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(54) **Title**: ELONGATE IMPLANT SYSTEM AND METHOD FOR TREATING PELVIC CONDITIONS

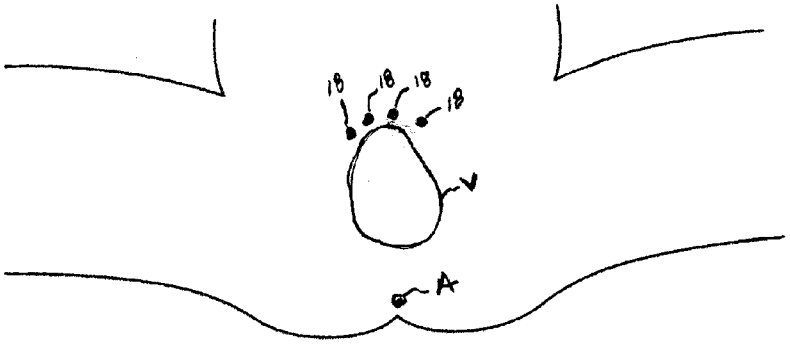

Fig. 9

(57) **Abstract**: Implant systems can include one or more needles, such as those used in pelvic floor repair procedures, and one or more elongate implants. A syringe or similar style hollow needle can be used to deliver the elongate mesh or other implant devices through one or more small stab incisions into the target tissue location inside the pelvis, proximate the vagina. The implant devices can be placed upon insertion through the incisions to engage and pull or tighten support tissue, such as the endopelvic fascia, pubocervical fascia, rectovaginal fascia, levator muscles, or other supportive muscles or tissue within the pelvis of the patient.

Elongate Implant System and Method for Treating Pelvic Conditions

Priority

This Application claims priority to and the benefit of U.S. Provisional Application No. 61/291,031, filed on December 30, 2009, which is hereby incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates generally to surgical methods and apparatus and, more specifically, to minimally invasive prolapse repair via needles, and methods for forming and using the same.

BACKGROUND OF THE INVENTION

Pelvic health for men and women is a medical area of increasing importance, at least in part due to an aging population. Examples of common pelvic ailments include incontinence (*e.g.*, fecal and urinary), pelvic tissue prolapse (*e.g.*, female vaginal prolapse), and conditions of the pelvic floor.

Urinary incontinence can further be classified as including different types, such as stress urinary incontinence (SUI), urge urinary incontinence, mixed urinary incontinence, among others. Other pelvic floor disorders include cystocele, rectocele, enterocele, and prolapse such as anal, uterine and vaginal vault prolapse. A cystocele is a hernia of the bladder, usually into the vagina and introitus. Pelvic disorders such as these can result from weakness or damage to normal pelvic support systems.

Urinary incontinence can be characterized by the loss or diminution in the ability to maintain the urethral sphincter closed as the bladder fills with urine. Male or

female stress urinary incontinence (SUI) generally occurs when the patient is physically stressed.

In its severest forms, vaginal vault prolapse can result in the distension of the vaginal apex outside of the vagina. An enterocele is a vaginal hernia in which the peritoneal sac containing a portion of the small bowel extends into the rectovaginal space. Vaginal vault prolapse and enterocele represent challenging forms of pelvic disorders for surgeons. These procedures often involve lengthy surgical procedure times.

Fecal incontinence, like urinary incontinence, has proven to be challenging to treat. Patients whose fecal incontinence is caused by external anal sphincter injury is treated surgically, as with a sphincteroplasty. Other patients are considered to have neurogenic or idiopathic fecal incontinence and efforts to treat these patients have been less successful. Various procedures, such as postanal repair, total pelvic floor repair, muscle transposition techniques, dynamic graciloplasty, artificial sphincter procedures, and sacral nerve stimulation. Success has been limited, and the various treatment modalities can result in morbidity.

There is a desire to obtain a minimally invasive yet highly effective repair devices and methods that can be used to treat incontinence (urinary or fecal), and/or organ prolapse and other pelvic conditions.

SUMMARY OF THE INVENTION

The present invention describes systems, needles and methods for treating pelvic conditions such as incontinence, vaginal prolapse (including various forms such as enterocele, cystocele, rectocele, apical or vault prolapse, uterine descent, etc.), and other pelvic conditions caused by muscle and ligament weakness.

Embodiments of the systems can include one or more needles, such as those used in pelvic floor repair procedures. A syringe or similar style hollow needle can be used to deliver elongate mesh or other implant devices through one or more small stab incisions into the target tissue location inside the pelvis. The implant devices can be placed upon insertion through the incisions to engage and pull or tighten support tissue, *e.g.*, endopelvic fascia, pubocervical fascia, rectovaginal fascia, levator muscles, or other supportive muscles or tissue within the pelvis of the patient. The devices can include one or more mesh members, rods, or braided members adapted to support the respective target tissue or organs.

The implant devices can engage, pull or otherwise tension tissue to cause the tissue to tighten and provide slack reduction for improved support. As such, embodiments of the implants can be utilized to eliminate the need for mesh or other supportive structures under the urethra that is common with incontinence slings.

The present invention can include surgical instruments, implantable articles, and methods for urological applications, particularly for the treatment of stress and/or urge urinary incontinence, fecal incontinence, and prolapse and perineal floor repairs. As noted, the usual treatments for incontinence include placing a sling to either compress the urethral sphincter or to elevate or support the neck of the bladder defects.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a cross-sectional schematic view of various relevant structures of the female anatomy in accordance with implantation of the present invention.

Fig. 2 shows a delivery tool in accordance with embodiments of the present invention.

Figs. 3-6 show exemplary elongate implants in accordance with embodiments of the present invention.

Fig. 7 shows a female patient and relevant anatomical structure.

Fig. 8 shows a female patient with an expanded vagina in preparation for implantation in accordance with embodiments of the present invention.

Figs. 9-11 show implantation of elongate implants within stab incisions in accordance with embodiments of the present invention.

Fig. 12 shows a cross-section schematic view of various relevant anatomical structures and deployed elongate implants in accordance with embodiments of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring generally to Figs. 1-12, various embodiments of pelvic repair systems 10 are disclosed. One aspect of the present invention is an apparatus and method of treating urinary incontinence in males or females. In various embodiments, one or more implants or implant members are placed in strategically located positions to pull up or otherwise tighten tissue and/or muscle lateral to the urethra, or anterior or posterior to the vagina, to generally re-establish the original anatomical structure of the patient.

Structures or portions of the various embodiments detailed herein can be constructed of materials such as polypropylene, polyglycolide, poly-l-lactides, or other known biodegradable (re-absorbable) or non-biodegradable polymers. Further, growth factors or stem cells can be seeded or otherwise provided with one or more of

the components of the devices to facilitate healing or tissue in-growth. In addition to introduction and deployment of the devices or components with a needle introducer device, a cannula or catheter system can be utilized as well.

Fig. 1 shows the general anatomical structure of the female anatomy, including the Urethra U, Vagina V, and Anus A.

The systems 10 can include one or more syringe or needle devices 12, as shown in Fig. 2. The needle devices 12 can include a hollow needle portion 14 and a handle portion 16. The need portion 14 can include an internal lumen adapted to receive, deploy and release one or more implants 18. The hollow needle portion 14 can include a distal tip 20 adapted to create and traverse one or more small stab incisions proximate (*e.g.*, anterior or posterior) the Vagina V. The needle portion 14 can be straight, curved or helical. Further, the device 12 can include one or more actuation or trigger mechanisms adapted to selectively retain or deploy one or more implants 18 from the device 12 (*e.g.*, needle lumen).

The distal tip 20 and at least a portion of the needle portion 14 are adapted for insertion to create and traversal into the stab incisions into the target tissue location inside the pelvis of the patient. The various systems 10, implants, tools, features and methods detailed herein are envisioned for use with or can utilize all or part of the known implant and repair systems (*e.g.*, for male and female), features and methods, including those disclosed in U.S. Patent Nos. 7,267,645, 7,500,945, 7,229,453, 7,407,480, 7,393,320, 7,351,197, 7,347,812, 7,303,525, 7,291,104, 7,025,063, 6,691,711, 6,648,921, 6,612,977, 6,592,515, and International Patent Publication Nos. WO 2010/027796, WO 2008/057261 and WO 2007/097994, and U.S. Patent Publication Nos. 2002/151762 and 2002/147382. Accordingly, the above-identified

disclosures and publications are fully incorporated herein by reference in their entirety.

Figs. 3-6 show various exemplary embodiments of the implants 18. Generally, the implants are constructed in an elongate or rod-shaped construct. The implants 18 can be shaped, constructed or formed as elongate mesh strips (Fig. 6), elongate rods (Fig. 5), or braided rods (Fig. 3). Further, various embodiments of the implants 18 can include one or more end anchors 22 to facilitate tissue engagement and retention during deployment and positioning. In addition, portions of the implants 18 can include extending members, protrusions, barbs, tines, surface roughness, surface edges or like features to facilitate tissue fixation of the implant 18 upon deployment.

As shown in Figs. 7-12, various available steps or procedures for the pelvic repair system 10 are depicted. First, the patient is placed in the supine position, as shown in Fig. 7. The vagina V is then expanded, as demonstrated in Fig. 8. Various known tools, retractors, balloons or like devices and procedures can be utilized to achieve this vaginal expansion.

One or more of the needle devices 12 are provided for external penetration or stab incisions proximate or along the periphery of the vagina V. Alternatively, the stab incisions can be first made by the physician with a surgical tool and then the needle devices 12 can be introduced to deploy the needle 14 and implants 18 through the one or more stab incisions.

Next, the needle device 12 can be inserted through the one or more incisions to deploy the implant 18 (*e.g.*, mesh, rod, braided material, or a like implant) into and from the inner lumen of the needle 14. Then, while holding the implant 18 in place, the hollow tube needle 14 is extracted to leave the implant 18 in place for pelvic floor

support. A number of these steps can be repeated until the desired number of needles or implants are deployed, or the desired support is achieved. The configurations of the present invention provide a system adapted to control the depth of the implant to provide consistency and optimal placement. Further, the distal tip 20 or needle 14, and the implant 18, are adapted to penetrate target tissue or anatomical structure within the pelvis, around the vagina V to provide the desired engagement and tissue support to address the incontinence or prolapse weaknesses.

In certain embodiments, the needle 14 is adapted for insertion through the stab incisions such that the implants 18 can be inserted into or otherwise engaged with internal support tissue around the vagina, urethra and the like, *e.g.*, pubocervical fascia, rectovaginal fascia, endopelvic fascia, levator muscles, just to name a few. As shown in Figs. 9-11, the spacing, placement and pattern for deploying implants 18 can vary greatly. Various anterior patterned (relative to vagina) and positioned implants 18 are shown in Figs. 9 and 11. Fig. 10 shows an exemplary posterior pattern and positioning for the implants 18. The quantity, positioning and incision points for the implants 18 shown in the figures are merely for demonstrative purposes and a myriad of other patterns and implant numbers are envisioned for the present invention. Fig. 12 demonstrates various exemplary implants 18 deployed and engaged within the patient to provide the desired support and tensioning of the present invention. The implants 18 can extend into the pelvic region or target engagement tissue a full length of the relative organ or lumen (*e.g.*, urethra U or vagina V), or along a distance short of the entire organ or lumen length.

Embodiments of the present invention provide key advantages over conventional methods and systems, including controlled implant depth to reduce implant variation, reduced risk of extrusion or erosion, reduced recovery time because

of the lack of large incisions, blunt dissections, sutures, and the like. Various portions of the systems 10 can be constructed of known or compatible polymer or metal materials (*e.g.*, Nitinol).

Alternative embodiments of the present invention can be used to restore levator ani structures to provide further support. Use of the system to restore or support other anatomical structures are envisioned as well. Further, guided catheter tools or systems, magnetically guided sensors and tools, and other known devices and delivery systems can be employed with the present invention as well.

All patents, patent applications, and publications cited herein are hereby incorporated by reference in their entirety as if individually incorporated, and include those references incorporated within the identified patents, patent applications and publications.

Obviously, numerous modifications and variations of the present invention are possible in light of the teachings herein. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced other than as specifically described herein.

CLAIMS

1. A pelvic floor repair system, comprising:

a needle delivery tool having a handle portion and a needle portion, wherein the needle portion includes an internal lumen;

one or more elongate implants adapted to at least partially insert within and deploy from the internal lumen of the needle portion; and

wherein a distal portion of the needle portion is adapted for insertion through one or more stab incisions proximate the vagina of a patient such that that the one or more elongate implant is engaged within the pelvic region of the patient to tissue proximate the vagina to generally maintain the tissue in its correct anatomical position to treat a pelvic floor disorder.

2. The system of claim 1, wherein the one or more elongate implants includes one or more elongate mesh implants.

3. The system of claim 1, wherein the one or more elongate implants includes one or more elongate rod implants.

4. The system of claim 1, wherein the one or more elongate implants includes one or more elongate braided implants.

5. The system of claim 1, wherein the one or more stab incisions are provided anterior to the vagina of the patient.

6. The system of claim 1, wherein the one or more stab incisions are provided posterior to the vagina of the patient.

7. The system of claim 1, wherein the one or more implants includes at least one end tissue anchor.

8. The system of claim 1, wherein the one or more implants are adapted to engage with tissue selected from the group consisting of: pubocervical fascia, rectovaginal fascia and levator muscles.

9. The system of claim 1, wherein the one or more implants includes at least three implants.

10. An implant system for treating pelvic disorders, comprising:

at least one needle delivery tool having a handle portion and a needle portion, wherein the needle portion includes an internal lumen;

a plurality of elongate implants adapted to at least partially insert within and deploy from the internal lumen of the needle portion; and

wherein a distal portion of the needle portion is adapted for insertion through a plurality of stab incisions proximate the vagina of a patient such that that the plurality of implants are deployed within respect stab incisions for internal tissue fixation proximate the vagina to generally maintain the tissue in its correct anatomical position.

11. The system of claim 10, wherein the plurality of elongate implants includes a plurality of elongate mesh implants.

12. The system of claim 10, wherein the plurality of elongate implants includes a plurality of elongate rod implants.

13. The system of claim 10, wherein the plurality of elongate implants includes a plurality of elongate braided implants.

14. The system of claim 10, wherein the plurality of stab incisions are provided anterior to the vagina of the patient.

15. The system of claim 10, wherein the plurality of stab incisions are provided posterior to the vagina of the patient.

16. The system of claim 10, wherein the plurality of implants include at least one end tissue anchor.

17. The system of claim 10, wherein at least one of the plurality of implants is adapted to engage with tissue selected from the group consisting of: pubocervical fascia, rectovaginal fascia and levator muscles.

18. A method of treating a pelvic disorder in a patient, comprising:

providing a delivery tool having a handle portion and a needle portion, wherein the needle portion includes an internal lumen;

providing a plurality of elongate implants;

making a plurality of stab incisions in the patient proximate the vagina;

providing at least one of the plurality of elongate implants within the internal lumen of the needle portion of the delivery tool;

inserting at least a portion of the needle portion within at least one of the plurality of stab incisions;

deploying at least one of the plurality of elongate implants within at least one of the plurality of stab incisions for fixation to internal tissue proximate the vagina; and

removing the inserted portion of the needle portion from the at least one of the plurality of stab incisions.

19. The method of claim 18, wherein making a plurality of stab incisions includes making a plurality of stab incisions anterior to the vagina.

20. The method of claim 18, wherein making a plurality of stab incisions includes making a plurality of stab incisions posterior to the vagina.

21. The method of claim 18, wherein providing a plurality of elongate implants includes providing a plurality of elongate mesh implants.

22. The method of claim 18, wherein providing a plurality of elongate implants includes providing a plurality of elongate rod implants.

23. The method of claim 18, wherein providing a plurality of elongate implants includes providing a plurality of elongate implants having one or more end tissue anchors.

AMENDED CLAIMS
received by the International Bureau on 11 May 2011 (11.05.2011)

CLAIMS

1. A pelvic floor repair system, comprising:

a needle delivery tool having a handle portion and a needle portion, wherein the needle portion includes an internal lumen;

one or more elongate implants adapted to at least partially insert within and deploy from the internal lumen of the needle portion; and

wherein a distal portion of the needle portion is adapted for insertion through one or more external stab incisions proximate and about the periphery of the vagina of a patient such that that the one or more elongate implant is inserted through the one or more external stab incisions and engaged within the pelvic region of the patient to tissue proximate the vagina to generally maintain the tissue in its correct anatomical position to treat a pelvic floor disorder.

2. The system of claim 1, wherein the one or more elongate implants includes one or more elongate mesh implants.

3. The system of claim 1, wherein the one or more elongate implants includes one or more elongate rod implants.

4. The system of claim 1, wherein the one or more elongate implants includes one or more elongate braided implants.

5. The system of claim 1, wherein the one or more stab incisions are provided anterior to the vagina of the patient.

6. The system of claim 1, wherein the one or more stab incisions are provided posterior to the vagina of the patient.

7. The system of claim 1, wherein the one or more implants includes at least one end tissue anchor.

8. The system of claim 1, wherein the one or more implants are adapted to engage with tissue selected from the group consisting of: pubocervical fascia, rectovaginal fascia and levator muscles.

9. The system of claim 1, wherein the one or more implants includes at least three implants.

10. An implant system for treating pelvic disorders, comprising:

at least one needle delivery tool having a handle portion and a needle portion, wherein the needle portion includes an internal lumen;

a plurality of elongate implants adapted to at least partially insert within and deploy from the internal lumen of the needle portion; and

wherein a distal portion of the needle portion is adapted for insertion through a plurality of external stab incisions proximate the vagina of a patient such that that the plurality of implants are deployed through respective external stab incisions for internal tissue fixation proximate the vagina to generally maintain the tissue in its correct anatomical position.

11. The system of claim 10, wherein the plurality of elongate implants includes a plurality of elongate mesh implants.

12. The system of claim 10, wherein the plurality of elongate implants includes a plurality of elongate rod implants.

13. The system of claim 10, wherein the plurality of elongate implants includes a plurality of elongate braided implants.

14. The system of claim 10, wherein the plurality of stab incisions are provided anterior to the vagina of the patient.

15. The system of claim 10, wherein the plurality of stab incisions are provided posterior to the vagina of the patient.

16. The system of claim 10, wherein the plurality of implants include at least one end tissue anchor.

17. The system of claim 10, wherein at least one of the plurality of implants is adapted to engage with tissue selected from the group consisting of: pubocervical fascia, rectovaginal fascia and levator muscles.

18. A method of treating a pelvic disorder in a patient, comprising:

providing a delivery tool having a handle portion and a needle portion, wherein the needle portion includes an internal lumen;

providing a plurality of elongate implants;

making a plurality of external stab incisions in the patient proximate the vagina;

providing at least one of the plurality of elongate implants within the internal lumen of the needle portion of the delivery tool;

inserting at least a portion of the needle portion through at least one of the plurality of external stab incisions;

deploying at least one of the plurality of elongate implants within at least one of the plurality of external stab incisions for fixation to internal tissue proximate the vagina; and

removing the inserted portion of the needle portion from the at least one of the plurality of external stab incisions.

19. The method of claim 18, wherein making a plurality of stab incisions includes making a plurality of stab incisions anterior to the vagina.

20. The method of claim 18, wherein making a plurality of stab incisions includes making a plurality of stab incisions posterior to the vagina.

21. The method of claim 18, wherein providing a plurality of elongate implants includes providing a plurality of elongate mesh implants.

22. The method of claim 18, wherein providing a plurality of elongate implants includes providing a plurality of elongate rod implants.

23. The method of claim 18, wherein providing a plurality of elongate implants includes providing a plurality of elongate implants having one or more end tissue anchors.

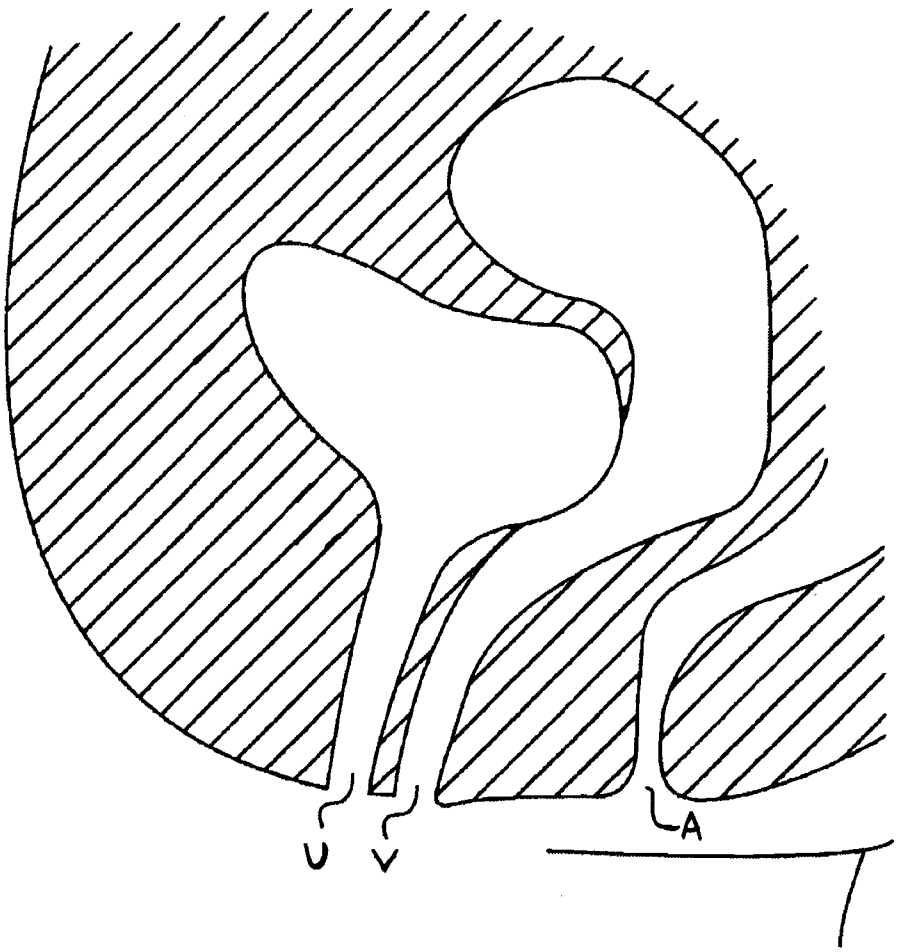

Fig. 1

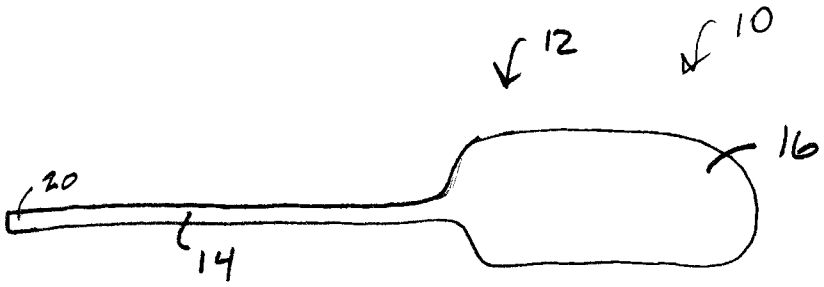

Fig. 2

Fig. 3

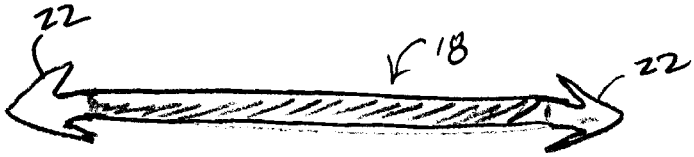

Fig. 4

Fig. 5

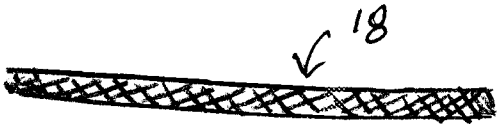

Fig. 6

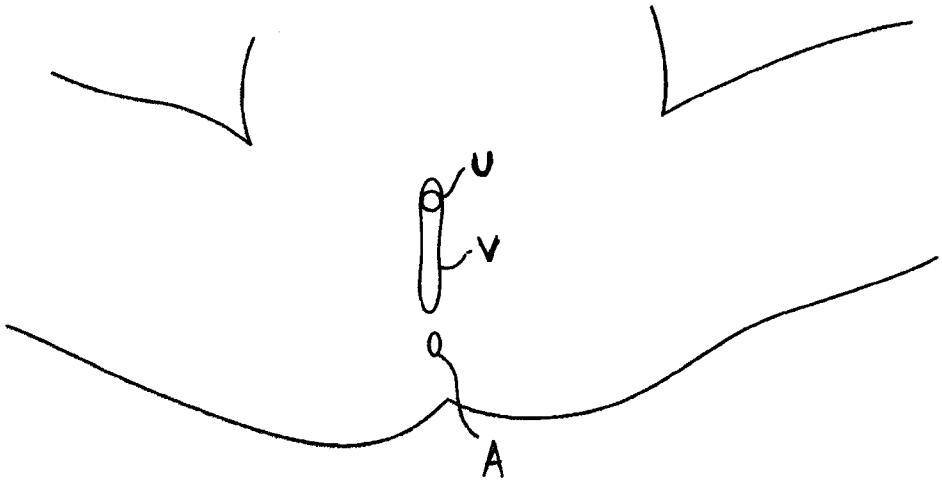

Fig. 7

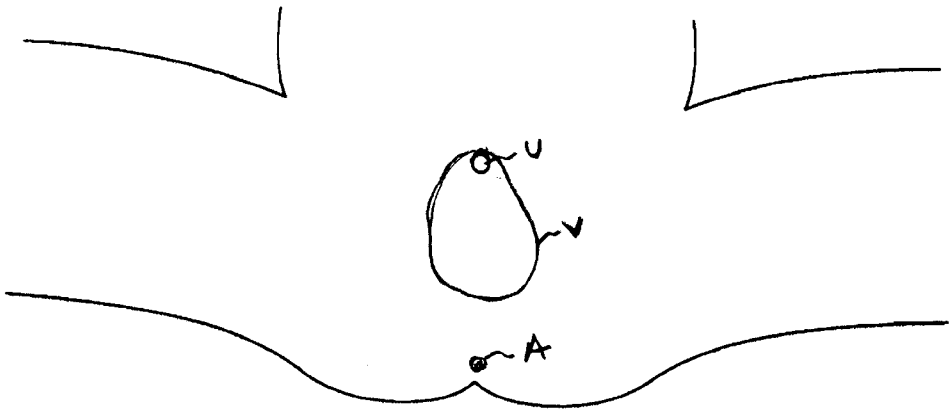

Fig. 8

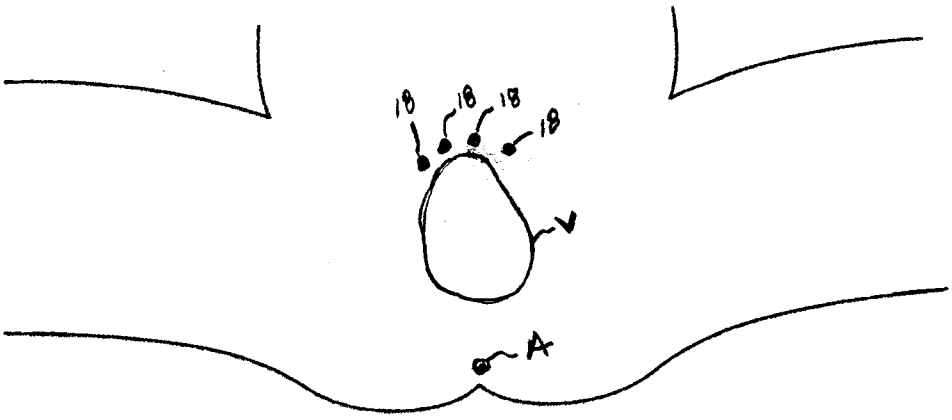

Fig. 9

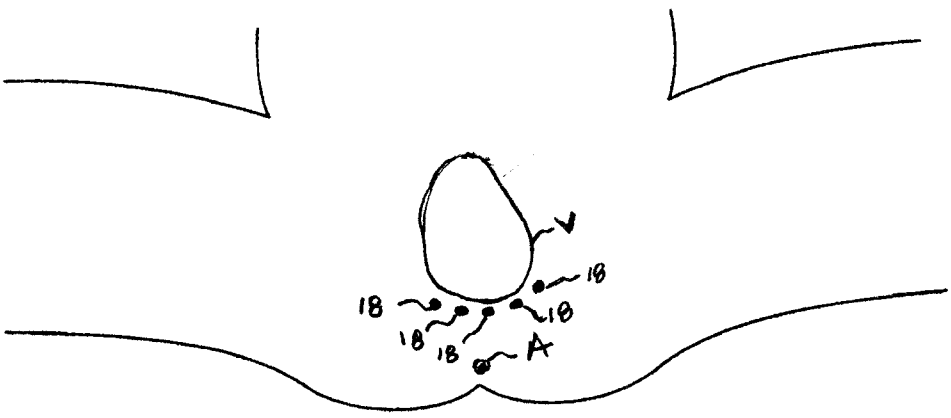

Fig. 10

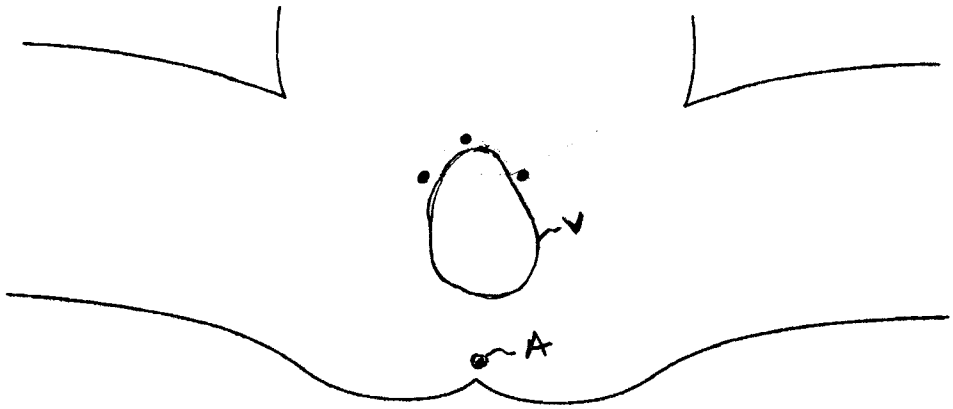

Fig. 11

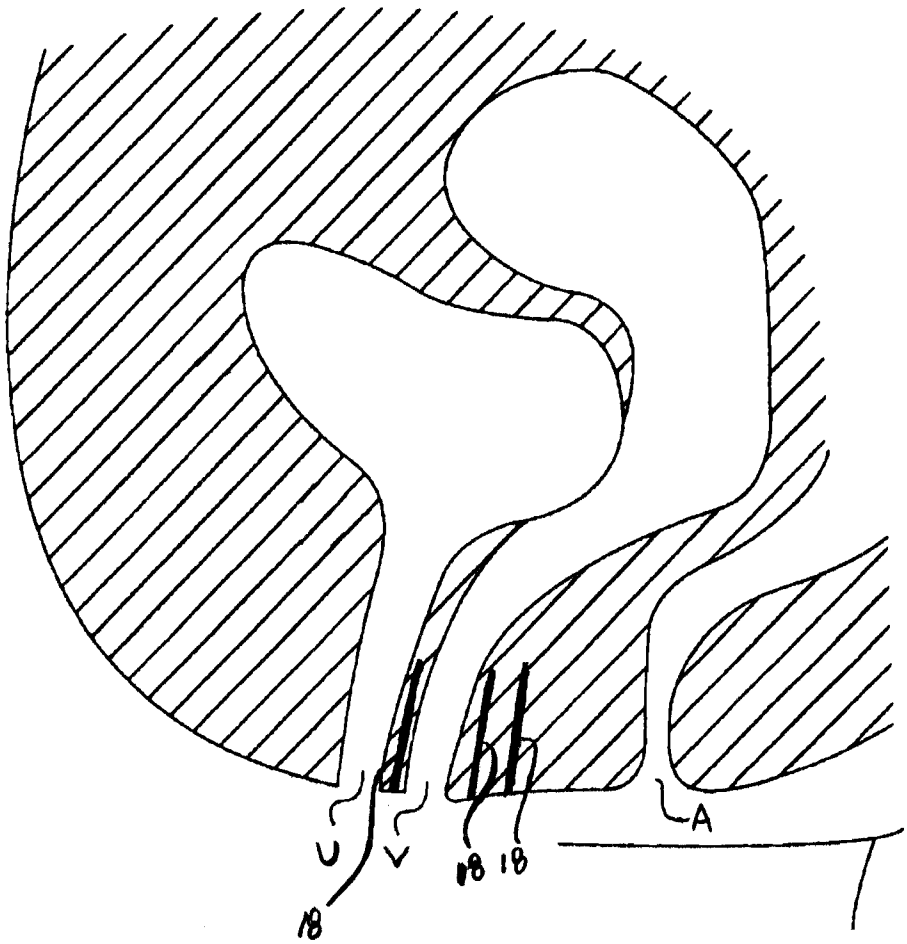

Fig. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/062342

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/00 (2011.01)
USPC - 600/30
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(8) - A61B 17/04; A61F 2/00, 2/02 (2011.01)
USPC - 600/30

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)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	WO 2007/097994 A2 (AMS RESEARCH CORPORATION) 30 August 2007 (30.08.2007) entire document	1-4, 7-13, 16-18, 21-23 ---------- 5-6, 14-15, 19-20
Y	US 7,407,480 B2 (STASKIN et al) 05 August 2008 (05.08.2008) entire document	5-6, 14-15, 19-20
A	US 6,612,977 B2 (STASKIN et al) 02 September 2003 (02.09.2003) entire document	1-23

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"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	Date of mailing of the international search report
14 February 2011	11 MAR 2011
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