instrument, positioned in the vagina,

**Figure 3A** is a diagram of the device of Figure 3 showing preferred gas flows when deployed in use.

10 **Figure 4** is a schematic representation of the medical instrument showing the instrument with a diaphragm dished away from the distal end of the instrument, positioned in the vagina,

**Figure 4A** is a diagram of the device of Figure 4 showing preferred gas flows when deployed in use.

15 **Figure 5** is a schematic representation of the medical instrument showing the instrument with a manually actuated mechanically deployed diaphragm, positioned in the vagina,

**Figure 5A** is a diagram of the device of Figure 5 showing preferred gas flows when deployed in use.

20 **Figure 6** is a schematic representation of the medical instrument showing the instrument with a thermally deployed diaphragm, positioned in the vagina,

**Figure 6A** is a diagram of the device of Figure 6 showing preferred gas flows when deployed in use.

25 **Figure 7** is a schematic representation of the medical instrument showing the instrument with a self deploying diaphragm, positioned in the vagina,

**Figure 7A** is a diagram of the device of Figure 7 showing preferred gas flows when deployed in use,

30 **Figure 8** is a diagrammatic view of a preferred device absent a pull on diaphragm or a fitted inflatable diaphragm but otherwise in accordance with the present invention in a perspective from one direction,

**Figure 9** is the device of Figure 8 shown in a different perspective view, and

**Figure 10** is an exploded diagram of the device of Figures 8 and 9.

Figure 1 depicts an embodiment of the medical apparatus for use in gynaecological surgery and in particular laparoscopic assisted vaginal hysterectomy. The apparatus comprises of an elongated handle **5** with a handle end **4** and a manipulator end **6**. Attached to or forming an integral part of the manipulator end is a manipulation tip **8** which is adapted to be inserted into the uterus **9**. Situated at the manipulator end **6** of the apparatus is a deformable and/or expandable and/or collapsing flat diaphragm **11** which acts to occlude the vagina **7**. Pneumoperitoneum can then be produced by passing gas from the handle **4** end of the device to the exit port **10** in the manipulator end **6** of the apparatus through a channel **3**. In another embodiment the apparatus may also feature a restricting device **2** to prevent the transfer of gas through the channel **3**.

Figure 2 depicts the preferred embodiment of the medical apparatus for use in gynaecological surgery and in particular laparoscopic assisted vaginal hysterectomy. The apparatus comprises an inflatable balloon cuff **15** which is capable of expanding to occlude the vagina **7**. Inflation of the balloon is achieved by the addition of a gas or liquid, but preferably air, through a port **12** and the handle end **4** of the apparatus. The inflation gas or liquid is then transmitted to the balloon **15** through a channel **14**. To maintain inflation and prevent uncontrolled deflation of the balloon the device may incorporate a restricting device **13**. This may take the form of a valve, restriction or preferably a clamp.

In another embodiment of the device as shown in Figure 3, the diaphragm **16** is deformable and/or expandable and/or collapsible and is contoured such that the majority of it, or all of it, is dished towards the distal end of the apparatus.

In another embodiment of the device as shown in Figure 4, the diaphragm **17** is deformable and/or expandable and/or collapsible and is contoured such that the majority of it, or all of it, is dished away from the distal end of the apparatus.

In another embodiment of the device as shown in Figure 5, the diaphragm **19** is configured such that it can be manually deformed and/or expanded and/or collapsed to occlude the vagina **7**. The means of manually deploying the diaphragm **19** may be by the application of reciprocal and/or rotary motions by the operator on a control surface **18** situated at the handle end of the apparatus.

In another embodiment of the device as shown in Figure 6, the diaphragm 21 may be configured such that it acts to occlude the vagina 7 in the presence or of absence of heat energy. This may be achieved through the addition of a heat sensitive metallic spring 20 or mechanism such as a bimetallic compound or a shape memory material.

5 In another embodiment of the device as shown in Figure 7, the diaphragm 22 may be configured to be self deploying, this may be realised through the use of a compressed material which when released deforms and/or expands and/or collapses to occlude the vagina 7.

10 Figures 1A through 7A show gas flows of the respective devices of Figures 1 to Figure 7. In each instance depending on the arrangement there is in use a ducting of a gas (e.g. carbon dioxide) from the manipulated end via appropriate tubing to issue out in the space beyond the diaphragm or inflated bladder. Also shown in the instance of Figure 2A is the inflation flow of a gas, for example, of air to the inflatable bladder.

15 In the construction of the device as shown in Figures 8 to 10 preferably there are five major components which lock together either by means of an adhesive, mechanical fastening or (ultrasonic) welding, or any mixture of such means, to form the completed device. Any suitable materials can be utilised for the components of the device of Figures 8 to 10 but preferably they are of a suitable sterilisable material. A suitable plastics or metal can be used for each, e.g. structural component (e.g. medically certified plastics such as ABS, styrenes, etc. or starch based materials, etc or a metal e.g. SS, or other appropriate metal).

20 The diaphragm is preferably a silicone, latex or other similar medically certified elastic material. A thermally activated diaphragm can be of nitinol or other shape memory alloy.

Shown specifically in Figure 10 is a tip 23, a left body moulding 24, a right body moulding 25, a sleeve 25 and a compression ring 27.

25 It can be seen that the left and right body moulding 24 and 25 can be mated reliant on pins of one component fixing into appropriate receiving parts of the other and vice versa. Desirably a compression ring 27 acts on the sleeve 25 to hold the left and right moulding parts together in addition to whatever fixing of one to the other is otherwise provided.

30 Also it can be seen that the double porting from the manipulation end for two ducting tubes an inflatable diaphragm as in Figure 1 (as in Figure 2) to be fitted as an option for it.

In the preferred arrangement as shown in Figure 10 the tip 23 is an component with a major portion thereof captured between the mouldings 24 and 25 with pins of each of the mouldings 24 and 25 being received within sleeves of the moulded tip component 23 on the centre lines shown. The tip has the requisite manipulator end suitable for the purpose  
5 previously described.

It is desirable therefor that the tip 23 as a separate component be located firmly between the moulded parts.

A pull on cuff (deformable but resilient) is then pulled over the tip onto the device at or near the sleeve 25. Gas tightness is to be ensured. Less critical is the fit if an inflatable  
10 cuff is pulled on provided it can connect to an inflating conduit.

Another embodiment is a device where the handle and tip are one piece with an integral cylindrical section between them. Rather than being injection moulded (as is preferred for the embodiment of Figures 8 to 10), the device may be thermoformed. Thermoforming (twin sheet) would result in a device that has a wall thickness (hollow) and  
15 require no assembly other than stretching the deformable but resilient cuff (dished away or dished towards the distal end) (- as in Figures 3 and 4 respectively) over the tip on to the cylindrical section near the tip to complete the assembly process.

In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of  
20 providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

**CLAIMS:**

1. A surgical apparatus comprising or including:

(a) an elongate housing, having a handle end and a manipulator end;

(b) a diaphragm situated distal the handle end of the housing;

5 (c) a manipulator integral with or fitted in the manipulator end of the elongate housing; defining, the manipulator a tip extending distal of said housing and said handle end thereof, and

10 (d) a passage for passing gas from the handle end of the housing, to at least one exit in or adjacent to the manipulator and distal of the handle end beyond the diaphragm,

wherein the diaphragm can be positioned in the vaginal tract and either without further deployment or with further deployment (i.e. inflation or other activation) establish a sufficient seal to define a gas inflatable peritoneal and abdominal cavity in which a pneumoperitoneum can be established by the passage of gas and its egress from said exit,

15 and therein the manipulator tip can be manipulated sufficiently by the handle end despite the gas sealing presence of the diaphragm to enable manipulation of the uterus.

2. An apparatus according to claim 1, wherein the diaphragm comprises a flat ring of fixed volume.

20 3. An apparatus according to claim 1, wherein the diaphragm comprises a ring of fixed volume, the majority of which, or all of which is, dished towards the distal end of the apparatus.

4. An apparatus according to claim 1, wherein the diaphragm comprises a ring of fixed volume, the majority of which, or all of which is, dished away from the distal end of the apparatus.

25 5. An apparatus according to claim 1, wherein the diaphragm may be mechanically deployed from a collapsed or relaxed state to an expanded less relaxed state.

6. An apparatus according to claim 1, wherein the diaphragm may be thermally deployed from a collapsed state to an expanded state.

30 7. An apparatus according to claim 1, wherein the diaphragm may be self deploying from a collapsed state to an expanded state.



8. An apparatus according to claim 1, wherein the passage for passing gas to the distal end of the device has multiple exit points.

9. A method of laparoscopic assisted vaginal hysterectomy comprising or including the steps of:

5 (i) inserting apparatus comprising or including

an elongate housing, having a handle end and a manipulator end;

a diaphragm situated distal the handle end of the housing;

a manipulator integral with or fitted in the manipulator end of the elongate housing;

10 defining, the manipulator a tip extending distal of said housing and said handle end thereof, and

a passage for passing gas from the handle end of the housing, to at least one exit in or adjacent to the manipulator and distal of the handle end beyond the diaphragm,

into a vagina, and if necessary deploying the diaphragm, so as to have the diaphragm fix the apparatus in place and to provide a sealed peritoneal and abdominal cavity;

15 (v) passing a gas through said passage and into the peritoneal and abdominal cavity to create pneumoperitoneum;

(vi) utilising the manipulator tip to manipulate the uterus from within the uterus prior to vaginal cut; and

20 (vii) utilising the manipulator tip to manipulate the uterus from outside the uterus after vaginal cut.

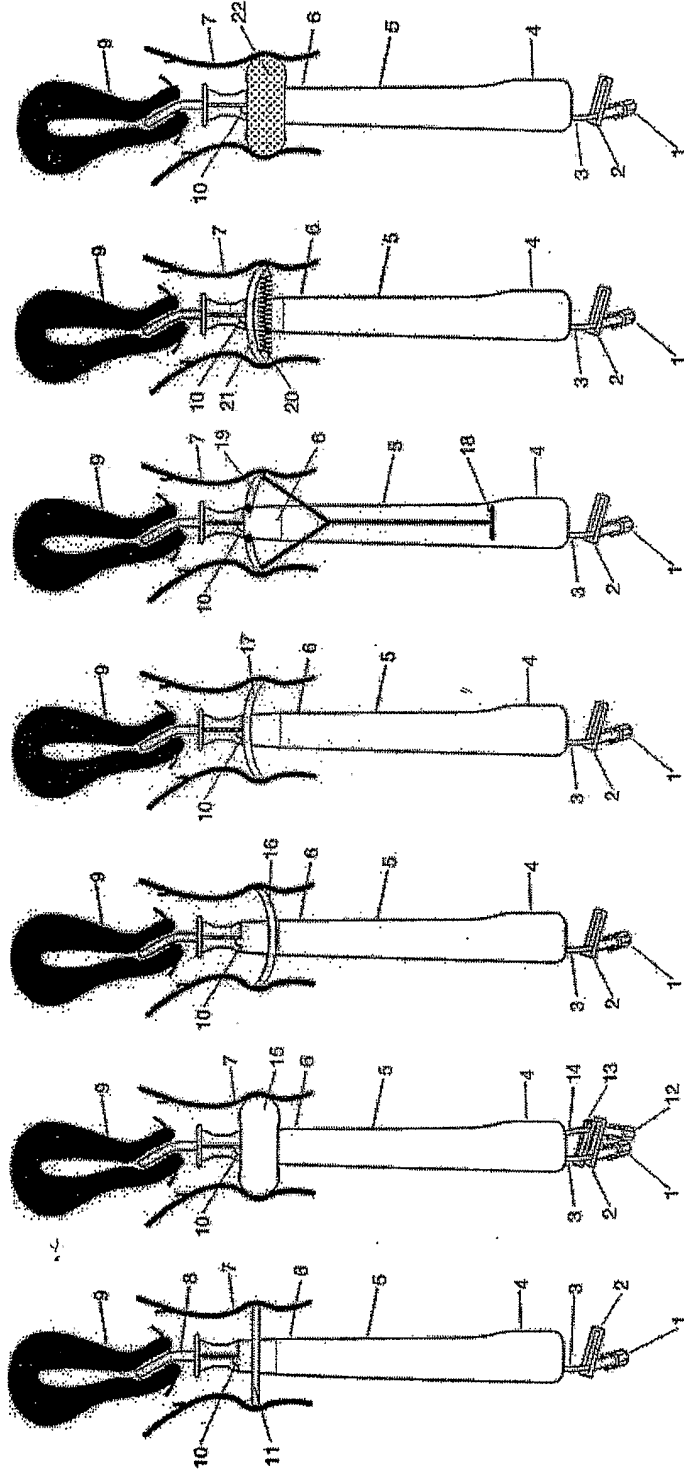


FIGURE 7

FIGURE 6

FIGURE 5

FIGURE 4

FIGURE 3

FIGURE 2

FIGURE 1

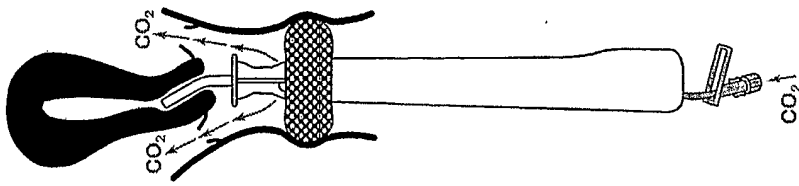


FIG 7A

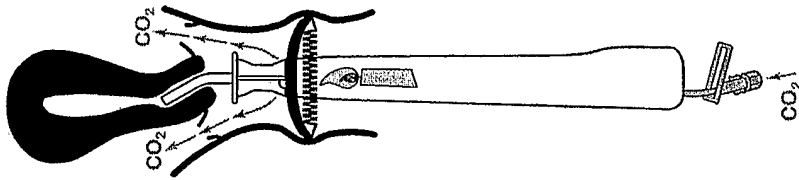


FIG 6A

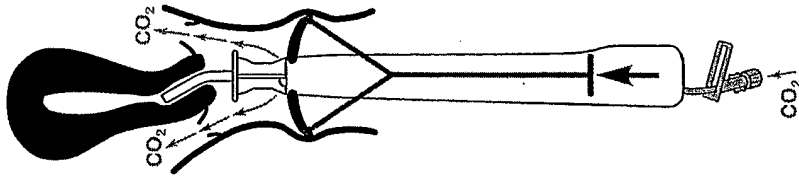


FIG 5A

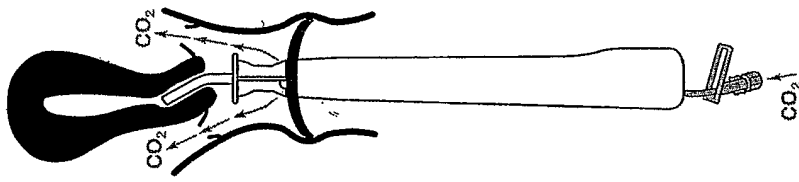


FIG 4A

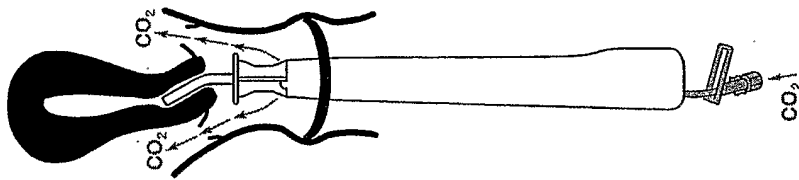


FIG 3A

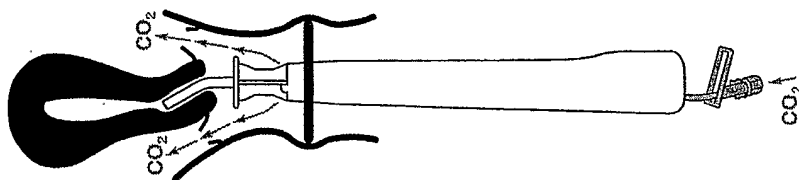


FIG 2A

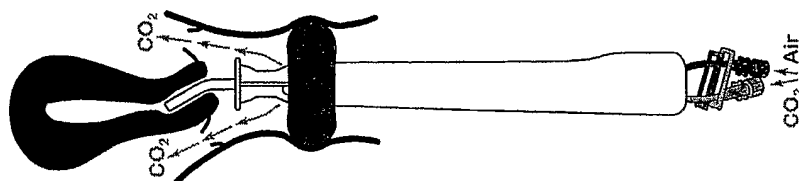
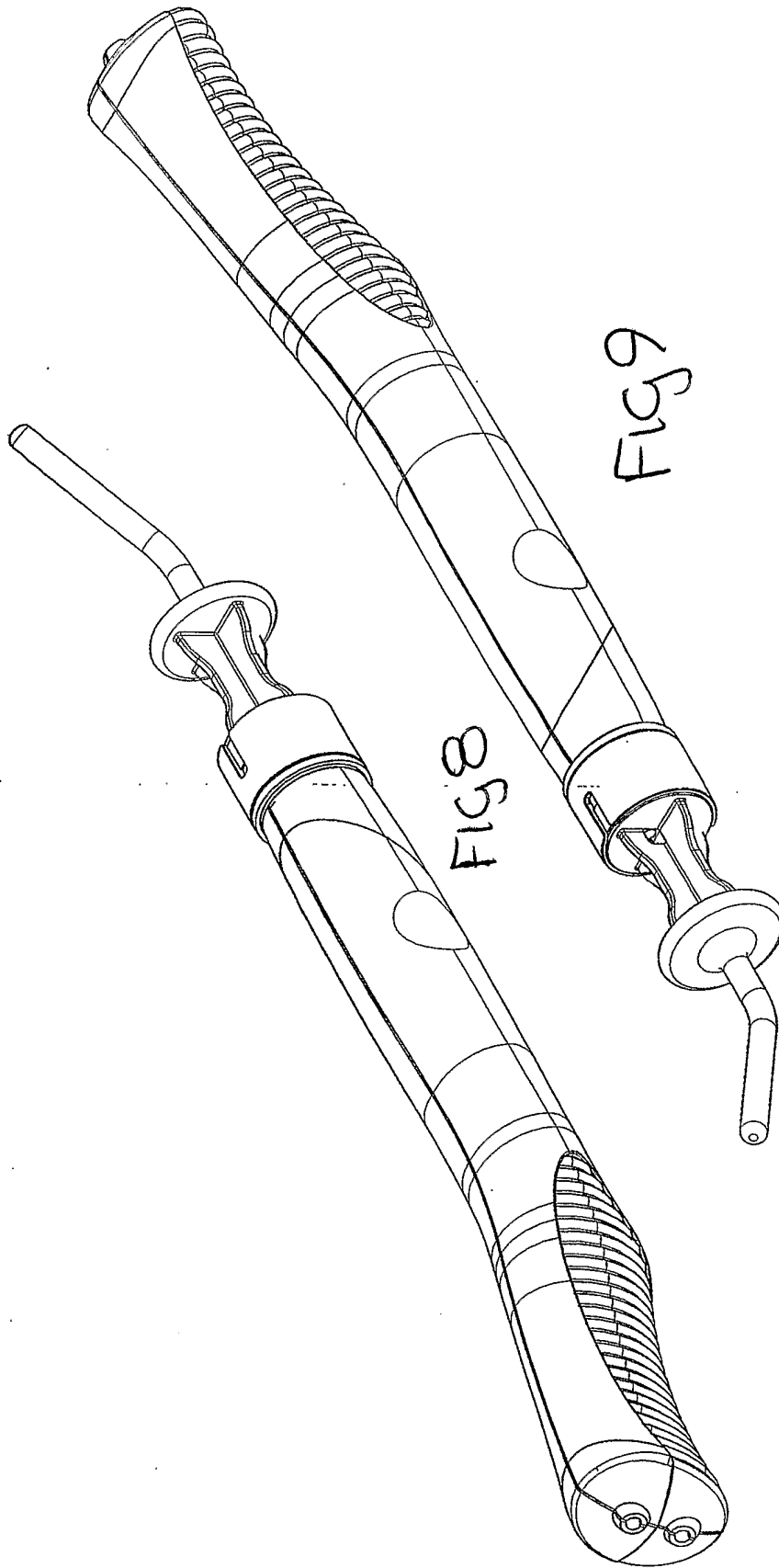
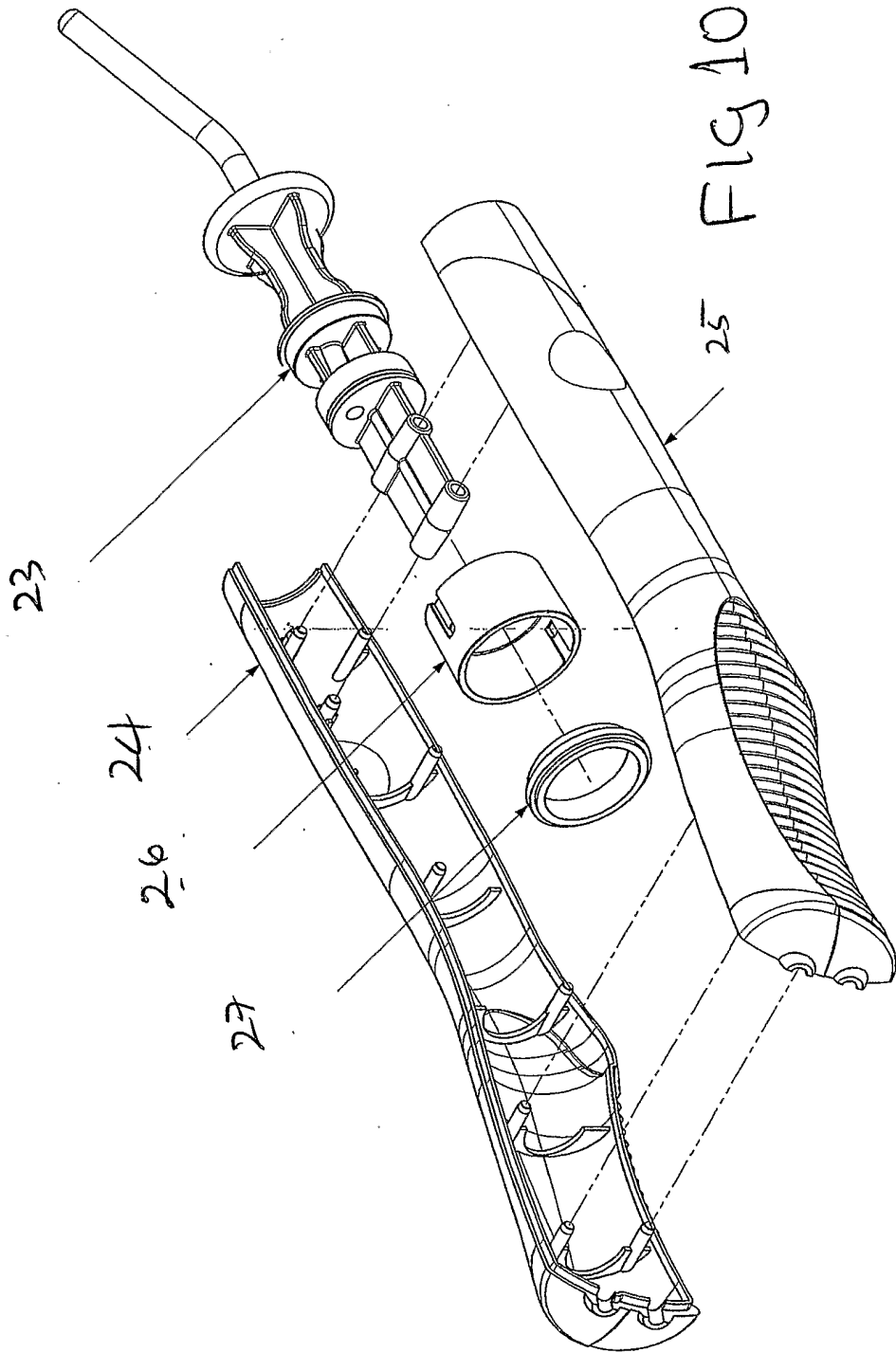


FIG 1A





## INTERNATIONAL SEARCH REPORT

International application No.

PCT/NZ2006/000143

## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. *A61B 17/42* (2006.01)

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)

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)

DWPI and keywords: hysterectomy and seal and vagina and pneumoperitoneum

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6235037 B1 (EAST et al.) 22 May 2001 Column 7 lines 28 to 39	1,2,4-6,8,9
Y	US 5357980 A (SEITZINGER) 25 October 1994 Column 2 lines 46 to 48	1-4,6-9
Y	US 5840077 A (ROWDEN et al.) 24 November 1998 Whole document	1-4,6-9
A	EP 642766 A2 (UNITED STATES SURGICAL CORPORATION) 15 March 1995 Whole document	

 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	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  
12 October 2006

Date of mailing of the international search report

24 OCT 2006

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/NZ2006/000143

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4258721 A (PARENT et al.) 31 March 1981 Whole document	
A	US 3948270 A (HASSON) 6 April 1976 Whole document	

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/NZ2006/000143

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	6235037	AU	29174/97	NZ	332938	WO	9745053
US	5357980	NIL					
US	5840077	AU	39533/95	EP	0786962	US	5520698
		US	5643285	WO	9611641		
EP	0642766	AU	20841/92	CA	2075226	CA	2075233
		CA	2088884	CA	2101293	CA	2106243
		CA	2132055	EP	0531710	EP	0557806
		EP	0582295	EP	0606531	JP	5200040
		SG	106122	US	5199419	US	5381788
		US	5383888	US	5391180	US	5431662
		US	5490819	US	5514157	US	5554101
		US	5571115	US	5578048	US	5607450
		US	5766205	US	5782859	US	6806725
		US	7087071	US	2002177874	US	2002177875
US	4258721	DE	2806750	DE	2902829	FR	2415451
		FR	2417302	GB	2014457	JP	54110683
		SE	7901344	US	4249528		
US	3948270	NIL					
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.							
END OF ANNEX							