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(54) **FLEXIBLE SUTURING INSTRUMENT**

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INSTRUMENT DE SUTURAGE FLEXIBLE

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Description

Cross-Reference to Related Applications

[0001] This application claims the benefit of and priority to United States Provisional Application No. 61/451,366, filed on March 10, 2011.

Technical Field

[0002] The invention generally relates to suturing instruments for placing sutures. The suturing instruments of the invention can be used to access difficult-to-reach treatment areas within the body of a patient.

Background Information

[0003] Suturing body tissue is a time consuming aspect of many surgical procedures. For many surgical procedures, it is necessary to make a large opening in the human body to expose the area that requires surgical repair. There are instruments available, such as endoscopes, that allow viewing of certain areas of the human body through a small puncture wound without exposing the entire body cavity. Endoscopes can be used in conjunction with specialized surgical instruments to detect, diagnose, and repair areas of the body that previously required open surgery to access.

[0004] Some surgical instruments used in endoscopic procedures are limited by the manner in which they access the areas of the human body in need of repair. In particular, the instruments may not be able to access tissue or organs located deep within the body or that are in some way obstructed. Also, many of the instruments are limited by the way they grasp tissue, apply a suture, or recapture a needle and suture. Furthermore, many of the instruments are complicated and expensive to produce due to the numerous parts and/or subassemblies required to make them function properly.

[0005] Suturing instruments, and more specifically suturing instruments used in endoscopic procedures, are generally rigid and do not provide the operator a range of motion to access difficult-to-reach parts of the anatomical region requiring sutures. Accordingly, multiple instruments of various configurations and sizes typically are used to access all of the necessary tissue areas. These limitations of known suturing instruments complicate the endoscopic procedure for the surgeon by requiring the insertion and removal of multiple instruments from a surgical site as the target suturing area changes during the course of the surgical procedure.

[0006] Patent application US 2003/0233107 A1 discloses suturing instruments that are dimensioned and configured to apply sutures to approximate, ligate, or fixate tissue in, for example, open, miniincision, trans-vaginal, laparoscopic, or endoscopic surgical procedures. In some embodiments, the suturing instruments include a distal portion that is deflectably and/or pivotally coupled

to the remainder of the instrument for improved maneuverability and functionality during surgery. In other embodiments, the suturing instruments are capable of housing multiple needle and suture assemblies and/or reloading the needle and suture assembly without removing the instrument from the surgical site.

[0007] Patent application US 2011/0040308 A1 relates to devices, systems and methods for endoscopic suturing or stitching through an access tube or the like. An endoscopic stitching device is provided and includes a handle assembly; an elongate shaft supported by and extending from the handle assembly; and an end effect or supported on a distal end of the elongate shaft. The end effect or includes a neck assembly configured and adapted for articulation in one direction between a substantially linear configuration and an off-axis configuration, and a pair of juxtaposed jaws pivotally associated with one another. Each jaw defines a suture needle receiving recess formed in a tissue contacting surface thereof.

Summary of the Invention

[0008] The invention generally relates to suturing instruments with improved maneuverability, efficiency and functionality for use during a surgical procedure, such as an endoscopic or laparoscopic procedure. The invention is defined in the characterizing portion of appended claim 1. Preferred embodiments are set forth in the dependent claims.

[0009] The embodiments described herein are illustrative only and not intended to be limiting. Instruments or other devices similar or equivalent to those described herein can be used in the practice or testing of the present invention.

Brief Description of the Drawings

[0010] In the drawings, like structures are referred to by like numerals throughout the several views. Note that the illustrations in the figures are representative only, and are not drawn to scale, the emphasis having instead been generally placed upon illustrating the principles of the invention and the disclosed embodiments. In the following description, various embodiments of the present invention are described with reference to the following drawings.

FIG. 1A depicts the general structure of a suturing instrument according to the invention; FIG. 1B is a view of the suturing instrument depicted in FIG. 1A that shows the elongate shaft and the suturing head deflected off of a longitudinal axis extending along the suturing instrument.

FIG. 2 illustrates a suturing head for use in a suturing instrument according to the invention.

FIG. 3 depicts an example of a needle for use in a suturing instrument of the invention.

FIG. 4 depicts an example of a needle catch for use

in a suturing instrument according to the invention. FIG. 5 depicts an example of a handle coupled to an elongate shaft of a suturing instrument according to the invention, and shows an example of an actuating mechanism that is disposed within the handle and coupled to a needle deployment system that is partially disposed within the elongate shaft.

FIG. 6 is a cross-sectional view of a distal portion of a suturing instrument according to the invention depicting a needle deployment system coupled to a needle carrier disposed within a suturing head.

FIGS. 7A-7G depicts a suturing instrument having a flexible distal portion, and the multiple different directions and/or planes in which the distal portion can be bent or deflected.

FIG. 8 is an exploded view a handle of a suturing instrument according to the invention, depicting the components of a control system disposed within the handle.

FIG. 9 is an expanded view of a portion of the control system depicted in FIG. 8.

FIG. 10 depicts an alternative embodiment of a handle including a control system for use in a suturing instrument according to the invention.

FIG. 11 depicts an alternate orientation of the handle depicted in FIG. 10.

FIG. 12 is a cross-sectional view of the handle depicted in FIG. 10, illustrating the components of a control system disposed within the handle.

FIG. 13A is an alternate view of the handle depicted in FIG. 12; FIG. 13B is an expanded view of a portion of FIG. 12.

FIG. 14 depicts a link used to form an articulation structure for use in a suturing instrument according to the present invention.

FIG. 15 depicts a schematic rendering of an articulation structure formed by stacking a series of the links shown in FIG. 14.

FIG. 16 depicts an enlarged portion of the articulation structure shown in FIG. 15.

FIG. 17 depicts a schematic rendering of the articulation structure shown in FIG. 15 bent in an upward direction.

FIGS. 18A-18C illustrate alternative embodiments of an articulation structure formed of a number of stacked discs for use in a suturing instrument in accordance with the present invention.

Description

[0011] Embodiments of the invention are described below. It is, however, expressly noted that the invention is not limited to these embodiments, but rather the intention is that variations, modifications and equivalents that are apparent to a person skilled in the art are also included.

[0012] Suturing instruments having a shapeable elongate shaft, an elongate shaft with a preformed bend and/or a passively deflectable suturing head, have been

described in U.S. Patent Application Publication Nos. 2004/0181243, 2006/0041263, and 2008/0109015. The present invention provides suturing instruments having flexible elongate shafts that can be controllably deflected by a user (e.g., a surgeon) in a plurality of directions and/or planes, with improved precision and maneuverability over previous designs. The suturing instruments provide a minimally invasive tool that is useful in endoscopic or laparoscopic procedures, particularly in intra-abdominal, intra-vaginal, and rectal and procedures, which typically involve difficult-to-reach areas within a body.

[0013] A flexible suturing instrument according to the invention is used, for example, to access areas within a human body to ligate, fixate, or approximate tissue. The suturing instrument generally throws one or more stitches intracorporeally. **FIG. 1A** depicts the general structure of a suturing instrument **100** according to an illustrative embodiment of the invention. As shown in **FIG. 1A**, suturing instrument **100** generally includes a handle **1**, an elongate shaft **2** extending from the handle **1** and including a distal portion **2a**, and a suturing head **3** extending from a distal end **2b** of the distal portion **2a** the elongate shaft **2**. At least a portion of the elongate shaft is adapted to be flexible such that it can be deflected in one or more directions and/or planes relative to a longitudinal axis extending along the elongate shaft. For example, the distal portion **2a** of the elongate shaft **2** is adapted to be flexible such that it can be deflected off of a longitudinal axis **A** extending along the suturing instrument (**FIG. 1B**). Alternatively, the entire length of the elongate shaft **2** is adapted to be flexible such that portions of the shaft can be deflected in one or more directions and/or planes relative to the longitudinal axis **A** extending along the suturing instrument.

[0014] One or more cables or pull wires extend from the handle **1** into the distal portion **2a** of the elongate shaft **2** and are configured for actively controlling deflection of the flexible portion of elongate shaft **2** relative to a longitudinal axis extending along the length of the elongate shaft **2**. The one or more cables or pull wires can extend from the handle **1**, within the elongate shaft **2**, and into the distal portion **2a**. Alternatively, the one or more cables or pull wires can extend from handle, along the outside of elongate shaft **2**, and into the distal portion **2a**. In certain embodiments, the one or more pull wires terminate in the distal portion of the shaft, but the wires can terminate elsewhere such as in the suturing head **3**.

[0015] In certain embodiments, at least a portion of elongate shaft **2** includes a flexible coil, such as a Bowden coil. For example, the distal portion **2a** of the elongate shaft can include a flexible coil. Alternatively, the entire length of the elongate shaft **2** can include a flexible coil. The flexible coil can be passively and/or actively bent into one or more shapes. For example, the flexible coil can passively conform to the shape of a bodily passage during insertion into the passageway. The flexible coil instead can be actively bent into a shape by a user's

hand(s) prior to insertion into a bodily passage or cavity, such that the shaft 2 retains that shape during use. The flexible coil will be stiffer in embodiments where physical manipulation of the coiled portion of the shaft 2 result in that portion of the shaft 2 retaining its modified shape (such as an "S" shape). The stiffer the flexible coil, the harder it is to bend, but the more it will resist changing from its bent shape. The one or more pull wires extending from the handle 1 into the distal portion 2a of the elongate shaft instead can be used to actively control deflection of the flexible coil portion of the shaft 2.

[0016] In alternative embodiments, at least a portion of the elongate shaft 2 includes an articulation structure that forms an articulated portion of the shaft 2 and allows the articulated portion to be controllably deflected by the one or more pull wires extending from the handle 1. For example, the distal portion 2a of the elongate shaft can be articulated and thus controllably deflected in one or more planes relative to the longitudinal axis of the elongate shaft 2 using the one or more pull wires extending from the handle 1 to the distal portion 2a of the shaft 2. Alternatively, the entire length of the elongate shaft 2 can include an articulation structure that enables the entire length of the elongate shaft 2 to be actively and controllably deflected in one or more planes relative to the longitudinal axis of the elongate shaft 2 using the one or more pull wires. Examples of articulation structures suitable for use with the suturing instruments of the invention are described in detail below.

[0017] A flexible outer sleeve can be placed over the flexible coil portion and/or the articulated portion of the elongate shaft to provide a smooth exterior surface. The outer sleeve can be made from soft, thin polyurethane, LLDPE, silicon, pellethane, polyurethane, or other approved biocompatible materials such as polyethylene, polypropylene or polyvinyl alcohol. Additionally, the outer sleeve can be coated with a hydrophilic, lubricious coating such as HYDROPASS™ hydrophilic coating available from Boston Scientific Corporation, of Natick, Mass., and described in U.S. Pat. Nos. 5,702,754 and 6,048,620. Additionally, the outer sleeve can be coated with a drug agent to treat internal body tissues.

[0018] Turning now to the suturing head components of the suturing instruments of the invention, an exemplary embodiment of the suturing head 3 is depicted in FIG. 2. As shown in FIG. 2, suturing head 3 defines an opening or needle exit port 4 through which a needle carrier 5 advances a needle 6 that is releasably held within needle carrier 5. Suturing head 3 includes a curved portion 7, needle carrier 5, and a needle catch 8. The curved portion 7 defines a needle carrier channel 9, which ends at needle exit port 4. The curved portion 7 also defines an opening 10 for receiving tissue. Needle carrier 5 is movably disposed within needle carrier channel 9 in the curved portion 7 such that needle carrier 5 is capable of moving out of the suturing head into an extended position, and back into the suturing head into a retracted position. A distal portion 11 of the needle carrier 5 defines a lumen

12 dimensioned for holding/receiving the non-penetrating end of the needle 6. Preferably, the needle carrier 5 is configured to move out of suturing head 3 in a semi-circular path towards needle catch 8, such that needle 6 is released from needle carrier 5 and retained in needle catch 8. However, it should be noted that the exact structure and operation of the suturing head 3 can vary based on the type of head used.

[0019] Referring now to FIG. 3, the needle 6 includes a tissue penetrating tip 13 and a shaft 14 coupled to the tip 13, thereby forming shoulder 15. The shaft 14 is coupled to a suture 16. The needle 6 is inserted into lumen 12 of needle carrier 5 and held by a slight friction fit. Referring now to FIG. 4, needle catch 8 includes one or more openings 17 defined by successive ribs 18. Needle catch 8 receives tip 13 of needle 6 (coupled to suture 16) through opening 17, the ribs 18 deflect slightly to allow needle 6 to pass through. After the formed shoulder 15 of needle 6 has passed ribs 18, the ribs 18 spring back to their original position defining the openings 17 and needle 6 remains captured in needle catch 8. It should be noted that the needle 6 and needle catch 8 shown are merely one possible type and other designs may be selected.

[0020] Suturing instrument 100 further includes a needle deployment system that is disposed in at least a portion of the elongate shaft 2 and coupled to needle carrier 5 for moving the needle carrier 5 between the extended and retracted positions. Various configurations and components of needle deployment systems suitable for use in the suturing instruments of the invention are described in U.S. Pat. No. 5,713,910 to Gordon et al., U.S. Pat. No. 5,578,044 to Gordon et al., U.S. Pat. No. 5,575,800 to Gordon, U.S. Pat. No. 5,540,704 to Gordon et al., U.S. Pat. No. 5,458,609 to Gordon et al., and U.S. Pat. No. 5,364,408 to Gordon. In an exemplary embodiment, the needle deployment system extends longitudinally through the elongate member 2 to the suturing head 3 where a distal portion 19 of the needle deployment system is coupled to needle carrier 5 within the suturing head 3 (FIG. 6).

[0021] The handle component 1 of suturing instrument 100 can include an actuating mechanism 110 that is disposed within the handle 1 and coupled to a proximal portion of the needle deployment system for actuating the needle deployment system. In the illustrative embodiment depicted in FIG. 5, the actuating mechanism 110 includes an actuator button 117 and a shaft 116 (together 112). The actuating mechanism 110 is coupled to a bearing 118, a hole 121, a button end 119, and a wireform 103. The bearing 118 rides along a surface 105 that is formed by the inside of the elongate shaft 2. The wireform 103 is inserted into the hole 121, coupling it to the actuator button 117. A spring 115 encircles the wireform 103, abuts the button end 119, and is compressed between the button end 119 and a spring washer 113.

[0022] The distal portion 19 of the needle deployment system depicted in FIG. 5 includes the spring washer

113, a center tube 107, a pusher wire 111, and a guidance sleeve 109. The spring washer 113 is seated upon the center tube 107. The center tube 107 is housed by the surface 105 and is constrained in the distal portion 106 of the suturing instrument 100. The pusher wire 111 is attached to the wireform 103 by means of a weld, a crimp, a coupling, adhesive, or other means, and is slideably disposed within the guidance sleeve 109, the sleeve 109 being disposed within a surface 123 formed by the inside diameter of the center tube 107. In one embodiment, the pusher wire 111 is constructed of a shape memory material, for example, a nickel titanium alloy such as Nitinol™. Preferably, the shape memory material is chosen for its combination of properties that allow for bendability and high column strength when constrained.

[0023] Referring now to the illustrative embodiment depicted in FIG. 6, the distal portion of the suturing instrument 100 depicted in FIGS. 1 and 5 includes the distal portion 2a of the elongate shaft 2 and a distal portion of the needle deployment system 19 coupled to the needle carrier within suturing head 3. The distal portion of the needle deployment system depicted in FIG. 6 includes the pusher wire 111, a backstop washer 156, a pocket 160 that includes a back wall 162, a coupling 150, a track 152, a downstop washer 158, a pocket 164 that includes a wall 166, and a carrier wire 154. The pusher wire 111 of the needle deployment system is attached by welding or other means to the coupling 150, which is slideably disposed within the track 152. The coupling 150 is attached to the carrier wire 154, which by virtue of its attachment to the coupling 150 is also slideably disposed within the track 152. The carrier wire 154 is mechanically coupled to the extendable needle carrier 5 by means of a weld, a coupling, adhesives, or other means. The coupling 150 abuts the backstop washer 156 that is slideably disposed about the pusher wire 111 and is contained within the pocket 160 that includes the back wall 162, against which the backstop washer 156 rests. The track 152 terminates distally in the pocket 164 that includes the wall 166. The downstop washer 158 is slideably disposed about the carrier wire 154 and constrained within the pocket 164.

[0024] Referring again to the handle component of the suturing instruments of the invention, handle 1 of the suturing instrument 100 can further include a control system coupled to the one or more pull wires for actively controlling deflection of the flexible portion of the elongate shaft. Various configurations of handles that include a control system coupled to one or more pull wires for controllably deflecting an elongate shaft of an endoscopic medical device, or a portion thereof, are described in U.S. Patent Application Publication No. 2008/0300462 and 2010/0121147.

[0025] One illustrative embodiment of a handle configuration that includes a control system and is suitable for use in the suturing instruments of the invention is depicted in FIG. 8 and FIG. 9. As shown in FIGS. 8 and 9, the handle 1 includes a control system 22 to actively control

the deflection of the distal portion 2a of the elongate shaft 2. In the illustrated embodiment, the control system 22 comprises two activation hubs (rotatable cams) 24, 26, and four pull wires 28, 30, 32, 34. Each activation hub 24, 26 is connected to two of the pull wires and allows the user (e.g., a surgeon) to manipulate the distal portion 2a of the elongate shaft 2 in one plane of deflection. Additional activation hubs and/or pull wires could be included in the control system 22 depending on how many planes of deflection are desired. The pull wires 28, 30, 32, 34 are made from stainless steel, polymer filaments, or other metals and alloys such as, for example, Nitinol™. [0026] The first activation hub 24 is movably attached to the right side of the handle 20 from the perspective of the user and includes a floating cam 36 and a cam stop 38. The proximal ends of pull wires 30 and 34 are connected to the floating cam 36. When the user rotates the first activation hub 24 in a clockwise direction, as indicated by line A on FIG. 9, tension is applied to pull wire 34, and tension is released from pull wire 30, thereby deflecting the distal portion 2a of the elongate shaft 2 to the left. Conversely, when the user rotates the first activation hub 24 in the opposite, counter-clockwise direction, tension is applied to pull wire 30 and tension is released from pull wire 34, thereby deflecting the distal portion 2a to the right.

[0027] The user can achieve up and down deflection of the distal portion 2a of elongate shaft 2 by rotating the second activation hub 26 in a similar manner. The second activation hub 26 is movably attached to the left side of the handle 1 from the perspective of the user and includes a floating cam 40 and a cam stop (not shown). The proximal ends of pull wires 28 and 32 are connected to floating cam 40. When the user rotates the second activation hub 26 in a clockwise direction as indicated by line B on FIG. 9, tension is applied to pull wire 28, and tension is released from pull wire 32, thereby deflecting the distal portion 2a in an upward direction. Conversely, when the user rotates the second activation hub 26 in the opposite, counter-clockwise direction, tension is applied to pull wire 32 and tension is released from pull wire 28, thereby deflecting the distal portion 2a in a downward direction. The control system 22 could comprise additional components or alternative means for achieving deflection of the distal portion 2a of the elongate shaft 2.

[0028] The handle/control system can be used to deflect the flexible portion of the elongate shaft in one or more directions and/or planes relative to a longitudinal axis extending along the shaft. The control system can also be used to simultaneously deflect two or more portions of the elongate shaft in different planes relative to the longitudinal axis. For example, the control system can be used to deflect the distal portion 2a of the elongate shaft 2 into two or more different planes relative to the longitudinal axis, as shown in FIGS. 7A-7G.

[0029] Another illustrative embodiment of a handle configuration that includes a control system and is suitable for use in the suturing instruments of the invention

is shown in **FIGS. 10-13**. In **FIG. 10**, the handle **1** includes an elongate housing **312**, which includes a proximal end portion **314** and a distal end portion **316** and control system **310** disposed within the elongate housing **312**. The elongate housing **312** further includes a first grip portion **318** and a second grip portion **320** different than the first grip portion. Each of the first grip portion **318** and second grip portion **320** is adapted to be held or grasped by a hand of a user. The elongate housing **312** (and control system **310**) is couplable to the elongate shaft **2**.

[0030] The elongate housing **312** is adapted to be in a first orientation when the first grip portion **318** is operatively held by the hand of the user. For example, as illustrated in **FIG. 11**, when the user holds the elongate housing **312** of the steering mechanism **310** by the first grip portion **318**, the elongate housing is in a substantially horizontal orientation. The user (e.g., a surgeon) can operate the steering button **322** with a single finger of the hand holding the first grip portion **318**.

[0031] As shown in **FIG. 12** and **FIG. 13**, control system **310** includes the steering button **322**, a first cam **330**, a second cam **350**, and first, second, third, and fourth wires **332, 334, 352, 354**.

[0032] The first cam **330** moves in response to movement of the steering button **322**. The first cam **330** is adapted to move the flexible portion of the elongate shaft **2** along the first plane when the first cam moves in response to movement of the steering button **322**. As illustrated in **FIG. 12**, the first cam **330** is at least partially disposed in the cavity **324** of the elongate housing **312**. The first cam **330** is coupled to the elongate housing **312** by a frame **336**. The frame **336** is coupled to an inner surface of the elongate housing **312** defining the cavity **324**. In the embodiment illustrated in **FIG. 12** and **FIG. 13**, the frame **336** includes a first supporting arm **342**, a second supporting arm **344**, and a central arm **346**. The first supporting arm **342** and second supporting arm **344** are each coupled to the elongate housing **312**. The central arm **346** extends between and is coupled to the first and second supporting arms **342, 344**.

[0033] In the embodiment illustrated in **FIG. 13A**, the central arm **346** defines an opening or pocket adapted to receive a portion of the first cam **330**. The first cam **330** is coupled to the central arm **346**. The first cam **330** can be coupled to the central arm **346** by any known coupling mechanism, including, but not limited to, a pin or other mechanical fastener.

[0034] The first cam **330** is movable with respect to the frame **336**. The first cam **330** is movable between at least a first position (illustrated in **FIG. 12**), a second position different than the first position, and optionally a third position different from the first and second positions.

[0035] The first cam **330** is coupled to the steering button **322**. In some embodiments, as illustrated in **FIG. 12** and **FIG. 13**, the first cam **330** is fixedly coupled to the stem **326** of the steering button **322**.

[0036] The first cam **330** is coupled to each of the first wire **332** and the second wire **334**. As illustrated in **FIG.**

12 and **FIG. 13**, the first and second wires **332, 334** are coupled to the first cam **330** at spaced locations. The first wire **332** can be coupled to the first cam **330** proximate to the steering button **322**. In the embodiment illustrated in **FIG. 12**, the second wire **334** is coupled to a portion of the first cam **330** different than the portion of the cam coupled to the first wire **332**. The first wire **332** and the second wire **334** are each adapted to move in response to movement of the first cam **330**. Additionally, the first and second wires **332, 334** are each coupled to the elongate member **302** of the suturing instrument **100**. Thus, movement of the first and second wires **332, 334** moves the elongate shaft **2**.

[0037] Referring again to **FIG. 12**, as the steering button **322** is moved in its first direction along a first axis (as indicated by arrow A_1), the first cam **330** correspondingly moves to a second position different than its first position. As the first cam **330** moves towards its second position, the first cam moves (or pulls on) the first wire **332**. The first wire **332** moves the flexible portion of the elongate shaft **2** in its first direction along the first plane (e.g., "up"). **[0038]** To return the elongate shaft **2** to its starting position (or the linear or relaxed position), the steering button **322** is moved in its second direction until the first cam **330** is moved (or returned) to its first position. In some embodiments, at least one of the steering button **322** and the first cam **330** is biased towards a first (or starting) position.

[0039] The handle/control systems depicted in **FIGS. 8-13** are provided for illustrative purposes only and are not intended to be limiting. The handle/control system component of the suturing instruments of the invention may also include levers, knobs, robotics, a joystick, or other control features, all of which would be known to those knowledgeable about medical devices

[0040] Now referring back to the elongate shaft **2**, in certain embodiments, at least a portion of the elongate shaft **2** includes an articulation structure that provides flexibility to the articulated portion of the elongate shaft. For example, the distal portion **2a** of the elongate shaft **2** can include an articulation structure. Alternatively, the entire elongate shaft **2** can include an articulation structure. The articulation structure can be used in conjunction with a flexible coil to provide a suturing instrument having increased flexibility and controlled maneuverability. The articulation structure can also be used as the sole means of providing flexibility to at least a portion of the elongate shaft. The articulation structure is coupled to the one or more pull wires for controllably deflecting the flexible and/or articulated portion of the elongate shaft **2**. Various articulation structures that are suitable for use in the suturing devices of the invention are described in U.S. Patent No. 7,591,783 and U.S. Patent Application Publication No. 2008/0287741.

[0041] One embodiment of an articulation structure **200** which can be used with the present invention is made of a series of stacked links **212** that are positioned adjacent to one another, defining an inner lumen **214** and

movable with respect to each other. Referring now to **FIG. 14**, a link **212** according to one embodiment includes a front face **216** and a rear face **218**. Each link may be deep drawn, rolled and welded, stamped, injection molded, or otherwise formed of stainless-steel or other bio-compatible material that allows the link **212** to be rigid while having a thin wall profile in order to maximize the size of the inner lumen **214**.

[0042] The front face **216** of the link **212** includes a pair of oppositely arranged engagement surfaces that bisect the link **212** and define a pair of pivot points **220** that engage the corresponding rear face **218** of an adjacent link **212**. The pivot points **220** are rounded over forming substantially cylindrical surfaces that serve as bearings. The front face **216** of the link **212** further includes two tapered sections **222** that are angled proximally away from the pivot point **220**. The two tapered sections **222** are oriented at an angle of A° with respect to the longitudinal axis **224** of the link **212**. The terms proximal and distal require a point of reference. In this application, the point of reference is the perspective of the user. Therefore, the term proximal will always refer to an area closest to the user, whereas distal will always refer to an area away from the user.

[0043] Similarly, the rear face **218** of the link **212** includes two sloped sections **226** that are angled distally away from a relatively flat surface **228** of the rear face **218** forming a wedge shaped recess **230** with a vertex **232** for receiving the pivot points **220** of the adjacent link **212**. As with the tapered sections **222** at the front face **216** of the link, the sloped sections **226** of the rear face **218** are oriented at an angle of B° with respect to the longitudinal axis **224**. Additionally, the vertex **232** is rounded to form a substantially cylindrical surface to engage the rounded over surface of the pivot points **220**.

[0044] A plurality of wire channels **234**, **236**, **238**, **240**, are integrally formed in the link **212** itself or otherwise disposed on the inner surface **242** of the link **212**. The wire channels are radially spaced at predetermined distances around the circumference of the link **212**. As shown in **FIG. 14**, channels **236** and **240** are positioned at the pivot points **220**, while channels **234** and **238** are rotated 90° with respect to channels **236** and **240**.

[0045] Referring now to **FIGS. 15-17**, the articulation structure **200** is created by stacking a number of links **212a**, **212b**, **212c**, etc., such that that the pivot points **220** of each link **212** are aligned with the vertex **232** of the adjacent link **212**. Locking pull-wires **246** and **250** disposed in wire channels **236** and **240** provide tension to hold adjacent links **212a**, **212b**, **212c**, etc., together while the one or more pull-wires designated in **FIGS. 15-17** as **244** and **248** are components of the control system for bending the articulation structure in the desired direction.

[0046] Pull wires **244** and **248** can be coupled to the control system disposed within or on handle, such as the control system **22** illustrated in **FIGS. 8** and **9**.

[0047] The proximal ends of pull-wires **244** and **248**

can be connected to the rotatable cam in the control system **22** and the distal ends of the pull-wires **244** and **248** are connected to the distal end **254** of the articulation structure **200** (**FIG. 16**). As shown in **FIG. 17**, when the user rotates the rotatable cam in control system **22** in the clockwise direction as indicated by line C on, tension is applied to pull-wire **244**, and tension is released from pull-wire **248**, thereby deflecting the distal end **254** of the articulation structure in an upward direction. Conversely, when the user rotates the control cam **252** in a counter-clockwise direction, tension is applied to pull-wire **248** and released from pull-wire **244**, thereby deflecting the distal end **254** in a downward direction.

[0048] The deflection capability of the articulation structure **200** is a function of the difference between angles A and B and the number of links N, which can be represented by the formula: deflection angle = $(A-B)/2 \times (N-1)$. For example, in the embodiment shown in **FIG. 15**, if angle A is 140° , angle B is 100° , and there are 11 links including the first and last link the deflection would be 200° . The radius of deflection is a function of the angle difference and the length of the link (i.e., shorter links will produce a smaller bend radius).

[0049] Other illustrative embodiments of an articulation structure **1000** for use in the suturing devices of the invention are depicted in **FIGS. 18A-18C**. Referring now to **FIG. 18A**, the articulation structure **1000** is made of a series of stacked rings **1002a**, **1002b**, **1002c**, etc. Each ring is preferably formed of a deep-drawn steel or other metal that allows the ring to be stiff while having a thin wall profile in order to maximize the size of the inner lumen. Positioned at equal intervals around the outer circumference of the ring are inwardly extending concave recesses **1004** that receive short spring sections **1006** that are used to join adjacent rings together. Two springs on opposite sides of a ring **1002** are used to join adjacent rings together. For example, if three rings **1002a**, **1002b**, and **1002c** are aligned, the rings **1002a** and **1002b** are joined together with spring segments located at 0° and 180° on the rings, while ring **1002b** is joined to ring **1002c** with orthogonally aligned spring segments located at 90° and 270° around the rings. A gap is formed between adjacent rings so that the pair of springs forms a flexible joint that can bend in directions that are the away from the longitudinal axis of the articulation structure but has limited ability to compress the articulation structure in the direction of the longitudinal axis of the articulation structure. Each spring **1006** is secured within the concave recess **1004** of the ring **1002** using an adhesive, crimping, welding, or with other securing mechanism.

[0050] In the embodiment depicted in **FIG. 18A**, one or more pull wires pass through the center of the spring segments and/or on the outer circumference of the articulation structure. The one or more pull wires are coupled to a control system disposed within or on handle 1 (e.g., the control system **22** depicted in **FIGS. 8** and **9**, or control system **310** depicted in **FIGS. 10-13**). As such, the articulation structure can be controllably deflected by the pull

wires coupled to the control system.

[0051] FIG. 18B illustrates an alternative embodiment of the articulation structure shown in **FIG. 18A**. In this embodiment, the articulation structure comprises a number of deep drawn or otherwise formed metal rings **1008a**, **1008b**, **1008c** that are joined together with springs that are located on the inner circumference of each ring. Each ring is connected to an adjacent ring with a pair of spring segments located on opposite sides of the ring. The springs **1010** are secured to the inner circumference of the rings **1008** with an adhesive or by welding, or using other securing means. In the embodiment shown in **FIG. 18B**, the one or more pull wires are routed through the spring segments and are more closely positioned to the longitudinal axis of the articulation structure. Being closer to the longitudinal axis may require more force on a pull wire to bend the articulation structure in a desired direction.

[0052] FIG. 18C shows another embodiment of an articulation joint that is similar to the articulation joint shown in **FIG. 18B**. However, in this embodiment, the articulation joint is comprised of a number of rings **1022a**, **1022b**, **1022c** having oppositely arranged concave recesses **1024** and convex recesses that allow a spring **1015** having alternate tightly and loosely wound segments to pass on the outside of one ring and on the inside of an adjacent ring in an alternating fashion. The oppositely arranged convex and concave recesses allow a spring to be secured to the ring with an adhesive, welding, or other bonding mechanism.

[0053] Although the discs of the articulation structures described herein are generally circular in shape, it will be appreciated that other shapes could be used.

[0054] The embodiments of flexible and/or articulated suturing instruments described herein are provided for illustrative purposes only and are not intended to be limited. Additional deflection sections and/or pull-wires could be included in the elongate shaft of the suturing instrument and/or the control system, depending on how many planes of deflection are desired.

[0055] The suturing instrument's component materials should be biocompatible. For example, the handle **1**, the elongate shaft **2**, and portions of the suturing head **3** and needle deployment system, or portions thereof, may be fabricated from extruded, molded, or machined plastic material(s), such as polypropylene, polycarbonate, or glass-filled polycarbonate. Other components, for example the needle **6**, may be made of stainless steel. Preferably, the pull-wires are made from stainless steel, polymer filaments, strong textile or synthetic material such as Kevlar® or nylon, or other metals and alloys such as, for example, Nitinol™ which is a nickel-titanium alloy. Other suitable materials will be apparent to those skilled in the art. The material(s) used to form the suture should be biocompatible. The surgeon will select the length, diameter, and characteristics of the suture to suit a particular application. Additionally, the mechanical components and operation are similar in nature to those dis-

closed in U.S. Patent Nos. 5,364,408, 5,575,800, 6,048,351, and 6,346,111, and commonly owned U.S. Application Serial No. 10/210,984 (published as U.S. Patent Application Publication No. 2004/00343 72).

[0056] Certain embodiments according to the invention have been disclosed. These embodiments are illustrative of, and not limiting on, the invention. Other embodiments, as well as various modifications and combinations of the disclosed embodiments, are possible and within the scope of the disclosure.

Claims

1. A suturing instrument (100), comprising:

a handle (1);
an elongate shaft (2) extending from the handle (1), at least a portion of the elongate shaft (2) being flexible;
one or more pull wires (28, 30, 32, 24) extending from the handle (1) into the flexible portion of the elongate shaft (2) for deflecting the flexible portion of elongate shaft (2); and
a suturing head (3) extending from a distal end (2b) of the elongate shaft (2), the suturing head (3) comprising a needle carrier channel (9), a needle carrier (5) configured to releasably hold a needle (6), and a needle catch (8), the needle carrier (5) being movably disposed within the needle carrier channel (9);

characterized in that the elongate shaft (2) comprises a flexible coil, the flexible coil configured to be bent by a user's hand in a shape prior to insertion into a body passage such that the flexible coil retains the shape during use.

2. The suturing instrument (100) of claim 1 wherein the needle carrier (5) is configured to move along the needle carrier channel (9) out of the suturing head (3) into an extended position, and back into the suturing head (3) into a retracted position.

3. The suturing instrument (100) of claim 2 further comprising a needle deployment system at least partially disposed within the elongate shaft (2) and coupled to needle carrier (5) for moving the needle carrier (5) between the extended position and the retracted position, wherein the needle deployment system is preferably configured to move the needle carrier (5) out of the suturing head (3) in a semi-circular path towards the needle catch (8) such that the needle (6) held by the needle carrier (5) is released from the needle carrier (5) and retained in the needle catch (8).

4. The suturing instrument (100) of claim 3 wherein the

handle (1) includes an actuating mechanism (110) coupled to the needle deployment system for actuating the needle deployment system.

5. The suturing instrument (100) of claim 1 wherein the handle (1) includes a control system (22, 310) coupled to the one or more pull wires (28, 30, 32, 24) for controlling deflection of the flexible portion of the elongate shaft (2). 5
6. The suturing instrument (100) of claim 5 wherein the control system (22, 310) includes a rotatable cam (24, 26) coupled to the one or more pull wires (28, 30, 32, 24) and/or the control system (22, 310) includes one or more knobs, hubs or levers attached to the one or more pull wires (28, 30, 32, 24). 10
7. The suturing instrument (100) of claim 1 wherein the elongate shaft (2) is capable of being deflected into multiple different planes relative to a longitudinal axis (A) of the elongate shaft (2). 15
8. The suturing instrument (100) of claim 1 wherein the flexible coil comprises a Bowden coil, wherein the elongate shaft (2) preferably includes an outer sleeve disposed on the outside of the flexible coil to provide a smooth exterior surface. 20
9. The suturing instrument (100) of claim 1 wherein at least a portion of the elongate shaft (2) includes an articulation structure (200, 1000), wherein preferably the flexible portion of the elongate shaft (2) includes an articulation structure (200, 1000). 25
10. The suturing instrument (100) of claim 9 wherein the articulation structure (200) comprises a series of stacked links (212, 212a, 212b, 212c) disposed adjacent to one another and movable with respect to each other, each link (212) including a front face (216) tapered to a pair of pivot points (220) and a rear face (218) defining a wedge shaped recess (230) for receiving the pivot points (220) of the adjacent link (212, 212a, 212b, 212c), and wherein said one or more pull-wires (246, 250) are configured for providing tension to the articulation structure (200) and holding the adjacent links (212, 212a, 212b, 212c) together. 30
11. The suturing instrument (100) of claim 9 wherein the articulation structure (200) comprises: 35
a first articulation section, the first articulation section includes a first series of stacked links (212, 212a, 212b, 212c) disposed adjacent to one another and movable with respect to each other, each link (212, 212a, 212b, 212c) including a front face (216) tapered to a pair of pivot 40
points (220) and a rear face (218) defining a wedge shaped recess (230) for receiving the pivot points (220) of the adjacent link (212, 212a, 212b, 212c);
a second articulation section, the second articulation section includes a second series of stacked links (212, 212a, 212b, 212c) disposed adjacent to one another and movable with respect to each other, each link (212, 212a, 212b, 212c) including a front face (216) tapered to a pair of pivot points (220) and a rear face (218) defining a wedge shaped recess (230) for receiving the pivot points (220) of the adjacent link (212, 212a, 212b, 212c), the wedge shaped recesses (230) of the first articulation section radially offset from the wedge shaped recesses of the second articulation section;
wherein said one or more pull wires (246, 250) are configured for providing tension to the articulation structure (200, 1000) and holding the adjacent links (212, 212a, 212b, 212c) together. 45
12. The suturing instrument (100) of claim 9 wherein said articulation structure (1000) comprises:
a number of ring links (1002a, 1002b, 1002c), each having an inner circumference and an outer circumference, each ring link (1002a, 1002b, 1002c) including:
two concave recesses (1004) with openings that face radially outward from the outer circumference of the ring link that are positioned on opposite sides of the outer circumference of the ring link; and
two concave recesses with openings that face radially inward from the inner circumference of the ring link that are positioned on opposite sides of the inner circumference of the ring link and are oriented at 90 degrees to the two concave recesses (1004) positioned on opposite sides of the outer circumference of the ring link; and
a plurality of spring segments that are secured within the concave recesses (1004) on the outer circumferences and inner circumferences of the ring links (1002a, 1002b, 1002c) to join adjacent ring links (1002a, 1002b, 1002c) together and that are bendable in the articulating joint;
wherein the concave recesses (1004) on the outer circumference of a given ring link are aligned with the concave recesses on the inner circumference of an adjacent ring link (1002a, 1002b, 1002c) in the articulating joint. 50
13. The suturing instrument (100) of claim 12 wherein the spring segments define apertures adapted to receive the one or more pull wires therethrough. 55
14. The suturing instrument (100) of claim 1, wherein

points (220) and a rear face (218) defining a wedge shaped recess (230) for receiving the pivot points (220) of the adjacent link (212, 212a, 212b, 212c);
a second articulation section, the second articulation section includes a second series of stacked links (212, 212a, 212b, 212c) disposed adjacent to one another and movable with respect to each other, each link (212, 212a, 212b, 212c) including a front face (216) tapered to a pair of pivot points (220) and a rear face (218) defining a wedge shaped recess (230) for receiving the pivot points (220) of the adjacent link (212, 212a, 212b, 212c), the wedge shaped recesses (230) of the first articulation section radially offset from the wedge shaped recesses of the second articulation section;
wherein said one or more pull wires (246, 250) are configured for providing tension to the articulation structure (200, 1000) and holding the adjacent links (212, 212a, 212b, 212c) together.

12. The suturing instrument (100) of claim 9 wherein said articulation structure (1000) comprises:
a number of ring links (1002a, 1002b, 1002c), each having an inner circumference and an outer circumference, each ring link (1002a, 1002b, 1002c) including:
two concave recesses (1004) with openings that face radially outward from the outer circumference of the ring link that are positioned on opposite sides of the outer circumference of the ring link; and
two concave recesses with openings that face radially inward from the inner circumference of the ring link that are positioned on opposite sides of the inner circumference of the ring link and are oriented at 90 degrees to the two concave recesses (1004) positioned on opposite sides of the outer circumference of the ring link; and
a plurality of spring segments that are secured within the concave recesses (1004) on the outer circumferences and inner circumferences of the ring links (1002a, 1002b, 1002c) to join adjacent ring links (1002a, 1002b, 1002c) together and that are bendable in the articulating joint;
wherein the concave recesses (1004) on the outer circumference of a given ring link are aligned with the concave recesses on the inner circumference of an adjacent ring link (1002a, 1002b, 1002c) in the articulating joint. 50
13. The suturing instrument (100) of claim 12 wherein the spring segments define apertures adapted to receive the one or more pull wires therethrough. 55
14. The suturing instrument (100) of claim 1, wherein

the handle (1) includes a control system (22, 310);
 the elongate shaft (2) includes a distal portion (2a),
 one or more pull wires (28, 30, 32, 24) extending from the handle (1) into the distal portion (2a) of the elongate shaft (2), the one or more pull wires (28, 30, 32, 24) coupled to the control system (22, 310) to allow active control of the flexible portion of the elongate shaft (2); and
 the suturing head (3) extends from a distal end (2b) of the distal portion (2a) of the elongate shaft (2).

15. The suturing instrument (100) of claim 1, wherein

the elongate shaft (2) includes a distal portion (2a), at least a portion of the shaft (2) being flexible and including an articulation structure (200, 1000);
 one or more pull wires (28, 30, 32, 24) extend from the handle (1) into the distal portion (2a) of the elongate shaft (2) for deflecting the articulated portion of elongate shaft (2); and
 the suturing head (3) extends from a distal end (2b) of the distal portion (2a) of the elongate shaft (2).

Patentansprüche

1. Nähinstrument (100), welches aufweist:

einen Handgriff (1);
 eine längliche Welle (2), die sich von dem Handgriff (1) weg erstreckt, wobei zumindest ein Bereich der länglichen Welle (2) flexibel ist;
 einen oder mehrere Zugdrähte (28, 30, 32, 24), die sich von dem Handgriff (1) aus in den flexiblen Bereich der länglichen Welle (2) erstrecken, um den flexiblen Bereich der länglichen Welle (2) auszulenken; und
 einen Nähkopf (3), der sich von einem distalen Ende (2b) der länglichen Welle (2) weg erstreckt, wobei der Nähkopf (3) einen Nadelträgerkanal (9), einen Nadelträger (5), der zum lösbaren Halten einer Nadel (6) konfiguriert ist, und einen Nadelhalter (8) aufweist, wobei der Nadelträger (5) bewegbar innerhalb des Nadelträgerkanals (9) angeordnet ist;
dadurch gekennzeichnet, dass die längliche Welle (2) eine flexible Spule aufweist, welche flexible Spule konfiguriert ist, vor der Einführung in einen Körperdurchgang durch die Hand eines Benutzers so in eine Form gebogen zu werden, dass die flexible Spule die Form während des Gebrauchs beibehält.

2. Nähinstrument (100) nach Anspruch 1, bei dem der Nadelträger (5) konfiguriert ist, sich entlang des Nadelträgerkanals (9) aus dem Nähkopf (3) heraus in eine verlängerte Position und zurück in den Nähkopf (3) in eine zurückgezogene Position zu bewegen.

3. Nähinstrument (100) nach Anspruch 2, weiterhin aufweisend ein Nadelentfaltungssystem, das zumindest teilweise innerhalb der länglichen Welle (2) angeordnet und mit dem Nadelträger (5) gekoppelt ist, um den Nadelträger (5) zwischen der ausgefahrenen Position und der zurückgezogenen Position zu bewegen, wobei das Nadelentfaltungssystem vorzugsweise konfiguriert ist, den Nadelträger (5) aus dem Nähkopf (3) auf einem halbkreisförmigen Pfad zu dem Nadelhalter (8) derart zu bewegen, dass die von dem Nadelträger (5) gehaltene Nadel (6) von dem Nadelträger (5) freigegeben und in dem Nadelhalter (8) zurückgehalten wird.

4. Nähinstrument (100) nach Anspruch 3, bei dem der Handgriff (1) einen Betätigungsmechanismus (110) enthält, der mit dem Nadelentfaltungssystem gekoppelt ist, um das Nadelentfaltungssystem zu betätigen.

5. Nähinstrument (100) nach Anspruch 1, bei dem der Handgriff (1) ein Steuersystem (22, 310), das mit dem einen oder den mehreren Zugdrähten (28, 30, 32, 24) gekoppelt ist, um eine Auslenkung des flexiblen Bereichs der länglichen Welle (2) zu steuern, enthält.

6. Nähinstrument (100) nach Anspruch 5, bei dem das Steuersystem (22, 310) einen drehbaren Nocken (24, 26), der mit dem einen oder den mehreren Zugdrähten (28, 30, 32, 24) gekoppelt ist, enthält, und/oder das Steuersystem (22, 310) eine(n) oder mehrere Knöpfe, Naben oder Hebel, die an dem einen oder den mehreren Zugdrähten (28, 30, 32, 24) angebracht sind, enthält.

7. Nähinstrument (100) nach Anspruch 1, bei dem die längliche Welle (2) in der Lage ist, in mehrere verschiedene Ebenen relativ zu einer Längsachse (A) der länglichen Welle (2) ausgelenkt zu werden.

8. Nähinstrument (100) nach Anspruch 1, bei dem die flexible Spule eine Bowden-Spule aufweist, wobei die längliche Welle (2) vorzugsweise eine äußere Manschette enthält, die auf der Außenseite der flexiblen Spule angeordnet ist, um eine glatte äußere Oberfläche zu erhalten.

9. Nähinstrument (100) nach Anspruch 1, bei der zumindest ein Teil der länglichen Welle (2) eine Gelenkstruktur (200, 1000) enthält,

wobei vorzugsweise der flexible Bereich der länglichen Welle (2) eine Gelenkstruktur (200, 1000) enthält.

10. Nähinstrument (100) nach Anspruch 9, bei dem die Gelenkstruktur (200) eine Reihe von gestapelten Gliedern (212, 212a, 212b, 212c) aufweist, einander benachbart angeordnet und mit Bezug zueinander bewegbar sind, wobei jedes Glied (212) eine Vorderfläche (216), die konisch zu einem Paar von Schwenkpunkten (220) verläuft, und eine Hinterfläche (218), die eine keilförmige Vertiefung (230) für die Aufnahme der Schwenkpunkte (220) des benachbarten Glieds (212, 212a, 212b, 212c) definiert, enthält, und wobei der eine oder die mehreren Zugdrähte (246, 250) konfiguriert sind zum Ausüben einer Spannung auf die Gelenkstruktur (200) und zum Zusammenhalten der benachbarten Glieder (212, 212a, 212b, 212c).

11. Nähinstrument (100) nach Anspruch 9, bei dem die Gelenkstruktur (200) aufweist:

einen ersten Gelenkabschnitt, welcher erste Gelenkabschnitt eine erste Reihe von gestapelten Gliedern (212, 212a, 212b, 212c), die benachbart zu einander angeordnet und mit Bezug zueinander bewegbar sind, enthält, wobei jedes Glied (212, 212a, 212b, 212c) eine Vorderfläche (216), die konisch zu einem Paar von Schwenkpunkten (220) hin verläuft, und eine Hinterfläche (218), die eine keilförmige Vertiefung (230) für die Aufnahme der Schwenkpunkte (220) des benachbarten Glieds (212, 212a, 212b, 212c) definiert, enthält,

einen zweiten Gelenkabschnitt, welcher zweite Gelenkabschnitt eine zweite Reihe von gestapelten Gliedern (212, 212a, 212b, 212c), die benachbart zueinander und mit Bezug zueinander bewegbar sind, enthält, wobei jedes Glied (212, 212a, 212b, 212c) eine Vorderfläche (216), die konisch zu einem Paar von Schwenkpunkten (220) hin verläuft, und eine Hinterfläche (218), die eine keilförmige Vertiefung (230) für die Aufnahme der Schwenkpunkte (220) des benachbarten Glieds (212, 212a, 212b, 212c) definiert, enthält, und wobei die keilförmigen Vertiefungen (230) des ersten Gelenkabschnitts gegenüber den keilförmigen Vertiefungen des zweiten Gelenkabschnitts radial versetzt sind;

wobei der eine oder die mehreren Zugdrähte (246, 250) konfiguriert sind zum Ausüben einer Spannung auf die Gelenkstruktur (200, 1000) und zum Zusammenhalten der benachbarten Glieder (212, 212a, 212b, 212c).

12. Nähinstrument (100) nach Anspruch 9, bei dem die

Gelenkstruktur (1000) aufweist:

eine Anzahl von Ringgliedern (1002a, 1002b, 1002c), die jeweils einen inneren Umfang und einen äußeren Umfang haben, wobei jedes Ringglied (1002a, 1002b, 1002c) enthält:

zwei konkave Vertiefungen (1004) mit Öffnungen, die von dem äußeren Umfang des Ringglieds radial nach außen gewandt sind und auf entgegengesetzten Seiten des äußeren Umfangs des Ringglieds positioniert sind; und zwei konkave Vertiefungen mit Öffnungen, die von dem inneren Umfang des Ringglieds radial nach innen gewandt sind und auf entgegengesetzten Seiten des inneren Umfangs des Ringglieds positioniert und um 90 Grad gegenüber den konkaven Vertiefungen (1004), die auf entgegengesetzten Seiten des äußeren Umfangs des Ringglieds positioniert sind, orientiert sind; und

mehrere Federsegmente, die innerhalb der konkaven Vertiefungen (1004) des jeweiligen äußeren Umfangs und des jeweiligen inneren Umfangs der Ringglieder (1002a, 1002b, 1002c) befestigt sind, um benachbarte Ringglieder (1002a, 1002b, 1002c) miteinander zu verbinden, und die in der Gelenkverbindung biegsam sind;

wobei die konkaven Vertiefungen (1004) des äußeren Umfangs eines gegebenen Ringglieds mit den konkaven Vertiefungen des inneren Umfangs eines benachbarten Ringglieds (1002a, 1002b, 1002c) in der Gelenkverbindung ausgerichtet sind.

13. Nähinstrument (100) nach Anspruch 12, bei dem die Federsegmente Öffnungen definieren, die für die Aufnahme des einen oder der mehreren Zugdrähte durch diese hindurch angepasst sind.

14. Nähinstrument (100) nach Anspruch 1, bei dem

der Handgriff (1) ein Steuersystem (22, 310) enthält;

die längliche Welle (2) einen distalen Bereich (2a) enthält,

ein oder mehrere Zugdrähte (28, 30, 32, 24) sich von dem Handgriff (1) in den distalen Bereich (2a) der länglichen Welle (2) erstrecken, der eine oder die mehreren Zugdrähte (28, 30, 32, 24) mit dem Steuersystem (22, 310) gekoppelt sind, um eine aktive Steuerung des flexiblen Bereichs der länglichen Welle (2) zu ermöglichen; und der Nähkopf (3) sich von einem distalen Ende (2b) des distalen Bereichs (2a) der länglichen Welle (2) erstreckt.

15. Nähinstrument (100) nach Anspruch 1, bei dem

die längliche Welle (2) einen distalen Bereich (2a) enthält, zumindest ein Bereich der Welle (2) flexibel ist und eine Gelenkstruktur (200, 1000) enthält;

ein oder mehrere Zugdrähte (28, 30, 32, 24) sich von dem Handgriff (1) in den distalen Bereich (2a) der länglichen Welle (2) erstrecken, um den Gelenkbereich der länglichen Welle (2) auszu-
lenken; und
der Nähkopf (3) sich von einem distalen Ende (2b) des distalen Bereichs (2a) der länglichen Welle (2) weg erstreckt.

Revendications

1. Instrument de suturage (100), comprenant :

une poignée (1) ;

un arbre allongé (2) qui s'étend depuis la poignée (1), au moins une partie de l'arbre allongé (2) étant flexible ;

un ou plusieurs fil(s) de traction (28, 30, 32, 24) qui s'étend(ent) depuis la poignée (1) à l'intérieur de la partie flexible de l'arbre allongé (2) pour dévier la partie flexible de l'arbre allongé (2) ; et

une tête de suturage (3) qui s'étend depuis une extrémité distale (2b) de l'arbre allongé (2), la tête de suturage (3) comprenant un canal de support d'aiguille (9), un support d'aiguille (5) qui est configuré de manière à ce qu'il tienne de façon libérable une aiguille (6), et un moyen de capture d'aiguille (8), le support d'aiguille (5) étant disposé de façon mobile à l'intérieur du canal de support d'aiguille (9) ;

caractérisé en ce que l'arbre allongé (2) comprend un enroulement flexible, l'enroulement flexible étant configuré de manière à ce qu'il soit fléchi par la main d'un utilisateur selon une forme avant son insertion à l'intérieur d'un passage du corps de telle sorte que l'enroulement flexible conserve la forme pendant son utilisation.

2. Instrument de suturage (100) selon la revendication 1, dans lequel le support d'aiguille (5) est configuré de manière à ce qu'il soit déplacé le long du canal de support d'aiguille (9) pour qu'il soit amené en dehors de la tête de suturage (3) selon une position étendue et pour qu'il soit ramené à l'intérieur de la tête de suturage (3) selon une position rétractée.

3. Instrument de suturage (100) selon la revendication 2, comprenant en outre un système de déploiement d'aiguille qui est au moins partiellement disposé à l'intérieur de l'arbre allongé (2) et qui est couplé au support d'aiguille (5) pour déplacer le support d'aiguille (5) entre la position étendue et la position

rétractée ; dans lequel :

le système de déploiement d'aiguille est de préférence configuré de manière à ce qu'il déplace le support d'aiguille (5) pour qu'il soit amené en dehors de la tête de suturage (3) selon une trajectoire semi-circulaire en direction du moyen de capture d'aiguille (8) de telle sorte que l'aiguille (6) qui est supportée et maintenue par le support d'aiguille (5) soit libérée du support d'aiguille (5) et soit retenue dans le moyen de capture d'aiguille (8).

4. Instrument de suturage (100) selon la revendication 3, dans lequel la poignée (1) inclut un mécanisme d'actionnement (110) qui est couplé au système de déploiement d'aiguille pour actionner le système de déploiement d'aiguille.

5. Instrument de suturage (100) selon la revendication 1, dans lequel la poignée (1) inclut un système de commande (22, 310) qui est couplé aux un ou plusieurs fils de traction (28, 30, 32, 24) pour commander la déviation de la partie flexible de l'arbre allongé (2).

6. Instrument de suturage (100) selon la revendication 5, dans lequel le système de commande (22, 310) inclut une came pouvant être entraînée en rotation (24, 26) qui est couplée aux un ou plusieurs fils de traction (28, 30, 32, 24) et/ou le système de commande (22, 310) inclut un ou plusieurs bouton(s), élément(s) formant moyeu ou levier(s) qui est/sont lié(s) aux un ou plusieurs fils de traction (28, 30, 32, 24).

7. Instrument de suturage (100) selon la revendication 1, dans lequel l'arbre allongé (2) dispose de la capacité de pouvoir être dévié à l'intérieur de multiples plans différents par rapport à un axe longitudinal (A) de l'arbre allongé (2).

8. Instrument de suturage (100) selon la revendication 1, dans lequel l'enroulement flexible comprend un enroulement de Bowden, dans lequel l'arbre allongé (2) inclut de préférence une gaine externe qui est disposée sur l'extérieur de l'enroulement flexible de manière à assurer une surface extérieure sans aspérités ou lisse.

9. Instrument de suturage (100) selon la revendication 1, dans lequel au moins une partie de l'arbre allongé (2) inclut une structure d'articulation (200, 1000), dans lequel de préférence la partie flexible de l'arbre allongé (2) inclut une structure d'articulation (200, 1000).

10. Instrument de suturage (100) selon la revendication 9, dans lequel : la structure d'articulation (200) comprend une série

de liaisons empilées (212, 212a, 212b, 212c) qui sont disposées de manière à ce qu'elles soient adjacentes les unes aux autres et qui peuvent être déplacées les unes par rapport aux autres, chaque liaison (212) incluant une face avant (216) qui présente une inclinaison ou conicité par rapport à une

paire de points de pivotement (220) et une face arrière (218) qui définit un évidement en forme de coin (230) pour recevoir les points de pivotement (220) de la liaison adjacente (212, 212a, 212b, 212c) ; et dans lequel :

11. Instrument de suturage (100) selon la revendication 9, dans lequel la structure d'articulation (200) comprend :

une première section d'articulation, la première section d'articulation inclut une première série de liaisons empilées (212, 212a, 212b, 212c) qui sont disposées de manière à ce qu'elles soient adjacentes les unes aux autres et qui peuvent être déplacées les unes par rapport aux autres, chaque liaison (212, 212a, 212b, 212c) incluant une face avant (216) qui présente une inclinaison ou conicité par rapport à une

paire de points de pivotement (220) et une face arrière (218) qui définit un évidement en forme de coin (230) pour recevoir les points de pivotement (220) de la liaison adjacente (212, 212a, 212b, 212c) ; et une seconde section d'articulation, la seconde section d'articulation inclut une seconde série de liaisons empilées (212, 212a, 212b, 212c) qui sont disposées de manière à ce qu'elles soient adjacentes les unes aux autres et qui peuvent être déplacées les unes par rapport aux autres, chaque liaison (212, 212a, 212b, 212c) incluant une face avant (216) qui présente une inclinaison ou conicité par rapport à une

paire de points de pivotement (220) et une face arrière (218) qui définit un évidement en forme de coin (230) pour recevoir les points de pivotement (220) de la liaison adjacente (212, 212a, 212b, 212c), les évidements en forme de coin (230) de la première section d'articulation étant décalés radialement par rapport aux évidements en forme de coin de la seconde section d'articulation ; dans lequel :

lesdits un ou plusieurs fils de traction (246, 250) sont configurés de manière à ce qu'ils exercent une tension sur la structure d'articulation (200, 1000) et de manière à ce qu'ils maintiennent ensemble les liaisons adjacentes (212, 212a,

212b, 212c).

12. Instrument de suturage (100) selon la revendication 9, dans lequel ladite structure d'articulation (1000) comprend :

un certain nombre de liaisons en forme d'anneau (1002a, 1002b, 1002c) dont chacune comporte une circonférence interne et une circonférence externe, chaque liaison en forme d'anneau (1002a, 1002b, 1002c) incluant :

deux évidements concaves (1004) qui comportent des ouvertures qui sont dirigées radialement vers l'extérieur depuis la circonférence externe de la liaison en forme d'anneau, lesquels évidements sont positionnés sur des côtés opposés de la circonférence externe de la liaison en forme d'anneau ; et

deux évidements concaves qui comportent des ouvertures qui sont dirigées radialement vers l'intérieur depuis la circonférence interne de la liaison en forme d'anneau, lesquels évidements sont positionnés sur des côtés opposés de la circonférence interne de la liaison en forme d'anneau et sont orientés à 90 degrés par rapport aux deux évidements concaves (1004) qui sont positionnés sur des côtés opposés de la circonférence externe de la liaison en forme d'anneau ; et

une pluralité de segments de ressort qui sont fixés fermement à l'intérieur des évidements concaves (1004) sur les circonférences externes et sur les circonférences internes des liaisons en forme d'anneau (1002a, 1002b, 1002c) de manière à ce qu'ils joignent des liaisons en forme d'anneau adjacentes (1002a, 1002b, 1002c) ensemble et qui peuvent être fléchis au niveau de la jonction d'articulation ; dans lequel :

les évidements concaves (1004) sur la circonférence externe d'une liaison en forme d'anneau donnée sont alignés avec les évidements concaves sur la circonférence interne d'une liaison en forme d'anneau adjacente (1002a, 1002b, 1002c) au niveau de la jonction d'articulation.

13. Instrument de suturage (100) selon la revendication 12, dans lequel les segments de ressort définissent des ouvertures qui sont adaptées de manière à ce qu'elles reçoivent les un ou plusieurs fils de traction au travers d'elles-mêmes.

14. Instrument de suturage (100) selon la revendication 1, dans lequel :

la poignée (1) inclut un système de commande (22, 310) ;

l'arbre allongé (2) inclut une partie distale (2a) ;

un ou plusieurs fil(s) de traction (28, 30, 32, 24) qui s'étendent depuis la poignée (1) à l'intérieur de la partie distale (2a) de l'arbre allongé (2), les un ou plusieurs fils de traction (28, 30, 32, 24) étant couplés au système de commande (22, 310) pour permettre une commande active de la partie flexible de l'arbre allongé (2) ; et la tête de suturage (3) s'étend depuis une extrémité distale (2b) de la partie distale (2a) de l'arbre allongé (2).

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15. Instrument de suturage (100) selon la revendication 1, dans lequel :

l'arbre allongé (2) inclut une partie distale (2a), au moins une partie de l'arbre (2) étant flexible et incluant une structure d'articulation (200, 1000) ; un ou plusieurs fil(s) de traction (28, 30, 32, 24) qui s'étendent depuis la poignée (1) à l'intérieur de la partie distale (2a) de l'arbre allongé (2) pour dévier la partie articulée de l'arbre allongé (2) ; et la tête de suturage (3) s'étend depuis une extrémité distale (2b) de la partie distale (2a) de l'arbre allongé (2).

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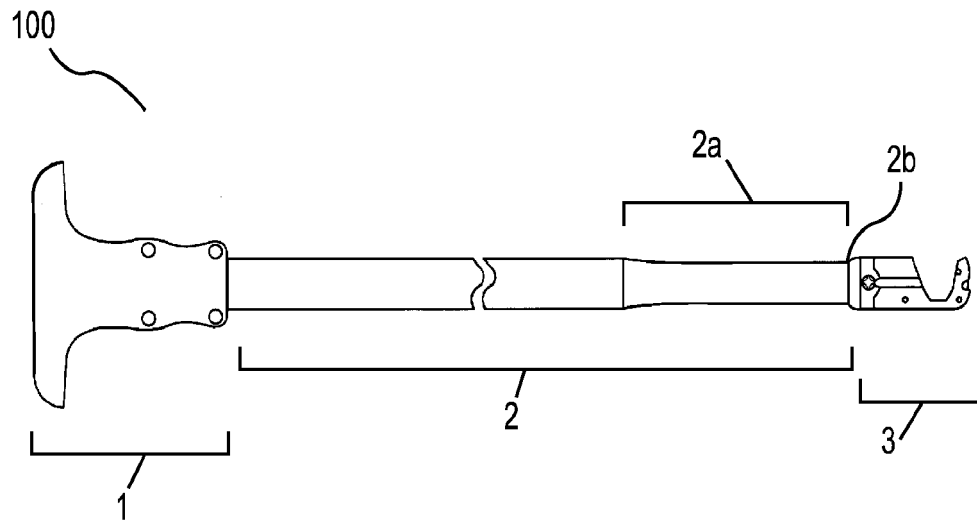


Figure 1A

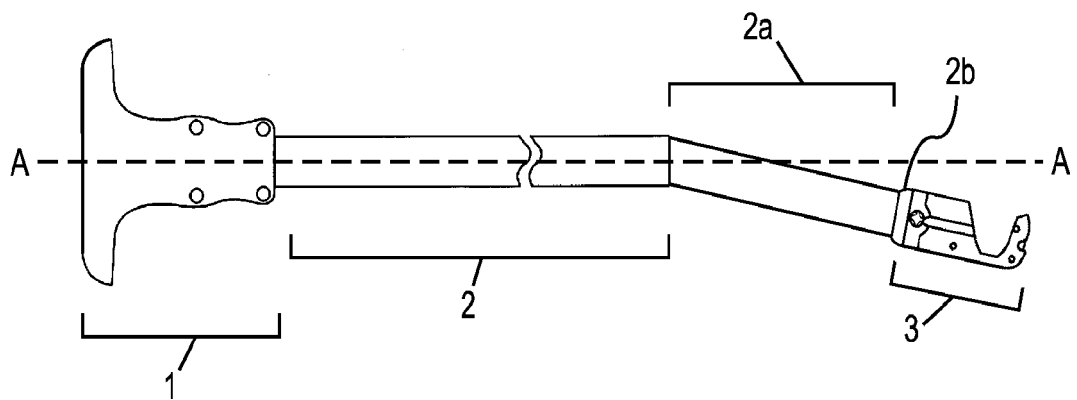


Figure 1B

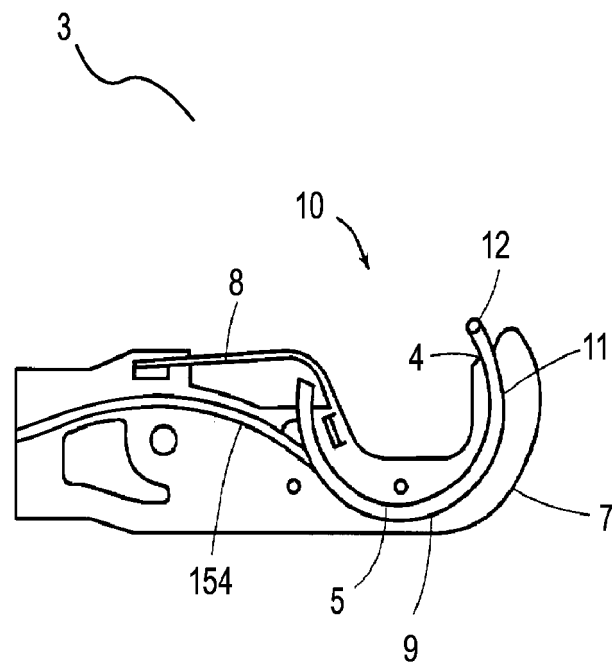


Figure 2

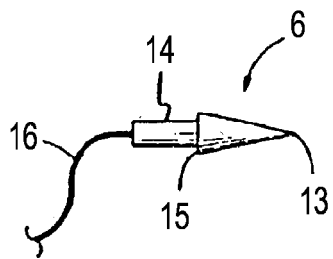


Figure 3

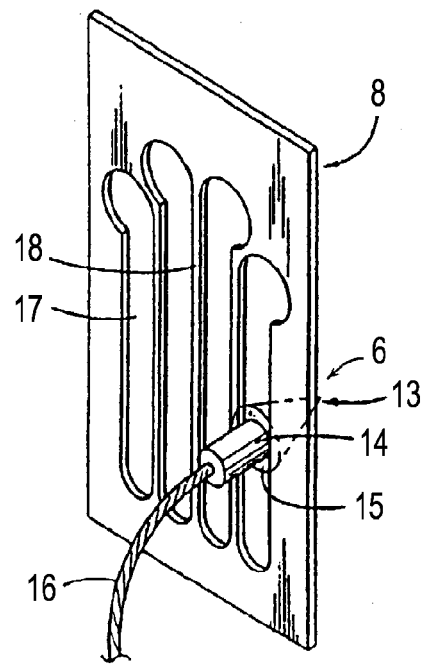


Figure 4

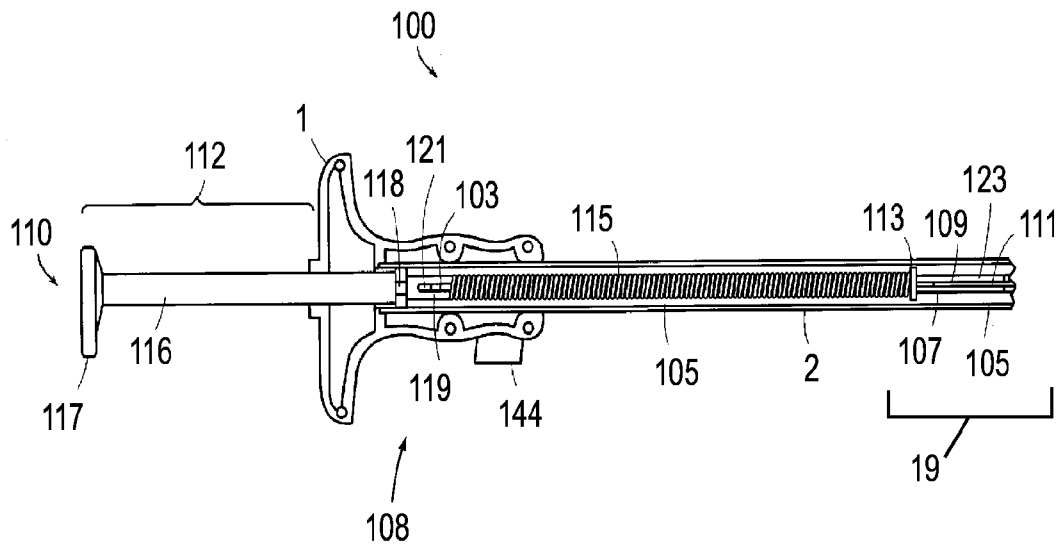


Figure 5

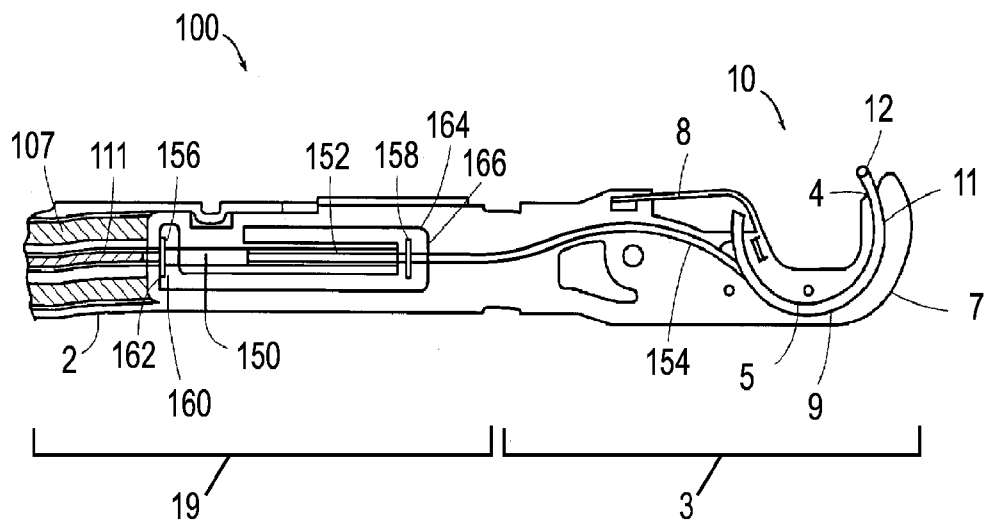


Figure 6

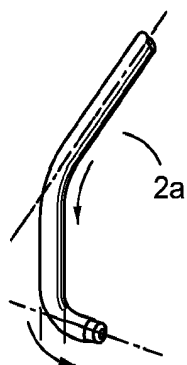


Figure 7C

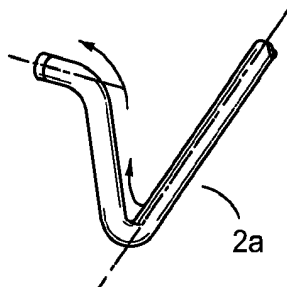


Figure 7D

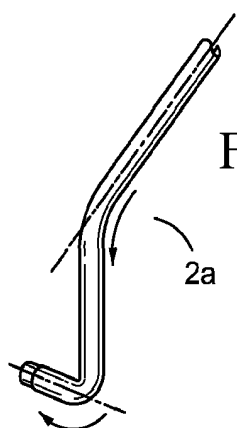


Figure 7E

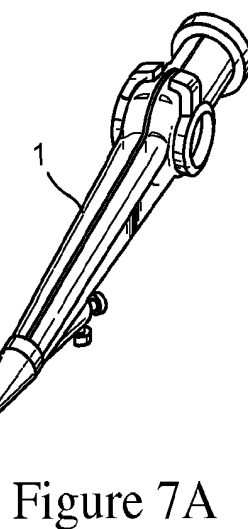


Figure 7A

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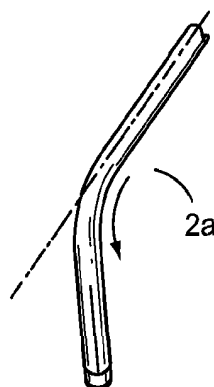


Figure 7B

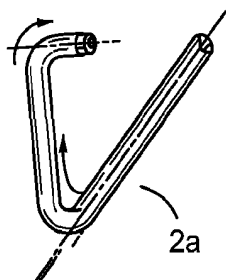


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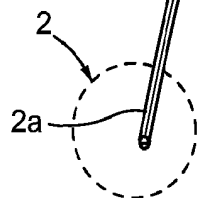


Figure 7G

Figure 8

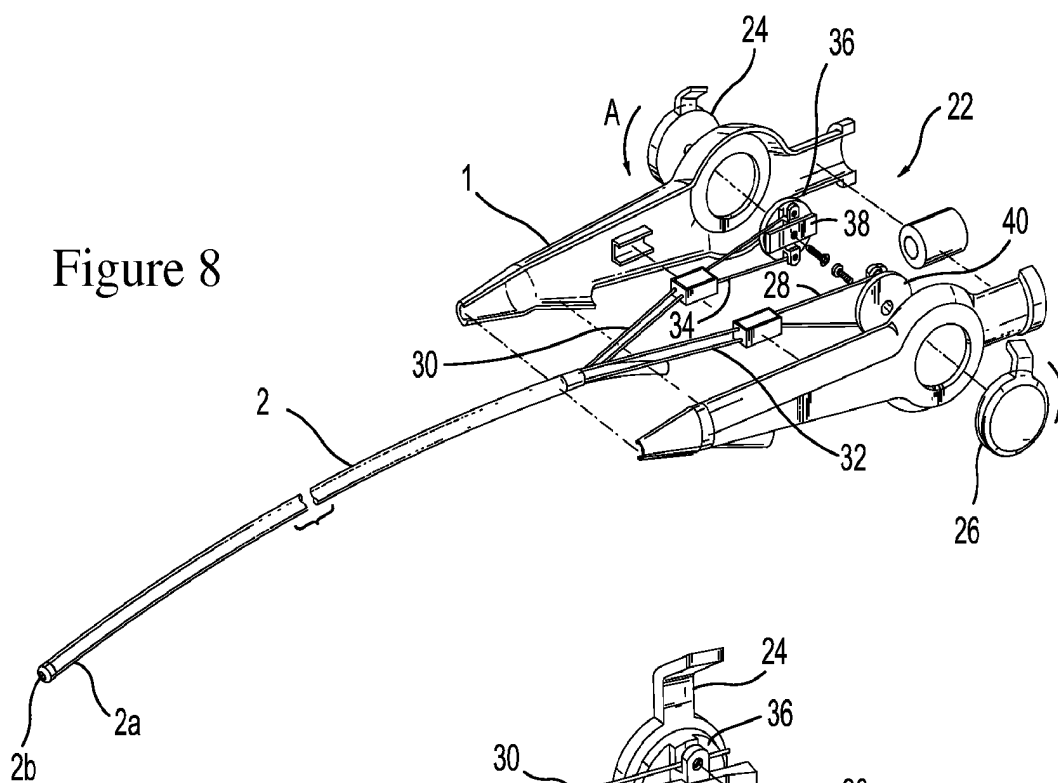


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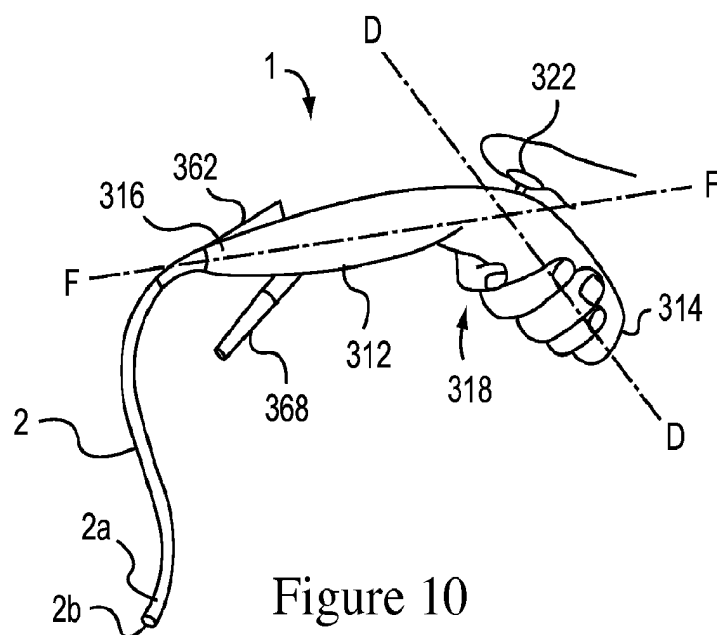
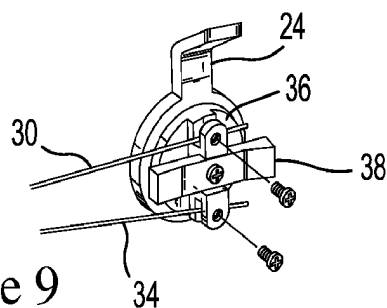


Figure 10

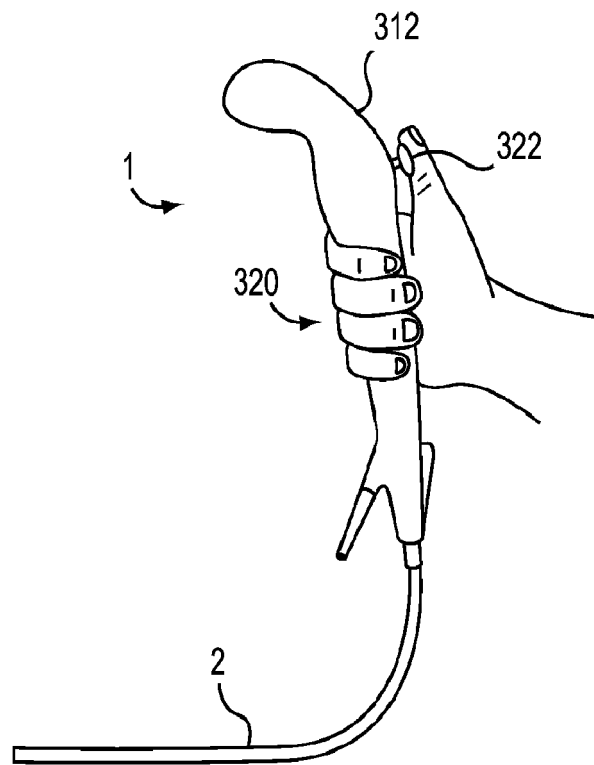


Figure 11

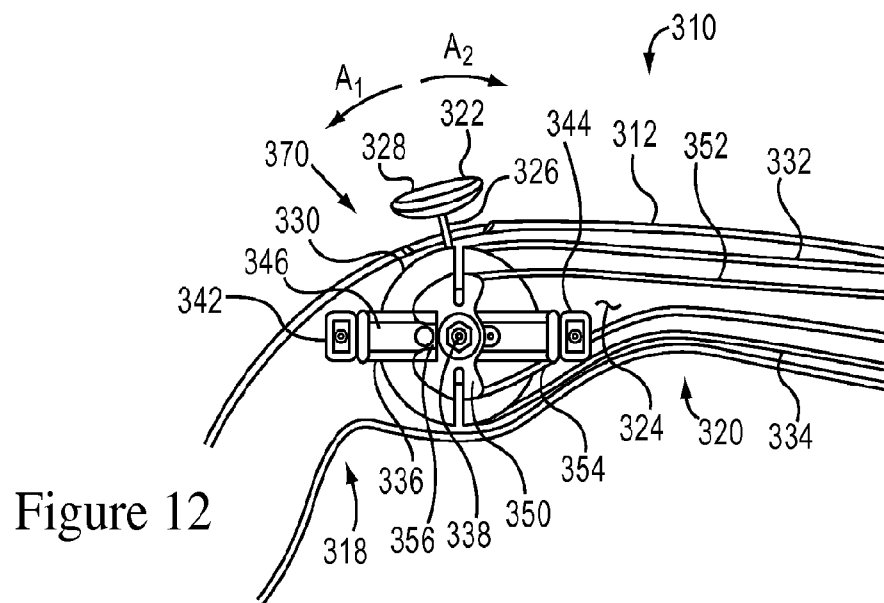


Figure 12

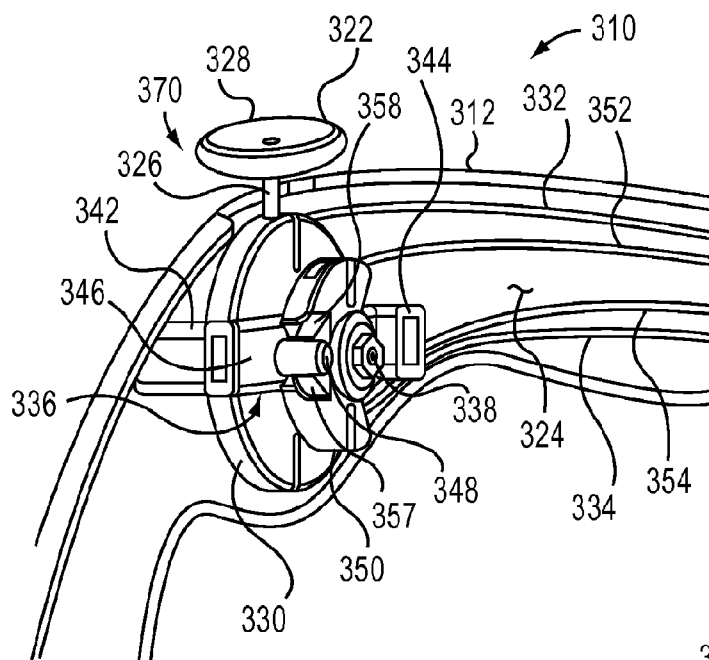


Figure 13A

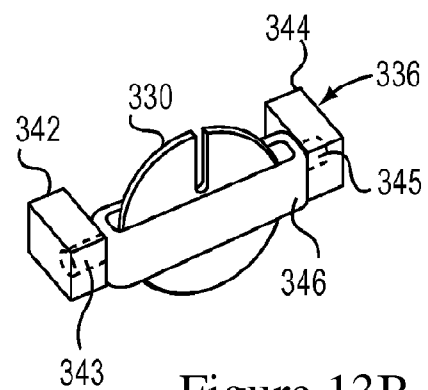
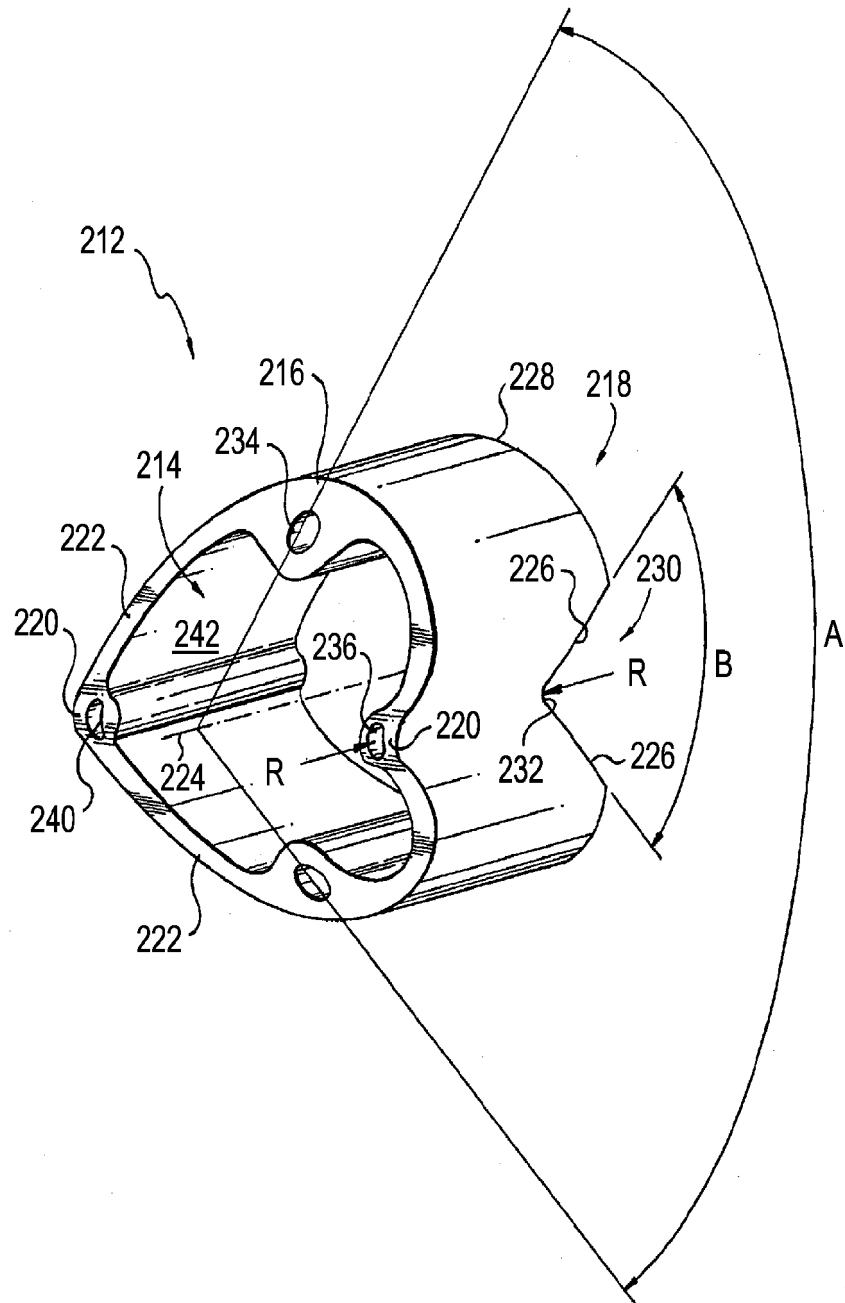


Figure 13B

Figure 14



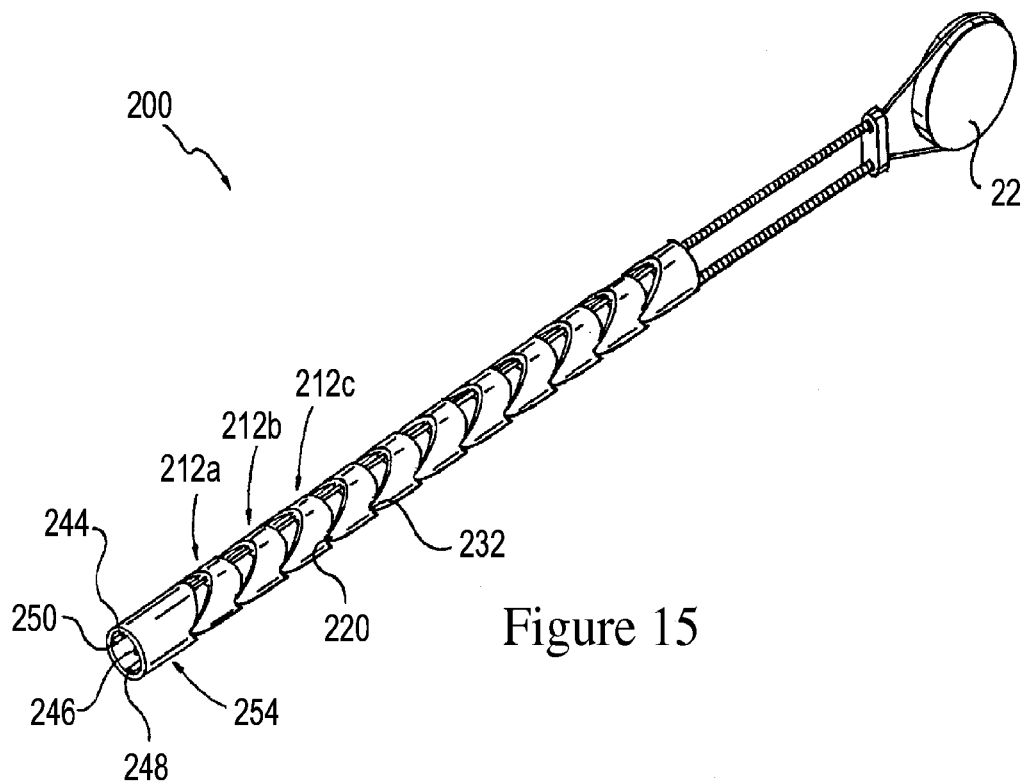


Figure 15

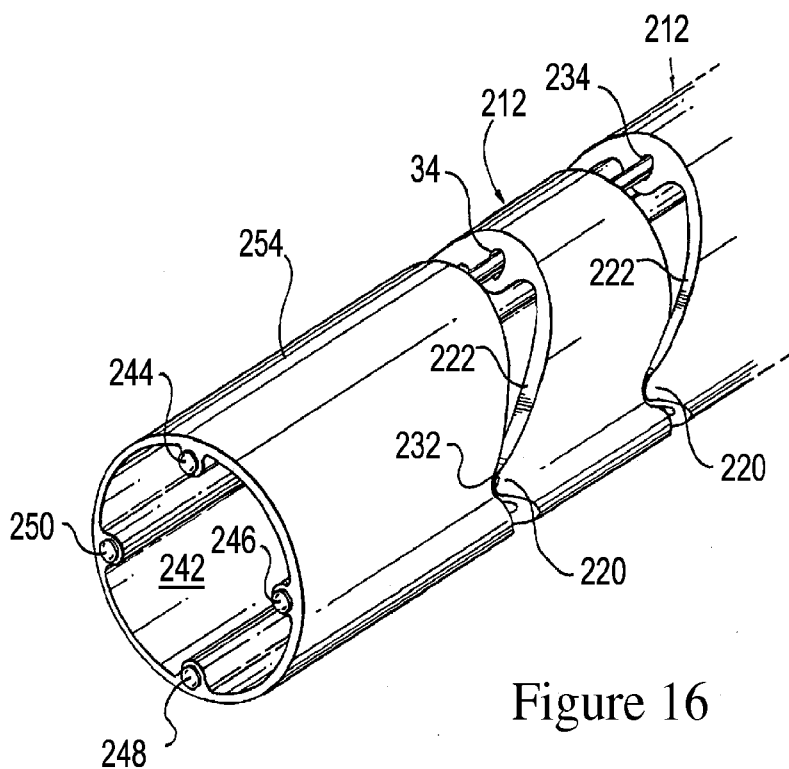


Figure 16

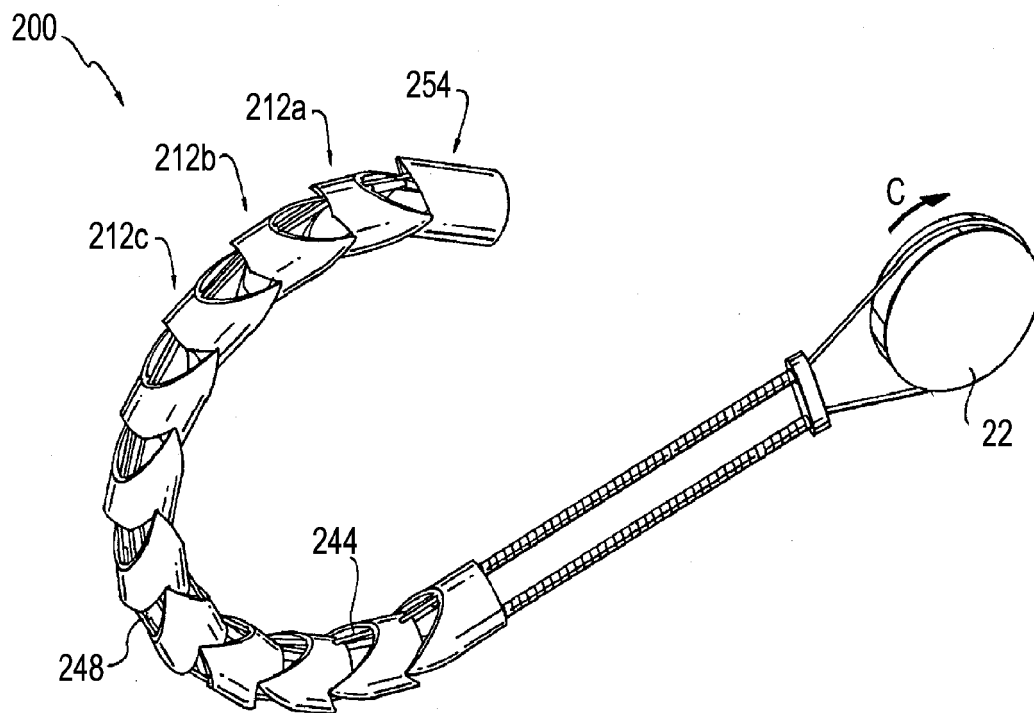


Figure 17

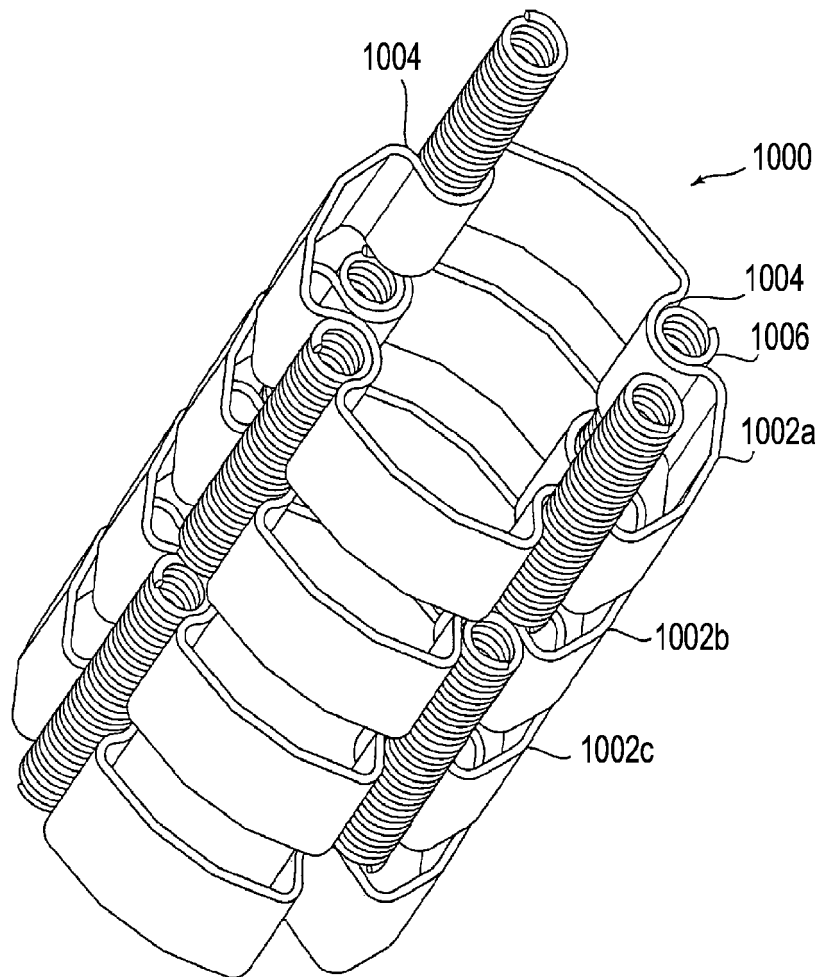


Figure 18A

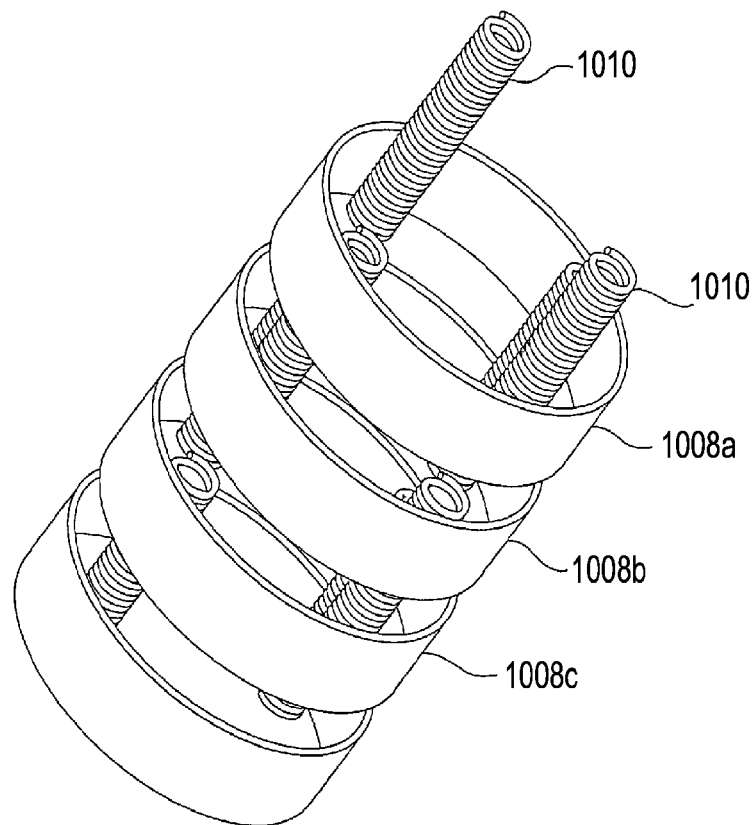


Figure 18B

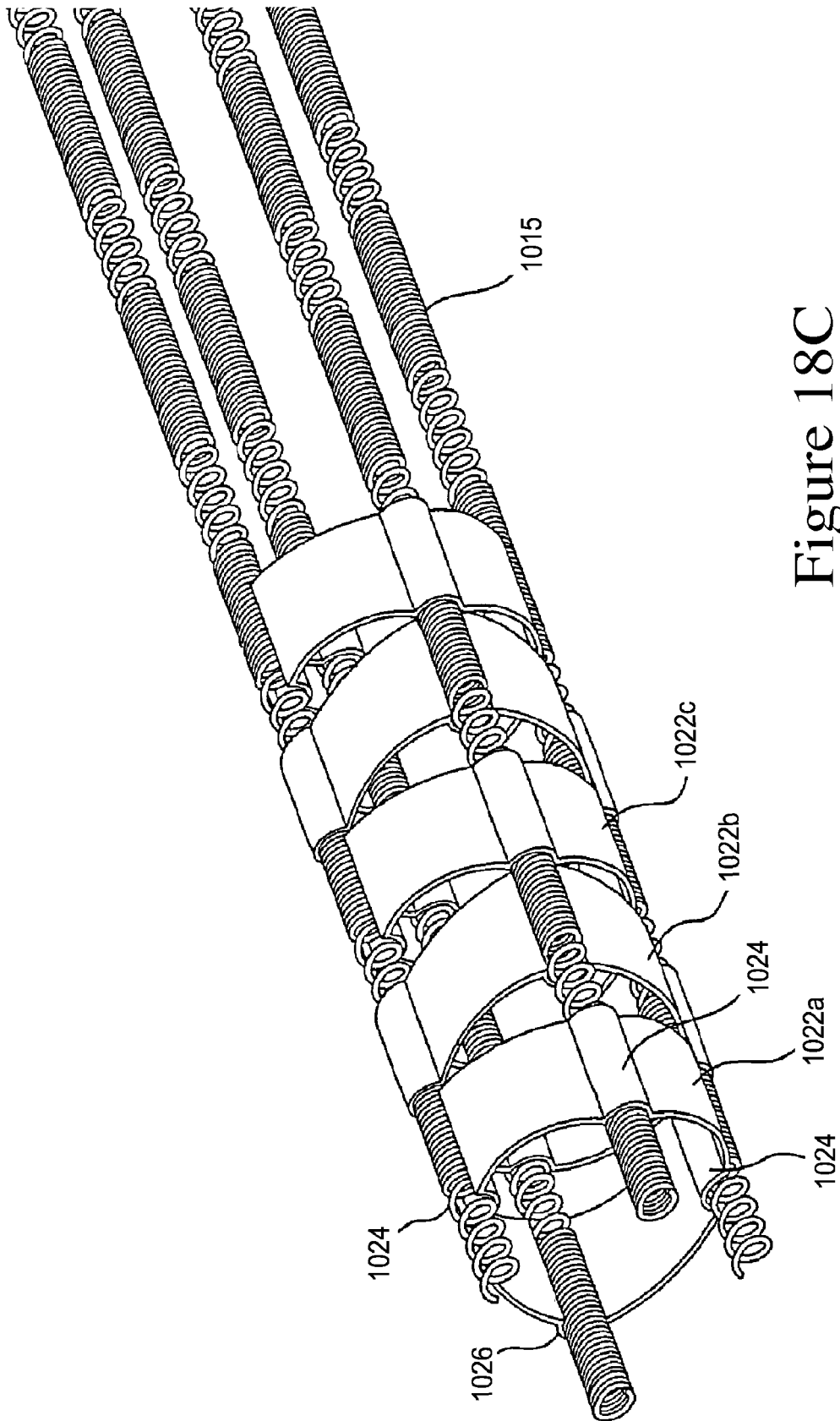


Figure 18C

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	灵活的缝合器械		
公开(公告)号	EP2683304B1	公开(公告)日	2019-09-25
申请号	EP2012706761	申请日	2012-02-21
[标]申请(专利权)人(译)	波士顿科学西美德公司		
申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED , INC.		
当前申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED , INC.		
[标]发明人	FAIRNENY TY		
发明人	FAIRNENY, TY		
IPC分类号	A61B17/04		
优先权	61/451366 2011-03-10 US		
其他公开文献	EP2683304A1		
外部链接	Espacenet		

摘要(译)

缝合器械包括手柄，细长轴和缝合头。一根或多根拉线从手柄延伸到细长轴中，以在一个或多个方向和/或平面上可控制地偏转细长轴的可偏转部分，以改善内窥镜或腹腔镜手术过程中患者体内的可操纵性，并且改变缝合头的位置。

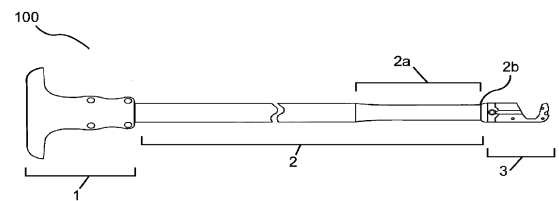


Figure 1A

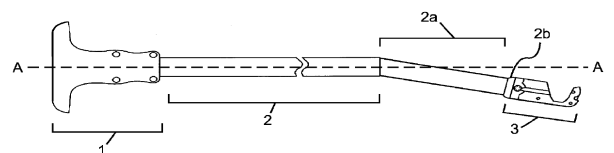


Figure 1B