



- (51) **International Patent Classification:**
F16B 13/06 (2006.01) *A61B 17/84* (2006.01)
A61B 17/68 (2006.01)
- (21) **International Application Number:** PCT/US2015/050483
- (22) **International Filing Date:** 16 September 2015 (16.09.2015)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
14/487,895 16 September 2014 (16.09.2014) US
14/487,951 16 September 2014 (16.09.2014) US
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- (81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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.
- (84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).
- Published:**
— *with international search report (Art. 21(3))*

(54) **Title:** WOVEN RETENTION DEVICES, SYSTEMS, PACKAGING, AND RELATED METHODS

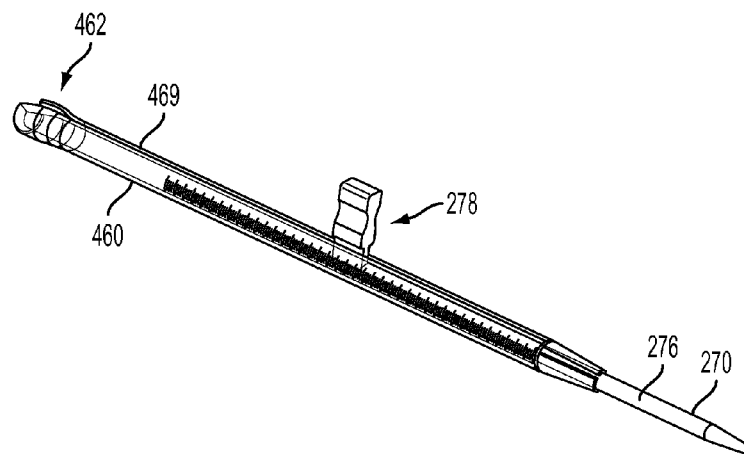


FIG. 7B

(57) **Abstract:** A system for implanting a woven retention device into bone includes a woven retention device, a delivery tube, and a push rod. The woven retention device includes a distal end that is tapered to a distal tip, a proximal end for receiving a fastener, and a sleeve body between the distal and proximal ends. The delivery tube includes distal and proximal openings, and a compression portion over at least a distal end of the delivery tube. The push rod can be slideably received within the delivery tube and has a distal end for pushing the woven retention device through the distal opening of the delivery tube.



Woven Retention Devices, Systems, Packaging, and Related Methods

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present invention claims priority to U.S. Application No. 14/487,895, filed September 16, 2014 and U.S. Application No. 14/487,951, filed September 16, 2014, the contents of which are hereby incorporated by reference herein in their entireties.

TECHNICAL FIELD OF INVENTION

[0002] The present invention relates generally to a woven retention device kit or system and method for inserting a woven retention device into bone.

BACKGROUND

[0003] In orthopedic surgery it is common to secure a bone screw to a patient's bone. Bone fracture repair is surgery to fix a broken bone using plates, nails, screws, or pins. It is common in the treatment of fractures to attach a plate to the bone utilizing bone screws. The resulting construct prevents motion of the fractured bone so that the bone can heal. Alternatively, one or more screws may be inserted across the break to hold it place.

[0004] In the treatment of spinal disorders, pedicle screws are inserted into the patient's vertebrae to serve as anchor points that can then be connected with a rod. This construct prevents motion of the vertebral segments that are to be fused.

[0005] In the treatment of detached tendons, screw-like tissue anchors are inserted into the patient's bone to serve as an anchor for the reattachment of the tendon.

[0006] One complication with the use of bone screws is the loss of fixation or grip between the bone screw and the patient's bone. Another complication with the use of bone screws is the stripping of the hole in the bone when the bone screw is inserted. This results in the loss of purchase and holding strength of the bone screw.

[0007] The presence of osteoporotic bone can increase the likelihood of complications by reducing the purchase or grip of the bone screw to the patient's bone, resulting in a loss of holding strength and loosening of the bone screw or pullout of the bone screw.

[0008] Current solutions to secure bone screws have not adequately addressed screw failure and the underlying causes of screw failure. In addition, there exists a need for simple and effective methods to insert such orthopedic devices and systems, as well as simple and easy to use kits or systems that can enable surgeons to more effectively treat patients.

BRIEF SUMMARY OF THE INVENTION

[0009] According to an embodiment of the present invention, a system for implanting a woven retention device into bone is provided. The system may include a woven retention device having a distal end that is tapered to a distal tip, a proximal end for receiving a fastener, and a sleeve body between the distal and proximal ends. The system may also include a delivery tube including a distal opening and a proximal opening, the delivery tube having a compression portion over at least a distal end of the delivery tube. The system also may include a push rod to be slideably received within the delivery tube and having a distal end to push the woven retention device through the distal opening of the delivery tube.

[0010] According to some embodiments of the present invention, the woven retention device may be able to be radially compressed to a compressed state when at least part of the sleeve body is within the compression portion. The sleeve body may have a first outer diameter in an uncompressed state and a second outer diameter in the compressed state, the second outer diameter being smaller than the first outer diameter. The compression portion can include a narrowed region at or near the distal opening of the delivery tube, the narrowed region having an inner diameter that is less than the first outer diameter of the sleeve body. The delivery tube may include a side wall opening extending longitudinally along at least a portion of the delivery tube. The push rod may be arranged such that at least a portion of the push rod extends outside of the delivery tube through the side wall opening during at least a portion of a progression of the distal end of the push rod inside the delivery tube. The compression portion may include a plurality of end slots in the delivery tube at a distal portion of the delivery tube. The plurality of slots can include an odd number of end slots at the distal portion of the delivery tube. The compression

portion can further include a plurality of prongs disposed between slots of the plurality of slots, the prongs being able to compress the woven retention device as the woven retention device is advanced through the distal opening.

[0011] According to some embodiments of the present invention, the system may further include a fastener that can be disposed within the woven retention device when the woven retention device is within the bone hole.

[0012] According to some embodiments of the present invention, the system may further include a measuring device arranged to measure a desired length of the woven retention device to be inserted into the bone hole.

[0013] According to some embodiments of the present invention, the system may further include a cutting device to cut the woven retention device based on the desired length measured by the measuring device. The measuring device may include indicia arranged to indicate a distance from the distal tip of the woven retention device to a reference point, the reference point being a point at which the woven retention device is able to be cut to achieve the desired length. The indicia can be arranged on a wall of the delivery tube. The designated cutting point may be the proximal opening of the delivery tube.

[0014] According to some embodiments of the present invention, the system further includes a package containing at least one of the woven retention device, the delivery tube, and the push rod. The package may contain the woven retention device. The indicia can be arranged on the package. The woven retention device may be mounted on the package in a predetermined relationship relative to the indicia. The package can further include the delivery tube. The woven retention device may be pre-loaded within the delivery tube. The package can include a mounting surface to which the woven retention device is mounted, a measuring surface including at least one set of measuring indicia, the measuring surface being slideable relative to the mounting surface, and a cutting indicator fixed to the measuring surface, the cutting indicator being able to indicate a location on the woven retention device where cutting is to be performed. The measuring surface may be slideably received within an envelope including the mounting surface. The measuring surface includes at least one window through which the at least one set of measuring indicia are viewable, the at least one window being arranged to indicate a distance from the distal tip of the woven retention device to the location where the cutting indicator

indicates the cut is to be performed. The at least one set of measuring indicia can include a plurality of sets of measuring indicia, each set of the plurality of sets of measuring indicia being calibrated based on a diameter of the woven retention device when the woven retention device is in a relaxed state.

[0015] According to an embodiment of the present invention, a method of inserting a woven retention device into a bone hole is provided. The method includes providing a woven retention device having a distal end that is tapered, a proximal end to receive a fastener, and a sleeve body between the distal and proximal ends. The method includes providing a delivery tube including a distal opening and a proximal opening, the distal opening having a compression portion over at least a distal end of the delivery tube. The method also includes providing a push rod having a distal end to push the woven retention device through the distal opening of the delivery tube. The method further includes positioning the distal opening of the delivery tube near an opening of the bone hole in a bone surface and advancing the woven retention device through the compression portion of the distal opening of the delivery tube and into the bone hole by pushing on an interior of the tapered distal end of the woven retention device using the distal end of the push rod.

[0016] According to some embodiments, the delivery tube has a side wall opening. The push rod may be arranged such that at least a portion of the push rod passes within the side wall opening of the delivery tube when advancing the woven retention device through the distal opening. The delivery tube can have an end slot at a distal portion of the delivery tube, and may have three end slots at the distal portion of the delivery tube. In an embodiment, the woven retention device is advanced into the bone hole until the proximal end of the woven retention device is substantially flush with the bone surface.

[0017] In an embodiment, the method further includes compressing the woven retention device at least near the distal opening of the delivery tube as the woven retention device is advanced through the distal opening, where the delivery tube includes a narrowed region near the distal opening for compressing the woven retention device. The narrowed region has an inner diameter that is less than an outer diameter of the sleeve body. The method may further include inserting the woven retention device into the delivery tube through a proximal opening of the delivery tube. In some embodiments, the method further includes inserting the fastener into the woven

retention device through the proximal end of the woven retention device after the woven retention device is placed in the bone hole.

[0018] In an embodiment, the method includes cutting the woven retention device, before inserting the woven retention device into the bone hole, to a desired length based on a depth of the bone hole. A proximal end portion of the woven retention device may be cut to achieve the desired length. The method according to some embodiments includes measuring a portion of the woven retention device to determine a location along a length of the woven retention device to perform the cutting. In some embodiments, the delivery tube includes indicia for measuring a desired length of the woven retention device, the indicia being on a wall of the delivery tube. The method can include measuring the desired length of the woven retention device using the indicia, and cutting the woven retention device to the desired length prior to inserting the woven retention device into the bone hole. The measuring of the desired length can include aligning the distal end of the woven retention device with the indicia indicating the desired length of the woven retention device, and also may include cutting a portion of the sleeve body that extends proximally to the proximal opening of the delivery tube. The method may also include measuring a desired length of the woven retention device using indicia provided on a packaging of at least one of the woven retention device, the delivery tube, and the push rod, and cutting the woven retention device to the desired length.

[0019] According to some embodiments, the method of using the woven retention device includes compressing the woven retention device with a compressing portion of the delivery lumen while inserting the woven retention device into the bone hole. The method may include cutting off an excess portion of the woven retention device based on measuring the desired length of the woven retention device. The method may include positioning the distal opening of the delivery tube near an opening of the bone hole. The measuring may include aligning a distal end of the woven retention device with a measuring tool, where the excess portion of the woven retention device can include a portion near a proximal end of the woven retention device. The measuring tool may include indicia on the delivery tube, and the excess portion includes a portion proximal to a proximal end of the delivery tube. The measuring may be performed while the distal end of the woven retention device is within the delivery tube. In an embodiment, the measuring includes using a slideable measuring apparatus that can hold the woven retention

device and output a distance based on a distance relationship between two ends of the slideable measuring apparatus.

[0020] In an embodiment, a method of inserting a woven retention device into a bone hole includes positioning a distal opening of a delivery lumen near an opening of the bone hole, pushing the woven retention device through the distal opening using a push rod, a distal end of the push rod being arranged within the delivery lumen to push the woven retention device and at least a portion of a proximal end of the push rod remaining outside of the delivery lumen, and advancing the woven retention device to a desired depth within the bone hole using the push rod. In an embodiment, the portion of the push rod that remains outside of the delivery lumen is connected to a portion of the push rod that is within the delivery lumen via a slotted opening in a side wall of the delivery lumen. The method can also include applying a force to the portion of the proximal end of the push rod that remains outside of the delivery lumen to push the push rod.

[0021] In some embodiments, the method includes compressing the woven retention device with a compressing portion of the delivery lumen while inserting the woven retention device into the bone hole. The method can include cutting off an excess portion of the woven retention device based on the measuring. The method may also include positioning the distal opening of the delivery tube near an opening of the bone hole. The measuring can include aligning a distal end of the woven retention device with a measuring tool. The method may also include where the excess portion of the woven retention device includes a portion near a proximal end of the woven retention device. The measuring tool can have indicia on the delivery tube, and the excess portion includes a portion proximal to a proximal end of the delivery tube. The measuring may be performed while the distal end of the woven retention device is within the delivery tube. In an embodiment, the method includes using a slideable measuring apparatus that is configured to hold the woven retention device and output a distance based on a distance relationship between two ends of the slideable measuring apparatus.

[0022] According to an embodiment of the present invention, a method of inserting a woven retention device into a bone hole includes measuring a desired length of the woven retention device to be inserted into the bone hole, pushing the woven retention device through a distal opening of a delivery tube using a push rod, and advancing the woven retention device to a desired depth within the bone hole using the push rod.

[0023] In some embodiments, the method includes cutting off an excess portion of the woven retention device based on the measuring. The method may include positioning the distal opening of the delivery tube near an opening of the bone hole. The measuring can include aligning a distal end of the woven retention device with a measuring tool. The method may also include where the excess portion of the woven retention device includes a portion near a proximal end of the woven retention device. The measuring tool can be indicia on the delivery tube, and the excess portion can be a portion proximal to a proximal end of the delivery tube. The measuring can be performed while the distal end of the woven retention device is within the delivery tube and can use a slideable measuring apparatus that is configured to hold the woven retention device and output a distance based on a distance relationship between two ends of the slideable measuring apparatus.

[0024] Additional features, advantages, and embodiments of the invention are set forth or apparent from consideration of the following detailed description, drawings and claims. Moreover, it is to be understood that both the foregoing summary of the invention and the following detailed description are exemplary and intended to provide further explanation without limiting the scope of the invention as claimed.

BRIEF DESCRIPTION OF DRAWINGS

[0025] The accompanying drawings, which are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate preferred embodiments of the invention and together with the detailed description serve to explain the principles of the invention. In the drawings:

[0026] Fig. 1A shows an exploded view of a push rod, a woven retention device and a delivery tube that have not been pushed into each other, according to an embodiment of the invention, as well as the combination of the elements after the push rod has pushed the retention device through a portion of the delivery tube, according to an embodiment of the invention.

[0027] Fig. 1B shows a delivery tube that is positioned near a bone hole and a retention device configured to be pushed through the delivery tube, according to an embodiment of the invention.

[0028] Fig. 1C shows a partial cut-away view of a delivery tube that is positioned near a bone hole and a push rod pushing the retention device through the delivery tube, according to an embodiment of the invention.

[0029] Fig. 2 shows a partial cut-away view of an implanted woven retention device with a screw being inserted after a retention device has been inserted into a bone hole, according to an embodiment of the invention.

[0030] Fig. 3 shows a screw fully inserted into a woven retention device in a bone hole, according to an embodiment of the invention.

[0031] Fig. 4 shows a delivery tube having measurement indicia that allows for measuring an appropriate length of the woven retention device, and cutting the excess amount of the retention device, according to an embodiment of the invention.

[0032] Fig. 5A shows a woven retention device becoming compressed due to passing through the compression portion of the delivery tube, according to an embodiment of the invention.

[0033] Fig. 5B shows a close-up view of delivery tube disposed partially in a bone hole, according to an embodiment of the invention.

[0034] Figs. 6A-6E show various views of a delivery tube with a measurement scale and a side wall opening on the delivery tube, according to an embodiment of the invention.

[0035] Figs. 7A and 7B show a slideable push rod and delivery tube with a measuring scale, according to an embodiment of the invention.

[0036] Figs. 8A-8E show a slotted delivery tube, push rod with a planar surface handle that is perpendicular to the longitudinal axis of the delivery tube, and a stopper coupled to the push rod inside the delivery tube, according to an embodiment of the invention.

[0037] Figs. 9A-9D show a packaging system with a slideable measuring mechanism for measuring and cutting the woven retention device, according to an embodiment of the invention.

[0038] Figs. 10A-10D show multiple packaging, delivery tubes and push rod embodiments, according to embodiments of the invention.

[0039] Figs. 11A and 11B show packaging elements of the woven retention device system with the packaging including a measuring mechanism, according to an embodiment of the invention.

[0040] Fig. 12 shows packaging elements of the woven retention device system in a long form of the push rod, according to an embodiment of the invention.

[0041] Fig. 13 shows packaging elements of the woven retention device system with a push rod having an offset handle portion, according to an embodiment of the invention.

[0042] Fig. 14 shows separated elements of the woven retention device system shown in Fig. 13, according to an embodiment of the invention.

[0043] Fig. 15 shows the elements of the woven retention device system of Fig. 13 in an arrangement for inserting the woven retention device into a bone, according to an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0044] The devices, systems and methods described herein may be used in the area of orthopedics and, in particular, orthopedic repairs. These include various devices, systems and methods directed to fixing and/or retaining fasteners in orthopedic applications. Fixing or retaining fasteners to bone tissue is complicated by the underlining bone tissue. Understanding that an underlying cause of failure with internal fixation in bone tissue is the bone, the devices, systems and methods described herein provide for solutions that address the implant site. At the implant site, the hole and the bone benefit from an enhanced interface.

[0045] The fixation and/or retention devices, systems and methods described herein maximize fixation and/or retention in the bone tissue, including, osteoporotic bone, bone of a poor quality, and mechanically poor bone in addition to healthy bone tissue. The fixation and/or retention devices, systems and methods described herein may be used with any type of fixation including any types of screws, pins, or other fasteners.

[0046] The devices, systems and methods described herein enhance the interaction of a bone anchor to a bone hole to provide enhanced fixation. Additionally, the devices, systems and methods may repair the surface of the bone hole following damage to the bone hole as in the case

of stripping of the hole in the bone when a bone screw is over-tightened. Also, the devices, systems and methods provide for an enhanced bone hole surface for the reattachment of tendons in, for example, anterior/posterior cruciate ligament repair procedures, rotator cuff repair procedures, etc. The devices enhance the surface of a bone hole to enhance fixation of a bone anchor to bone and permits bone ingrowth into its structure. The devices enhance the interaction between the surface of a bone hole and the fixation device. The devices interdigitate with the bony structure and interact with the fixation device. The device alone, as a single device, enhances the surface of a bone hole to enhance fixation of a bone anchor to bone and accommodates variations in the diameter and depth of the bone hole. The devices, systems and methods can enhance fixation without requiring the use of cement and/or adhesives. However, according to some embodiments, cements and/or adhesive can be used in addition to or in place of another bone anchor such as a screw, pin, or other orthopedic implant.

[0047] Also described herein are methods of using these devices and systems, including methods of inserting fixation devices into a bone hole of a patient. The methods may use insertion tools, kits or systems, and/or device or system packaging that aid a user of the fixation devices to achieve a desired placement and fit of the fixation device within the bone hole of the patient, in order to achieve optimal performance of the fixation device. Also described herein are kits used for inserting fixation devices into a bone hole of a patient. The kits may include the fixation devices and tools for implanting the fixation devices. The kits may also include packaging of the fixation devices and tools.

[0048] Referring now to the figures, Figs. 1A, 1B, and 1C show examples of components of a kit including a woven retention device for inserting into a bone hole 150 of a bone 152 to interface with a bone surface 154 in the bone hole 150. Fig. 1A shows woven retention devices 100, 100' for insertion into respective bone holes 150, 150'. Woven retention device 100 is shown in an exploded view with respect to a delivery tube 160 and push rod 170 used for inserting the woven retention device 100 into bone hole 150. The woven retention device 100 includes a proximal end 102 with a proximal opening 103, a distal end 104 that is tapered 105 to a distal tip 106, and a sleeve body 108 extending between the proximal and distal ends 102, 104. The proximal end 102 may be able to receive a fastener (not shown in Fig. 1A) through the proximal opening 103. The delivery tube 160 also includes a proximal end 162 with a proximal opening 163, a distal end 164 with a distal opening 165, and a tube body 166 extending between

the proximal and distal ends 162, 164. The push rod 170 has a proximal end 172, a distal end 174 with a distal tip 175, and a rod body 176.

[0049] In an embodiment, a method of using a kit for inserting the woven retention device 100 into the bone hole 150 includes pushing the woven retention device 100 through the delivery tube 160 using the push rod 170. For example, Fig. 1A shows woven retention device 100' being pushed through the delivery tube 160 with the push rod 170. In the embodiment shown, at least part of the push rod 170 is inserted into the delivery tube 160 through the proximal opening 163 of the delivery tube 160, and the distal tip 175 of the push rod 170 exerts a force on an interior of the woven retention device 100' in at least the distal end 104 of the woven retention device 100'. It is contemplated that the tip 175 of the push rod 170 may push on a distal-most interior wall of the distal tip 106 and/or on at least a portion of the tapered portion 105.

[0050] In some embodiments, the distal tip of the push rod may be shaped to at least partially conform to a shape of the interior surface of the distal tip of the tapered portion of the woven retention device. For example, the distal tip of the push rod may be tapered or otherwise shaped to contact the inner surface of the woven retention device. In some embodiments, the distal tip of the woven retention devices may be closed, while in other embodiments the distal tip may have an opening with a smaller diameter than the proximal opening of the woven retention device. In a case where the distal end of the woven retention device is open, the diameter at the distal tip may be small enough so that the push rod does not extend through the opening when pushing the woven retention device through the delivery tube and into the bone hole.

[0051] As shown in Fig. 1A, the delivery tube 160 may include a compression portion 168 at least at or near the distal end 164 of the delivery tube 160. The compression portion 168 can force the woven retention device 100' to radially contract as the woven retention device 100' is pushed through the distal opening 165 with the push rod 170. In some embodiments, the compression portion 168 may be a portion of the delivery tube 160 with an inner diameter that is smaller than an outer diameter of the woven retention device 100' when the woven retention device 100' is in a relaxed state. Further details of the compression portion 168 according to some embodiments will be discussed further below.

[0052] According to an embodiment of the method of using a kit for inserting a woven retention device into a bone, the distal opening 165 of the delivery tube 160 may be positioned at

or near the opening 156 of the bone hole 150, as shown in Fig. 1B. As such, when the woven retention device 100' is pushed through the delivery tube 160 and is compressed by the compression portion 168, the woven retention device 100' can easily be inserted into the bone hole 150 due to the radially contracted state of the woven retention device 100' from the compression portion 168. For example, the contracted state of the woven retention device 100' allows it to easily enter the opening 156 without being obstructed by the periphery of the opening 156. Also, by staying at least partially contracted even after passing through the compression portion 168 and entering the bone hole 150, the woven retention device 100' can avoid obstructions in the bone hole 150 itself due to irregularities in the bone hole 150. According to some embodiments, the woven retention devices 100, 100' have a construction such that they return to their relaxed state after passing fully through the compression portion 168, the relaxed state being one in which the woven retention device 100, 100' has a diameter d_r (Fig. 1B) that is larger than a diameter d_c (Fig. 1C) when in the compressed state.

[0053] It is possible that the size of the bone hole 150 may prevent the woven retention devices 100, 100' from fully returning to their relaxed state if the bone hole 150 has an inner diameter that is smaller than an outer diameter of the woven retention device in the relaxed state.

Nonetheless, the woven retention device 100 will be biased to expand or return to the relaxed state. In one embodiment, the woven retention device can elastically expand and/or self-expand to the relaxed state. In expanding towards the relaxed state, the woven retention device will press against the bone surface 154 of the bone hole 150. It is also possible that the bone hole 150 has an inner diameter that is larger than the outer diameter of the woven retention device in a relaxed state. In such a case, the woven retention device may not fully contact the bone surface 154 of the bone hole 150 when the woven retention device is in the relaxed state. However, the woven retention device may transition to an expanded state when a fastener is later inserted into the woven retention device. Thus, in the expanded state, the woven retention device can provide the desired interaction between the fastener and the bone hole. Therefore, according to the properties of the woven retention device and the compression portion 168 of the delivery tube 160, a system and method may be provided which allows for easy insertion of the woven retention device 100, 100' into the bone hole 150 while nonetheless ensuring the desired interaction between the woven retention device, the fastener, and the bone surface 154.

[0054] As shown in Fig. 2, the method according to some embodiments includes inserting a fastener 180 into the woven retention device 100 after the woven retention device 100 is placed into the bone hole 150. In the embodiment shown in Fig. 2, the fastener 180 is a bone screw. However, embodiments of the invention are not limited to bone screws, and other fasteners such as rods, pins, prosthetic devices, or other devices can be inserted into the woven retention device 100. As shown in Fig. 3, the fastener 180 may be inserted fully into the woven retention device 100 such that a proximal end 182 of the fastener 180 is substantially flush with the proximal end 102 of the woven retention device 100 or with the surface of the bone 152.

[0055] According to some embodiments, a method of inserting a woven retention device may include removing an excess portion of the woven retention device 100 so that it fits as desired in a bone hole of a particular size. In this regard, embodiments include kits to aid a user or operator of the woven retention device to easily measure, cut, and insert the woven retention device. Fig. 4 shows an example of such an embodiment. The woven retention device 100 is at least partially inserted into a measuring tube 260 that is equipped with a mechanism for measuring the woven retention device 100. In this example, the measuring is accomplished using measuring indicia 261 on the side of the measuring tube 260. According to an embodiment of the method, the woven retention device 100 is at least partially inserted into the measuring tube 260 until the distal end 104 of the woven retention device 100 reaches a desired position relative to the measuring indicia 261. The relative position of the woven retention device 100 can be appreciated by the measuring tube 260 having a clear tube body 266. After the woven retention device 100 is inserted to the desired position, a portion of the distal end 104 of the woven retention device 100 may be removed using scissors 190, for example, as shown in Fig. 4. In an embodiment, the woven retention device 100 is cut at a point approximately level the proximal opening 263 of the measuring tube 260. Therefore, the measuring indicia 261 can be arranged such that the measuring indicia 261 measure a distance from the proximal opening 263 of the measuring tube 260 and, correspondingly, a length of the woven retention device 100 from the distal end 104 of the woven retention device 100 to proximal opening 263 (or other position where the woven retention device 100 is cut).

[0056] According to some embodiments, a portion of the delivery tube 360 near the distal end 364 includes one or more distal slots 367 as shown in Fig. 5A. The distal slots 367 define one or more prongs 368 at or near the distal end 364 of the delivery tube 360. The compression portion

of the delivery tube 360 can be formed from these compression prongs 368. For example, as shown in Fig. 5A, the compression prongs 368 are biased radially inward towards a longitudinal axis of the delivery tube 360, thus forming a narrowed distal opening 365 of the delivery tube 360.

[0057] According to some embodiments, there can be an odd number of distal slots 367 on the distal end 364 of the delivery tube 360. An odd number can provide more circumferentially uniform compression of the woven retention device because the distal slots are not aligned with each other. An even number of slits would have the slots aligned if the slots are placed symmetrically about the circumference of the delivery tube.

[0058] As shown in Fig. 5B, the distal end 364 of the delivery tube 360, according to an embodiment, may be brought into closer proximity to the bone hole 150, even to the point of being partially inserted into the bone hole 150. Insertion of the distal end 364 of the delivery tube 360 can be aided by the tapering of the distal end 364 resulting from the compression prongs 368 and distal slots 367.

[0059] Figs. 6A through 6E show an example of the delivery tube according to an embodiment. Three distal slots 467 and three compression prongs 468 are formed in the distal end 464 of the delivery tube 460. Measuring indicia 461 are visible in Figs. 6B and 6C along the body of delivery tube 460. As shown in Fig. 6C, the delivery tube 460 also has a slotted opening (push guide 469) formed along a substantial length of the delivery tube 460. As discussed below, the push guide 469 can assist in pushing the woven retention device through the entirety of the delivery tube 460 until the woven retention device has fully exited the delivery tube 460 into the bone hole. In some embodiments, the push guide 469 is contiguous with the proximal opening at the proximal end 462 of the delivery tube 460. In other embodiments, the push guide 469 may be separated from the proximal opening on the proximal end 462. The push guide 469 can also allow an operator of the delivery tube 460 to see a position of the woven retention device through the opening. Thus, the delivery tube 460 need not be made of a transparent material for using the measuring indicia 461.

[0060] Figs. 7A and 7B show an embodiment in which the delivery tube 460 is outfitted with a push rod 270 having a rod lever 278 on or near the proximal end 272 of the push rod 270. The rod lever 278 extends radially outward from the rod body 276 through the push guide 469. An

operator of the system can slide the rod lever 278 back and/or forth in the push guide 469 so that the push rod 270 may be easily movable along a substantial length of the delivery tube 460 by an operator of the system. Therefore, the push rod 270 does not need to be long enough for the proximal end 272 of the push rod 270 to remain proximal to the proximal end 462 of the delivery tube 460 because the operator can maintain control of the push rod 270 via the push guide 469. Thus, a more compact system is provided, saving both space and material costs.

[0061] Figs. 8A through 8E show examples of another embodiment of the kit. The woven retention device 400 is fixed to a stopper 377 to which the push rod 370 is coupled. In an embodiment, an unseen portion of the push rod 370 extends past stopper 377 to push the woven retention device 400 out of the delivery tube. Coupling between the push rod 370 and the stopper 377 is achieved by locking portion 379. The push rod 370 can be de-coupled from the stopper 377 by a rotation of the push rod 370 about its longitudinal axis. After being decoupled, the push rod 270 can be at least partially retracted from the woven retention device 400 (see Fig. 8C) so that a distal portion of the woven retention device can be cut. Fig. 8C also reveals part of the push rod 370 that was previously inside the woven retention device 400 when the push rod 370 was coupled to the stopper 377.

[0062] The rod lever 378 of the push rod 370 has a substantially planer surface that is perpendicular to the longitudinal axis of the push rod 370. Figs. 8A-8C also show how the compression prongs 468 of the delivery tube 460 can spread apart from one another when the woven retention device 400 is being pushed through them. Thus, the compression prongs 468 can be flexible to allow the woven retention device 400 to pass through the compression prongs 468 while also radially compressing the woven retention device 400 due to the inward bias of the compression prongs 468.

[0063] Some embodiments may include additional systems for packaging, measuring, and preparing the woven retention device for use. Figs. 9A-9C show a packaging and preparation system for the woven retention device 100 according to an embodiment. The packaging 130 includes a backing card 131 on which the woven retention device 100 is mounted in mounting loops 132a, 132b. The backing card 131 may include two cards 131a, 131b that are movable relative to one another. The pullout card 131b may be pulled out from the stationary card 131a by pulling the pullout card 131b in the pull tab area 138. When the pullout card 131b is pulled

outwardly from the stationary card 131a, the mounting loop 132b, which is attached to the pullout card 131b, also moves relative to the mounting loop 132a, which is attached to the stationary card 131a. As the pullout card 131b is moved, one or more measuring indices 140 within the measurement windows 136 will move relative to a marker 142 of the stationary card 131a. The measurement indicated by the marker 142 corresponds to a distance between a point on the woven retention device 100 indicated by a marker on the movable mounting loop 132b and the distal tip (not shown) of the woven retention device 100 that is attached at the attachment portion 133. Therefore, according to some embodiments, a user of the woven retention device 100 cut the woven retention device 100 to any desired length using the measuring system provided on the packaging of the woven retention device 100. For example, when the desired length is obtained in the measurement window 136, the user can cut the woven retention device 100 where indicated by the marker on the movable mounting loop 132b (e.g., a point indicated by the words “cut here” in Figs. 9A-9C). After cutting, the portion of the woven retention device 100 between the attachment portion 133 and the movable mounting loop 132b may be inserted into a bone using other methods described herein.

[0064] In some embodiments, multiple measurement windows 136 are provided in the packaging system 130. Each of the multiple measurement windows 136 may have measuring indices that are calibrated for woven retention devices of a certain type. For example, in an embodiment, the measurement windows 136 may each be calibrated for a woven retention device of a different size, diameter, or weave pattern. In one embodiment, as shown in Fig. 9D, the measurement windows are staggered to calibrate each set of indices to differently constructed or sized woven retention devices. For example, a first measurement window 136a may have measuring indices for a small-diameter woven retention device 100 (e.g., 3.0 mm in diameter). A second window 136b may have measuring indices for a medium-diameter woven retention device 100 (e.g., 5.0 mm in diameter). A third window 136c may have measuring indices for a large-diameter woven retention device 100 (e.g., 9.0 mm in diameter). These diameters are given as examples only. The number of measuring windows 136 provided and the diameters or other properties used to differentiate the measuring scales are not limited to these examples.

[0065] According to an embodiment, the packaging may also include mounting portions 134 for a push rod (not shown in Figs. 9A-9C). Examples of various embodiments of the packaging and retention device systems 230a-230d are shown in Figs. 10A-10D. The packaging system

230c is shown in more detail in Figs. 11A and 11B. The packing system 230c has a similar construction to the embodiment shown in Figs. 9A-9D. However, in packaging system 230c, push rod 470c is shown mounted in a push rod holder portion 234. In addition, delivery tube 560c is also included in the packaging 230c, as well as two woven retention devices 300c. Packaging 230c also differs from the embodiment in Figs. 9A-9D because a movable mounting and cutting guide 232 extends over both woven retention devices so that both can optionally be measured and/or cut at the same time. The distal end 304c is arranged on an opposite end of the woven retention devices 300c, so the measuring indicia in measurement windows 136 correspond to a length between the distal end 304c and the position of the movable mounting and cutting guide 232.

[0066] In some embodiments, as shown in packaging systems 230a and 230b, the woven retention devices 300a, 300b can be packaged within the delivery tubes 560a, 560b, respectively. This results in compact packaging and, in some embodiments, a woven retention device that can be immediately deployed from the delivery tube. Alternatively, even when packaged within the delivery tube, the woven retention device can be at least partially removed from the delivery tube for measuring and cutting. The push rod 470a also has a bent portion 479, which will be discussed further with respect to Figs. 13-15.

[0067] Also in Fig. 10, packaging system 230d shows an embodiment in which a delivery tube 560d is packaged with a straight push rod 470d. The delivery tube 560d and push rod 470d may be reusable, while the woven retention device is not reusable because they are implanted into the patient. Thus, it is contemplated that, in some embodiments, the woven retention device can be packaged separately from the delivery tube and/or push rod. Alternatively, the woven retention device can be packaged with one or both of the delivery tube and the push rod. When the woven retention device is included in the package with the delivery tube, the woven retention device can be pre-inserted into the delivery tube. By packaging the woven retention device within the delivery tube, a user of the system can avoid the step of inserting the woven retention device into the delivery tube.

[0068] Figs. 11A and 11B show close-up views of packaging system 230c according to one embodiment. The measurement windows 136 include two windows for two different scales: 136', 136" for woven retention devices with diameters of 5.0 mm and 9.0 mm, respectively.

Although a third measurement window is shown, no measuring indices are provided for that window in the example shown. However, measurement windows 136' and 136'' may be used for a different measuring scale corresponding to a woven retention device having a diameter of 3.0 mm, for example. It is contemplated that the two woven retention devices 300c' and 300c'' can have two different diameters, corresponding to the scales used in measurement windows 136' and 136''. Thus, in Figs. 11A and 11B, woven retention device 300c' may have a diameter of 5.0 mm, and woven retention device 300c'' may have a diameter of 9.0 mm. The two separate lines of measuring indices 240 can be seen more clearly in Fig. 11B, which is shown with the pull out card 232b partially pulled apart from the stationary card 231a.

[0069] Fig. 12 shows a variation on the embodiment of the packaging system 230d from Fig. 10D. In Fig. 12, packaging system 230d' includes delivery tube 560d, and push rod 470d, as well as woven retention device 300d being pre-loading in the delivery tube 560d. Because no push guide 469 is providing along the side wall of the delivery tube 560d, the push rod 470d in the embodiment shown must be long enough to at least extend from one side of the delivery tube 560d to the other side in order to push the woven retention device 300d out of the delivery tube 560d and into a bone of a patient. This long push rod 470d results in a larger overall package.

[0070] In contrast, according to the embodiment shown in Fig. 10A as packaging system 230a, and the embodiments shown in Figs. 13-15, a delivery tube 560a with a push guide 569, as shown in Fig. 14, can provide an overall shorter package 230a and push rod 470a that is shorter in length. The push rod 470a does not necessarily have to be longer than the delivery tube 560a, because the push guide 569 allows the push rod 470a to slide down the length of the delivery tube 560a. The bent portion 479 of the push rod 470a allows the handle 477 to remain outside of the delivery tube 560a while the distal end 474 of the push rod 470a pushes the woven retention device 300 inside the delivery tube 560a.

[0071] The push guide 569 can be seen more clearly in Fig. 14, where the components of packaging system 230a are separated. In some embodiments, the push guide 569 may extend over only part of the length of the delivery tube 560a. In this way, the push rod 470a may be prevented from all the way through the distal opening 565a of the delivery tube 560a. However, it is possible that the push guide 569 may extend over the entire length of the delivery tube 560a in some embodiments. The length of the push guide 569 may be coordinated with the placement

and length of the measuring indicia 461 so that the woven retention device 300 can be measured using the entire range of the measuring indicia 461 based on the distance the woven retention device 300 can be pushed by the push rod 470a.

[0072] Fig. 15 shows an embodiment of the parts from Figs. 13 and 14 as they are used to push the woven retention device 300 through the delivery tube 560a. The distal end 304a of the woven retention device 300 is shown protruding from the delivery tube 560a, as the woven retention device 300 passes through the compression prongs 468 formed by the distal slots 467. Due to the bent portion 479 of the push rod and the push guide 569, the handle 477 is able to extend beyond the proximal opening 563 of the delivery tube 560a, on an outside of the delivery tube 560a. Thus, the embodiment shown in Fig. 15 provides a compact and sufficient kit and method of inserting a woven retention device into a bone.

[0073] The foregoing descriptions include examples of embodiments of the woven retention devices and tools for using and inserting the woven retention devices. However, variations in these devices and system are contemplated within the scope of the invention. For example, in some embodiments, the distal tip of the woven retention devices may be closed, while in other embodiments the distal tip may have an opening with a smaller diameter than the proximal opening of the woven retention device.

[0074] EXAMPLES

[0075] The following is provided as an example of sizes and dimensions of a delivery tube and push rod according to an example of one embodiment of the invention. However, embodiments are not limited to the following dimensions.

[0076] The push rod may be formed of stainless steel (e.g., 316 SS). In an embodiment where the push rod is formed without the bent portion 479, the push rod may have an overall length of 300 mm, where a handle portion of the push rod may be about 50 mm long and the elongated arm that is inserted into the delivery tube and woven retention device may be 250 mm. In an embodiment where the push rod is formed with the bent portion 479, the overall length may be shorter. The elongated arm may have a diameter of about 2 mm. The diameter of the elongated arm may be smaller or larger, as long as the elongated arm is able to slide within the delivery tube and push the woven retention device. The handle portion may have a diameter of 8 mm, for example.

[0077] The delivery tube may have an overall length of about 180 mm. If a push guide is formed in the side of the delivery tube, then the push guide may extend for about 160 mm along the length of the delivery tube. A length of the compression prongs and end slots formed in the delivery tube may be about 15 mm. The outer diameter of the delivery tube may be about 8.5 mm, and an inner diameter may be about 7 mm. The distal opening formed at the tip of the compression prongs may have a diameter of 2.5 mm. This diameter may expand as the woven retention device is pushed through the flexible compression prongs, in some embodiments. The measurement scale of the measuring indices on the delivery tube may be spaced about 0.5 mm apart, in one example.

[0078] Although the foregoing description is directed to the preferred embodiments of the invention, it is noted that other variations and modifications will be apparent to those skilled in the art, and may be made without departing from the spirit or scope of the invention. Moreover, features described in connection with one embodiment of the invention may be used in conjunction with other embodiments, even if not explicitly stated above.

CLAIMS

1. A system for implanting a woven retention device into bone, the system comprising:
 - a woven retention device having a distal end that is tapered to a distal tip, a proximal end configured to receive a fastener, and a sleeve body between the distal and proximal ends;
 - a delivery tube including a distal opening and a proximal opening, the delivery tube having a compression portion over at least a distal end of the delivery tube; and
 - a push rod configured to be slideably received within the delivery tube and having a distal end configured to push the woven retention device through the distal opening of the delivery tube.

2. The system according to claim 1, wherein the woven retention device is configured to radially compress to a compressed state when at least part of the sleeve body is within the compression portion, and
 - wherein the sleeve body has a first outer diameter in an uncompressed state and a second outer diameter in the compressed state, the second outer diameter being smaller than the first outer diameter.

3. The system according to claim 1, wherein:
 - the delivery tube comprises a side wall opening extending longitudinally along at least a portion of the delivery tube, and
 - the push rod is arranged such that at least a portion of the push rod extends outside of the delivery tube through the side wall opening during at least a portion of a progression of the distal end of the push rod inside the delivery tube.

4. The system according to claim 1, wherein the compression portion comprises a plurality of end slots in the delivery tube at a distal portion of the delivery tube.
5. The system according to claim 4, wherein the plurality of slots comprises an odd number of end slots at the distal portion of the delivery tube.
6. The system according to claim 4, wherein the compression portion further comprises a plurality of prongs disposed between slots of the plurality of slots, the prongs being configured to compress the woven retention device as the woven retention device is advanced through the distal opening.
7. The system according to claim 2, wherein the compression portion comprises a narrowed region at or near the distal opening of the delivery tube, the narrowed region having an inner diameter that is less than the first outer diameter of the sleeve body.
8. The system according to claim 2, wherein the woven retention device is configured to be expanded to a relaxed state from the compressed state.
9. The system according to claim 8, wherein the woven retention device is configured to be expanded by self-expanding the woven retention device.

10. The system according to claim 1, further comprising a fastener configured to be disposed within the woven retention device when the woven retention device is within the bone hole.
11. The system according to claim 1, further comprising a measuring device arranged to measure a desired length of the woven retention device to be inserted into the bone hole.
12. The system according to claim 11, further comprising a cutting device configured to cut the woven retention device based on the desired length measured by the measuring device.
13. The system according to claim 11, wherein the measuring device comprises indicia arranged to indicate a distance from the distal tip of the woven retention device to a reference point, the reference point being a point at which the woven retention device is able to be cut to achieve the desired length.
14. The system according to claim 13, wherein the indicia are arranged on a wall of the delivery tube.
15. The system according to claim 14, wherein the designated cutting point is the proximal opening of the delivery tube.
16. The system according to claim 13, further comprising a package containing at least one of the woven retention device, the delivery tube, and the push rod.

17. The system according to claim 16, wherein:
the package contains the woven retention device,
the indicia are arranged on the package, and
the woven retention device is mounted on the package in a predetermined relationship relative to the indicia.
18. The system according to claim 16, wherein:
the package further contains the delivery tube, and
the woven retention device is pre-loaded within the delivery tube.
19. The system according to claim 16, wherein the package comprises:
a mounting surface to which the woven retention device is mounted,
a measuring surface including at least one set of measuring indicia, the measuring surface being slideable relative to the mounting surface, and
a cutting indicator fixed to the measuring surface, the cutting indicator being configured to indicate a location on the woven retention device where cutting is to be performed.
20. The system according to claim 19, wherein the measuring surface is slideably received within an envelope comprising the mounting surface.
21. The system according to claim 19, wherein the measuring surface includes at least one window through which the at least one set of measuring indicia are viewable, the at least one

window being arranged to indicate a distance from the distal tip of the woven retention device to the location where the cutting indicator indicates the cut is to be performed.

22. The system according to claim 19, wherein the at least one set of measuring indicia includes a plurality of sets of measuring indicia, each set of the plurality of sets of measuring indicia being calibrated based on a diameter of the woven retention device when the woven retention device is in a relaxed state.

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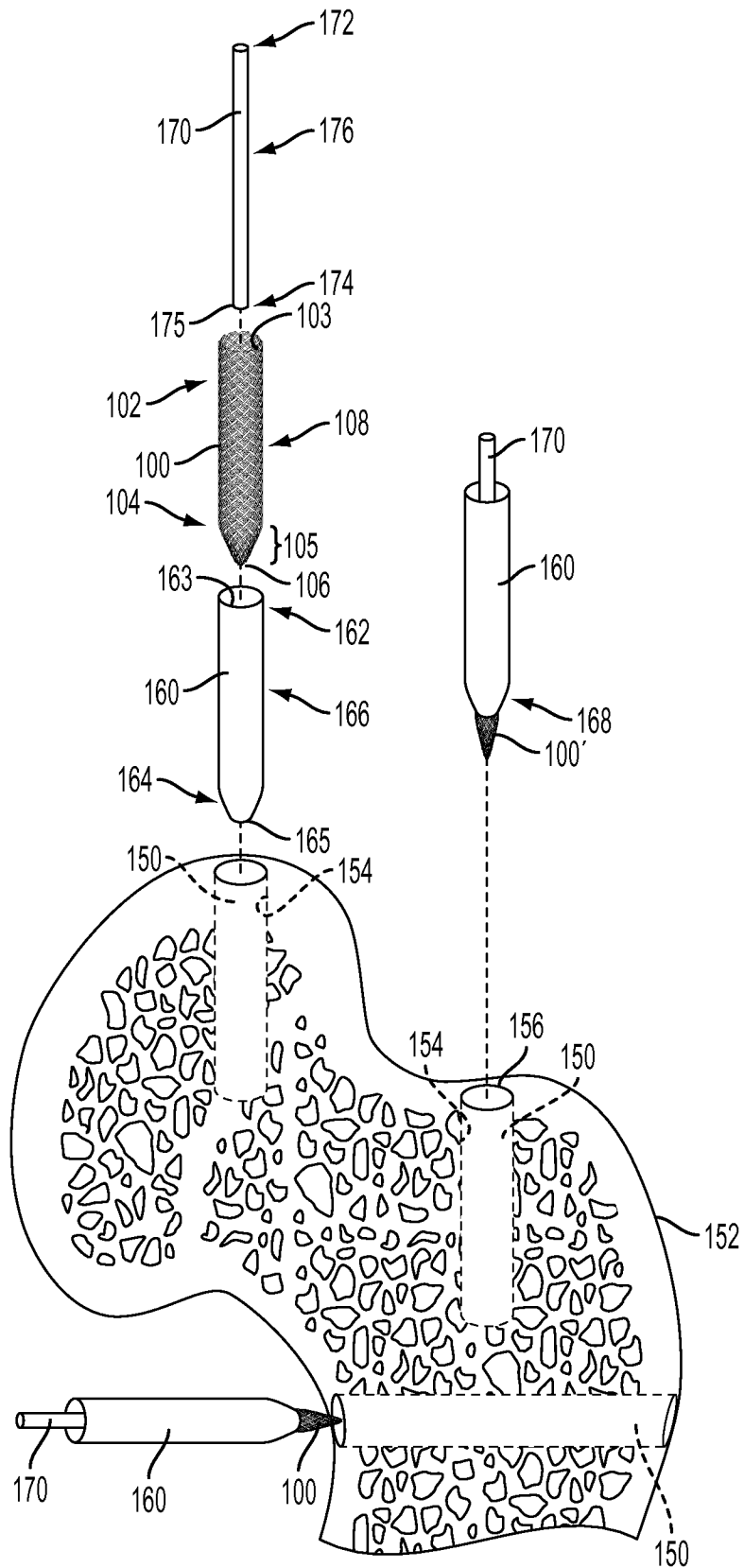


FIG. 1A

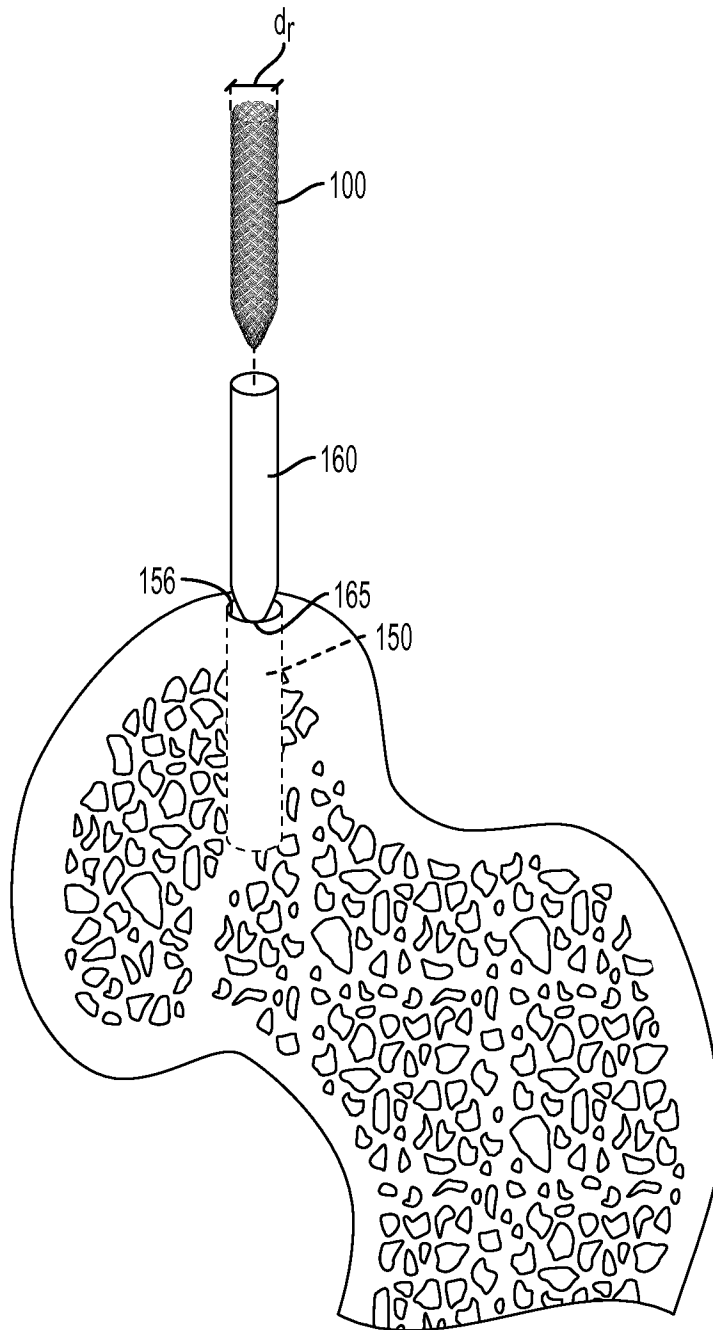


FIG. 1B

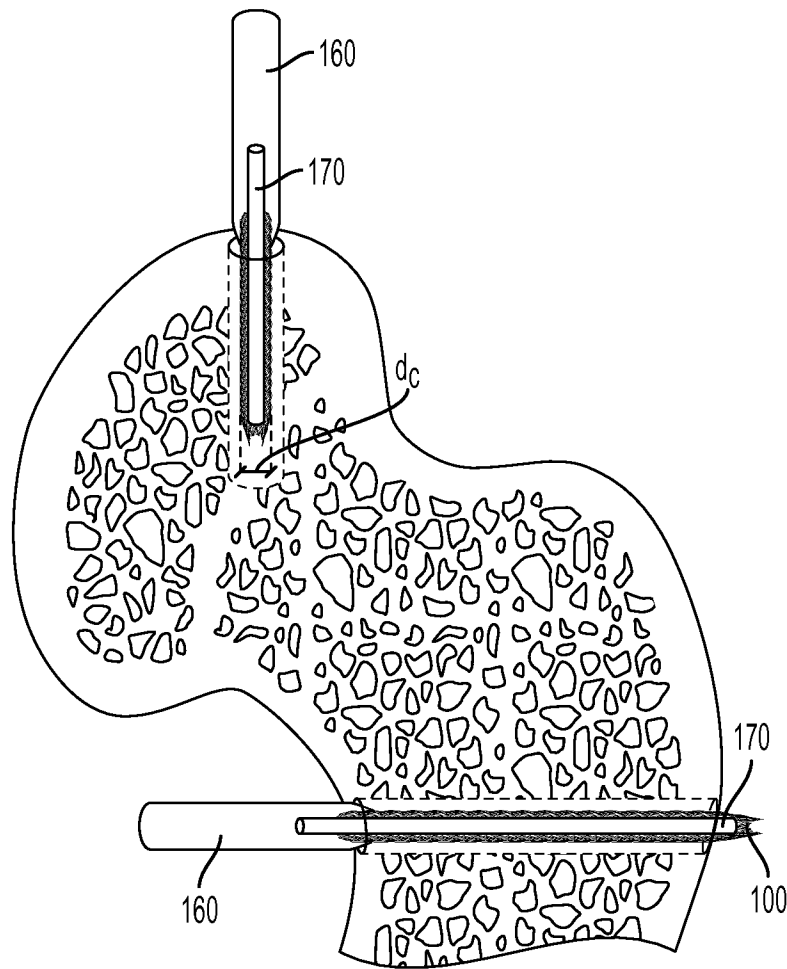


FIG. 1C

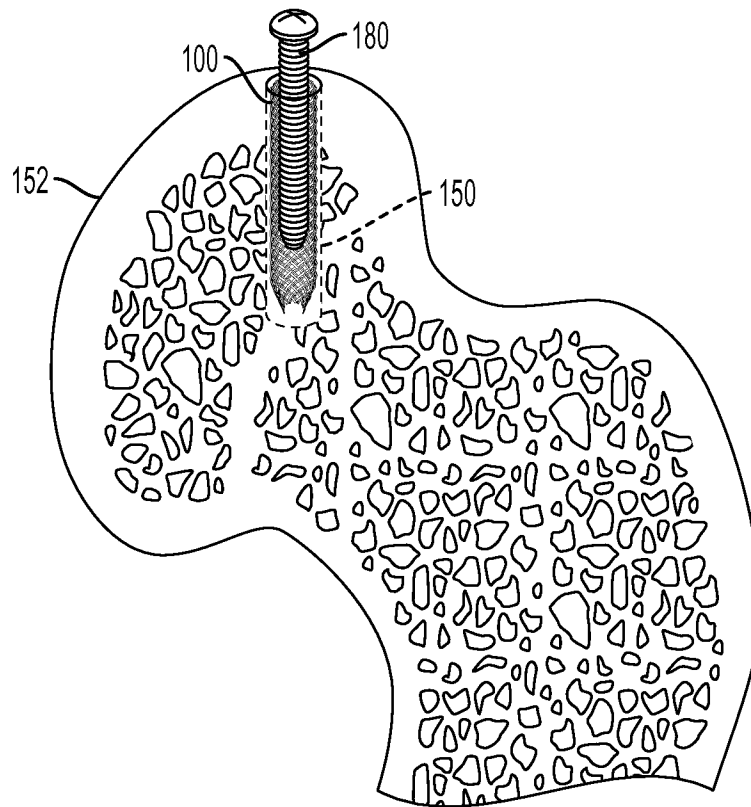


FIG. 2

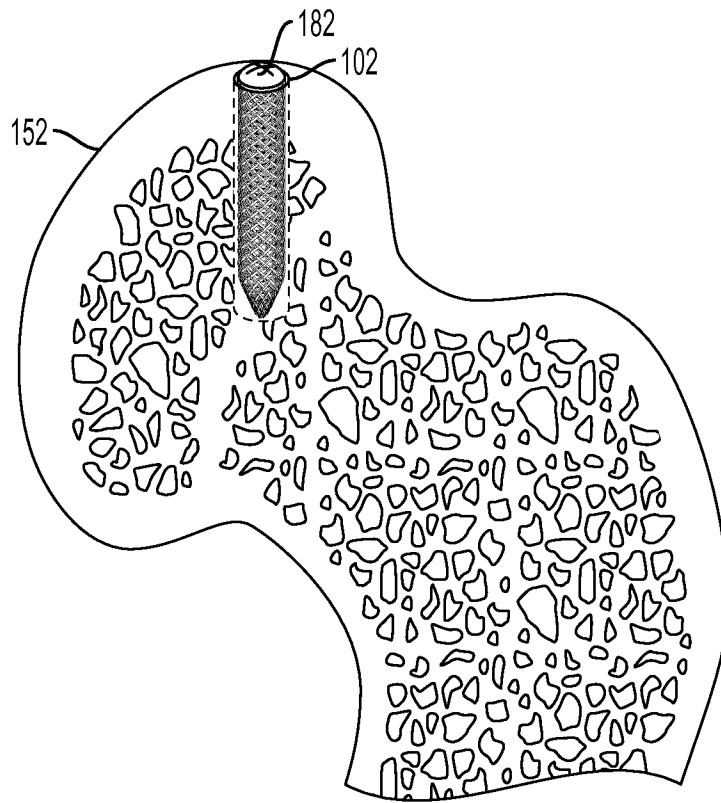


FIG. 3

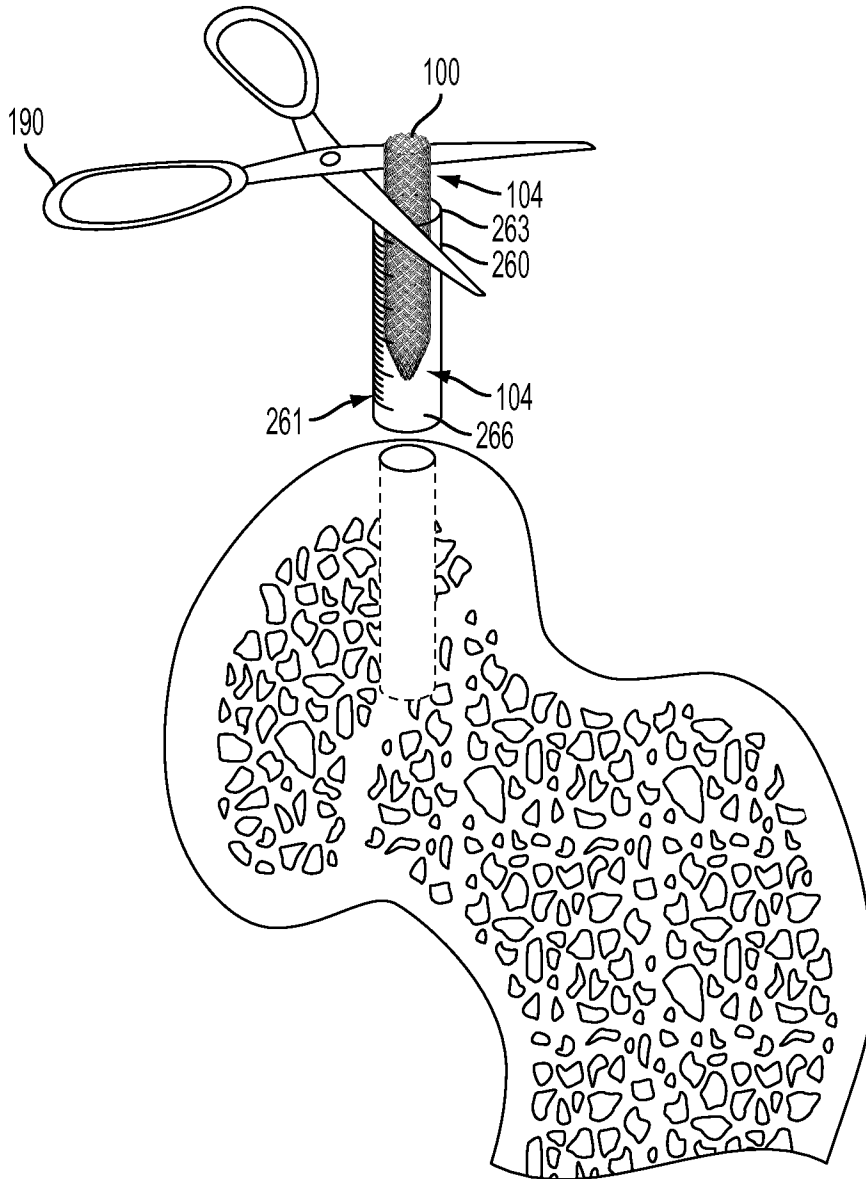


FIG. 4

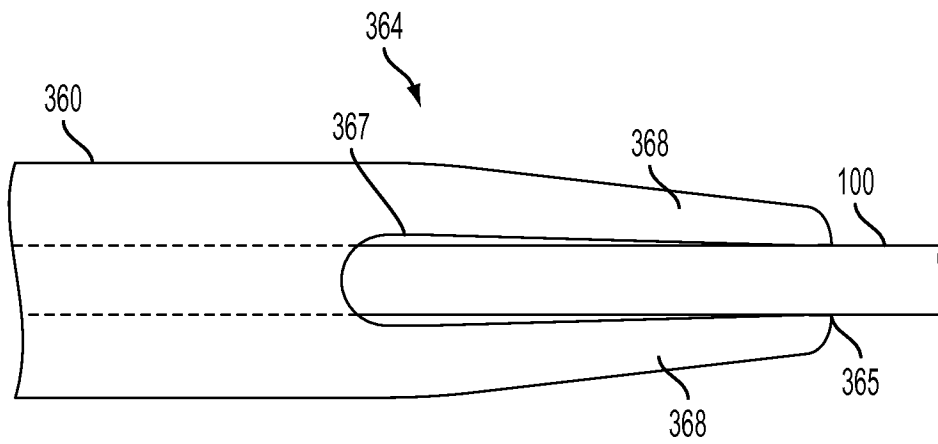


FIG. 5A

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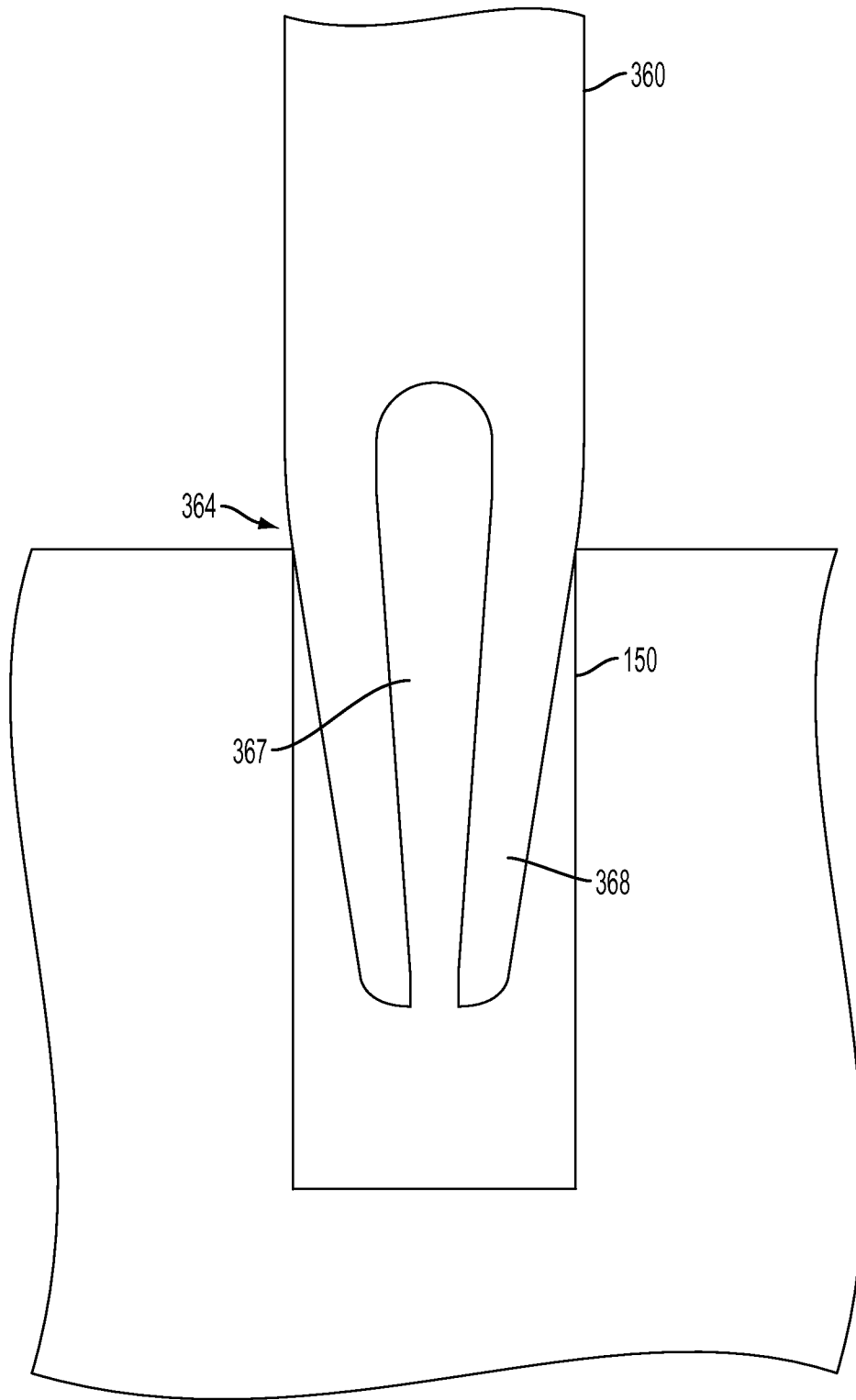


FIG. 5B

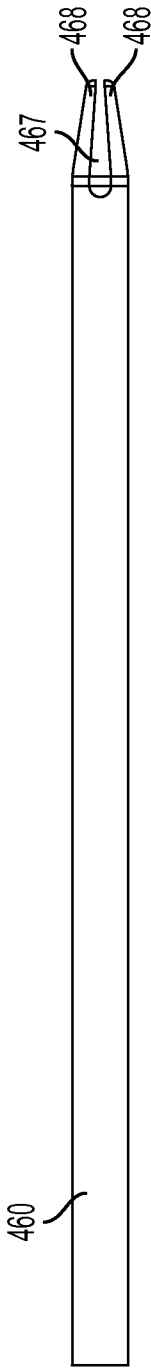


FIG. 6A

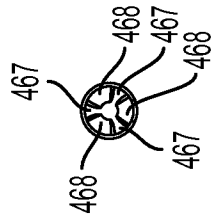


FIG. 6D

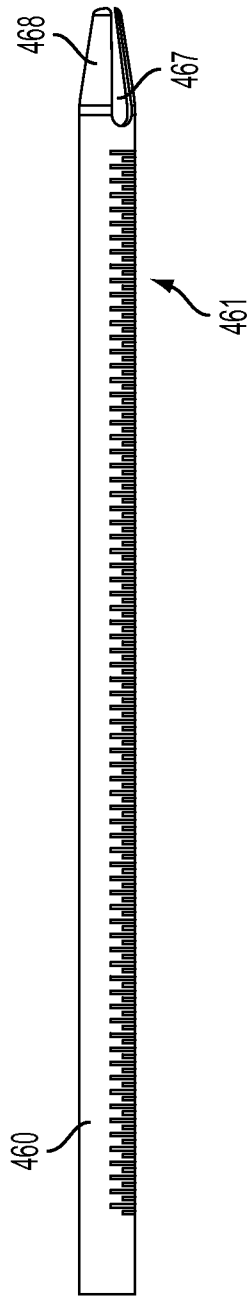


FIG. 6B

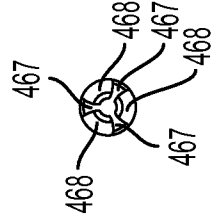


FIG. 6E

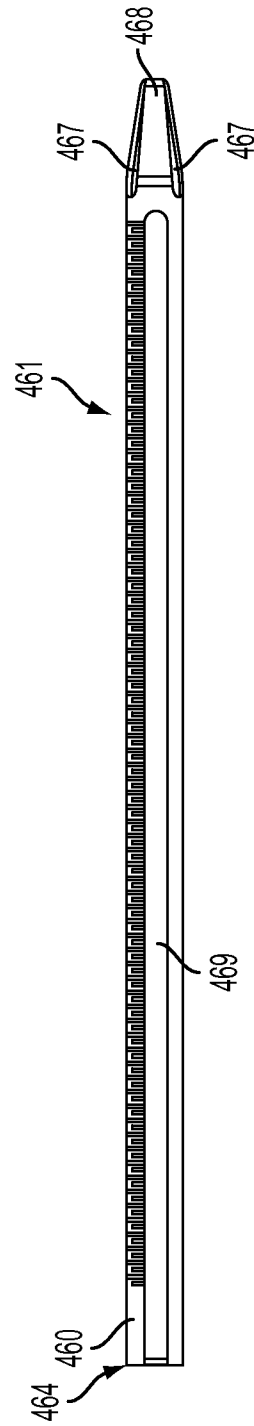


FIG. 6C

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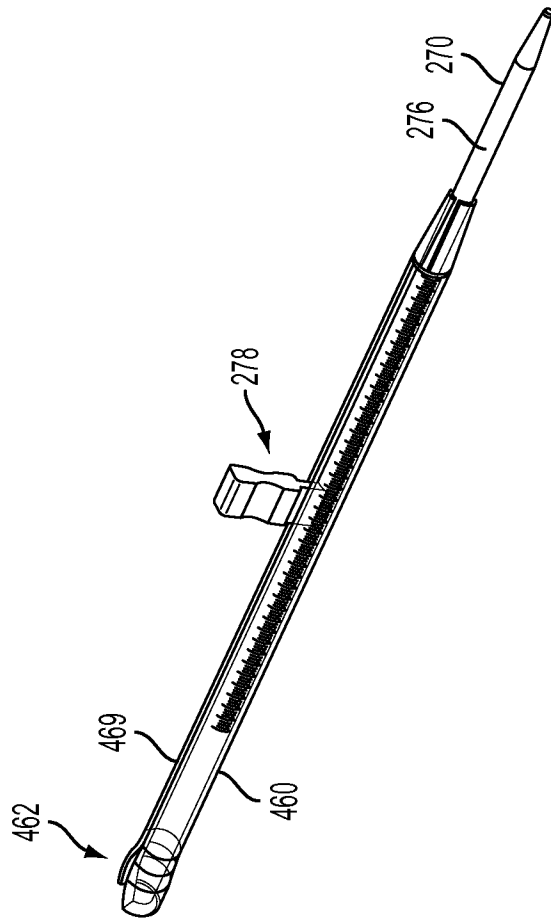


FIG. 7B

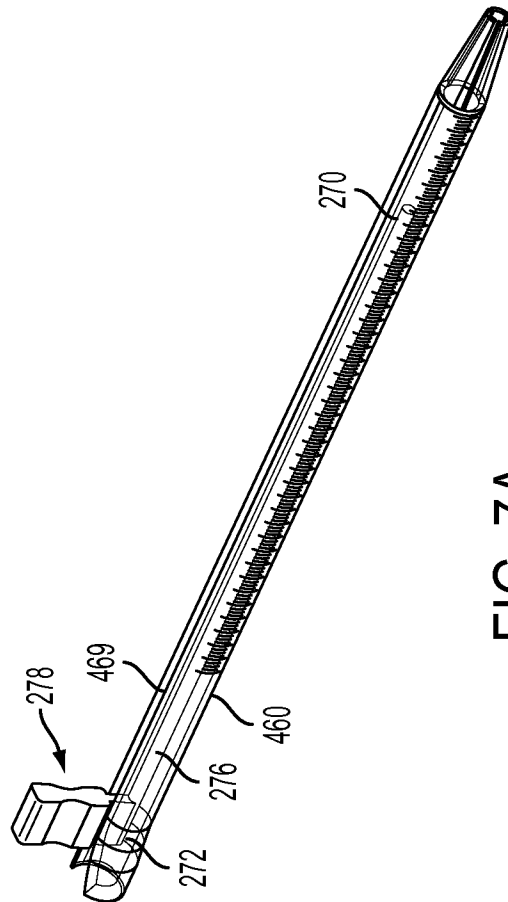


FIG. 7A

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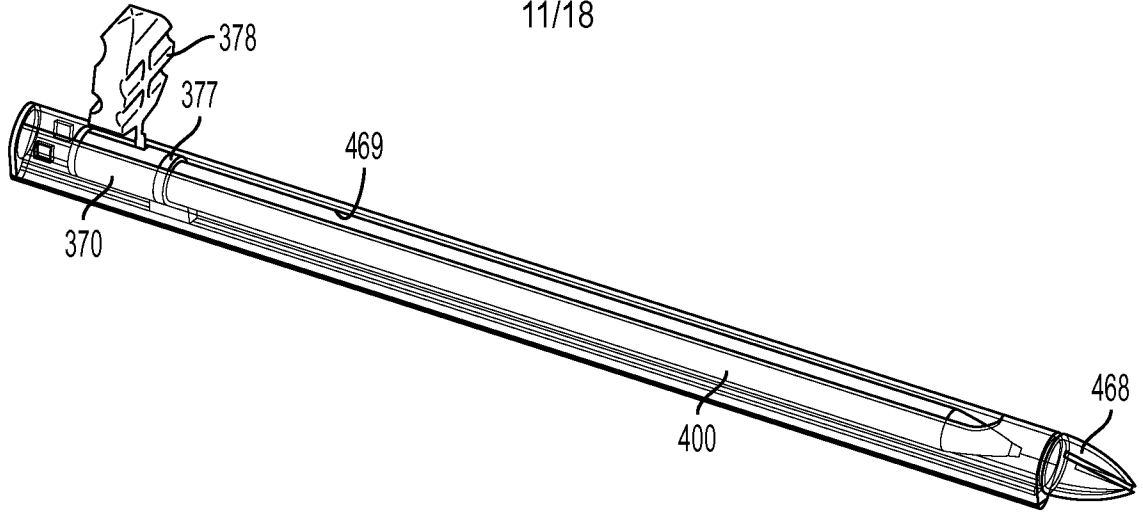


FIG. 8A

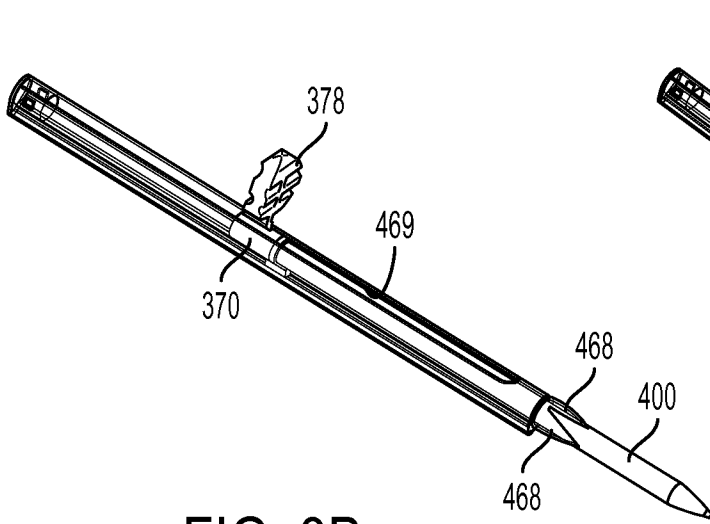


FIG. 8B

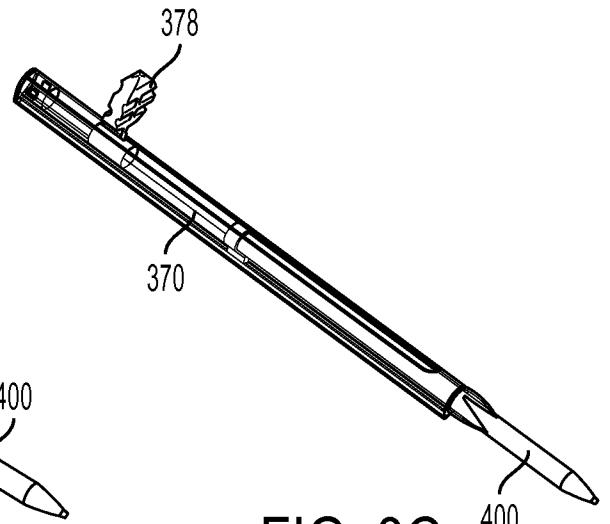


FIG. 8C

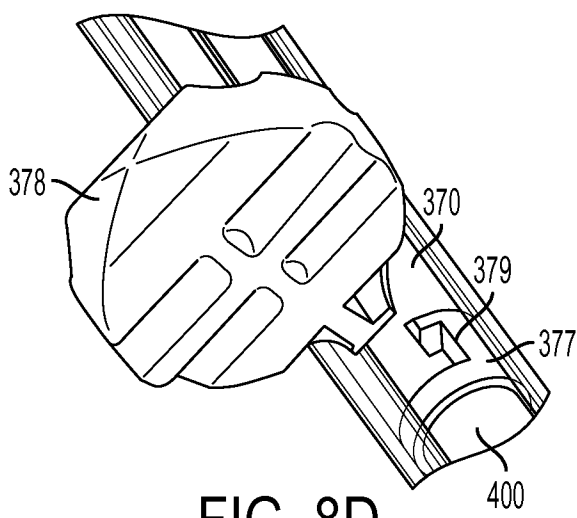


FIG. 8D

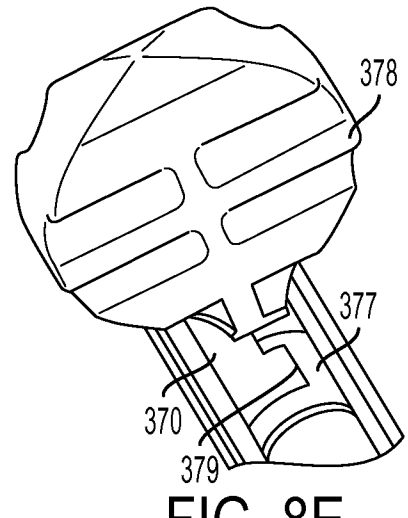


FIG. 8E

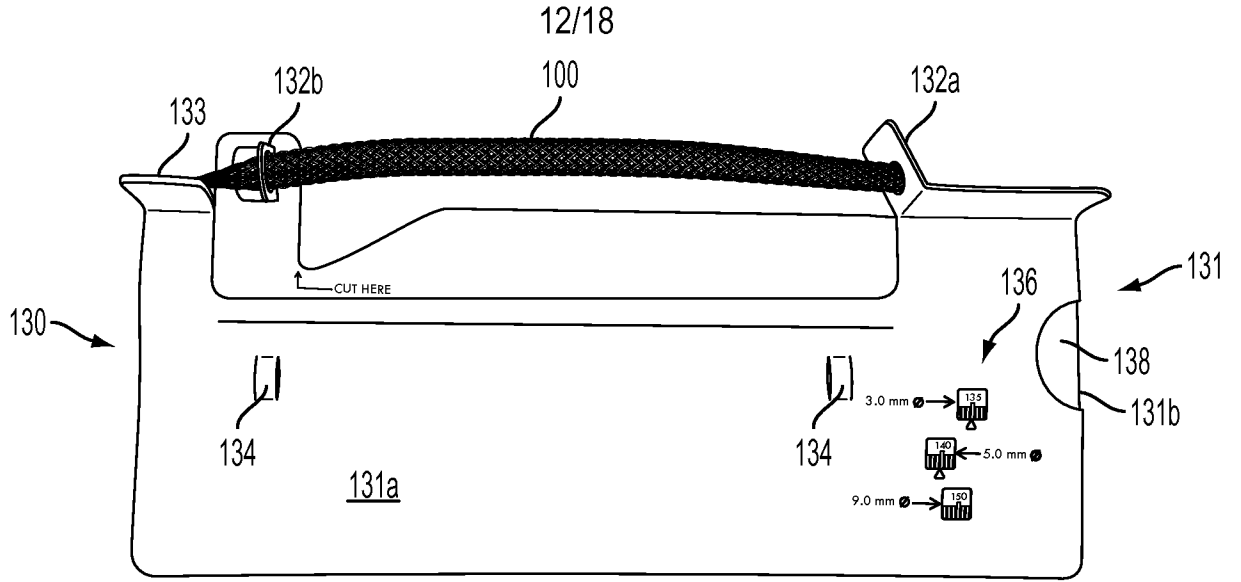


FIG. 9A

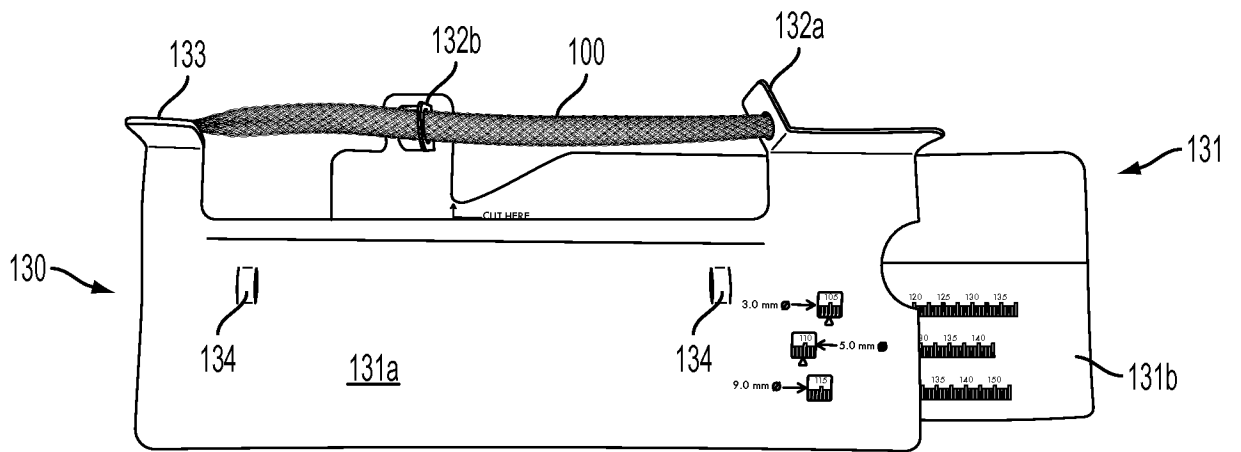


FIG. 9B

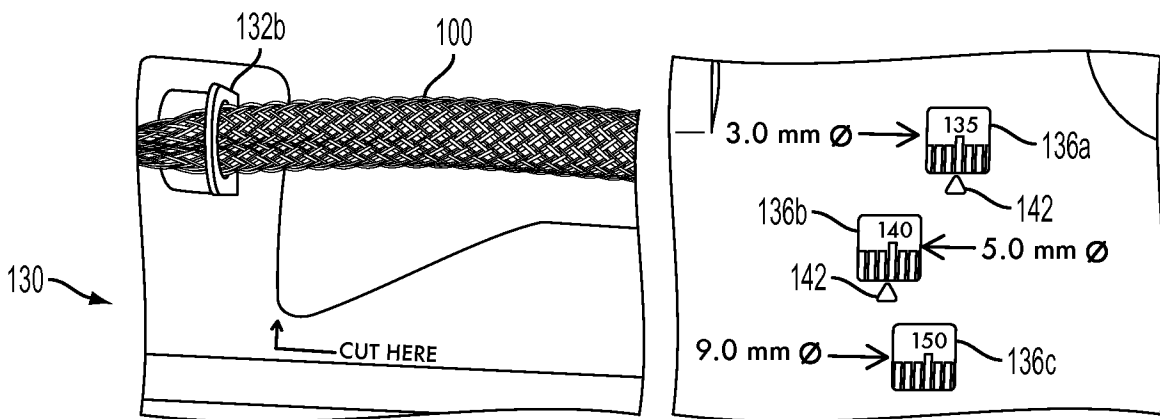


FIG. 9C

FIG. 9D

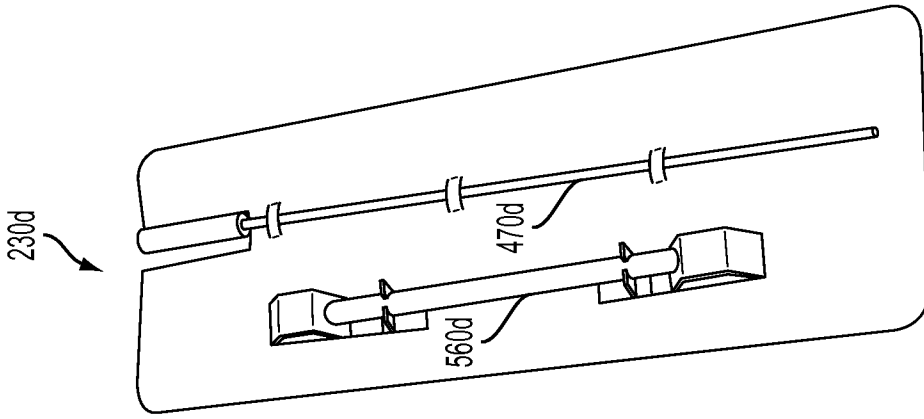


FIG. 10D

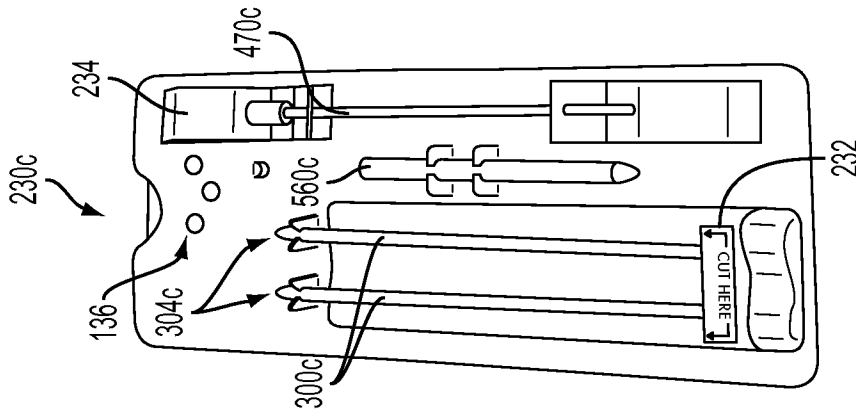


FIG. 10C

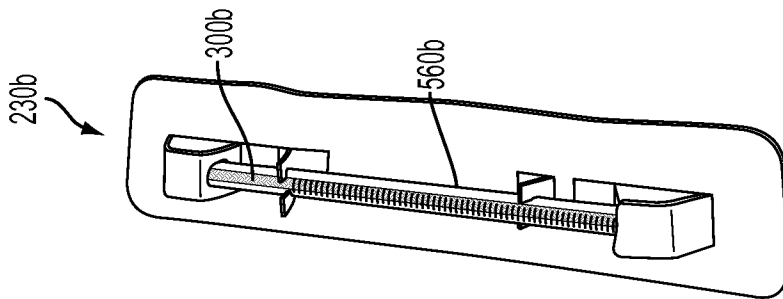


FIG. 10B

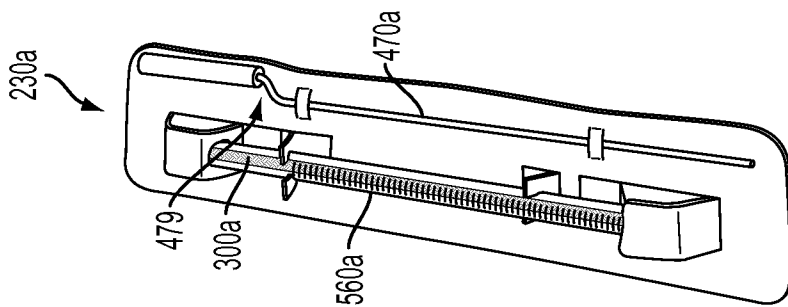


FIG. 10A

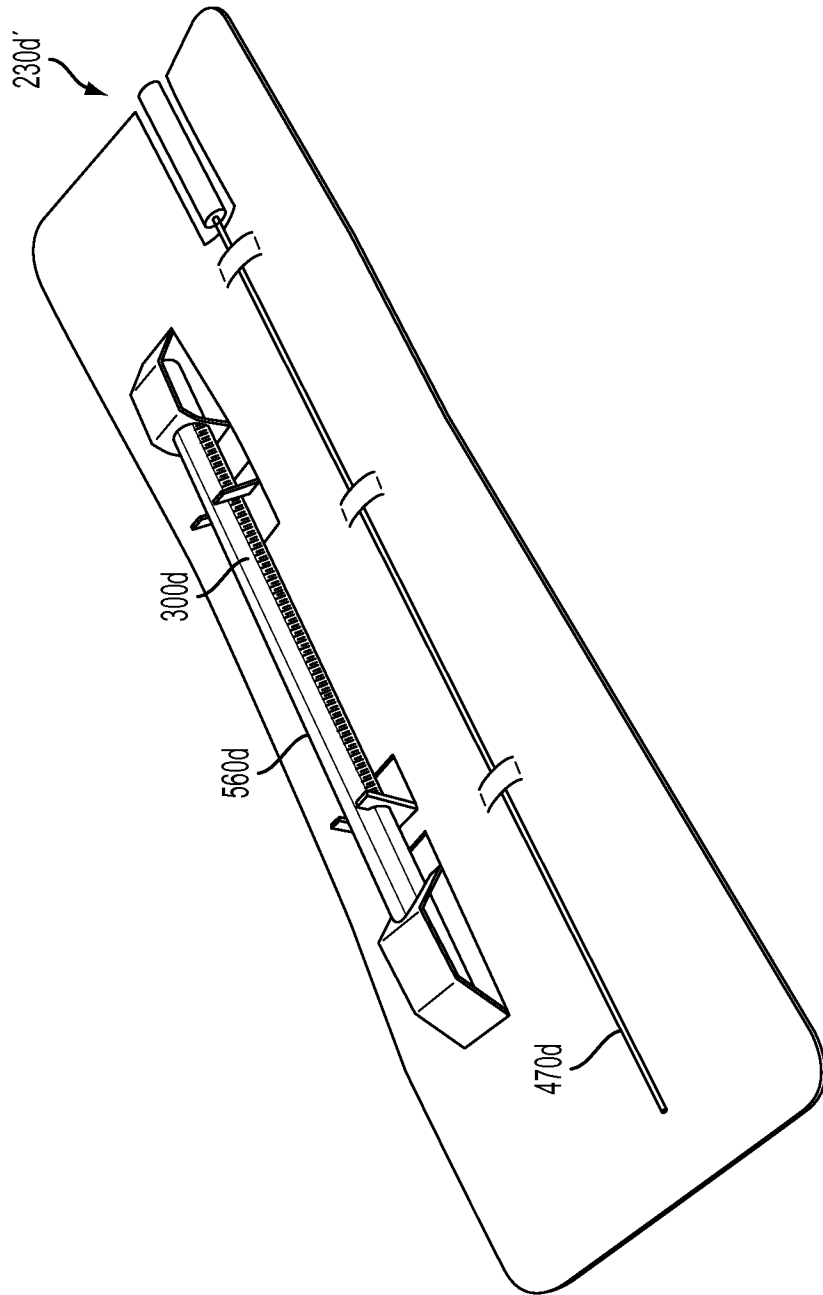


FIG. 12

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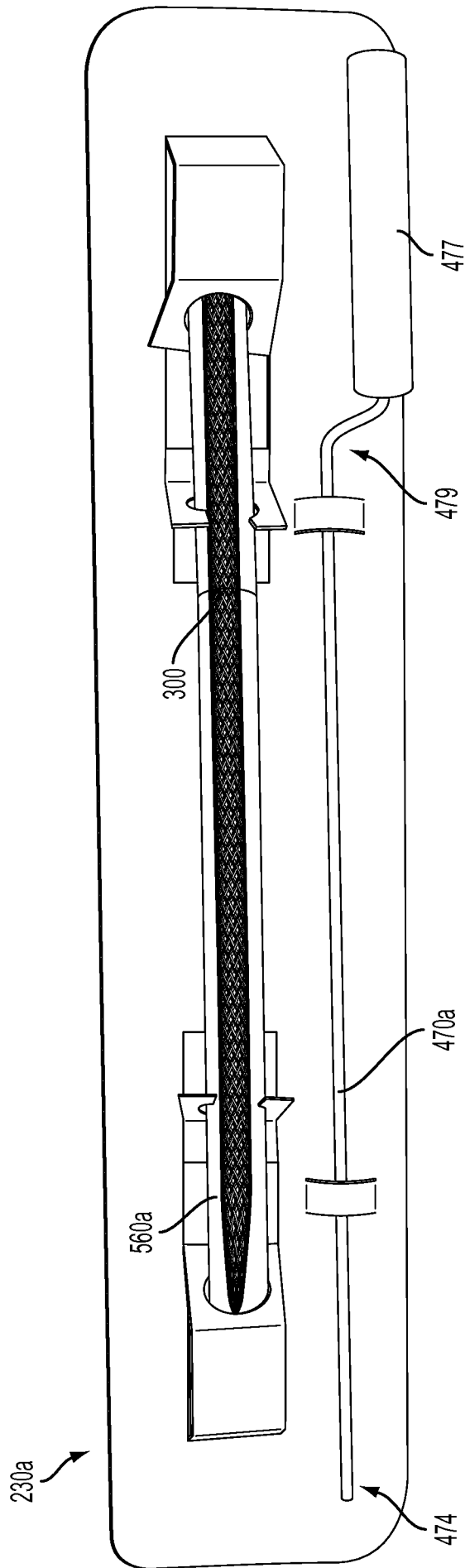


FIG. 13

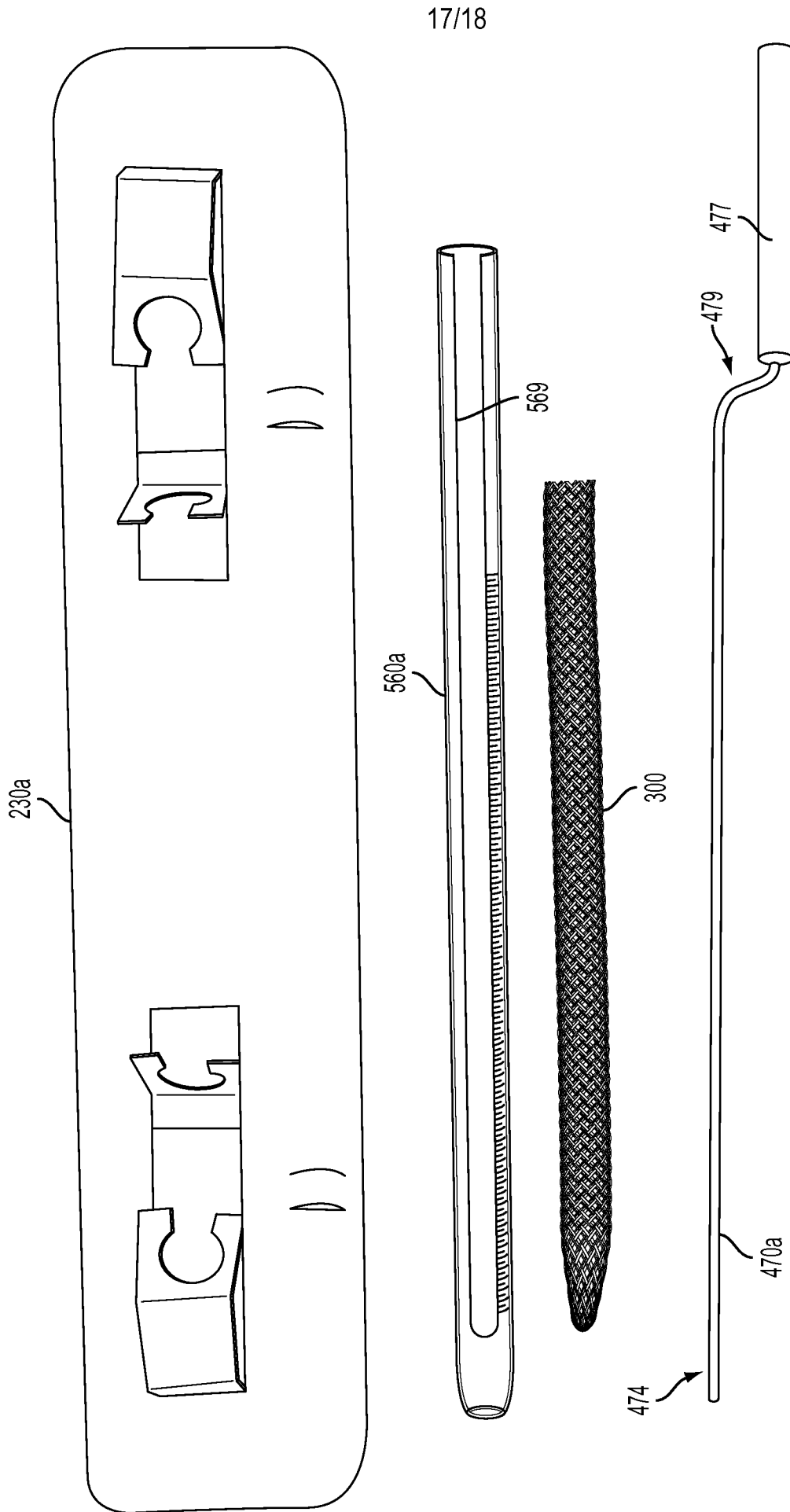


FIG. 14

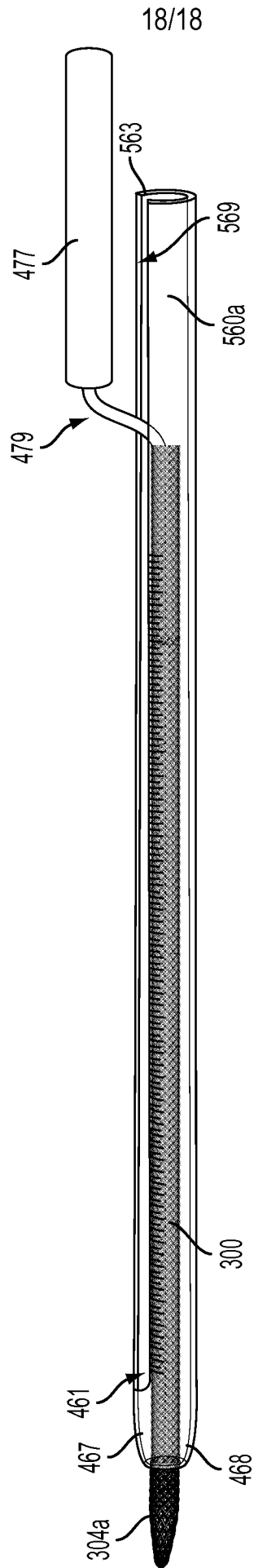


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US15/50483

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - F16B 13/06; A61B 17/68, 17/84 (2015.01)
CPC - A61B 17/686, 17/8685, 17/844
 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): F16B 13/06; A61B 17/68, 17/84, A61 F 2/08 (2015.01)
 CPC: A61B 17/686 , 17/8685, 17/844; A61F 2002/0888

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 practicable, search terms used)
 PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google/Google Scholar; IP.com; PubMed/MEDLINE:
 screw*, pedicle*, bone*, mesh*, wov*, weav*, braid*, graft*, compress*, deliver*.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5984926 A (JONES, AAM) November 16, 1999; abstract; figures 1, 3, 3C, 6-7; column 7, lines 20-35, lines 64-67; column 8, lines 1-13	1-22
A	US 2004/0068267 A1 (HARVIE, F et al.) April 08, 2004; abstract; figures 10, 10A-10B, 13, 13A-13J; paragraphs [0113]-[0114], [0118], [0120]	1-22
A	WO 2010/042293 A1 (SYNTHES, USA LLC) April 15, 2010; abstract; paragraph [0026], figures 11A-11B, 12A-12B	1-22
A	US 2004/0024456 A1 (BROWN, JR., CH et al.) February 05, 2004; abstract; figures 2A-2C; paragraphs [0069], [0074]	1-22

Further documents are listed in the continuation of Box C. 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	"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
"E" earlier application or patent but published on or after the international filing date	"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
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Date of the actual completion of the international search 20 November 2015 (20.11.2015)	Date of mailing of the international search report 28 DEC 2015
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