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- (71) Applicants: **THE UAB RESEARCH FOUNDATION, INC.** [US/US]; 701 20th Street South AB 770, Birmingham, AL 35294-0107 (US). **SOUTHERN RESEARCH INSTITUTE**; 2000 Ninth Avenue South, Birmingham, AL 35202 (US).
- (72) Inventors: **KHOURY, Joseph**; 2700 Watkins Glen Drive, Vestavia Hills, AL 35216 (US). **HERGENROTHER, Robert, W.**; 105 Caber Court, Vestavia Hills, AL 35242 (US). **SCHEXNAILDER, Patrick, J.**; 165 Brook Trace Drive, Hoover, AL 35244 (US).
- (74) Agents: **MILLER, Carin, R.** et al.; Thomas|Horstemeyer LLP, 400 Interstate North Parkway, SE, Suite 1500, Atlanta, GA 30339 (US).
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(54) Title: KNOTLESS ANCHOR DEVICES AND SYSTEMS AND USES THEREOF

(57) Abstract: Described herein are knotless anchor devices, knotless tulip heads, and systems thereof. Also described herein are methods of using the knotless fixation devices knotless tulip heads, and systems thereof.

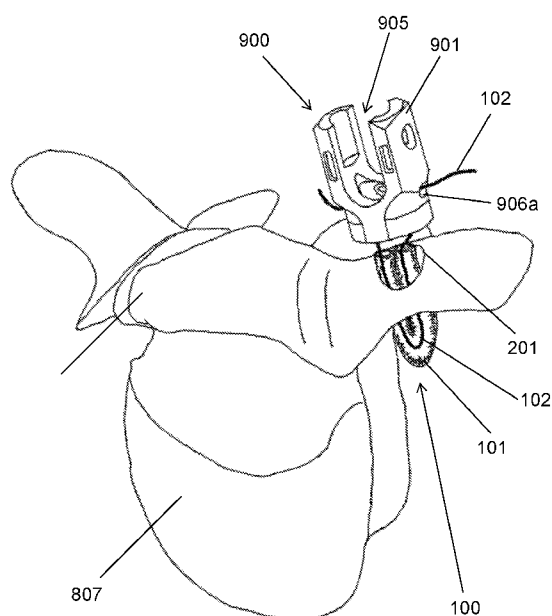


FIG. 11



SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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KNOTLESS ANCHOR DEVICES AND SYSTEMS AND USES THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application claims the benefit of and priority to co-pending U.S. Provisional
Patent Application No. 62/258,113, filed on November 20, 2015, the contents of which is
incorporated by reference herein in its entirety.

PARTIES TO A JOINT RESEARCH AGREEMENT

10 A joint research agreement entitled “Collaborative Research and Development Agreement Regarding Medical Devices between the Board of Trustees of the University of Alabama for the University of Alabama at Birmingham (“UAB”) and the UAB Research Foundation (“UABRF”) and Southern Research Institute (“SRI”)” effective June 1, 2014 is in place and encompasses this invention.

15 BACKGROUND

Scoliosis is a sideways curvature of the spine, which can require surgery to prevent worsening or correct the aberrant curvature of the spine. In cases requiring surgery, fixation rods are secured to the vertebrae, most commonly with pedicle screws or pedicle hooks. The use of such devices requires drilling in the spine close to the spinal column, which increases the risk associated with these procedures. As such, there exists a need for improved devices and methods for anchoring or otherwise attaching *inter alia* medical devices, tendons, and ligaments.

SUMMARY

Provided herein are embodiments of a knotless anchor device, where the knotless anchor device can have a flexible sleeve having a middle portion, a flexible strand having two ends, and where the knotless anchor device is configured such that it does not require the entire flexible sleeve to be inserted in a hole or cavity to achieve fixation of the knotless anchor device within the hole or cavity upon compression of the flexible sleeve and where the middle portion is configured to create a folded end in a hole or cavity and further configured to compress within the hole or cavity when a tension is applied to the two ends of the flexible strand. The flexible sleeve can form a tube having a longitudinal cavity extending the entire length of the flexible sleeve. The flexible strand can be passed through the longitudinal cavity and wherein a portion of the flexible strand extends beyond each end of the flexible sleeve. The flexible sleeve can be composed of a material selected from the group of: polyester, polyethylene, polypropylene, polyethylene terephthalate,

polyetheretherketone (PEEK), polyamide, polyimide, nylon, cotton, silk, and other suitable natural or synthetic materials. The flexible sleeve can be composed of filaments that are woven, braided, or twisted together. The flexible sleeve further has one or more directional barbs coupled to or integrated with the outside of the flexible sleeve. The flexible strand can be composed of a material selected from the group of: polyester, polyethylene, polypropylene, polyethylene terephthalate, polyetheretherketone (PEEK), polyamide, polyimide, nylon, cotton, silk, other suitable natural or synthetic materials, and combinations thereof. The diameter of the flexible strand can range from about 0.5 mm to about 5 mm. The outer diameter of the flexible sleeve can range from about 1 mm to about 7 mm.

Also provided herein are embodiments of a tulip head that can be used in conjunction with a knotless anchor device provided herein. The tulip head can have at least two channels, where each channel can be configured to receive a strand of a knotless anchor device as provided herein, where the tulip head can be further configured to receive a compression screw, and where the tulip head can be further configured to receive a compression ring. The channels can each have at least two openings, wherein the openings are each on different surfaces of the tulip head. The tulip head can be configured to receive a fixation rod.

In other embodiments, the tulip head can have one or more V-cleat notches, wherein each of the V-cleat notches are present on an external surface of the tulip head, and wherein each V-cleat notch is configured to receive a flexible strand of a knotless anchor device as provided herein. The tulip head can have at least two V-cleat notches. The V-cleat notches can be on opposing sides of the tulip head.

The tulip head can be composed of a material selected from the group of: stainless steel, titanium, cobalt-chrome, rigid plastics such as PEEK, HDPE, polyimide, polycarbonate, acrylonitrile-butadiene-styrene (ABS), and styrene-butadiene-styrene (SBS) and combinations thereof.

Also provided herein are methods that can include the step of folding the flexible sleeve of a knotless anchor device of claim 1 to create a folded end; inserting the folded end into a hole in a substrate such that only a portion of the flexible sleeve is passed through the hole; pulling on one or both ends of the flexible strand of the knotless anchor device as provided herein to compress the flexible sleeve within the hole to secure the knotless anchor device in the hole. The method can further include the step of fixing one or both ends of the flexible strand after compression of the sleeve. The step of fixing the ends of the flexible strand can include the step of applying a cinch ring, tying, or passing the strand through a channel or a V-cleat notch of a tulip head provided herein. The hole can be in a bone of a subject. The bone can be a vertebra. The hole can be in the transverse process of the vertebra.

BRIEF DESCRIPTION OF THE DRAWINGS

Further aspects of the present disclosure will be readily appreciated upon review of the detailed description of its various embodiments, described below, when taken in conjunction with the accompanying drawings.

Figs. 1A-1D show embodiments of a knotless anchor device in an open (Fig. 1A) or folded position (Fig. 1B) and a cross-sectional view (Fig. 1C) and a side view (Fig. 1D) of a flexible sleeve of the knotless anchor device.

Figs. 2A-2B show fixation of the knotless anchor device of Figs. 1A-1D in a hole in a substrate, such as bone. Fig. 2A shows partial insertion of a sleeve of the knotless anchor device in a hole prior to compression of the knotless anchor device. Fig. 2B shows the knotless anchor device after compression of the sleeve and fixation within the hole.

Figs. 3A-3B show photographs demonstrating an embodiment of the knotless anchor device in operation before (Fig. 3A) and after (Fig. 3B) sleeve compression.

Fig. 4 shows a table demonstrating components that can be used in a knotless anchor device as described herein.

Fig. 5 shows a table demonstrating the ability of the individual components set forth in Fig. 4 to pass through holes of varying sizes.

Fig. 6 shows a table demonstrating the results of a fixation test using knotless anchor devices made from components described in Fig. 4.

Figs. 7A-7C shows a graph (Fig. 7A) demonstrating the results of a tensile test of a flexible strand alone (control; Fig. 7B) and the flexible strand within a flexible sleeve (knotless anchor device) (Fig. 7C) when secured to a vertebra. (n=3). The flexible sleeve used for the test is a 1/8" (3.18 mm) white round-sleeve.

Figs. 8A-8C show current pedicle devices and their use in fixation procedures. Fig. 8A shows a typical pedicle screw. Fig. 8B shows a typical pedicle hook. Fig. 8C shows typical pedicle screws and pedicle hooks utilized in conjunction with fixation rods for spinal fixation.

Fig. 9 shows an embodiment of a tulip head system configured to be used with a knotless anchor device provided herein.

Fig. 10 shows the separate components of the tulip head system of Fig. 9.

Fig. 11 shows the use of the tulip head system of Figs. 9-10 with a knotless anchor device to anchor the tulip head system to a bone.

Fig. 12 shows another embodiment of a tulip head configured to be used with a knotless anchor device provided herein, where the tulip head has a "V" notch.

Fig. 13 shows the use of the tulip head of Fig. 12 with a knotless anchor device to anchor the tulip head to a bone.

Figs. 14A-14B show photographs demonstrating the use of the knotless anchor system in conjunction with traditional anchoring devices (e.g. pedicle screws) to anchor a fixation rod to a vertebral column.

Fig. 15 shows the use of a knotless anchor device as provided herein in use with a clamp to interface the knotless anchor device to a fixation rod.

Figs. 16A-16B demonstrate integration of a knotless anchor device as provided herein to a fixation rod using a clamp.

Fig. 17 shows the integration of a knotless anchor device as provided herein with a clamp.

Figs. 18A-18D show photographs demonstrating the typical placement and angle of a drill hole made in a vertebra for insertion of a typical anchoring device (e.g. pedicle screw or pedicle hook) (Figs. 18A-18B) or a knotless anchor device provided here in the transverse process (Figs. 18C-18D) for a spinal fixation procedure.

Figs. 19A-19F show photographs demonstrating a method of anchoring a fixation rod to a vertebra using a knotless anchor device provided herein.

Fig. 20 demonstrates insertion of a knotless anchor device into a drill hole made in the transverse process of a vertebra.

Fig. 21 demonstrates compression of the flexible sleeve of the knotless anchor device that is inserted into the transverse process of a vertebra.

Fig. 22 further demonstrates compression of the flexible sleeve of the knotless anchor device that is inserted into the transverse process of a vertebra.

Fig. 23 demonstrates the test set up for how the hold power of the knotless device was tested when inserted in the transverse process of a vertebra.

DETAILED DESCRIPTION

Before the present disclosure is described in greater detail, it is to be understood that this disclosure is not limited to particular embodiments described, and as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges and are also

encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosure, the preferred methods and materials are now described.

All publications and patents cited in this specification are herein incorporated by reference as if each individual publication or patent were specifically and individually indicated to be incorporated by reference and are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The citation of any publication is for its disclosure prior to the filing date and should not be construed as an admission that the present disclosure is not entitled to antedate such publication by virtue of prior disclosure. Further, the dates of publication provided could be different from the actual publication dates that may need to be independently confirmed.

As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present disclosure. Any recited method can be carried out in the order of events recited or in any other order that is logically possible.

Embodiments of the present disclosure will employ, unless otherwise indicated, techniques of biomedical engineering, mechanical engineering, physiology, anatomy, medicine and the like, which are within the skill of the art. Such techniques are explained fully in the literature.

Discussion

Spinal fusion is commonly performed in the United States to correct spinal deformities (such as scoliosis), correct spinal instability after spine decompression procedures and trauma and prevent motion over several spine segments in the case of arthritis, spinal tumors and other sources of pain. During a spinal fusion procedure, the spine is exposed from the back by moving the muscles aside and spinal fusion hardware is implanted in order to correct the undesired spinal curvature. Bone graft material is then inserted between the vertebrae to cause the vertebrae to fuse together.

Spinal fusion implants have evolved over time and now provide great power of correction. In most cases, screws are passed through the pedicles of the vertebrae from

back to front, and rods are then passed through openings formed in the heads of the screws. The rods maintain the desired orientation of the spine and enable the vertebrae to fuse in that orientation.

In severe scoliosis cases, the pedicle is malformed and unable to receive a pedicle screw for spinal fixation devices. This malformation is usually at the apex of spinal curvature, and is also where fixation is most needed. In current procedures, surgeons may either place screws under less than ideal conditions or use alternative methods of fixation (such as hooks or sublaminar wires) which pose their own risks incumbent upon entering the spinal canal and provide less powerful 3 dimensional correction of deformity. In some cases, no implants can safely be placed at the apex thereby limiting the power of the corrective maneuvers. Therefore, it is desirable to have alternative means for affixing mechanical implants where spinal malformations occur.

With that said, described herein are knotless anchor devices that can contain a flexible sleeve and a flexible strand, where the flexible strand is operatively coupled to flexible sleeve. The knotless anchor device can be configured such that when passed partially through a hole, the strand can be manipulated and cause the sleeve to be fixed within the hole. In use, the knotless anchor device can be folded on itself to form a folded end. The folded end can then be passed through a hole, such as a hole on an anchor device, such that only part of the sleeve is passed through the hole. One or both ends of the flexible strand can be pulled to secure the knotless fixation device within the hole. Also described herein are tulip head systems and devices that can facilitate spinal fixation without a pedicle screw.

Insofar as the knotless anchor devices described herein do not require that the entire sleeve be passed through a hole to secure the device in place, the devices described herein require less space than other similar devices, which can be an advantage when used in places with very limited space. Additionally, the devices described herein may be removed, or adjusted, through coordinated manipulation of the sleeve and strand. Other devices, methods, features, and advantages of the present disclosure will be or become apparent to one having ordinary skill in the art upon examination of the following drawings, detailed description, and examples. It is intended that all such additional devices, methods, features, and advantages be included within this description, and be within the scope of the present disclosure.

With a general understanding of the knotless anchor devices in mind attention is directed to Figs. 1A-1D, which show embodiments of a knotless anchor device 100 in an open (Fig. 1A) or folded position (Fig. 1B) and a cross-sectional view (Fig. 1C) and a side view (Fig. 1D) of a flexible sleeve 101 of the knotless anchor device 100. The knotless anchor device 100 can contain a flexible sleeve 101 and a flexible strand 102. The flexible

sleeve 101 can form a tube having a wall portion having a first opening at a first end 103, which extends the length of the flexible sleeve 101 to form a longitudinal cavity that can end at a second opening at a second end 104 of the flexible sleeve 101.

The flexible strand 102 can have a first end 106 and a second end 107. The flexible strand 102 can be passed through the first opening 103 the flexible sleeve 101, through the longitudinal cavity and out of the second opening 104 of the flexible sleeve 101. The flexible strand 102 can be coupled to the flexible sleeve such that each end 106, 107 of the flexible strand 102 extends beyond each end 103, 104 of the flexible sleeve. In some embodiments, more than one flexible strand can be coupled to the flexible sleeve.

As shown in Figs. 1C-1D, the flexible sleeve 101 that is configured as a tube can have a width (w), an inner diameter (d1), an outer diameter (d2) and a length (l). The width of the flexible sleeve 101 can range from about 0.010 mm to 3.5 mm or more, with a preferred width of about 0.025 mm to about 1 mm. The minimum inner diameter of the flexible sleeve can be equal to or greater than the diameter of the flexible strand. The inner diameter can range from about 0.5 mm to 5 mm or more, with a preferred inner diameter of about 1 mm to about 4 mm. The outer diameter can range from about 1 mm to about 7 mm or more, with a preferred outer diameter of about 1.5 mm to about 5 mm. The length can range from about 1 mm to 200 mm or more, with a preferred length of about 20 mm to about 120 mm. The width of the flexible sleeve 101 can be uniform along the length of the flexible sleeve 101. In other embodiments, the width of the flexible sleeve 101 can vary along the length of the flexible sleeve. The width of the flexible sleeve 101 at the first opening 103 and the second opening 104 can be the same or different. The inner diameter of the flexible sleeve 101 at the first opening 103 and the second opening 104 can be the same or different. The outer diameter of the flexible sleeve 101 at the first opening 103 and the second opening 104 can be the same or different. The cross-sectional shape of the openings and longitudinal cavity of the flexible sleeve 101 can be any desired shape, including but not limited to, circular, oval, elliptical, and polygonal.

The flexible sleeve 101 can be made of one or more of the following materials polyester, polyethylene, polypropylene, polyethylene terephthalate, polyetheretherketone (PEEK), polyamide, polyimide, nylon, cotton, silk, or other natural or synthetic materials. The flexible sleeve 101 can be made of woven, braided, or twisted filaments. The filaments can be cylindrical, oval, hexagonal, or flat tubular in cross-section and be with or without a core.

The filaments can all be made of the same material or the filaments can be made of different materials. Further all the filaments contained in a flexible sleeve 101 can be of the same composition and/or shape or can have a mixture of filaments of one or more different compositions and/or shape.

In some embodiments, the flexible sleeve 101 can contain one or more barbs on the exterior surface of the sleeve. The barbs can be directional barbs. "Directional barbs" as used herein, can refer to barbs that allow movement of the flexible sleeve in one direction and when moved in the opposite direction undergo a change in position relative to the flexible sleeve such that they resist motion in one direction. This can increase the holding power of the knotless anchor.

The flexible strand 102 can have a diameter ranging from about 0.5 mm to about 5 mm, with a preferred diameter of about 1 mm to about 4 mm. The flexible strand 102 can be made of one or more materials that can be selected from, but are not limited to, the following: suture material, polyester, polyethylene, polyethylene terephthalate, nylon, cotton, silk, wire, or other natural or synthetic materials. Other suitable materials will be appreciated by those of skill in the art. The flexible strand 102 can range in length from about 2 cm to about 100 cm, with a preferred length of about 4 cm to about 20 cm. After the knotless anchor device is in place, either before or after the tulip head is interfaced with, e.g. a fixation rod, the flexible strand can be cut to any desired length.

Discussion of the knotless anchor device 100 continues with Figs. 2A and 2B, which show fixation of the knotless anchor device of Figs. 1A-1D in a hole or cavity 201 in a substrate 200, such as (but not limited to) bone, screw head, fixation rod, clamp, tendon, ligament, and other devices having a hole. As shown in Fig. 2A the knotless anchor device of Fig. 1A can be folded (see Fig. 1B) and passed through the hole or cavity 201 in the substrate 200 such that the folded end 105 extends on one side of the substrate 200 and the open ends of the flexible sleeve 101 (103, 104) and the ends of the flexible strand 102 (106, 107) extend on the other side of the substrate 200. Until a tension is applied to one or both ends of the flexible strand 102 the knotless anchor device 100 is in an uncompressed state as shown in Figs. 2A and 3A.

The flexible sleeve 101 can be compressible. As discussed above, the knotless anchor device 100 can be placed through a hole or cavity 201 in a substrate 200 such that the ends of the flexible sleeve 101 and flexible strand 102 remain outside of the hole, such that when compressed, a middle portion of the flexible sleeve 101 and flexible strand 102 that is within the hole or cavity 201 is compressed in at least one dimension to anchor the knotless anchor within the hole or cavity 201. The knotless anchor device 100 can be compressed when a tension is applied to one or both ends (106, 107) of the flexible strand. The knotless anchor device 100 is shown in a compressed state in Figs. 2B and 3B.

As shown in Figs. 2A-2B, the knotless anchor device 100 can be configured such that only a portion of the flexible sleeve 101 is required to be passed through a hole or cavity 201 to achieve fixation of the knotless anchor device 100 within the hole or cavity 201 upon compression of the flexible sleeve 101. In short, unlike conventional knotless anchors that

require the entire sleeve to be passed through a hole or into a cavity to secure the anchor, the knotless anchor devices provided herein only require a portion of the flexible sleeve 101 to be passed through the hole or into a cavity 201 to secure the knotless anchor device 100 upon compression of the flexible sleeve 101. It will be understood that upon adding tension to the flexible strand 102 (e.g. by pulling the end(s) of the flexible strand 102) such that at least the folded end 105 and the middle portion of the flexible sleeve 101 that is within the hole or cavity 201 can become compressed. In some embodiments, the ends of the flexible sleeve 101 with the openings 103, 104 that are outside of the hole or cavity 201 can be in a compressed or uncompressed state after tension is applied to the flexible strand 102.

Tension can be applied to the flexible strand 102 using fingers, pliers, forceps, or other device as needed. The end(s) 106,107 of the flexible strand 102 can be pulled in the opposite direction from which the knotless anchor device 100 was inserted into the hole. The end(s) 106,107 of the flexible strand 102 can be secured to maintain compression of the flexible sleeve 101 once the tension is removed from the end(s) 106,107 of the flexible strand 101. The end(s) 106,107 of the flexible strand 102 can be secured, for example, via a cinching device (ring or otherwise), rubber band, by tying in a knot or suture with the flexible strand end(s) 106, 107, or by securing with a knotless tulip head or system as described elsewhere herein. Other methods to secure the end(s) 106, 107 of the flexible strands 102 will be appreciated by those of skill in the art.

As discussed above, the flexible sleeve 101 can be configured such that when the knotless anchor device 100 is in a compressed state, the knotless anchor device is fixed within the hole or cavity 201. The knotless anchor device 100 can be removed from the hole by removing compression of the flexible sleeve 101. In some embodiments, for example, this can be accomplished by pushing the sleeve further into the hole or cavity 201 and pulling one side of the flexible strand 102 and/or flexible sleeve 101 at the same time.

With embodiments of the knotless anchor device in mind, attention is directed to Figs. 8A-13, which discuss features and embodiments of a knotless tulip head and system that can be used with a knotless anchor device described herein. Discussion of the knotless tulip head and system begins with Figs. 8A-8C, show current pedicle devices and their use in fixation procedures. The pedicle screw 800 (or hook 804) is driven into the vertebra 807. The poly-axial tulip head (801) can receive a fixation rod (806) that secures more than one vertebrae 807 in place. The fixation rod 806 is held firmly in place by a set-screw (803). Typically, spinal fixation hardware consists of a pedicle screw 800 (or hook 804) that is implanted within drill hole made in the vertebral pedicle. Attached to the pedicle screw can have a screw portion 802 and a tulip head 801, which can rotate (about the long axis (dotted line, Fig. 8A of the pedicle screw 800) and/or change its angular relation with the long axis of the screw portion 802.

As previously mentioned, in some instances a pedicle screw (or hook) cannot be used or is otherwise undesirable. Further for at least spinal fixation procedures, the use of pedicle screws or hooks require that they be placed in the vertebral pedicle into the spinal channel, which places the pedicle screws/hooks precariously close to the spinal column. As such, there is significant risk in using pedicle screws (or hooks) and complications (including damage to the spinal column and/or other nerves). In some instances to avoid the risk, practitioners will forgo the use of pedicle screws (or hooks) in some of the vertebrae, which can reduce the chance of a successful spinal fixation or resort to inferior non-pedicle procedures.

The knotless anchor devices, tulip heads, and systems thereof described herein do not require the use of pedicle screws (or hooks). The knotless anchor devices have been previously described in greater detail. Attention is now turned to knotless tulip heads that are configured to receive one or more ends of the flexible strands of the knotless anchor devices described herein. In this way the knotless tulip heads described herein can be used in with a knotless anchor device provided herein and are suited for fixation procedures where use of a pedicle screws (or hooks) is undesirable.

With this in mind, attention is directed to Figs. 9-13, which show embodiments of a knotless tulip head 901 and systems 900 and their use with knotless anchor devices described elsewhere herein. As shown in Figs. 9-10, the knotless tulip head can have one or more channels 906a,b (collectively 906) that extend through the body portion of the knotless tulip head 901. The channels 906 can have one or more openings on one or more external surface(s) of the body portion of the knotless tulip head 901. Where the channels have more than one opening, the openings of the channel(s) 906 can be on the same or different surfaces. The channels 906 can be configured to receive a flexible strand of the knotless anchors described herein. The knotless tulip head 901 can be configured to receive a compression screw 903 and a compression ring 904. The knotless tulip head 901 can be configured to contain a space 905 to receive a fixation rod and set screw. The knotless tulip head 901 can contain any number of other holes in addition to those already discussed. The compression ring 904 can contain one or more prongs 907a,b (collectively 907) extending from a surface of the compression ring 904.

In operation, as shown in Fig. 11, the end of the flexible strand 102 can be passed through the channel(s) 906 of the knotless tulip head 901 shown in Figs. 9-10. The compression screw 903 and compression ring 904 can be coupled to the knotless tulip head 901 by inserting the compression ring 903 into the space 905 configured to receive a fixation rod and into the base portion 908 of the knotless tulip head 901. The compression ring 904 can contain one or more prongs 907. In other embodiments, a compression ring 904 without prongs can be used. The knotless tulip head can be configured to receive the prong(s) 907

of the compression ring 904. The knotless tulip head 901 can be configured such that the prongs can extend into the channel(s) 906 when operatively coupled to the knotless tulip head 901. When an end of a flexible strand 102 is in the channel 906, the prong 907 of the compression ring 904 can apply a pressure to and/or penetrate the wall of the flexible strand 102 and thus can secure the flexible strand 102 in the channel 906 by preventing the flexible strand 102 from sliding out of the channel 906. In some embodiments, the prong(s) 907 can act as a ratchet and allowing one way movement of the end of the flexible strand 102 through the channel(s) 906 when the compression ring 904 is coupled to the knotless tulip head 901.

The base portion 908 of the tulip head 901 can be further configured to receive the compression screw 903. The compression screw 903 can be inserted through the opening in the middle of the compression ring 904. During a procedure, the knotless tulip head 901 can be positioned in the correct location, and the practitioner can tighten the compression screw 903 by screwing the compression screw 903 into the base portion of the tulip head 901 to secure the compression ring 904 in place in the knotless tulip head 901. This can press the compression ring against the end of the flexible strand 102 within a channel 906 of the knotless tulip head 901, which can secure the flexible strand 102 and knotless tulip head in place 901. The practitioner can alter the position of the knotless tulip head 901 by loosening the compression screw, altering the position of the knotless tulip head 901, and retightening the compression screw 903. The practitioner can rotate and/or alter the knotless tulip head's 91 angular orientation applying a tension to the flexible strand 102 located between the vertebra 807 and knotless tulip head 901.

In other embodiments, the knotless tulip head 901 does not utilize compression screw 903 or compression ring 904. As shown in Fig. 12, some embodiments, the knotless tulip head 901 can contain one or more V-cleat notches 1200 a, b (collectively, 1200). The V-cleat notches 1200 can have cleat teeth 1201 that can be configured to grab the flexible strand of a knotless anchor device described herein. The V-cleat notches 1200 can be formed in the body portion of the knotless tulip head 901. As shown in Fig. 13, in operation, the ends of the flexible strand 102 can be pulled into the V-cleat notches 1200 while pushing the knotless tulip head into position in a direction substantially perpendicular to the cleat teeth. Tension in the flexible strand 102 between the vertebra 805 (or other substrate) and knotless tulip head 901 can cause the flexible strand 102 to be wedged further into the V-cleat 1200. Adjustment of the knotless tulip head 901, even when under tension, can be achieved by pulling one or both ends of the flexible strand 901 strand away from the knotless tulip head 901 in a direction that is substantially parallel to the cleat teeth 1201. Once the tulip head is positioned correctly, the practitioner can affix the ends of the flexible strand 102 such that the knotless tulip head 901 cannot separate from the flexible strands. This can be

accomplished, for example, by knotting or otherwise securing the ends of the flexible strand 102.

In some procedures a fixation rod can be coupled to one or more of the knotless tulip heads 905. Although the knotless tulip heads 901 are described herein as being used with the knotless anchor devices 100 herein, it will be appreciated that they can be used with other knotless and/or conventional devices generally known. In other embodiments, the knotless tulip head 901 can be configured to receive a set screw and a fixation rod can be secured in the space 905 in the upper portion of the configured to receive a tulip head 901 for the fixation rod using set a screw. The knotless anchor device 100, which can be previously affixed to a bone (such as a vertebra) can be brought towards the knotless tulip head 904, which can be anchored to the fixation rod. As shown in Figs. 16-17, the knotless fixation devices, described herein can be used with clamps to secure a fixation rod, other devices, tendons, or ligaments, to the knotless fixation anchors.

This knotless anchor devices, systems and knotless tulip heads and systems can be used in a number of fixation applications, including the anchoring of devices/tissues to tendons, ligaments, and bones. With respect to spinal fixation procedures, the knotless anchor devices and systems provided herein can interface with spinal fixation implants, such as the knotless tulip heads described herein.

The knotless anchor devices can be implanted into a subject using any desirable method. In the context of a spinal fixation procedure, the knotless anchor devices provided herein can be inserted in the conventional position in the pedicle. As shown in Figs. 18A-18B, the drill hole 201 made in a pedicle of the vertebra 201 to provide a place to insert the anchor device is close to spinal nerve roots and the spinal column 1800, which can increase the risk of complications of the spinal fixation procedure. In some cases the pedicle bone is insufficient or the shape of the spine is such that the pedicle is unavailable for an anchor. In these cases the vertebra may not be able to be used as an anchor point, which can reduce the success of the procedure. Other portions of the vertebra 201 (e.g. transverse process) cannot necessarily receive a pedicle screw or hook because of insufficient bone integrity. The knotless anchor devices provided herein allow spinal fixation to occur using anchor points in the transverse process. As shown in Figs. 18C-18D, the drill holes 201 can be made in the transverse process of the vertebra 805 such that the holes and the knotless anchor device are directed away from the spinal cord 1800 and farther from the nerve roots 1800 than drill holes 201 made for using a pedicle screw in the pedicle as described in relation to Figs. 18A-18B. At least in this way the knotless device can provide an advantage over current anchor devices.

A method of implanting a fixation rod system using the knotless anchor devices provided herein in the transverse process of the vertebra is shown in Figs. 19A-19F. As

shown in Fig. 19A, the method can begin by drilling a hole in the transverse process of the vertebra. As shown in Fig. 19B, the folded end of the knotless anchor device can be inserted into the drill hole such that the flexible sleeve is partially inserted through the hole and the flexible sleeve can be compressed to secure the knotless anchor device in the hole by applying a tension to each end of the flexible strand. As shown in Fig. 19C, the ends of the flexible strand can be used to couple the knotless anchor to a knotless tulip head configured to receive a fixation rod. As shown in Fig. 19D, a fixation rod can be placed in the upper portion of the knotless tulip head and be set in the knotless tulip using a set screw. Figs. 19E-19F show different views of the fixation rod anchored to the transverse process of the vertebra using a knotless anchor and knotless tulip head as shown in Fig. 19D. Insofar as this method anchors the fixation rod to the transverse process, the procedure can be less risky because the drill hole is placed farther away from the nerve roots and spinal column and can offer an alternative anchor point when a conventional pedicle anchor point is otherwise unavailable.

EXAMPLES

Now having described the embodiments of the present disclosure, in general, the following Examples describe some additional embodiments of the present disclosure. While embodiments of the present disclosure are described in connection with the following examples and the corresponding text and figures, there is no intent to limit embodiments of the present disclosure to this description. On the contrary, the intent is to cover all alternatives, modifications, and equivalents included within the spirit and scope of embodiments of the present disclosure.

Example 1

Figs. 3A-3B show photographs demonstrating an embodiment of the knotless anchor device in operation before (Fig. 3A) and after (Fig. 3B) flexible sleeve compression as discussed in relation, for example, to Figs. 2A and 2B. Fig. 3A shows the knotless anchor device in an uncompressed state. Fig. 3B shows the knotless anchor device in a compressed state after the ends of the flexible strand were pulled. Fig. 4 shows a table showing example materials and their characteristics suitable for use in the knotless anchor devices provided herein. Some of these materials were used in the construction of the device shown in Figs. 3A-3B. A relationship between holding the power of the knotless fixation device and diameter of the hole in the substrate, the diameter of the flexible strand, and diameter of the flexible sleeve was observed as demonstrated by the results demonstrated in Figs. 4-6.

To further test the holding power of the knotless anchor device, tensile testing was performed on polyester braided line (control, 135 lb (600 N) test) and the flexible strand within an embodiment of a flexible sleeve in a replica of the transverse process of T12 vertebra (4th generation biomechanical composite bone #3429-12, Pacific Research Laboratories) using the following procedure. First, holes approximately 9/64" (3.57 mm) in diameter were drilled thru the transverse process and a folded end of the knotless fixation device (flexible strand operatively coupled to the flexible sleeve) partially thru the hole. The folded end extended approximately 8 mm through the other side of the hole before being compressed. The total length of the flexible sleeve was about 16 mm. Next, the vertebrae was affixed into an aluminum channel using bone cement while making sure the flexible strand is vertical.

The knotless anchor device was then compressed by grasping the flexible sleeve with fingers and pulling the flexible strand with moderate force to compress the flexible sleeve into a ball-like shape around the hole (Fig. 3B). The ends of the flexible strand were then secured around a test piece using a double fisherman's knot. The control flexible strand (which was braided polyester secured to a test piece using a double fisherman's knot). The control flexible strand was 135 lbs (600 N) test. The knot was not allowed to 'sit' over the testing apparatus and the knot was kept between the sample and the pulling end. The tensile/pull out strength was tested. The flexible strands were kept parallel to the pulling direction (or direction that the strain/tension was applied). The strain at 5 mm/min was tested, The results of the strain test are demonstrated in Fig. 7. No difference in tensile strength between the control and experimental set-up was observed. This experiment shows there was no difference in the holding power of the knotless anchor compared to the flexible strand control.

Example 2

The anatomical interference when inserting a knotless anchor device as provided herein into a transverse process (thoracic region) of a vertebra using a SawBone spine model was evaluated. The procedure and results are demonstrated in Figs. 20-24. As shown in Figs. 20-24, the strings highlighted by the solid circles were not part of the knotless anchor device but were to hold the ribs of the SawBone spine model in place. The knotless anchor device tested was composed of (0.0625" (1.59 mm) diameter Goldblatt G06995 mason's line, 135 lbs (600 N) test (the flexible strand) that was threaded through 1.75" (44.5 mm) length of Atkins & Pearce sample 16-840 (flexible sleeve).

A Ø4.0 mm hole was drilled and the folded end of the knotless anchor device was pushed into the hole. The length of the flexible sleeve was about 3" (7.6 cm) to allow the knotless anchor device to be inserted deep into the hole and yet allowing the ends to remain

on the posterior face of the transverse process. The knotless anchor device was folded and inserted through the drill hole in the transverse process (Fig. 20).

A couple of methods to secure the knotless anchor device into the drill hole were tried. As shown in Fig. 21, in one method, one end of the flexible sleeve was held stationary using a curved hemostat while the flexible strand was pulled on to apply tension to compress the flexible sleeve within the hole, followed by holding the other end of the flexible sleeve stationary and applying tension to the other flexible strand. As shown in Fig. 21, in, both ends of the flexible sleeve were grasped while simultaneously pulling on both ends of the flexible strand. This produced compression and formation of a knot-like ball.

As shown in Fig. 23, the test was repeated using both methods to secure the knotless anchor device using mason's line having a diameter of about 0.0468" (1.19 mm) as the flexible strand. The knotless device that included the smaller diameter flexible strand was easier to insert into the Ø4.0 mm drill hole and produced comparable holding power to the knotless device having the larger diameter flexible strand (Figs. 20-22).

For the tests described above, as demonstrated in Fig. 23, the holding power was estimated by tying the loose ends of the flexible strand around a force gauge and pulling the flexible strand in line with the hole on the other end of the force gauge. The larger diameter flexible strand was pulled out of the drill hole at about 47 lbf (209 N). The smaller diameter flexible strand tested was pulled out at about 43 lbf (191 N). As a comparison, a pedicle screw was inserted into the SawBone spinal model and a force of about 55lbf (245 N) was applied without pulling the pedicle screw out from the bone.

No anatomical interference in placing the knotless anchor device in the transverse process were observed. Further the angle of drilling the hole in the transverse process (as opposed to drilling into the pedicle) can decrease the risk of complication of such spinal fixation procedures as the hole is further away from the nerve root and spinal column. Though the holding power of the knotless anchor devices tested were less than that of a typical pedicle screw, the holding power of the knotless anchor devices tested should be sufficient as they produced a pull out force in the range of 40-50 lbf, (178- 222 N) particularly for those procedures where the knotless anchor device is further connected to a rod with other conventional anchors used at other points.

We claim:

1. A knotless anchor device comprising:
a flexible sleeve having a middle portion;
a flexible strand having two ends, and
where the knotless anchor device is configured such that it does not require the entire flexible sleeve to be inserted in a hole or cavity to achieve fixation of the knotless anchor device within the hole or cavity upon compression of the flexible sleeve and
where the middle portion is configured to create a folded end in a hole or cavity and further configured to compress within the hole or cavity when a tension is applied to the two ends of the flexible strand.
2. The knotless anchor device, of claim 1, wherein the flexible sleeve forms a tube having a longitudinal cavity extending the entire length of the flexible sleeve.
3. The knotless anchor device of any one of claims 1-2, wherein the flexible strand is passed through the longitudinal cavity and wherein a portion of the flexible strand extends beyond each end of the flexible sleeve.
4. The knotless anchor device of claim 1, wherein the flexible sleeve comprises a material selected from the group consisting of: polyester, polyethylene, polypropylene, polyethylene terephthalate, polyetheretherketone (PEEK), polyamide, polyimide, nylon, cotton, silk, and other suitable natural or synthetic materials.
5. The knotless anchor device of claim 4, wherein the flexible sleeve comprises filaments that are woven, braided, or twisted together.
6. The knotless anchor device of claim 1, wherein the flexible sleeve further comprises one or more directional barbs coupled to or integrated with the outside of the flexible sleeve.
7. The knotless anchor device of claim 1, wherein the flexible strand comprises a material selected from the group consisting of: polyester, polyethylene, polypropylene, polyethylene terephthalate, polyetheretherketone (PEEK), polyamide, polyimide, nylon, cotton, silk, and other suitable natural or synthetic materials.

8. The knotless anchor device of claim 1, wherein the diameter of the flexible strand ranges from about 0.5 mm to about 5 mm.

9. The knotless anchor device of claim 1 or 8, wherein the outer diameter of the flexible sleeve ranges from about 1 mm to about 7 mm.

10. A tulip head comprising:
at least two channels, where each channel is configured to receive a strand of a knotless anchor device of claim 1,
where the tulip head is further configured to receive a compression screw,
and
where the tulip head is further configured to receive a compression ring.

11. The tulip head of claim 10, wherein the channels each have at least two openings, wherein the openings are each on different surfaces of the tulip head.

12. The tulip head of claim 10, wherein the tulip head is configured to receive a fixation rod.

13. A tulip head comprising:
one or more V-cleat notches, wherein each of the V-cleat notches are present on an external surface of the tulip head, and wherein each V-cleat notch is configured to receive a flexible strand of a knotless anchor device as in claim 1.

14. The tulip head of claim 13, wherein the tulip head has at least two V-cleat notches.

15. The tulip head of claim 14, wherein the V-cleat notches are on opposing sides of the tulip head.

16. The tulip head of any one of claims 10-15, wherein the tulip head comprises a material selected from the group consisting of: stainless steel, titanium, cobalt-chrome, rigid plastics such as PEEK, HDPE, polyimide, polycarbonate, acrylonitrile-butadiene-styrene (ABS), and styrene-butadiene-styrene (SBS).

17. A method comprising:
folding the flexible sleeve of a knotless anchor device of claim 1 to create a folded end;
inserting the folded end into a hole in a substrate such that only a portion of the flexible sleeve is passed through the hole;
pulling on one or both ends of the flexible strand of the knotless anchor device as in claim 1 to compress the flexible sleeve within the hole to secure the knotless anchor device in the hole.
18. The method of claim 17, further comprising the step of fixing one or both ends of the flexible strand after compression of the sleeve.
19. The method of claim 18, wherein fixing the ends of the fixing one or both ends of the strand comprises, applying a cinch ring, tying, or passing the strand through a channel or a V-cleat notch of a tulip head according to claim 11.
20. The method of any one of claims 17-19, wherein the hole is in a bone of a subject.
21. The method of claim 20, wherein the bone is a vertebra.
22. The method of claim 21, wherein the hole is in a transverse process of the vertebra.

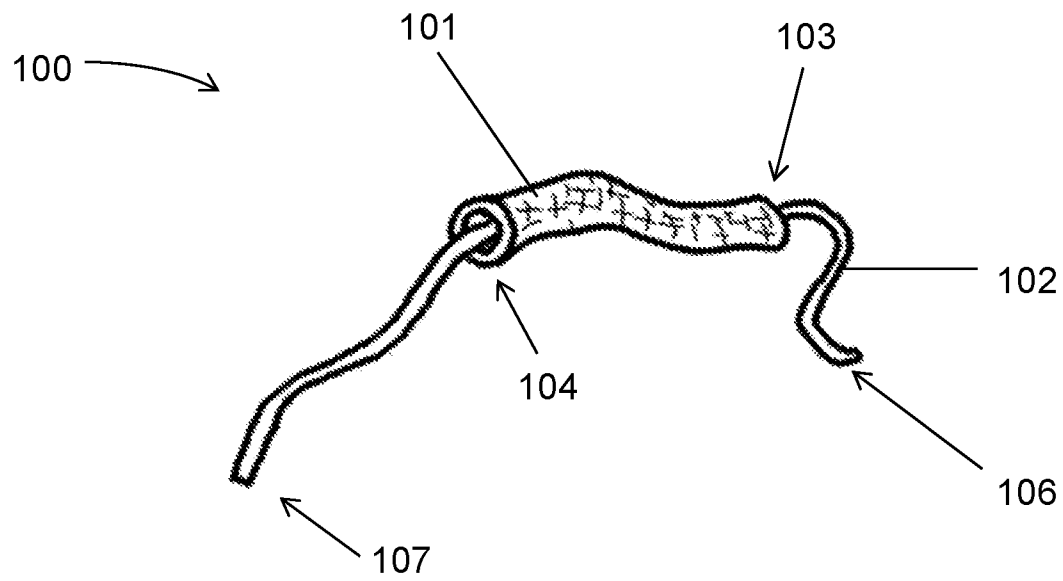


FIG. 1A

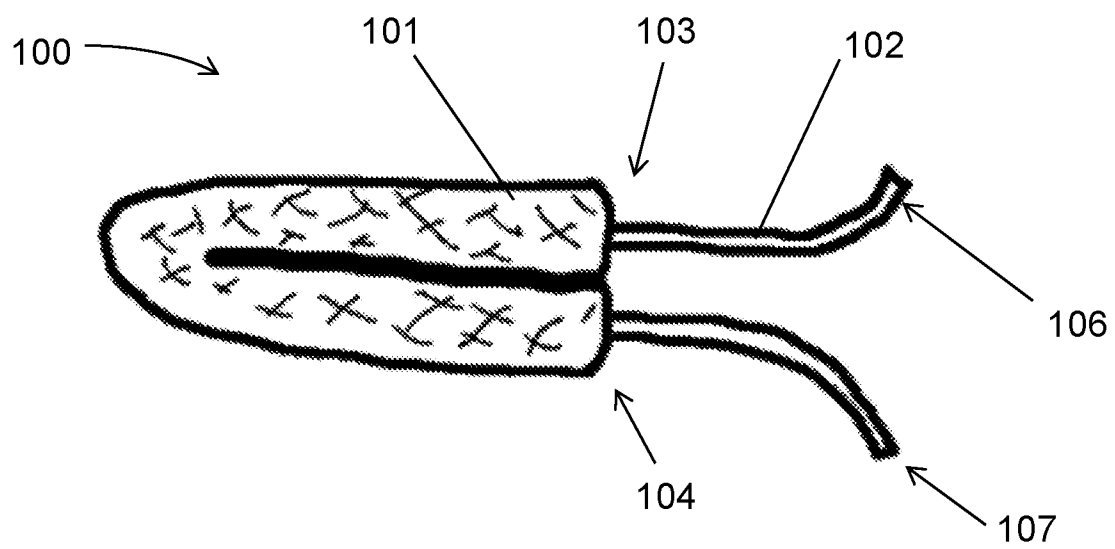


FIG. 1B

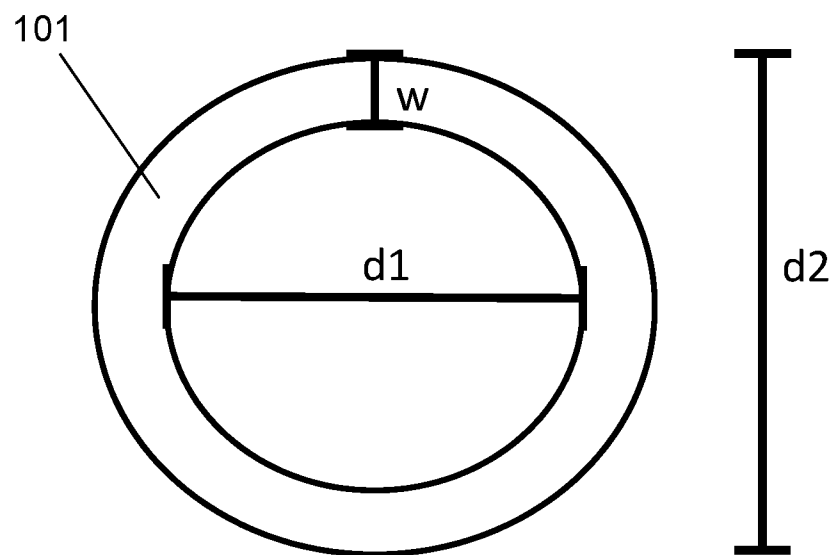


FIG. 1C

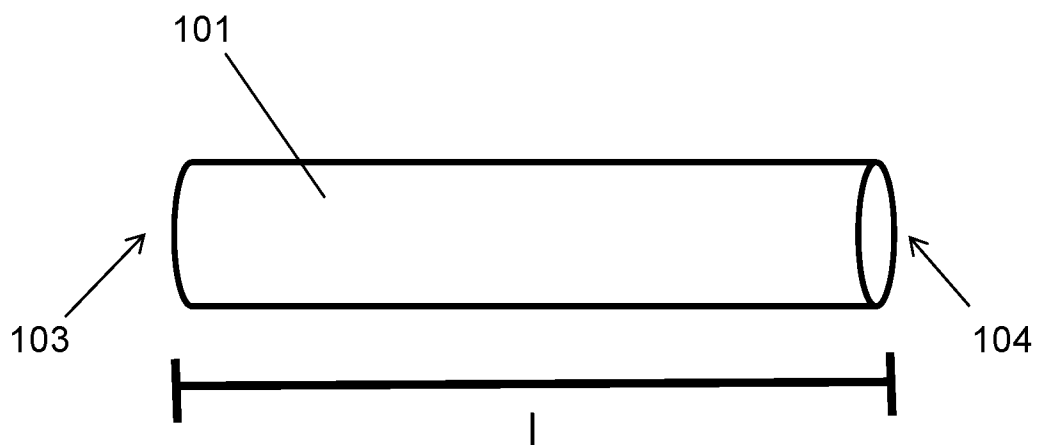


FIG. 1D

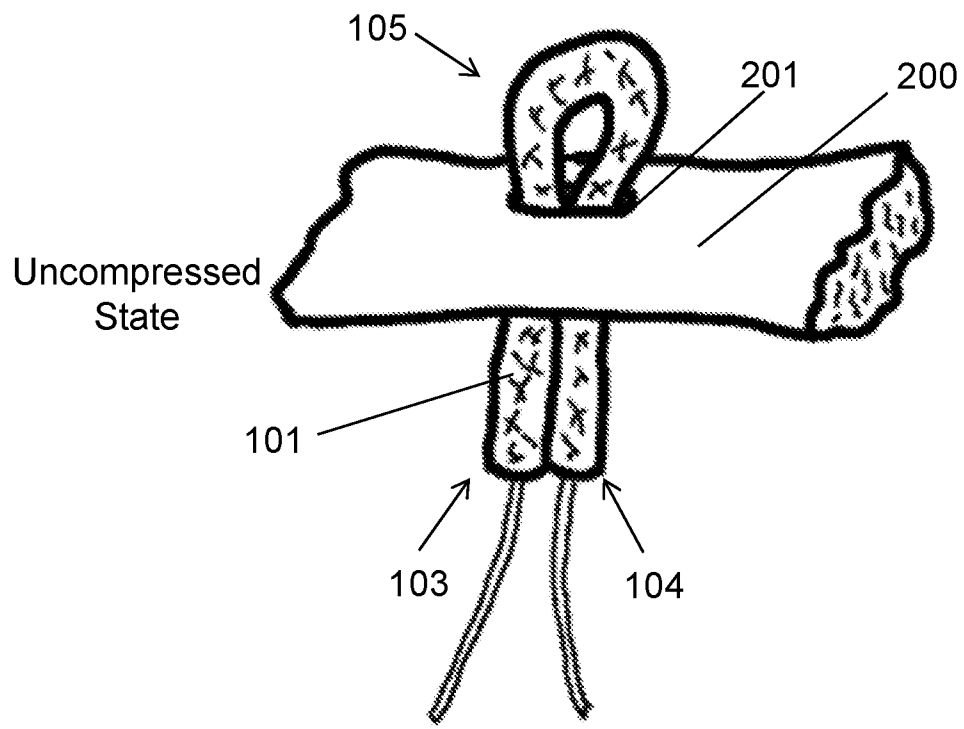


FIG. 2A

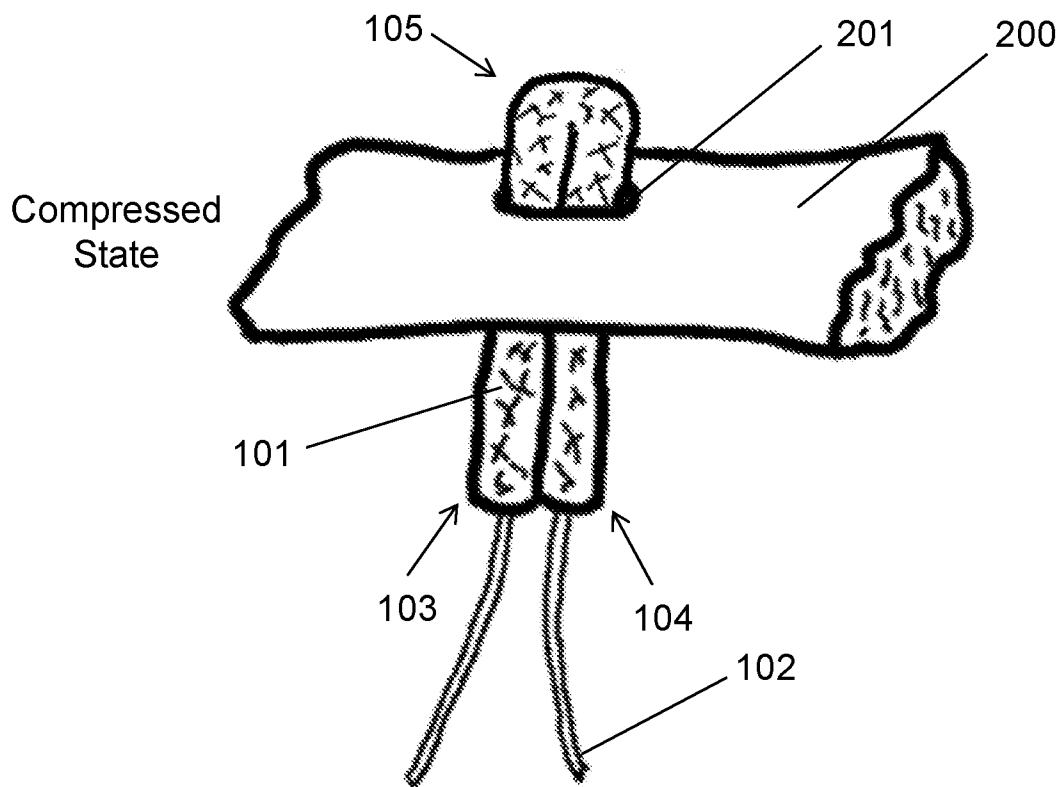
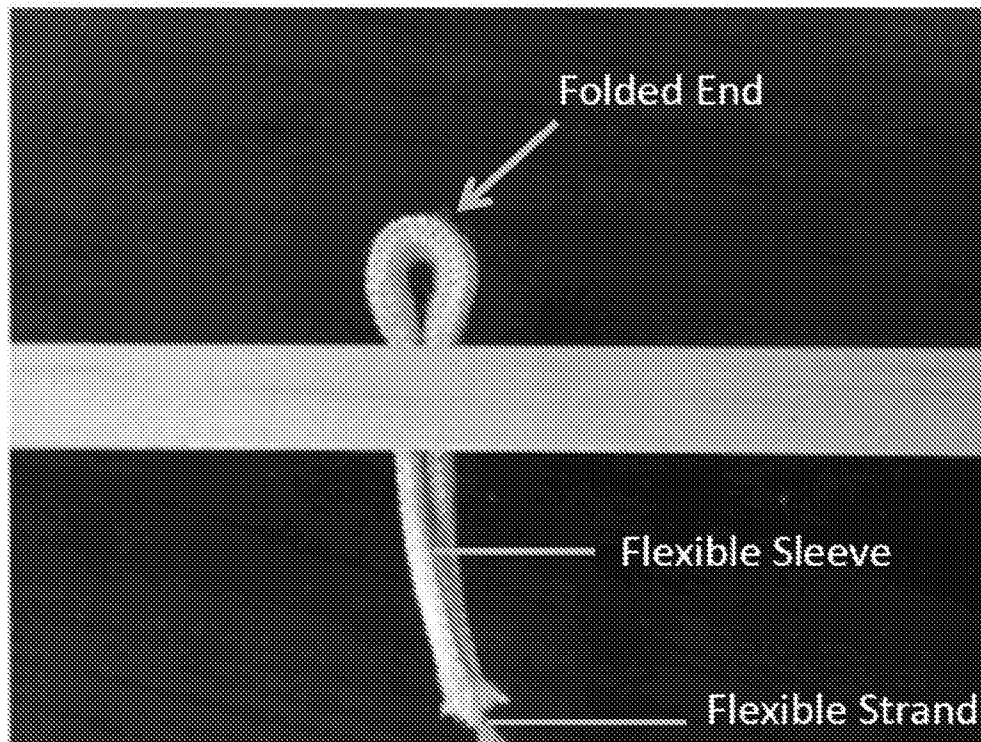
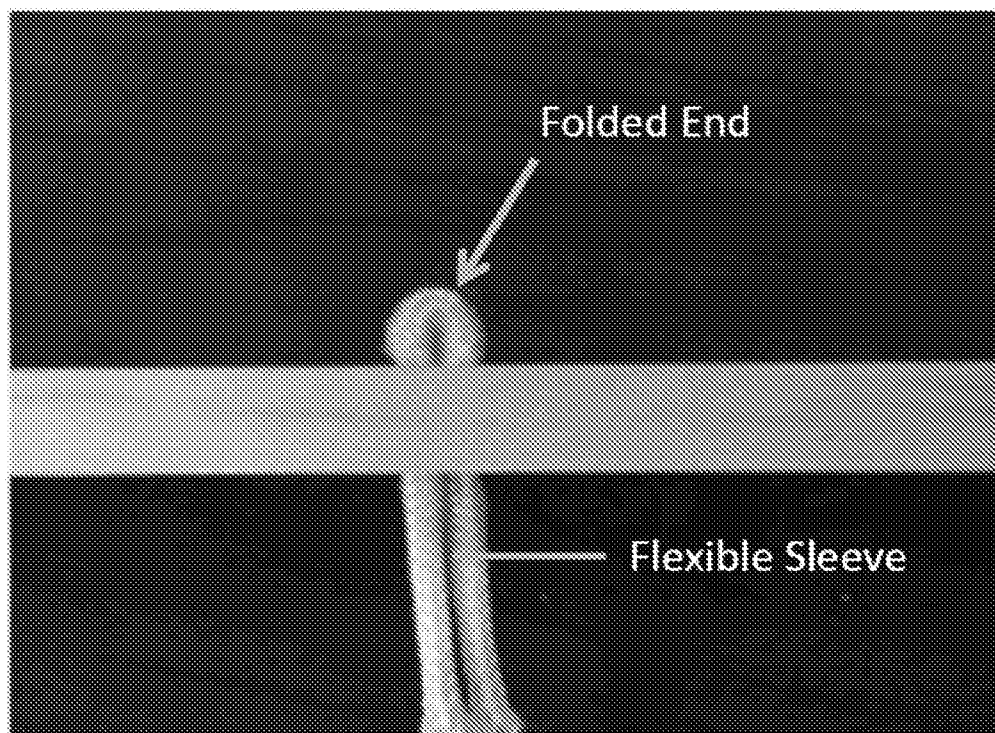


FIG. 2B



Uncompressed
State

FIG. 3A



Compressed
State

FIG. 3B

Component	Width	Composition	Description
Strand	1/16" (1.6 mm)	Polyester	Goldblatt G06995 mason's line
Grey Sleeve-3/16	3/16" (4.8 mm)	Polyester	Light grey flat braided cord with 4 longitudinal strands along center removed
Black Sleeve-2/16-3/16	1/8" - 3/6" (3.1-4.8 mm)	Polyester	Black round string with 3 longitudinal stands along center removed
White Sleeve-1/8 Round	1/8" (3.1 mm)	Polyester	White round braid with no longitudinal strands along center. Atkins & Pearce sample # 16-840
White Sleeve-1/4 Flat	1/2" (6.4 mm)	Nylon	White flat braid with no central canal. Atkins & Pearce sample # 25-660

FIG. 4

	Hole Diameter									
Individual components	1/8" (3.2 mm)	9/64" (3.6 mm)	11/64" (4.4 mm)	3/16" (4.8 mm)	13/64" (5.2 mm)	7/32" (5.6 mm)	15/64" (6.0 mm)	1/4" (6.4 mm)	5/16" (7.9 mm)	3/8" (9.5 mm)
Strand	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance
Black Sleeve-2/16-3/16	Couldn't get through	Minimal resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance
White Sleeve-1/3 Round	Minimal resistance	Minimal resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance
White Sleeve-1/4 Flat	Hole too small	Minimal resistance	Minimal resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance	No resistance

FIG. 5

	Hole Diameter									
Strand threaded through sleeve	1/8" (3.2 mm)	9/64" (3.6 mm)	11/64" (4.4 mm)	3/16" (4.8 mm)	13/64" (5.2 mm)	7/32" (5.6 mm)	15/64" (6.0 mm)	1/4" (6.4 mm)	5/16" (7.9 mm)	3/8" (9.5 mm)
Grey Sleeve-3/16	Hole too small	Hole too small	Couldn't pull through	Couldn't pull through	Couldn't pull through	Couldn't pull through	Couldn't pull through	Moderate resistance with creep	No Resistance	No Resistance
Black Sleeve-2/16-3/16	Hole too small	Needed tool to push through hole— Couldn't pull through	Couldn't pull through	Moderate resistance with creep	Moderate resistance with creep	No Resistance	No Resistance	No Resistance	No Resistance	No Resistance
White Sleeve-1/8 Round	Hole too small	Hole too small	Couldn't pull through	Couldn't pull through	Couldn't pull through	Couldn't pull through	Moderate resistance with creep	Moderate resistance with creep	No Resistance	No Resistance

FIG. 6

5mm/min Strain Rate

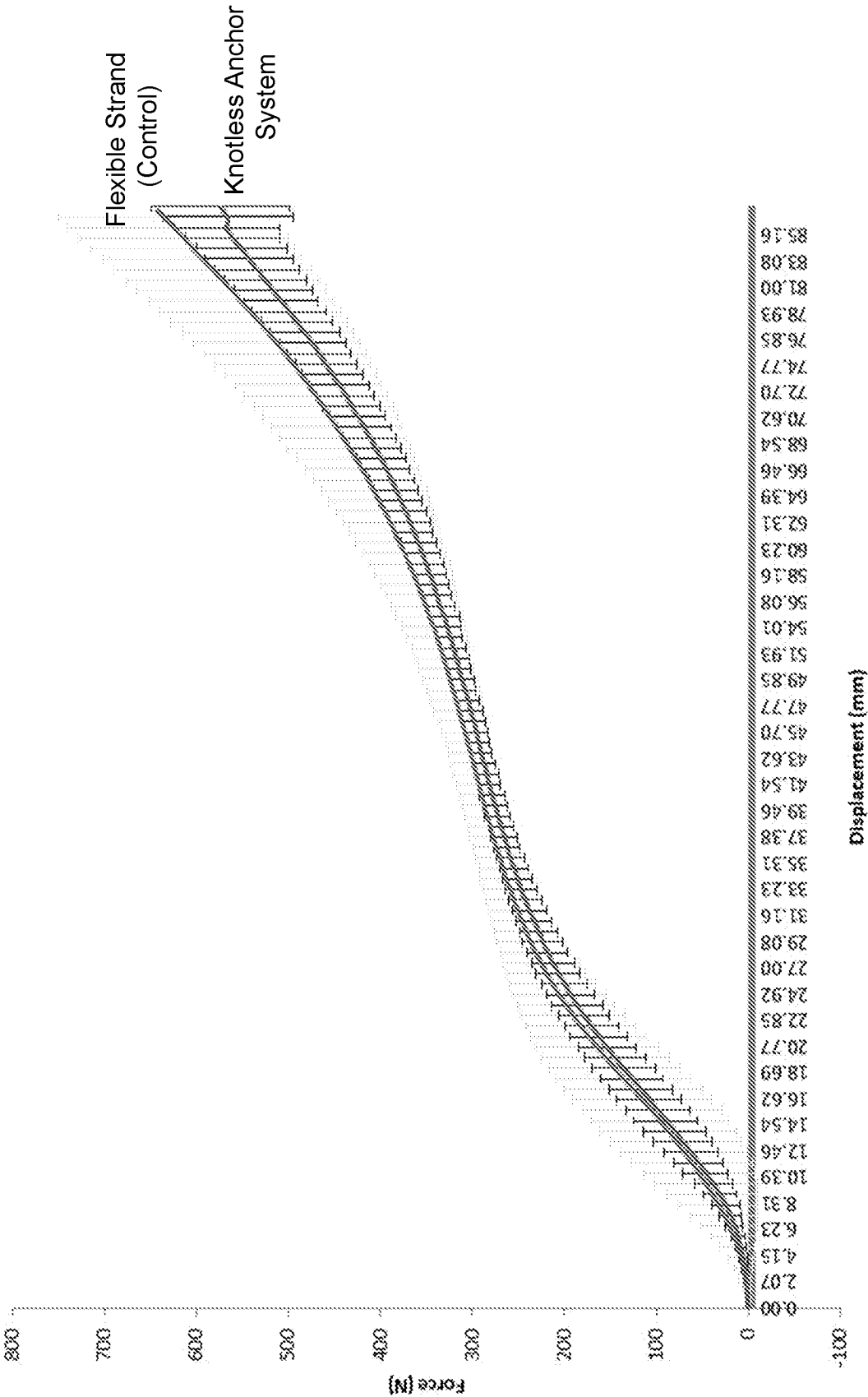


FIG. 7A

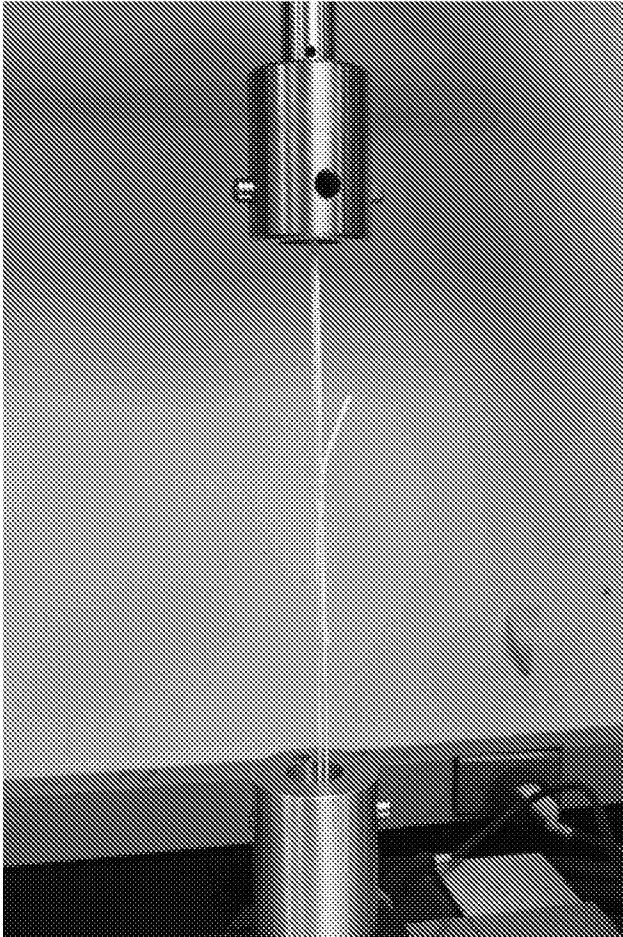


FIG. 7B

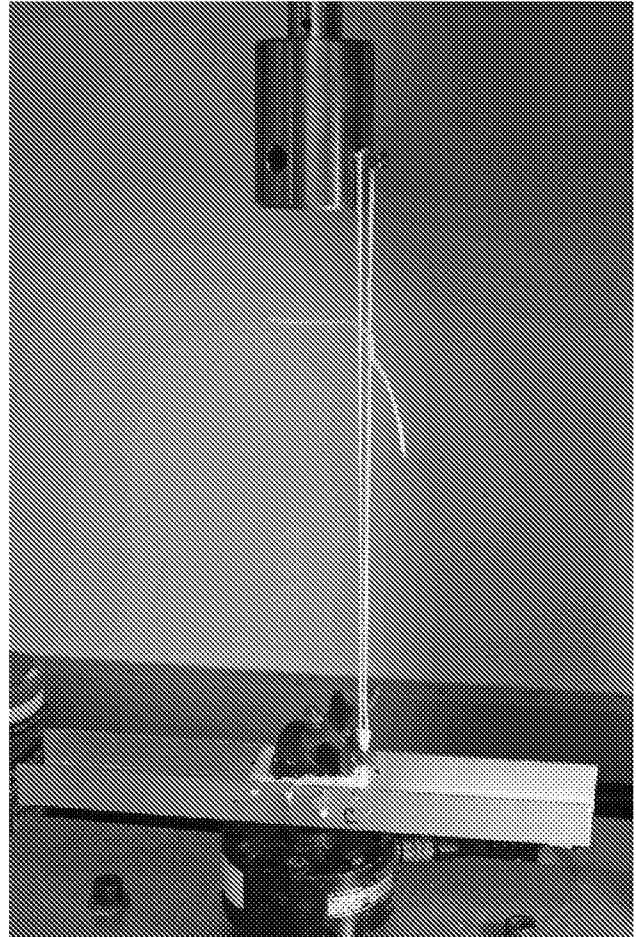


FIG. 7C

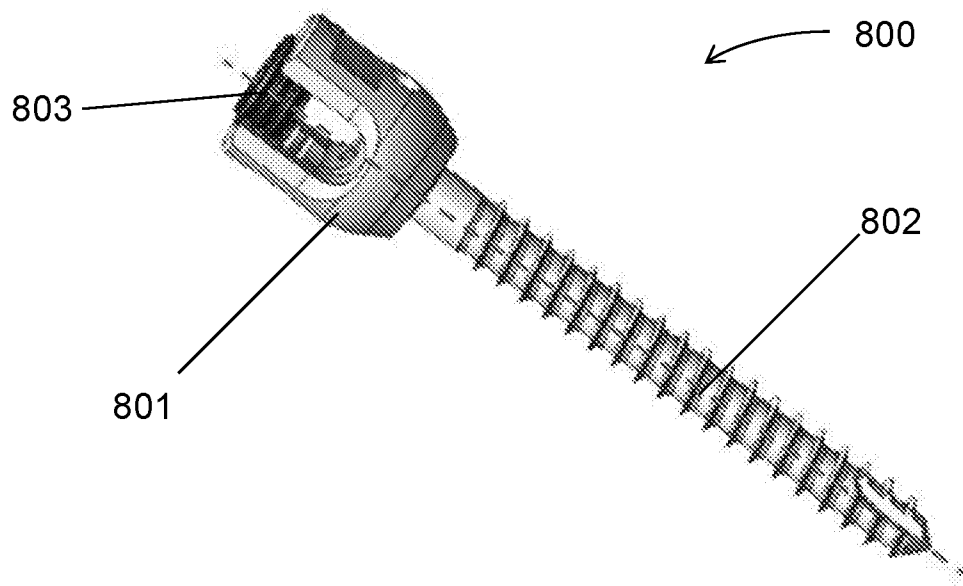


FIG. 8A

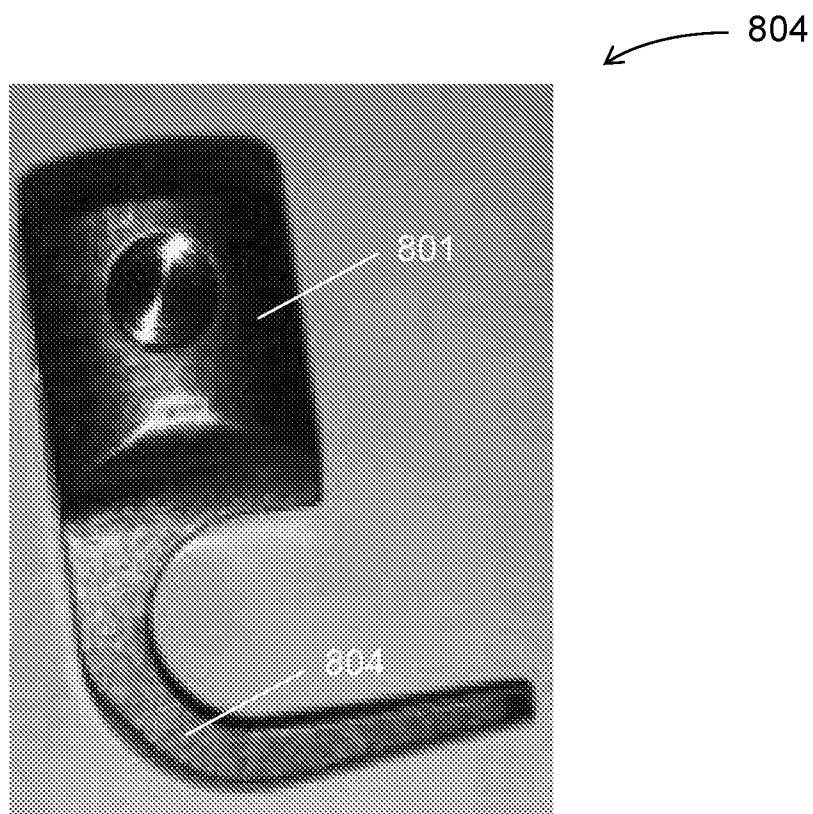
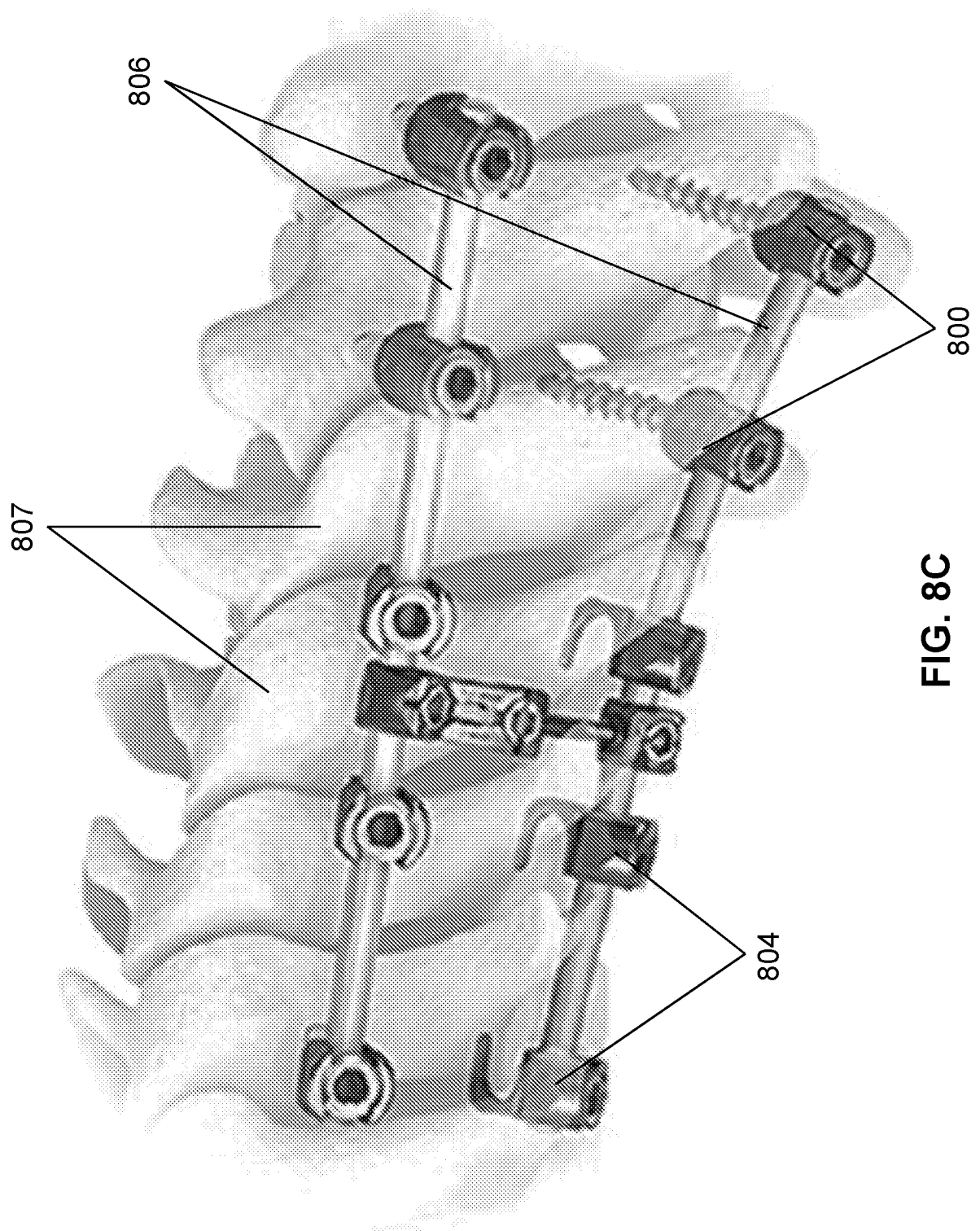


FIG. 8B



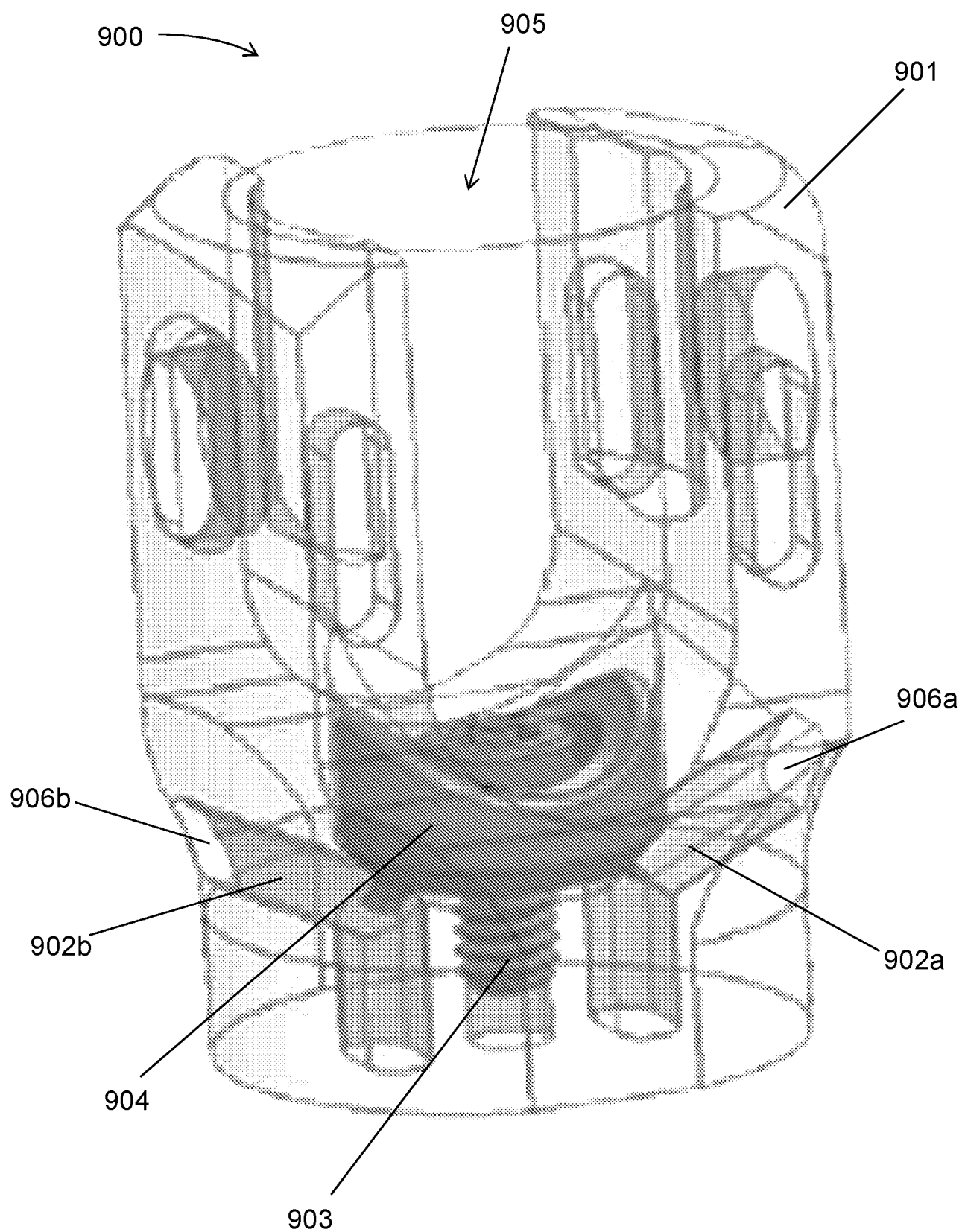


FIG. 9

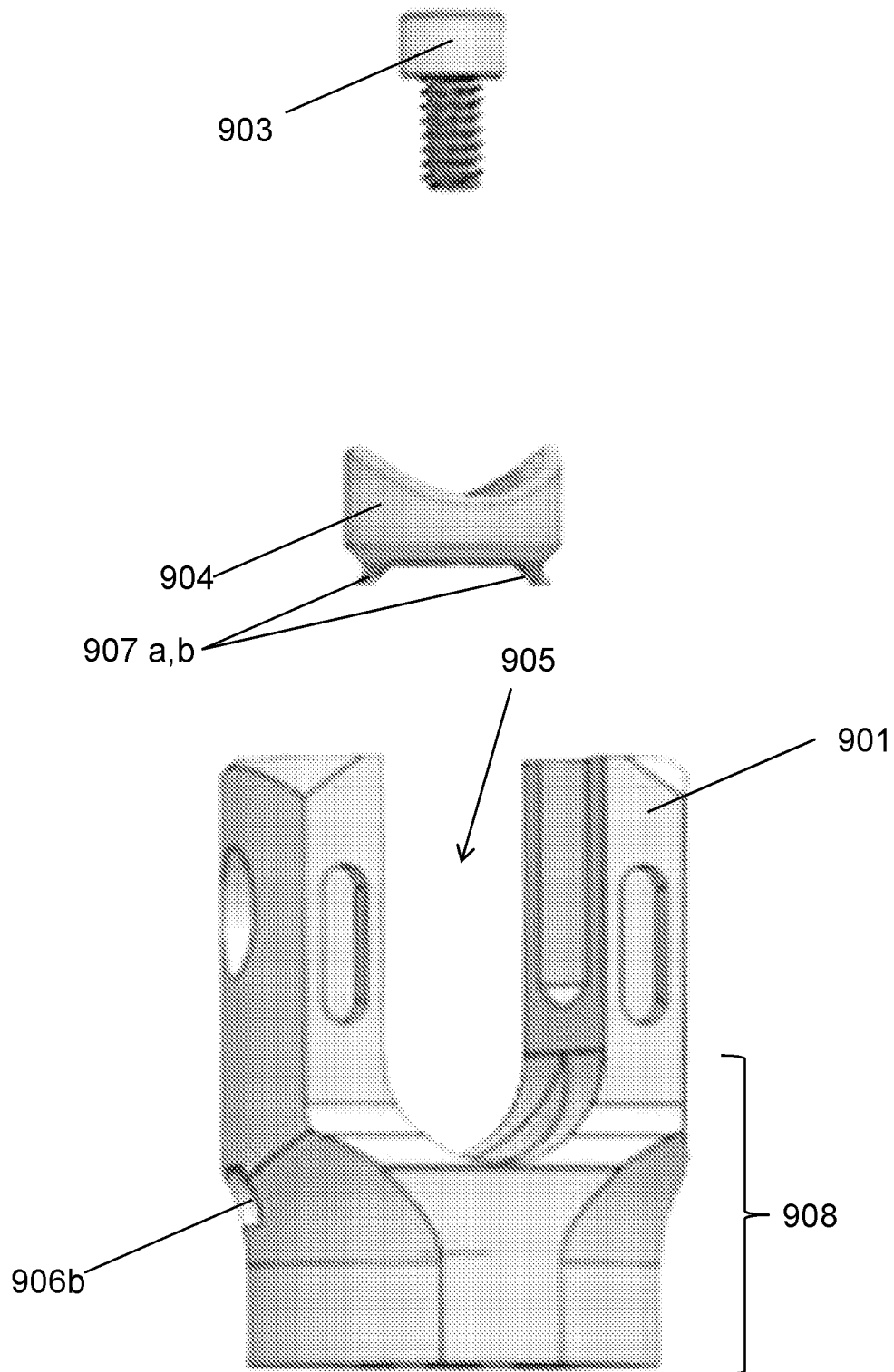


FIG. 10

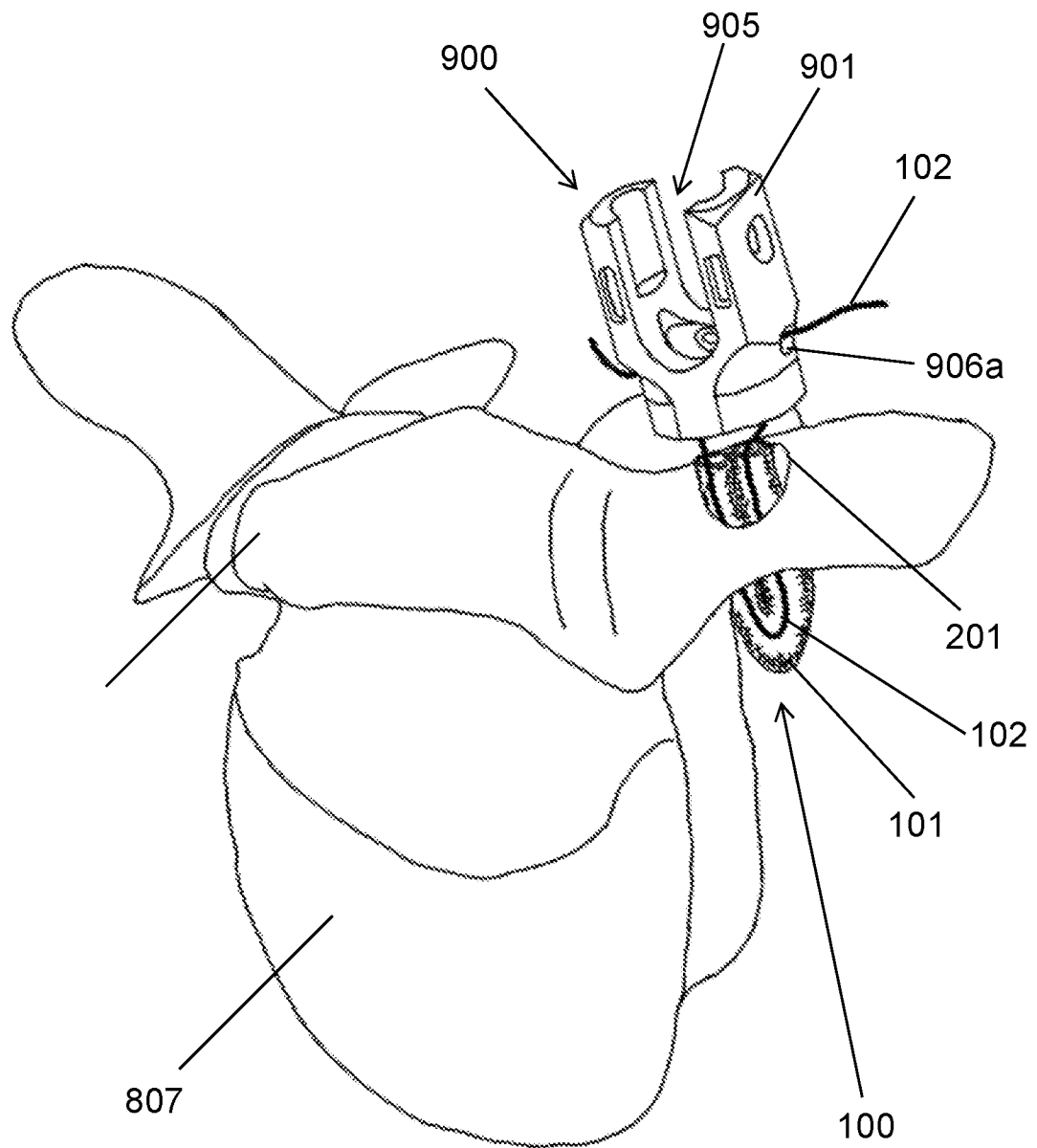


FIG. 11

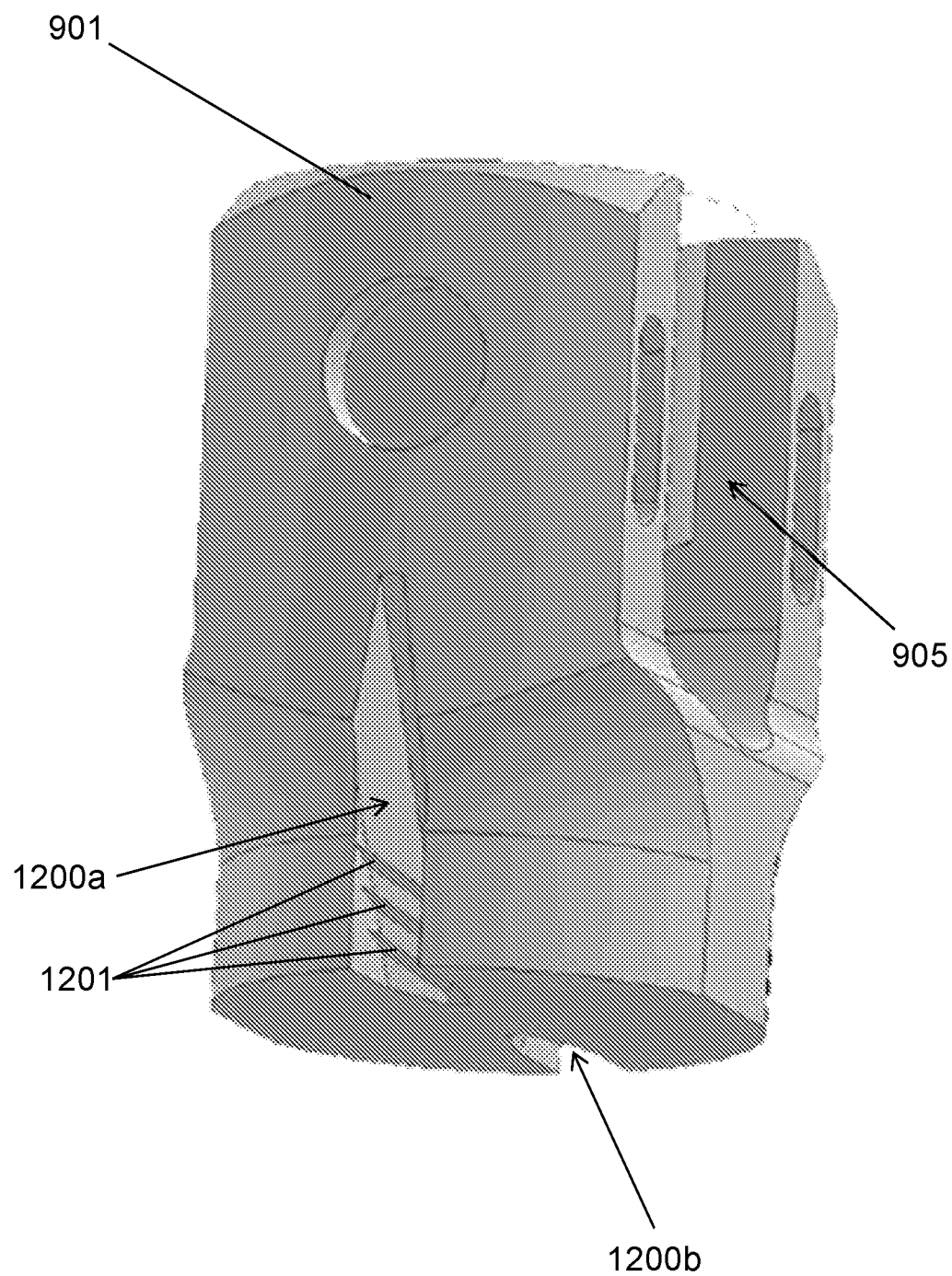


FIG. 12

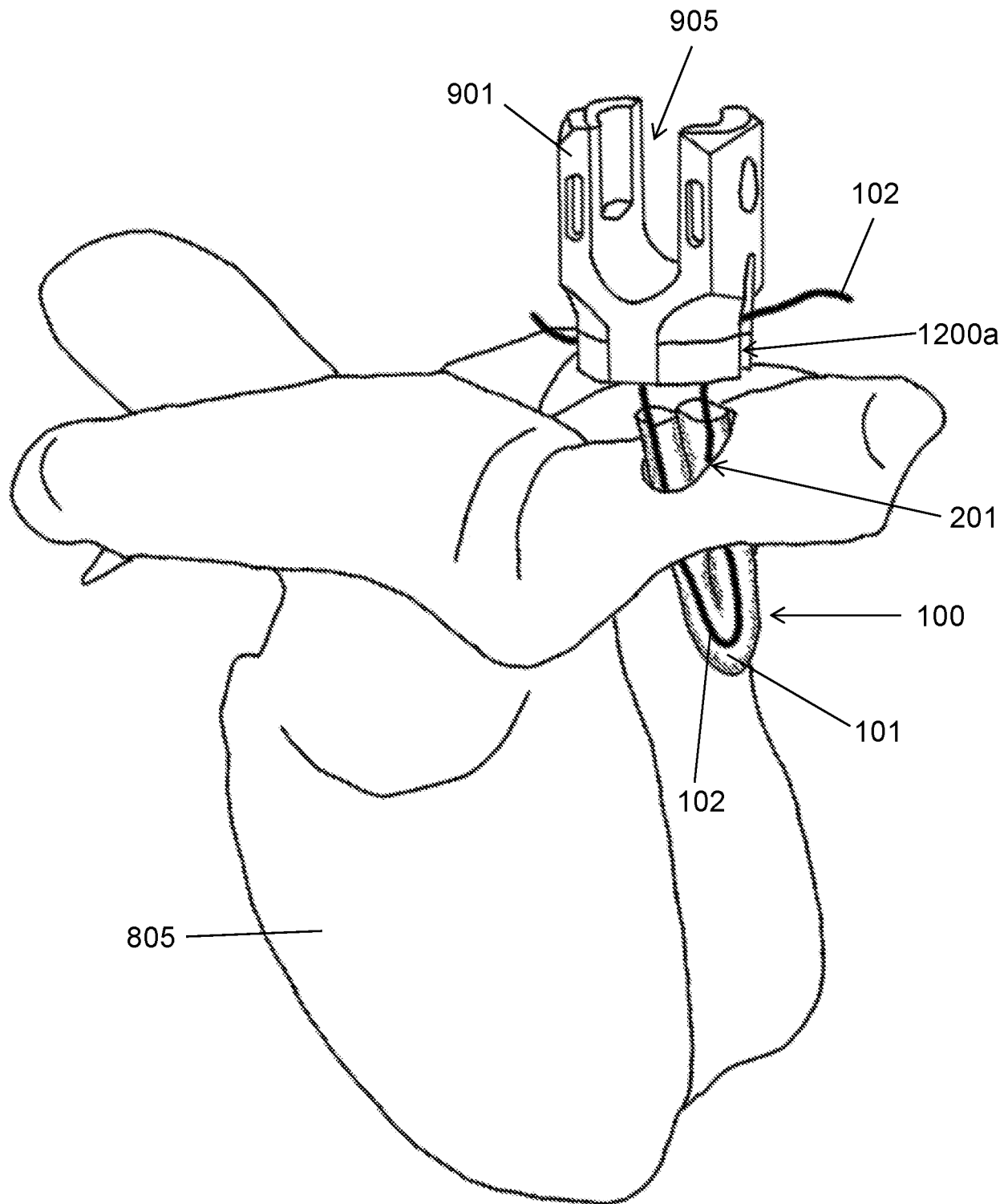


FIG. 13

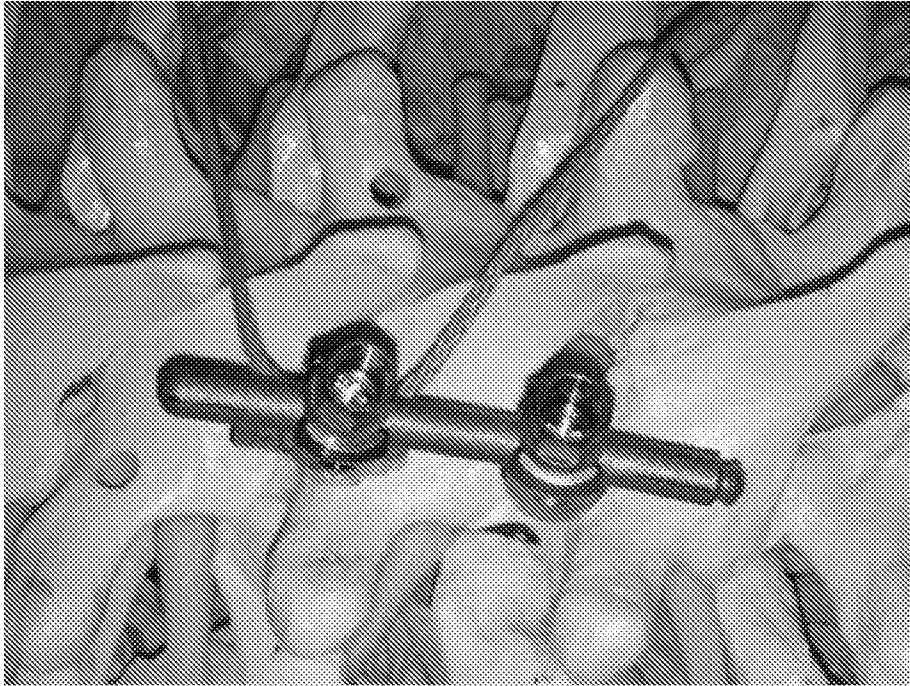


FIG. 14A



FIG. 14B



FIG. 15

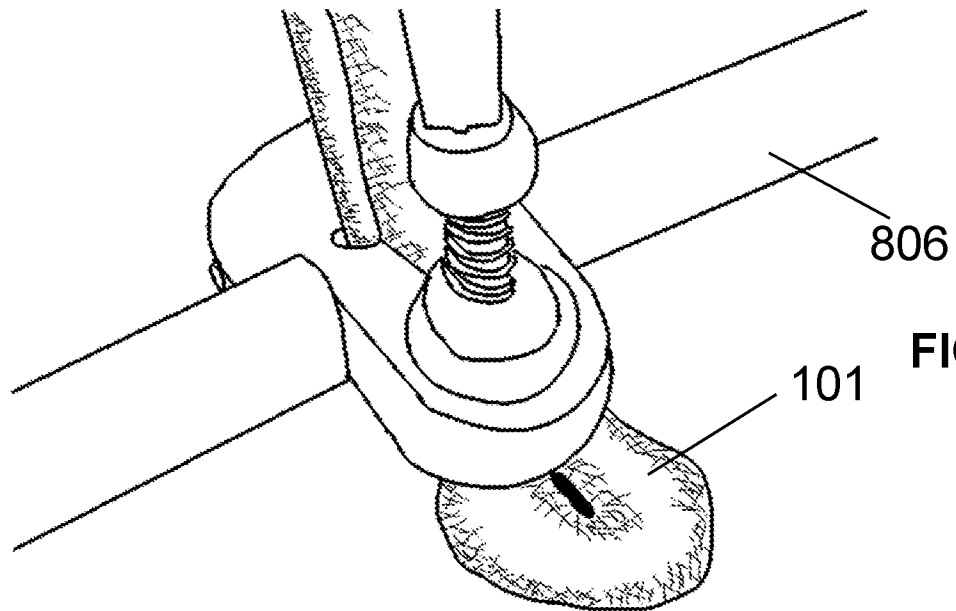


FIG. 16A

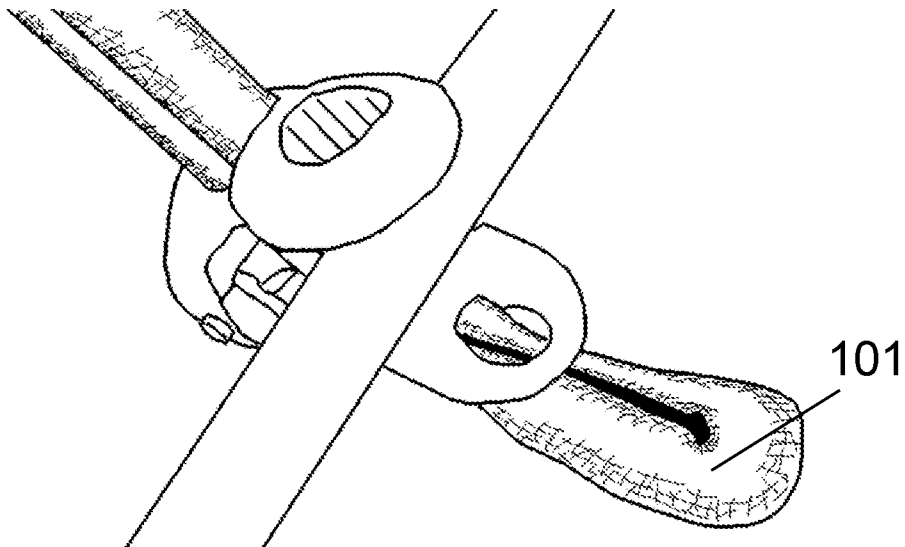


FIG. 16B

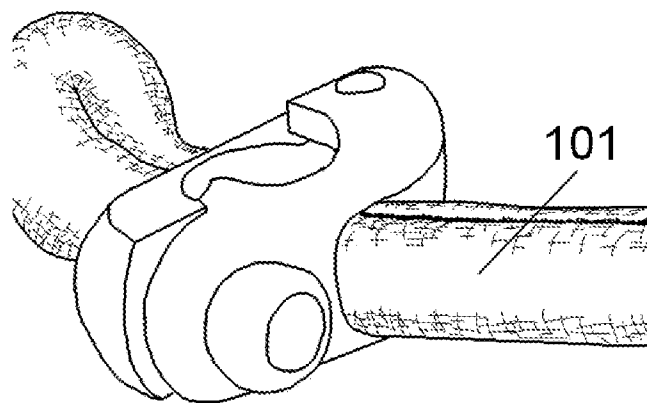
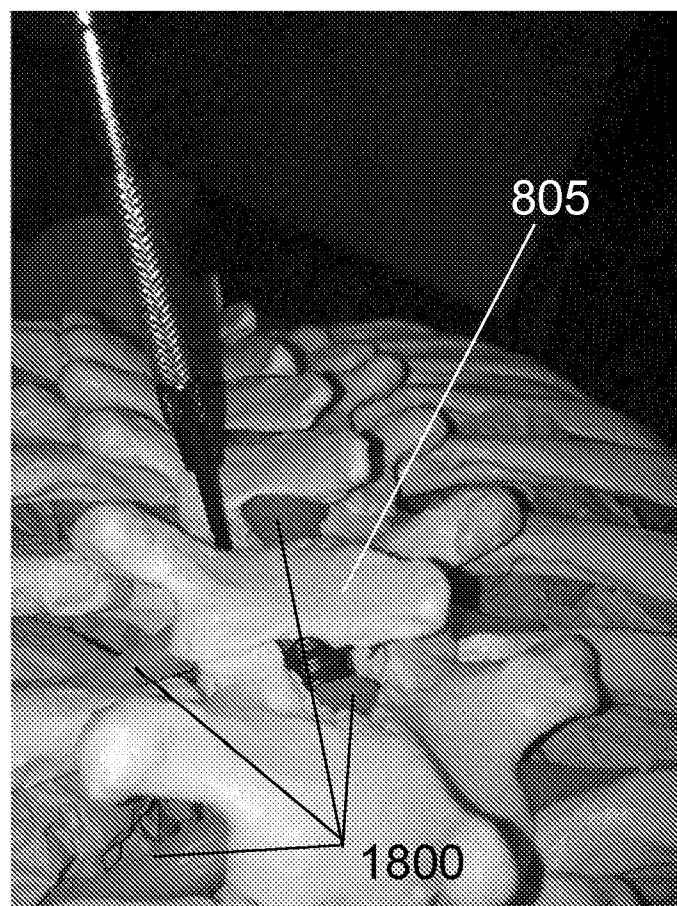
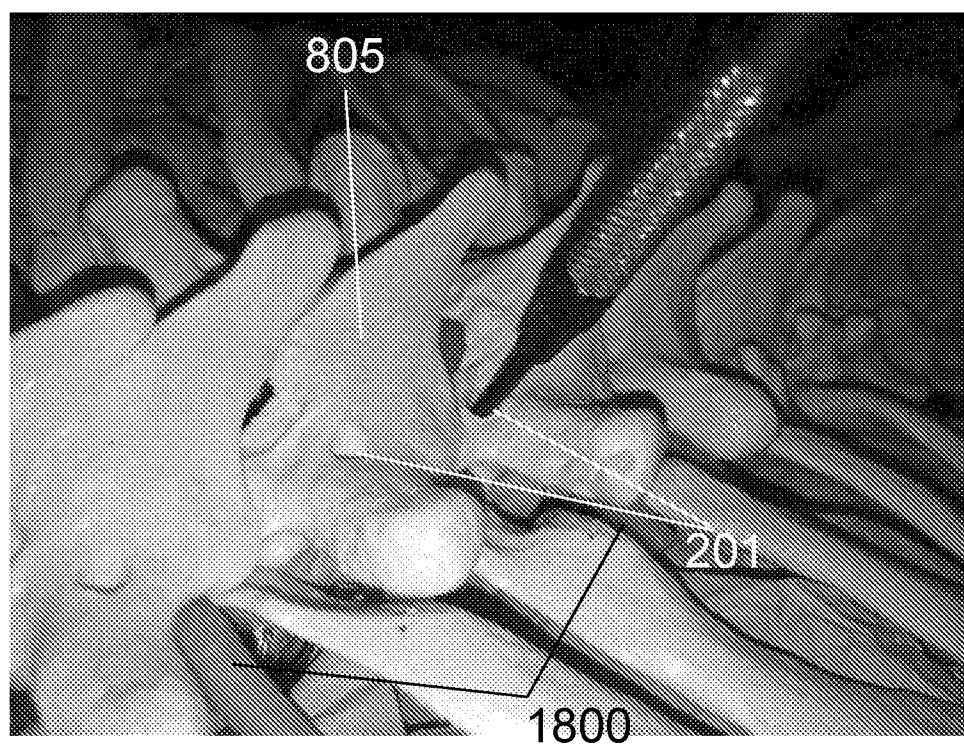


FIG. 17

**FIG. 18A****FIG. 18B**

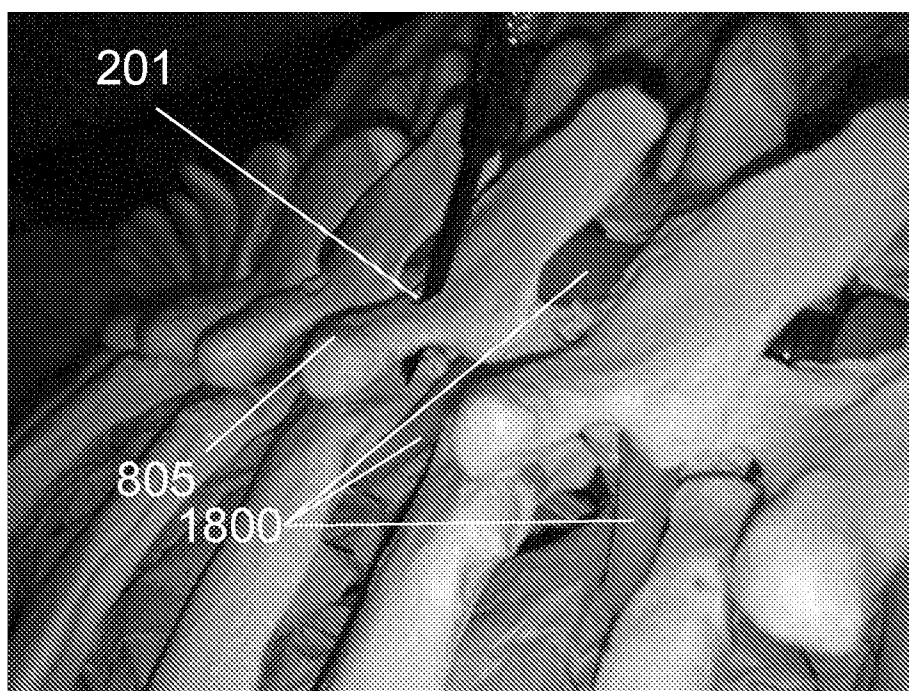


FIG. 18C

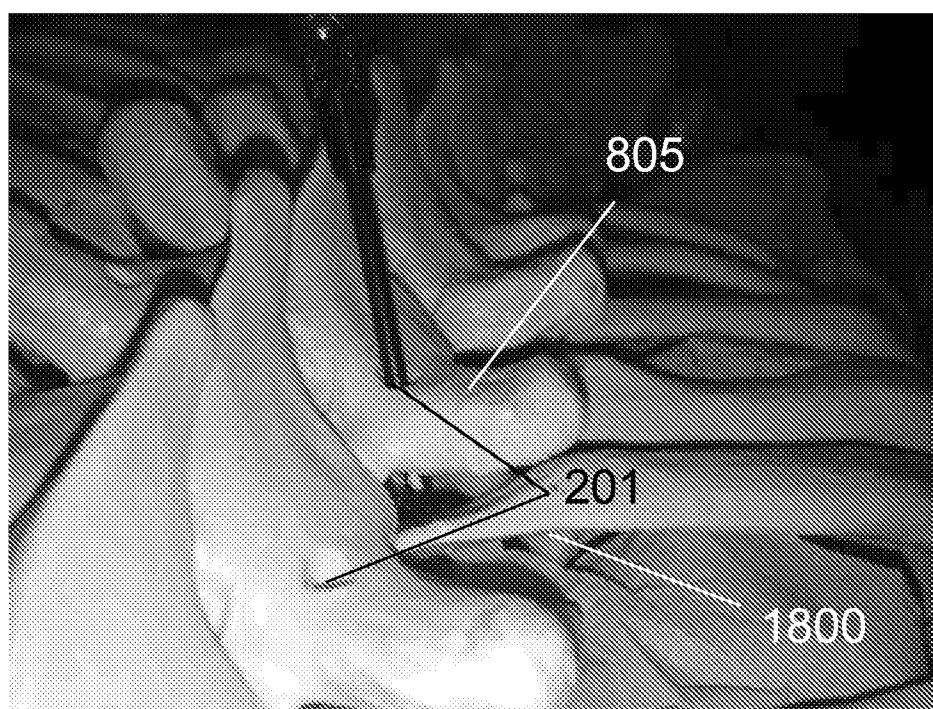


FIG. 18D

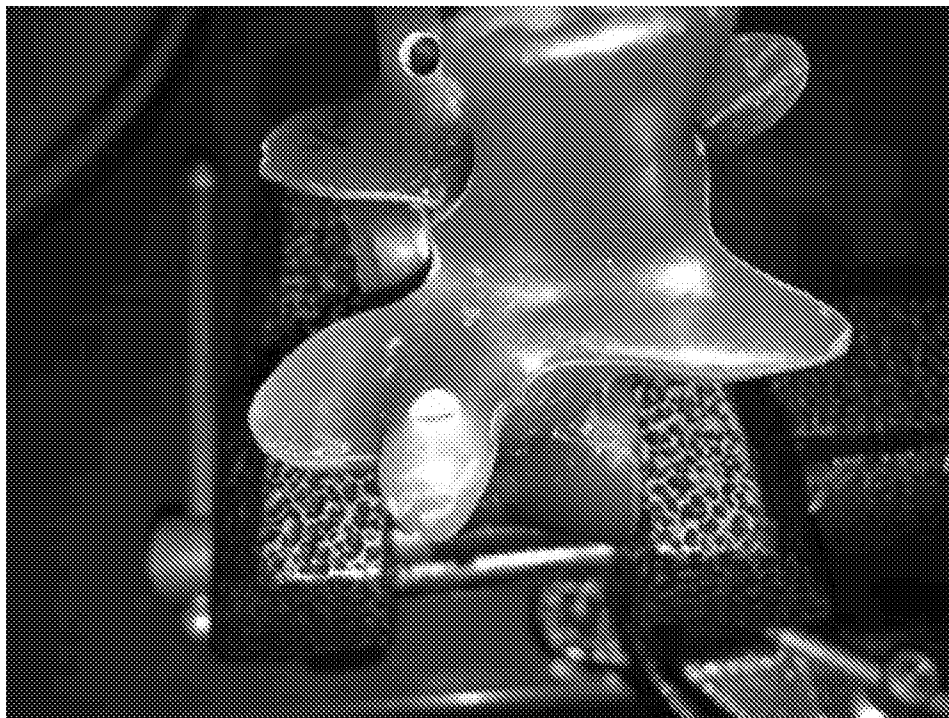


FIG. 19A

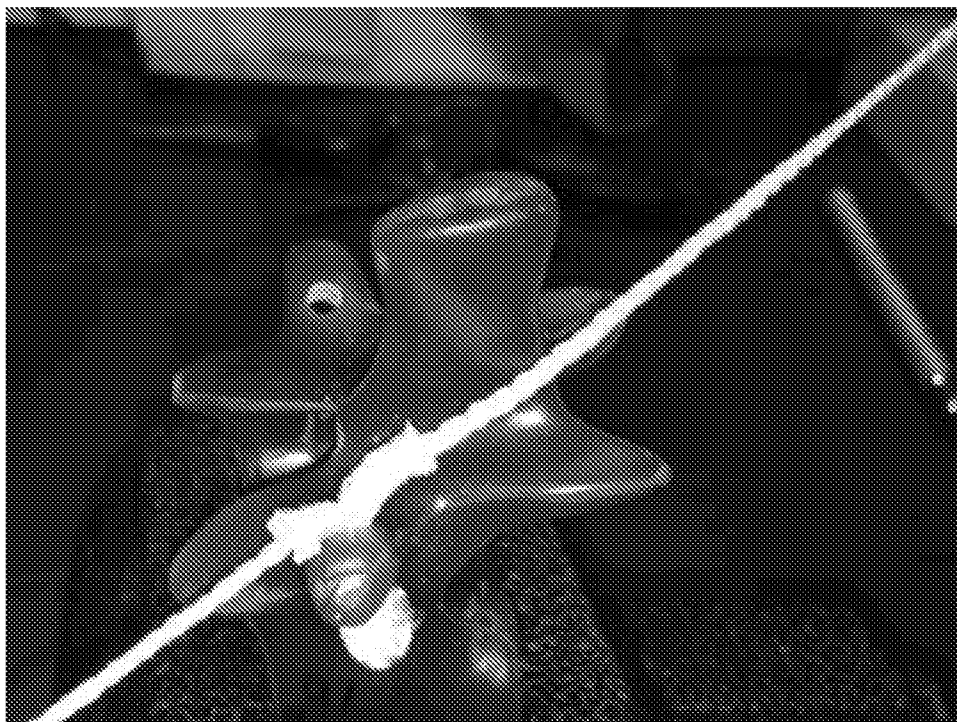


FIG. 19B

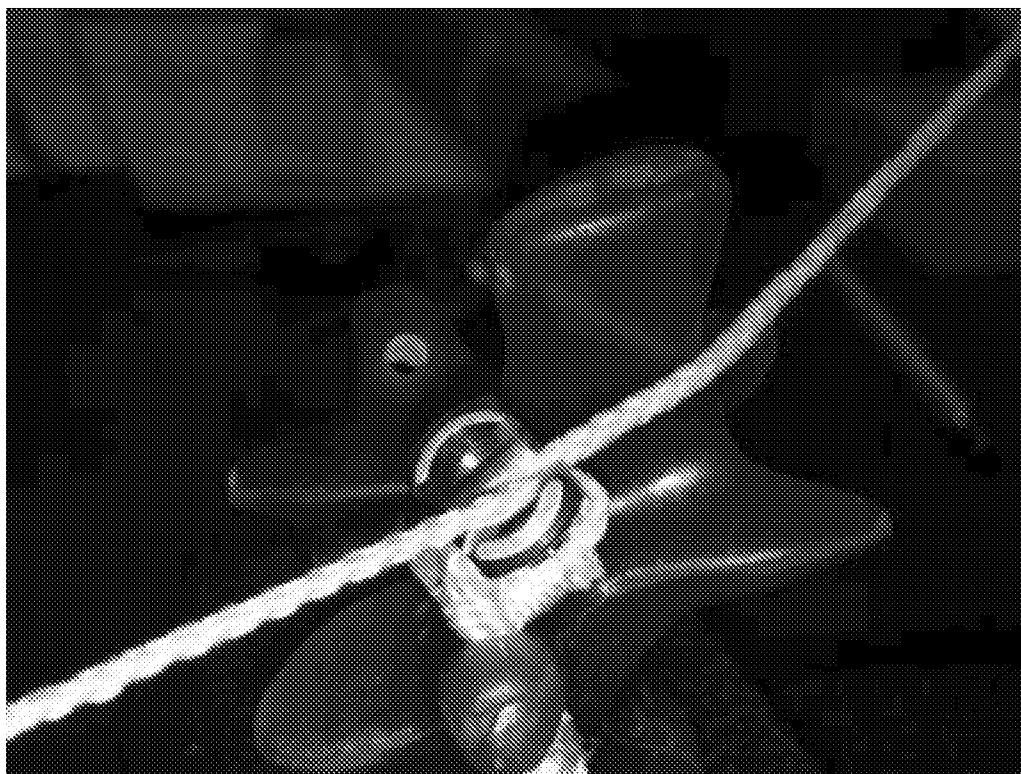


FIG. 19C



FIG. 19D



FIG. 19E

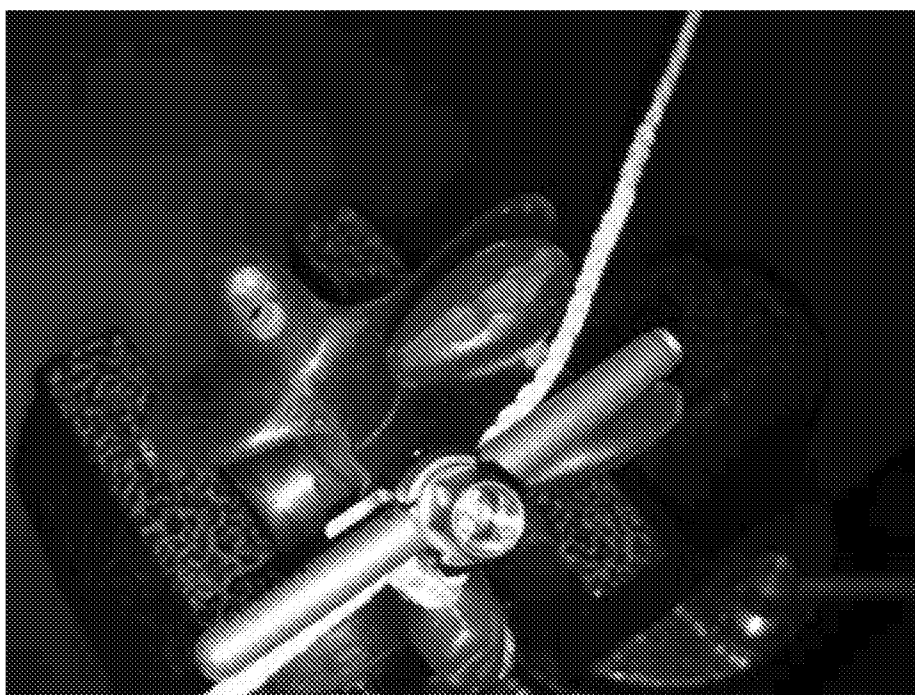


FIG. 19F

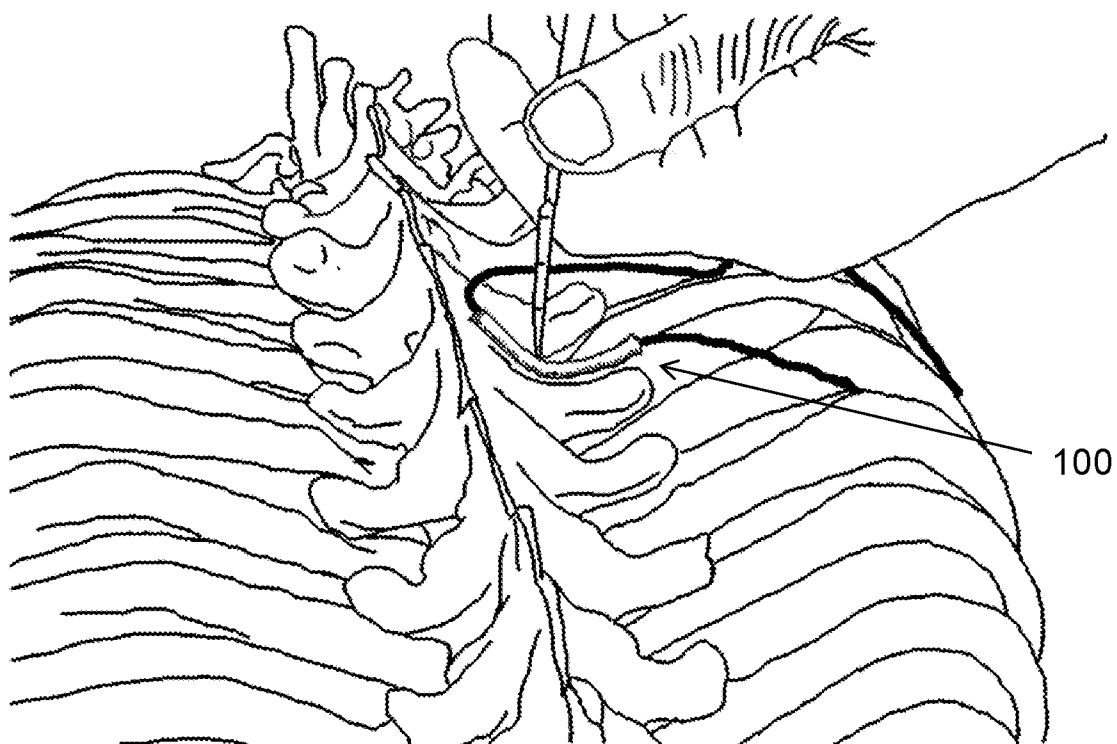


FIG. 20

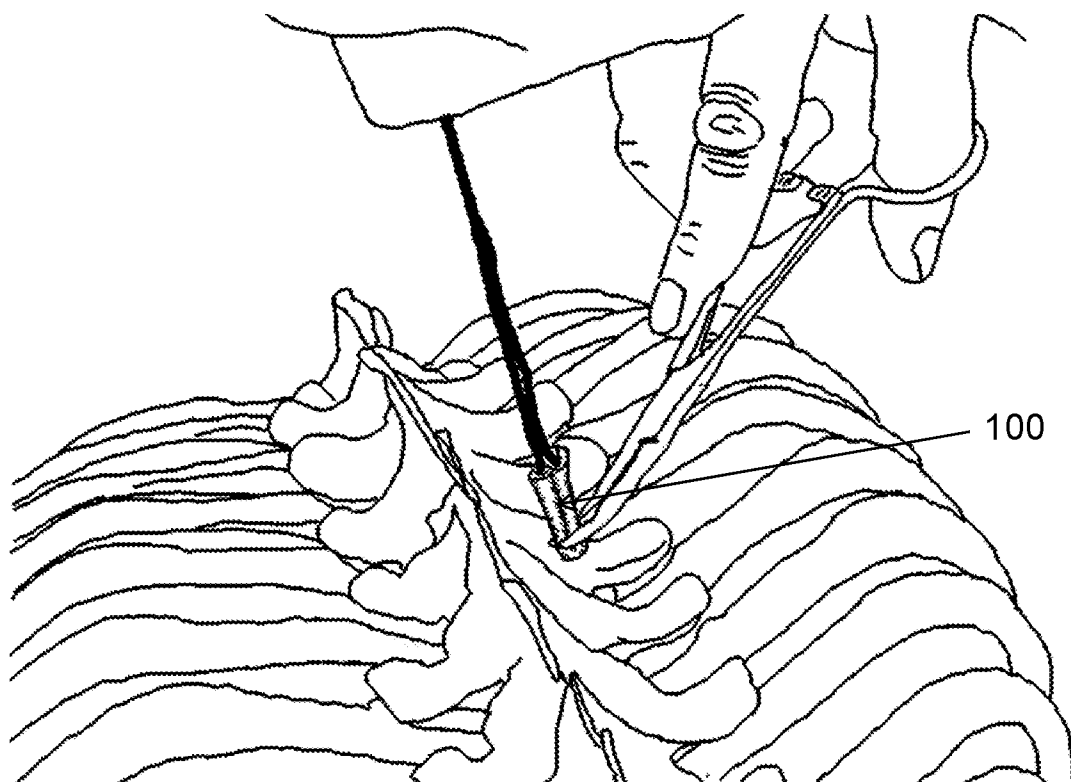
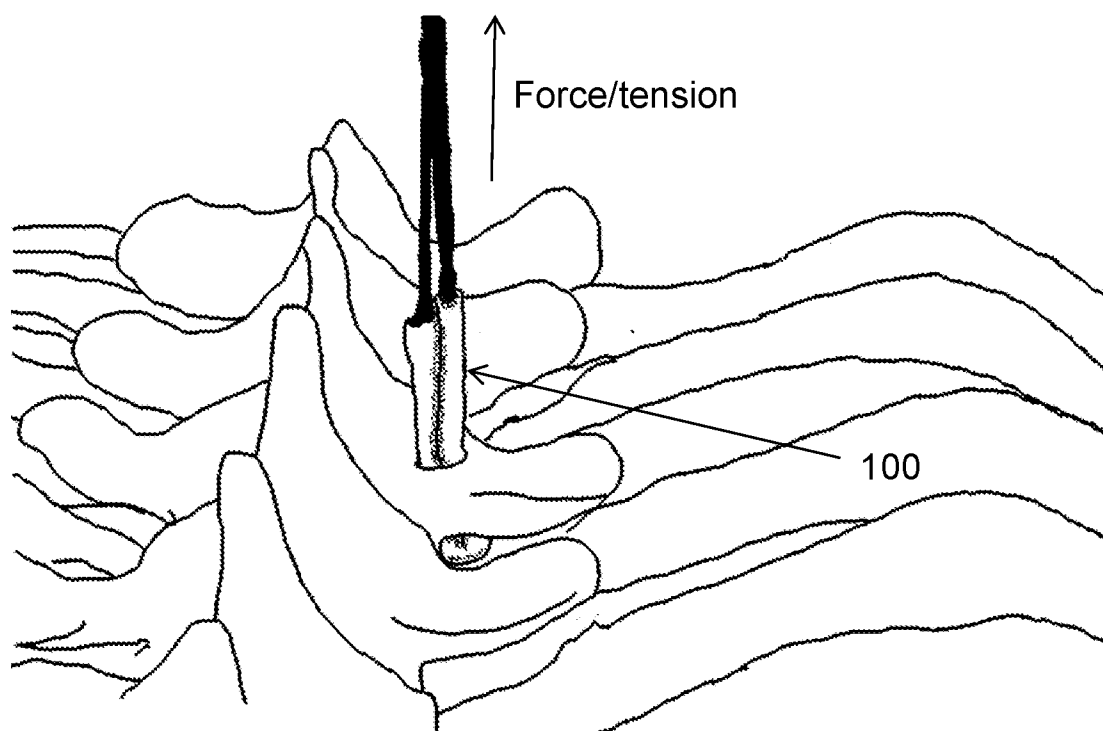
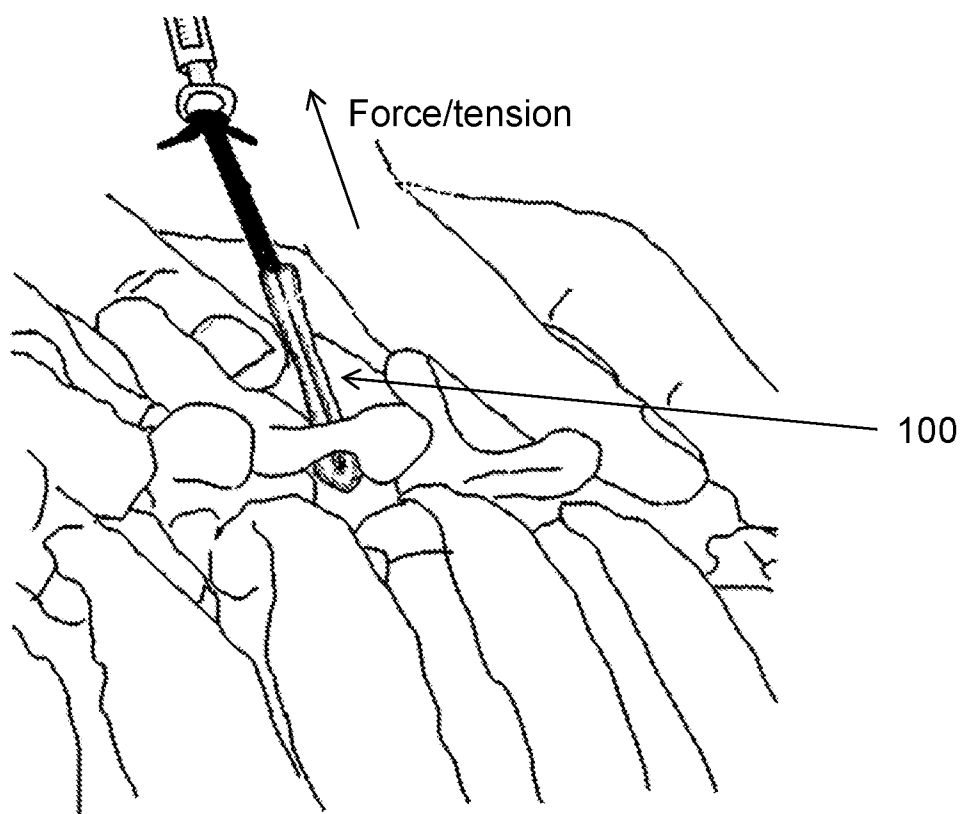


FIG. 21

**FIG. 22****FIG. 23**

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 16/62855

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/04 (2017.01)

CPC - A61B 17/0401, A61B 2017/0445, A61B 2017/0458, A61B 2017/0414, A61B 2017/0496

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 17/04 (2017.01)

CPC - A61B 17/0401, A61B 2017/0445, A61B 2017/0458, A61B 2017/0414, A61B 2017/0496

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 CPC - A61B 2017/0454, A61B 2017/0456, A61B 2017/045, A61B 2017/0406; A61B 17/04*, 2017/04*; USPC - 606/232
 (Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);

Search Terms: Knotless, knot less, anchor*, suture anchor, sleeve, tube, tubular, hollow, flex*, bend*, fold*, compress*, collaps*, barb*, anchor*, strant, suture, thread, filament, strand, pull*, tension*

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2013/0131722 A1 (MARCHAND et al.) 23 May 2013 (23.05.2013) Entire document, especially Abstract, para[0038]- para[0039], para[0042], para[0046]- para[0047] and FIGS. 1-3.	1-5, 7-9 ----- 6
Y	US 2014/0074160 A1 (DENHAM et al.) 13 March 2014 (13.03.2014) Entire document, especially Abstract, para[0039] and FIGS. 13.	6
A	US 2014/0052179 A1 (DREYFUSS et al.) 20 February 2014 (20.02.2014) Entire document.	1-9
A	US 5,989,252 A (FUMEX) 23 November 1999 (23.11.1999) Entire document.	1-9
A	US 6,511,498 B1 (FUMEX) 28 January 2003 (28.01.2003) Entire document.	1-9
A	US 2007/0185532 A1 (STONE et al.) 09 August 2007 (09.08.2007) Entire document.	1-9
A	US 2014/0249577 A1 (PILGERAM) 04 September 2014 (04.09.2014) Entire document.	1-9
A	US 2014/0257382 A1 (MCCARTNEY) 11 September 2014 (11.09.2014) Entire document.	1-9
A	US 2015/0164497 A1 (CALLISON et al.) 18 June 2015 (18.06.2015) Entire document.	1-9

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


* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

27 February 2017

Date of mailing of the international search report

31 MAR 2017

Name and mailing address of the ISA/US
 Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
 P.O. Box 1450, Alexandria, Virginia 22313-1450
 Facsimile No. 571-273-8300

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 16/62855

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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-9, directed towards a knotless anchor device

Group II: Claims 10-16 directed towards tulip heads

Group III: Claims 17-22 directed towards a method of using a knotless anchor device

The inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding technical features for the following reasons:

----- see continuation sheet -----

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 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.:
1-9

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.

----- Continuation of Box III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet) -----

Special Technical Features

Groups I and III include the special technical features of a knotless anchor device comprising a sleeve and a strand.

Group III includes the special technical features of method steps including particular use steps (claim 17) folding the flexible sleeve of a knotless anchor device to create a folded end; inserting the folded end into a hole in a substrate such that only a portion of the flexible sleeve is passed through the hole; pulling on one or both ends of the flexible strand of the knotless anchor device (claim 18) further comprising the step of fixing one or both ends of the flexible strand after compression of the sleeve, not required by Group I.

Group II includes the special technical features of tulip heads comprising two channels or one or more V-cleat notches.

Common Technical Features

Groups II shares with Groups I and III, the special technical features of a strand. However, a strand is well known in the art. US 2013/0131722 A1 to Marchand et al. (hereinafter: Marchand) describes a strand (filament 20, FIGS. 1-2; para[0039]).

Finally, group I and III are related to an apparatus (Group I) and method(s) of using the apparatus (Group III). These groups therefore share the technical features of the apparatus of claim 1, however, these shared technical features fail to provide a contribution over the prior art of Marchand. Marchand describes a knotless anchor device (FIG. 1; Abstract) comprising: a flexible sleeve having a middle portion (sleeve member 11 with middle portion between 12b and 12e, FIGS. 1-2; para[0038]); a flexible strand having two ends (filament 20 with ends 21 and 22, FIGS. 1-2; para[0039]), and where the knotless anchor device is configured such that it does not require the entire flexible sleeve to be inserted in a hole or cavity to achieve fixation of the knotless anchor device within the hole or cavity upon compression of the flexible sleeve (para[0046]-[0047], FIGS. 2, 3B, 3C: note only middle portion of the sleeve contacts the wall and provides holding force and thus the end portions need not be in the hole); and where the middle portion is configured to create a folded end in a hole or cavity and further configured to compress within the hole or cavity when a tension is applied to the two ends of the flexible strand (para[0046]-[0047]; FIGS. 2, 3C, 3C).

Thus, Groups I-III lack unity of invention because they do not share a same or corresponding special technical feature providing a contribution over the prior art.