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(54) **Title:** DEVICES AND METHODS FOR CREATING A KNOT FOR SURGICAL SUTURING

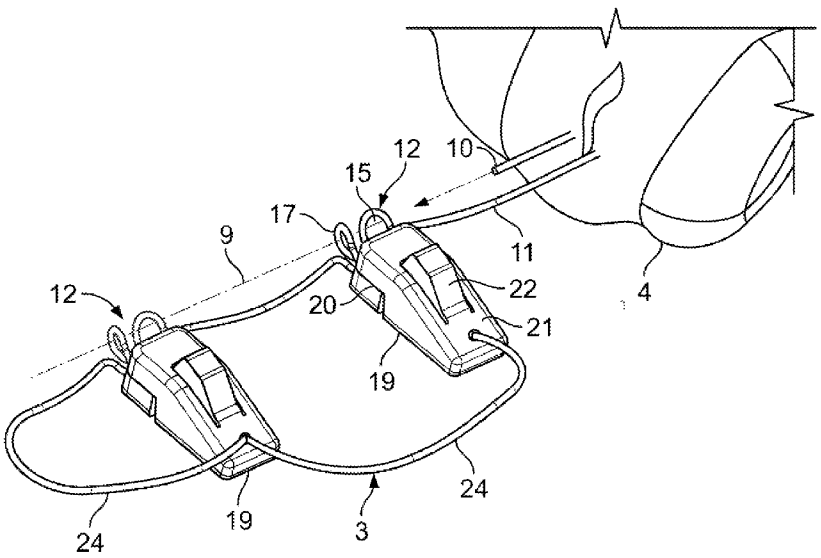

FIG. 8

(57) **Abstract:** Disclosed herein are device and methods for surgical suturing securing of any suture, ligature, or similar structure and, more particularly, to a devices and methods that allow a physician to quickly secure the suture or ligature material with a knot.

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DEVICES AND METHODS FOR CREATING A KNOT FOR SURGICAL SUTURING

CROSS-REFERENCE

[0001] This application is a non-provisional of U.S. Provisional Application No.: 60/997,396 filed October 4, 2007 and entitled DEVICE WITH PREFORMED HITCH KNOT FOR SURGICAL SUTURING the entirety of which is incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] This invention relates to surgical securing of any suture, ligature, or similar structure and, more particularly, to devices and methods that allow a physician to quickly secure the suture or ligature material with a knot. The term knot is intend to include any intersection of interlaced material such as a crossing of a line or suture over at least one looped portion in a manner that is intended to secure the line or suture. The devices and methods are especially useful when the physician must create a knot without being able to directly manipulate the structure such as an intracorporeal knot (i.e., a knot within the body or any structure anatomically direct where use of the hands is difficult, impractical, or impossible). The methods and devices are also directed to a method of cinching a knot utilizing the device features.

[0003] Although the methods and devices discussed herein relate to securing of sutures, ligatures, or any like structures. For sake of convenience, the term suture or suturing shall include such sutures, ligatures, or any like structure.

[0004] Suturing tissue during an open surgical procedure can be a tedious and delicate procedure. Less invasive surgical (LIS) techniques, such as laparoscopic, endoscopic, arthroscopic, and robotic surgery, are generally performed through small incisions using specialized instruments to perform desired surgical procedures. In LIS procedures, tying sutures and other knots is especially difficult. Frequently, the knot

tying process significantly extends the time of the procedure. In the current state of less invasive surgery, the surgeon is unable to view directly the site of the surgery, but instead must rely upon a two-dimensional image that both magnifies the site and denies depth perception. This lack of depth perception poses a tremendous challenge for intracorporeal knot tying. Due to this constraint, extensive training is required by the surgeon before attempting to perform these types of procedures. Another difficulty presented by LIS surgery is the constraint of working in a confined space. The physician must position the instruments used for LIS surgery in this confined space in a particular orientation in relation to one another and in relation to the patient. This restriction of the maneuverability of the instruments adds even more challenges to intracorporeal knot tying.

[0005] Internal knot tying normally requires at least two operating cannulae (or other access ports) and an associated pair of graspers, otherwise referred to as needle holders or suture holders. For a square knot, two throws are created by manipulating the suture and needle with the graspers. The first throw may be a simple overhead knot or may be a surgeon's knot. Additional throws may be applied over the second throw to provide additional security. It is important that sequential throws are in the proper direction to correctly make the intended knot. For example, inadvertently creating throws in the opposite directions produces a "granny" knot that is less secure than a square knot or surgeon's knot.

[0006] Previous devices acknowledge the challenge described above and attempt to use a preformed knotted loop or loops in a suture. Such knotted loops allow the suture to be tied by passing a free end of the suture through the loop and tightening the loop on the suture after the wound has been closed. U.S. Pat. No. 5,454,834 (incorporated by reference herein), describes a suture material with an inherently stable loop or coil feature for forming a knot. This approach has limitations on the effectiveness and reliability of maintaining the loops in the desired shape. There are a number of patented instrument type devices that describe pre-tied knots restrained at the distal end of a rod or tube; U.S. Pat. No. 5,893,592, U.S. Pat. No. 5,792,151, U.S. Pat. No. 5,769,862, U.S. Pat. No. 5,741,280, U.S. Pat. No. 5,129,912, and U.S. Pat. No. 5,472,446. These instrument type devices require complexity and components that result in prohibitive

expense.

[0007] Fig. 1A illustrates the square knot and Fig. 1B illustrates a surgeons knot. Physicians commonly use both knots in surgical procedures. To create these types of knots intracorporeally, grasper instruments are used to manipulate a needle **2** and a first end **10** and/or second end **11** of a suture **3**. The suture **3** can be a single suture or two ends of separate sutures can be tied together. While the above-described knots are most common, the invention described below can accommodate any type of knot that requires looping or formation of one end of a suture in a particular profile or shape.

[0008] As shown in Figs. 2A to 2D, for suturing of tissue, the physician pierces tissue with the needle 2, and the attached suture 3 is grasped with a first grasper 1. Fig. 2A illustrates the suture 3 then being placed around a second grasper 5, which executes a circular motion and guides the suture 3 with its shank in such a way that the suture 3 is wound in a spiral around the jaw parts 6 of the second grasper 5. Fig. 2B shows the next step. The opposite end of the suture 3, attached to the needle 2, is then grasped with these jaw parts 6 of the first grasper 1 and drawn through the spiral winding. If each end of the suture 3 is now pulled with a grasper, as shown in Fig. 2C, the so-called base knot is formed. In order to hold this base knot in its position or secure the tension once it has been created, a so-called finishing knot, shown in Fig. 2D, is tied tightly over the base knot in the same manner.

[0009] In view of the above, a need remains to allow a physician to quickly and easily secure a knot in a suture type material especially when attempting to secure the knot during LIS procedures. The need exist for a low cost, simple to use, device to aid in the tying of a variety of knots intracorporeally.

SUMMARY OF THE INVENTION

[0010] The invention is a suturing method and device that primarily involves a suture assembly consisting of; 1) a partially tied surgical knot that is positioned along a suture, and 2) a support structure to maintain the form of the partially tied knot and aid in manipulation and positioning of the partially tied knot. The assembly may include a

series of these partially tied knots and structures spaced along the suture length. The partially tied knot will usually consist of a loop or loops, depending on the desired knot configuration. The support structure is a simple clamp or support construct that releasably holds unto the partially tied knot in the desired orientation unto the knot is completed by passage of one end of the suture through the loop or loops of the partially tied knot. The assembly may consist of other elements and features, such as a tether line, a needle passage protector, a clamp release feature, an orientation feature to aid correct direction of the passage suture through the loop or loops, or other enhancing elements and features to facilitate functionality and ease of use.

[0011] The support structure for releaseably holding the partially tied knot can be minimized in size, thus allowing the entire suture assembly to fit down a cannula and be placed in the body cavity. The support structure and suture can be manipulated and controlled with a standard needle holder, thus eliminating the need for additional specialized, expensive instruments. In a first method of use, the support structure is securely held by a needle holder, while the jaws at the distal tip of a second needle holder are advanced through the loop. The first needle holder then releases the support structure, and is then manipulated to grasp the needle near the proximal end. The needle is advanced through or around the desired tissue. As the needle tip is exposed, it is guided into the open jaws of the second needle holder. The jaws of the second needle holder are then closed to securely clamp onto the tip of the needle. The needle is then released by the first needle holder. The first needle holder is used to grasp the support structure and secure it while the jaws of the second needle holder are retracted back through the loop, carrying the needle and suture with it. The support structure is then separated from the loop. The opposing ends of the suture are then put in tension to produce a finished knot. Obviously, other methods of use are applicable depending on the design of the support, the design of the knot, and the surgical procedure being performed.

[0012] The support structure can be produced from a few, or even one, low cost component. This simplicity provides for an effective, low cost solution to reducing the time and difficultly associated with intracorporeal knot tying.

[0013] One variation of the devices described herein include a ligature and/or suture device configured for creating a knot in a flexible line, comprising a length of suture having a proximal end and a distal end, a loop support member configured to releaseably secures a segment of the suture within a portion of the support member such that the segment forms at least one loop pattern and wherein when one of the proximal or distal ends advances through the loop pattern, the loop support member can selectively release the segment to create a knot.

[0014] The variations of the devices include a support member configured in a small size such that the entire device can be delivered through a cannula, catheter, introducer, port or trocar and placed inside the body. In addition, the devices described herein can be constructed in a simple manner, often from less than two components.

[0015] Another variation of the device includes a surgical knot fixation assembly comprising a length of suture, a loop support member having a suture receiving portion such that a segment of the suture can be releasably maintained in a loop shape when a portion of the segment of the suture is held within the suture receiving portion. The variations of the surgical fixation assemblies described herein can include a pair of mating jaws, such that upon separation of the jaws, the segment releases from the loop support member. These the mating jaws can be spring biased to close.

[0016] Alternatively, or in combination, the suture receiving portion can include or comprise a cavity within the loop support member. In certain variations, the device can include a pair of release surfaces each release surface adjacent to the cavity such that pulling on a first and second ends of the suture cause the suture to move against the release surface and out of the cavity to release the segment from the loop support member.

[0017] Additional components can be employed to assist in creating the knot. For example, the devices and methods can include a funnel member, where a portion of the segment surrounds the funnel member such that an end of the suture can move within the funnel to cross within the loop shape.

[0018] In most variations, the suture contains a plurality of loop support members. The

loop support member can form loop shapes that are similar, different, or have combination of shapes.

[0019] The invention also includes methods of securing tissue. In one example, the method includes advancing a suture through or around the tissue, the suture having at least one loop support member, where a segment of the suture is maintained in a loop shape when a portion of the segment of the suture is releasably held in the loop support member, retracting an end of the suture through the loop shape, releasing the portion of the segment suture from the loop support member, and forming at least a partial knot in the suture by pulling the end of the suture.

[0020] Another method includes advancing a suture through or around the tissue, the suture having at a plurality of segments each held respectively by a plurality of loop support members, each loop support member holding the respective segment of the suture in a partial hitch knot shape, navigating an end of the suture through a first partial hitch knot adjacent to a first loop support member to create a first full hitch knot, releasing the first loop support member from the suture without releasing a second loop support member from the suture, fully cinching the first partial hitch knot by pulling on at least one of the ends of the suture. The methods may subsequently release at least the second loop support member from the suture. For example, subsequently releasing at least the second loop support member from the suture comprises releasing the second loop support member without forming a second full knot. In another variation, subsequently releasing at least the second loop support member from the suture comprises advancing the end of the suture through the second partial hitch knot to create a second full knot and subsequently cinching the second full knot.

[0021] The methods and devices described herein are intended to show examples of possible variations of the devices. Modifications contemplated by those skilled in the art are intended to be within the scope of this disclosure. Such modifications include combinations of aspects of the various described embodiments or combinations of the embodiments themselves.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] Fig. 1A shows a square knot loop pattern.

[0023] Fig. 1B shows a surgeons knot loop pattern.

[0024] Fig. 2A shows the first step for the traditional method for intracorporeal knot tying of a surgeons knot.

[0025] Fig. 2B shows the second step for the traditional method for intracorporeal knot tying of a surgeons knot.

[0026] Fig. 2C shows the third step for the traditional method for intracorporeal knot tying of a surgeons knot.

[0027] Fig. 2D shows the forth step for the traditional method for intracorporeal knot tying of a surgeons knot.

[0028] Fig. 2A shows the first step for the traditional method for intracorporeal knot tying of a surgeons knot.

[0029] Fig. 3 shows two loops in the opposite direction that combine to create a preferred pattern for a partially tied square knot for use with the exterior shield type support structure.

[0030] Fig. 4 shows a suture length with a partially tied square knot on the distal suture end and proximal suture end positioned through the tissue.

[0031] Fig. 5 shows Fig 4.with the exterior shield type support structure as part of the suture assembly.

[0032] Fig. 6 shows two loops in the opposite direction that combine to create a preferred pattern for a partially tied square knot for use with the clip styles of support structures.

[0033] Fig. 7 shows a suture length with a series of spaced apart partially tied square knots on the distal suture end and the proximal suture end positioned through the tissue.

[0034] Fig. 8 shows Fig. 7 with the protruding tang clip type support structures as part of

the suture assembly.

[0035] Fig. 9 shows Fig. 8, but the proximal suture end has been passed through the loops of the proximally located protruding tang clip type support structure, and where the tang on the support structure is depressed and the support structure has released the loops.

[0036] Fig. 10 shows Fig. 7 with the suture tension release clip type support structures as part of the suture assembly.

[0037] Fig. 11 shows a top view of the suture tension release clip type support structure to illustrate how the suture ends extend from the support.

[0038] Fig. 12 shows Fig. 10, but the proximal suture end has been passed through the loops of the proximally located suture tension release clip type support structure, and where the extending ends of the suture have been tensioned to cause release of the loops from the support structure.

[0039] Fig. 13 shows one stage in a sequence of how the device could be used with graspers.

[0040] Fig. 14A and 14B show side views of an variation of loop support structures with tissue adhering structures.

DETAILED DESCRIPTION OF THE INVENTION

[0041] The devices and methods described herein can accommodate any number of suture materials ranging from absorbable, nonabsorbable, monofilament, multifilament, natural and synthetic as well as polymeric or metal type lines (herein, the term "suture" is intended to apply to any such line material regardless of whether the material is intended for suturing, applying ligatures, or other fixation). The present devices and methods can also accommodate sutures of a variety of diameters, strengths, durometers and flexibilities.

[0042] The devices and method of the present disclosure are useful to create "hitch"

type knots. A "hitch" is often defined as a knot that is used when tying a rope or line to something. However, a more accurate definition is that a hitch has the ability to be cinched down and conform to the size of the object to which it is tied. Hitch knots come in a variety of forms. "Two half hitches", shown in Fig. 3, configured such that the loops **8** adjacent, yet are in opposite coil directions, replicate the loop pattern of a square knot that is capable of being cinched. Other commonly known types of hitches have been devised that create a secure knot that is not prone to slippage. Common to most hitch knots is a straight section of line that passes through the loops of the knot. If this straight section of line is removed, a central axis **9** for passage is created (see Fig. 3).

[0043] A first variation of the device facilitates tying of a knot in a flexible suture that has a first end **10** extending through or around a tissue/organ **4** and a second end **11** extending away and wrapped around, thereby defining a loop pattern **12**, as shown in Fig. 4. The loop pattern **12** is preformed such that it creates the loops needed for a desired knot. The loop pattern **12** could be one half hitch, a combination of half hitches, or countless other loop configurations. Fig. 4, like Fig. 3, illustrates the loops of a square knot capable of being cinched. The central axis **9** of passage is shown aligned with the first end **10** of the suture line.

[0044] Fig. 5 shows a variation of a device with a loop support structure **13** that maintains a segment **12** of a suture **3** in loop pattern **17** (in this variation the loop pattern **17** is similar to that shown in Fig. 3). The loop pattern **17** can be pre-formed or simply temporarily formed while the suture **3** is held within the support structure **13**. For example, an adhesive or coating can be applied to the segment **12** when in the loop form to provide additional stability. Alternatively, the device can rely upon the natural properties of the suture to retain the loop form **17** when the segment **12** is placed within the loop support structure **13**.

[0045] The loop support structure **13** can optionally include a plate **14** for manipulation or holding by a grasper type instrument. For example, a physician can use the grasper to hold the plate **14** as another grasper manipulates a first end **10** of the suture thru the central axis passage **15** of the loop pattern **17**. Passing the first end **10** of the suture

thru the central axis passage **15** completes the hitch knot. As shown in FigS. 14A and 14B, additional variations of the loop support structure **13** can include a support structure **13** that has a clamp **32** or other tissue adhering structure **33** (such as barbs, hooks, protrusions, and/or a roughened surface) that adhere to tissue or provides increased friction when manipulating with other devices. As shown, the clamp **32** can be fitted with such tissue adhering structures **33** as well. In this manner, the support structure **13** can be temporarily affixed to tissue to allow the physician use of two grasper type instruments to manipulate the first end **10** of the suture through the loop pattern **17** or to manipulate the loop pattern **17** while advancing the end **10** of the suture **3** through the loop pattern **17**.

[0046] In this variation, the loop support structure **13** includes a sleeve or passage to give support and maintain the suture **3** segment **12** in the desired loop pattern **17**. The sleeve of the support structure **13** includes slots **16** for allowing release of the suture **3** from the loop support structure **13**. After the first end **10** of the suture traverses through the looped pattern **17** of the segment **12** the suture forms a loose knot. Once this loose knot is formed, the, the segment **12** can be separated from the suture support member **13** Tensioning on both free ends of the segment **12** tightens the knot. The knot can then be cinched down using the first end **10** of the suture **3** to secure the hitch knot to the tissue/organ **4**. The support structure **13** is removed and discarded.

[0047] Any number of above described support structures **13** can be provided on a single or multiple sutures. This allows the physician to create a number of passes or throws of an end of the suture through loops. In addition, the device can be provided separately with a suture so that the physician can create or space the segments formed into loops as desired. Since the physician (or a surgical assistant) can "load" the suture into the loop support structure **13** prior to, or contemporaneously with the procedure but outside of the body, the time required to load a suture into the support structure will not extend the procedure nor require significant skill as compared to tying an intracorporeal knot.

[0048] Fig. 6 illustrates another variation of a loop pattern **17** for use with a variation of a loop support structure as described herein. In this variation, the loop pattern **17** is configured to enable capturing portions of the suture between two surfaces (e.g., a

clamp type device). For example, a portion of the segment **12** at loop **18** where the sections of the loop cross over one another is useful for capturing the suture **3** within a loop support member. Fig. 7 shows a suture **3** having two loop patterns **17** formed therein. As shown, a first end **10** of the suture **3** extends through or around a tissue/organ **4** and a second end **11** forms one or more spaced loop patterns **17**. As noted above, any number of loop patterns **17** can be used along with any number of sutures. Though not illustrated, the end **10** of the suture **3** can optionally include a needle or tissue piercing member.

[0049] Another embodiment of the invention involves the support structure having the characteristics of a clamp or clip. Fig. 8 illustrates an additional variation of loop support members that rely on a clamping mechanism to secure segments **12** of the suture **3** in loop patterns **17**. The loop support structure or member **19** can be held at the clip base end **21** by a grasper while the physician directs the first end **10** of the suture **3** thru a central axis passage **15** of the loop pattern **17**. Passing the first end **10** of the suture thru the central axis passage **15** completes the hitch knot, which can then be cinched by further tightening of the end **10** away from the tightened loop pattern **17**. As with the previous variation, the base end **21** can include an additional clamp or other tissue adhering structure (such as barbs, hooks, or protrusions) that adhere to tissue. In this manner, the support structure **19** can be temporarily affixed to tissue to allow the physician use of two grasper type instruments to manipulate the first end **10** of the suture through the loop pattern **17** or to manipulate the loop pattern **17** while advancing the end **10** of the suture **3** through the loop pattern **17**.

[0050] Generally, the loop support structure **19** comprises a clip with two opposing surfaces **20** that capture at least a portion of a segment **12** that forms the suture loop pattern **17**. The opposing surfaces **20** secure the segment **12** in the loop pattern **17** thereby maintaining the loops in the desired shape. As with the previously described variations, the loop pattern **17** can be preformed or further supported via the use of an adhesive or coating that temporarily maintains the segment in the loop pattern. Alternatively, the segment **12** can simply revert to its natural state upon the removal of the loop support structure **19**. In the latter case, if the physician decides that additional numbers of throws or hitch knots are unnecessary, the physician can simply release the

segment **12** from the loop support structure **19**. This leaves a normal suture.

[0051] The clip of the support structure **19** can optionally include a tang feature **22** that protrudes from the general shape of the support structure **19**. Fig. 9 shows release of the loop support member **19** from the suture **3**. In variations having a tang feature **22**, depression of the tang feature **22** drives the opposing clip surfaces **20** away from one another, thus allowing the suture loop pattern **17** to separate from the support structure **19**. However, any release mechanism as known by those skilled in the art is within the scope of this device. After the hitch knot is formed (with an end **10** of the suture **3** passing through the preformed loop pattern **17**) and the suture **3** is separated from the support structure **19**, tensioning on both free ends **23** of the preformed loop pattern **17** tightens the knot. The knot can then be cinched down first end **10** of the suture line to secure the hitch knot to the tissue/organ **4**. The support structure **19** is removed and discarded. In an additional variation, the support structure **19** can include a tether **24** to prevent it from inadvertently being lost in the body cavity.

[0052] In an additional variation, a loop support member or structure **25** can employ a loop pattern release mechanism that is activated by applying tension to the free ends of the loop pattern. Similar to the previous variation, the loop pattern **17** is configured to enable capturing portions of the suture between two opposing surfaces. For example, Fig. 10 shows a flexible suture **3** that has a first end **10** extending through or around a tissue/organ **4** and a second end **11** having a plurality of spaced loop patterns **17** releaseably captured by loop support structures **25**. The leading support structure **19** is held at the clip proximal end **26** by a grasper while the first end **10** of the suture is traversed thru the central axis passage **15**. Passing the first end **10** of the suture thru the central axis passage **15** completes the hitch knot. In these examples, the support member **25** includes a funnel **31** to aid in directing the end **10** through the loop pattern **17**.

[0053] The support structure **25**, is further illustrated Fig. 11, includes a clip with a lower surface on the base **27** that opposes an upper surface on the top **28**, where the two surfaces capture the suture loop pattern **17** and secures it to provide support and maintain the loops in the desired shape. The base **27** and top **28** of the support structure

25 are secured at the proximal end **26** and free at the distal end **29,** thus providing the spring action for the clip. The base **27** includes two lateral posts **30** that extend toward the central axis **9**. Each post provides a surface for the corresponding free end **23** of the preformed loop pattern **17** to side across when being tensioned. This pulls the segment **12** of the suture **3** out of the base **27**. An additional feature shown integrally attached to the base **27** is a funnel **31.** The funnel serves to assist directing the suture through the loop pattern **17**. In addition, the funnel **31** can also be an indicator to identify the proper direction from which the end **10** of the suture should be feed through the loop pattern **17** when directionality of the adjacent hitches is preferred. The funnel **31** also acts to aid in stabilizing the loops of the loop pattern **17**. The funnel has a slot **32** through which the placed first end **10** of the suture can slide for separation from the support structure. The loops of the loop pattern **26** can slide of the smaller end of the funnel **31** for separation from the support structure. When tension is applied to the free ends end **23** of the loop pattern **17**, the tension is transferred along the suture to create a force that dislodges the captured sections **18** of the loop pattern **17** out of the hold of the opposing clip surfaces.

[0054] Fig. 12 reveals the leading preformed loop pattern **17** with the first end **10** of the suture traversing through it. The free ends **23** of the loop pattern **17** have been tensioned, and thus have caused the suture loop pattern **17** to separate from the support structure **25**. The knot can then be cinched down first end **10** of the suture line to secure the hitch knot to the tissue/organ **4**. The support structure **25** is removed and discarded. The support structure **25** can include a tether **24** to prevent it from inadvertently being lost in the body cavity.

[0055] Fig. 13 shows one example of a loop support structure **25** in use. As shown, the support structure **25** is securely held by a first grasper **1**, while the jaws at the distal tip of a second grasper **5** are advanced through the loop pattern **17**, as shown in Fig. 13. The first grasper **1** then releases the support structure **25**, and is then manipulated to grasp the needle **2** near the proximal end. The needle **2** is advanced through or around the desired tissue **4**. As the needle tip is exposed, it is guided into the open jaws **6** of the second grasper **5**. The jaws **6** of the second grasper **5** are then closed to securely clamp onto the tip of the needle **2**. The needle **2** is then released by the first grasper **1**.

The first grasper is used to grasp the support structure **25** and secure it while the jaws of the second grasper **5** are retracted back through the loop, carrying the needle **2** and first suture end **10** with it. The support structure is then separated from the loop pattern **17**. This could be achieved by simply pulling the support structure **25** away from the loop pattern **17** encircled about the second grasper **5**, until the loop pattern slips out of the grasping clip force of the support structure **25**. The suture loops could then be slipped off the end of the grasper shaft and jaws to expose the knot. Other alternatives, such as those described in the above embodiments could be utilized to release the loop pattern from the support structure. Moreover, the needle **2** and end **10** can be advanced from the tissue side of the suture **3** rather than the side shown in Fig. 13A. Regardless, once the segment of the suture **3** releases from the variation of the support structure used, the opposing ends of the loop pattern **23** are then put in tension to produce a finished knot. An advantage of using the technique described above is the jaws are utilized as a protective element to prevent the needle **2** from inadvertently damaging the suture while it is being passed through the loop pattern **17**. Other methods of use are applicable depending on the design of the support structure, the style and design of the knot, and the surgical procedure being performed.

CLAIMS

We Claim:

1. A ligature and/or suture device configured for creating a knot in a flexible line, comprising:

a length of suture having a proximal end and a distal end;

a loop support member configured to releaseably secure a segment of the suture within a portion of the support member such that the segment forms at least one loop pattern; and

wherein when one of the proximal or distal ends advances through the loop pattern, the loop support member can selectively release the segment to create a knot.

2. The device of claim 1, where the loop support member is configured in a small size such that the entire device can be delivered through a cannula and placed inside the body

3. The device of claim 1, where the loop support member comprises extensions on either side of the segment such that applying tension to the proximal and distal ends of the suture simultaneously, causes the segment to release from the support member.

4. The device of claim 1, where applying tension to the proximal end of the suture causes the suture loop or loops to release from the support member.

5. The device of claim 1, where applying tension to the distal end of the suture causes the suture loop or loops to release from the support member.

6. The device of claim 1, that includes a needle attached to the suture.

7. The device of claim 1, where the proximal end of the suture is placed through tissue prior to being placed through the loop.

8. The device of claim 1, where the loop support member is tethered to at least a second loop support member.

9. The device of claim 8, further comprising at least an additional plurality of loop support members each releasably holding a plurality of segments of suture in respective loop patterns along the length of the suture.

10. The device of claim 1, where the support member is manufactured from less than 2 components.

11. The device of claim 1, where the loop support member further includes a funnel adapted to guide an end of the suture or a needle through the loop pattern.

12. The device of claim 1, further including a portion adapted to be manipulated by needle holders or graspers.

13. The device of claim 1, further including a portion comprising an additional clamp section for temporarily attaching to tissue.

14. The device of claim 1, further including a portion comprising at least one feature comprising a hook, barb, or protrusion to temporarily affix the loop support member to tissue.

15. A surgical knot fixation assembly comprising:

a length of suture;

a loop support member having a suture receiving portion such that a segment of the suture can be releasably maintained in a loop shape when a portion of the segment of the suture is held within the suture receiving portion.

16. The surgical knot fixation assembly of claim 15, where the suture receiving portion comprises a pair of mating jaws, such that upon separation of the jaws, the segment releases from the loop support member.

17. The surgical knot fixation assembly of claim 16, where the mating jaws are spring biased to close.

18. The surgical knot fixation assembly of claim 15, where the suture receiving portion comprises a cavity within the loop support member.

19. The surgical knot fixation assembly of claim 18, further comprising a pair of release surfaces each release surface adjacent to the cavity such that pulling on a first and second ends of the suture cause the suture to move against the release surface and out of the cavity to release the segment from the loop support member.

20. The surgical knot fixation assembly of claim 18, further comprising a slot adjacent to the cavity such that when pulled, the segment can exit through the slot. to release the segment from the loop support member.

21. The surgical knot fixation assembly of claim 15, where the suture receiving portion comprises a funnel member, where a portion of the segment surrounds the funnel member such that an end of the suture can move within the funnel to cross within the loop shape.

22. The surgical knot fixation assembly of claim 15, further comprising a tang feature coupled to the suture receiving portion such that movement of the tang feature releases the segment from the suture receiving portion.

23. The surgical knot fixation assembly of claim 15, further comprising a protrusion, barb, or hook on a body such that the body can be temporarily affixed to tissue.

24. The surgical knot fixation assembly of claim 15, further comprising a grasping section such that the loop support member can be manipulated by a grasping instrument.

25. The surgical knot fixation assembly of claim 15, loop support member is configured in a small size such that the loop support member can be delivered through a cannula and placed inside the body

26. The surgical knot fixation assembly of claim 15, further comprising a needle attached to an end of the suture.

27. The surgical knot fixation assembly of claim 15, where the loop support member is tethered to at least a second loop support member.

28. The device of claim 1, further including a portion comprising at least one feature comprising a hook, barb, or protrusion to temporarily affix the loop support member to tissue.

29. A surgical knot fixation assembly for use with a length suture comprising:

a loop support member sized to fit within a 15mm diameter or smaller cannula, the loop support member having a suture receiving portion such that a segment of the suture can be releasably maintained in a loop shape when a portion of the segment of the suture is held within the suture receiving portion.

30. A method of securing tissue comprising:

advancing a suture through or around the tissue, the suture having at least one loop support member, where a segment of the suture is maintained in a loop shape when a portion of the segment of the suture is releasably held in the loop support member;

retracting an end of the suture through the loop shape;

releasing the portion of the segment suture from the loop support member; and

forming at least a partial knot in the suture by pulling the end of the suture.

31. The method of claim 30, where suture comprises a plurality of loop support members.

32. The method of claim 31, where each loop support member maintains the respective segment held therein in a similar loop shape.

33. The method of claim 31, where at least one loop support member of the plurality of loop support members maintains the respective segment held therein in different loop shape than an another loop support member.

34. The method of claim 30, where the suture and loop support member are introduced into a body of a patient in a minimally invasive manner.

35. The method of claim 34, where introducing the suture and loop support member comprises introducing the suture and loop support member through a trocar, cannula, catheter, introducer or port providing access to within the body.

36. A method of securing tissue comprising:

advancing a suture through or around the tissue, the suture having at a plurality of segments each held respectively by a plurality of loop support members, each loop support member holding the respective segment of the suture in a partial knot shape;

navigating an end of the suture through a first partial knot adjacent to a first loop support member to create a first full knot;

releasing the first loop support member from the suture without releasing a second loop support member from the suture;

fully cinching the first partial knot by pulling on at least one of the ends of the suture.

37. The method of claim 36, where the first partial knot and the first full knot comprise hitch knots.

38. The method of claim 36, further comprising subsequently releasing at least the second loop support member from the suture.

39. The method of claim 36, where subsequently releasing at least the second loop support member from the suture comprises releasing the second loop support member without forming a second full knot.

40. The method of claim 36, where subsequently releasing at least the second loop support member from the suture comprises advancing the end of the suture through the second partial knot to create a second full knot and subsequently cinching the second full knot.

41. The method of claim 36, further comprises advancing the suture and loop support members into a body of a patient through a trocar, cannula, catheter, introducer or port that provides access to within the body.

42. The method of claim 36, further comprises withdrawing the remaining plurality of loop support members from the body through a trocar, cannula, catheter, introducer or port that provides access to within the body.

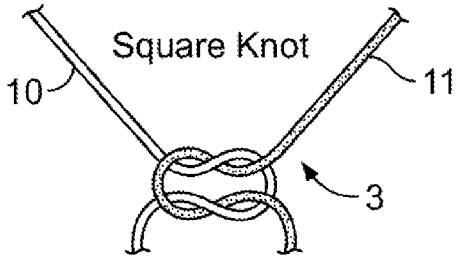

FIG. 1A

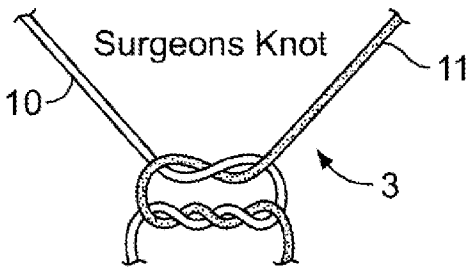

FIG. 1B

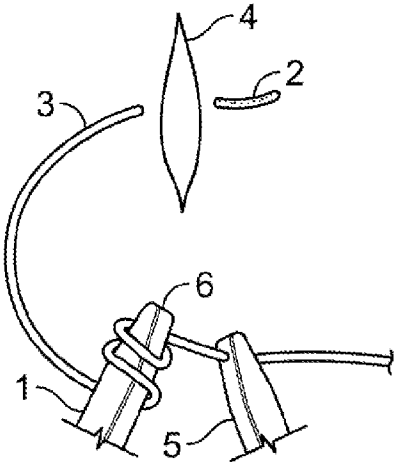

FIG. 2A

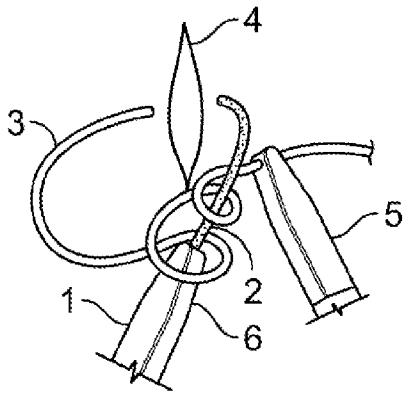

FIG. 2B

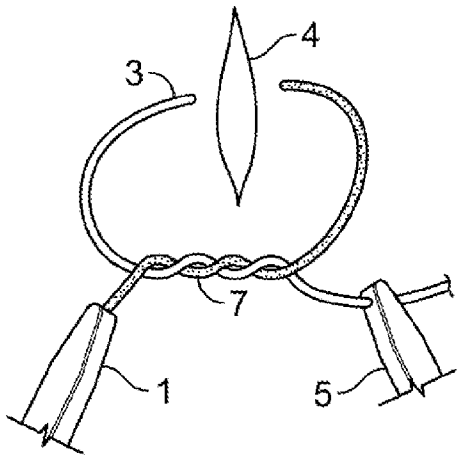

FIG. 2C

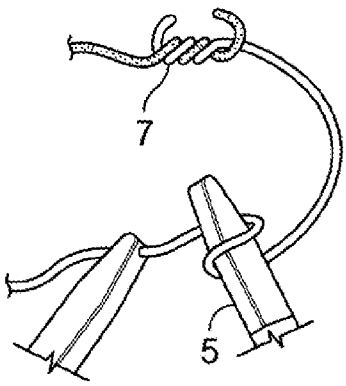

FIG. 2D

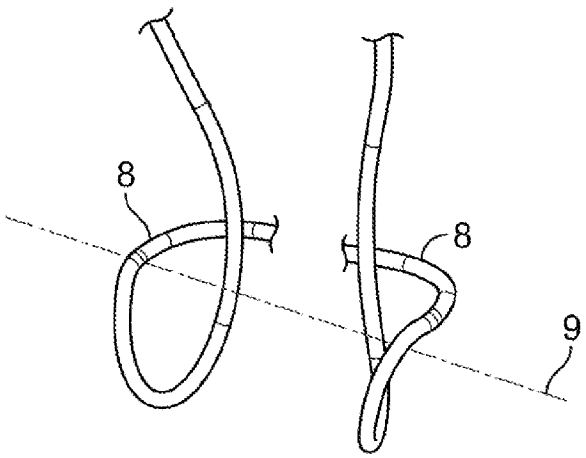

FIG. 3

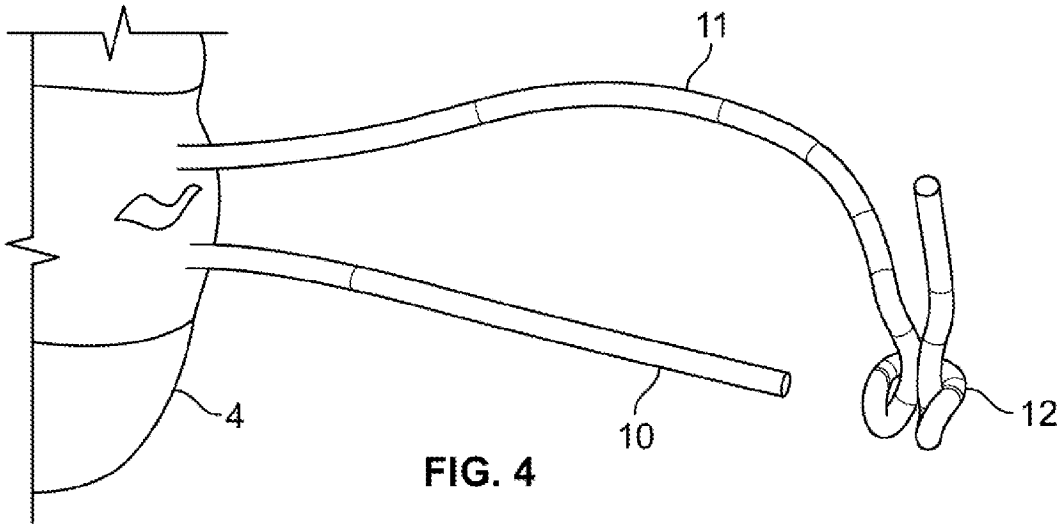

FIG. 4

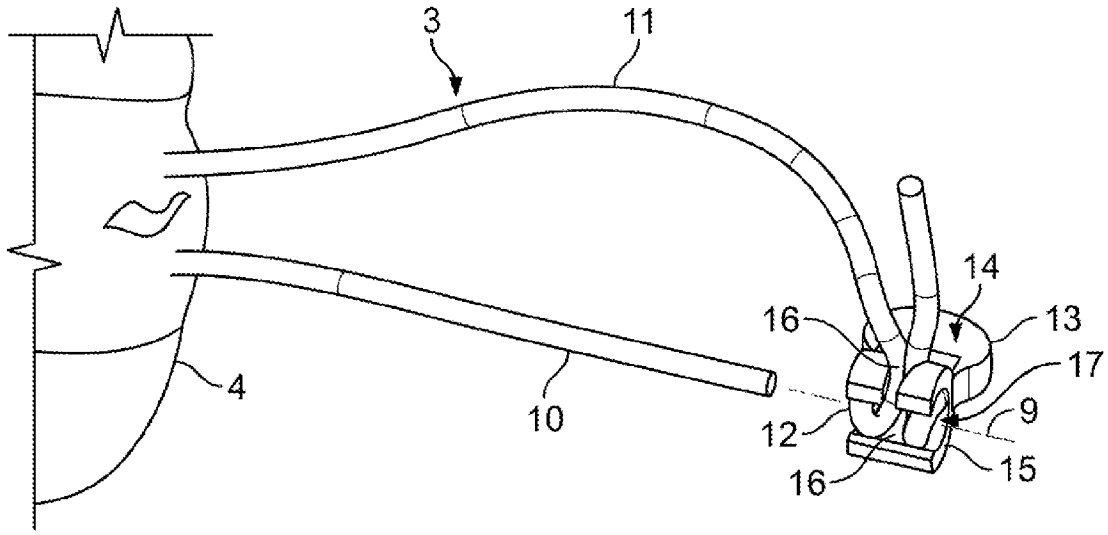

FIG. 5

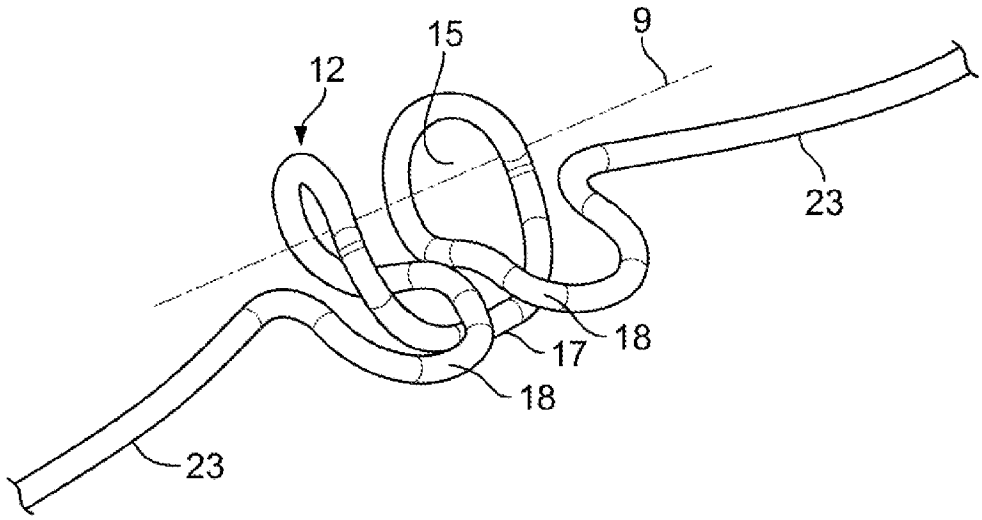

FIG. 6

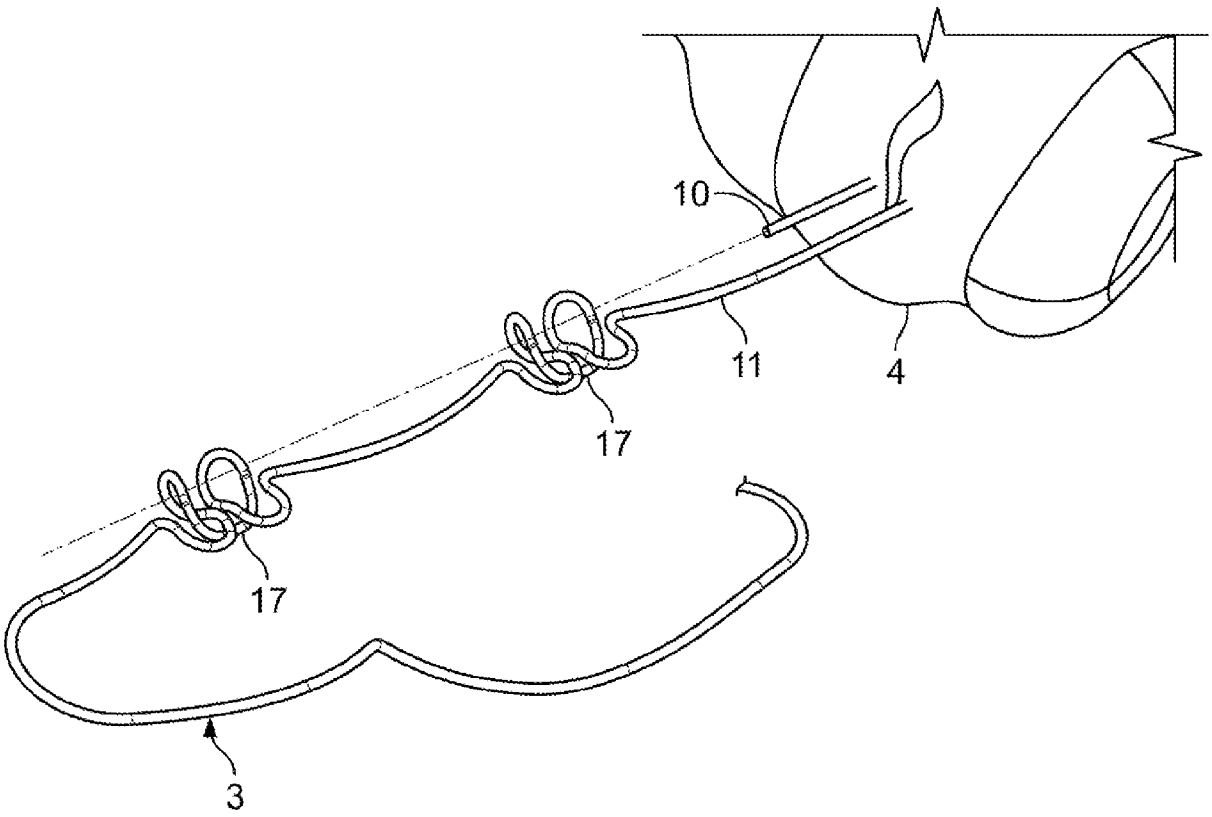

FIG. 7

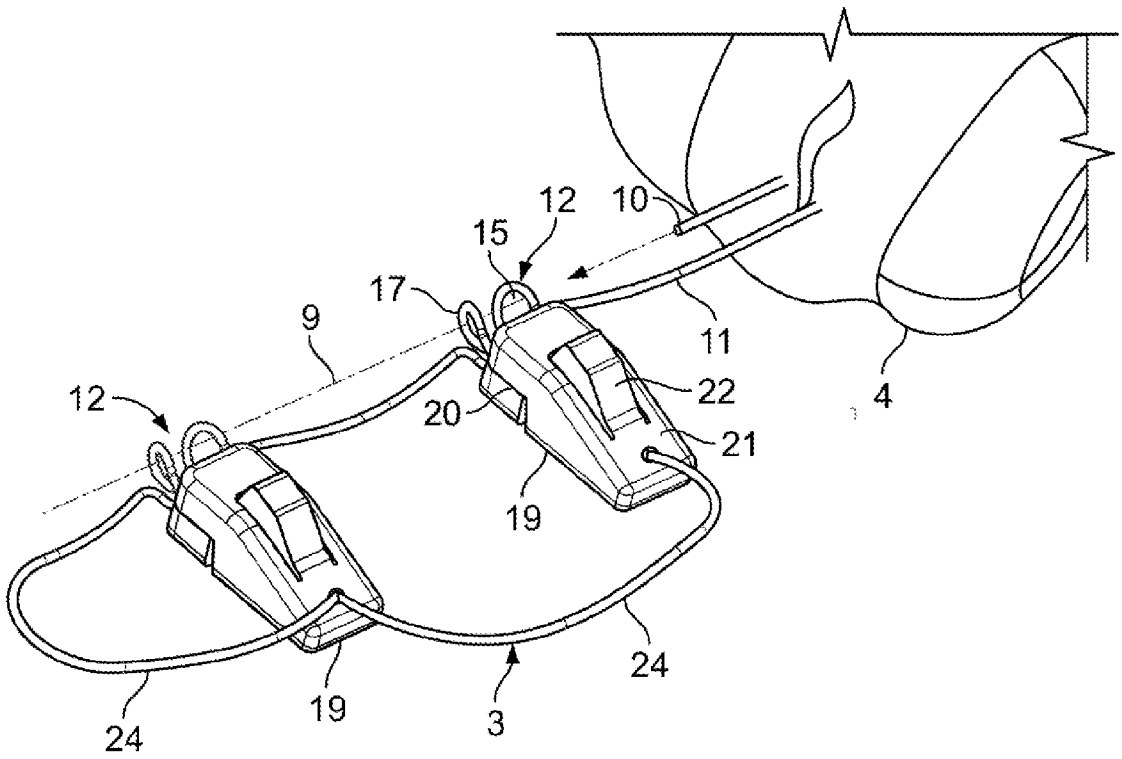
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FIG. 8

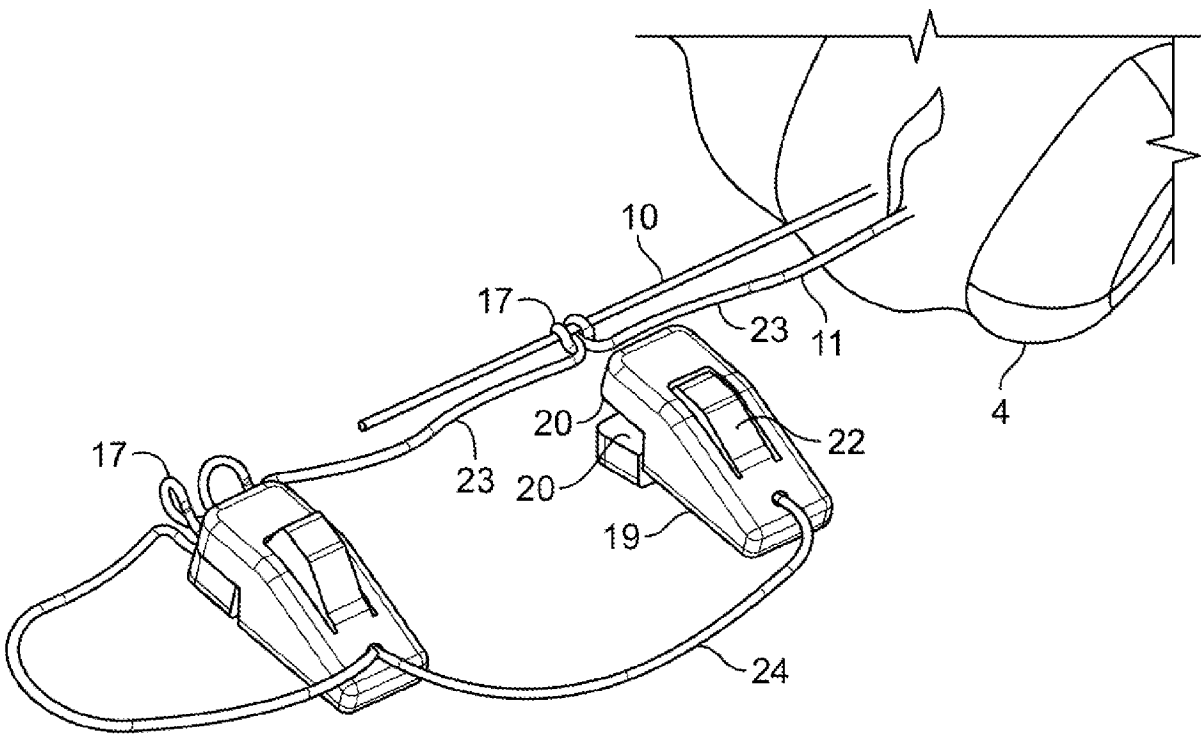
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FIG. 9

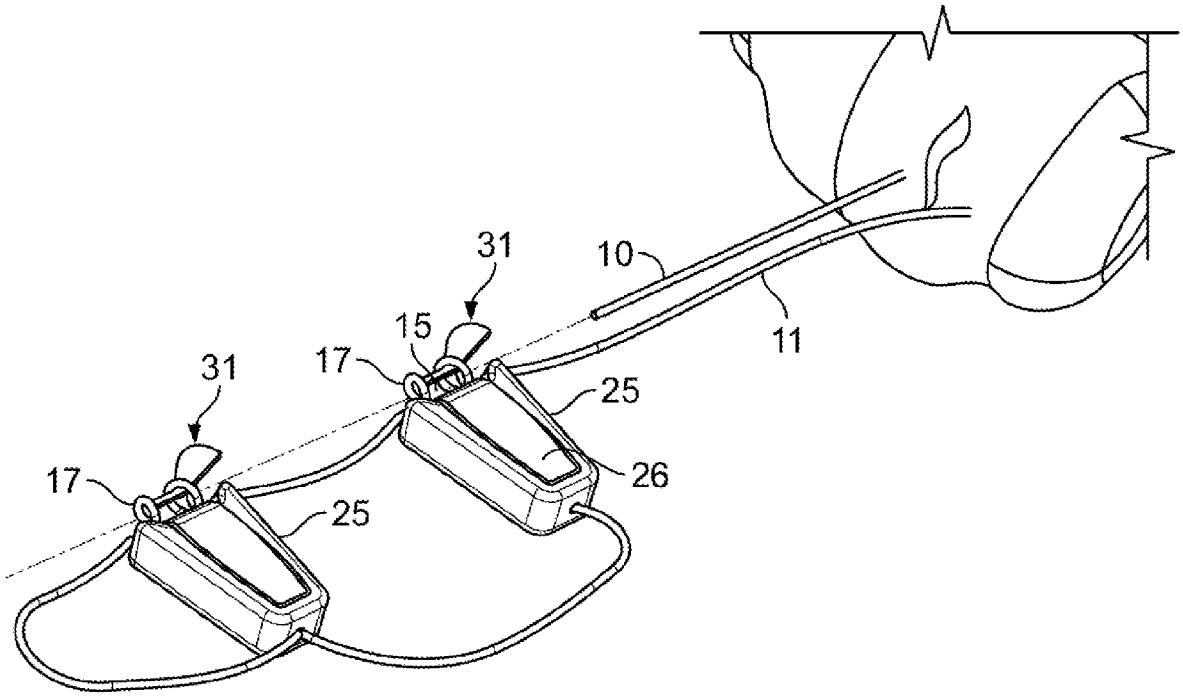

FIG. 10

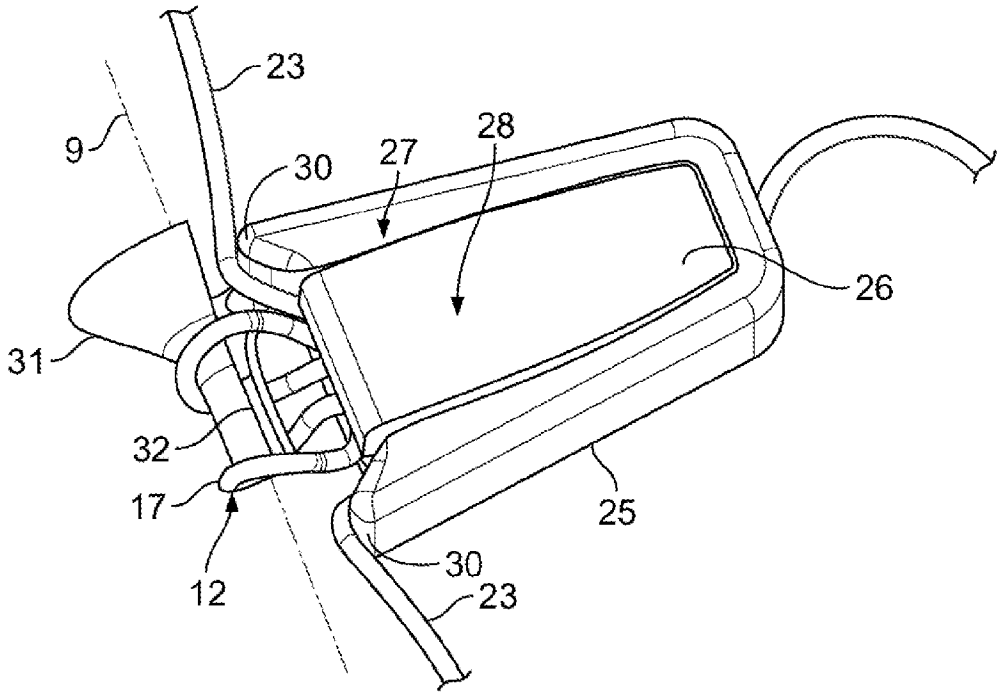

FIG. 11

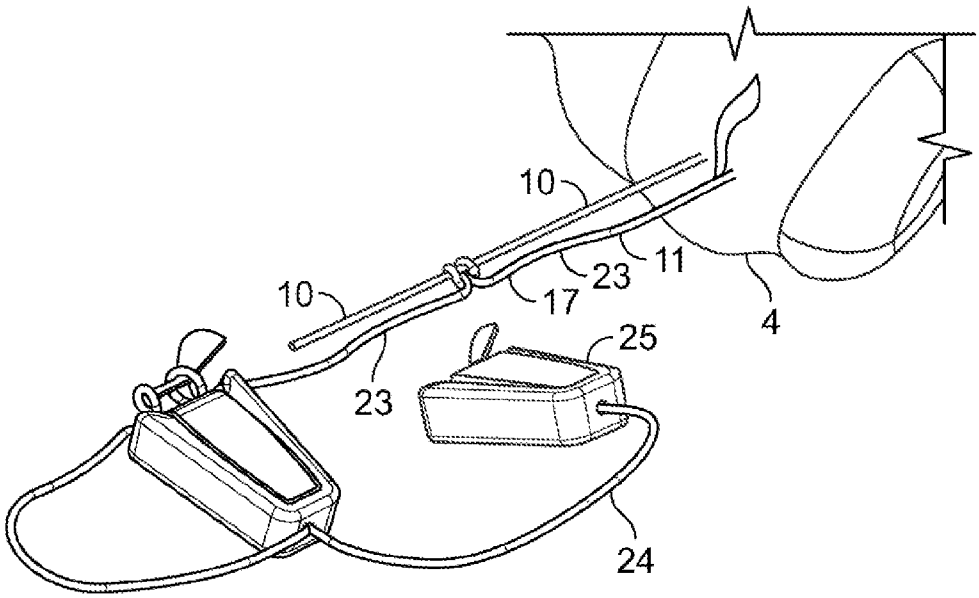

FIG. 12

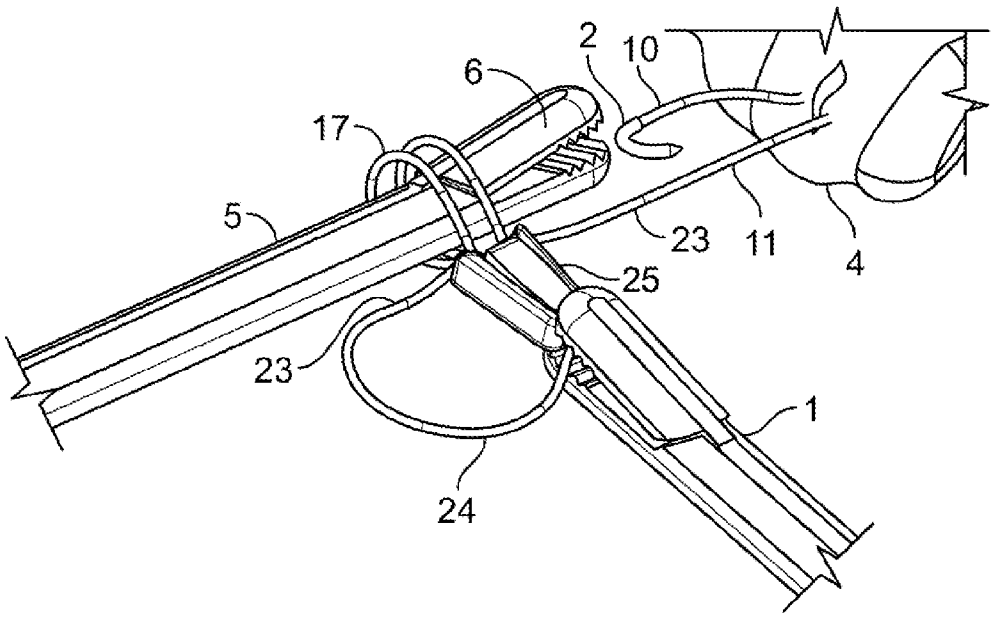

FIG. 13

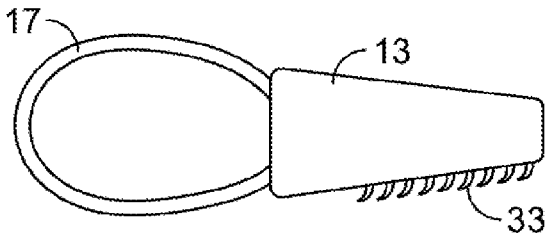

FIG. 14A

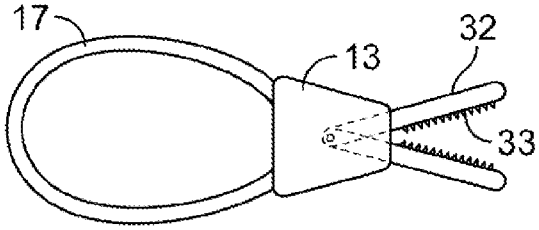

FIG. 14B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/78982

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/00 (2008.04)
USPC - 606/139
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/00 (2008.04)
USPC - 606/139

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) - A61B 17/00 (2008.04)
USPC - 606/139,148,144,228,215,216,225; 289/17,18.1, 1.5,2

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest: US PAT, US PGPUB, US OCR, EPO, JPO; Google Scholar; Keywords: suture, ligature, flexible, malleable, bendable, line, thread, know, loop, secure, affix, fix, fixation, cannula, trocar, needle, holder, grasper, grabber, hook, clamp, barb, protrusion

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,716,368 A (de la TORRE, et al.) 10 February 1998 (10.02.1998), col 1, ln 49-62; col 2, ln 14-20; col 2, ln 50-64; col 3, ln 42-53; col 5, ln 19-21; col 5, ln 30-34; col 5, ln 50-67; col 6, ln 7-16; col, 6, ln 42-60; col 8, ln 49-63; col 14, 6-16; FIGS. 1, 11-14, 22	1-36, 38-42 ----- 37
Y	US 5,591,177 A (LEHRER) 07 January 1997 (07.07.1997), col 10, ln 63-67	37

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 November 2008 (25.11.2008)	05 DEC 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774