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(71) Applicant and

(72) Inventor: **VAN DER WEIDEN, Robertus, Mattheus, Felix** [NL/NL]; Dorpsstraat 168, NL-2903 LB Capelle Aan Den Ijssel (NL).

(74) Agent: **FERGUSON, Alexander**; c/o Octrooibureau Vriesendorp & Gaade B.V., P.O. Box 266, NL-2501 AW The Hague (NL).

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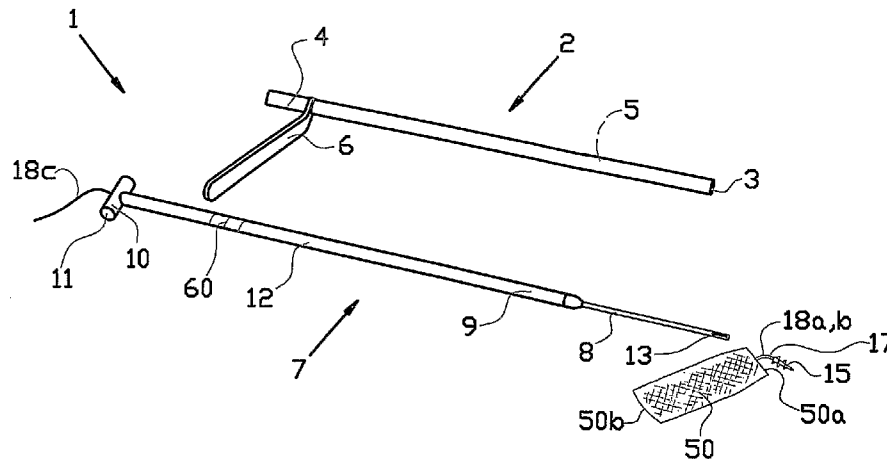
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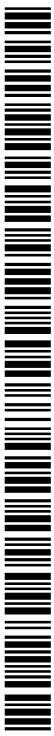
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(54) Title: ASSEMBLY AND METHOD FOR ATTACHING PARTICULARLY A VAGINA TO A SPINE



(57) **Abstract:** Assembly for use in the attachment of a patient's vaginal apex or uterus or rectum to her/his spine, comprising a first tube having a length adapted to the distance from the outer wall of the patient's abdomen to the sacrum, which first tube is provided with a distal end to be brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage from the distal to the proximal end thereof, a second tube or rod having a length that at least equals the length of the first tube, which second tube or rod is provided with a distal end and comprises an opposite proximal end, at least one attachment means provided with a distal end for attachment to the sacrum and a proximal end for attachment of an end of connection means for connection to the patient's vaginal apex or uterus or rectum, such as one or more threads, wherein the distal end of the second tube or rod and the proximal end of the attachment means are formed for functional mutual engagement, wherein the second tube or rod can be movably accommodated in the first tube - preferably snugly.



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Assembly and method for attaching particularly a vagina to a spine**BACKGROUND OF THE INVENTION**

After a patient has had a hysterectomy, the supporting ligaments of the vagina have usually also been removed. As a consequence the vagina
5 may bulge to the outside under pressure of other organs. A further consequence may be that the small intestine prolapses, which may cause an oppressive sensation in the lower abdomen.

In order to solve this, it is known to surgically move organs out of the
10 way, using tools that are introduced via a large incision in the abdomen, and attach a number of threads to the upper sacral segment or further above it on one of the lumbar vertebrae, and to attach those threads to a kind of mat, that is attached to the rear side of the vagina with threads. Said mat enable tissue ingrowth of its own accord.

15 A drawback is that the vagina will be more upright than is the case under natural circumstances. There is also the risk of haemorrhages due to damage to blood vessels at this level of the spine, particularly the sacral promontory. An oppressive sensation in the lower abdomen
20 might last, whereas bladder problems may also continue.

It was attempted to improve on this situation by suturing the threads at a lower location along the spine, near the coccyx. This was also done via a large incision in the abdominal wall.

After this type of surgery the patients have to stay in hospital for approximately two weeks, which entails high costs. The patients are furthermore inconvenienced by the surgery for a long time after that, particularly due to the large incision.

5

Similar problems may occur in case of prolapsed uteruses, particularly unpleasant oppressive sensations in the lower abdomen and/or against the bladder.

10 It is an object of the invention to improve on at least some of these drawbacks.

A further object of the invention is to provide an assembly and/or method wherein in case of a hysterectomy the vagina can be given a
15 natural orientation, particularly in a quick and/or simple way.

It is a further object of the invention to provide an assembly and/or method wherein in case of a hysterectomy the vagina can be suspended to a fixed point of the patient's body in a relatively small
20 surgical procedure.

SUMMARY OF THE INVENTION

From one aspect the invention to that end provides an assembly for use
25 in the attachment of a patient's vaginal apex or uterus or rectum to her/his spine, comprising a first tube having a length adapted to the distance from the outer wall of the patient's abdomen to the sacrum, which first tube is provided with a distal end to be brought into engagement with the sacrum and comprising an opposite proximal end
30 and having a first passage from the distal to the proximal end thereof, a second tube or rod having a length that at least equals the length of the first tube, which second tube or rod is provided with a distal end and

comprises an opposite proximal end, at least one attachment means provided with a distal end for attachment to the sacrum and a proximal end for attachment of an end of connection means for connection to the patient's vaginal apex or uterus or rectum, such as one or more
5 threads, wherein the distal end of the second tube or rod and the proximal end of the attachment means are formed for functional mutual engagement, wherein the second tube or rod can be movably accommodated in the first tube.

10 With the assembly according to the invention the connection means intended for attachment or suspension of the vagina, uterus or rectum can be attached to a lower location in the spine, due to which the orientation of the vagina or uterus etcetera, to be attached or suspended using the connections means, may correspond with the
15 natural orientation and uncomfortable oppressive sensations can be avoided.

Preferably the second tube or rod can be snugly accommodated in the first tube. Due to the snug accommodation of the second tube or rod in
20 the first tube the assembly can be utilised in combination with laparoscopic surgery, as a result of which the abdominal cavity need not be opened. The gas introduced into the abdominal cavity during such surgery in order to give room to intestines that have been moved out of the way by other tools, will not readily escape via both tubes. In
25 laparoscopic surgery valves for stopping gas are otherwise used. The invention provides a valve-less assembly, which as a result is easy to manufacture and clean.

Preferably the second tube or rod can be rotatably accommodated in
30 the first tube. The attachment means may be a bone screw or bone anchor, which screw can easily be screwed into the spine by means of the second tube or rod that is rotatable within the first tube.

For facilitating the attachment of the bone screw the proximal end of the second tube or rod may be provided with means for rotation of the second tube or rod. Ease of operation is further increased when the rotation means comprise an arm that is transverse to the second tube or rod, preferably projecting to both sides.

In one embodiment the distal end is formed for fittingly, particularly rotation-fixedly holding the proximal end of the attachment means. The second tube or rod may for instance form an internal cavity at the distal end. In said cavity the proximal end of the attachment means, particularly the bone screw, can be accommodated, preferably in a rotation-fixed manner. This is possible by using unround and/or polygonal cross-sections of hollow and proximal end of the bone screw, which cross-sections fit into each other. Thus a holding means for the attachment means is obtained in a simple way. The distal end of the second tube or rod may be narrowed.

In a further development of the assembly according to the invention, the second tube or rod extends into the first tube and at least a part of the connection means is attached to the attachment means and said part is situated within the first tube. This part of the connection means can be inserted into the abdominal cavity shielded by the first tube. Moreover the action of connection to the attachment means has taken place beforehand, so that said action need not be performed in the abdominal cavity, after placing the attachment means.

Preferably the said part of the connection means is situated between the first and the second tube or rod. Alternatively the second tube or rod may be provided with an accommodation space for them. In the first case the distal end of the second tube or rod can be narrowed for

together with the first tube forming an accommodation space for said part of the connection means.

In one embodiment the distal end of the second tube or rod forms an accommodation space for the proximal end of the attachment means and it is provided with a passage to the side, wherein an end portion of the said part of the connection means, such as a thread, extends through the passage. The attachment means can thus be properly held whereas it can nonetheless already be connected to the connection means and not hinder a rotation, yet be properly reachable after placement.

At least a part of the connection means can be attached to the attachment means and be situated around the distal end of the second tube or rod, wherein said end serves as carrier for said part of the connection means.

In one practical embodiment the said part of the connection means comprises a mat of material enabling bodily tissue ingrowth.

The mat can be wrapped or shirred up around the second tube or rod in a simple way.

In one embodiment the attachment means has a diameter that at least almost corresponds to the diameter of the first passage, so that the first tube can be kept as narrow as possible to further limit the adverse effects of the surgery.

Preferably the second tube or rod at the proximal end is provided with gauge means related to the sliding of the second tube or rod in the first tube corresponding to the attachment length of the distal end of the

attachment means, so that it is easy to ascertain whether the attachment means has penetrated sufficiently far into the spine.

For certainty of placement of the first tube the distal end of the first
5 tube may be provided with a serrated edge that engages into the surface of the spine.

For enhancing the manageability of the first tube, optionally having a second tube or rod inserted therein, the first tube may be provided with
10 a handle near the proximal end.

The connection means may comprise one or more threads that are attached to the attachment means and preferably comprise a mat of material enabling bodily tissue ingrowth, which mat can be attached to
15 threads.

In a further development the assembly according to the invention comprises a laparoscope, and preferably a viewing screen that is functionally connected to the laparoscope.
20

In a further development the assembly according to the invention is sterilely accommodated in a hermetically closed packaging, ready for use in surgery. The second tube or rod is then preferably inserted into the first tube.
25

From a further aspect the invention provides an assembly for use in the attachment of a patient's vaginal apex, uterus or rectum to her/his spine, comprising a first tube having a length adapted to the distance of the outer wall of the patient's abdomen to the sacrum, which first tube
30 is provided with a distal end to be brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage from the distal to the proximal end thereof, a second tube or

rod having a length that is at least equal to the length of the first tube, preferably larger, which second tube or rod is provided with a distal end and comprises an opposite proximal end, at least one attachment means that is provided with means for attachment to the sacrum and
5 means for attachment of connection means, such as one or more threads and/or a connection mat, wherein the distal end of the second tube or rod and the attachment means are formed for functional mutual engagement, wherein the first passage is suitable for accommodation of the connection means.

10

Preferably the first passage and the second tube or rod are adapted to each other for fitting accommodation of the second tube or rod. The connection means can be disposed between the first and the second tube or rod. The second tube or rod may form a cavity for
15 accommodation of the connection means, particularly the said mat. The second tube or rod may form a continuous cavity, from the proximal end to the distal end.

From a further aspect the invention provides an assembly for use in
20 surgery on a human body, comprising a first tube, provided with a distal end to be brought into engagement with a bone and comprising an opposite proximal end and having a first passage from the distal to the proximal end thereof, a second tube or rod having a length that is at least equal to the length of the first tube, preferably larger, which
25 second tube or rod is provided with a distal end and comprises an opposite proximal end, at least one attachment means provided with means for attachment to the bone and means for attachment of connection means, such as one or more threads and/or a connection mat, wherein the distal end of the second tube or rod and the
30 attachment means are formed for functional mutual engagement, wherein the first passage is suitable for accommodation of the

connection means. Preferably the second tube forms a cavity extending from the distal end, preferably to the proximal end.

From yet a further aspect the invention provides a method for attaching
5 the vagina to a patient's spine, wherein one or more threads are
attached to the spine by means of one or more bone screws and the
threads are used for indirect attachment of the vagina to the spine such
as via a mat. With the bone screws and using simple tools the threads
can be reliably secured to the spine remote from the spine. The incision
10 in the abdominal wall can remain small as a result.

Preferably the bone screws are attached in the sacrum, particularly
below the first segment thereof, as a result of which the orientation of
the vagina after attachment to the threads can be as natural as
15 possible.

With the threads a mat, which is known per se and which enables
ingrowth of natural tissue material, can be attached to the bone screw,
which mat at the other side is attached -preferably in a first step- to
20 the vagina, particularly the rear side of the apex area of the vagina.

In one embodiment thereof an incision is made in the abdominal wall, a
first tube is introduced through the incision, until it engages the spine, a
bone screw is attached in the spine using a screwdriver extending
25 through the first tube, the threads being attached to the bone screw,
the first tube and the screwdriver are retracted in order to make a
length of the threads attached to the bone screw free and the threads
(the portions attached to the bone screw after cutting them through)
are subsequently connected to the mat for attachment of the mat to
30 the spine.

From a further aspect the invention provides a method for attaching the vagina, uterus or rectum to a patient's spine, wherein one or more connection means, particularly a mat of material enabling bodily tissue ingrowth, are introduced into the abdominal cavity and are attached to the spine by means of attachment means, after which connection means are attached to the vagina, particularly the rear side of the apex area of the vagina, uterus or rectum.

In a time-efficient embodiment the mat already attached to the attachment means is introduced into the abdominal cavity.

In one embodiment an incision is made in the abdominal wall, a first tube is introduced through the incision, until its distal end engages the spine, a bone screw is attached in the spine using a screwdriver extending through the first tube, the connection means, such as mat and/or threads, being attached to the bone screw.

The incision in the abdominal wall can be kept limited if the size of the incision is kept adjusted to a guide stub, such as a Trocar, for the insertion of the first tube. The first tube is guided by the Trocar or something similar, that may have a diameter in the order of 1 cm, so that the incision is very local.

The connection means may be inserted in a condition accommodated in the fist tube.

Preferably the screwdriver used has a portion having a diameter that snugly fits the passage in the first tube, as well as a distal portion on which the mat has been arranged. If the screwdriver used has a diameter that snugly fits the passage in the first tube and is provided with a passage for the threads a leakage path between the first tube and the screwdriver is counteracted, so that possible gas in the

abdominal cavity, introduced for making laparoscopic surgery possible, cannot escape to too large an extent.

For instance prior to inserting the first tube a quantity of gas may be introduced into the abdominal cavity in order to enlarge it. According to the invention after filling the abdominal cavity with gas, a laparoscope can be inserted into the abdominal cavity via an incision in the abdominal wall, which laparoscope is functionally connected to a viewing screen. The later insertion of the first tube, particularly with inserted screwdriver having the bone screw placed thereon, can be properly monitored using the laparoscope, so that the bone screw can be placed with its distal end at the wanted location on the spine.

The number of incisions can be kept limited if the laparoscope is inserted at the location where the gas has been introduced.

In a further development of the method according to the invention further incisions are made through which tools are inserted for moving the intestines and attaching the connection means, such as threads, to the vagina, uterus (preferably at the location of the ligamenta sacrouterina) or rectum. The access size also remains limited for those tools.

Preferably the screwdriver fits such into the first tube that a leakage flow of gas between them is prevented to a large extent, so that the abdominal cavity remains at sufficient gas tension.

From a further aspect the invention provides a method for attaching the vagina, uterus or rectum to a patient's spine, wherein one or more connection means, particularly connection threads are introduced into the abdominal cavity and are attached to the spine by means of attachment means, after which a mat of material enabling bodily tissue

ingrowth connection means is attached to the threads and to the vagina, particularly the rear side of the apex area of the vagina, uterus or rectum.

- 5 Preferably an assembly according to the invention, as described above is used in a method according to the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

- 10 The invention will be elucidated on the basis of exemplary embodiments shown in the attached drawings, in which:

Figures 1A-F show a first example of a tool for an assembly according to the invention, in a first and second disassembled condition, in
15 assembled condition and in details, respectively;

Figures 2A and 2B show a second example of a tool for an assembly according to the invention, in disassembled condition and assembled
20 condition, respectively;

Figure 3 shows a top view of a patient's abdomen before the treatment with an assembly according to the invention;

Figures 3A-D show schematic cross-sections of the abdominal/pelvic
25 area of a recumbent patient during the successive stages of a method according to the invention, using the assembly of the figures 1A-F;

Figures 4A,B show two next stages in a method according to the invention, following figure 3D in a recumbent patient;

30 Figure 4C shows the result of the method according to the invention;

Figures 5A,B show schematic cross-sections of the abdominal/pelvic area of a recumbent patient during consecutive stages of a method according to the invention using the assembly of the figures 2A,B; and

- 5 Figures 6A,B show two next stages in a method according to the invention, following figure 5B in a recumbent patient.

DETAILED DESCRIPTION OF THE DRAWINGS

- 10 The assembly 1 in figures 1 A-C comprises a first, outer tube 2, made of stainless steel, having a continuous passage 5 and an open distal end 3 provided with small serrations 3a (figure 1F), and an open proximal end 4, near which end a handle 6 is attached to the outer tube.

15

- The assembly 1 further comprises a second, inner tube 7, optionally having a continuous passage 12, which extends from an open, narrowed distal end portion 8, to an open proximal end 10. After approximately 8-10 cm, the distal end portion 8 changes in proximal direction into a wider portion 9, which further continues up into the proximal end 10. At the proximal end 10 a T-shaped transverse rod 11 is attached, in which the passage 12 optionally continues. At the outer surface the second tube 7 is provided with gauge marks 60, indicating a longitudinal calibration.

25

As can be seen in figures 1D and 1E the distal end of the second inner tube 8 is provided with two opposite slits 13a,b, forming passages from the inside to the outside.

- 30 Furthermore shown is a mat 50 forming a connection means, the mat being a rectangular piece of monofilament, knitted from polypropene gauze (Gyne mesh (soft), Ethicon, Norderstedt, Germany, having a

width/length of approximately 3 cm/4 cm, which mat 50 is attached by means of threads 18a,b of a biocompatible polyester material to a titanium bone screw 15 (for instance type Arthrex AR-1925S via Arthrex (85757 Karlsfeld Germany and Naples FL34104, USA)), which is provided with a self-tapping bone screw thread 16 having a diameter of 6.5 mm and at the proximal side thereof a holder plate 17. The mat 50 can also be attached to the bone screw 15 in another way, for instance by means of a fixation ring. A screw having a wider head onto which the mat is hooked, may also be used. The holder plate 17 fits in the slits 13a,b, as can be seen in figure 1E, so that rotation of the tube 7 will also cause rotation of the screw 15. The holder plate 17 is furthermore held by friction in the slits 13a,b, so that the bone screw cannot inadvertently fall out of the distal end portion 8. Other ways of rotation-fixed and slip-free accommodation of the bone screw in the end portion are also possible. For instance the bone screw 15 may be provided with a hexagonal insertion pin, that clampingly fits into a distal end of the inner tube 7. If the passage 12 continues to the proximal end 10 a thread 18c may continue from the holder plate 7, and the bone screw 15 can be held in its place in the distal end portion 8 by means of a tensile force on said thread 18c.

The outer diameter of the inner tube 7 almost equals the inner diameter of the outer tube 2, so that the inner tube 7 can be slid and rotated within the outer tube 2 in a snug-fitting manner. The diameter of the bone screw 15 almost corresponds to the outer diameter of the inner tube 7. The diameter of the assembly 1 thus is as small as possible, in this example for instance 10 mm, a standard size for a Trocar which will be further discussed. The slit 13a and/or 13b is suitable for passing through the threads 18a,b, so that they need not end up in between the two tubes 2, 7. In this example the length of the outer tube 2 is 29.5 cm and the length of the inner tube 7 is 40 cm.

The assembly 101 in figures 2A,B comprises a first, outer tube 102, made of stainless steel, having a continuous passage 105 and an open distal end 103 provided with small serrations 103a, and an open proximal end 104, near which end a handle 106 is attached to the
5 outer tube 102.

The assembly 101 further comprises a second, inner tube 107, having a continuous passage 112, which extends from an open, narrowed distal end 108, to an open proximal end 10. After approximately 1 cm,
10 the distal end 108 changes in proximal direction into a wider portion 109, which further continues up into the proximal end 110. At the proximal end 110 a T-shaped transverse rod 111 is attached, in which the passage 112 continues. The further diameters and lengths of the inner tube 107 and outer tube 102 correspond to those of the previous
15 exemplary embodiment.

As can be seen in figure 2A, the connection threads 118a,b of a biocompatible polyester material have been passed from the distal end 108 to the proximal end 110, and they exit at both ends. At the distal
20 end the threads 118a,b are attached to a bone screw 15, comparable to bone screw 15, and to a holder pin 117 situated at the proximal side thereof. The holder pin 117 is unround and fits in a rotation-fixed manner, about its centre line, in a passage portion 112a in the distal end 108, which passage portion for this purpose is correspondingly
25 unround.

By drawing the threads 18a,b tighter at the proximal end, the pin 117 can be pulled into the passage portion 112a, and the second tube 107 is in the condition shown in figure 2B, in which, however, it is also
30 accommodated in the outer tube 102. The aforementioned mat is still separate here.

Figure 3 schematically shows a surgery set-up in top view, wherein a part of patient P is shown, with abdominal wall and bladder B. Above the pubic bone a so-called Trocar placement stub 20 is placed in the median line. Similar Trocars are placed at several places in the abdominal wall at the location of 21, 22, 23 and 24. Said Trocars are standard auxiliary tools in laparoscopic surgery, and are placed after making a small local incision in the abdominal wall, and with a narrowed portion extend through the abdominal wall, and are provided with continuous passages, as well as with a sealing therein, which sealing allows a tool through in a slidable, sealing manner.

Figure 3A shows the sacral segments S1-S5, as well as the fifth lumbar vertebra L5 and the transition therebetween, sacral promontory Pr.

Prior to placing the Trocars 20-24 a small incision is made at the location of (later on) wanted location of Trocar 23 and an insufflation needle 30, provided with a distal end 31 is inserted (direction F) through the abdominal wall into the abdominal cavity, after which carbon dioxide is introduced into the abdominal cavity (figure 3A) via the tube 30. As a result the volume of the abdominal cavity B is enlarged, due to which room is provided for engaging and moving the intestines during the subsequent actions and surgery.

Subsequently the insufflation needle 30 is retracted, and -after making the incision larger- the Trocar 23 is inserted. Due to the enlargement of the abdominal cavity this can take place safely. Gas escaping from the abdominal cavity is counteracted by the sealings in the Trocar 23.

Trocar 23, as shown in figure 3B, is used for inserting a laparoscope 40 into the abdominal cavity, which laparoscope is provided with a view end 41 and which by means of line 42 is functionally connected to

monitor 43. Via the monitor 43, the abdominal cavity can be viewed using the end 41 of the laparoscope 40.

While being monitored by the laparoscope, the other Trocars 20, 21, 5 24 and 25 are inserted. They are also provided with sealings for counteracting the escape of gas from the abdominal cavity.

Then the tools can be inserted in a controlled manner via the Trocars 10 21, 23 and 24.

Monitored via the laparoscope 40, the assembly of figure 1C is inserted via the Trocar 20, as shown in figure 3C. Due to the snug fit of the inner tube 2 in the outer tube 7 hardly any gas will be able to escape from the abdominal cavity.

15 The insertion of the assembly 1, monitored by means of the laparoscope 40, takes place such that the distal end 3 with the serrations 3a abuts an area of the spine that is situated relatively low, in this example the third segment S3 of the sacrum. When inserting the 20 assembly 1 the bladder B and the bowels I are kept pushed aside by tools, so that the placement can take place correctly.

When the serrations 3a of the distal end 3 are in proper engagement with the sacral segment S3, the bone screw 15 is pressed against the 25 sacral segment S3 or S4 in the median line, by pressing the proximal end 10 of the inner tube 7. Subsequently by engaging the T-part 11 with the fingers, the inner tube 7 is rotated about its axis within the outer tube 2, as a result of which the bone screw 15 with treaded part 16 is screwed into the sacral segment S3 (figure 3D).

30 When based on movement/position of the grade marks 60 with respect to the proximal edge of the first tube 2 it is ascertained that the inner

tube 7 has moved a distance in distal direction in the tube 2, which distance corresponds to the length of the screw thread 16, the surgeon will stop rotating the T-transverse piece 11. Subsequently he will first retract the inner tube 7 a few centimetres in order to release the bone
5 screw 15 from the distal end 8. Subsequently the assembly 1, optionally first the first tube 2 separately over some distance, is retracted, leaving behind the mat 50 that is connected to the bone screw 15 by means of threads 18a,b (figure 4A).

10 The free end of the mat 50 is subsequently engaged by tools inserted through the Trocars, and using further tools inserted through the Trocars, is attached with sutures near one of the mat edges to the rear side of the vaginal apex, particularly the posterior vaginal wall, using four mersilene or ethibond sutures (Ethicon, Norderstedt, Germany)
15 (figure 4B).

The mat 50 -in the recumbent position of the patient- extends tensionless between the vagina and the bone screw 15 (and thus S3 or S4). The vaginal axis is in an anatomically correct position (figure 4C).

20 After it is ascertained by means of the laparoscope 40 that the attachment of the vagina has been realised as desired, the tools are retracted from the abdominal cavity and from the Trocars, and the Trocars are removed and the incisions are sutured.

25 In the upright position of the patient (figure 4C) the mat 50, connecting the vaginal apex with S3 or S4, ensures that the vagina will not sag. In figure 4C it can also be seen that the vagina has assumed a more natural orientation. Line L is drawn as a reference thereof, which line
30 connects the lower edge of the pubic bone (Pb) with the lower side of S5 in the sagittal plane (the pubococcygeal reference line). The angle α the mat 50 is at to the line L preferably is less than 45° .

It is noted that the bone screw 15 may alternatively be placed in S2. Under certain conditions S5 can also be used.

5 When carrying out the method according to the invention on a uterus the mat 50 is sutured to the uterus at the location of the attachment of the ligamenta sacrouterina. In this embodiment the mat itself has also been attached to the bone screw beforehand by means of threads or other connection means.

10

When using the assembly 101 of the figures 2A,B the sequence may be slightly different. After the actions that are part of figures 3A,B have been carried out, the mat 50 that has not yet been attached to the bone screw 115 is, while being monitored by the laparoscope 40, first
15 inserted and by means of tools inserted through the Trocars, with sutures near one of the mat edges attached to the rear side of the vaginal apex, particularly the posterior vaginal wall, using four mersilene or ethibond sutures (Ethicon, Norderstedt, Germany). It is noted that for the sake of clarity the mat 50 has been left out in the figures 5A,B and
20 6A.

25

Via the Trocar 20 the assembly 101 of figure 2B is inserted, as shown in figure 5A. Due to the snug fit of the inner tube 102 in the outer tube 107 hardly any gas will be able to escape from the abdominal cavity.
The insertion of the assembly 101, monitored by means the laparoscope 40, takes place such that the distal end 103 with the serrations 103a abuts an area of the spine that is situated relatively low, in this example the third segment S3 of the sacrum. When
30 inserting the assembly 1 the bladder B and the bowels I are kept pushed aside by tools, so that placement can take place correctly. By

pulling the thread 118a,b extending out of the proximal end 110, the bone screw 115 can be pulled in place in end 103.

When the serrations 103a of the distal end 103 are in proper
5 engagement with sacral segment S3, the bone screw 115 is pressed
against the sacral segment S3 or S4 in the median line, by pressing the
proximal end 110 of the inner tube 107. Subsequently by engaging T-
part 111 with the fingers, the inner tube 107 is rotated about its axis
within the outer tube 102, as a result of which the bone screw 115
10 with threaded part 116 is screwed into the sacral segment S3 (figure
5B).

When based on movement of the grade marks 160 it is ascertained that
the inner tube 107 has moved a distance in distal direction in the tube
15 102, which distance corresponds to the length of the screw thread
116, the surgeon will stop rotating the T-transverse piece 111.
Subsequently he will first retract the inner tube 107 a few centimetres
in order to release the bone screw 115 from the distal end 108.
Subsequently the assembly 101 is retracted from the abdominal cavity
20 B, wherein the threads 118a,b that are connected to the bone screw
115, particularly its pin 117, slide through the passages 112, 112a and
exit from the distal end 108 of the inner tube 107 (figure 6A). The
threads 118a,b are then cut off at approximately 10 cm from the bone
screw 115.

25

This released portion of the threads 118a,b can then be engaged by
means of tools from the other Trocars. The threads 118a,b are passed
through the mat near the free opposite mat edge and subsequently the
mat 50 is placed at the lowest point of the abdominal cavity B (the
30 cavum Douglasi). The threads 118a,b passed through the mat 50 are
drawn tighter as a result of which the mat edge is pulled towards the

bone screw (figure 6B). Subsequently the threads 118a,b are tied, and the situation as shown in figure 4C is achieved.

The method and the assembly according to the invention can also be
5 used for fixation of the rectum.

Claims

1. Assembly for use in the attachment of a patient's vaginal apex or uterus or rectum to her/his spine, comprising a first tube having a length adapted to the distance from the outer wall of the patient's abdomen to the sacrum, which first tube is provided with a distal end
5 to be brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage from the distal to the proximal end thereof, a second tube or rod having a length that at least equals the length of the first tube, which second tube or rod is provided with a distal end and comprises an opposite proximal end, at least one
10 attachment means provided with a distal end for attachment to the sacrum and a proximal end for attachment of an end of connection means for connection to the patient's vaginal apex or uterus or rectum, such as one or more threads, wherein the distal end of the second tube or rod and the proximal end of the attachment means are formed for
15 functional mutual engagement, wherein the second tube or rod can be movably accommodated in the first tube - preferably snugly -.

2. Assembly according to claim 1, wherein the second tube or rod can be rotatably accommodated in the first tube.

20

3. Assembly according to claim 2, wherein the attachment means is a bone screw.

4. Assembly according to claim 2 or 3, wherein the proximal end of the second tube or rod is provided with means for rotation of the second tube or rod.
- 5 5. Assembly according to claim 4, wherein the rotation means comprise an arm that is transverse to the second tube or rod, preferably projecting to both sides.
6. Assembly according to any one of the preceding claims, wherein the
10 distal end of the second tube or rod is formed for fittingly, particularly rotation-fixedly holding the proximal end of the attachment means.
7. Assembly according to claim 6, wherein the second tube or rod has an internal cavity, which is at least formed at the distal end.
- 15
8. Assembly according to any one of the preceding claims, wherein the second tube or rod extends into the first tube and at least a part of the connection means is attached to the attachment means and situated within the first tube.
- 20
9. Assembly according to claim 8, wherein the said part of the connection means is situated between the first and the second tube or rod.
- 25 10. Assembly according to claim 9, wherein the distal end of the second tube or rod is narrowed for together with the first tube forming an accommodation space for said part of the connection means.
- 30 11. Assembly according to claim 9 or 10 and claim 7, wherein the distal end of the second tube or rod forms an accommodation space for the proximal end of the attachment means and is provided with a

passage to the side, wherein an end portion of the said part of the connection means, such as a thread, extends through the passage.

12. Assembly according to any one of the claims 1-7, wherein at least
5 a part of the connection means is attached to the attachment means and is situated around the distal end of the second tube or rod.

13. Assembly according to any one of the claims 8-12, wherein the
10 said part of the connection means comprises a mat of material enabling bodily tissue ingrowth.

14. Assembly according to claim 12 or 13, wherein the mat is wrapped or shirred up around the second tube or rod.

15 15. Assembly according to any one of the preceding claims, wherein the attachment means has a diameter that at least almost corresponds to the diameter of the first passage.

16. Assembly according to any one of the preceding claims, wherein
20 the second tube or rod at the proximal end is provided with gauge means related to the sliding of the second tube or rod in the first tube corresponding to the attachment length of the distal end of the attachment means.

25 17. Assembly according to any one of the preceding claims, wherein the distal end of the first tube is provided with a serrated edge.

18. Assembly according to any one of the preceding claims, wherein the first tube is provided with a handle near the proximal end.

30

19. Assembly according to any one of the preceding claims, wherein the connection means comprise one or more threads that are attached

to the attachment means and/or comprise a mat of material enabling bodily tissue ingrowth, which mat preferably can be attached to threads.

5 20. Assembly according to any one of the preceding claims, further comprising a laparoscope.

21. Assembly according to any one of the preceding claims, sterilely accommodated in a hermetically closed packaging.

10

22. Assembly according to claim 21, further comprising a viewing screen that is functionally connected to the laparoscope.

23. Method for attaching the vagina, uterus or rectum to a patient's spine, wherein one or more connection means, particularly a mat of material enabling bodily tissue ingrowth, are introduced into the abdominal cavity and are attached to the spine by means of attachment means, after which connection means are attached to the vagina, particularly the rear side of the apex area of the vagina, uterus or rectum.

15
20

24. Method according to claim 23, wherein the mat already attached to the attachment means is inserted into the abdominal cavity.

25 25. Method according to claim 23 or 24, wherein bone screws are used as attachment means.

26. Method according to claim 23, 24 or 25, wherein the attachment means are attached in the sacrum, particularly below the first segment thereof.

30

27. Method according to any one of the claims 23-26, wherein an incision is made in the abdominal wall, a first tube is introduced through the incision, until its distal end engages the spine, a bone screw is attached in the spine using a screwdriver extending through the first
5 tube, wherein the connection means, such as mat and/or threads, are attached to the bone screw.

28. Method according to claim 27, wherein the size of the incision is kept adjusted to a guide stub, such as a Trocar, for the insertion of the
10 first tube.

29. Method according to claim 27 or 28, wherein the connection means are inserted in a condition accommodated in the fist tube.

15 30. Method according to claim 27, 28 or 29, wherein the screwdriver used has a portion having a diameter that snugly fits the passage in the first tube, as well as a distal portion on which the mat has been arranged.

20 31. Method according to any one of the claims 23-30, wherein prior to inserting the first tube a quantity of gas is introduced into the abdominal cavity in order to enlarge it.

25 32. Method according to claim 31, wherein after filling the abdominal cavity with gas an incision is made in the abdominal wall and a laparoscope is inserted therethrough, which laparoscope is functionally connected to a viewing screen.

30 33. Method according to claim 32, wherein the insertion of the first tube, particularly with the inserted screwdriver with the bone screw placed thereon, is monitored using the laparoscope.

34. Method according to claim 32 or 33, wherein the laparoscope is inserted at a location where the gas has been introduced.
35. Method according to claim 32, 33 or 34, wherein further incisions
5 are made through which tools are inserted for moving the intestines and attaching the attachment means, such as a mat and/or threads, to the vagina, uterus (preferably at the location of the ligamenta sacrouterina) or rectum.
- 10 36. Method according to any one of the claims 31-35, depending on claim 30, wherein the screwdriver fits such into the first tube that a leakage flow of gas between them is prevented to a large extent, so that the abdominal cavity remains at sufficient gas tension.
- 15 37. Method according to any one of the claims 23-36, wherein use is made of the assembly according to any one of the claims 1-22.
38. Assembly for use in the attachment of a patient's vaginal apex, uterus or rectum to her/his spine, comprising a first tube having a
20 length adapted to the distance of the outer wall of the patient's abdomen to the sacrum, which first tube is provided with a distal end to be brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage from the distal to the proximal end thereof, a second tube or rod having a length that is at
25 least equal to the length of the first tube, preferably larger, which second tube or rod is provided with a distal end and comprises an opposite proximal end, at least one attachment means that is provided with means for attachment to the sacrum and means for attachment of connection means, such as one or more threads and/or a connection
30 mat, wherein the distal end of the second tube or rod and the attachment means are formed for functional mutual engagement,

wherein the first passage is suitable for accommodation of the connection means.

39. Assembly according to claim 38, wherein the first passage and the
5 second tube or rod are adapted to each other for fitting accommodation of the second tube or rod.

40. Assembly according to claim 38 or 39, wherein the connection means are disposed between the first and the second tube or rod.

10

41. Assembly according to claim 38 or 39, wherein the second tube or rod forms a cavity for accommodation of the connection means.

42. Assembly according to claim 41, wherein the connection means
15 comprise a mat of material and/or threads enabling bodily tissue ingrowth.

43. Assembly according to any one of the claims 38-42, wherein the second tube or rod forms a continuous cavity, from the proximal end to
20 the distal end.

44. Assembly for use in surgery on a human body, comprising a first tube, provided with a distal end to be brought into engagement with a bone and comprising an opposite proximal end and having a first
25 passage from the distal to the proximal end thereof, a second tube or rod having a length that is at least equal to the length of the first tube, preferably larger, which second tube or rod is provided with a distal end and comprises an opposite proximal end, at least one attachment means provided with means for attachment to the bone and means for
30 attachment of connection means, such as one or more threads and/or a connection mat, wherein the distal end of the second tube or rod and the attachment means are formed for functional mutual engagement,

wherein the first passage is suitable for accommodation of the connection means.

45. Assembly according to claim 44, wherein the second tube forms a
5 cavity extending from the distal end, preferably to the proximal end.

46. Assembly according to claim 44 or 45, wherein the attachment means is connected to a connection mat.

10 47. Assembly according to claim 46, wherein the connection mat is directly attached to the attachment means, such as by means of a fixation ring or by hooking onto it.

48. Assembly according to claim 46 or 47, wherein the connection mat
15 is accommodated within the first tube.

49. Assembly according to claim 48, wherein the connection mat is accommodated between the first tube and the second tube or rod.

20 50. Assembly according to claim 45, wherein one or more threads that are connected to the attachment means extend through the cavity out of the proximal end of the second tube or rod.

51. Method for attaching the vagina, uterus or rectum to a patient's
25 spine, wherein one or more connection means, particularly connection threads are introduced into the abdominal cavity and are attached to the spine by means of attachment means, after which a mat of material enabling bodily tissue ingrowth connection means is attached to the threads and –preferably prior to it- to the vagina, particularly the rear
30 side of the apex area of the vagina, uterus or rectum.

52. Assembly provided with one or more of the characterising measures described in the attached description and/or shown in the attached drawings.
- 5 53. Method comprising one or more of the characterising steps described in the attached description and/or shown in the attached drawings.

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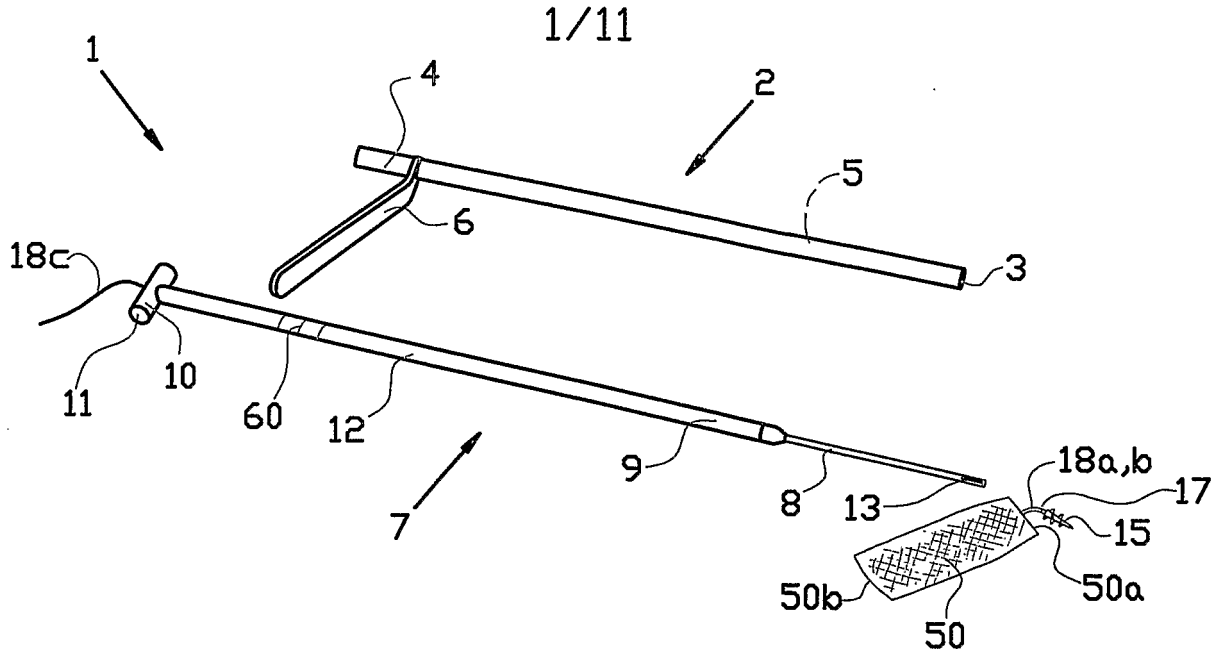


FIG. 1A

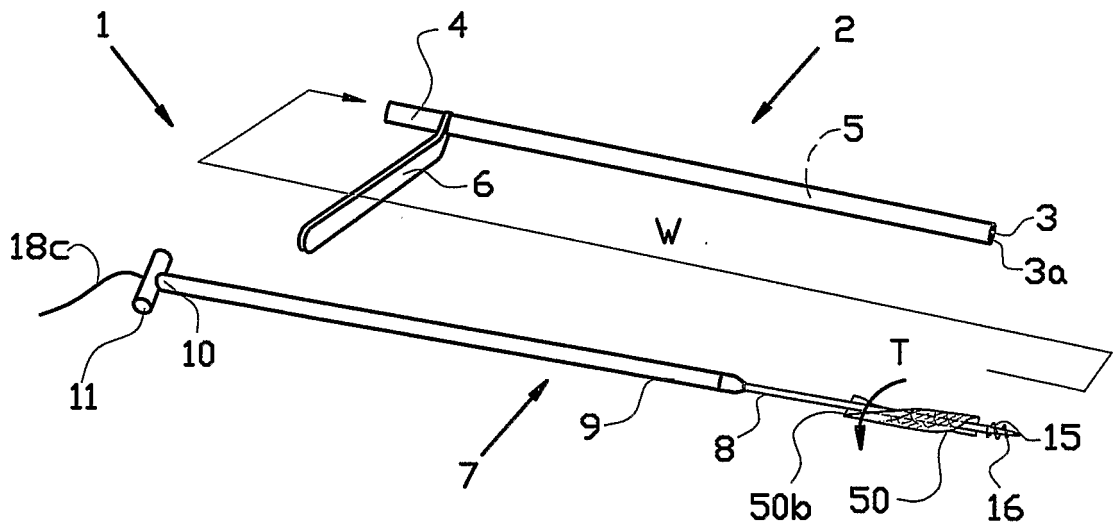


FIG. 1B

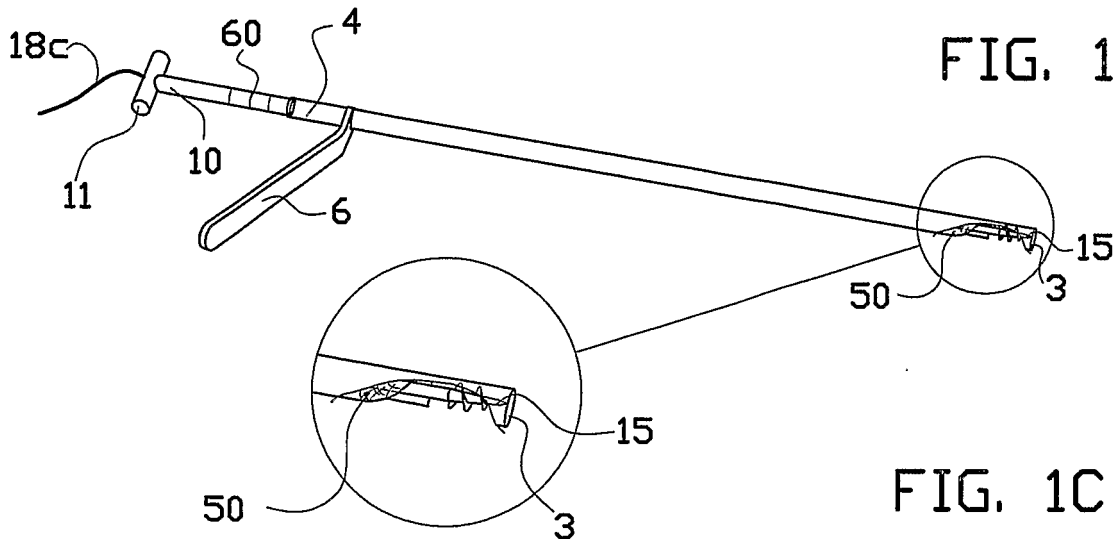


FIG. 1C

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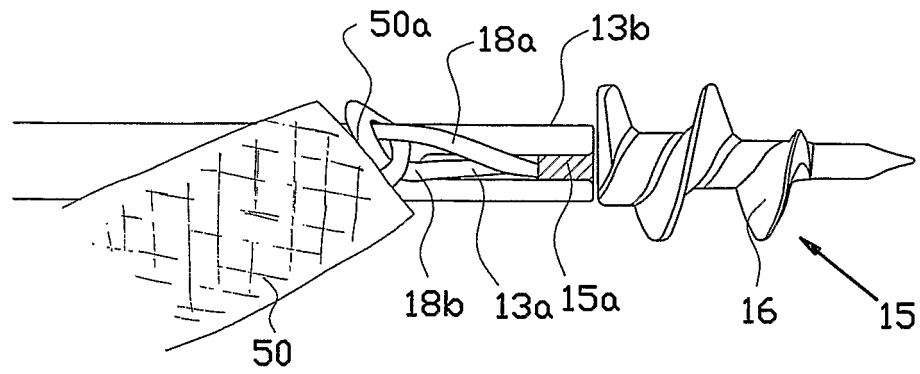


FIG. 1D

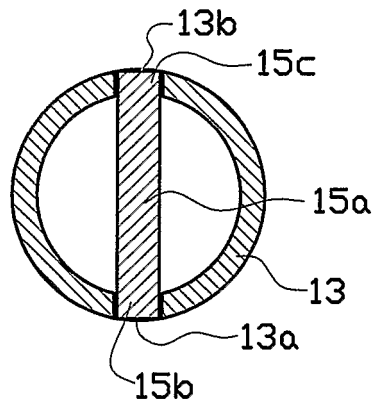


FIG. 1E

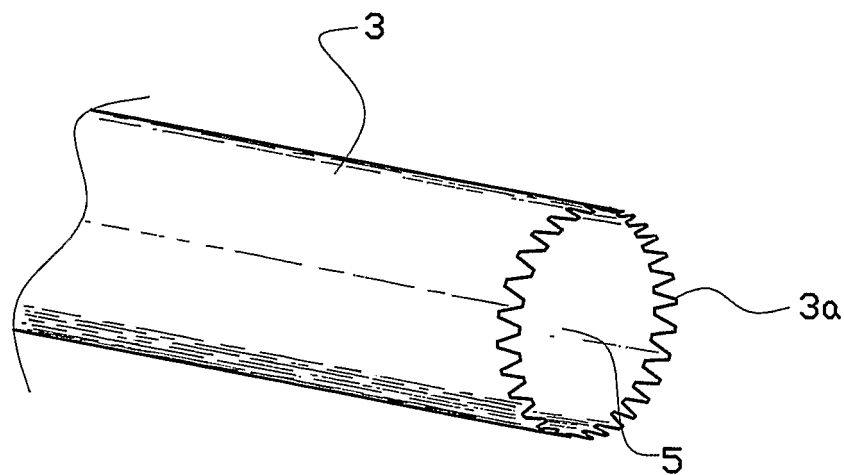
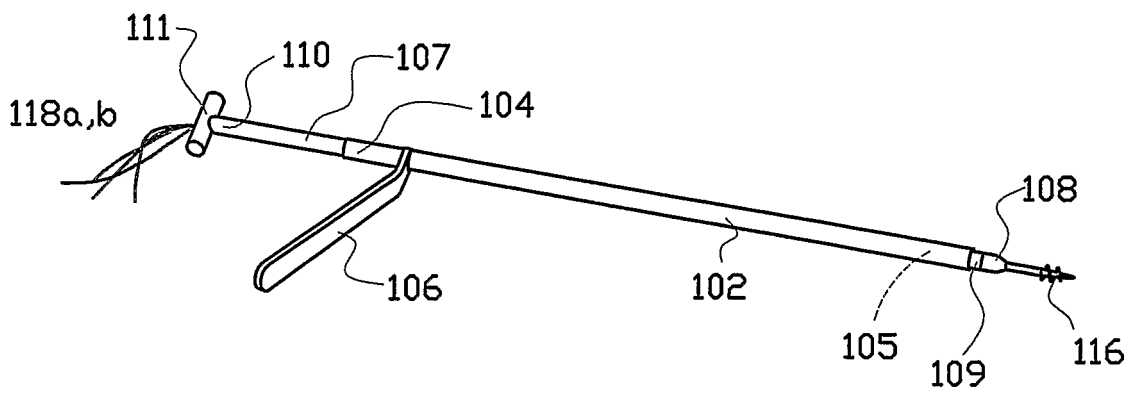
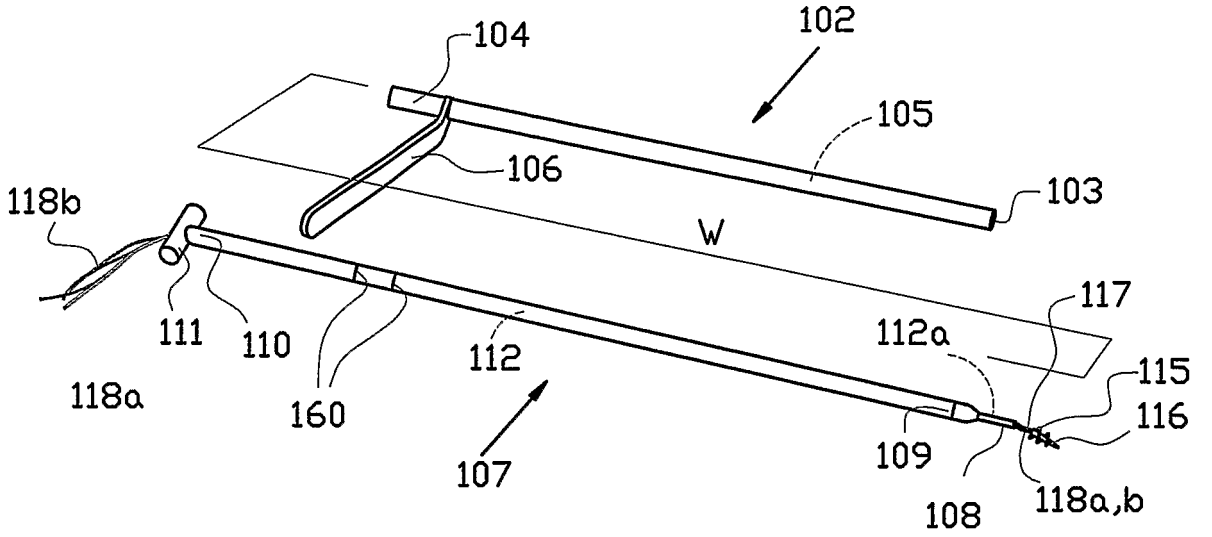


FIG. 1F



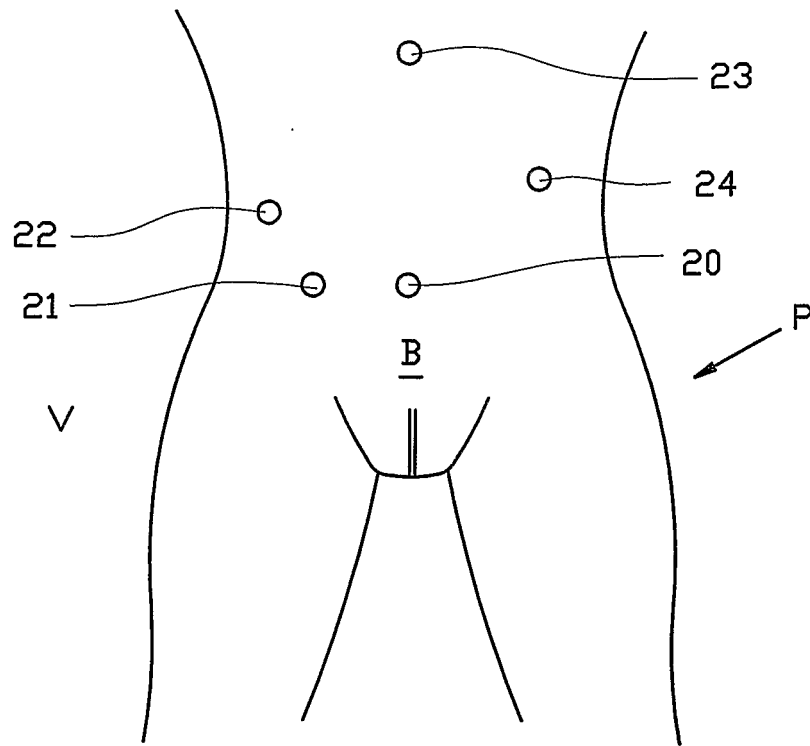


FIG. 3

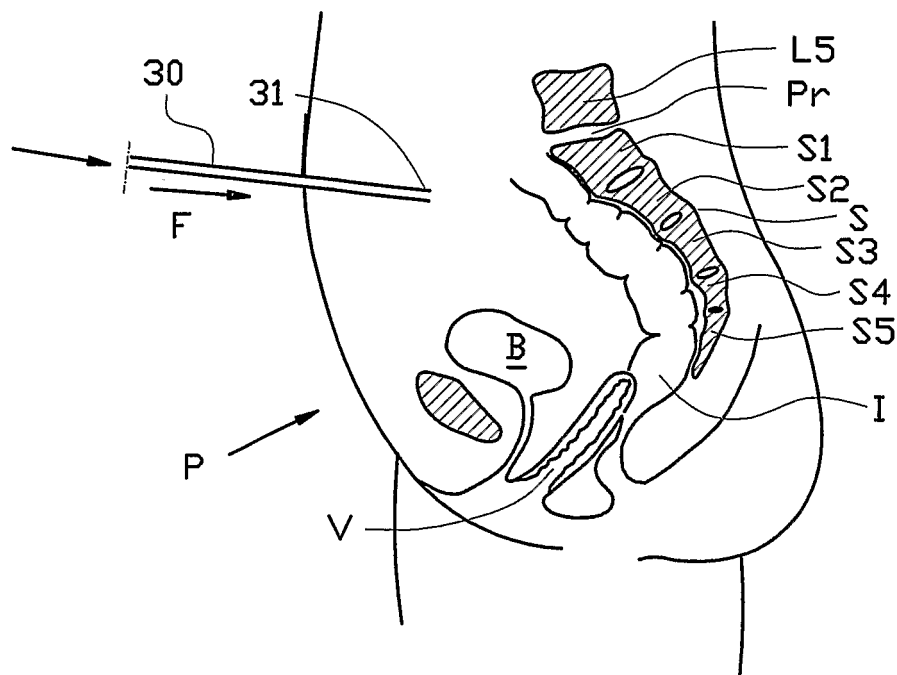


FIG. 3A

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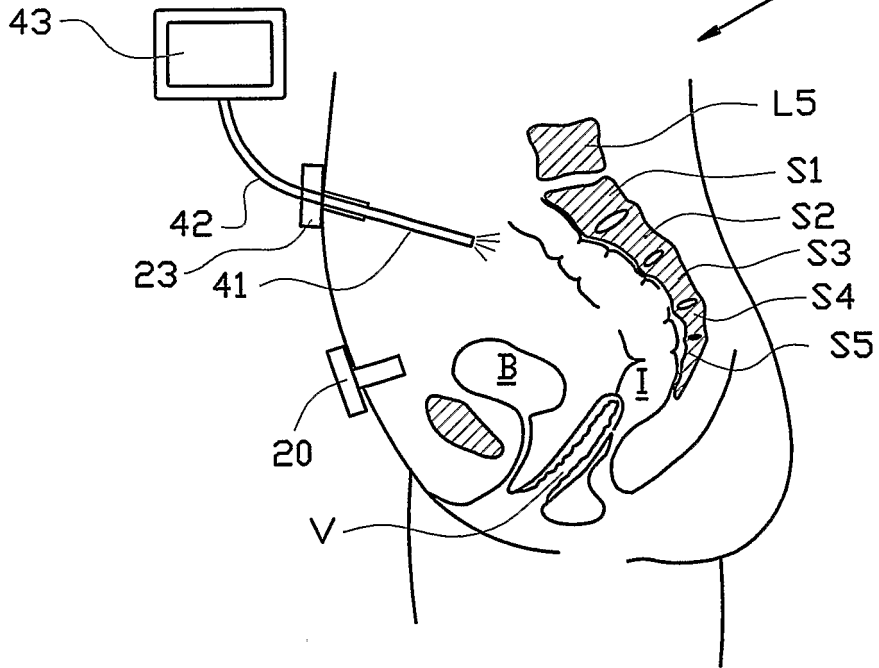


FIG. 3B

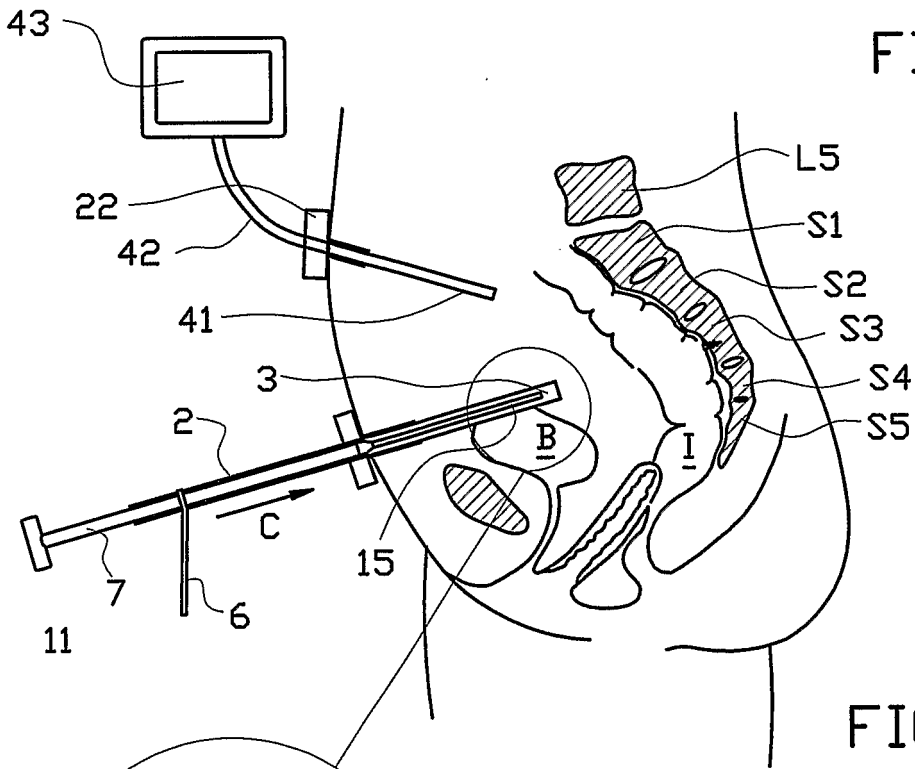
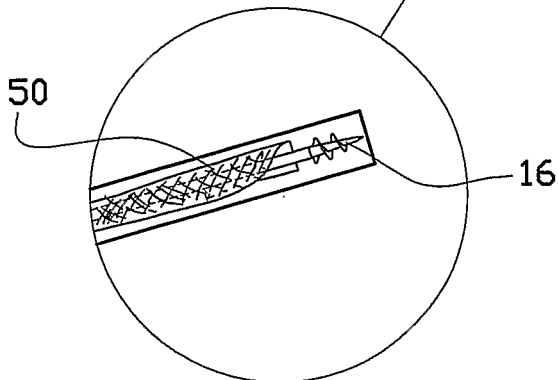


FIG. 3C



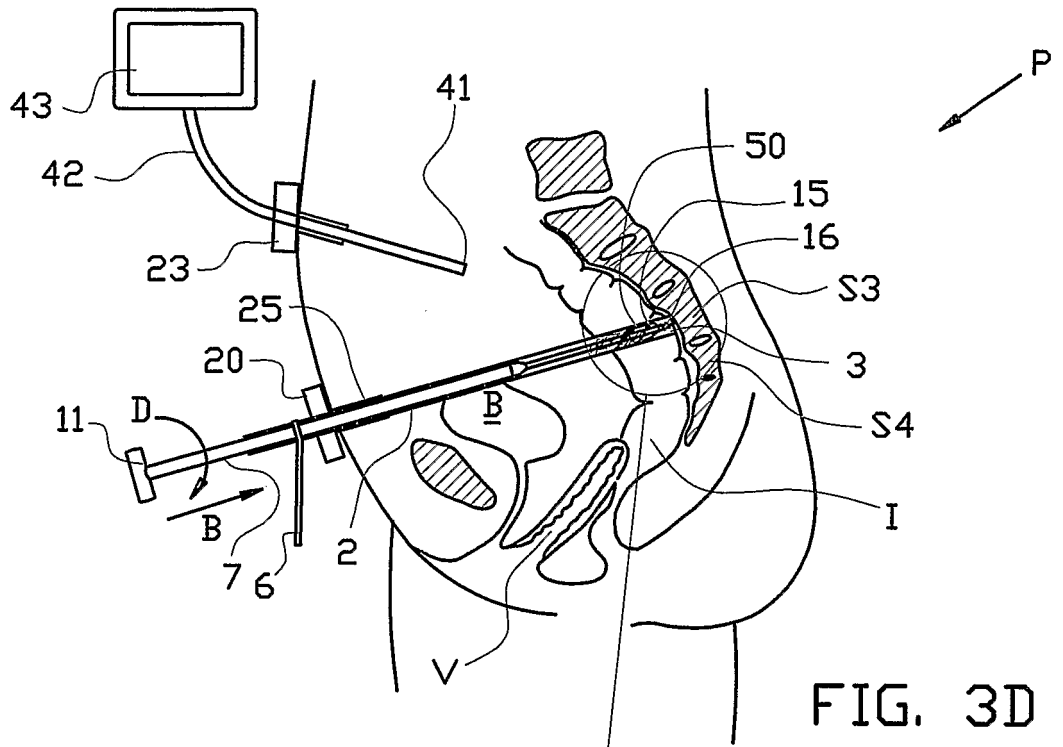
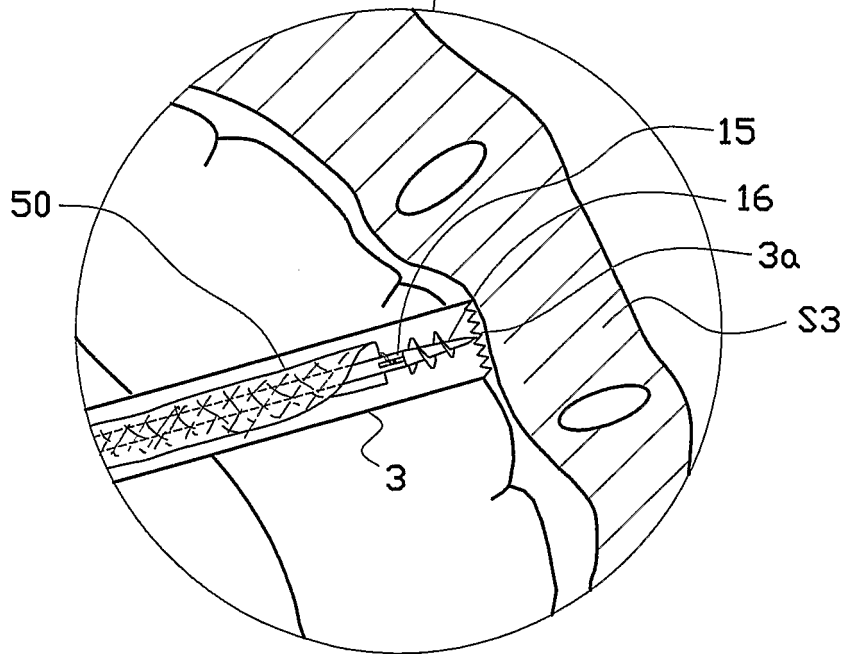
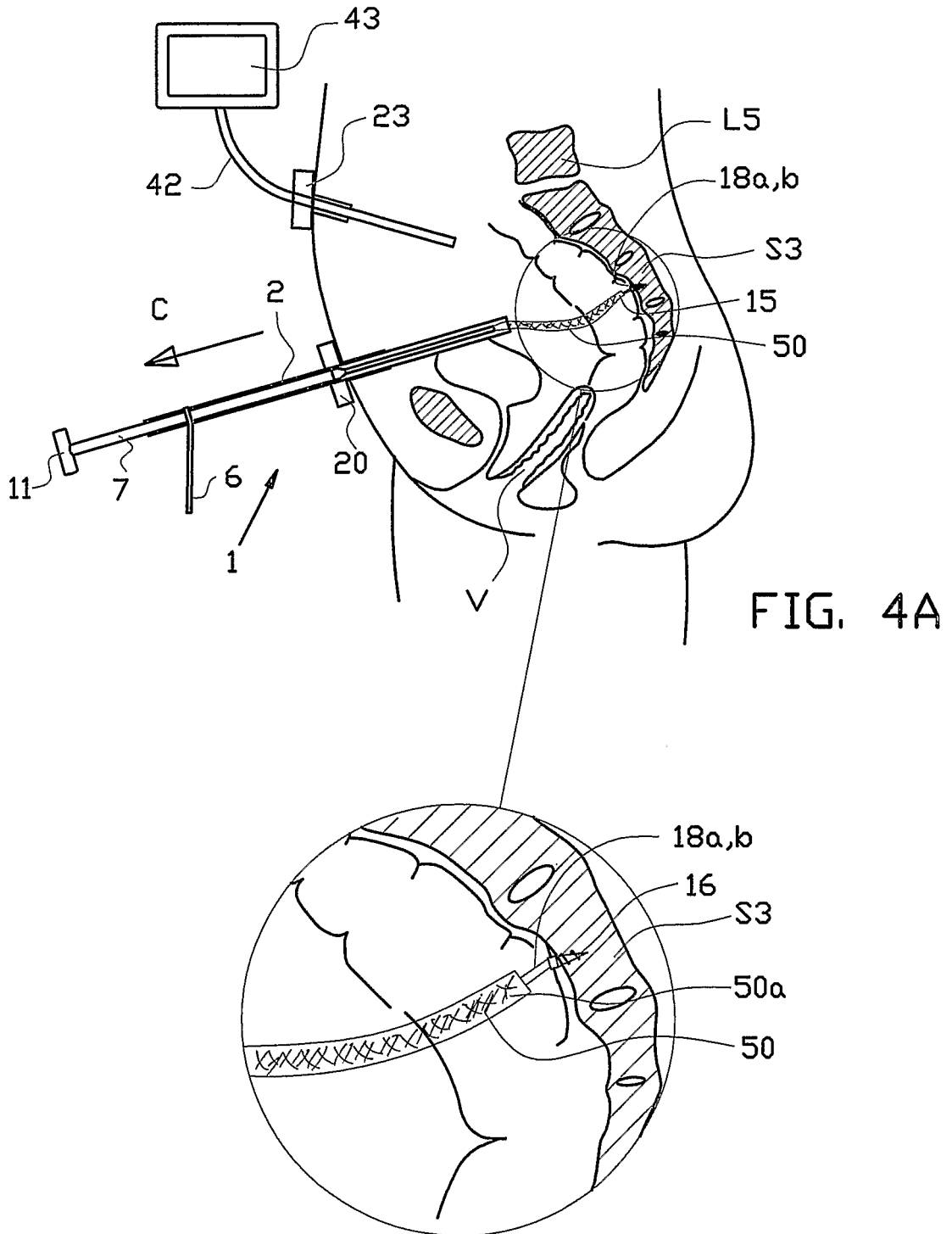


FIG. 3D





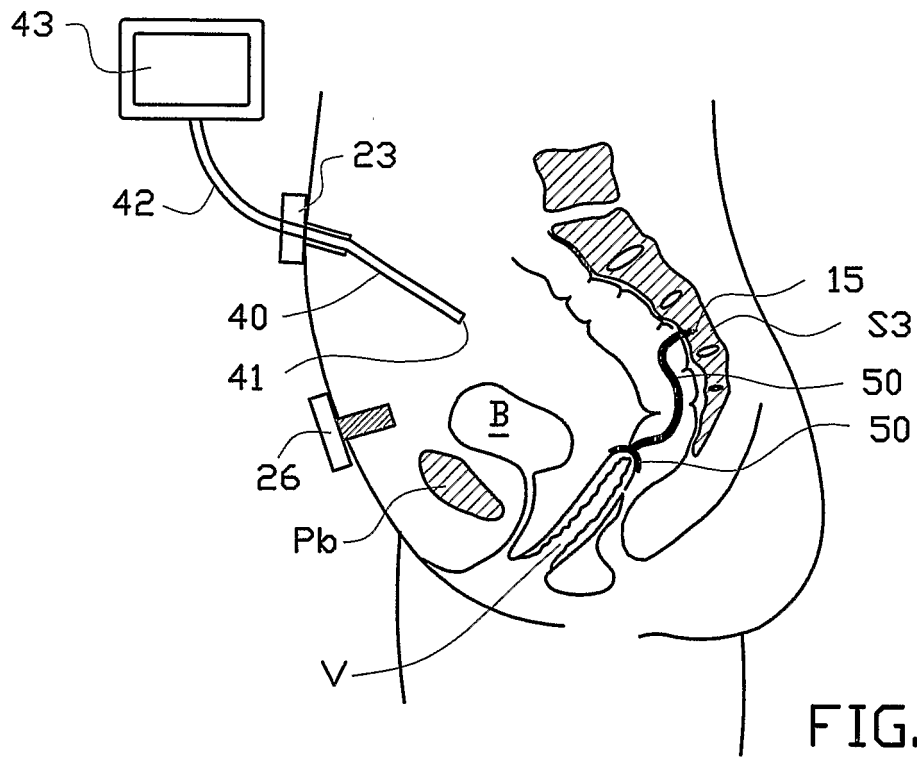


FIG. 4B

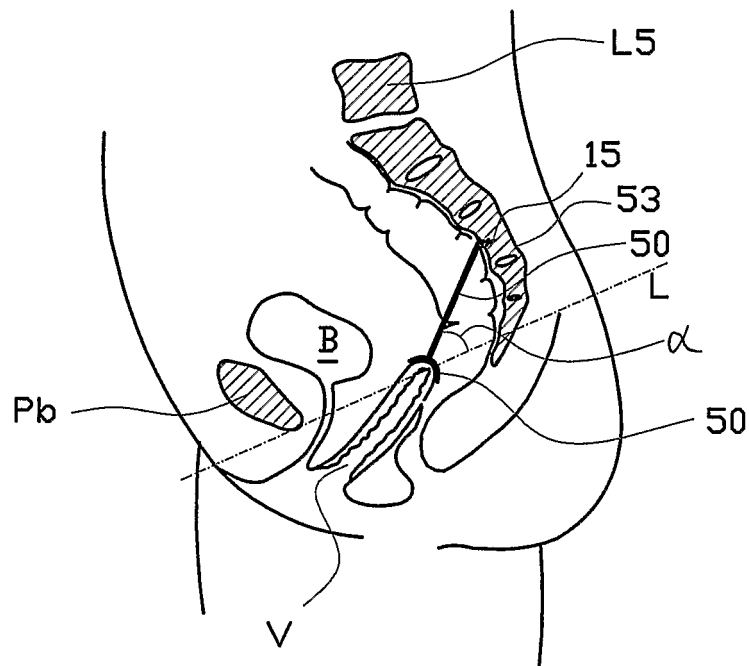


FIG. 4C

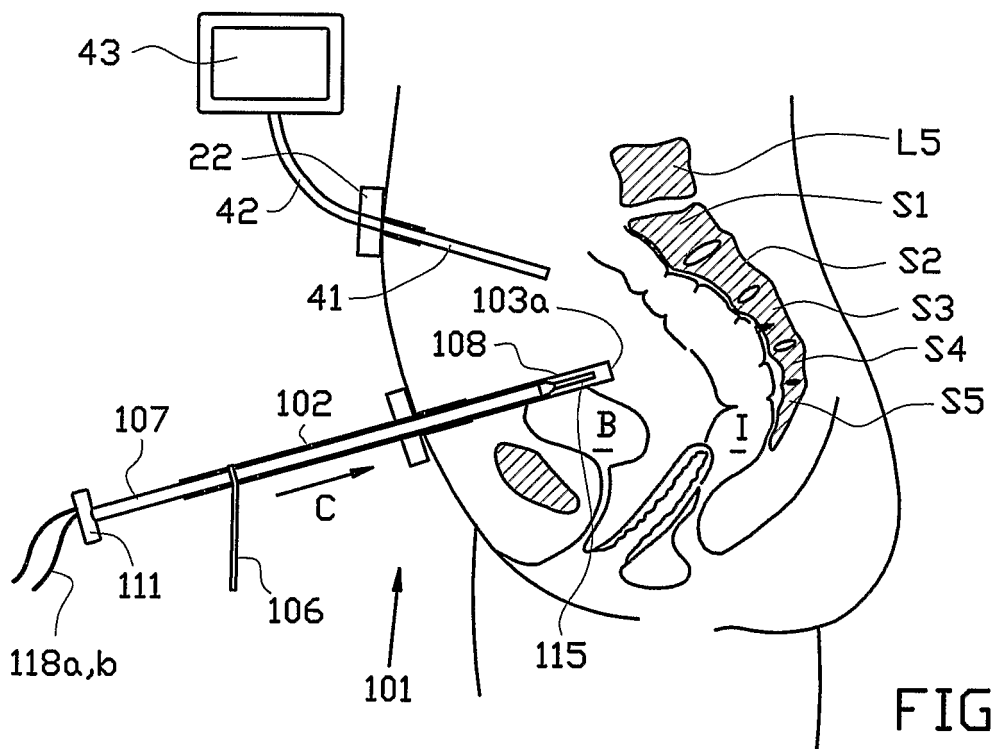
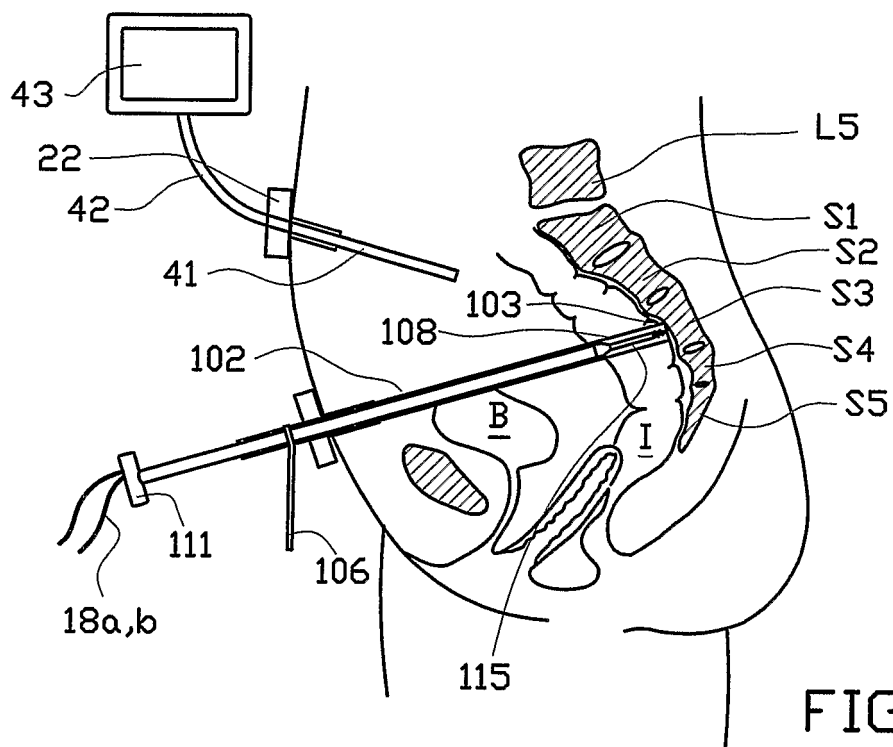
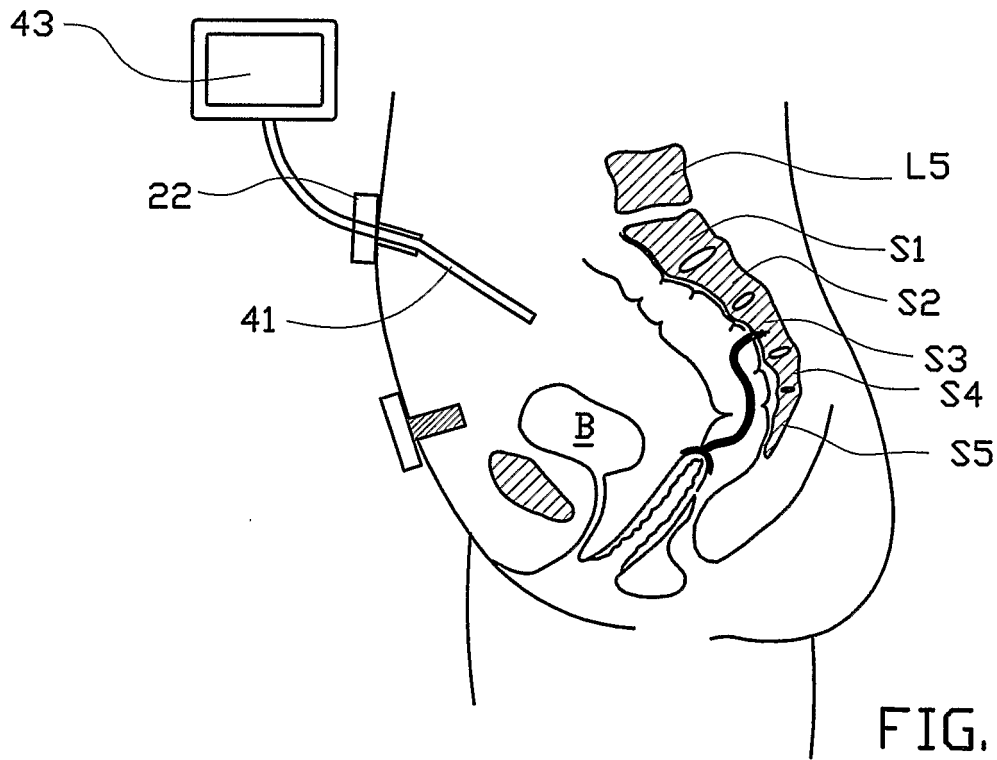
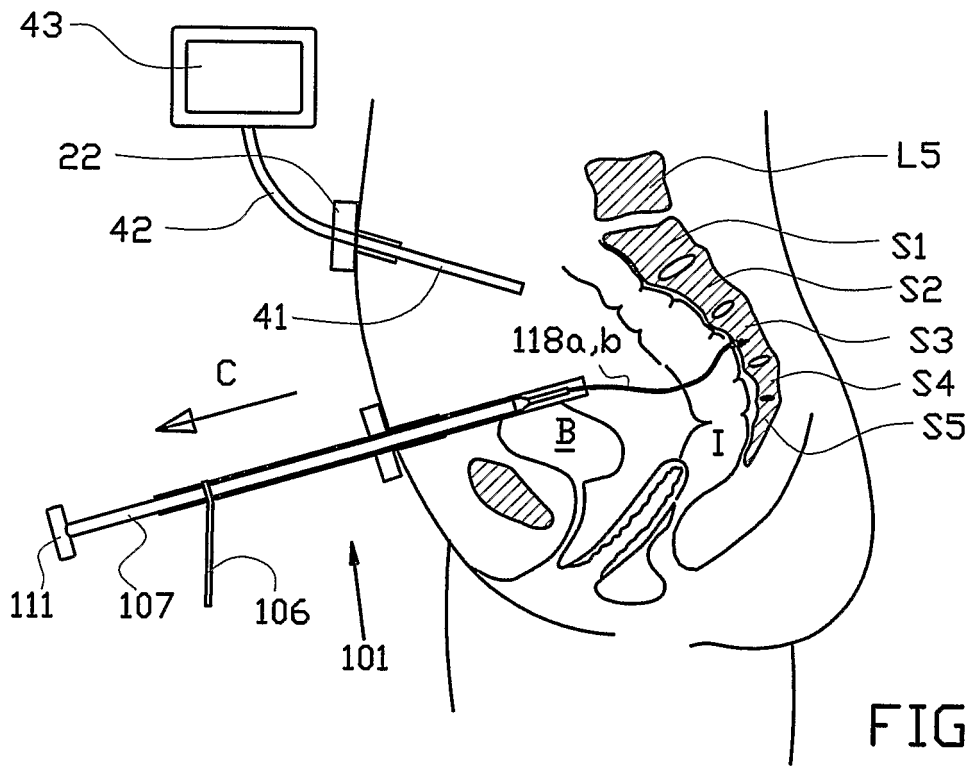


FIG. 5A





INTERNATIONAL SEARCH REPORT

Application No
PCT/NL2005/000037

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00 A61B17/04

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)
IPC 7 A61B

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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/195386 A1 (THIERFELDER CHRISTOPHER A ET AL) 16 October 2003 (2003-10-16)	1-9, 12, 16-22, 38-41, 43-45, 50, 52
Y	paragraph '0064!; figures 2,3,11 paragraph '0072! paragraph '0138! - paragraph '0145!	10, 11, 13-15, 42, 46-49
Y	US 5 954 057 A (LI ET AL) 21 September 1999 (1999-09-21) column 13, line 58 - column 14, line 10; figures 10-15 ----- -/--	10, 11, 13-15, 42, 46-49

Further documents are listed in the continuation of box C.

Patent family members are listed in 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 document 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

10 May 2005

Date of mailing of the international search report

18/05/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Moers, R

INTERNATIONAL SEARCH REPORT

 Application No
 PCT/NL2005/000037

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 5 458 608 A (WORTRICH ET AL) 17 October 1995 (1995-10-17) abstract; figure 2 -----	1,38,44
A	US 2003/078604 A1 (WALSHE CHRISTOPHER J) 24 April 2003 (2003-04-24) abstract; figure 16 -----	1,38,44
A	US 5 147 387 A (JANSEN ET AL) 15 September 1992 (1992-09-15) abstract; figure 1 -----	10,11, 13-15, 42,46-49
A	EP 0 807 415 A (OLYMPUS OPTICAL CO., LTD) 19 November 1997 (1997-11-19) figure 11b -----	17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NL2005/000037

Box 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.: 23-37, 51, 53
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
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 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 fee, this Authority did not invite payment of any additional fee.
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.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Application No

PCT/NL2005/000037

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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			JP 11076246 A	23-03-1999

专利名称(译)	用于将阴道特别地连接到脊柱的组件和方法		
公开(公告)号	EP1718215A1	公开(公告)日	2006-11-08
申请号	EP2005704567	申请日	2005-01-19
[标]申请(专利权)人(译)	范德柳条ROBERTUS M F KARL STORZ		
申请(专利权)人(译)	范柳, Robertus M. F. KARL STORZ GMBH & CO.KG		
当前申请(专利权)人(译)	范柳, Robertus M. F. KARL STORZ GMBH & CO.KG		
[标]发明人	VAN DER WEIDEN ROBERTUS M F KARL STORZ GMBH & CO KG		
发明人	VAN DER WEIDEN, ROBERTUS M. F. KARL STORZ GMBH & CO. KG		
IPC分类号	A61B17/00 A61B17/04 A61B17/34 A61B17/42		
CPC分类号	A61B17/42 A61B17/0401 A61B17/0469 A61B17/3421 A61B17/3468 A61B2017/00805 A61B2017/0409 A61B2017/0414 A61B2017/044 A61B2017/3488		
优先权	60/537027 2004-01-20 US 1026909 2004-08-25 NL		
其他公开文献	EP1718215B1		
外部链接	Espacenet		

摘要(译)

用于将患者的阴道尖端或子宫或直肠连接到她/他的脊柱的组件，包括第一管，其长度适合于从患者腹部的外壁到骶骨的距离，该第一管具有远端与骶骨接合并包括相对的近端并具有从其远端到近端的第一通道，第二管或杆的长度至少等于第一管的长度，第二管或杆设置有远端并且包括相对的近端，至少一个连接装置设置用于连接到骶骨的远端和用于连接连接装置的端部的近端，用于连接到患者的阴道尖端或子宫或直肠，例如一个或多个螺纹，其中第二管或杆的远端和连接装置的近端形成用于功能性相互接合，第二管或杆可以可移动地容纳在第一管中 - 优选地紧贴。