



(12) **United States Patent**
Chu

(10) **Patent No.:** **US 9,943,391 B2**
(45) **Date of Patent:** **Apr. 17, 2018**

- (54) **MEDICAL DEVICE AND METHOD FOR DELIVERING AN IMPLANT**
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- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 635 days.
- (21) Appl. No.: **14/201,321**
- (22) Filed: **Mar. 7, 2014**
- (65) **Prior Publication Data**
US 2014/0275752 A1 Sep. 18, 2014

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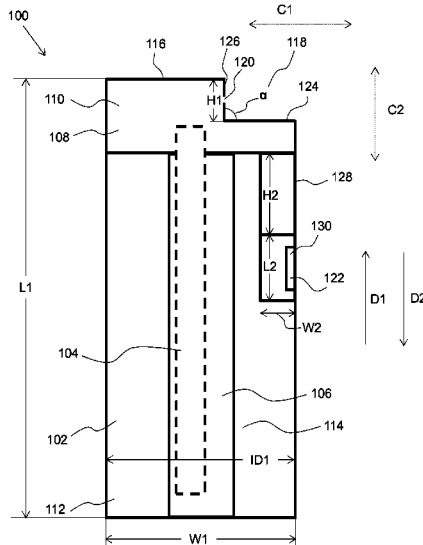
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- Related U.S. Application Data**
- (60) Provisional application No. 61/777,213, filed on Mar. 12, 2013.
- (51) **Int. Cl.**
A61B 17/04 (2006.01)
A61F 2/00 (2006.01)
(Continued)
- (52) **U.S. Cl.**
CPC *A61F 2/0045* (2013.01); *A61B 17/0469* (2013.01); *A61B 17/0625* (2013.01);
(Continued)
- (58) **Field of Classification Search**
CPC A61B 17/0469; A61B 17/0625; A61B 2017/06009
See application file for complete search history.

- (57) **ABSTRACT**
The present invention discloses a medical device that includes an elongate member, needle, needle deployment mechanism, and a head portion. The elongate member has a proximal portion, distal portion and a lumen defined along the elongate member. The needle deployment mechanism is disposed at least partially within the lumen. The head portion includes a tip portion that includes a front throat region, an opening, and a needle receiving portion. The front throat region includes a front edge and a lateral edge. The opening is defined by the lateral edge of the front throat region. The needle moves in and out of the device through the opening in a direction along the front edge of the front throat region. The needle receiving portion can be configured to capture the needle.

18 Claims, 19 Drawing Sheets



(51) **Int. Cl.**

A61B 17/062 (2006.01)
A61B 17/00 (2006.01)
A61B 17/06 (2006.01)
A61B 90/00 (2016.01)

(52) **U.S. Cl.**

CPC *A61B 2017/00805* (2013.01); *A61B*
2017/0608 (2013.01); *A61B 2090/036*
(2016.02)

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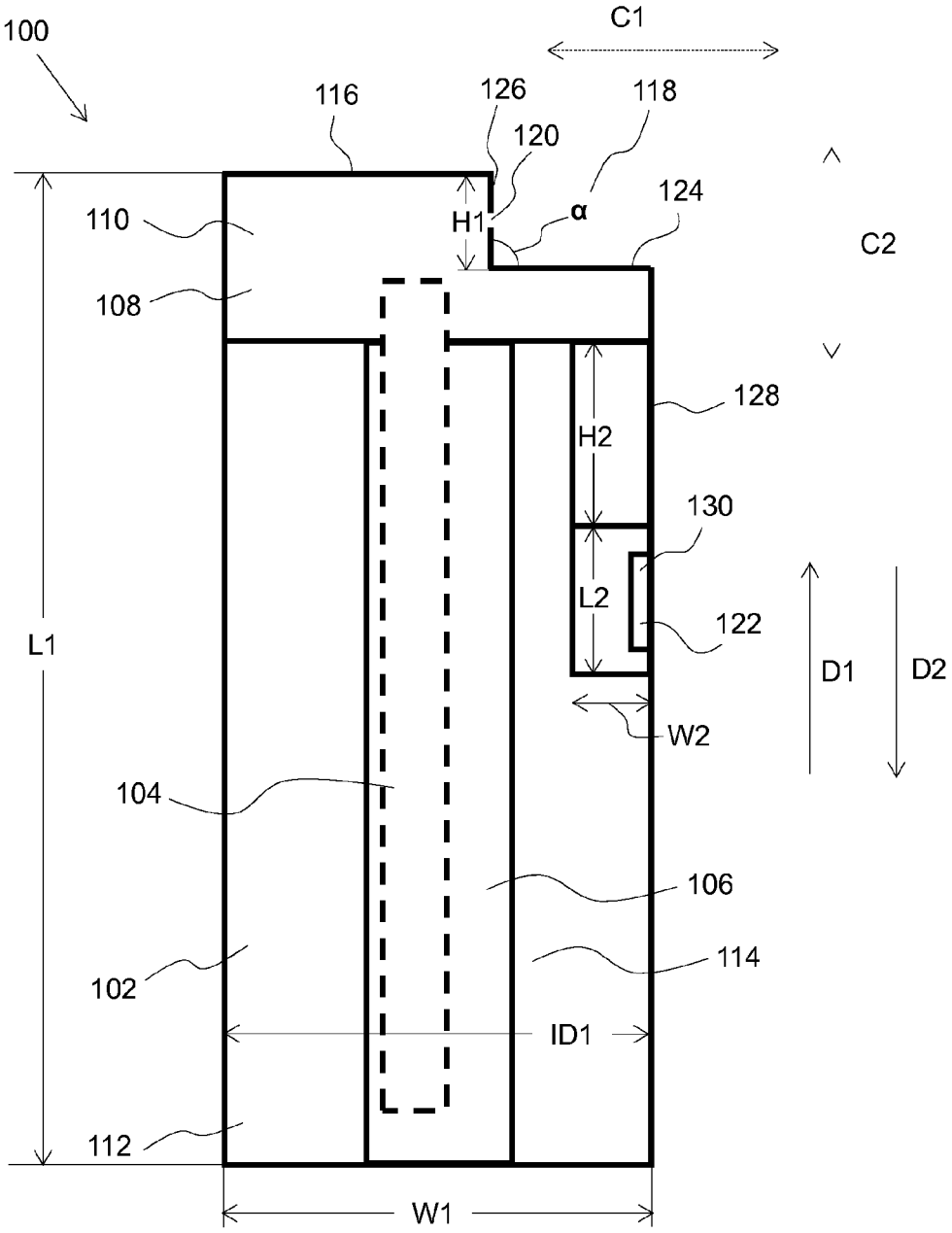


FIG. 1

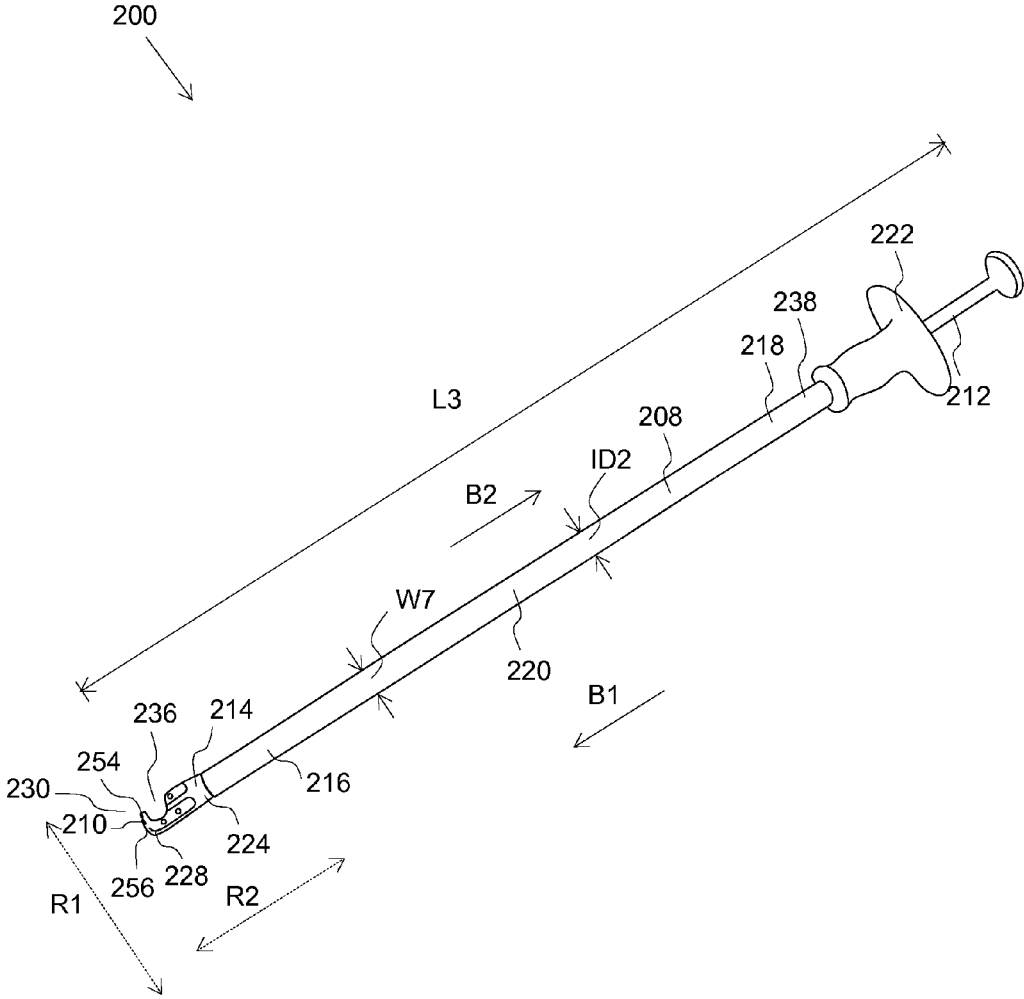


FIG. 2A

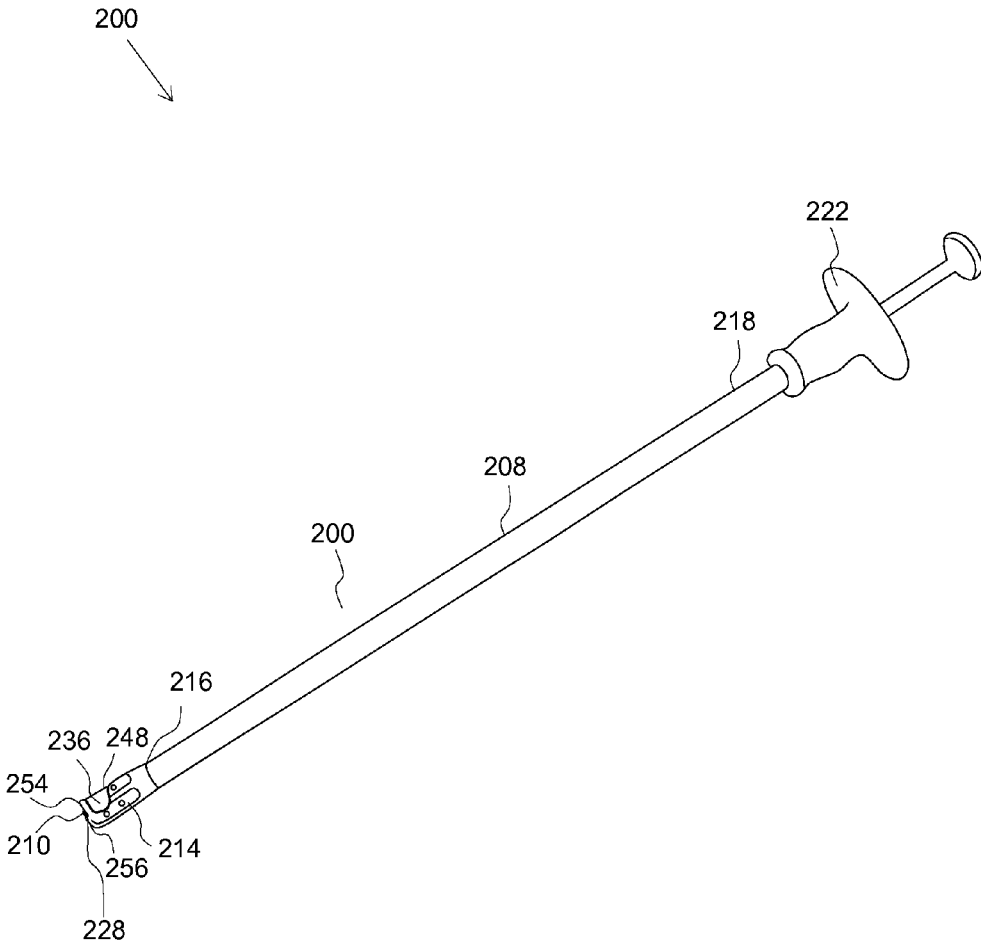


FIG. 2B

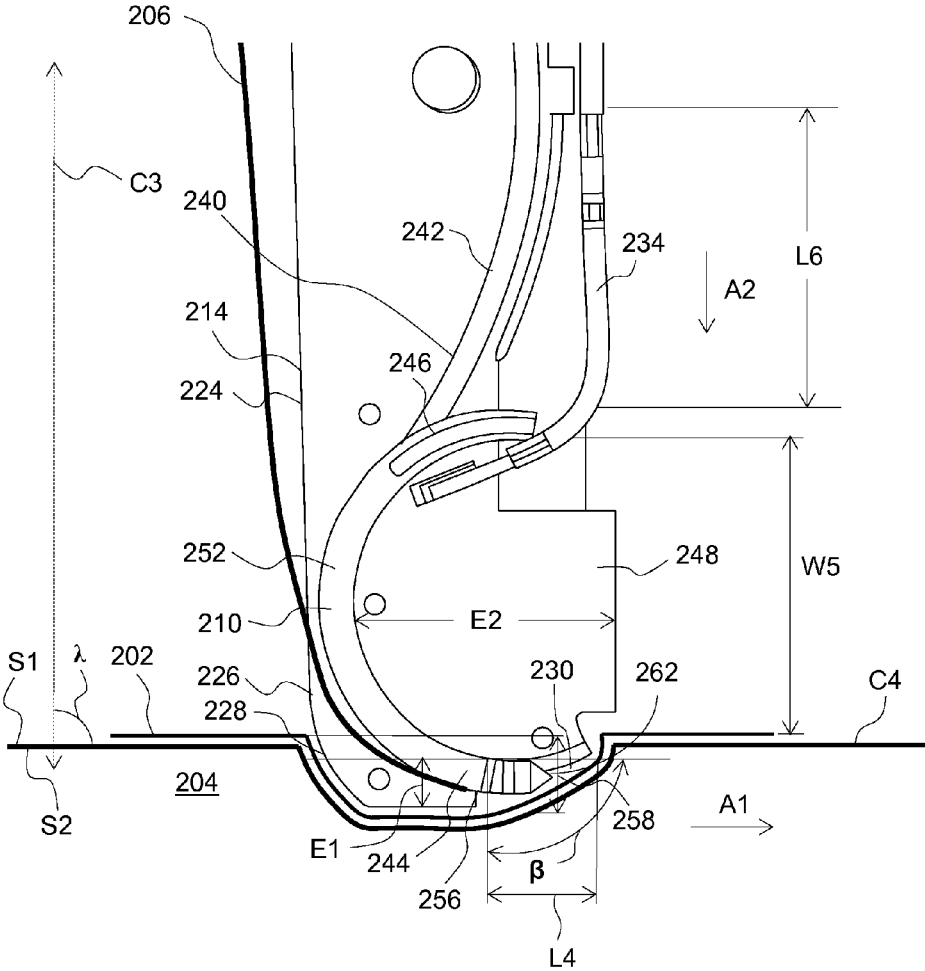


FIG. 2C

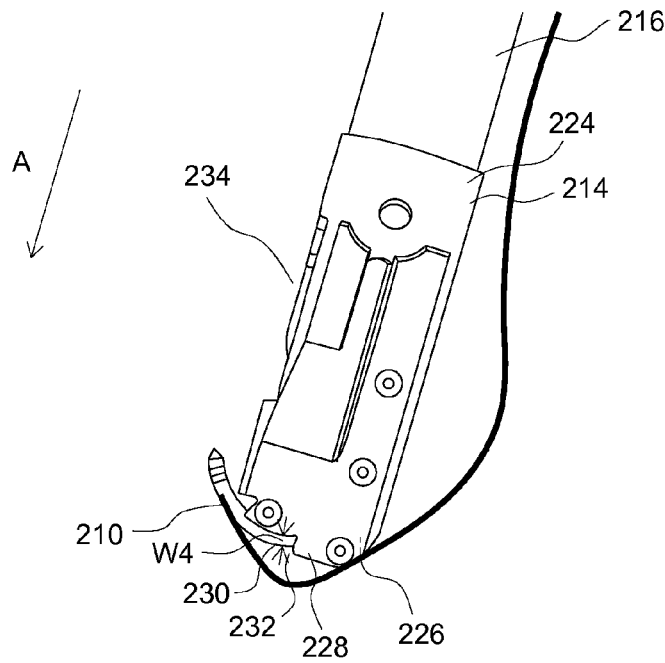


FIG. 2D

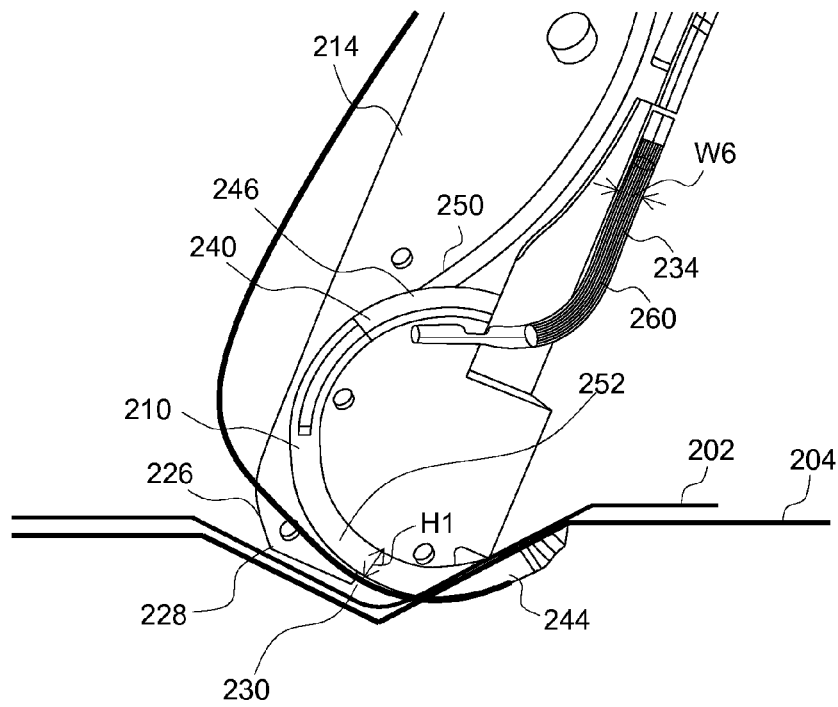


FIG. 2E

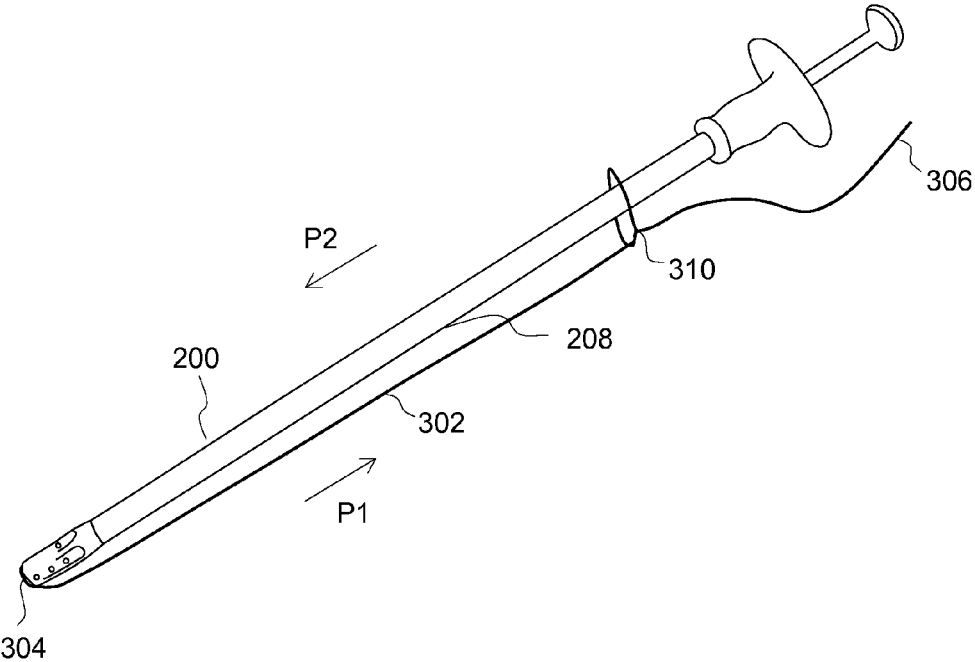


FIG. 3A

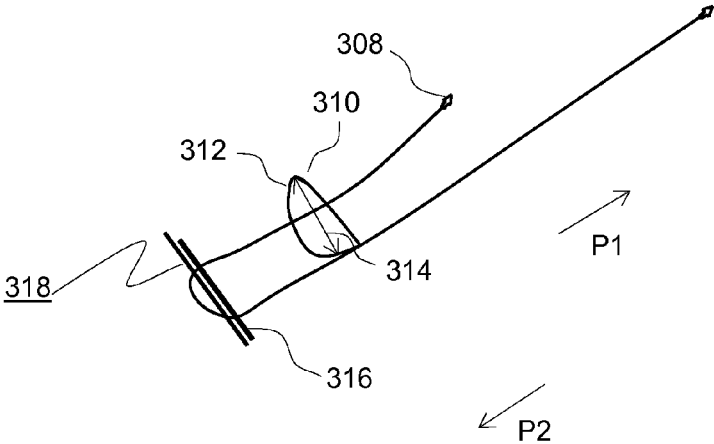


FIG. 3B

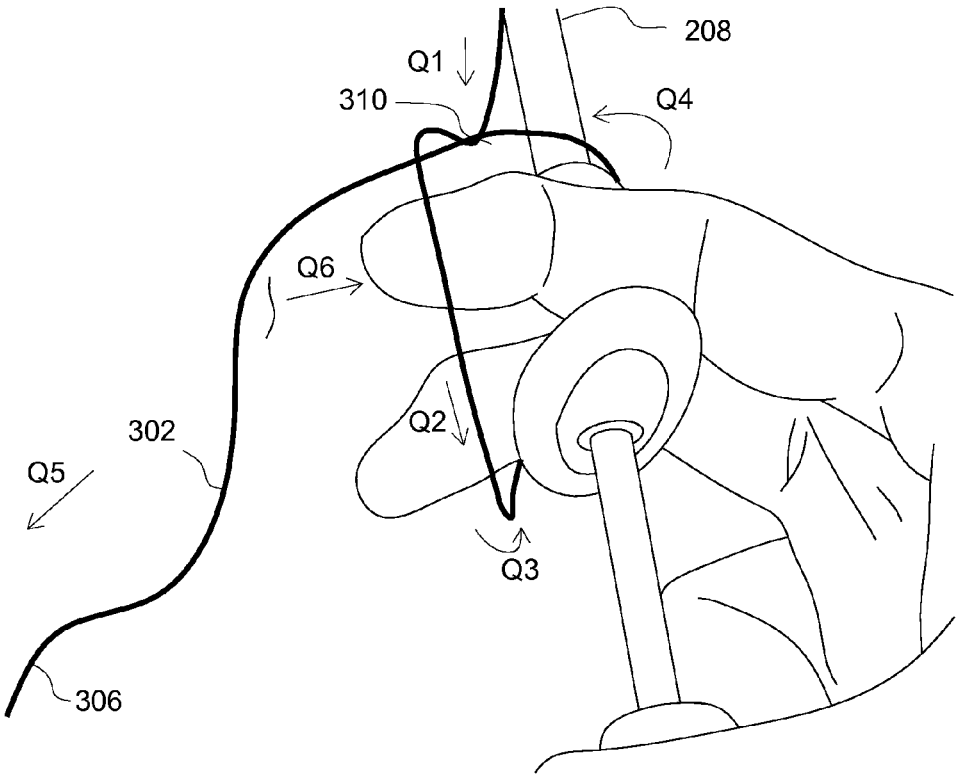


FIG. 3C

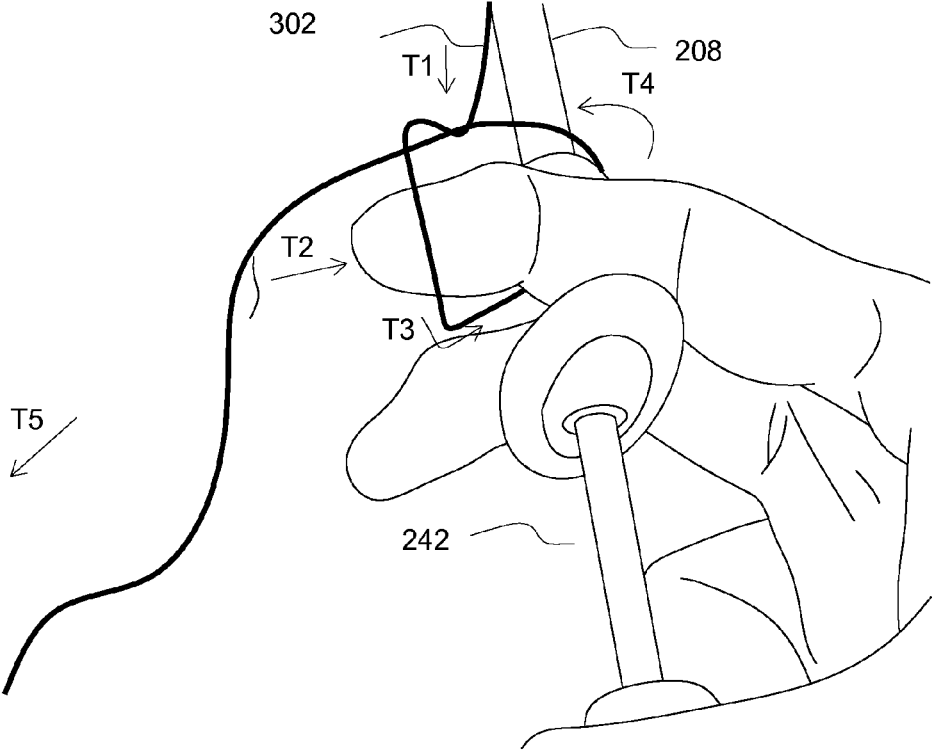
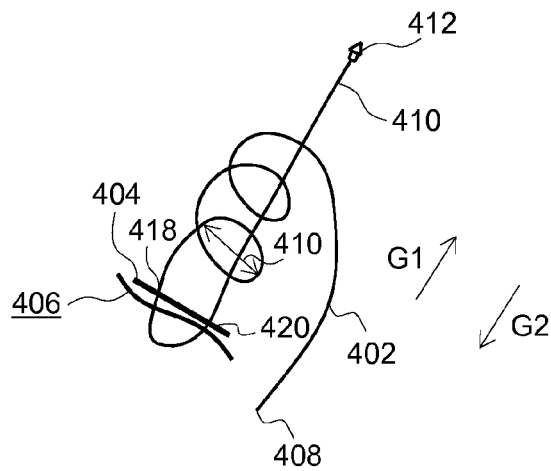
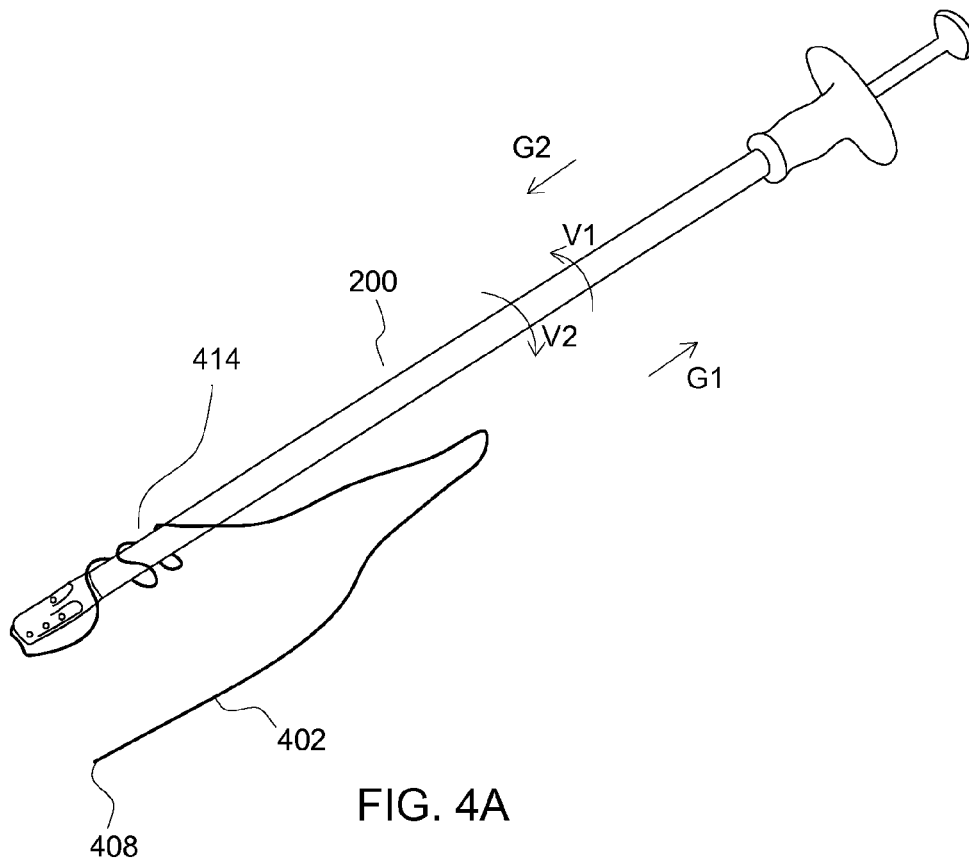


FIG. 3D



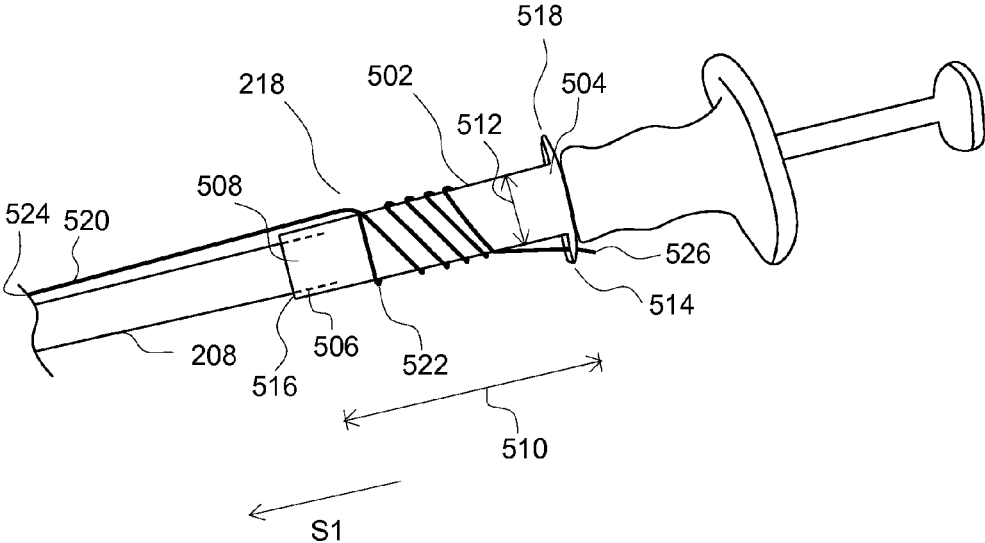


FIG. 5

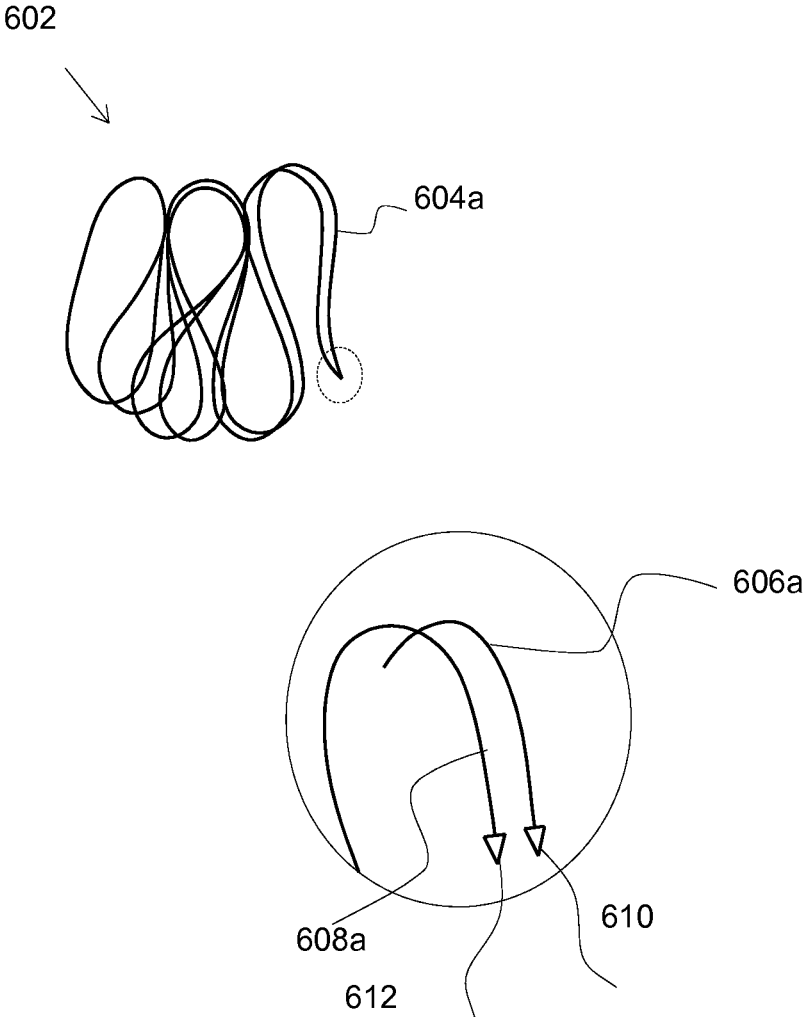


FIG. 6A

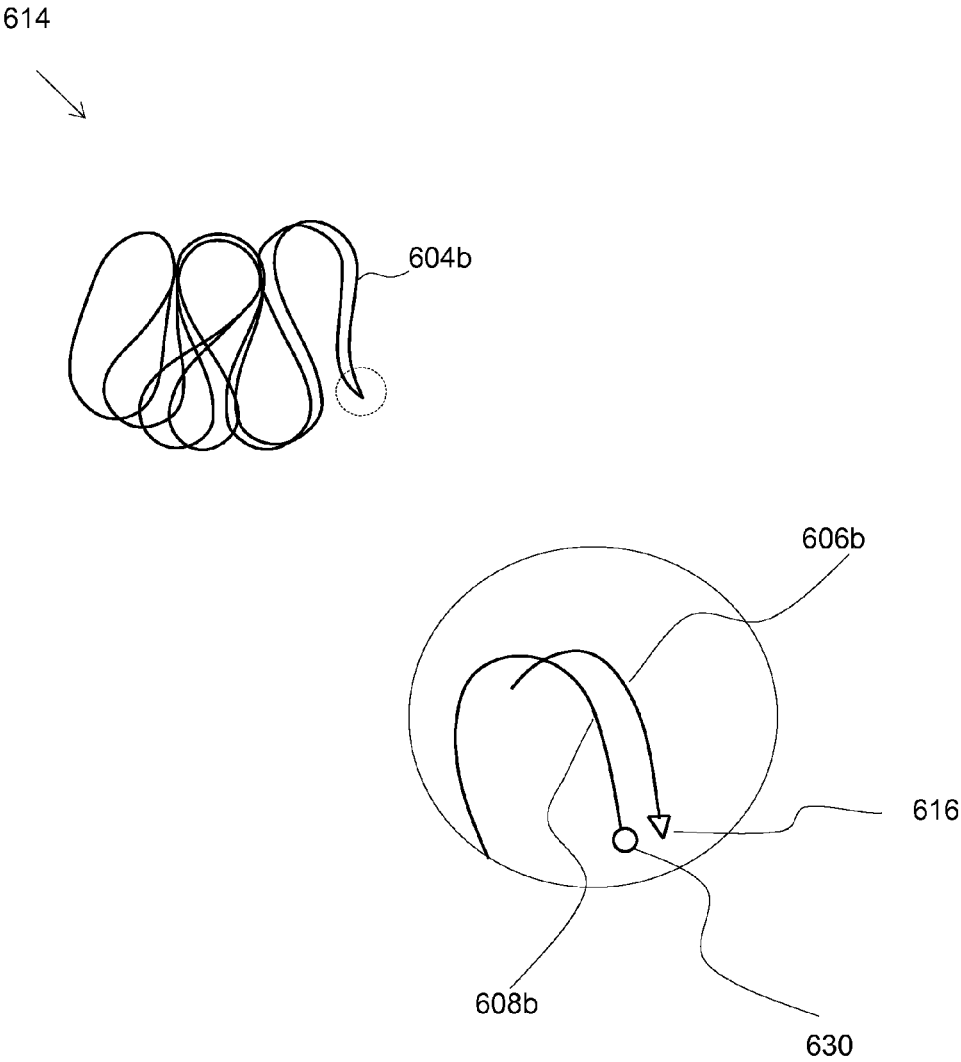


FIG. 6B

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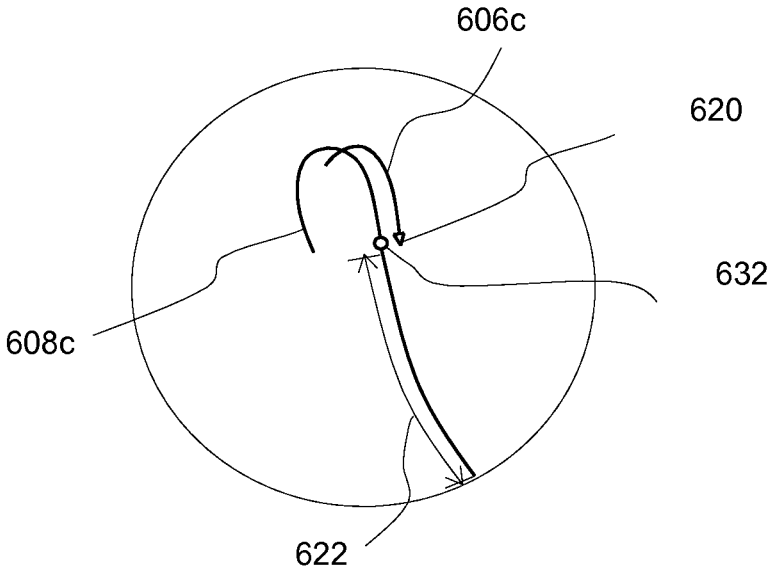
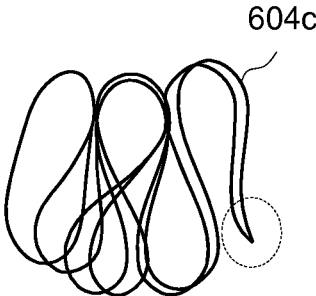


FIG. 6C

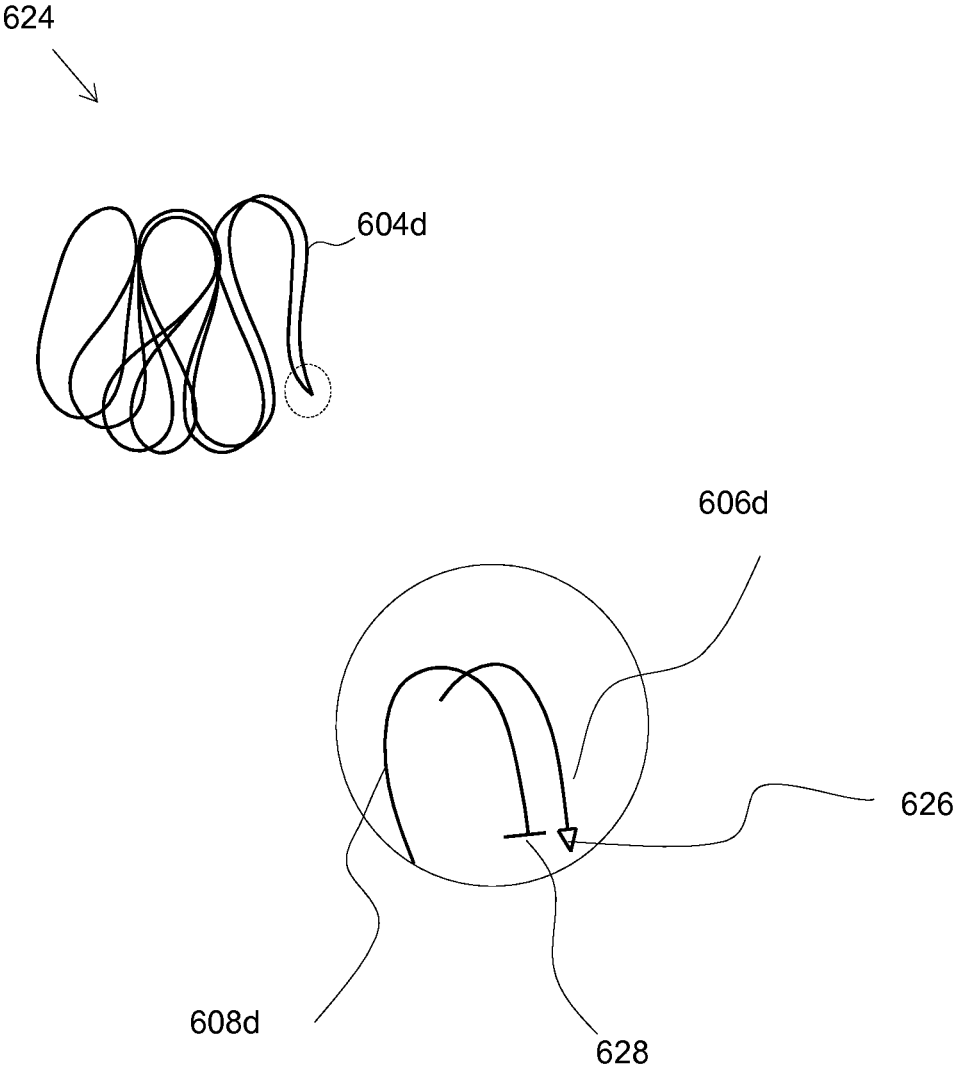


FIG. 6D

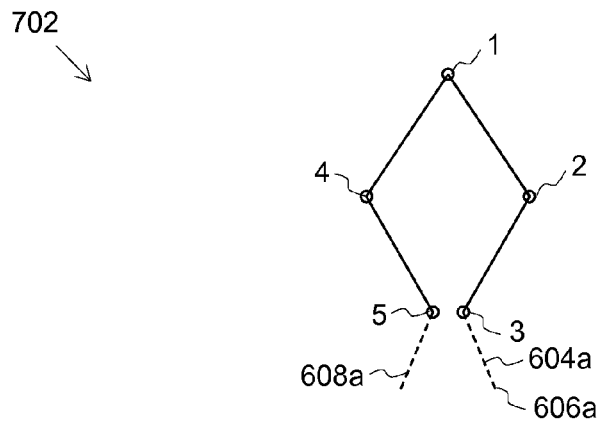


FIG. 7A

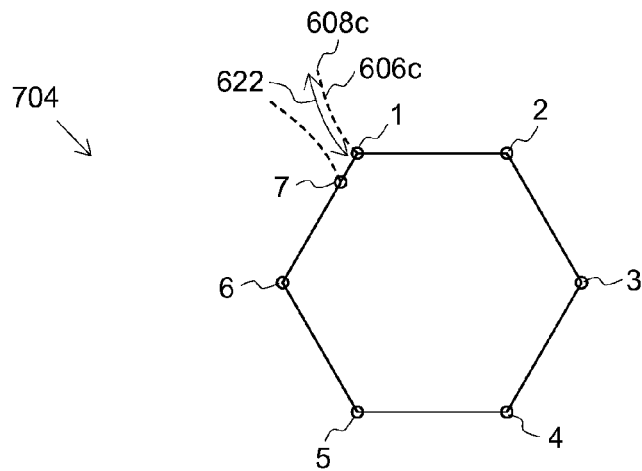


FIG. 7B

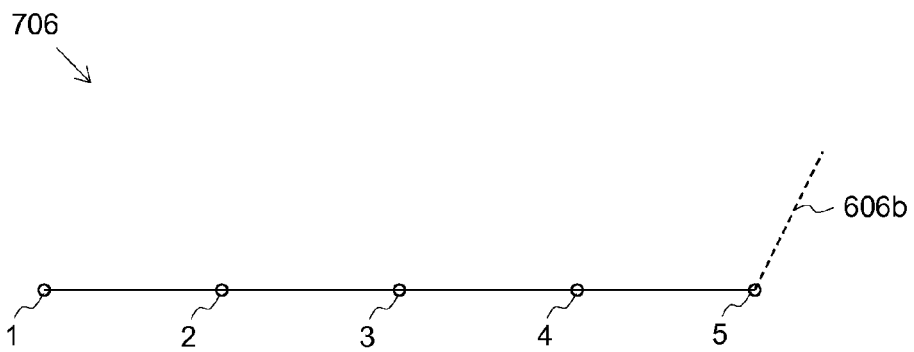


FIG. 7C

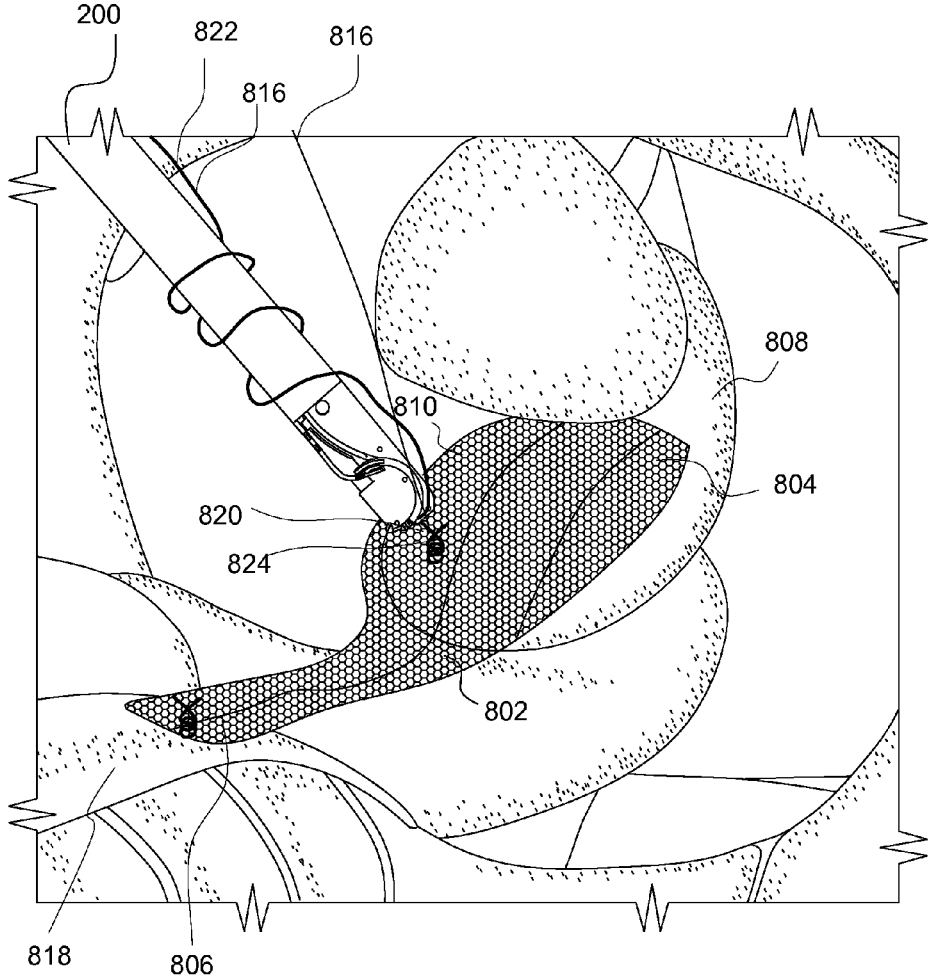


FIG. 8A

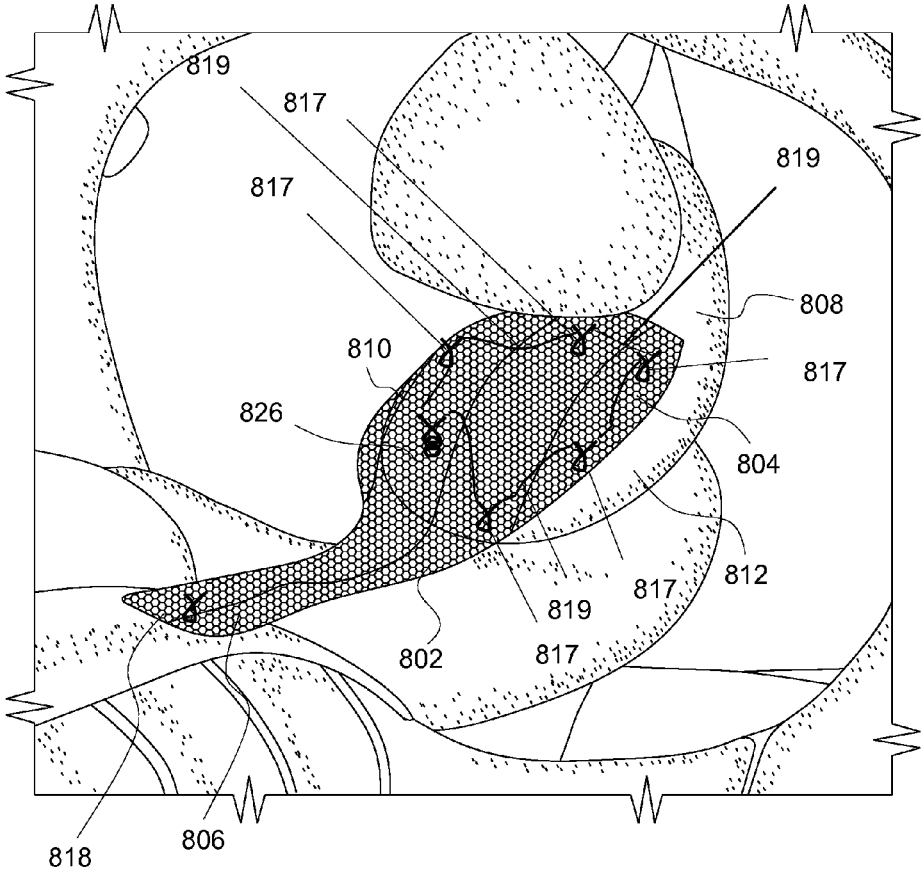


FIG. 8B

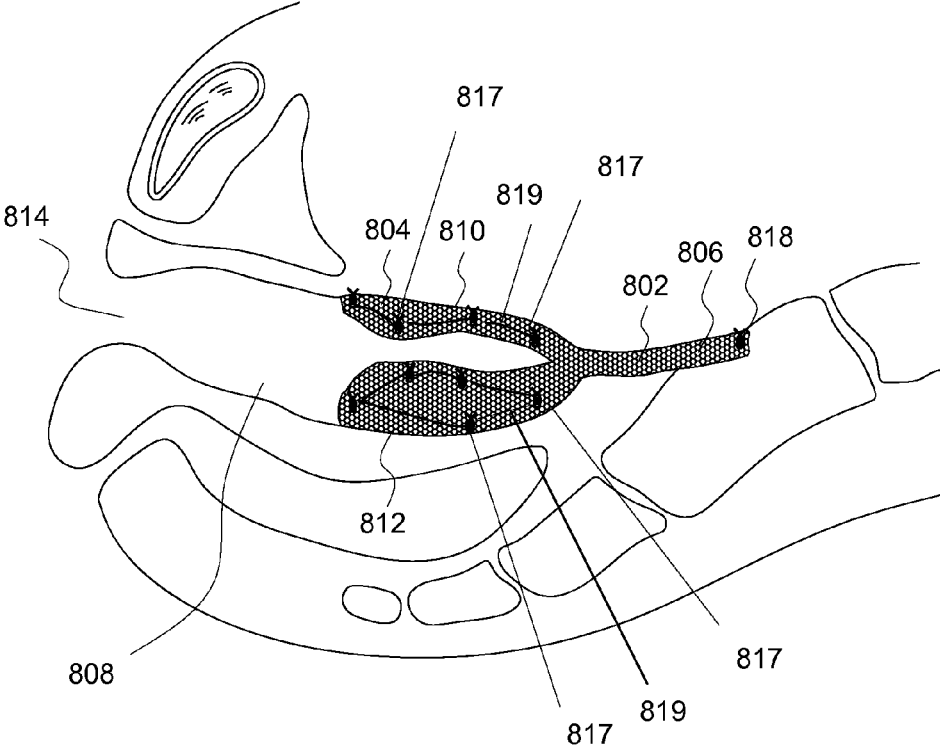


FIG. 8C

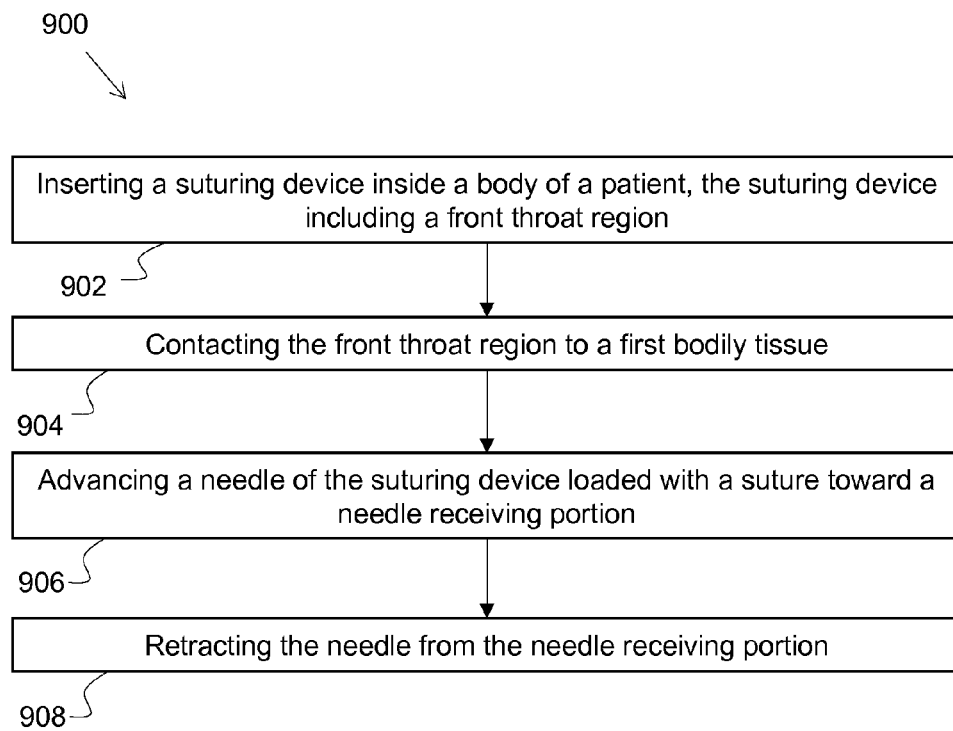


FIG. 9

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MEDICAL DEVICE AND METHOD FOR DELIVERING AN IMPLANT

CROSS-REFERENCE TO RELATED APPLICATION

This application is a Nonprovisional of, and claims priority to, U.S. Patent Application No. 61/777,213, filed on Mar. 12, 2013, entitled "MEDICAL DEVICE AND METHOD FOR DELIVERING AN IMPLANT", which is incorporated by reference herein in its entirety.

FIELD

The present invention generally relates to medical devices and procedures, and particularly to devices and methods for delivery and placement of implants in a patient's body for the treatment of pelvic organ prolapse.

DESCRIPTION OF THE RELATED ART

Pelvic organ prolapse is an abnormal descent or herniation of the pelvic organs. A prolapse may occur when muscles and tissues in the pelvic region become weak and can no longer hold the pelvic organs in place correctly.

Treatment for symptoms of the pelvic organ prolapse can include changes in diet, weight control, and lifestyle. Treatment may also include surgery, medication, and use of grafts or implants to support the pelvic organs.

Sacrocolpopexy is one such surgical technique that may be used to repair pelvic organ prolapse. This can be performed, such as, by using an open abdominal technique or with the use of minimally invasive surgery such as laparoscopy. The technique may include suspension of the apical portion of vagina (or sometimes the vaginal cuff after a hysterectomy) using an implant such that the technique may generally recreate the natural anatomic support or otherwise provide support to the vagina. In an example, a portion of the implant can be fixed to the apical portion of the vagina and a second portion of the implant can be fixed to the sacrum.

The procedure for implant fixation may require several knots of a suture, generally located over such as the apical portion of the vagina to securely fasten the implant to the vaginal walls. In an example, each of the suture knots may include several layers of knotting one over other which can be time consuming and complicated. Also, since the vaginal walls are thin, there may be a chance that the vaginal walls may get penetrated or damaged when using a laparoscopic needle such as through an abdomen.

Thus, in light of the above, there is a need for a device and method for placing an implant so as to reduce complexity and the time required to complete the procedure of implant fixation and also avoid damage to or penetration of the vaginal walls.

SUMMARY

In an embodiment, the invention discloses a medical device. The medical device includes an elongate member, a needle, a needle deployment mechanism, and a head portion. The elongate member has a proximal portion, a distal portion and a lumen defined along the elongate member. The needle can be disposed within the lumen of the elongate member. The needle deployment mechanism can be disposed at least partially within the lumen for moving the needle along the elongate member. The head portion includes a tip portion, and the head portion can be provided

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at the distal portion of the elongate member. The head portion includes a front throat region, an opening, and a needle receiving portion. The front throat region can be provided at the tip portion. The front throat region can have a front edge and a lateral edge. The front throat region defines an open space bounded between the lateral edge and the front edge to receive a bodily tissue therein. The opening can be defined by the lateral edge of the front throat region. The opening can extend from the lumen of the elongate member such that the needle moves in and out of the device through the opening in a direction along the front edge of the front throat region. The needle receiving portion can be configured to capture the needle.

In an embodiment, the invention discloses a medical device. The medical device includes an elongate member, a needle, a needle deployment mechanism, and a head portion. The elongate member has a proximal portion, a distal portion and a lumen defined along the elongate member. The needle can be disposed within the lumen of the elongate member. The needle deployment mechanism can be disposed at least partially within the lumen for moving the needle along the elongate member. The head portion includes a tip portion, and the head portion can be provided at the distal portion of the elongate member. The head portion further includes a front throat region, a second throat region, an opening, and a needle receiving portion. The front throat region can be provided at the tip portion. The front throat region can have a front edge and a lateral edge. The front throat region defines an open space bounded between the lateral edge and the front edge. The second throat region is provided sidewise on the head portion with respect to the front throat region and defines an open space for receiving a body tissue therein. The opening can be defined by the lateral edge of the front throat region. The opening can extend from the lumen of the elongate member such that the needle moves in and out of the device through the opening, in a direction along the front edge of the front throat region. The needle receiving portion can be configured to capture the needle.

In an embodiment, the invention discloses a method for placing an implant. The method includes inserting a medical device inside the body of a patient. The medical device includes an elongate member, a needle disposed within the elongate member, and a head portion. The head portion includes a front throat region having a front edge and lateral edge such that the front throat region defines an open space bounded between the front edge and the lateral edge. The method includes contacting the front throat region to a first bodily tissue. The method includes advancing the needle of the medical device, loaded with a suture, toward the needle receiving portion so as to cause the needle to extend through an opening in a direction along the front edge and penetrate through the implant and a portion of the first bodily tissue. The opening is defined by the lateral edge. The method includes retracting the needle from the needle receiving portion.

BRIEF DESCRIPTION OF THE FIGURES

The invention and the following detailed description of certain embodiments, thereof, may be understood with reference to the following figures:

FIG. 1 is a schematic diagram of a medical device for placing an implant within a patient's body, in accordance with an embodiment of the present invention.

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FIG. 2A is a perspective view of a medical device for placing an implant within a patient's body, in accordance with an embodiment of the present invention.

FIG. 2B is a perspective view of a medical device, along with a depth adaptor, for placing an implant within a patient's body, in accordance with an embodiment of the present invention.

FIG. 2C is an enlarged perspective view of a head portion of the medical device of FIG. 2B engaged with a bodily tissue and an implant.

FIG. 2D is an enlarged perspective view of the head portion of the medical device of FIG. 2B in another view, in accordance with an embodiment of the present invention.

FIG. 2E is an enlarged perspective view of the head portion of the medical device of FIG. 2B with a needle pierced within a bodily tissue and an implant, in accordance with an embodiment of the present invention.

FIG. 3A is a perspective view of a medical device loaded with a suture forming a noose around the device, in accordance with an embodiment of the present invention.

FIG. 3B is a perspective view of a suture engaged with a portion of a bodily tissue and an implant such as during implant fixation, in accordance with an embodiment of the present invention.

FIG. 3C is a perspective view of the suture noose formation technique, in accordance with an embodiment of the present invention.

FIG. 3D is a perspective view of the suture noose formation technique, in accordance with another embodiment of the present invention.

FIG. 4A is a perspective view of a medical device loaded with a suture forming a coil around the device, in accordance with an embodiment of the present invention.

FIG. 4B is a perspective view of a suture engaged with a portion of a bodily tissue and an implant such as during implant fixation, in accordance with an embodiment of the present invention.

FIG. 5 is a perspective view of a portion of a cartridge loaded on a medical device, in accordance with an embodiment of the present invention.

FIG. 6A is a perspective view of a suture arrangement with a dart coupled to each end of the suture, in accordance with an embodiment.

FIG. 6B is a perspective view of a suture arrangement with a dart coupled to a first end of the suture and a knot placed on a second end, in accordance with an embodiment.

FIG. 6C is a perspective view of a suture arrangement with a dart at a first end of the suture and a knot placed on the suture proximal to a second end, in accordance with an embodiment.

FIG. 6D is a perspective view of a suture arrangement with a dart coupled to a first end of the suture and a T-shaped second end, in accordance with an embodiment.

FIG. 7A is a tetrahedral pattern for placing a suture to a bodily implant, in accordance with an embodiment of the present invention.

FIG. 7B is a polygonal pattern for placing a suture to a bodily implant, in accordance with an embodiment of the present invention.

FIG. 7C is a linear pattern for placing a suture to a bodily implant, in accordance with an embodiment of the present invention.

FIG. 8A is a schematic view of placing an implant within a patient's body, through a medical device, in accordance with an embodiment of the present invention.

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FIG. 8B is a schematic view of the placed implant of FIG. 8A within the patient's body, in accordance with an embodiment of the present invention.

FIG. 8C is a schematic view of the placed implant of FIG. 8A within the patient's body in a different view, in accordance with an embodiment of the present invention.

FIG. 9 is a flowchart illustrating a method of placing an implant in a patient's body, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION

Detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure. Further, the terms and phrases used herein are not intended to be limiting, but to provide an understandable description of the invention.

The terms "a" or "an," as used herein, are defined as one or more than one. The term "another," as used herein, is defined as at least a second or more. The terms "including" and/or "having", as used herein, are defined as comprising (i.e., open transition).

In general, the invention is directed to systems, methods, and devices for treating vaginal prolapse. However, the invention may be equally employed for other treatment purposes such as pelvic organ prolapse or other pelvic disorders such as incontinence. As described below in various illustrative embodiments, the invention provides systems, methods, and devices employing a medical device configured to deliver or place an implant within a patient's body to support pelvic organs for the treatment of pelvic organ prolapsed or other pelvic disorders.

The term patient may be used hereafter for a person who benefits from the medical device or the methods disclosed in the present invention. For example, the patient may be a person whose body is operated with the use of the medical device disclosed by the present invention in a surgical treatment. For example, in some embodiments, the patient may be a human female, human male or any other mammal.

The terms proximal and distal described in relation to various devices, apparatuses, and components as discussed in the subsequent text of the present invention are referred to with a point of reference. The point of reference, as used in this description, is a perspective of an operator. The operator may be a surgeon, a physician, a nurse, a doctor, a technician, and the like who may perform the procedure of delivering and placing the bodily implants into the patient's body as described in the present invention. The term proximal refers to an area that is closest to the operator. The term distal refers to an area that is farthest from the operator.

FIG. 1 is a schematic diagram of a medical device 100. In various embodiments, the medical device 100 is configured to deliver an implant within a patient's body or place or fix an implant such as by placing sutures through the implant and bodily tissues. The medical device 100 includes an elongate member 102, a needle 104, a needle deployment mechanism 106 and a head portion 108. The needle 104 and the needle deployment mechanism 106 are at least partially

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disposed within the elongate member **102**. The head portion **108** can be provided at or removably coupled to a portion of the elongate member **102**.

The elongate member **102** includes a distal portion **110** and a proximal portion **112** with a length L1 of the elongate member **102** extending between the distal portion **110** and the proximal portion **112** longitudinally. In accordance with various embodiments, the length L1 of the elongate member **102** can vary based on the requirements. In various embodiments of the invention, a portion of the length L1 defines a working length (not shown) of the medical device **100**. The working length may be defined as a portion of the medical device **100** that can be inserted into the patient's body during the surgical procedure. In some embodiments of the invention, the working length is different from the length L1 of the elongate member **102** and the working length can range from about 9 cm to about 45 cm (approximately 3.5 inches to 17.7 inches). In various other embodiments, the working length can be different based on the requirements. The elongate member **102** defines a width W1. The width W1 may vary based on requirements. In some embodiments, the width W1 may vary along the length L1 of the elongate member **102**.

The elongate member **102** defines a lumen **114** extending from the proximal portion **112**, running across the length L1 of the elongate member **102** and culminating at the distal portion **110** of the elongate member **102**. The lumen **114** defines an inner diameter ID1 of the elongate member **102**. The lumen **114** of the elongate member **102** is configured to receive and house at least some other elements and portions of the medical device **100**. For example, the elongate member **102** can be configured to house at least a portion of the needle deployment mechanism **106** and the needle **104** within a space formed within the lumen **114**.

The elongate member **102** further includes a handle (not shown) that is configured to be held by an operator while performing a surgical procedure. In some embodiments, the handle forms an integral part of the elongate member **102** and extends from the elongate member **102** proximally. In some other embodiments, the handle may be a separate component and can be mechanically coupled to the elongate member **102** at the proximal portion **112**. In some embodiments of the invention, the handle is provided with a thumb-tab to increase the efficiency of the handle. A physician or a user can hold the handle by placing his finger or thumb on the thumb-tab.

The distal portion **110** of the elongate member **102** includes or is coupled to the head portion **108**. The head portion **108** includes a tip portion **116**, a front throat region **118**, an opening **120** defined by the front throat region **118** and a needle receiving portion **122**. In some embodiments, the front throat region **118** is disposed at another location along the elongate member **102**. For example the front throat region may be disposed at a location proximal of the distal portion or the distal most portion of the elongate member.

In an embodiment, the tip portion **116** includes the front throat region **118**. The front throat region **118** can be defined in a direction parallel to a lateral axis C1 of the medical device **100**. The front throat region **118** includes a front edge **124** and a lateral edge **126**. In some embodiments, the front edge **124** can define a substantially circular profile. In some embodiments, the front throat region **118** can define any other profile so as to facilitate the needle **104** movement toward the needle receiving portion **122**.

The lateral edge **126** abuts the front edge **124** and forms a throat angle α between the lateral edge **126** and the front edge **124**. In some embodiments, the throat angle α can be

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90 degrees so that the front edge **124** and the lateral edge **126** are perpendicular to each other. In some embodiments, the throat angle α can be less than 90 degrees. In some embodiments, the throat angle α can be more than 90 degrees. The lateral edge **126** can have a height H1 such that the penetration depth of the needle **104** within the bodily tissue can be limited to H1.

The front throat region **118** defines an open space bounded between the front edge **124** and the lateral edge **126** to receive a bodily tissue therein. In some embodiments, the bodily tissue can be forced or prolapsed into the front throat region **118**. In some embodiments, the front throat region **118** can be configured or used to suture a portion of a Y-shaped implant to an anterior and a posterior vaginal wall. In some embodiments, the front throat region **118** can be configured or used to suture a portion of a Y-shaped implant to such as a sacrum. In some embodiments, the front throat region **118** can be configured or used to suture a portion of any other type of implant to various bodily tissues such as vaginal walls, sacrum or locations proximate the sacrum, uterus, vaginal apex and other pelvic tissues.

The opening **120** can be defined by the lateral edge **126** of the front throat region **118**. The opening **120** is in communication with the lumen **114** of the elongate member **102** such that the needle **104** moves in and out of the medical device **100** through the opening **120** in a direction A1 along the front edge **124** of the front throat region **118**.

In some embodiments, the head portion **108** includes a second throat region **128**. The second throat region **128** can be defined parallel to a longitudinal axis C2 of the medical device **100**. In some embodiment, the lateral axis C1 and the longitudinal axis C2 are perpendicular or substantially perpendicular to each other, thereby orienting the front throat region **118** and the second throat region **128** perpendicular to each other. In some other embodiments, the direction of orientation of the front throat region and the second throat region may not be perpendicular. In some embodiments, the second throat region **128** can be defined between the needle receiving portion **122** and the tip portion **116**. The second throat region **128** can define an open space for receiving a bodily tissue. The second throat region **128** can define a width W3 and a height H2 such that the height H2 is generally greater than the height H1 of the lateral edge **126** of the front throat region **118**, thereby configuring the second throat region **128** for deeper penetration into the bodily tissue than the front throat region **118**. In other embodiments, however, the height H2 of the second throat region **128** can be equal to or smaller than the height H1 of the front throat region **118**. In some embodiments, the second throat region **128** can be configured or used to suture a portion of a Y-shaped implant to such as a sacrum or tissues proximate to the sacrum. In some embodiments, the second throat region **128** can be configured or used to suture a portion of any other type of implant to various bodily tissues such as vaginal walls, sacrum uterus, vaginal apex and other pelvic tissues.

The needle receiving portion **122** is provided at the head portion **108** to capture the needle **104**. The needle receiving portion **122** can include a recess **130** for receiving at least a portion of the needle **104**. In accordance with some embodiments of the invention, the needle receiving portion **122** can have a length L2. The length L2 of the needle receiving portion **122** defines depth of the recess **130** that the needle **104** can, at maximum, enter into the needle receiving portion **122** after contacting a surface of the needle receiving portion **122**. The length L2 can vary based on the requirements. In some embodiments of the invention, the needle receiving

portion 122 can have a width W2. The width W2 can vary based on the requirements. As mentioned above, the needle receiving portion 122 includes or defines the recess 130. In various embodiments, the recess 130 can be in the form of a slot, an aperture, an opening, or any other type of a hollow space on the needle receiving portion 122 such that the recess 130 is configured to receive a suture or a dart (as explained later). In some embodiments, the width W2 of the needle receiving portion 122 can be designed to accommodate multiple recesses similar to the recess 130. In some embodiments, the multiple recesses may be configured to assure the capture or securement of a needle that has been deflected slightly after being passed through bodily tissue. In some embodiments, the recess 130 can be, for example, an L-shaped slot or a T-shaped slot.

In some embodiments, the medical device 100 can be configured to place or suture a Y-shaped implant to the bodily tissue such that the front throat region 118 can be configured to suture a portion of the Y-shaped implant to the anterior and the posterior vaginal wall, and the second throat region 128 can be configured to suture a portion of the Y-shaped implant to the sacrum or tissues proximate the sacrum. In other embodiments, the medical device 100 can be configured to place or suture other types of implants also to various bodily tissues. In some embodiments, the medical device 100 may be used to suture a mesh of any shape or of any number of legs, arms or projections. For example, the medical device 100 may be used to suture a V-shaped or a U-shaped implant into bodily tissue. In some embodiments, the medical device 100 may be used to suture implants that include any number of legs, arms, or projections to bodily tissues.

In some embodiments, the medical device can include a depth adapter (not shown in FIG. 1). In some embodiments, the depth adapter is permanently or fixedly coupled within the second throat region 128 (to effectively close the second throat region 128). In other embodiments, the depth adapter can be removably fitted in the second throat region 128 and the depth of the second throat region 128 can be adjusted depending on the requirements such as depending on the height of a bodily tissue penetration needed. In some embodiments, the depth adapter may be used in the second throat region 128 such as when a bodily tissue may surround the second throat region 128 and there can be possibility of prolapse of a portion of the bodily tissue in the second throat region 128, which may not be needed. This can, for example, occur when the front throat region 118 contacts a bodily tissue such that the longitudinal axis C2 of the medical device 100 or a direction of the front throat region 118 is at an angle lesser or greater than 90 degrees (non-perpendicular) with respect to a surface or plane of the bodily tissue during contact. However, even during non-perpendicular contact in cases when there may not be a surrounding tissue nearby the second throat region 128, the depth adapter may not be necessarily needed. Therefore, in various embodiments, an operator may decide to use or not to use the depth adapter as per specific requirements.

In some embodiments, the front throat region 118 can contact a bodily tissue such that the longitudinal axis C2 of the medical device 100 or a direction of the front throat region 118 is at an angle of 90 degree with respect to a surface or plane of the bodily tissue during contact that is to say a perpendicular or straight contact of the front throat region 118 to a surface of the bodily tissue. In such cases, the penetration depth of the needle 104 into the bodily tissue can be limited to the height of the front throat region 118 and thus the penetration depth can be controlled by configuring

the front throat region 118 accordingly. In such embodiments, the depth adapter may not be required in the second throat region 128. However, in some embodiments, the depth adapter may still be used though not necessary.

The medical device 100 includes the needle deployment mechanism 106 disposed at least partially within the lumen 114 for moving the needle 104 along the elongate member 102. The needle deployment mechanism 106 defines a proximal portion and a distal portion. The proximal portion of the needle deployment mechanism 106 can be coupled to the handle of the elongate member 102. The distal portion of the needle deployment mechanism 106 can be coupled to the needle 104. In some embodiments, the distal portion of the needle deployment mechanism 106 can extend into the head portion 108 of the elongate member 102. The needle deployment mechanism 106 is configured to move the needle 104 along the elongate member 102. The needle deployment mechanism 106 moves the needle 104 between a retracted position and a deployed position. In the deployed position, the needle deployment mechanism 106 causes the needle 104 to extend out of the lumen 114 of the elongate member 102 and extend out through the opening 120. Various types of actuating mechanisms may be deployed within, or coupled to the needle deployment mechanism 106 for moving the needle 104 in and out of the opening 120. The medical device 100 can be moved from the retracted state to the deployed state by actuating the needle deployment mechanism 106 along a direction D1. After being moved to the deployed state, the needle deployment mechanism 106 can be moved to the retracted state by actuating the needle deployment mechanism 106 along a direction D2 which is opposite to the direction D1. In some embodiments, the needle deployment mechanism 106 is biased to its retracted state.

In some embodiments, the retracted position of the needle deployment mechanism 106 may also be referred to as the retracted position of the medical device 100 and similarly, the deployed position of the needle deployment mechanism 106 may also be referred to as the deployed position of the medical device 100 interchangeably throughout this document, and without any scope limitations.

The medical device 100 further includes the needle 104 disposed within the lumen 114 of the elongate member 102. The needle 104 of the medical device 100 can be coupled to or disposed within the needle deployment mechanism 106. The needle 104 is configured to move toward the recess 130 of the needle receiving portion 122 while being shifted to the deployed state from the retracted state of the medical device 100. In some embodiments, the needle 104 is at least partially disposed into the lumen 114 of the elongate member 102 of the medical device 100. The needle 104 is configured to at least partially exit the lumen 114 in the deployed state and may be completely contained inside the lumen 114 in the retracted state of the medical device 100.

In some embodiments of the invention, the needle 104 is a curved needle 104. In some embodiments, the needle 104 has a substantially circular cross section. In some embodiments, the needle 104 can have a shape different than a circular cross-sectional shape. In some embodiments, the needle 104 can have a cross-sectional shape (or outer shape) of any type of a polygon. For example, the needle 104 can have a square or a rectangular cross-sectional shape (or outer profile). In some embodiments, the needle 104 can have a tapered shape and/or a tapered portion (e.g., tapered from a proximal portion to a distal portion). In such embodiments, the needle 104 can have a varying diameter or width.

In some embodiments, at least a portion of the needle **104** can be formed of a flexible material. For example, a portion of the needle **104** that remains disposed within the lumen **114** when the medical device **100** is in the retracted state can be configured to flex or bend. In some embodiments, at least a portion of the needle **104** can be formed of the flexible material so that the portion of the needle **104** can conform to a profile of the lumen **114** as the needle **104** is slidably moved within the lumen **114**. In some embodiments, the needle **104** can conform to a profile of the needle deployment mechanism **106** as the needle **104** is slidably moved within the needle deployment mechanism **106**. The needle may have any shaped tip useful for puncturing tissue. For example, the needle may have a standard bevel shape, multiple bevels, multipoints, or a single point.

In some embodiments, the needle **104** can be loaded with a suture coupled to a dart. The suture can be coupled to the dart at one end and the other end can be manipulated by the user (as will be explained in more detail below). The dart can be coupled to the suture at one end and the other end can be pointed. The pointed end of the dart can pierce through the bodily tissues. In some embodiments, the suture dart arrangement can be removably coupled to the needle deployment mechanism **106**. In some embodiments, the suture dart arrangement can be, at least, partially disposed into the needle deployment mechanism **106**. As the needle deployment mechanism **106** is actuated toward the direction D1, the needle **104** moves toward the needle receiving portion **122**. The needle **104** pierces the bodily tissue placed between the tip portion **116** and the needle receiving portion **122**. The suture dart arrangement that is coupled to the needle **104** is thereby effectively passed through the bodily tissue. The suture is coupled to the needle **104**; therefore it will also pass through the bodily tissue along with the needle **104**. In some embodiments, the dart can be permanently coupled to the suture such as to catch the dart in the needle receiving portion **122** while the medical device **100** is inside the body of the patient and pull the dart and the suture along with the medical device **100** out of the body of the patient thereafter (explained later).

In some embodiments, the suture can be braided. In some embodiments, the suture can be a monofilament. The suture can be made of medical grade polymers such as polypropylene. In some embodiments, the suture can be made of a bio-absorbable material. After the bodily tissue grows over the implant, the suture may not be further required to fixate the implant to the tissue and therefore, a bio-absorbable suture is desirable. The dart and any extra suture can be removed from the body of the patient after placing the implant such as to avoid any internal tissue injury due to presence of any pointed materials. In some embodiments, laparoscopic scissors or cutters can be used to trim the sutures.

FIGS. 2A-2E illustrate various perspective views of a medical device **200** and portions of the medical device **200** that can be used for placing or suturing a bodily implant **202** to a bodily tissue **204** inside a body of a patient. The bodily implant **202** can be sutured to the bodily tissue **204** by using a suture **206** loaded over at least a portion of the medical device **200**.

FIG. 2A is a perspective view of the medical device **200**, in accordance with an embodiment of the present invention. The medical device **200** includes an elongate member **208**, a needle carrier **210**, a needle deployment mechanism **212** and a head portion **214**. The needle carrier **210** and the needle deployment mechanism **212** are, at least, partially disposed within the elongate member **208**. The head portion

214 can be provided at a portion of the elongate member **208**. The medical device **200** defines a lateral axis R1 and a longitudinal axis R2. In some embodiments, the lateral axis R1 is perpendicular to the longitudinal axis R2.

The elongate member **208** includes a distal portion **216** and a proximal portion **218** with a length L3 of the elongate member **208** extending between the distal portion **216** and the proximal portion **218** longitudinally. The elongate member **208** defines a width W7. In some embodiments, the elongate member **208** is sized to be inserted or disposed within a cannula or lumen of a laparoscopic trocar. In various embodiments of the invention, the length L3 includes a working length (not shown) of the medical device **200**. The working length may be defined as a portion of the medical device **200** that can be inserted into the patient's body during a surgical procedure. The elongate member **208** defines a lumen **220** extending from the proximal portion **218**, running across the length L3 of the elongate member **208** and culminating at the distal portion **216** of the elongate member **208**. The lumen **220** defines an inner diameter ID2 of the elongate member **208**. The lumen **220** of the elongate member **208** is configured to receive and house at least some other elements and portions of the medical device **200**. For example, the elongate member **208** can be configured to house at least a portion of the needle deployment mechanism **212** and the needle carrier **210** within a space formed within the lumen **220**. The elongate member **208** further includes a handle **222** that is configured to be held by an operator while performing a surgical procedure.

The distal portion **216** of the elongate member **208** includes or is coupled to the head portion **214**. The head portion **214** defines a proximal portion **224** and a distal portion **226**. The head portion **214** includes a tip portion **228**, a front throat region **230**, an opening **232** defined by the front throat region **230**, and a needle receiving portion **234**. In accordance with the illustrated embodiment, the head portion **214** includes a second throat region **236** also.

The medical device **200** further includes the needle deployment mechanism **212** disposed at least partially within the lumen **220** for moving the needle carrier **210** along the elongate member **208**. The needle deployment mechanism **212** defines a proximal portion **238** and a distal portion **240**. The proximal portion **238** of the needle deployment mechanism **212** can be coupled to the handle **222** of the elongate member **208**. The distal portion **240** of the needle deployment mechanism **212** can be coupled to the needle carrier **210**. The distal portion **240** of the needle deployment mechanism **212** can extend into the head portion **214** of the elongate member **208**. The needle deployment mechanism **212** moves the needle carrier **210** between a retracted position and a deployed position. The retracted position of the needle carrier **210** may be referred to as the position where the needle carrier **210** resides inside the lumen **220** of the elongate member **208**. The deployed position of the needle carrier **210** may be referred to as the position where, at least, a portion of the needle carrier **210** resides outside the lumen **220** of the elongate member **208**. The needle deployment mechanism **212** includes or is coupled to an actuator **242** (shown in FIG. 2C).

The actuator **242** is disposed at the proximal portion **218** of the elongate member **208** of the medical device **200** and extends up to the needle carrier **210**. In some embodiments, the actuator **242** may extend from the proximal portion **218** to a medial portion of the elongate member **208** and may also extend to the distal portion **216**, in some embodiments. The actuator **242** is configured to move the needle carrier **210** out of the opening **232** at the distal portion **216** of the

elongate member **208**. The actuator **242** is connected to the needle carrier **210**. The actuator **242** can either be in the retracted position (not shown) or in the deployed position (not shown). In the deployed position, the actuator **242** causes the needle carrier **210** to extend out of the lumen **220** of the elongate member **208**. Various types of actuating mechanisms may be deployed within or coupled to the actuator **242** for moving the needle carrier **210** out of the opening **232**. The medical device **200** can be configured to change its configuration from the retracted state to the deployed state by actuating the needle deployment mechanism **212** along a direction B1. After being actuated to the deployed state, the needle deployment mechanism **212** can be shifted to the retracted state by actuating the needle deployment mechanism **212** along a direction B2 which is opposite to the direction B1. In some embodiments, the needle deployment mechanism **212** is biased to its retracted state.

The medical device **200** further includes the carrier or needle carrier **210** disposed within the lumen **220** of the elongate member **208**. The needle carrier **210** of the medical device **200** is coupled to the distal portion **240** of the needle deployment mechanism **212**. The needle carrier **210** defines a distal portion **244** and a proximal portion **246**. The proximal portion **246** of the needle carrier **210** is coupled to the actuator **242** of the needle deployment mechanism **212**. The distal portion **244** of the needle carrier **210** is configured to enter the needle receiving portion **234** (discussed later) while in the deployed state. The needle carrier **210** can have a shape of various types and of various cross-sections, as discussed above in conjunction with FIG. 1. In some embodiments, the distal portion **244** of the needle carrier **210** defines a channel **252** for holding a suture or a dart (explained later). In some other embodiments, the channel **252** may extend along an entire length of the needle carrier **210**.

In some embodiments, the needle carrier **210** is, at least, partially disposed into the lumen **220** of the elongate member **208** of the medical device **200**. The needle carrier **210** is configured to at least, partially exit the lumen **220** in the deployed state and may be completely contained inside the lumen **220** in the retracted state of the medical device **200**. In some embodiments, at least a portion of the needle carrier **210** can be formed of a flexible material, such as, discussed above in conjunction with FIG. 1.

FIG. 2B is a perspective view of the medical device **200** according to an embodiment. In the illustrated embodiment, the medical device **200** includes a depth adapter **248**. Referring to FIG. 2B in conjunction with FIG. 2A, the medical device **200** is illustrated along with the penetration depth adapter **248**. The penetration depth adapter **248** is placed in the second throat region **236** of the medical device **200**. The depth adapter can be configured to be removably coupled to or placed in the second throat region **236**. The front throat region **230** and the second throat region **236** are described below in conjunction with figures that show the enlarged views. While FIG. 2B illustrates the medical device **200** with a depth adapter **248** removably coupled thereto, in other embodiments, the depth adapter **248** is fixedly or permanently coupled to the medical device **200**. For example, in some embodiments, the depth adapter is integrally or monolithically formed with the head or distal portion of the medical device. In such embodiments, the integrally or monolithically formed depth adapter blocks a portion of or eliminates the second throat portion as describe herein with respect to the removable depth adapter **248**.

FIG. 2C is an enlarged perspective view of the head portion **214** of the medical device **200** engaged with the

bodily tissue **204** and the bodily implant **202**. FIG. 2D is another enlarged perspective view of the head portion **214** of the medical device **200**, taken at a different angle. Referring now to FIGS. 2C and 2D in conjunction with FIGS. 2A-2B, the medical device **200** is further described below.

In some embodiments, the needle carrier **210** is mechanically connected to the actuator **242** through a carrier wire **250** and is disposed within the lumen **220** of the elongate member **208** in the tip portion **228**. As mentioned above, the head portion **214** includes the tip portion **228**, the front throat region **230**, the second throat region **236**, the opening **232** defined by the front throat region **230** and the needle receiving portion **234**.

The tip portion **228** includes the front throat region **230**. The front throat region **230** can be defined parallel to the lateral axis R1 of the medical device **200**. The front throat region **230** includes a front edge **254** and a lateral edge **256**. The front edge **254** defines a length L4 extending through the front edge **254**. The front edge **254** can define a substantially circular profile.

The lateral edge **256** abuts the front edge **254** thereby forming a throat angle β between the lateral edge **256** and the front edge **254**. In some embodiments, the throat angle β can be 90 degrees so that the front edge **254** and the lateral edge **256** can be perpendicular to one another. The lateral edge **256** defines a height E1 along a plane C3 of the lateral edge **256**. In some embodiments, the height E1 limits a penetration depth **258** of the needle carrier **210**, as will be discussed later. In some embodiments, the height E1 can be 2 mm thereby allowing the needle carrier **210** penetration into the bodily tissue **204** within a range of 1 mm to 2 mm. In some embodiments, the penetration into the bodily tissue **204** is less than 1 mm. In some embodiments, the front edge **254** and the lateral edge **256** are not perpendicular to one another. In some embodiments, the front edge **254** or the lateral edge **256** may be curved or include a curved portion.

The front throat region **230** defines an open space bounded between the front edge **254** and the lateral edge **256** to receive the bodily tissue **204** therein. The front throat region **230** can be an empty area where the bodily tissue **204** can be forced into. In some embodiments, the bodily tissue **204** can be prolapsed into the front throat region **230**. In some embodiments, the front throat region **230** can be configured or used to suture a portion of a Y-shaped implant to an anterior and a posterior vaginal wall, as discussed later.

The opening **232** can be defined by the lateral edge **256** of the front throat region **230** anywhere on the lateral edge **256**. The opening **232** can be in communication with the lumen **220** of the elongate member **208** such that the needle carrier **210** moves in and out of the medical device **200** through the opening **232** in a direction A1 (shown in FIG. 2C) along the length L4 of the front edge **254** of the front throat region **230**. The opening **232** can define a width W4 such that the width W4 is smaller than the height E1 of the lateral edge **256** of the front throat region **230**. The opening **232** allows movement of the needle carrier **210** out of the elongate member **208**.

The second throat region **236** can define an open space for receiving the bodily tissue **204**. In some embodiments, the second throat region **236** can be defined parallel to the longitudinal axis R2 on the medical device **200**. In some embodiments, the lateral axis R1 and the longitudinal axis R2 are perpendicular to each other. In some embodiment, the lateral axis R1 and the longitudinal axis R2 are non-perpendicular to each other. In some embodiments, the front throat region **230** and the second throat region **236** are perpen-

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dicular to each other. In some embodiments, the front throat region 230 and the second throat region 236 are non-perpendicular to each other.

In some embodiments, the second throat region 236 can be defined between the needle receiving portion 234 and the tip portion 228 such that the second throat region 236 contacts the tip portion 228 on one side and the needle receiving portion 234 on the other side. The second throat region 236 can define a width W5 and a height E2 such that the height E2 is greater than the height E1 of the lateral edge 256 of the front throat region 230, thereby, configuring the second throat region 236 for deeper penetration into the bodily tissue 204 than the front throat region 230. In some embodiments, the second throat region 236 can be configured to place or suture the bodily implant 202 over a sacrum of a body of a patient. In some embodiments, the medical device 200 can be configured to place or suture a Y-shaped implant to the bodily tissue 204 such that the front throat region 230 can be configured to suture a portion of the Y-shaped implant to the anterior and the posterior vaginal walls, and the second throat region 236 can be configured to suture a portion of the Y-shaped implant to the sacrum.

The needle receiving portion 234 is provided at the head portion 214 to capture the needle carrier 210. The needle receiving portion 234 can include a recess 260 for receiving at least a portion of the needle carrier 210. In accordance with some embodiments of the invention, the needle receiving portion 234 can have a length L6. The length L6 of the needle receiving portion 234 defines depth of the recess 260 that the needle carrier 210 can, at maximum, enter into the needle receiving portion 234 after contacting a surface of the needle receiving portion 234. The length L6 can vary based on the requirements. In some embodiments of the invention, the needle receiving portion 234 can have a width W6. The width W6 can vary based on the requirements. As mentioned above, the needle receiving portion 234 includes or defines the recess 260. In various embodiments, the recess 260 can be in the form of a slot, an aperture, an opening, or any other type of a hollow space on the needle receiving portion 234, such that, the recess 260 is configured to receive the suture 206, or a dart (as explained later). In some embodiments, the recess 260 can be, for example, an L-shaped slot or a T-shaped slot.

In accordance with some embodiments of the present invention; the plane C3 of the lateral edge 256 of the front throat region 230 can form a contact angle λ with a plane C4 of the bodily tissue 204 when the front throat region 230 contacts the bodily tissue 204 and hence, the bodily implant 202. In some embodiments, the tip portion 228 can contact the bodily tissue 204 in a direction A2 that is perpendicular to the plane C4. In some embodiments, the contact angle λ can be 90 degrees, thereby; contacting only the tip portion 228 of the medical device 200 perpendicular to the bodily tissue 204. In such cases, the penetration depth 258 of the front throat region 230 within the bodily tissue 204 is generally not greater than the height E1 of the front throat region 230. As the front throat region 230 is an empty space, therefore, the bodily tissue can be forced into it on application of a force along the height E1 at the proximal portion 224 of the elongate member 208. After the medical device 200 has penetrated to a depth equal to the height E1, the front edge 254 would stop the medical device 200 to penetrate further into the bodily tissue 204. At this point, the needle deployment mechanism 212 is actuated (as would be explained later in detail). Upon actuation, the needle carrier 210 comes out of the elongate member 208 through the opening 232 and enters the front throat region 230 and

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moves along the front edge 254 of the front throat region 230. Therefore, the maximum depth of the bodily tissue 204 that can be penetrated by the needle carrier 210 would be equal to or lesser than (depending upon location of the opening 232 on the lateral edge 256) the penetration depth 258 of the front throat region 230 (i.e. height E1 of the front throat region 230). In an example, the bodily tissue 204 can be a vaginal wall such as an anterior vaginal wall or a posterior vaginal wall. In normal circumstances, the vaginal wall has a thickness greater than 1 mm, therefore, the penetration depth 258 of less than 1 mm would result in a needle tissue bite, which would not let penetrate through the vaginal wall and into the vaginal lumen 220. In some embodiments, soft tissue within the vaginal lumen can be used as the anchoring or suturing tissue.

As illustrated in FIG. 2D, the needle carrier 210 can also come out of the opening 232 and move along the length L4 of the front throat region 230 in the direction A1. The suture 206 can form a loop or coil (explained later). This coil can slide over the head portion 214 along the direction B1 without catching or snagging at the front throat region 230. In the illustrated embodiment, the needle carrier 210 pushes the suture or needle that is coupled thereto through the bodily tissues 204 toward the needle catch or receiving portion 234.

FIG. 2E is a perspective view of a portion of the medical device 200 engaged with the bodily tissue 204 and the implant 202 at a contact angle of less than 90 degrees. In some embodiments, a laparoscopic approach may be used for suturing the bodily implant 202 to the bodily tissue 204. In such cases, the contact angle can be limited by a laparoscopic cannula which may be less than 90 degrees, as illustrated in FIG. 2E. In such embodiments, the open space in the second throat region 236 can be closed so as to not allow surrounding tissues to prolapse into the second throat region 230.

As shown in FIGS. 2C-2E, a penetration depth adaptor 248 can be fitted in the second throat region 236. The second throat region 236 can be fitted with the penetration depth adaptor 248 to control the needle tissue bite. This may be required such as when the second throat region 236 contacts the bodily tissues for penetration such as during suturing on the sacrum or proximate the sacrum. In some embodiments, it may be required when there are surrounding tissues proximate the second throat region 236 that may prolapse into the second throat region 236 during abutting of the front throat region 230 to the surface of the bodily tissues. For example, in some embodiments, when the contact angle λ formed by the front throat region 230 with the plane C4 of the bodily tissue 204 is less than or greater than 90 degrees, the surrounding tissues, if any, may prolapse into the second throat region 236. In some embodiments, the depth adaptor 248 can be sized for accordingly controlling the depth of penetration in the second throat region 236. In some embodiments, the depth adaptor 248 can be sized to control the depth of penetration (i.e., depth of bite) into tissues, for example, to prevent inadvertent punctures into bones, organs, tendons, or other tissues. The depth adaptor 248 can be opaque, translucent, or transparent to allow for visualization during placing the medical device 200 onto the bodily tissue 204. In alternative embodiments, the medical device 200 can include a plurality of adaptors similar to the adaptor 248 that can include color coding or other markings to identify their sizes or penetrating depths. In some embodiments, the depth adaptor 248 has a smooth outer surface. In other words, in some embodiments, the outer surface of the depth adaptor 248 does not have (or is devoid of) sharp or

jagged surfaces. In such embodiments, a portion of a suture, including a suture loop, may easily slide past or along the outer surface of the depth adaptor **248**. In some embodiments, the depth adaptor **248** may be adjustable. For example, in some embodiments, the depth adaptor **248** may have a first portion and a second portion movable with respect to the first portion. The depth adaptor **248** may be set at a first configuration (with the first portion at one location with respect to the second portion) and may be set at a second configuration (with the first portion at a different location with respect to the second portion) to achieve or help facilitate a different amount of penetration depth.

In some embodiments, the depth adapter **248** can be removed from the device. In such embodiments, when the depth adapter **248** is removed, the height of the second throat region **236** can be greater than the height of the front throat region **230**. Therefore, the second throat region **236** can define a larger empty space than the front throat region **230**. This enables deeper penetration of bodily tissues through the second throat region **236** than the first throat region **230**. Thus, the second throat region **236** can be used for suturing the implant to bodily tissues where a deeper penetration may be needed such as suturing to the sacrum or proximate the sacrum as discussed above. And, the front throat region **230** can be used for suturing the implant to the bodily tissues that may not require a deep penetration such as suturing the implant to the vaginal walls where a deeper penetration may not be preferred while operating laparoscopically so as to avoid piercing the vaginal walls to the lumen of the vagina.

In the illustrated embodiment of FIG. 2C, the needle carrier **210** does not penetrate through the entire thickness of the vaginal wall. The vaginal wall can have a side S1 facing the bodily implant and a side S2 facing the vaginal lumen. The suture **206** is shown entering on side S1 of the bodily tissue **204**, not penetrating through side S2, and exiting back through side S1.

The front throat region **230** can control or limit the depth of penetration to the height of the front throat region **230** with or without a use of the depth adapter **248** when the front throat region **230** contacts the bodily tissues in a direction perpendicular to the direction of the plane C4 of the bodily tissue **204**. However, in some embodiments, when the front throat region **230** contacts the surface of the bodily tissue at an angle, a portion of the surrounding tissues may be prolapsed into the second throat region **236**. Therefore, the needle may pierce the tissue prolapsed into the second throat region **236** which may not be required. In such cases, the depth adapter **248** may be fitted in the second throat region **236** when the contact angle λ is less than or greater than 90 degrees. In some embodiments, the depth adapter **248** may be fitted in the second throat region **236** when the second throat region **236** contacts the bodily tissues such as during suturing of the implant to the sacrum or proximate tissues such as to limit the penetration depth. In such cases, the penetration depth may be controlled by adjusting the size of the depth adapter **248** or the size of the open space of the second throat region **236**. In some embodiments, the front throat region **230** may include a curved region or opening.

In some embodiments, the actuator **242** is configured to actuate the medical device **200** to the deployed position from the retracted position. The actuator **242** moves the needle carrier **210** along the direction B1 and back to the retracted position from the deployed position by moving the needle carrier **210** along the direction B2. In some embodiments, actuating can include moving the needle deployment mechanism **212** or the needle carrier **210** in the direction B1. The needle carrier **210** can be moved slidably into the lumen **220**

in the direction B1 along the lumen **220** and away from the proximal portion **218** of the elongate member **208**, and toward the front edge **254** of the front throat region **230**. The front throat region **230** provides an empty space that receives the bodily tissue **204** to be sutured with the implant **202**. Generally, in some embodiments, the height E1 of the lateral edge **256** decides the penetration depth **258** of the needle carrier **210** into the bodily tissue **204**. The needle carrier **210** moves out of the elongate member **208** through the opening **232** defined on the lateral edge **256** of the front throat region **230** and pierces through the bodily tissue **204**. The needle carrier **210** moves along the length L4 toward the front edge **254** of the front throat region **230** while travelling inside the bodily tissue **204**. Upon further actuation of the needle deployment mechanism **212**, the needle carrier **210** reaches an end of the front throat region **230** and comes out of the bodily tissue **204**. The height E1 of the lateral edge **256** of the front throat region **230** can control the penetration depth **258** of the needle carrier **210** into the bodily tissue **204**. The needle carrier **210** can now follow a predefined pathway and travel toward the needle receiving portion **234** of the medical device **200** until the needle carrier **210** has moved into the recess **260**. The recess **260** acts as a capture slot for the needle carrier **210** when it moves toward the needle receiving portion **234** on being actuated along the direction B1.

In some embodiments, actuating can include moving the medical device **200** in the direction B2. The needle carrier **210** can be moved slidably into the lumen **220** in the direction B2 along the lumen **220** and toward the proximal portion **218** of the elongate member **208**, and away from the needle receiving portion **234** of the medical device **200** until the needle carrier **210** has moved out of the needle receiving portion **234** and is back into the lumen **220** of the elongate member **208** completely. In some embodiments, the actuator **242**, as discussed above, can be configured to move the medical device **200** back and forth along the direction B1 and B2.

The medical device **200** can be used to place multiple sutures using a single needle carrier **210** similar to the needle carrier **210**. The medical device **200** can be used for placing multiple layers of sutures over one other in order to create more robust sutures or suture knots thereby leading to effective and efficient placing of the implant **204**. In some embodiments, the bodily implant **202** can be a Y-shaped implant.

The above embodiments discussed the use of the front throat region **230** for receiving the bodily tissue **204** to be sutured. In still some embodiments (e.g. where the depth adapter **248** is at least partially removed from the second throat region **236**), the medical device **200** can be placed in the body in such a way that the bodily tissue **204** (to be sutured) is present within the second throat region **236**. When the needle carrier **210** is actuated along direction B1, it passes through the second throat region **236** (where the bodily tissue **204** is placed) and moves toward the recess **260** of the needle receiving portion **234**. As the height E2 of the second throat region **236** is greater than the height E1 of the front throat region **230** generally, the medical device **200** can have a greater penetration depth **258**, in such embodiments, when the tissue is placed in the second throat region **236**. The retraction of the needle carrier **210** or the medical device **200** toward the retracted state can be done in a manner as that described for other embodiments above.

FIG. 3A is a perspective view of the medical device **200** loaded with a suture **302**, in accordance with an embodiment of the present invention. FIG. 3B is a perspective view of the

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suture **302** engaged with a portion of a bodily tissue **318** and an implant **316** such as during implant fixation, in accordance with an embodiment of the present invention.

The suture **302** includes a first end **304** and a second end **306**. In some embodiments, the suture **302** can include a dart **308** coupled to the first end **304** of the suture **302**. The first end **304** with the dart **308** can be loaded onto the needle carrier **210**. In an embodiment, the suture **302** can be wrapped around the medical device **200** so as to cross over the first end **304** and the second end **306**, such as, to form a suture noose **310**. In some embodiments, the suture noose **310** can be placed over the proximal portion **218** of the elongate member **208**. The suture noose **310** can be formed by a suture cross-over of the two suture ends **304** and **306**. In some embodiments, the suture noose **310** can be prefabricated and can be loaded onto the medical device **200** by loading the first end **304** with the dart **308** over the needle carrier **210** and passing the medical device **200** through the suture noose **310**, such that, the suture noose **310** is proximate the proximal portion **218** of the elongate member **208**. In some embodiments, the suture noose **310** can be positioned proximate the handle **222** of the elongate member **208**.

In some embodiments, the suture noose **310** can be formed by tying the first suture end **304** and the second suture end **306** into a running knot or a loop **312**, as illustrated in FIG. 3B. The running knot **312** defines a diameter **314** of the suture noose **310**. The running knot **312** can be configured so that the diameter **314** decreases, making the suture noose **310** smaller when either of the first end **304** and the second end **306** of the suture is pulled along a direction P1.

The medical device **200** can be inserted inside the body of a patient by using a laparoscopic approach. When the needle deployment mechanism **212** is actuated in a direction P2, the dart **308** loaded onto the needle carrier **210** moves toward the needle receiving portion **234** along with the suture **302**. The dart is received by the needle receiving portion **234** and the first end **304** of the suture **302** attached to the dart **308** passes through the bodily tissue **318**. The second end **306** of the suture **302** can be pulled by the user along the direction P1. The suture noose **310**, thus, can slide over the elongate member **208** along the direction P2 when the second end **306** is pulled along the direction P1. In some embodiments, the diameter **314** of the suture noose **310** decreases and the suture noose **310** slides over the elongate member **208** along the direction P2 when the second end **306** is pulled along the direction P1. The diameter **314** would decrease and the noose **310** will slide till the suture **302** cinches the bodily implant **316** to the bodily tissue **318** thereby forming a knot, referred to as slip-tie knot. The needle deployment mechanism **212** can now be actuated in the direction P1 so that the needle carrier **210** returns back in the head portion **214** of the medical device **200**. The dart **308** can remain trapped inside the needle receiving portion **234** and the suturing device can be removed from the body of the patient.

In some embodiments, the slip-tie knot, as described above, can be strengthened by crossing the first end **304** and the second end **306** of the suture **302** over each other external to the body of the patient. The externally formed crossover can be pushed inside the body of the patient to form a second layer of the suture knot over the slip-tie knot. The process of forming external suture crossovers can be repeated to form multiple layers of suture knots (as illustrate later by FIGS. 8A-8C) so as to secure the bodily implant **316** to the bodily tissue **318**. The two suture ends **304** and **306** can be manually trimmed so as to leave no excess material

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or sharp edges inside the body of the patient. In some embodiments, laparoscopic scissors or cutters can be used to trim the sutures. The medical device **200** can then move onto a new location on the bodily implant **316** and the bodily tissue **318** to place another knot with a new suture.

In some embodiments, the suture noose **310** can be formed using a two finger technique, as illustrated in FIG. 3C. In accordance with the illustrated technique, the suture **302** along with the dart **308** is loaded onto the needle carrier **210** (illustrated in FIGS. 3A and 3B). The remaining portion of the suture **302** extends over the elongate member **208** along a direction Q1 and brought toward the proximal portion **218** of the elongate member **208**. The suture **302** is wrapped around an index finger and a middle finger of an operator along a direction Q2. The suture **302** is then directed underneath the medical device **200**, as indicated a direction Q3. The suture **302** is then brought over the actuator **242** and the elongate member **208** and crossed over a suture portion present there along a direction Q4 so as to form the suture noose **310**. This makes the portion of the suture **302** proximate the second end **306** crossed over the portion of the suture **302** proximate the first end **304**. The second end **306** of the suture **302** is pulled through the newly formed suture noose **310** along a direction such as Q5 to form a loop or crossover as indicated by a direction Q6. The loop formed can be similar to the lop **312** as described by FIG. 3A.

In some embodiments, the suture noose **310** can be formed using a single finger technique as illustrated in FIG. 3D. In the illustrated technique, the suture **302** along with the dart **308** is loaded onto the needle carrier **210** (in a manner similar to illustrated in FIGS. 3A and 3B). The remaining portion of the suture **302** extends over the elongate member **208** along a direction T1 and brought toward the proximal portion **218** of the elongate member **208**. The suture **302** is wrapped around an index finger of an operator along a direction T2. The suture **302** is then directed underneath the medical device **200**, as indicated by arrow T3. The suture **302** is then brought over the actuator **242** and the elongate member **208** and crossed over the portion of the suture **302** present there, so as to form the suture noose **310** along a direction T4. This makes the portion of the suture **302** proximate the second end **306** crossed over the portion of the suture **302** proximate the first end **304**. The second end **306** of the suture **302** is pulled through the newly formed suture noose **310** along a direction T5 to form a loop such the loop **312** or crossover. In some embodiments, a post may be used instead of the index finger of the operator. The loop formed can be similar to the loop **312** as described by FIG. 3A.

The techniques described by the way of FIGS. 3A-3D can be effectively and efficiently used to place multiple layers of suture knots so as to secure the bodily implant with the bodily tissue. In other embodiments, several other techniques may also be used to form the noose without any limitations.

FIG. 4A is a perspective view of the medical device **200** loaded with a suture **402**, in accordance with an embodiment of the present invention. FIG. 4B is a perspective view of the suture engaged with a portion of a bodily implant **404** (also referred to as implant **404**) placed over a portion of a bodily tissue **406**. In some embodiments, a single suture like the suture **402** can be used to place a series of suture knots one over another forming multiple suture knot layers or at distinct locations. The suture **402** can include a first end **408** and a second end **410**. The suture **402** can be secured to the bodily implant **404** and the bodily tissue **406** by manipulat-

ing one of the first end **408** and the second end **410**, while the other end can be secured to the bodily tissue **406**.

In accordance with the embodiments illustrated in FIGS. **4A** and **4B**, the suture **402** can be used to place a knot referred to as a twist tie knot. Generally, the first end **408** of the suture is first secured to the bodily tissue **406**. The second end **410** of the suture **402**, along with the dart **412**, can be loaded onto the needle carrier **210** of the medical device **200**. The medical device **200** can then be rotated along a direction **V1** or **V2** so as to cause the suture **402** to be wound around the elongate member **208** and form a suture coil **414** over the elongate member **208**. The suture coil **414** can define a diameter **416**. In the illustrated embodiment, the suture coil **414** is shown to be formed proximate the head portion **214** of the medical device **200**. However, in other embodiments, it can be positioned at other locations. The rotation of the medical device **200** can be repeated multiple times at the discretion of the operator. The rotation of the medical device **200** is generally done after insertion of the medical device **200** inside a body of a patient and before actuation of the needle deployment mechanism **212** for advancing the needle carrier **210** out of the opening **232**.

FIG. **4B** is a perspective view of the suture **402** with the first end **408** of the suture **402** placed inside or secured to the bodily tissue **406**.

The first end **408** of the suture **402** is fixed inside the bodily tissue **406** while the second end **410** is darted and loaded onto the needle. The second end **410** advances through the bodily implant **404** and the bodily tissue **406** upon actuation of the needle deployment mechanism **212**. The dart **412** enters the bodily tissue **406** at an entry site **418**. The height **E1** of the front throat region **230** prevents a deeper penetration of the dart **412** into the bodily tissue **406**, therefore the dart **412** covers a distance equal to the height **E1** inside the bodily tissue **406** and moves out of the bodily tissue **406** from an exit side **420**. The bodily implant **404** can be placed over the bodily tissue **406** and therefore the dart **412** pierces the bodily implant **404** and moves toward the needle receiving portion **234**. The dart **412** is then received by the needle receiving portion **234**. The medical device **200** with the dart **412** inside the needle receiving portion **234** can be pulled by the operator along a direction **G1** toward the outside the body of the patient. The pulling of the suture **402** along the direction **G1** results in sliding of the suture coil **414** along a direction **G2** toward the bodily implant **404**. As the suture **402** is further pulled along the direction **G1**, the diameter **416** of the suture coil **414** decreases and the suture coil **414** gets closer to the bodily implant **404** till the suture coil **414** cinches the bodily implant **404** against the bodily tissue **406**, thereby forming a twist tie over the bodily implant **404** for securing the bodily implant **404** over the bodily tissue **406**.

The dart **412** can be retrieved from the needle receiving portion **234** with the second end **410** of the suture **402** still attached to the dart **412**. This dart **412** along with the second end **410** of the suture **402** can be loaded onto the needle carrier **210** for placing another twist tie knot over the first twist tie knot so as to strengthen the suture knot. The placing of multiple coil layers can prevent the suture **402** from loosening and facilitate in efficiently placing the bodily implant **404** over the bodily tissue **404**. The second end **410** of the suture **402** can be trimmed, as discussed with reference to FIGS. **3A-3E** after placing the knot.

In some embodiments, the twist tie knot can be placed at different locations over the bodily implant **404** to accelerate the process of placing the implant over the bodily tissue **406**. In these embodiments, the free second end **410** from previ-

ous knot many be used for placing a next knot at a different location and the fixed first end **408** may provide an anchorage for the next knot.

FIG. **5** is a suture cartridge **502** used along with the medical device **200** for placing a suture **520** to a bodily implant and a bodily tissue, in some embodiments. The bodily implant and the bodily tissues can be similar to the bodily implant **202** and the bodily tissue **204** as described by FIGS. **2A-2E**. The suture cartridge **502** can be loaded over the medical device **200**. The suture **520** can be similar to the suture **302** or the suture **402**. The suture **520** can include a first end **524** and a second end **546**. In some embodiments, the suture cartridge **502** can be used to place multiple suture layers over the bodily implant **202** (similar to as described by FIGS. **3A-3D** and **4A-4B**) to secure the implant **22** over the bodily tissues **204**. The suture cartridge **502** can be a tubular shaped or a member of any other shape. The suture cartridge **502** defines a proximal end **504**, a distal end **506** and a lumen **508** extending from the proximal end **504** to the distal end **506** such that the proximal end **504** is proximate the handle **222** of the elongate member **208** of the medical device **200** when the medical device **200** is inserted in the lumen **508**. The suture cartridge **502** defines a length **510** extending from the proximal end **504** to the distal end **506**. The suture cartridge **502** defines a width **512**. The proximal end **504** can include a first slit **514** and the distal end **506** can include a second slit **516** for the suture **520** to pass through. In some embodiments, the proximal end **504** of the suture cartridge **502** can include at least one ear **518**. The ear **518** can be fabricated as a protrusion or projection at the proximal end **504** of the suture cartridge **502**. In some embodiments, the ear **518** can be present circumferentially around the suture cartridge **502** at the proximal portion **504**. In some embodiments, the ear **518** can be present on a portion of an outer surface of the cartridge **502** at the proximal portion **504**. The ear **518** can be used by the operator while loading the suture cartridge on the elongate member **208** of the medical device **200**. The ear **518** can facilitate coupling of the suture cartridge **502** with the elongate member **208**. In some embodiments, the elongate member **208** can be inserted through the lumen **508** of the suture cartridge **502** and the suture cartridge **502** can be a snap fitted onto the elongate member **208** or can be fitted through other coupling and fitting mechanisms.

A pre-fabricated suture noose **522** can be loaded over the suture cartridge **502** such as around the tubular shaped cartridge. The suture noose **522** can be similar to the suture noose **310** as described by FIGS. **3A-3D**. The first end **524** of the suture **520** can include the dart **308** or **412** (similar to as described by FIGS. **3A-3D** and **4A-4B**) and can be passed through the second slit **516** of the distal end **506** of the suture cartridge **502**. The suture **520** is then extended over the elongate member **208** along a direction **51** and can be loaded onto the needle carrier **210** as illustrated in FIG. **3A**. The second end **526** of the suture **520** is passed through the first slit **514** of the proximal end **504** of the suture cartridge **502** and can be used by the operator as described in FIGS. **3A-3D** or FIGS. **4A-4B**. In some embodiments, the suture cartridge **502** can be available as a separate device. In some embodiments, the suture cartridge **502** can be available within a kit that contains the medical device **200** and the cartridge. In some embodiments, the kit may include a plurality of such suture cartridges preloaded with the suture noose **522**.

FIGS. **6A-6D** illustrate some exemplary suture arrangements that may be used in conjunction with the medical device **100** or **200** in order to suture a bodily implant to a bodily tissue using procedures and techniques described in

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conjunction with FIGS. 3A-3D, FIGS. 4A-4B and FIG. 5. The bodily implant and the bodily tissues can be similar to the bodily implant 202, 316 or 404 and the bodily tissue 204, 318, or 406 as described by FIGS. 2A-2E, 3A-3D and 4A-4B.

FIG. 6A is a perspective view of a suture arrangement 602, in accordance with an embodiment of the invention. The suture arrangement 602 includes a suture 604a. The suture 604a has a first end 606a and a second end 608a. The first end 606a includes a first dart 610 loaded on to it and the second end 608 includes a second dart 612 loaded on to it. Such sutures like the suture 604a may be referred to as double darted sutures. The double darted suture such as the suture 604a can be used when the suture knots require both the suture ends 606a and 608a rendered free for manipulation. For example, the first end 606a includes the first dart 610 and the second end 608a includes the second dart 612 and therefore, each of the two ends can be rendered free for further manipulation on decoupling of the respective dart 610 or 612 from the suture 604a when the darts 610 or 612 enter the needle receiving portion 234. An example of suture arrangement using the suture 604a is described by way of FIG. 7A.

FIG. 6B is a perspective view of a suture arrangement 614. The suture arrangement 614 includes a suture 604b. The suture 604b has a first end 606b and a second end 608b. The first end 606b includes a dart 616 loaded on to it and the second end 608b includes a knot 630. Such sutures like the suture 604b may be referred to as end termination sutures. The end termination sutures such as the suture 604b can be used when the suture knots require one end of the suture such as the end 604b to be free for further manipulation and another end of the suture 604b to be fixed inside the body of the patient. For example, the first end 606b includes the dart 616 and therefore, the first end 606b can be rendered free for further manipulation on decoupling of the dart 616 from the suture 604b when the dart 616 enters the needle receiving portion 234. The second end 608b includes the knot 630; therefore the second end 608b can generally get fixed inside the body of the patient. An example of suture arrangement using the suture 604b is described by way of FIG. 7C.

FIG. 6C is a perspective view of another embodiment of suture arrangement 618. The suture arrangement 614 includes a suture 604c. The suture 604c has a first end 606c and a second end 608c. The first end 606c includes a dart 620 loaded on to it. A knot 632 is provided proximal to the second end 608c followed by a suture length 622. Such sutures like the suture 604c may be referred to as end termination sutures. In some embodiments, the suture arrangement 618 may be used for placing the slip-tie knot as described by FIGS. 3A-3D. In some embodiments, the suture arrangement 618 may be used for placing the twist tie knot as described by FIGS. 4A-4B. The suture 604c can be used to place suture knots wherein, both suture ends are free for further manipulation and one of the suture ends includes an obstruction so as to hold the suture in place. For example, the suture 604c includes the first end 606c with the dart 620 that can be decoupled from the suture 604c, thereby, rendering the first end 606c free for further manipulation. The second end 608c includes the knot 632 followed by the length 622. The knot 632 would terminate further movement of the suture 604c through the bodily tissue such as the bodily tissue 204 or 318 or 406. The length 622 would be available to the operator for further manipulation similar to the first end 606c. An example of suture arrangement using the suture 604c is described by way of FIG. 7B.

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FIG. 6D is a perspective view of another embodiment of suture arrangement 624. The suture arrangement 614 includes a suture 604d. The suture 604d has a first end 606d and a second end 608d. The first end 606d includes a dart 626 loaded on to it and the second end 608d includes a T shaped end 628. In some embodiments, the second end 608d can include any kind of termination feature that can prevent further passage of the suture 608d into the bodily tissue such as the bodily tissue 204, 318, or 406. Such sutures like the suture 604d may be referred to as end termination sutures. The end termination sutures such as the suture 604d can be used when the suture knots require one end of the suture 604d to be free for further manipulation and another end of the suture 604d be fixed inside the body of the patient. For example, the first end 606d includes the dart 626 and therefore, the first end 606d can be rendered free for further manipulation on decoupling of the dart 626 from the suture 604b when the dart 626 enters the needle receiving portion 234. The second end 608d includes the T-shaped end 628; therefore, the second end 608d can get fixed inside the body of the patient. An example of suture arrangement using the suture 604d is described by way of FIG. 7C.

In some embodiments, the suture arrangement 602, 614, 618 and 624 may be used for placing the slip-tie knot as described by FIGS. 3A-3D. In some embodiments, the suture arrangement 602, 614, 618 and 624 may be used for placing the twist tie knot as described by FIGS. 4A-4B.

FIGS. 7A-7C are schematic views of patterns of sutures for placing a bodily implant (such as the bodily implant 202, 316, or 404) over a bodily tissue (such as the bodily tissue 204 or 318 or 406), in accordance with an embodiment of the present invention.

FIG. 7A is a tetrahedral pattern 702 of a suture such as the suture 604a, 604b, 604c, 604d, in accordance with an embodiment of the present invention. In an embodiment, the double darted suture 604a, as described by FIG. 6A, may be used for the tetrahedral pattern 702. In the illustrated embodiment, a slip-tie knot similar to as described in FIG. 3B can be used such as at a point 1 to place a first knot. The slip-tie knot at the point 1 renders both the suture ends 606a and 608a free outside the bodily tissue such as the bodily tissue 204 or 318 or 406 for further manipulation. In some embodiments, the knot used at the point 1 may include a single knot layer. In some embodiments, the knot used at the point 1 may include multiple layers of suture knotting. Subsequent knots such as at points 2, 3, 4, and 5 can be placed using twist tie procedure that does not require any suture noose formation, such as described in FIG. 4A. The first end 606a of the suture 604a may be used to place suture knots on a series of suture points. For example, the first end 606a of the suture 604a may be used to place suture knots on points 2 and 3. The second end 608a of the suture may be used to place suture knots on a series of other suture points. For example, the second end 608a of the suture 604a may be used to place suture knots on points 4 point 5. The first end 606a and the second end 608a, after placing the suture knots on the points 3 and 5, may be crossed over externally and pushed inside, similar to placing a slip-tie knot as explained by the way of FIGS. 3A-3B. At any point in the tetrahedral pattern 702, the suture knots may include a single layer or multiple layers. In some embodiments, a medical device, different from the medical device 100 or 200, may be used for placing sutures in accordance with such suture arrangements.

FIG. 7B is a polygonal pattern 704 of a suture (such as the suture 604a, 604b, 604c or 604d), in accordance with an embodiment of the present invention. In some embodiments,

the suture **604d** as described by FIG. 6C may be used for the polygonal pattern **704** so as to render the length **622** from the second end **608d** of the suture **604d** free for manipulation. In some embodiments, a slip-tie knot similar to as described by the FIG. 3A can be placed, such as, at a point 1. The slip-tie knot at the point 1 renders both the suture ends **606d** and **608d** free outside the bodily tissue such as the bodily tissue **204** or **318** or **406** for further manipulation. The slip tip-knot can be placed at the point 1 using the second end **608d** and the length **622** of the suture **604d** can be left undisturbed external to the body, and the first end **606d** can be used to place the twist tie knots (as explained by FIGS. 4A-4B) on points 2-7. After placing the twist tie knot such as at the point 7, the length **622** proximal to the second end **608d** can be crossed over externally with the first end **606d**. In some embodiments, the knot as described above can be strengthened by crossing the first end **606d** and the second end **608d** of the suture **606d** over each other external to the body of the patient. The externally formed crossover can be pushed inside the body of the patient to form a second layer of the suture knot over the slip-tie knot. The process of forming external suture crossovers can be repeated to form multiple layers of suture knots so as to secure the bodily implant such **202**, **316** or **404** to the bodily tissue such as the bodily tissue **204**, **318**, or **406**. Any excess suture can be trimmed so as to not leave any extra material inside the body of the patient. At any point over the polygonal pattern **704**, the suture knots may include a single layer or multiple layers. In some embodiments, the multiple layers of the suture knots may be placed by using technique as described by FIGS. 4A-4B. In some embodiments, the multiple layers of knots can be placed by using the technique as described by FIGS. 3A-3D. In some embodiments, a medical device different from the medical device **100** or **200** may be used for placing suture arrangement described above.

FIG. 7C is a linear pattern **706** of a suture (such as the **604a**, **604b**, **604c** or **604d**), in accordance with an embodiment of the present invention. In some embodiments, the sutures as described by FIG. 6B and FIG. 6D may be used for the linear suture pattern **706** so as to render the second end **608b** or **608c** of the suture **604b** or **604c** terminated inside the body of the patient. The suture knots can be placed in an open shaped pattern over the bodily implant such **202**, **316** or **404**. For example, the knots can be placed in a C-shape, a linear shape, or any other open arrangement. The knot can be similar to the slip-tie knot as explained by FIG. 3A placed such as at a point 1. In an embodiment, subsequent knots such as the knot at points 2-5 can be such as similar to the twist knots as explained by FIGS. 4A-4B. The suture can be tied after placing the suture knot at point 5 in case of use of the end termination suture. At any point in the linear pattern **706**, the suture knots may include a single layer or multiple layers. In some embodiments, the multiple layers of the suture knots may be placed by using the technique as described by FIGS. 4A-4B. In some embodiments, the multiple layers of knots can be placed by using the technique as described by FIGS. 3A-3D. In some embodiments, a medical device, different from the medical device **100** or **200**, may be used for placing the suture arrangement described above.

FIGS. 8A-8C illustrate a method or process for placing an implant **802** within a body of a patient. FIG. 8A is a schematic view of placing an implant **802** within a patient's body using a medical device, in accordance with an embodiment of the present invention. FIG. 8B is a schematic view of the placed implant **802** within a patient's body, in accordance with an embodiment of the present invention.

The bodily implant **802** is sutured to the anterior vaginal wall **810**, posterior vaginal wall **812** (not visible in FIG. 8B, but visible in FIG. 8C), and the sacrum **818**. FIG. 8C is a schematic view of the placed implant **600** within a patient's body in another view. As illustrated, in some embodiments, the medical device **200** is configured to suture a Y-shaped implant like the implant **802** to a body portion such that the front throat region **230** sutures a portion of the Y-shaped implant to the anterior vaginal wall **810** and the posterior vaginal wall **812**, and the second throat region **236** sutures a portion of the Y-shaped implant to the sacrum **818**.

The medical device **100** or **200** can be used inside a body of a patient in order to place a bodily implant **802** using techniques described above in conjunction with various figures. In some embodiments, the medical device **100** or **200** can be used for placing the bodily implant **802** inside a body of a patient for pelvic floor reconstruction. The bodily implant **802** can include a proximal portion **804** and a distal portion **806**. The bodily implant **802** can be placed over the bodily tissue such that the proximal portion **804** of the implant **802** can be sutured to a vagina **808** and the distal portion **806** can be sutured to a sacrum **818** of the body of the patient.

In an embodiment, a laparoscopic approach can be used for placing and suturing of the bodily implant **802** over the vagina **808** of the patient. An anterior vaginal wall **810** and a posterior vaginal wall **812**, as illustrated, are collectively referred to as the vaginal walls **810** and **812**. In an embodiment, the medical device **200** can be inserted inside the body of the patient through such as a laparoscopic cannula and can be moved toward the vaginal walls **810** and **812** of the vagina **808**. A suture **816** can be coupled to the needle carrier **210** of the medical device **200**. The suture **816** can have a first end **820** and a second end **822**. The suture **816** can be similar to the sutures **206**, **302**, **402**, **520**, **604a**, **604b**, **604c**, **604d** as described in conjunction with FIGS. 2A-7C.

In some embodiments, at least a portion of the second throat region **236** of the medical device **200** can be blocked by using a depth adapter similar to the depth adapter **248**. The at least partial blocking of the second throat region **236** can avoid deeper penetration by the medical device **200** into bodily tissues such as when the second throat region contacts the bodily tissues such as to suture the implant to the sacrum or proximate tissues. In some embodiments, the at least partial blocking of the second throat region **236** may be desirable when the front throat region **230** contacts the bodily tissues and there are surrounding tissues nearby the second throat region that may prolapse into the second throat region **236** during abutting of the front region **230** to the tissues.

The front throat region **230** of the medical device **200** can be pressed against, at least, one of the vaginal walls **810** and **812**. As the front throat region **230** is an empty space, a portion of bodily tissues from the vaginal walls **810** and **812** gets pressed into it. The needle deployment mechanism **212** of the medical device **200** can then be actuated so as to move the needle carrier **210**, coupled to the suture **816** (and needle member), out of the opening **232** and into the vaginal wall **810** or **812** to place sutures. The height E1 of the front throat region **230** defines the penetration depth of the needle into the vaginal walls **810** and **812**. The thickness of the vaginal walls **810** and **812** is generally less than 2 mm and therefore a penetration depth of less than 2 mm (or less than the thickness of the vaginal wall) would allow the needle to pierce the tissue of the vaginal walls without completely penetrating through the vaginal walls **810** and **812**. This

would facilitate coupling the suture **816** to the vaginal walls **810** and **812** without piercing through the vaginal walls **810** and **812**.

The placement of a suture knot **824** over or into the vagina walls **810** and **812** can be done using any of the methods, techniques and arrangements described above in conjunction with various FIGS. or by using hands or using conventionally known methods. In some embodiments, each of the anterior vaginal wall **810** and the posterior vaginal wall **812** can have up to 6 suture knots like the suture knot **824** placed over the implant **802**, though in other embodiments, the number of suture knots **824** can be lesser or even more than six. In some embodiments, a second knot can be placed over a suture knot **824** to further strengthen the suture knot **824**. The multiple layer suture knot is depicted as **826** in the FIG. **8A**.

In one embodiment, and as illustrated in FIGS. **8A-AC** more than one suture knot may be formed using the same suture and at different locations along the vaginal wall. In such an embodiment, the plurality of knots are coupled or connected together via a suture bridge as illustrated in FIG. **8B**. As illustrated in FIG. **8A**, once one knot **1010** has been placed in the vaginal wall **810** to at least partially secure the implant **802** to the body of the patient, the device **200** may be used to place another knot. Specifically, after placing the first knot **802**, the device **200** can be removed from the body of the patient. The needle member may be removed from the needle catch and reloaded in the needle carrier of the device **200**. The suture may also be wrapped or coiled around the shaft of the device **200** as illustrated in FIG. **8A**. The device **200** may then be reinserted into the body of the patient and positioned at a location for placing another suture knot within the body of the patient. For example, the location may be proximate the first knot or disposed a distance from the first knot. In some embodiments, the device **200** is disposed within the body such that a portion of the implant **802** and a portion of the anchoring bodily tissue (such as the tissue of or proximate the vaginal wall) is disposed within the front throat region or recess **230**. The device **200** can be actuated to pass the needle and suture **816** pass through the implant **802** and the anchoring bodily tissue. As described above, the needle may then be captured or contained within the needle catch. The needle carrier can then be retracted leaving the suture **816** extending through the implant **802** and the bodily tissue. The device **200** can then be refracted from the body of the patient. As the device **200** is retracted, the suture (which is coupled to the needle catch) passes through the coils or loops of the suture that are disposed about the shaft of the device. The passing of the end of the suture **816** through the coils or loops of the suture and the corresponding movement of the coils or loops toward the implant **802** form the suture knot and secure the portion of the implant **802** to the body of the patient.

As illustrated in FIG. **8B**, this process can be repeated additional times to form a plurality of knots. Each of the knots is formed with the same length of suture and is therefore coupled together via a length of the suture **816**. These lengths of suture may be referred to as suture bridges **819**. This process can be performed any number of times to form any number of knots **817**. The knots **817** may be arranged in any pattern or array (such as the patterns or arrays illustrated in FIGS. **7A-7C**).

In some embodiments, the suture bridges **819** are configured to provide support to the knot structures **817**. For example, in some embodiments, the sutures bridges **819** help maintain the integrity of each knot **817** and may help prevent the knots **817** from unraveling. In some embodiments, once

the desired number of knots has been placed, a first end and a second end of the suture may be knotted or tied together using any known technique.

In the illustrated embodiment and as best illustrated in FIG. **8C**, a separate set of knots are used to suture the implant to the anterior vaginal wall **810** and the posterior vaginal wall **812**. For example, a first suture is used to form several knots to the anterior vaginal wall **810** and a different or separate suture is used to form several knots to the posterior vaginal wall **812**.

After placement of the suture knots over the vaginal walls **810** and **812**, in the illustrated embodiment, the medical device **200** may be used to suture a portion of the implant **802** to the sacrum or bodily tissue located proximate the sacrum. In some embodiments, after the implant **802** is coupled to the vaginal walls **810** and **812**, the implant is tensioned (so as to provide the appropriate support and positioning to the vagina) and then coupled to the sacrum. In some embodiments, prior to the placement or attachment of the implant **802** to the sacrum, the medical practitioner dissects at least a portion of the peritoneum of the patient.

In some embodiments, the device **200** is used to suture or couple the implant **802** to the sacrum. For example, a knot or a series of knots (as discussed above) may be formed to couple the implant **802** to the sacrum or to tissue proximate the sacrum. In some embodiments, the second throat region **236** of the medical device **200** may be used to suture the implant **802** to the sacrum **818**. In other embodiments, placing the suture knots to the sacrum **818** can be done using any known suturing or coupling method.

Referring to FIG. **9**; in conjunction with FIGS. **2A-2F**, **3A3A-3D**, **4A-4B**, **5**, **6A-6D**, and **7A-7C**, and **8A-8C**, illustrates a method **900** for placing the bodily implant into the body of a patient is described.

The method **900** includes inserting a suturing device or a medical device inside a body of a patient at step **902**. In some embodiments, the suturing device can be similar to the medical device **100** or medical device **200**. For the purpose of explanation of the method **900**, the medical device **200** has been taken into consideration. For the purpose of describing the method **800**, the term suturing device is being used interchangeably with the term medical device **200**. In an embodiment, the medical device **200** can be inserted into a body of a patient using a laparoscopic approach, such as, through an abdominal incision. In an embodiment, the laparoscopic approach can be used for placing and suturing of the bodily implant **802** over the vagina **808** of the patient. In an embodiment, the medical device **200** can be inserted inside the body of the patient through, such as, a laparoscopic cannula, such as, a 10 mm cannula or any other cannula and can be moved toward the vagina **808**. The suture **816** can be coupled to the needle carrier **210** of the medical device **200**.

The method **900** further includes contacting the front throat region **230** to a first bodily tissue at step **904**. In some embodiments, the first bodily tissue can be the anterior vaginal wall **810**. In some embodiments, the first bodily tissue can be the posterior vaginal wall **812**. In some embodiments, the second throat region **236** of the medical device **200** can be blocked by using the depth adapter **248** for purpose of suturing the bodily implant **802** to the vaginal walls **810** and **812**. In other embodiments, however, the second throat region **236** may be kept open and unblocked. The front throat region **230** of the medical device **200** can be pressed against at least one of the vaginal walls **810** and **812**.

As the front throat region **230** is an empty space, a portion of bodily tissues from the vaginal walls **810** and **812** gets pressed into it.

In some embodiments, the method **800** can include contacting the second throat region **236** to a second bodily portion for fixing a portion of the implant to the second bodily tissue with the use of the second throat region **236** as described by FIGS. **8A-8C**. In some embodiments, the second bodily portion can be the sacrum **818** of the body of a patient.

The method **800** includes advancing the needle of the suturing device **200** at step **906** after the front throat region **230** or the second throat region **236** contacts the bodily tissues such as the vaginal walls **810** and **812** or the sacrum **818**. The needle carrier **210** can be loaded with the suture **816**. The needle carrier **210** can be advanced toward the needle receiving portion **234** so as to cause the needle carrier **210** to extend through the opening **232**. The needle deployment mechanism **212** of the medical device **200** can then be actuated so as to move the needle carrier **210** coupled to the suture **816** out of the opening **232** and into the vaginal wall **810** or **812** or the sacrum **818** to place sutures. The height **E1** of the front throat region **230** defines the penetration depth of the needle into the vaginal walls **810** and **812** if the bodily tissue is the vaginal walls **810** and **812** and the depth adapter **248** is fitted in the second throat region **236**. In such embodiments, the thickness of the vaginal walls **810** and **812** is generally less than 2 mm and therefore a penetration depth of less than 2 mm would allow needle piercing without penetrating through the vaginal walls **810** and **812**. This would facilitate in placing the suture **816** over the vaginal walls **810** and **812** without piercing through the vaginal walls **810** and **812**. In some embodiments, placing the suture knots over the vagina walls **810** and **812** or the **818** sacrum can be done using any of the methods, techniques and arrangements described above in conjunction with various figures.

In some embodiments, a noose similar to the suture noose **310** is slidably tied to the elongate member. In some embodiments, the method **900** includes pulling the second end **822** of the suture **816** while the needle carrier **210** advances toward the needle receiving portion **234** such that the suture noose **310** cinches with the implant **802** and forms a first knot **824** as described by FIGS. **3A-3E** and illustrated in FIG. **8A**. In some embodiments, the method **900** further comprises forming a second noose tied to the elongate member and pulling the second end of the suture **816** while the needle carrier **210** advances toward the needle receiving portion **234** such that the second noose cinches with the implant **802** and the first knot and forms a second knot over the first knot. This leads to formation of multiple knot layers such as **826** as described by FIGS. **3A-3E**.

In some embodiments, the method **800** can further include securing the first end **820** of the suture **816** to the first bodily tissue, for example, the vaginal walls **810** or **812**. The method further includes rotating the medical device **200** such that the suture **200** forms a coil around the elongate member **208**, as described by FIGS. **4A-4B**. The method further comprises pulling the second end **822** of the suture **816**, during advancement of the needle carrier **210**, in a direction **B2**, that is opposite the direction **B1** of advancement of the needle carrier **210** such that the suture coil cinches with the implant **802** and forms the knot **824**, as explained by the FIG. **4B**. The method **900** can further include rotating the medical device **200** again after retracting the needle carrier **210**, so as the suture to coil around the elongate member **208**. The method further includes advancing

the needle carrier **210** toward the needle receiving portion **234** again and pulling the second end **822** of the suture in the direction **B2**, opposite the direction **B1** of advancement of the needle carrier **210** so as the suture coil to cinch with the implant **802** and form a second knot like the knot **824** at a different location of the first bodily tissue, as described by FIG. **4B**. This leads to formation of multiple knot layers such as the knot layer **826** as described by FIGS. **3A-3E**. The knots can then be tied.

Any excess suture left after placing the implant **802** can be trimmed from the body of the patient so as not leave any excess material inside the body. In some embodiments, the suture can be braided. In some embodiments, the suture can be a monofilament. The suture can be made of medical grade polymers such as polypropylene. In some embodiments, the suture can be made of a bio-absorbable material. After the bodily tissue grows over the implant, the suture may not be further required to fixate the implant to the tissue and therefore a bio-absorbable suture may be needed.

The method **800** further includes retracting the needle from the needle receiving portion after placing the suture knots. The suturing device is removed from the body after placing the suture knots.

In some embodiments, a medical device includes an elongate member having a proximal portion, a distal portion and a lumen defined along the elongate member; a needle disposed within the lumen of the elongate member; a needle deployment mechanism disposed at least partially within the lumen for moving the needle along the elongate member; and a head portion including a tip portion and provided at the distal portion of the elongate member. The head portion includes a front throat region provided at the tip portion and having a front edge and a lateral edge, the front throat region defining an open space bounded between the lateral edge and the front edge to receive a bodily tissue therein; an opening defined by the lateral edge of the front throat region and extending from the lumen of the elongate member such that the needle moves in and out of the device through the opening in a direction along the front edge of the front throat region; and a needle receiving portion configured to capture the needle.

In some embodiments, the device includes a second throat region provided in a direction substantially perpendicular with respect to the front throat region and defining an open space for receiving a bodily tissue therein. In some embodiments, the device is configured to suture an implant to a bodily tissue, wherein the front throat region is configured to suture a portion of the implant to an anterior and a posterior vaginal wall, and the second throat region is configured to suture a portion of the implant to a sacrum. In some embodiments, the implant is a Y-shaped implant

In some embodiments, the height of the second throat region is greater than height of the front throat region such that the second throat region is configured for deeper needle penetration into a tissue than the front throat region. In some embodiments, the height of the front throat region is 2 millimeter (mm) or less and is configured to limit a penetration depth of the needle within a range of 1 mm to 2 mm, when the needle contacts a body tissue in a direction perpendicular to a plane of the bodily tissue. In some embodiments, the device includes a depth adapter configured to removably fit into a second throat region. In some embodiments, the depth adapter, when fitted in a second throat region, is configured to control penetration depth of the needle through the front throat region when the needle contacts a bodily tissue in a non-perpendicular direction with respect to a plane of the bodily tissue.

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In some embodiments, the device is configured to be attached to a suture loaded with a dart at least at one end of the suture. In some embodiments, the suture includes a noose tied to the elongate member of the device.

In some embodiments, the device includes a cartridge having a lumen such that the elongate member is inserted within the lumen of the cartridge, and the suture is tied around the cartridge.

In some embodiments, a medical device includes an elongate member having a proximal portion, a distal portion and a lumen defined along the elongate member; a needle disposed within the lumen of the elongate member; a needle deployment mechanism disposed at least partially within the lumen for moving the needle along the elongate member; and a head portion including a tip and provided at the distal portion of the elongate member. The head portion a front throat region provided at the tip and having a front edge and a lateral edge, the front throat region defining an open space bounded between the lateral edge and the front edge; a second throat region provided in a direction substantially perpendicular with respect to the front throat region and defining an open space for receiving a body tissue therein; an opening defined by the lateral edge of the front throat region and in communication with the lumen of the elongate member such that the needle moves in and out of the device through the opening in a direction along the front edge of the front throat region; and a needle receiving portion configured to capture the needle.

In some embodiments, the device includes a depth adapter configured to be fitted within the second throat region. In some embodiments, the device is configured to suture an implant to a body portion. The front throat region is configured to suture a portion of the implant to an anterior and a posterior vaginal wall, and the second throat region is configured to suture a portion of the implant to a sacrum. In some embodiments, the implant is a Y-shaped implant. In some embodiments, the device is configured to be attached to a suture. The suture may include a dart loaded or coupled to at least at one end of the suture.

In some embodiments, a method for placing an implant includes inserting a medical device inside a body of a patient, the medical device including an elongate member, a needle disposed within the elongate member, and a head portion including a front throat region having a front edge and lateral edge such that the front throat region defines an open space bounded between the front edge and the lateral edge; contacting the front throat region to a first bodily tissue; advancing the needle of the medical device loaded with a suture toward the needle receiving portion so as to cause the needle to extend through an opening, defined by the lateral edge, in a direction along the front edge and penetrate through the implant and a portion of the first bodily tissue; and retracting the needle from the needle receiving portion.

In some embodiments, the first bodily tissue is a vaginal wall. In some embodiments, the first bodily tissue is an anterior vaginal wall. In some embodiments, the first bodily tissue is a posterior vaginal wall.

In some embodiments, the medical device includes a second throat region provided in a direction substantially perpendicular with respect to the front throat region, and the method includes contacting the second throat region to a second bodily portion for fixing a portion of the implant to a second bodily tissue with a use of the second throat region. In some embodiments, the second bodily portion is a sacrum. In some embodiments, the medical device is inserted within the body through a laparoscopic approach.

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In some embodiments, the suture includes a noose that is slidably tied or coupled to the elongate member and the method includes pulling a free end of the suture while the needle advances toward the needle receiving portion such that the noose cinches with the implant and forms a first knot. In some embodiments, the method includes forming a second noose tied to the elongate member; and pulling a free end of the suture while the needle advances toward the needle receiving portion such that the second noose cinches with the implant and the first knot and forms a second knot over the first knot. In some embodiments, the method includes securing a first free end of the suture to the first bodily tissue; rotating the device such that the suture forms a coil around the elongate member; and pulling a second free end of the suture, during advancement of the needle, in a direction opposite the direction of advancement of the needle such that the suture coil cinches with the implant and forms a knot. In some embodiments, the method includes rotating the device again after retracting the needle so as the suture to coil around the elongate member; advancing the needle toward the needle receiving portion again; and pulling the second free end of the suture in a direction opposite the direction of advancement of the needle so as the suture coil to cinch with the implant and form a second knot at a different location of the first bodily tissue. In some embodiments, the method includes trimming a portion of an excess suture. In some embodiments, the method includes removing the medical device from the body.

While the invention has been disclosed in connection with the preferred embodiments shown and described in detail, various modifications and improvements thereon will become readily apparent to those skilled in the art. Accordingly, the spirit and scope of the present invention is not to be limited by the foregoing examples, but it is to be understood in the broadest sense allowable by law.

What is claimed is:

1. A medical device comprising;

an elongate member having a proximal portion, a distal portion and a lumen defined along the elongate member;

a needle disposed within the lumen of the elongate member;

a needle deployment mechanism disposed at least partially within the lumen for moving the needle along the elongate member;

a head portion including a tip portion and provided at the distal portion of the elongate member, the head portion including:

a front throat region provided at the tip portion and a distal most portion of the elongate member, the front throat region having a front edge and a lateral edge, the lateral edge extending parallel to a longitudinal axis of the elongate member, the front edge being disposed perpendicular to the lateral edge, the front throat region defining a first open space bounded between the lateral edge and the front edge to receive a bodily tissue therein, the lateral edge having a height that limits a penetration depth of the needle;

an opening defined by the lateral edge of the front throat region and extending from the lumen of the elongate member such that the needle moves in and out of the device through the opening of the lateral edge in a direction along the front edge of the front throat region;

a second throat region defining a second open space, the second open space defining a larger empty space than the first open space; and

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a needle receiving portion configured to capture the needle.

2. The medical device of claim 1, wherein the second throat region is provided in a direction perpendicular with respect to the front throat region.

3. The medical device of claim 1, and the medical device is configured to suture an implant to the bodily tissue, wherein the front throat region is configured to suture a portion of the implant to an anterior and a posterior vaginal wall, and the second throat region is configured to suture a portion of the implant to a sacrum.

4. The medical device of claim 1, wherein a height of the second throat region is greater than the height of the lateral edge.

5. The medical device of claim 1, wherein the height of the lateral edge is 2 millimeter (mm) or less and is configured to limit a penetration depth of the needle within a range of 1 mm to 2 mm, when the needle contacts the bodily tissue in a direction perpendicular to a plane of the bodily tissue.

6. The medical device of claim 1, and including a depth adapter configured to removably fit into the second throat region.

7. The medical device of claim 6, wherein the depth adapter, when disposed within the second throat region, is configured to control penetration depth of the needle through the front throat region when the needle contacts tissue in a non-perpendicular direction with respect to a plane of the bodily tissue.

8. The medical device of claim 1, further comprising:
a suture configured to be attached to the medical device, the suture being loaded with a dart at least at one end of the suture.

9. The medical device of claim 8, wherein the suture includes a noose tied to the elongate member of the device.

10. The medical device of claim 8, and including a cartridge having a lumen such that the elongate member is inserted within the lumen of the cartridge, and the suture is tied around the cartridge.

11. A medical device comprising:

an elongate member having a proximal portion, a distal portion and a lumen defined along the elongate member;

a needle disposed within the lumen of the elongate member;

a needle deployment mechanism disposed at least partially within the lumen for moving the needle along the elongate member;

a head portion including a tip and provided at the distal portion of the elongate member, the head portion including:

a front throat region provided at the tip, the front throat region being defined by a step from a distal most portion of the elongate member, the front throat region having a front edge and a lateral edge, the lateral edge extending parallel to a longitudinal axis of the elongate member, the lateral edge being disposed perpendicular to the front edge, the front throat region defining a first open space bounded between the lateral edge and the front edge, the lateral edge having a height that limits a penetration depth of the needle;

a second throat region provided in a direction perpendicular with respect to the front throat region and

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defining a second open space for receiving a body tissue therein, the second open space defining a larger empty space than the first open space;
an opening defined by the lateral edge of the front throat region and in communication with the lumen of the elongate member such that the needle moves in and out of the device through the opening in a direction along the front edge of the front throat region; and

a needle receiving portion configured to capture the needle.

12. The medical device of claim 11, and including a depth adapter configured to be disposed within the second throat region, the depth adaptor configured to limit a penetration depth of the needle.

13. The medical device of claim 11, and the medical device is configured to suture an implant to a body portion, wherein the front throat region is configured to suture a first portion of the implant to an anterior and a posterior vaginal wall, and the second throat region is configured to suture a second portion of the implant to a sacrum.

14. The medical device of claim 11, and is configured to be attached to a suture, the suture further including a dart loaded at least at one end of the suture.

15. A method for placing an implant, the method comprising:

inserting a medical device inside a body of a patient, the medical device including an elongate member, a needle disposed within the elongate member, and a head portion including a front throat region, the front throat region being defined by a step from a distal most portion of the elongate member, the front throat region having a front edge and lateral edge, the front edge defining at least a portion of a most distal face of the elongate member, the lateral edge extending parallel to a longitudinal axis of the elongate member, the lateral edge being disposed perpendicular to the front edge, the front throat region defining a first open space bounded between the front edge and the lateral edge, the head portion including a second throat region defining a second open space, the second open space defining a larger empty space than the first open space, the medical device including a depth adaptor disposed within the second throat region;

contacting the front throat region to a first bodily tissue; contacting the second throat region to a second bodily tissue such that an amount of the second bodily tissue entering the second throat region is limited by the depth adaptor;

advancing the needle of the medical device loaded with a suture toward a needle receiving portion so as to cause the needle to extend through an opening, defined by the lateral edge, in a direction along the front edge and penetrate through the implant and a portion of the first bodily tissue; and

retracting the needle from the needle receiving portion.

16. The method of claim 15, wherein the first bodily tissue is a vaginal wall.

17. The method of claim 15, wherein the first bodily tissue is an anterior vaginal wall.

18. The method of claim 15, wherein the first bodily tissue is a posterior vaginal wall.

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