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(71) **Applicant** *(for all designated States except US)*: **WILSON-COOK MEDICAL, INC.** [US/US]; 4900 Bethania Station Road, Winston-Salem, NC 27105 (US).

(72) **Inventor; and**
(75) **Inventor/Applicant** *(for US only)*: **DUCHARME, Richard, W.** [US/US]; 317 Crowne Oak Circle, Winston-salem, NC 27106 (US).

(74) **Agent**: **GOEDERTIER, Katie, B.**; Brinks Hofer Gilson & Lione, P.O. Box 10087, Chicago, IL 60610 (US).

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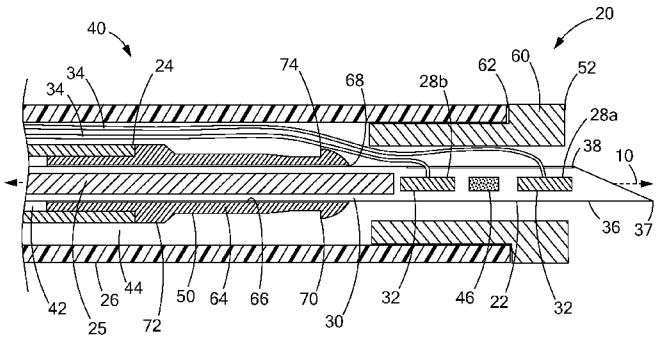
(54) **Title**: MEDICAL DEVICES, SYSTEMS, AND METHODS FOR RAPID DEPLOYMENT AND FIXATION OF TISSUE ANCHORS

Fig. 1



(57) **Abstract**: Medical devices, systems and related methods for delivering a plurality of tissue anchors. The medical devices generally comprise a needle and an over-the-needle suture lock, employed via inner and outer sheaths. The medical systems include a plurality of tissue anchors and at least one biodegradable or resorbable spacer member positioned between adjacent tissue anchors in conjunction with the medical devices.

MEDICAL DEVICES, SYSTEMS, AND METHODS FOR RAPID DEPLOYMENT AND FIXATION OF TISSUE ANCHORS

FIELD OF THE INVENTION

[0001] The present invention relates generally to medical devices for placing tissue anchors in bodily walls, such as for closing perforations in tissue.

BACKGROUND OF THE INVENTION

[0002] Perforations in bodily walls may be naturally occurring, or formed intentionally or unintentionally. In order to permanently close these perforations and allow the tissue to properly heal, numerous medical devices and methods have been developed employing sutures, adhesives, clips, staples and the like. One class of such devices is commonly referred to as tissue anchors, T-anchors or visceral anchors. Exemplary tissue anchors are disclosed in U.S. Pat. No. 5,123,914, U.S. Application No. 11/946,565, and U.S. Provisional Application No. 61/166,364, entitled "Tissue Anchors and Medical Devices for the Rapid Deployment of Tissue Anchors" to Ducharme, the entire contents of which are incorporated by reference herein.

[0003] Multiple tissue anchors may be used to close a perforation. Difficulties arise in sequentially deploying multiple tissue anchors because the distal-most tissue anchor is being pushed directly upon by an adjacent tissue anchor. Thus, as the distal-most tissue anchor is deployed, the proximally adjacent tissue anchor is already partially deployed and can easily fall out of the introduction needle. Moreover, deploying numerous tissue anchors individually can be tedious and time consuming due to reloading the various tissue anchors into the introduction needle and individually deploying the tissue anchors. There is also difficulty in maintaining the position of the device, while a new tissue anchor is loaded and placed back through the device.

[0004] Tissue anchors typically include a crossbar or some anchoring member connected to suture. The anchoring member and suture may take many forms, but generally a needle is used to pierce tissue and deliver the anchoring member on one side of the tissue, leaving the suture extending back to the other side of the tissue. The sutures of one or more tissue anchors are collected and connected together, such as through tying the sutures together. Manually tying suture strands together to close a perforation can be very complex and time consuming. For example, a significant level of skill and coordination is

required by the medical professional, especially when the perforation and sutures are difficult to access within the body, such as in endoscopic or laparoscopic procedures. The numerous difficulties with manually tying sutures are well documented. In order to address these and other issues of manual suture tying, various automatic suture tying systems have been developed. Unfortunately, such automatic systems are often complex and costly, difficult to use, and limited to use in certain situations.

BRIEF SUMMARY OF THE INVENTION

[0005] The present invention provides medical devices, systems, and related methods for delivering tissue anchors. One embodiment of such a medical device, constructed in accordance with the teachings of the present invention, generally comprises at least one tissue anchor having an anchoring member connected to a suture. A needle having a needle lumen is sized to slidably receive the at least one tissue anchor. The needle and the needle lumen define a longitudinal axis of the medical device.

[0006] The medical device further includes an over-the-needle suture lock for fixing the suture after suture lock fixes the suture after delivery of the at least one tissue anchor. The suture lock comprises a plug and a retaining sleeve. The plug has a main body having a first internal wall defining a first internal passageway. The retaining sleeve has a tubular body having a second internal wall defining a second internal passageway. The second internal passageway is sized to receive the plug therein and engage the suture of the at least one tissue anchor between the plug and the second internal wall of the retaining sleeve. Both the first and second internal passageways are sized to slidably receive the needle during delivery of the at least one tissue anchor.

[0007] In this embodiment, an inner sheath is engageable with the plug and has an inner sheath lumen sized to slidably receive the needle. An outer sheath is engageable with the retaining sleeve and has an outer sheath lumen sized to slidably receive the inner sheath and the plug. Translation of the inner sheath causes the plug to slide over the needle.

[0008] A method of delivering a tissue anchor is also provided in accordance with the teachings of the present invention. A medical device, such as one of the devices described above, is provided. The medical device is delivered to a position proximate the tissue. The needle is deployed by translating the needle relative to the inner and outer sheaths. The tissue anchor is deployed by translating the tissue anchor relative to the needle such that the tissue anchor exits the needle lumen. When the medical device includes a plurality of tissue anchors serially aligned within the needle lumen, the step of

deploying the tissue anchor is repeated for at least a portion of the plurality of tissue anchors.

[0009] A method of securing at least one anchor is also provided in accordance with further teachings of the present invention. The at least one anchor includes an anchoring member connected to a suture. The at least one anchor is slidably disposed within a needle, the needle is slidably disposed within an inner sheath, and the inner sheath is slidably disposed within an outer sheath. The needle is deployed by translating the needle relative to the inner and outer sheaths. The at least one anchor is deployed from the needle by translating the at least one anchor relative to the needle such that the at least one anchor exits the needle lumen. The suture of the at least one anchor is secured with a suture lock. The suture lock includes a plug and a retaining sleeve. The plug has a main body with a first internal wall defining a first internal passageway. The retaining sleeve has a tubular body with a second internal wall defining a second internal passageway. The suture is pre-loaded within the second internal passageway of the retaining sleeve and the retaining sleeve is sized to receive the plug therein in a locked configuration. Both the first and second internal passageways slidably receive the needle.

[0010] In a further aspect, the step of securing the suture includes translating the retaining sleeve and the plug distally over the needle.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The accompanying drawings incorporated in and forming a part of the specification illustrate several aspects of the present invention, and together with the description serve to explain the principles of the invention. In the drawings:

[0012] FIG. 1 is a plan view, partially in cross-section, of a medical delivery device constructed in accordance with the teachings of the present invention;

[0013] FIG. 2 is a perspective view of a suture lock of a medical delivery device constructed in accordance with the teachings of present invention;

[0014] FIG. 3 is a side view of a plug forming a portion of the suture lock depicted in FIG. 2;

[0015] FIG. 4 is a cross-sectional view of a retaining sleeve forming a portion of the suture lock depicted in FIG. 2;

[0016] FIG. 5 is a perspective view of the suture lock depicted in FIG. 2, showing the suture lock in a locked configuration; and

[0017] FIGS. 6-10 depict steps in a method for using a medical device in accordance with the teachings of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0018] Turning now to the figures, FIG. 1 depicts a medical device 20 constructed in accordance with the teachings of the present invention. The medical device 20 generally comprises a needle 22 and a suture lock 48, which may be employed via inner and outer sheaths 24 and 26. The medical device 20 is designed for delivering tissue anchors 28a, b through tissue, e.g., for closing a perforation 14, or for apposing tissue, for example, in gastroesophageal reflux disease (GERD) therapy, or bariatric surgery in which an anastamosis is formed, or for use in other procedures. The device 20 preferably includes a pusher 25 extending through the needle 22 for expelling the anchors 28 therefrom.

[0019] The tissue anchors 28a, b and the medical device 20, employed via inner and outer sheaths 24 and 26 and pusher 25, form a medical system 40. That is, the medical device 20 may be utilized with a number of different tissue anchors, and therefore the medical device 20 may be provided separately such that the medical professional may utilize tissue anchors of his or her own choosing. At the same time, the medical device 20 may also be provided with tissue anchors 28a, b "pre-loaded", thereby forming a medical system 40 in accordance with the teachings of the present invention.

[0020] The needle 22 defines a needle lumen 30 and a longitudinal axis 10 of the medical device 20. The needle 22 is preferably constructed of a metal or alloy such as stainless steel or nitinol, although other metals, alloys and plastics can be used for the needle 22, as is known in the art. The needle lumen 30 is sized to slidably receive a plurality of tissue anchors 28a, b therein. In particular, the tissue anchors 28a, b generally comprise an anchoring member 32 and a suture 34 attached thereto, and the anchoring member 32 is received within the needle lumen 30 along with a portion of the suture 34. The suture 34 is preferably formed from a flexible material, such as nylon and of the monofilament variety, although the suture 34 may be formed from metal wire, including single filament and multi-filament wires, and wound and braided wires, plastic strings, rope and the like. The suture 34 preferably has a diameter in the range of about 0.20 mm to about 0.35 mm, and most preferably about 0.287 mm, although other sizes may be used and the suture lock 48 sized accordingly.

[0021] A distal end 36 of the needle 22 also defines a needle slot 38 that is longitudinally extending and opens longitudinally at the distal end 36 of the needle 22. The slot 38 is sized to receive the sutures 34 therein. The slot 38 may be sized and structured to frictionally engage the sutures 34 therein to provide improved retention of the tissue anchors

28a, b within the distal end 36 of the needle 22 during manipulation of the needle, e.g., during preparation for a procedure. The slot 38 may have a width sized to be less than or equal to a width of the sutures 34. In this manner, the needle 22 frictionally engages the sutures 34 to retain the tissue anchors 28a, b within the needle lumen 30. It will be recognized that the needle 22 may not include the slot 38, although it is preferable to keep the sutures 34 safe from the sharp distal tip 37 of the needle 22 through provision of the slot 38, or the width of the slot 38 can be sized larger than a diameter of the sutures 34.

[0022] Applicants have discovered that sequentially deploying more than one tissue anchor from the distal end of a needle can lead to improper positioning of the tissue anchors due to proximally arranged tissue anchors prematurely deploying during the deployment of adjacent distally arranged tissue anchors. Accordingly, a biodegradable or resorbable spacer member 46 is preferably positioned between anchoring members 32 of the tissue anchors 28a, b within the needle lumen 30. While the figures illustrate one spacer member 46 positioned between two tissue anchors 28a, b, it will be recognized by those skilled in the art that a larger number of tissue anchors 28a, b may be disposed within the needle lumen 30, and thus a larger number of spacer members 46 may likewise be disposed within the needle lumen 30. In addition, more than one spacer member 46 may be positioned between adjacent tissue anchors 28a, b to provide a larger distance between tissue anchors 28a, b.

[0023] As used herein, the term "resorbable" refers to the ability of a material to be absorbed into a tissue and/or body fluid upon contact with the tissue and/or body fluid. A number of resorbable materials are known in the art, and any suitable resorbable material can be used. Examples of suitable types of resorbable materials include resorbable homopolymers, copolymers, or blends of resorbable polymers. Specific examples of suitable resorbable materials include poly-alpha hydroxy acids such as polylactic acid, polylactide, polyglycolic acid (PGA), or polyglycolide; tri- methlyene carbonate; polycaprolactone; poly-beta hydroxy acids such as polyhydroxybutyrate or polyhydroxyvalerate; or other polymers such as polyphosphazines, polyorgano- phosphazines, polyanhydrides, polyesteramides, poly- orthoesters, polyethylene oxide, polyester-ethers (e.g., poly- dioxanone) or polyamino acids (e.g., poly-L-glutamic acid or poly-L-lysine). There are also a number of naturally derived resorbable polymers that may be suitable, including modified polysaccharides, such as cellulose, chitin, and dextran, and modified proteins, such as fibrin and casein. Another example of a suitable resorbable material includes bio-remodelable, extracellular matrix material (ECM). One suitable form of ECM is harvested from porcine or bovine small intestine submucosa (SIS). SIS is a resorbable, acellular, naturally occurring tissue matrix

composed of ECM proteins in various growth factors. Similarly, a number of biodegradable materials that degrade, but are not necessarily resorbed or adsorbed by the bodily tissues, are known in the art and any suitable biodegradable material can be used.

[0024] The longitudinal length of the needle slot 38, which is sized to receive the sutures 34 of the tissue anchors 28a, b therein, is dependent upon the number of tissue anchors 28a, b and spacer members 46 within the needle lumen 30 and the lengths of the corresponding anchoring members 32 of the tissue anchors 28a, b and the spacer members 46. For example, if the anchoring members 32 of the tissue anchors 28a, b are about the same in length (and if more than one spacer members 46 are used and they are about the same in length), the length of the needle slot 38 may be represented by the following equation:

[0025] $L = L_T(n_T) + L_S(n_S) - \frac{1}{2} L_T$,

[0026] wherein L represents the longitudinal length of the needle slot 38, L_T represents the length of the anchoring members 32 of the tissue anchors 28a, b, n_T represents the number of tissue anchors 28a, b within the needle lumen 30, L_S represents the length of the spacer members 46, and n_S represents the number of spacer members 46 within the needle lumen. Preferably, there is one spacer member 46 positioned between adjacent tissue anchors 28a, b such that the number of spacer members 46 is one less than the number (n_T) of tissue anchors 28a, b. The length of the anchoring members 32 is preferably between around 6 mm and 10 mm, most preferably around 8 mm. The length of the spacer members 46 is preferably between around 3 mm and 6 mm, most preferably around 5 mm. In one preferred construction in which the needle 22 houses two tissue anchors 28a, b disposed within the needle lumen 30 and one spacer member 46 positioned between the two tissue anchors, the needle 22 has an outer diameter of about .042 inches, an inner diameter of about .032 inches, and the slot 38 has a longitudinal length of about 12 mm to about 21 mm, and most preferably about 17 mm. In the currently preferred embodiment, two anchors and one spacer are used in the system 40.

[0027] The medical device 20 further includes an over-the-needle suture lock 48 for fixing the sutures 34 of the tissue anchors 28a, b after delivery of the tissue anchors 28a, b through a bodily wall 12. An over-the-needle suture lock 48, in accordance with the teachings of the present invention, allows the sutures 34 of the tissue anchors 28a, b to be preloaded within the suture lock 48 during delivery of the tissue anchors 28a, b through the bodily wall 12. The suture lock 48 generally includes a locking pin or plug 50 and a retaining sleeve 52 which cooperate to fix the sutures 34 of the tissue anchors 28a, b relative to tissue of the bodily wall 12 for closing the perforation 14 in the bodily wall 12. Although the

retaining sleeve 52 and plug 50 have been depicted as having circular cross-sections, it will be recognized that other cross-sectional shapes may be used including triangular, square, etc.

[0028] As best seen in FIGS. 2-5, the retaining sleeve 52 generally includes a tubular body 54 having an interior surface 56 defining an interior passageway 58. A peripheral rim 60 is formed at a distal end of the tubular body 54, and defines a shoulder 62 which is used for placement of the retaining sleeve 52, as will be discussed in further detail herein. Generally, the retaining sleeve 52 receives the sutures 34 of the tissue anchors 28a, b within the interior passageway 58. The sutures 34 are then fixed in place using the plug 50, which is designed to fit within the passageway 58 and pinch or compress the sutures 34. It will also be recognized that the plug 50 may have many configurations (e.g. regular or irregular shapes), and constructions (e.g. cast, molded, machined, wound (such as with wire), etc.) so long as a portion of the plug 50 cooperates with the retaining sleeve 52 to fix the sutures 34.

[0029] As best seen in FIGS. 2-5, the plug 50 generally includes a main body 64 having an interior surface 66 defining an interior passageway 68 sized to slidably receive the needle 22. The main body 64 and the interior passageway 68 define a longitudinal axis 65. The main body 64 includes a grip 70 and a stop 72, each extending radially from the main body 64. In the illustrated embodiment, the grip 70 is formed at a distal end of the plug 50, although it could be moved proximally along the length of the main body 64. The grip 70 defines an annular edge 74 that is used to engage the sutures 34, as will be discussed in more detail herein. The grip 70 includes a leading surface 76 located distally of the annular edge 74, and a trailing surface 78 located proximally of the annular edge 74. The leading surface 76 tapers, and most preferably is curved such as the dome-shaped surface (e.g., semi-spherical) shown in FIGS. 2-3. At the same time, the trailing surface 78 is generally transverse to the longitudinal axis 65. The leading and trailing surfaces 76, 78 have apertures corresponding to the interior passageway 68 in the plug 50 such that they are annular or ring shaped. While the trailing surface 78 has been shown as perpendicular to the longitudinal axis 65 in the figures, any shape or angle relative to the leading surface 76 which is sufficient to define the annular edge 74 suitable for gripping the sutures 34 is encompassed herein and by the use of the term “transverse.” As shown in FIG. 3, the main body 64 also includes a tapered portion 64a and reduced diameter portion 64b located between the grip 70 and the stop 72.

[0030] The stop 72 is longitudinally spaced from the grip 70 and is used to control the position of the plug 50 within the retaining sleeve 52. The stop 72 generally includes a

distally facing surface 79 and a proximally facing surface 80. The proximally facing surface 80 and the main body 64 define a shoulder 82 which is used to position the plug 50, as will be discussed in more detail herein. The stop 72 is positioned relative to the grip 70 to prevent the grip 70 from passing completely through the internal passageway 58 of the retaining sleeve 52.

[0031] Interconnection of the plug 50 and retaining sleeve 52 will now be described with reference to FIGS. 5 and 9-10, which depict a locked configuration of the suture lock 48 (the unlocked configuration being shown in FIGS. 1-2 and 6-8). Generally, the interior passageway 58 of the retaining sleeve 52 is sized to receive at least a portion of the plug 50 therein. In the locked configuration, the main body 64 and grip 70 are received within the interior passageway 58 of the retaining sleeve 52. As best seen in FIG. 10, the sutures 34 are compressed between the grip 70 and the interior surface 56 of the tubular body 54. As the plug 50 is advanced (i.e. distally) from left to right in FIGS. 9-10, the tapered leading surface 76 of the grip 70 allows the plug 50 to be translated distally relative to the sutures 34 and retaining sleeve 52. However, due to the generally sharp annular edge 74, it is more difficult to move the sutures 34 distally relative to the plug 50. In this manner, the sutures 34 are maintained in a fixed relationship relative to one another and to the tissue of the bodily wall 12.

[0032] As will be described in more detail herein, the sutures 34 are generally in tension, due in part to the natural elasticity of the bodily tissue 12, which generally attempts to pull the sutures 34 distally. Accordingly, while the plug 50 may be advanced through the retaining sleeve 52 and slid alongside the sutures 34 into the locked configuration, the tension on the sutures 34 also exerts a distally directed force on the plug 50 via the grip 70 and its annular edge 74. As such, the suture lock 48 is a form of self-motivating locking device that promotes secure fixation of the sutures 34 relative to the tissue 12. At the same time, the sutures 34 may be pulled in the proximal direction to adjust suture tension, suture lock position, and/or perforation closure, even when the suture lock 48 is in the locked configuration.

[0033] It can also be seen in FIG. 10 that the main body 64 is sized to at least partially compress the sutures 34 against the interior surface 56 of the tubular body 54. At the same time, the tapered portion 64a and reduced diameter portion 64b provide an area of limited or no contact with the sutures 34. These areas may be sized to adjust the level of friction between the sutures 34 and the suture lock 48, for example based on the type and size of suture material. The stop 72 abuts against a proximal end surface 55 of the tubular body 54, thereby limiting the position of the plug 50 within the retaining sleeve 52. The

distally facing surface 79 of the stop 72 is generally tapered to slightly compress the sutures 34 against the tubular body 54, while still allowing the sutures 34 to exit the suture lock 48 and be translated in a proximal direction.

[0034] The components of the suture lock 48 may be constructed of various materials, such as stainless steel, titanium, nitinol or other metals/alloys, although various ceramics or plastics can also be employed, such as polycarbonates (PC), polyamides including Nylon(TM), polytetrafluorethylenes (i.e. PTFE and EPTFE), polyethylene ether ketones (PEEK), polyvinylchlorides (PVC), polyimides, polyurethanes, and polyethylenes (high, medium or low density), including multi-layer or single layer constructions with or without reinforcement wires, coils or filaments. In one preferred construction, the plug 50 has a length of about .259 in, the main body 64 has an outer diameter of about .065 in along a center region and an outer diameter of about .060 in along a proximal region (which is received within the inner sheath 24) and an inner diameter of about .045 in defining the interior passageway 68, the stop 72 has an outer diameter of about .080 in, and the annular edge 74 defining the grip 70 has an outer diameter of about .072 in. In this construction, the retaining sleeve 52 has a length of about .150 in, and the tubular body 54 has an outer diameter of about .100 in and an inner diameter of about .080 in defining the interior passageway 58. While these dimensions of a currently preferred embodiment have been described, the dimensions may be increased or decreased, scaled up or down, to accommodate differently sized anchors, sutures, needles, sheaths, and bodily walls or tissue structures.

[0035] The inner sheath 24 defines an inner sheath lumen 42 which is sized to slidably receive the needle 22 therein. The inner sheath 24 is sized and positioned to engage or abut the shoulder 82 of the plug 50. The outer sheath 26 defines an outer sheath lumen 44 which is sized to slidably receive the inner sheath 24 and the plug 50 therein. The outer sheath 26 is sized and positioned to engage or abut the shoulder 62 of the retaining sleeve 52. In one preferred construction, the inner sheath 24 has an outer diameter of about .068 in and an inner diameter of about .045 in such that the proximal portion of the main body 64 of the plug 50 (having an outer diameter of about .060 in) is press fit within the distal end of the inner sheath 24, wherein the inner sheath 24 stretches slightly to hold the plug 50 in place. The plug 50 can then be detached from the inner sheath 24 with a relatively low force. In this preferred construction, the outer sheath 26 has an outer diameter of about .131 in and an inner diameter of about .095 in such that the tubular body 54 of the retaining sleeve 52 (having an outer diameter of about .100 in) is press fit within the distal end of the outer sheath 26, wherein the outer sheath 26 stretches slightly to hold

the retaining sleeve 52 in place. The retaining sleeve 52 can then be detached from the outer sheath 26 with a relatively low force.

[0036] These dimensions may be increased or decreased, scaled up or down, to accommodate different sized anchors, sutures, needles, suture locks, bodily walls or tissue structures. For example, the inner diameter of the inner and outer sheaths 24 and 26 may be sized larger relative to the plug 50 and retaining sleeve 52, respectively. In this manner, the plug 50 and the retaining sleeve 52 are received by and maintained within the distal ends of the inner and outer sheaths 24 and 26, respectively, by an adhesive or any other suitable means known in the art.

[0037] The inner and outer sheaths 24 and 26 are preferably formed of a plastic such as polytetrafluorethylene (PTFE), expanded polytetrafluorethylene (EPTFE), polyethylene ether ketone (PEEK), polyvinylchloride (PVC), polycarbonate (PC), polyamide including nylon, polyimide, polyurethane, polyethylene (high, medium or low density), or elastomers such as Santoprene®, including multi-layer or single layer constructions with or without reinforcement wires, coils or filaments. The needle 22, inner and outer sheaths 24 and 26, and the pusher 25 are preferably elongated structures that are flexible, allowing navigation within a patient's body such as during endoscopic or laparoscopic procedures. As such, a suitable handle or control mechanism will be connected to the proximal ends of the needle 22, inner and outer sheaths 24 and 26, and the pusher 25 for relative translation of these components by the medical professional, as is known in the art. At the same time, the medical devices 20 and systems 40 are also applicable to other tissue anchor placement devices that may be used in open surgery, on external wounds, or that otherwise do not require an elongated medical device to access the targeted tissue.

[0038] The medical device 20 may be sized to be used through an accessory channel of an endoscope or alongside an endoscope, or in combination with other devices used in conjunction with endoscopes, for example, endoscopic suction devices or fluid injection devices.

[0039] The medical device 20 is operable between at least a delivery configuration, depicted in FIG. 6, and a deployed configuration, depicted in FIGS. 7-8. In the delivery configuration, the needle 22 is substantially contained within the outer sheath lumen 44 so as to protect bodily structures from the sharp distal tip 37 of the needle 22 during introduction of the medical device 20. In the deployed configuration, the needle 22 is translated relative to the inner and outer sheaths 24 and 26 such that the needle 22 projects beyond the distal end 27 of the outer sheath 26. The pusher 25 is translated relative to the needle 22 such that the distal-most tissue anchor 28a is urged distally out of the distal tip 37

of the needle 22. The suture 34 connected to the tissue anchor 28a also slides distally within the needle slot 38 and exits the needle 22. After deployment of the distal-most tissue anchor 28a, the needle 22 is retracted within the outer sheath lumen 44, the medical device 20 is repositioned, and the steps of translating the needle 22 relative to the outer sheath 26 and the pusher 25 relative to the needle 22 are repeated for additional tissue anchors.

[0040] A system and method for delivering the tissue anchors 28a, b through tissue 12 and employing the suture lock 48, in accordance with the teachings of the present invention, will now be described with reference to FIGS. 6-10. The method includes providing a medical system having a plurality of tissue anchors and at least one resorbable spacer member positioned in between adjacent tissue anchors, a needle and inner and outer sheaths, and a suture lock, such as the medical system 40 depicted in FIGS. 1 and 6-10. As shown in FIG. 6, the medical system 40 is delivered to a position proximate the bodily tissue 12 that has been targeted for placement of the tissue anchors 28a, b. The medical system 40 may include a visualization system for assisting in locating the tissue 12, identifying a target site for deployment of the tissue anchors 28a, b, and monitoring operation of the medical device 20 and system 40. For example, visualization techniques may include catheter-based fiber optic systems, fluoroscopy, ultrasound or the like. In addition, the needle 22 can have markings designed for viewing under fluoroscopy, and the distal end 36 of the needle 22 can have a surface of enhanced ultrasonic reflectivity, such by being roughened, having dimples or other incongruities, or having embedded particles.

[0041] The tissue anchors 28a, b are disposed within the needle lumen 30 at the distal end 36 of the needle 22 and a spacer member 46 is disposed between the tissue anchors 28a, b. Spaces between the spacer member 46 and the tissue anchors 28a, b have been shown for clarity, but the spacer member 46 and the tissue anchors 28a, b would generally be abutting end-to-end within the needle lumen 30. The sutures 34 follow a somewhat tortuous path from within the needle lumen 30, through the needle slot 38, extending proximally within the outer sheath lumen 44 between the interior surfaces of the retaining sleeve 52 and the outer sheath 26 and the exterior surfaces of the plug and the inner sheath 24, the sutures 34 effectively being preloaded within the suture lock 48 and extending to a proximal end of the medical device 20. Accordingly, this tortuous path can be sufficient to retain the tissue anchors 28a, b within the needle lumen 30, through frictional engagement of the sutures 34 between the exterior surface of the inner sheath 24 and the interior surface of the outer sheath 26.

[0042] The medical device 20 and system 40 are operated into their deployed configuration, as shown in FIG. 7. In particular, the needle 22 is deployed through the bodily

tissue 12 by translating the needle 22 relative to the inner and outer sheaths 24 and 26. The distal-most tissue anchor 28a is then deployed from the needle 22 by translating the tissue anchor 28a relative to the needle 22 so that the tissue anchor 28a exits the needle lumen 30. As shown in FIG. 1, the tissue anchors 28a, b and the spacer member 46 positioned therebetween are shown aligned within the needle lumen 30 along the longitudinal axis 10 of the needle lumen 30 and medical device 20 such that the pusher 25 may be slidably received within the inner sheath lumen 24 and used to engage and press on the proximal-most tissue anchor 28b. Generally, the pusher 25 is advanced distally to press upon the anchoring member 32 of the proximal-most tissue anchor 28b, which will in turn transmit force through the spacer member 46 and the distal-most tissue anchor 28a, thus advancing the distal-most tissue anchor 28a out of the needle lumen 30. It will be recognized by those skilled in the art that other structures or mechanisms can replace the pusher 25 and effectively advance the tissue anchors 28a, b. As the anchoring member 32 of the distal-most tissue anchor 28a is translated distally, the suture 34 connected thereto likewise moves along the needle slot 38 until the entire tissue anchor 28a is freed from the medical device 20, wherein the suture 34 connected to the tissue anchor 28a is released from the needle slot 38.

[0043] If, during deployment of the distal-most tissue anchor 28a, the spacer member 46 is moved distally to a position slightly past the needle tip 37, the pusher 25 may be retracted slightly and, due to the adequate clearance between the spacer member 46 and the inner diameter of the needle 22, as the needle pierces the tissue 12, the spacer member 46 is easily moved proximally within the needle lumen 30 to ensure that the sharpened needle tip 37 is able to pierce through the tissue 12 for deployment of the remaining tissue anchors 28a, b.

[0044] Turning to FIG. 8, the needle 22 is retracted back through the bodily tissue 12 by translating the needle 22 proximally, repositioned at a different position about the perforation 14, and redeployed back through the tissue 12 by translating the needle 22 relative to the inner and outer sheaths 24 and 26. The pusher 25 is then further advanced distally to deploy the spacer member 46 and the proximal tissue anchor 28b, wherein the suture 34 of the tissue anchor 28b is released from within the needle slot 38. The spacer member 46 may be deployed through the tissue 12 with the proximal tissue anchor 28b, as shown in FIG. 8. Alternatively, the spacer member 46 may be deployed within the body prior to passing the needle 22 through the tissue 12 to deploy the proximal anchor 28b. For example, the spacer member 46 may be deployed within the gastrointestinal tract, wherein the spacer member 46 passes naturally. Since the spacer member 46 is resorbable, it is

inconsequential that it is left within the patient's body. Thus, if the spacer member 46 accidentally falls out of the tip 37 of the needle 22 before being deployed with the proximal tissue anchor 28b, this is of no consequence. The proximal tissue anchor 28b is still positioned sufficiently proximal within the needle lumen 30 to be deployed appropriately at the repositioned location. In further embodiments of the invention, the spacer member 46 may contain antibiotics or other drugs, hormones, or growth factors that facilitate healing of the tissue 12 around the implanted tissue anchors 28a, b.

[0045] Rather than removing the medical device 20 from the body to reload the needle 22 with additional tissue anchors 28a, b, the medical system 40, in accordance with the teachings of the present invention, provides the ability to sequentially deploy multiple tissue anchors, in which tissue anchors and spacer members disposed between adjacent tissue anchors are preloaded within the needle 22. Accordingly, the longitudinal length of needle slot 38 can be sized to accommodate any number of sutures 34. The method may therefore include withdrawing the needle 22 from the bodily tissue 12 by translating the needle 22 proximally, and then repeating the steps of translating the needle 22 through the tissue 12 and deploying another tissue anchor 28 therethrough.

[0046] After the tissue anchors 28a, b are deployed on the distal side of the bodily tissue 12, the needle 22 is retracted back through to the proximal side of the bodily tissue 12 and retracted within the inner sheath lumen 42. The needle 22 may be removed from within the medical device 20 at this time or it may be removed with the entire medical device 20 after fixation of the sutures 34 relative to the tissue 12. As depicted in FIGS. 9-10, the suture lock 48 is engaged to fix the sutures 34 relative to the bodily tissue 12. Notably, the system 40 again does not require removal from the body, as it includes the over-the-needle suture lock 48. The retaining sleeve 52 is fitted onto the distal end 27 of the outer sheath 26. The outer sheath 26 may take the form of any sheath or catheter known in the art, but preferably has sufficient strength and rigidity for both longitudinal and rotational force transmission, while still providing flexibility for navigation of a patient's body. Exemplary sheaths are sold by Cook Medical, Inc. It will also be recognized that other sheaths or pushing elements may be employed, such as solid wires or wire guides, clamps, graspers and the like. Magnets could likewise be employed to releasably connect the outer sheath 26 to the retaining sleeve 52.

[0047] The outer sheath lumen 44 is sized to receive the tubular body 54 of the retaining sleeve 52, while a distal end surface 29 of the outer sheath 26 abuts against the shoulder 62 of the retaining sleeve 52. Generally, the outer sheath 26 and retaining sleeve 52 are loosely press fit such that the retaining sleeve 52 may be readily controlled and

positioned using the outer sheath 26. Likewise, the retaining sleeve 52 maintains its connection to the outer sheath 26 during placement of the plug 50 within the retaining sleeve 52, while at the same time the retaining sleeve 52 is also readily disconnected from the outer sheath 26 at the end of the procedure. It will be recognized that the outer sheath 26 and retaining sleeve 52 need not be sized to frictionally engage, as the tensioned sutures 34 and the tissue 12 will generally maintain the position of the retaining sleeve 52 on the outer sheath 52 during placement of the plug 50, such as is shown in FIGS. 9 and 10.

[0048] With reference to FIGS. 6-10, the sutures 34 are preloaded or threaded through the interior passageway 58 of the retaining sleeve 52 and through the outer sheath lumen 44. The outer sheath 26 is used to distally translate the retaining sleeve 52 over the sutures 34 to a position proximate the tissue 12 and perforation 14. The sutures 34 are tensioned in order to draw the perforation 14 closed and press the tissue 12 against the peripheral rim 60 of the retaining sleeve 52.

[0049] As shown in FIGS. 6-9, the inner sheath 24 is press fit with the plug 50, although the two structures may simply abut each other for longitudinal translation. The inner sheath 24 may have a construction similar to the outer sheath 26 or other catheter described above. In the depicted embodiment, the inner sheath 24 includes a distal end 23 sized to abut against the shoulder 82 and receive the main body 64 of the plug 50, respectively. Accordingly, the inner sheath 24 is connected to the plug 50 and together they are translated distally through the outer sheath lumen 44. If the needle 22 has not yet been withdrawn from the medical device 20 during securing of the sutures 34, the inner sheath 24 causes the plug 50 to slide over-the-needle 22. The plug 50 is pressed into engagement with the retaining sleeve 52 to fix the sutures 34 therebetween. With the sutures 34 in tension (e.g. by pulling them in a proximal direction), the plug 50 is advanced through the interior passageway 58 of the retaining sleeve 52, whereby the sutures 34 are compressed between the grip 70 and the interior surface 56 of the retaining sleeve 52. It can therefore be seen that relative translation of the outer sheath 26 and the inner sheath 24 controls the relative positions of the retaining sleeve 52 and the plug 50 to operate the suture lock 48 between a locked configuration and an unlocked configuration.

[0050] As previously discussed, the leading surface 76 of the grip 70 is slid along the sutures 34 as the plug 50 is distally advanced through the interior passageway 56. With further advancement, the main body 64 also engages the sutures 34 and at least partially compresses them against the interior surface 56 of the retaining sleeve 52. The annular shape of the grip 70 allows the sutures 34 to be positioned anywhere around the outer periphery of the grip 70 and plug 50. Distal movement of the plug 50 is eventually limited by

the stop 72, and namely the distally facing surface 79 of the stop 72 abutting against the proximal end surface 55 of the retaining sleeve 52. The tension on the sutures 34 grips into the annular edge 74 of the grip 70, and serves to promote movement of the plug 50 in the distal direction, as well as resist proximal movement and unlocking of the suture lock 48.

[0051] When in the locked configuration (and when partially locked such as when the plug 50 is partially placed within the retaining sleeve 52 but not fully seated), the grip 70 is structured to permit further translation of the sutures 34 proximally, i.e. away from the tissue 12, and prevent translation of the sutures 34 distally, i.e. towards the tissue 12. Further, the sutures 34 may be individually pulled or tensioned in order to orient the suture lock 48 relative to the bodily tissue 12 and perforation 14, even when the sutures 34 are compressed by the plug 50 and retaining sleeve 52, such as when the suture lock 48 is in the locked configuration. As such, tension on the sutures 34 may be modified to adjust how the perforation 14 is closed. This represents a marked improvement over existing suture locks, which typically are permanently fixed in position along the sutures such that adjustment during and after the locking procedure, i.e. in partially locked and finally locked configurations, is not possible.

[0052] In the fully locked configuration, as shown in FIG. 10, the tension on the sutures 34, as well as the natural elasticity of the tissue 12, results in a force being transmitted through the sutures 34 to the grip 70 biasing it in the distal direction. In this manner, the retaining sleeve 52 and plug 50 are interconnected through their respective frictional engagement with the sutures 34 and compression thereof. In the locked condition, the entire medical device 20 may be removed from the patient at once, the inner and outer sheaths 24 and 26 being easily removed from the retaining sleeve 52 and the plug 50, respectively. Alternatively, the inner sheath 24 and needle 22 may be removed first and the outer sheath 26 removed separately. The sutures 34 may be trimmed as necessary with endoscopic scissors and the like. To release the suture lock 48, the sutures 34 may be cut, or the outer sheath 26 may be used to hold the retaining sleeve 52 while the plug 50 is grasped (such as with a snare, forceps, or similar device) and physically withdrawn against the friction and tension of the sutures 34.

[0053] Accordingly, the present invention provides a medical system and method capable of delivering multiple tissue anchors in a controlled manner, as well as locking the anchors together (e.g., to close a perforation) without needing to withdraw and introduce the system (or multiple medical devices) any number of times, thereby saving time and improving efficiency. Since the sutures connected to the tissue anchors are preloaded within the over-the-needle suture lock, one medical system is provided for both the delivery

of multiple tissue anchors and the fixation of their sutures. The medical system is simple and reliable in use, provides complete perforation closure, and is adaptable to a variety of suture fixation and perforation closure applications. For example, any number of suture strands may be employed and the relative sizes of the plug and retaining sleeve may be adjusted based on suture size, perforation size and the like. The interconnection of the plug and retaining sleeve is such that the suture lock is self-motivated and biased towards a locked configuration, thereby assisting and promoting complete perforation closure as well as control over the position of the suture lock relative to the tissue being sutured through adjustment of the suture strands even when they are compressed. Further description of the interconnection between the plug and retaining sleeve may be found in co-pending U.S. Application No. 12/125,525, the entire contents of which are incorporated by reference herein. Adjustment of individual suture tension and location of the suture lock are also possible during and after placement of the suture lock. At the same time, the inner and outer sheaths provide a simple system for deployment of multiple tissue anchors that can be traversed through the body of a patient to even the most remote locations.

[0054] It will be recognized by those skilled in the art that, while the methods described above generally include placing the tissue anchors in tissue through an internal bodily lumen, it will be recognized that the devices and methods may be used on any layer of material (e.g. fabrics, cloth, polymers, elastomers, plastics and rubber) that may or may not be associated with a human or animal body and a bodily lumen. For example, the devices and methods disclosed herein can find use in laboratory and industrial settings for placing devices through one or more layers of material that may or may not find application to the human or animal body, and likewise closing holes or perforations in layers of material that are not bodily tissue. Some examples include sewing or stitching and related manufacturing, working with synthetic tissues, connecting polymeric sheets, animal studies, and post-mortem activities.

[0055] The foregoing description of various embodiments of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise embodiments disclosed. Numerous modifications or variations are possible in light of the above teachings. The embodiments discussed were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as

determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

CLAIMS

1. A medical device comprising:

at least one tissue anchor, the at least one tissue anchor having an anchoring member connected to a suture;

a needle having a needle lumen sized to slidably receive the at least one tissue anchor, the needle and the needle lumen defining a longitudinal axis of the medical device;

a suture lock for fixing the suture after delivery of the at least one tissue anchor, the suture lock comprising,

a plug having a main body having a first internal wall defining a first internal passageway, and

a retaining sleeve having a tubular body having a second internal wall defining a second internal passageway sized to receive the plug therein and engage the suture of the at least one tissue anchor between the plug and the second internal wall of the retaining sleeve, wherein both the first and second internal passageways are sized to slidably receive the needle during delivery of the at least one tissue anchor;

an inner sheath engageable with the plug and having an inner sheath lumen sized to slidably receive the needle, wherein translation of the inner sheath causes the plug to slide over the needle; and

an outer sheath engageable with the retaining sleeve and having an outer sheath lumen sized to slidably receive the inner sheath and the plug.

2. The medical device of claim 1, wherein the plug includes a grip and a stop, each extending radially from the main body, the stop defining a first shoulder facing proximally, the retaining sleeve including a peripheral rim extending radially from the tubular body defining a second shoulder facing proximally, wherein the inner sheath is sized and positioned to abut the first shoulder of the plug, and wherein the outer sheath is sized and positioned to abut the second shoulder of the retaining sleeve.

3. The medical device of claim 1, wherein the suture lock is operable between an unlocked configuration during delivery of the at least one tissue anchor through tissue and a locked configuration after delivery of the at least one tissue anchor through tissue, the plug and the retaining sleeve being separated in the unlocked configuration and being engaged in the locked configuration, the plug and the retaining sleeve sized and structured

to compress the suture of the at least one tissue anchor between the plug and the second internal wall of the retaining sleeve in the locked configuration.

4. The medical device of claim 1, wherein the medical device is operable between a delivery configuration and a deployed configuration, the inner sheath, the plug, and the needle being substantially contained within the outer sheath lumen in the delivery configuration, the needle projecting beyond a distal end of the outer sheath and the retaining sleeve in the deployed configuration.

5. The medical device of claim 1, wherein the suture of the at least one tissue anchor extends proximally and in between the plug and the retaining sleeve.

6. The medical device of claim 1, wherein the suture of the at least one tissue anchor extends in a proximal direction along an exterior of the inner sheath and within the outer sheath lumen.

7. The medical device of claim 1, wherein the suture of the at least one tissue anchor is pre-loaded within the suture lock.

8. The medical device of claim 1, wherein a distal end of the needle defines a needle slot sized to receive the suture of the at least one tissue anchor therein.

9. The medical device of claim 1, wherein the at least one tissue anchor includes a plurality of tissue anchors, and wherein the anchoring members of the plurality of tissue anchors are serially aligned within the needle lumen.

10. The medical device of claim 9, further comprising a pusher slidably received within the needle lumen, the pusher sized and positioned to engage a proximal-most anchoring member of the plurality of tissue anchors.

11. The medical device of claim 9, wherein the plurality of tissue anchors includes first and second tissue anchors having first and second respective anchoring members, the medical device further comprising at least one resorbable spacer member disposed between the first and second anchoring members within the needle lumen.

12. The medical device of claim 11, wherein a distal end of the needle defines a needle slot sized to receive the suture of each tissue anchor of the plurality of tissue anchors therein, the needle slot including a slot length dependent upon the number and length of the anchoring members of the plurality of tissue anchors and upon the number and length of the spacer members received within the needle lumen.

13. A method of securing at least one anchor, the at least one anchor including an anchoring member connected to a suture, the method comprising:

deploying a needle by translating the needle relative to an inner and an outer sheath, the at least one anchor being slidably disposed within the needle, the needle being slidably disposed within the inner sheath, and the inner sheath being slidably disposed within the outer sheath;

deploying the at least one anchor from the needle by translating the at least one anchor relative to the needle such that the at least one anchor exits the needle lumen; and

securing the suture of the at least one anchor with a suture lock, the suture lock including a plug and a retaining sleeve, the plug having a main body with a first internal wall defining a first internal passageway, the retaining sleeve having a tubular body with a second internal wall defining a second internal passageway, the suture being pre-loaded within the second internal passageway of the retaining sleeve, the retaining sleeve sized to receive the plug therein in a locked configuration, both the first and second internal passageways slidably receiving the needle.

14. The method of claim 13, wherein the securing the suture includes translating the retaining sleeve and the plug distally over the needle.

15. The method of claim 13, wherein securing the suture includes:

engaging the retaining sleeve with the outer sheath;

placing the suture in tension;

engaging the plug with the inner sheath; and

moving the inner sheath relative to the outer sheath to position the plug within the second internal passageway of the retaining sleeve, the suture being compressed between the plug and the retaining sleeve.

16. The method of claim 15, further comprising the step of pulling the suture in a proximal direction while pushing the inner sheath and the plug distally, the inner sheath and the plug being pushed distally relative to the outer sheath and the retaining sleeve.

17. The method of claim 16, wherein the plug includes a grip extending radially from the main body defining an annular edge, the suture being compressed between the grip and the second internal wall of the retaining sleeve.

18. The method of claim 13, wherein the at least one anchor includes a plurality of anchors serially aligned within the needle lumen, and wherein the step of deploying the anchor is repeated for at least a portion of the plurality of anchors.

19. The method of claim 18, wherein the plurality of anchors includes first and second anchors having first and second respective anchoring members, at least one spacer member being positioned between the first and second anchoring members.

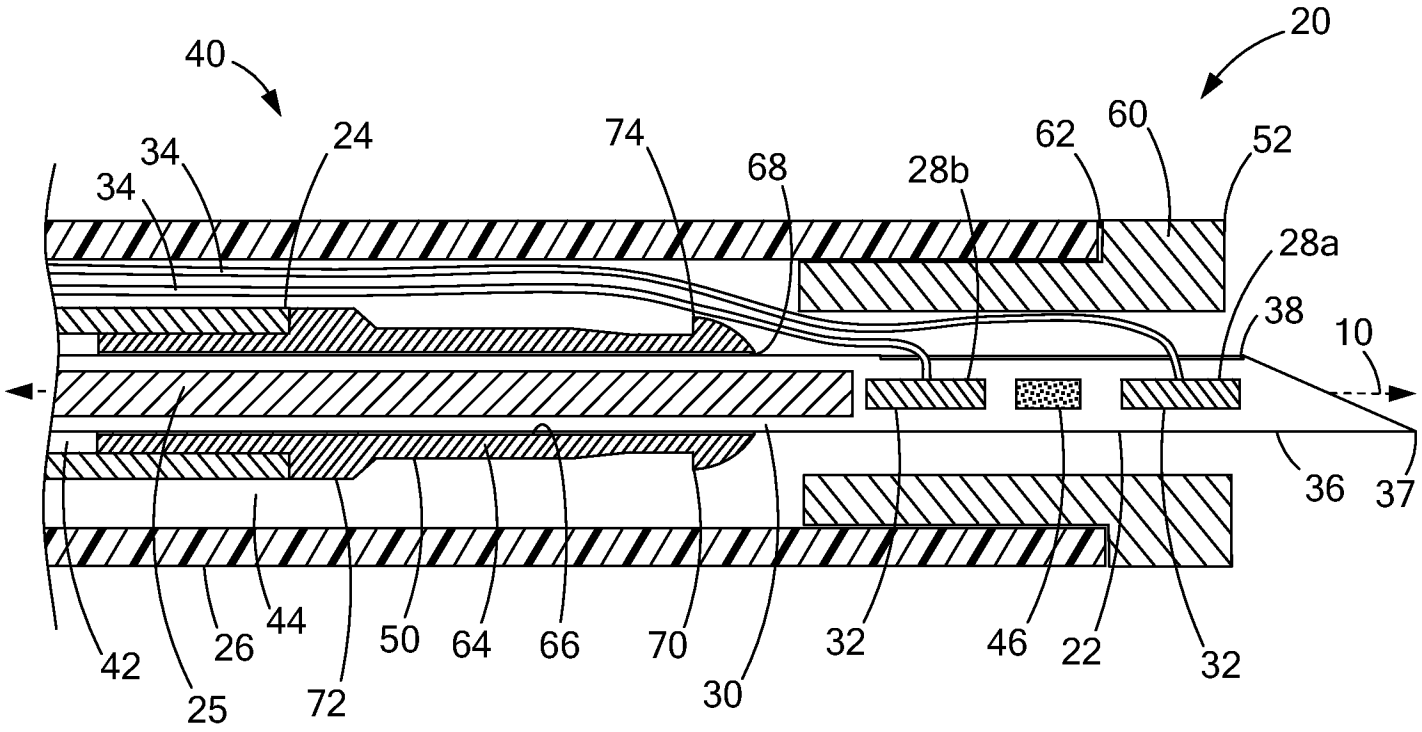

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Fig. 1

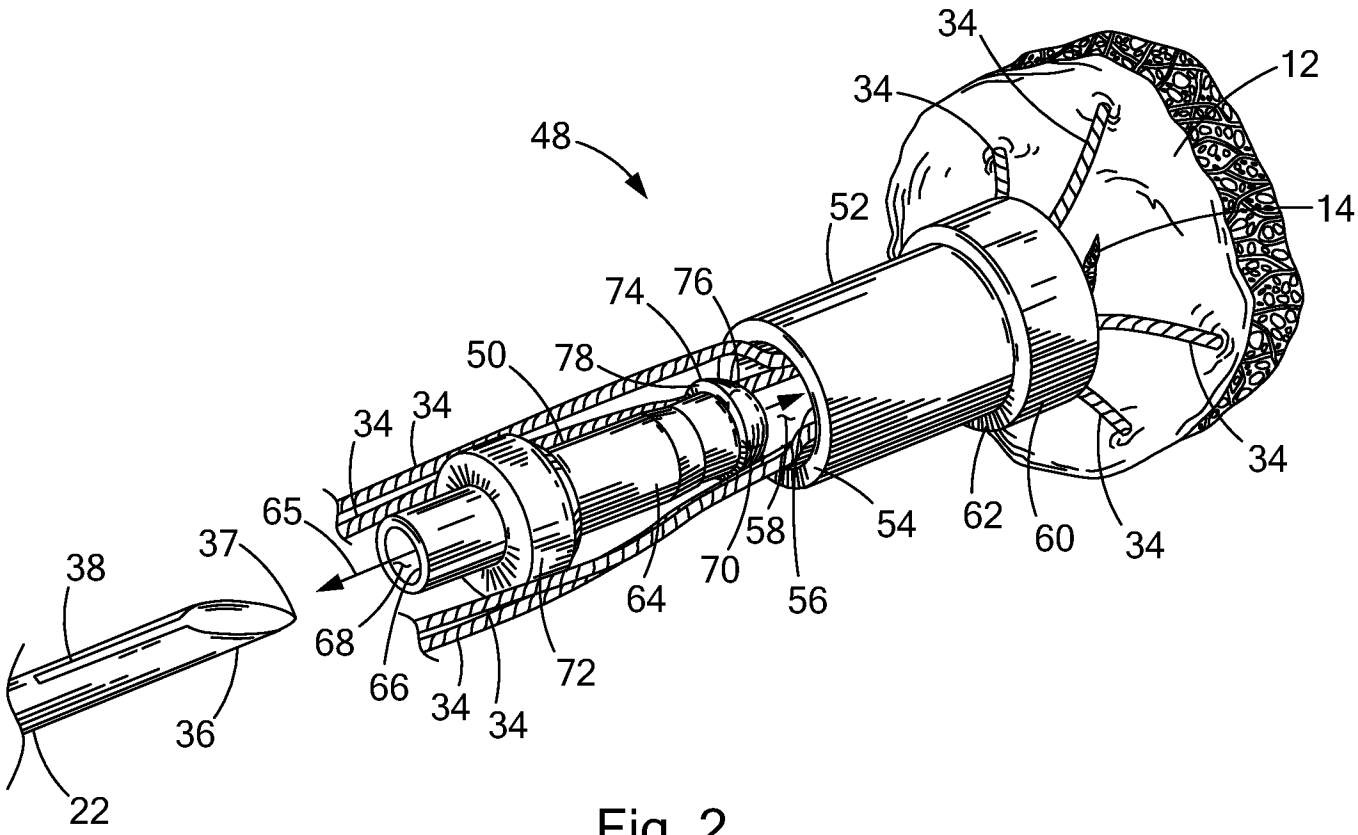
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Fig. 2

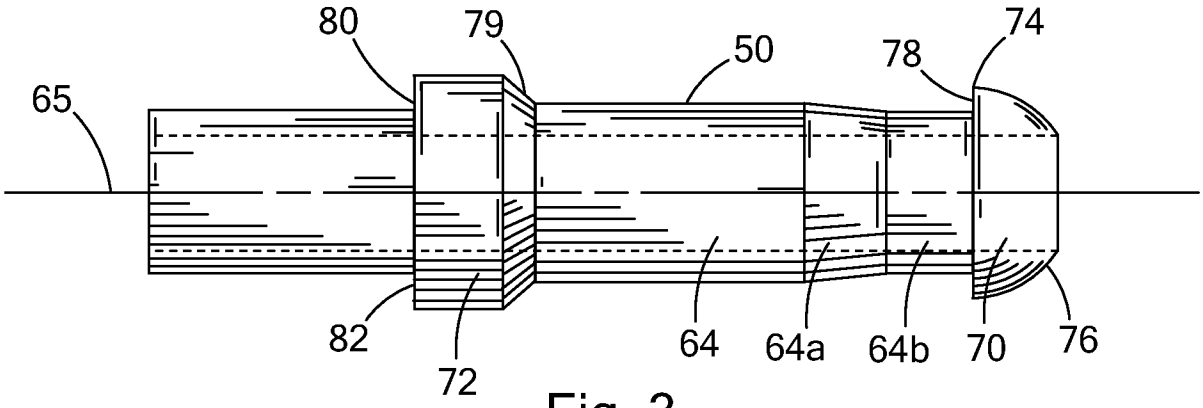

Fig. 3

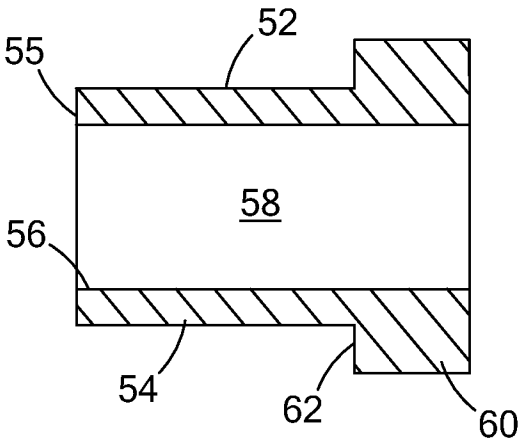

Fig. 4

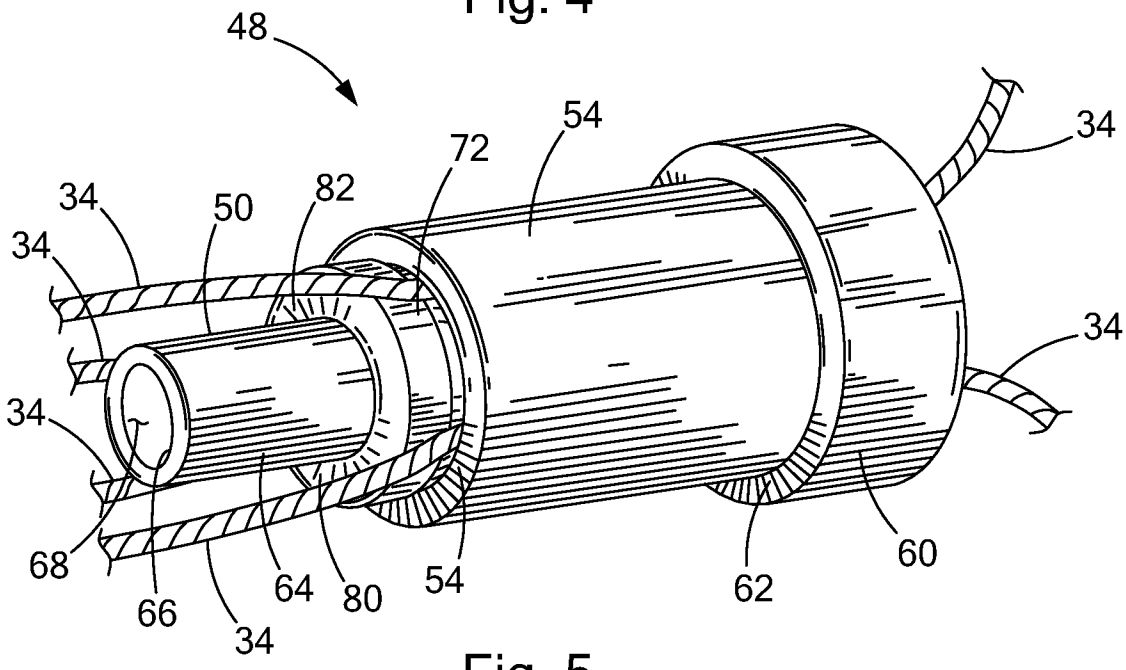

Fig. 5

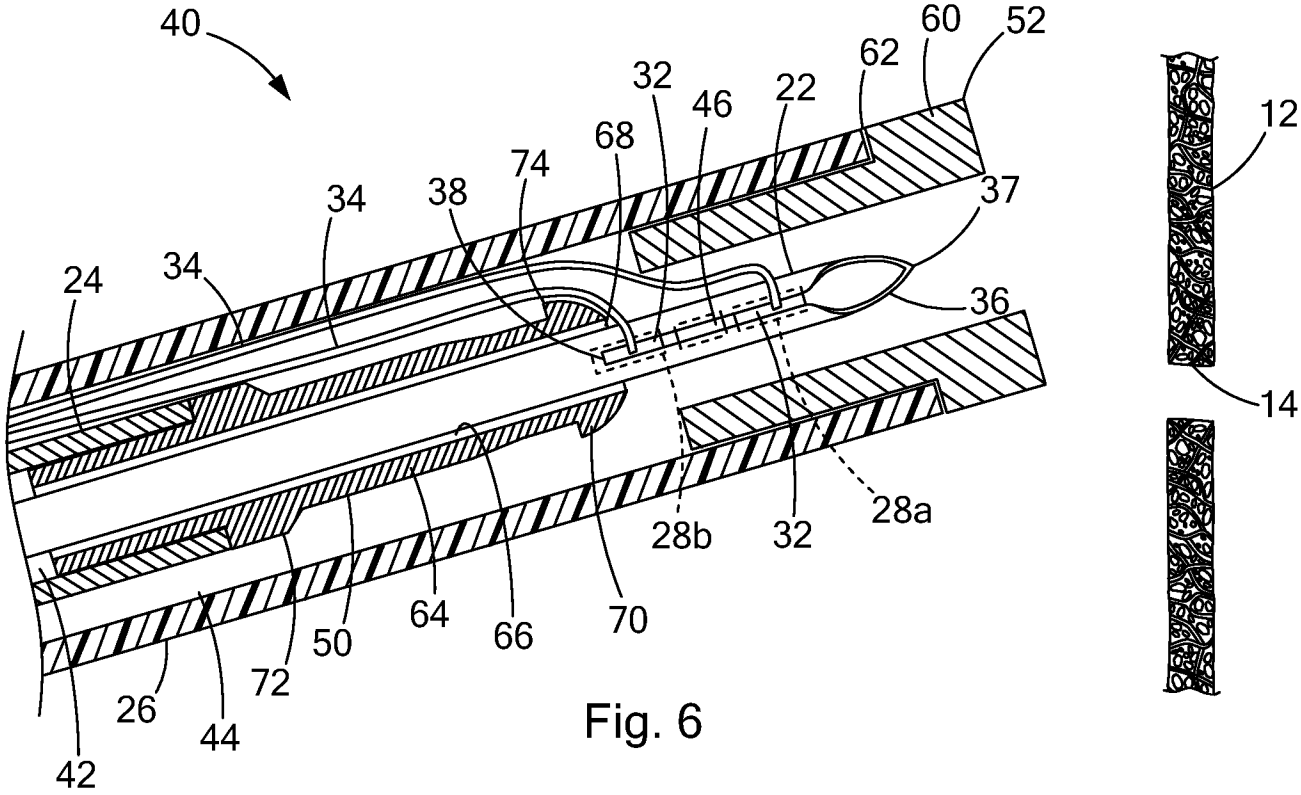
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Fig. 6

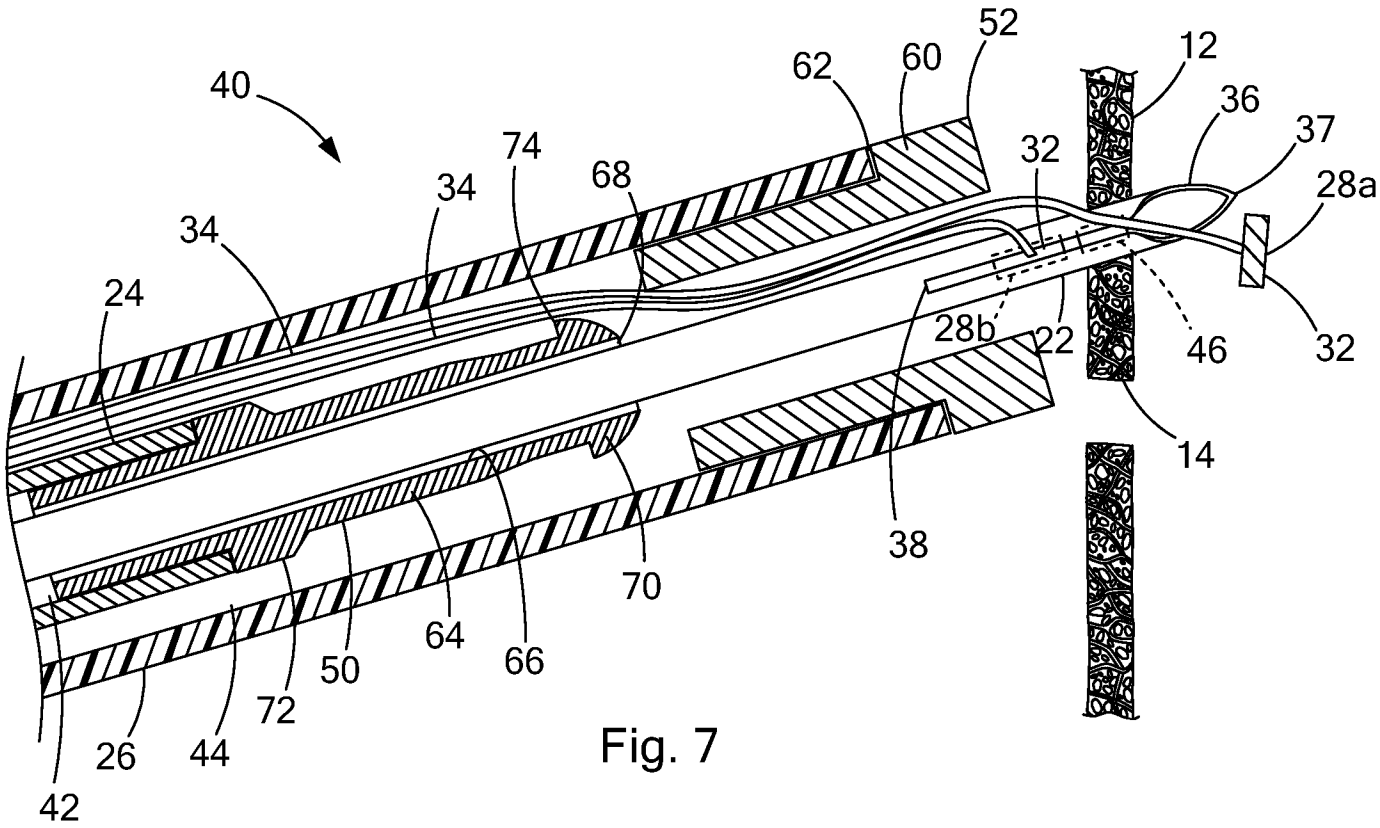
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Fig. 7

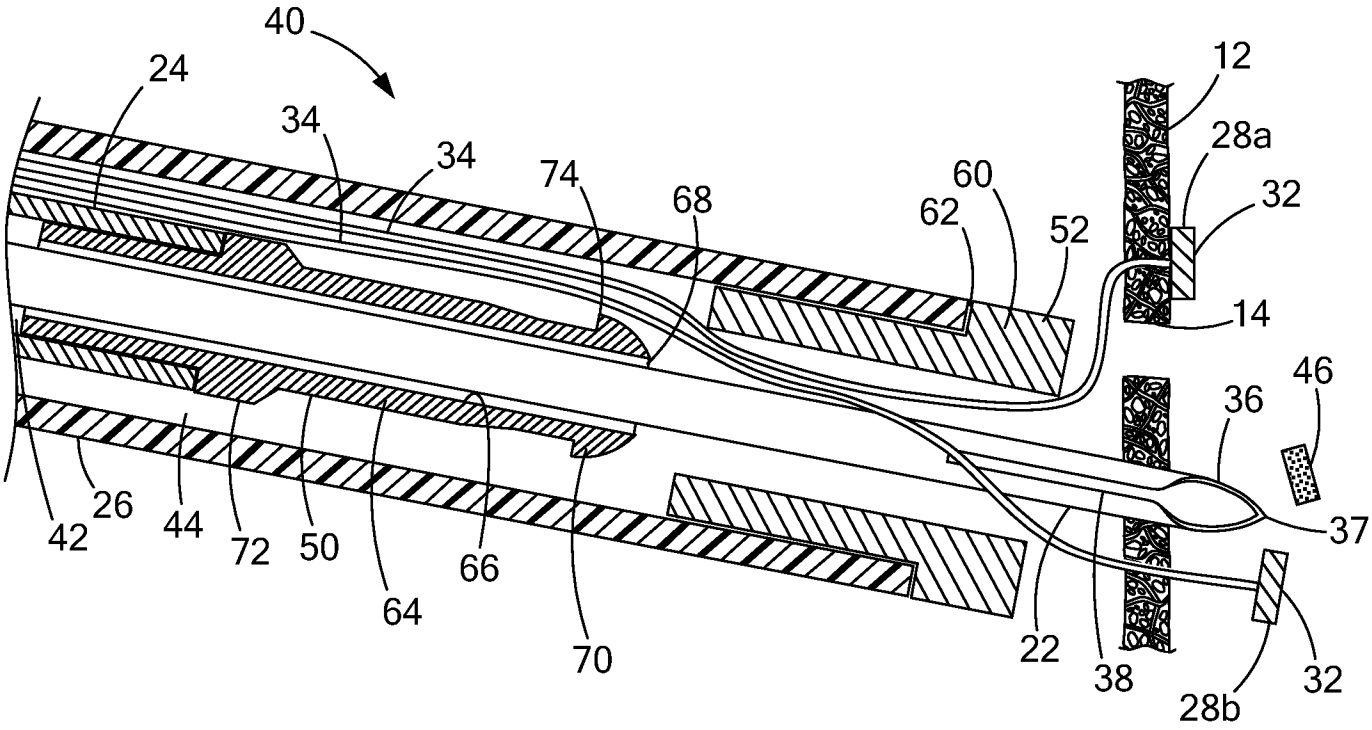
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Fig. 8

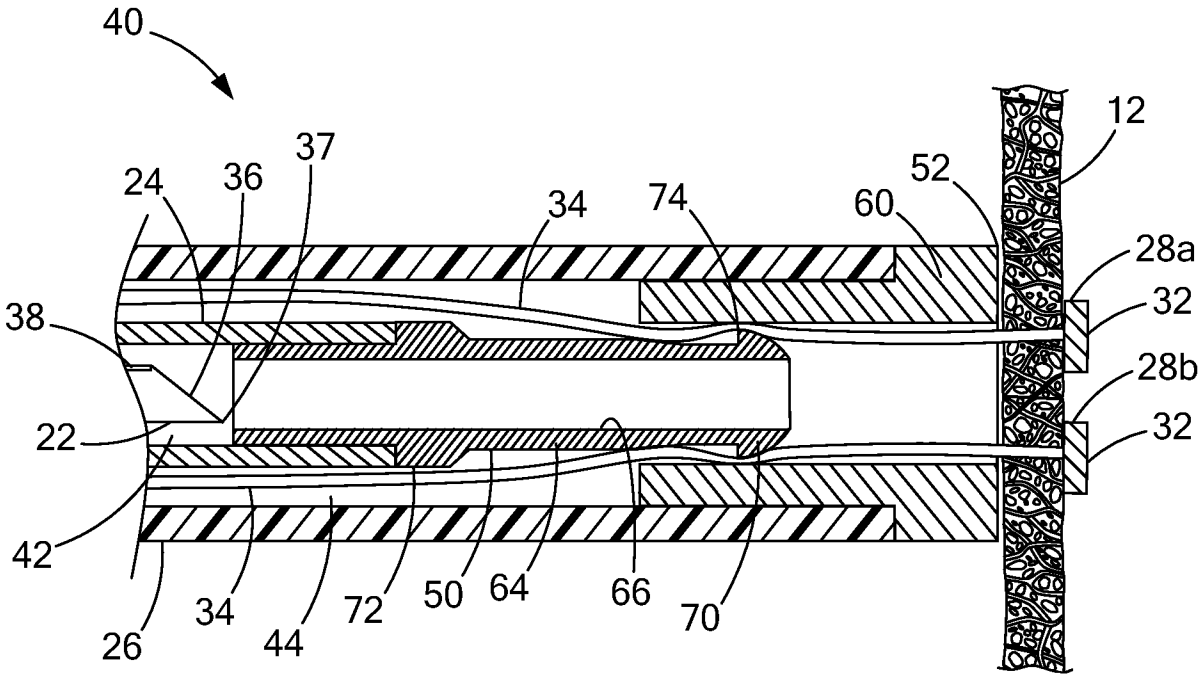
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Fig. 9

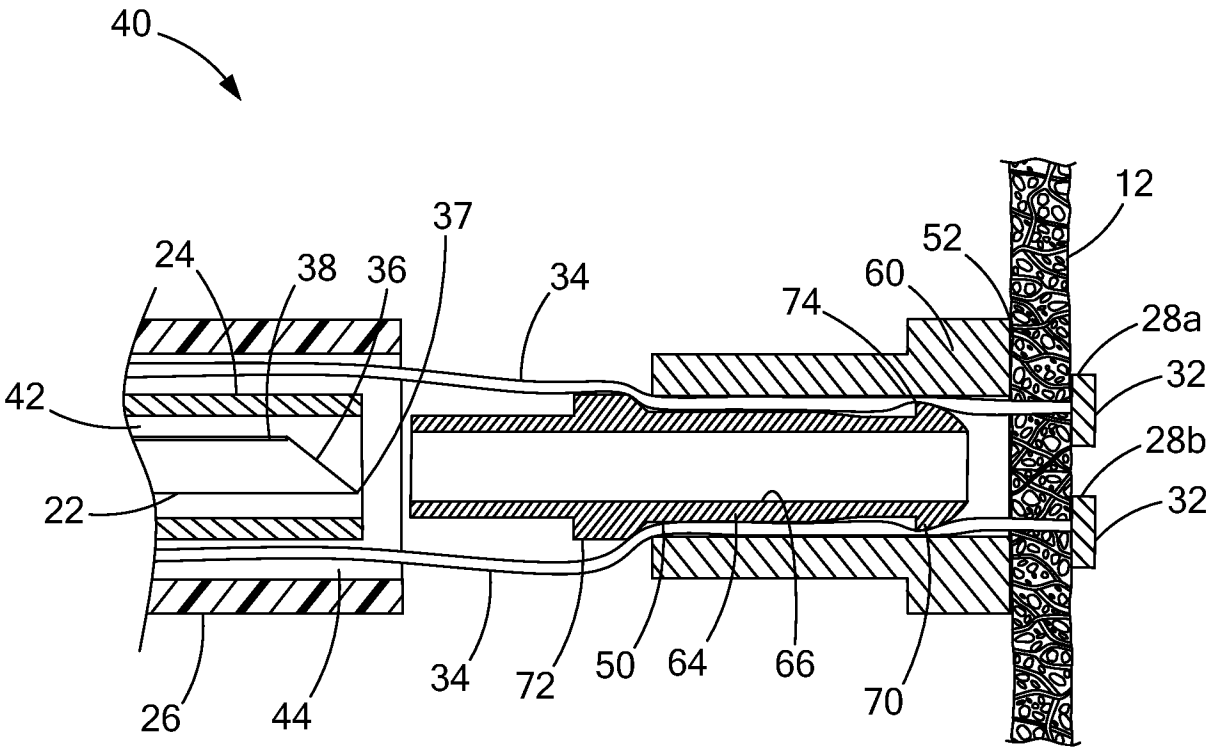
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Fig. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/029798

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04
ADD. A61B17/06 A61B17/00

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)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 2 042 105 A2 (OLYMPUS MEDICAL SYSTEMS CORP [JP]) 1 April 2009 (2009-04-01) abstract; figures 2-3,9b,10-12	1
A	WO 2006/044837 A2 (GHER EDUCATION TEMPLE UNIVERSI [US]; MILLER LARRY S [US]) 27 April 2006 (2006-04-27) abstract; figures 1,8,10,12-13 paragraph [0048]	1,3,4, 7-12
A	US 2008/300629 A1 (SURTI VIHAR C [US]) 4 December 2008 (2008-12-04) cited in the application abstract; figures 1-2,6-9	1
A	EP 1 598 018 A1 (OLYMPUS CORP [JP]) 23 November 2005 (2005-11-23) abstract; figures 1-6	1

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* 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 document 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
4 June 2010	11/06/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Macaire, Stéphane

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/029798

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/069847 A1 (HASHIBA KIYOSHI [BR] ET AL) 12 March 2009 (2009-03-12) abstract; figures 1-4	1

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/029798

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-19
because they relate to subject matter not required to be searched by this Authority, namely:

Pursuant to Article 17(2)(a)(i) and Rule 39.1 (iv) PCT, the subject-matter of claims 13-19 has not been searched, since it is directed to a method for treatment of the human body by surgery (step of deploying the needle; see also description [0004]).

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2010/029798

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 2042105 A2	01-04-2009	CN 101396293 A	01-04-2009
		JP 2009082716 A	23-04-2009
		KR 20090033140 A	01-04-2009
		US 2009088780 A1	02-04-2009
WO 2006044837 A2	27-04-2006	AU 2005295418 A1	27-04-2006
		BR PI0516940 A	23-09-2008
		CA 2584405 A1	27-04-2006
		EP 1802238 A2	04-07-2007
		JP 2008516733 T	22-05-2008
		US 2010036395 A1	11-02-2010
US 2008300629 A1	04-12-2008	EP 2150183 A1	10-02-2010
		WO 2008147875 A1	04-12-2008
EP 1598018 A1	23-11-2005	JP 2005329238 A	02-12-2005
		US 2005261710 A1	24-11-2005
US 2009069847 A1	12-03-2009	AU 2008289258 A1	26-02-2009
		CA 2696575 A1	26-02-2009
		EP 2187820 A2	26-05-2010
		WO 2009026078 A2	26-02-2009