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Declarations under Rule 4.17:

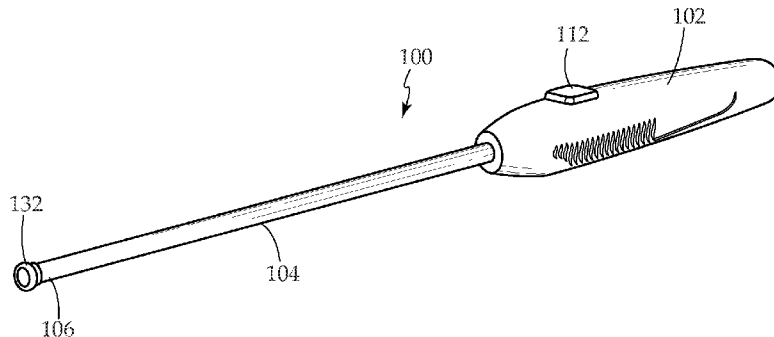
- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
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(54) **Title:** ANCHOR TIP ORIENTATION DEVICE AND METHOD

FIG. 1



(57) **Abstract:** A surgical device for inserting an anchor, including a handle having an actuator, an outer barrel shaft extending from the handle to a distal end and having a channel therethrough, and an outer barrel tip the distal end thereof having an elastomeric septum, a drive pin within the channel, and an implantable anchor removably coupled to the drive pin. The outer barrel shaft is coupled to an actuator for movement between a first extended position wherein the outer barrel shaft tip substantially cover the anchor, and a second retracted position where the outer barrel shaft tip do not cover the anchor. When the shaft is in the first position, the elastomeric septum of the outer barrel tip circumferentially surrounds and engages the anchor to thereby stabilize the anchor prior to deployment, and when the shaft is in the second position, the elastomeric septum does not engage the anchor.



ANCHOR TIP ORIENTATION DEVICE AND METHOD

Field of the Invention

The present invention relates generally to the field of medical devices and instruments, and more particularly to devices and methods for inserting implantable anchors
5 during surgical procedures.

Background

Many different surgical procedures require implantation of anchors and the like for various reasons. For example, some hernia repairs utilize anchors of some type to hold a hernia repair mesh in place during healing. Another example is vaginal vault prolapsed
10 repair, where the vaginal cuff is attached or otherwise secured to tissue within the pelvic cavity, such as the sacrospinous ligament. In one described method for such repairs, the vaginal cuff is secured to the sacrospinous ligament using two surgical anchors that are inserted through the vaginal cuff and ligament using a suitable instrument, with trailing sutures tied together within the vagina.

15 With this procedure as with many others, proper orientation of the anchor can be critical during implantation. Without proper orientation, the anchor may not deploy properly and may not adequately hold the tissue. The delivery device or instrument must be able to contact and possibly manipulate the tissue prior to deployment of the anchor, all without altering the positioning of the anchor relative to the instrument. This is of particular
20 importance during blind procedures where the surgeon cannot verify relative positioning prior to implantation. If the orientation changes, the tissue penetrating end may not be aligned properly, requiring unacceptably high tissue penetration forces and/or less than optimal tissue grasping ability. Further, once the tip of the anchor does penetrate the desired tissue plane(s), it must be effectively uncoupled from the delivery device so that it remains in
25 place as the delivery device is retracted from the tissue.

Accordingly, what is needed is an improved device and method for ensuring that proper positioning of an anchor or the like relative to an inserter can be maintained during implantation of the anchor.

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Summary of the Invention

A surgical device for inserting an implantable anchor is provided having a handle including an actuator, an outer barrel shaft extending outwardly from the handle to a distal end and having a channel extending therethrough, a outer barrel tip positioned at the distal end of the outer barrel shaft and having an elastomeric septum therein, a drive pin longitudinally aligned with and positioned within the outer barrel shaft channel, and an implantable anchor removably coupled to a distal end of the drive pin. The outer barrel shaft is coupled to the actuator for movement between a first extended position wherein the outer barrel shaft and outer barrel tip substantially cover the anchor, and a second retracted position where the outer barrel shaft and outer barrel tip do not cover the anchor. When the shaft is in the first position, the elastomeric septum of the outer barrel tip circumferentially surrounds and engages the anchor to thereby stabilize the anchor prior to deployment, and when the shaft is in the second position, the elastomeric septum does not engage the anchor.

In one embodiment the anchor has a tissue penetrating distal end, and may further include a filamentary element coupled to and extending from the anchor. The anchor and filamentary element may be made of an absorbable, biocompatible material, such as polydioxanone.

In yet another embodiment, the anchor has a bore extending therein from a proximal end, with the bore being sized and shaped so as to receive therein and form an interference fit with a distal end of said drive pin.

Also provided is a surgical anchor introducer having a handle, an outer barrel extending outwardly from said handle to a distal tip and having a channel extending therethrough, an elastomeric septum positioned within the distal tip of the outer barrel, an elongated drive pin positioned within the outer barrel, and an implantable anchor coupled to a distal end of the drive pin. The outer barrel shaft is movable relative to the drive pin and anchor between a first position where the outer barrel shaft substantially covers the anchor, and a second position where the outer barrel shaft does not cover the anchor. When the shaft is in the first position, the elastomeric septum circumferentially surrounds and engages the anchor to thereby stabilize the anchor prior to deployment, and when the shaft is in the second position, the elastomeric septum does not engage the anchor.

The anchor may further include a tissue penetrating distal end, and a filamentary element may further be coupled to and extend from the anchor. The anchor and filamentary element may be comprised of an absorbable, biocompatible material, such as polydioxanone.

5 In yet another embodiment, the anchor has a bore extending therein from a proximal end, with the bore being sized and shaped so as to receive therein and form an interference fit with a distal end of said drive pin

The outer barrel may be movable between an extended position in the first position and a retracted position in the second position, and may be so movable by an actuator button coupled thereto and positioned on the handle.

10 In yet another embodiment, the drive pin may be movable between a retracted position in the first position and an extended position in the second position, and may be so movable by an actuator button coupled thereto and positioned on the handle.

The elastomeric septum may be positioned within an outer barrel tip located at the distal end of the outer barrel.

15 Also provided is a surgical anchor introducer including a handle, an outer barrel extending outwardly from said handle to a distal tip and having a channel extending therethrough, an elastomeric septum positioned within the distal tip of the outer barrel, an elongated drive pin positioned within the outer barrel, an implantable anchor coupled to a distal end of the drive pin, and a means for moving the outer barrel shaft relative to the drive
20 pin and anchor between a first position wherein the outer barrel shaft substantially covers the anchor, and a second position where the outer barrel shaft does not cover the anchor. When the shaft is in the first position, the elastomeric septum circumferentially surrounds and engages the anchor to thereby stabilize the anchor prior to deployment, and when the shaft is in the second position, the elastomeric septum does not engage the anchor.

25 These and other objects, features and advantages of the present invention will be apparent from the following detailed description of illustrative embodiments thereof, which is to be read in connection with the accompanying drawings.

Brief Description of the Drawings

Fig. 1 illustrates one embodiment of an insertion device according to the present invention;

5 Figs. 2a and 2b are side views of the insertion device of Fig. 1 in the retracted and extended positions respectively;

Fig. 3 is an enlarged, cross-sectional view of the distal end of the insertion device of Fig. 1;

Fig. 4 is an enlarged, perspective view of the distal end of the insertion device of Fig. 1;

10 Fig. 5 illustrates how the anchor is mounted on the drive pin within the insertion device of Fig. 1;

Fig. 6 is a sectional view of Fig. 5; and

Figs. 7a-7d illustrate selected steps for using the device of Fig. 1 in an exemplary surgical procedure.

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Detailed Description

The insertion device according to the present invention includes a handle 102, and an outer barrel 104 extending outwardly therefrom to a distal end 106. As is best seen in Fig. 3, positioned within the outer barrel 104 is an elongated drive pin 110 with an implantable surgical anchor 116 mounted on its distal end 114. As will be described in further detail below, the outer barrel 104 is movable relative to the drive pin 110 by actuation of button 112 between a first position where the anchor is covered by the outer barrel and outer barrel tip 132 as shown in Fig. 2a, and a second position where the anchor extends distally beyond, and is not covered by, the outer barrel and outer barrel tip as shown in Fig. 2b. Although the outer barrel and outer barrel tip in the illustrated embodiment are separate components, it is to be understood that these elements may also be integrally formed. A channel 118 extending inwardly from the proximal end 120 of the anchor is configured to fit over the distal end 114 of the drive pin as shown in Fig. 6. The channel 118 and distal end 114 of the drive pin are sized and shaped so as to form an interference fit. The distal end 122 of the anchor is tapered, preferably sufficiently to form a tissue penetrating distal end. In the illustrated embodiment, a filamentary element 124 including a distal, bulbous end 126 also is coupled to and extends from the anchor. The filamentary element 124 passes through a second channel

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128 extending laterally through the anchor, with the bulbous end of the filamentary element being seated within a larger portion 130 of the channel as shown to thereby prevent the filamentary element from being pulled free from the anchor.

In a preferred embodiment, the anchor is comprised of a size 0 absorbable,
5 biocompatible material such as polydioxanone (PDS). The anchor is approximately 0.299-0.385 inches in length with a maximum outer diameter of approximately 0.080-0.100 inches, and the channel 118 is approximately 0.035 inches in diameter and 0.099-0.137 inches in length. The distal end of the corresponding drive pin preferably has an outer diameter of approximately 0.035 +/- 0.005 inches so as to form an interference fit, but not so tight as to
10 impede release of the anchor from the drive pin during implantation. The filamentary element 124 is preferably an absorbable, biocompatible material such as polydioxanone, or any other suitable suture material.

As indicated previously, maintaining the positioning of the anchor 116 relative to the drive pin 110 can be critical when trying to implant the anchor. Often the device must be
15 manipulated within the body to ensure implantation of the anchor in the right location. Further, the filamentary element 124 that extends from the anchor remains under slight tension. The frictional fit between the anchor and the distal end of the drive bore is insufficient to prevent the anchor from loosening or becoming slightly askew during manipulation of the delivery device. When out of position, the anchor will not drive straight
20 into tissue as intended when deployed. In some cases, the anchor will turn and jam or break during deployment. Further, if the frictional engagement is too great, deployment of the anchor may become difficult if not impossible.

In order to further stabilize positioning of the anchor prior to implantation, the present invention further includes an outer barrel tip 132 at the distal end of the insertion device. The
25 outer barrel tip extends circumferentially around the distal end 106 of the outer barrel 104, and surrounds and extends distally of the distal tip 122 of the anchor when the insertion device is in first position shown in Fig. 2a. The outer barrel tip includes within it an elastomeric septum 134, which engages the tip of the anchor circumferentially as shown in Fig. 3. The outer barrel tip 132 also preferably includes an opening or channel 136 extending
30 inwardly from the distal end 138 so that the distal tip of the anchor is visible from the distal end of the insertion device. The outer barrel tip may also be comprised of a clear or

translucent material so that the anchor position within the tip is readily visible by a user. During deployment, the outer barrel 104 and coupled outer barrel tip 132 is retracted relative to the drive pin 110 and anchor 116 by activating button 112 via any well known means. As this occurs, the anchor drives through the elastomeric septum 132 in the outer barrel tip in a
5 distal direction until the drive pin and anchor are exposed as illustrated in Fig. 2b..

A method of using the insertion device will now be described in detail with reference to Figs. 7a-7d. This method is an exemplary method, as it is to be understood that the insertion device has application to many other surgical procedures in which implantable anchors are deployed.

10 Pelvic organ prolapse can sometimes be repaired by attaching the apex of the vagina to the sacrospinous ligament via a vaginal approach rather than requiring surgical incisions. The general nature of this method is described in part in U.S. Patent No. 6,981,983, which is incorporated herein by reference in its entirety, and an improved procedure is described in co-pending U.S. Patent Application Serial No. _____, filed on June 10, 2011, which is
15 also incorporated by reference herein in its entirety.

The insertion device of the present invention can be utilized to facilitate these procedures by, via a vaginal route, palpating to find the sacrospinous ligament 140, aligning the distal end of the insertion device with the sacrospinous ligament, and activating the trigger mechanism as illustrated in Figs. 7a and 7b to deploy the anchor. As illustrated in
20 more detail in the enlarged portion of Fig. 7a, the anchor is deployed entirely through the vaginal wall and sacrospinous ligament 140, allowing the proximal end 102 of the anchor to catch or snag tissue on the far side of the ligament such that tension on the trailing filamentary element will not pull the anchor back through the ligament. For this particular treatment procedure, this can be performed twice with two different anchors in close
25 proximity as shown in Fig. 7c, and the respective trailing filamentary elements 124a, 124b tied together within the vaginal canal to approximate the vaginal apex 142 to the sacrospinous ligament as shown in Figs. 7c and 7d. The ends may be secured with multiple knots as shown, or fewer if desired. The ends of the filamentary elements are then trimmed, leaving the implantable anchors and knotted filamentary elements in place.

30 Although illustrative embodiments of the present invention have been described herein with reference to the accompanying drawings, it is to be understood that the invention

is not limited to those precise embodiments and that various other changes and modifications may be effected herein by one skilled in the art without departing from the scope or spirit of the invention.

What Is Claimed Is:

1. A surgical device for inserting an implantable anchor, comprising:
 - a handle including an actuator;
 - an outer barrel shaft extending outwardly from the handle to a distal end and having a channel extending therethrough;
 - a outer barrel tip positioned at the distal end of the outer barrel shaft and having an elastomeric septum therein;
 - a drive pin longitudinally aligned with and positioned within the outer barrel shaft channel;
 - an implantable anchor removably coupled to a distal end of the drive pin;
 - wherein the outer barrel shaft is coupled to the actuator for movement between a first extended position wherein the outer barrel shaft and outer barrel tip substantially cover the anchor, and a second retracted position where the outer barrel shaft and outer barrel tip do not cover the anchor, and wherein when the shaft is in the first position, the elastomeric septum of the outer barrel tip circumferentially surrounds and engages the anchor to thereby stabilize the anchor prior to deployment, and wherein when the shaft is in the second position, the elastomeric septum does not engage the anchor.
2. The surgical device according to claim 1, wherein the anchor has a tissue penetrating distal end.
3. The surgical device according to claim 2, further comprising a filamentary element coupled to and extending from the anchor.

4. The surgical device according to claim 3, wherein the anchor and filamentary element are comprised of an absorbable, biocompatible material.
5. The surgical device according to claim 4, wherein the anchor and filamentary element are comprised of polydioxanone.
6. The surgical device according to claim 3, wherein the anchor has a bore extending therein from a proximal end; the bore being sized and shaped so as to receive therein and form an interference fit with a distal end of said drive pin
7. A surgical anchor introducer, comprising:
 - a handle;
 - an outer barrel extending outwardly from said handle to a distal tip and having a channel extending therethrough;
 - an elastomeric septum positioned within the distal tip of the outer barrel;
 - an elongated drive pin positioned within the outer barrel;
 - an implantable anchor coupled to a distal end of the drive pin;wherein the outer barrel shaft is movable relative to the drive pin and anchor between a first position wherein the outer barrel shaft substantially covers the anchor, and a second position where the outer barrel shaft does not cover the anchor, and wherein when the shaft is in the first position, the elastomeric septum circumferentially surrounds and engages the anchor to thereby stabilize the anchor prior to deployment, and wherein when the shaft is in the second position, the elastomeric septum does not engage the anchor.

8. The introducer according to claim 7, wherein the anchor has a tissue penetrating distal end.
9. The introducer according to claim 8, further comprising a filamentary element coupled to and extending from the anchor.
10. The introducer according to claim 9, wherein the anchor and filamentary element are comprised of an absorbable, biocompatible material.
11. The introducer according to claim 10, wherein the anchor and filamentary element are comprised of polydioxanone.
12. The introducer according to claim 9, wherein the anchor has a bore extending therein from a proximal end; the bore being sized and shaped so as to receive therein and form an interference fit with a distal end of said drive pin
13. The introducer according to claim 7, wherein the outer barrel is movable between an extended position in the first position and a retracted position in the second position.
14. The introducer according to claim 13, wherein the outer barrel is movable between the extended and retracted positions by an actuator button coupled thereto and positioned on the handle.
15. The introducer according to claim 7, wherein the drive pin is movable between a retracted position in the first position and an extended position in the second position.

16. The introducer according to claim 15, wherein the drive pin is movable between the retracted and extended positions by an actuator button coupled thereto and positioned on the handle.

17. The surgical device according to claim 7, wherein the elastomeric septum is positioned within an outer barrel tip located at the distal end of the outer barrel.

18. A surgical anchor introducer, comprising:

a handle;

an outer barrel extending outwardly from said handle to a distal tip and having a channel extending therethrough;

an elastomeric septum positioned within the distal tip of the outer barrel;

an elongated drive pin positioned within the outer barrel;

an implantable anchor coupled to a distal end of the drive pin;

means for moving the outer barrel shaft relative to the drive pin and anchor between a first position wherein the outer barrel shaft substantially covers the anchor, and a second position where the outer barrel shaft does not cover the anchor, and wherein when the shaft is in the first position, the elastomeric septum circumferentially surrounds and engages the anchor to thereby stabilize the anchor prior to deployment, and wherein when the shaft is in the second position, the elastomeric septum does not engage the anchor.

FIG. 1

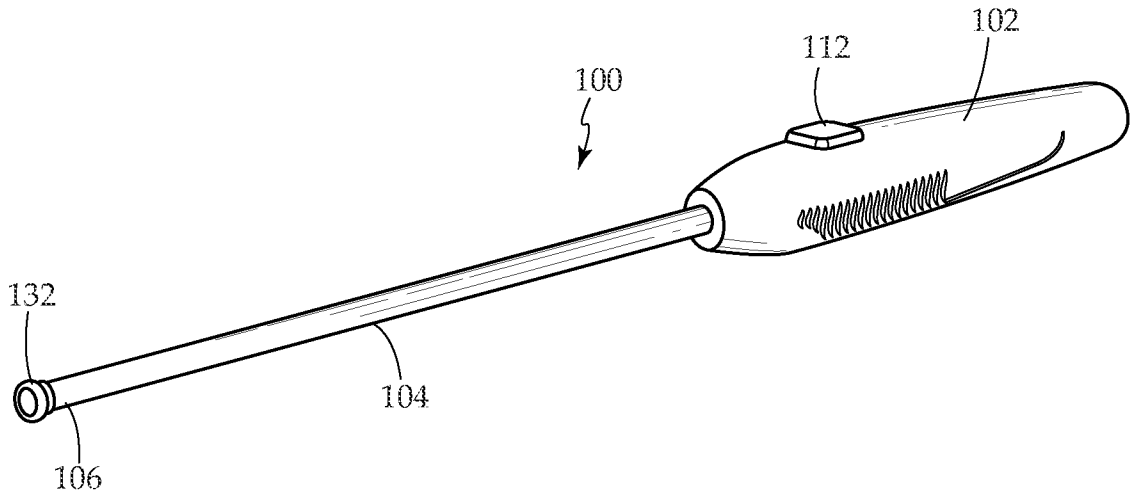


FIG. 2A



FIG. 2B

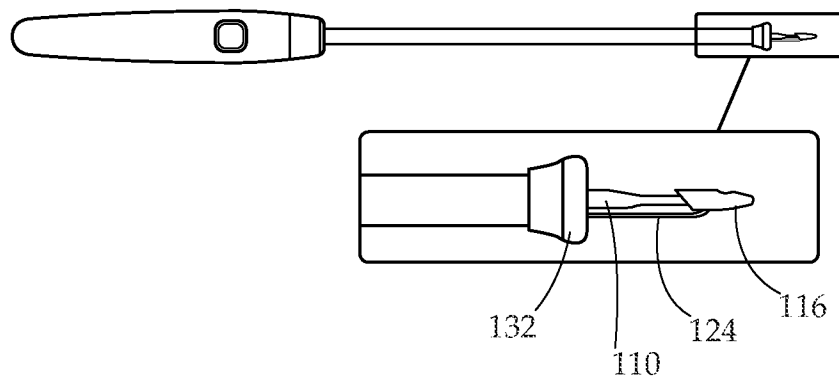


FIG. 3

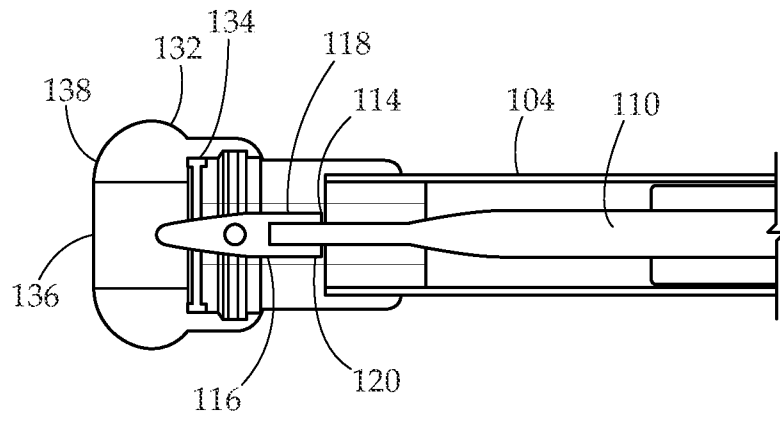


FIG. 4

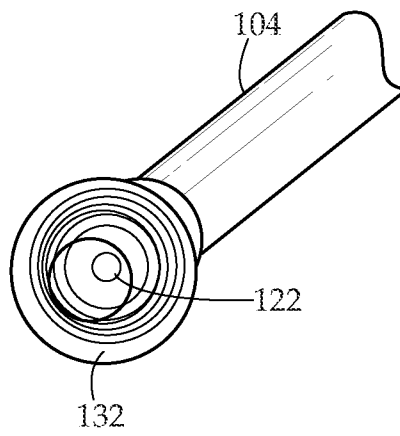


FIG. 5

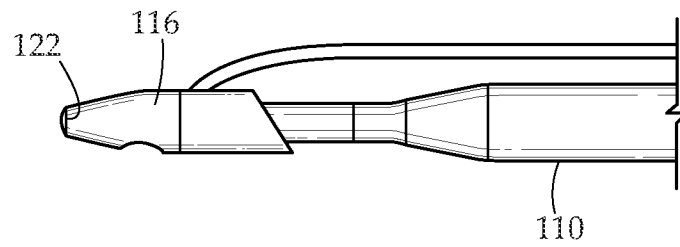


FIG. 6

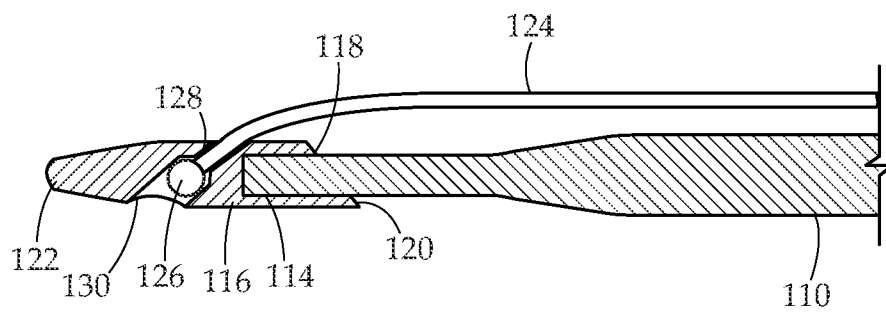


FIG. 7A

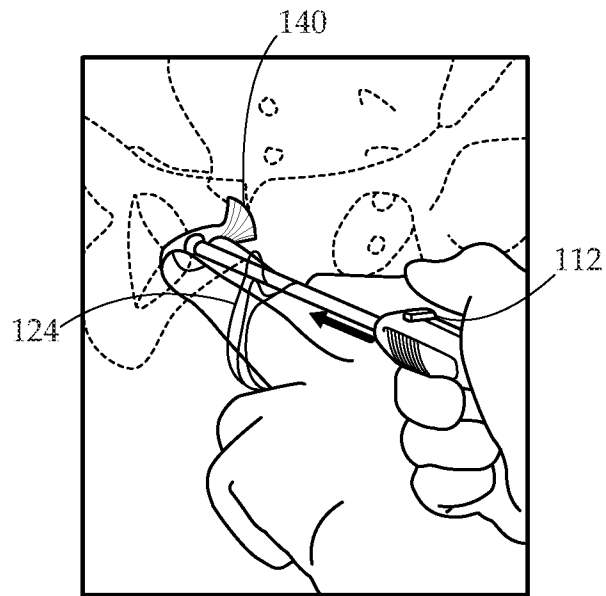


FIG. 7B

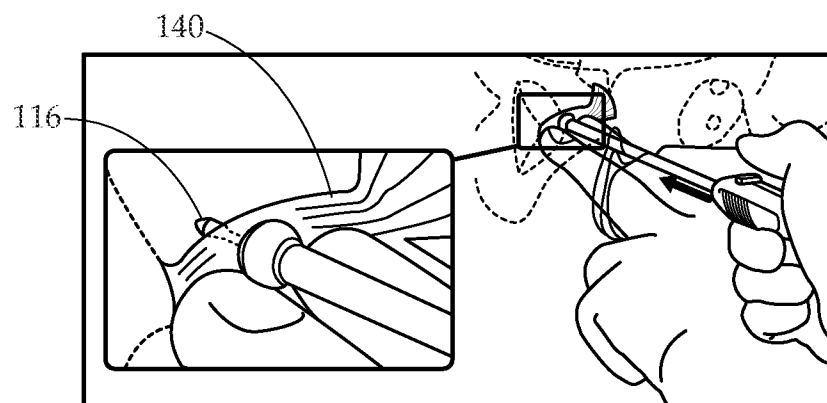


FIG. 7C

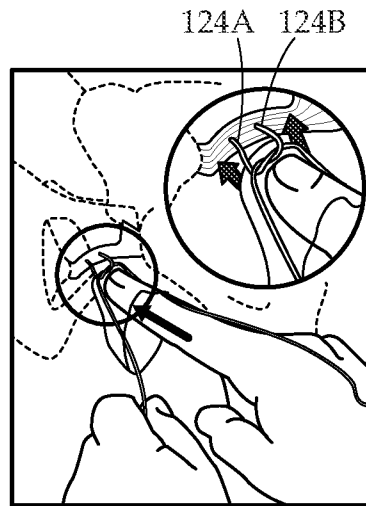
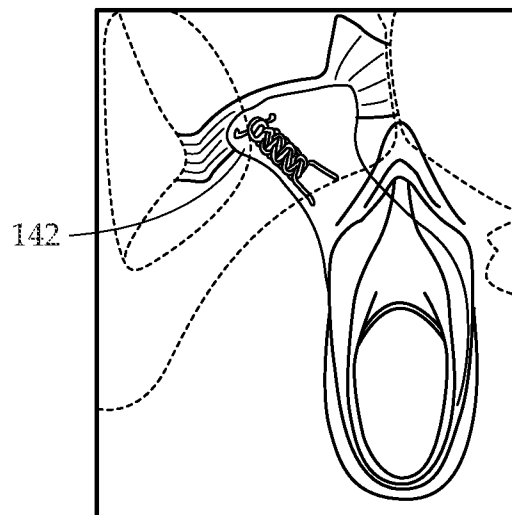


FIG. 7D



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US12/41005

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/04, 17/84; A61F 2/08 (2012.01)
USPC - 606/300, 60, 139, 232, 86R, 53, 1, 99, 144, 104

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, 17/84; A61F 2/08 (2012.01)
USPC: 606/300, 60, 139, 232, 86R, 53, 1, 99, 144, 104

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)

MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); Google/Google Scholar; Medine; DialogPRO; Anchor, actuator, screw, drive, pin, filament, guide, guidewire, deploy, tissue, organ, septum, valve, seal, handle, button, polydioxanone, laparoscopic, endoscopic, cannula

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/0228193 A1 (MATITYAHU, AM) September 18, 2008, figures 13a, 13b, 14a, 14b, 17a, 17b, 18a, 18b; paragraphs [0111], [0113], [0114], [0121]	1-18
Y	US 2005/0216028 A1 (HART, C et al.) September 29, 2005, figure 5, paragraphs [0008], [0014], [0064]	1-18
Y	US 6863671 B1 (STROBEL, M et al.) March 8, 2005, element 11; column 3, lines 65-67 to column 4, lines 1-4; column 2, lines 3-7	5, 11
Y	US 7510549 B2 (RUE, ML et al.) March 31, 2009, figures 1-3; column 4, lines 59-67 to column 5, lines 1-18; column 5, lines 19-23	14
Y	US 2009/0209804 A1 (SEILER, K et al.) August 20, 2009, figures 2a, 2b, paragraphs [0006], [0037]	16
A	US 7896897 B2 (GRESHAM, RD et al.) March 1, 2011, entire document	1-18

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
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"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	

Date of the actual completion of the international search

28 August 2012 (28.08.2012)

Date of mailing of the international search report

01 OCT 2012

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US12/41005

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 6,527,780 B1 (Wallace et al.) March 4, 2003	14, 16
A	US 5,456,284 (Ryan et al.) October 10, 1995	1-18
A	US 5,209,737 (Ritchart et al.) May 11, 1993	1-18
A	US 2005/0131349 A1 (Albrecht et al.) June 16, 2005	1-18
A	US 2007/0244426 A1 (Hart et al.) October 18, 2007	1-18
A	US 7,896,897 B2 (Gresham et al.) March 1, 2011	1-18