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(54) Title: SYSTEM FOR USE IN TREATMENT OF VERTEBRAL FRACTURES

(57) Abstract: Methods and devices that displace bone or other hard tissue to create a cavity in the tissue. Where such methods and devices rely on a driving mechanism for providing moving of the device to form a profile that improves displacement of the tissue. These methods and devices also allow for creating a path or cavity in bone for insertion of bone cement or other filler to treat a fracture or other condition in the bone. The features relating to the methods and devices described herein can be applied in any region of bone or hard tissue where the tissue or bone is displaced to define a bore or cavity instead of being extracted from the body such as during a drilling or ablation procedure.

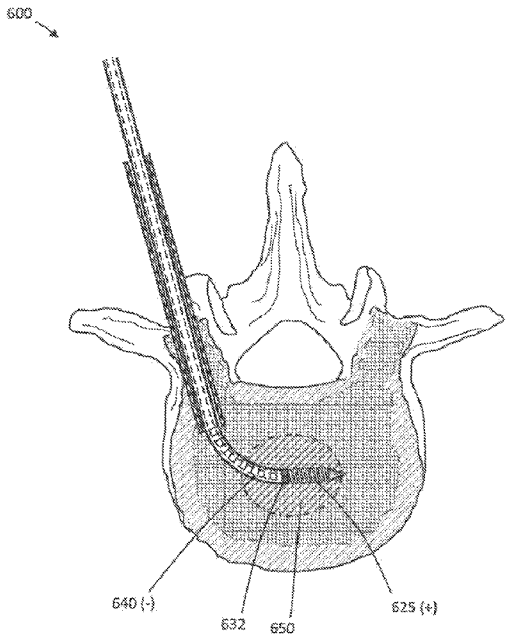


FIG. 23

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SYSTEM FOR USE IN TREATMENT OF VERTEBRAL FRACTURES

FIELD OF THE INVENTION

[0001] This invention relates to medical instruments and systems for creating a path or cavity in vertebral bone to receive bone cement to treat a vertebral compression fracture. The features relating to the methods and devices described herein can be applied in any region of bone or hard tissue where the tissue or bone is displaced to define a bore or cavity instead of being extracted from the body such as during a drilling or ablation procedure. In addition, the present invention also discloses methods and devices for ablating or coagulating tissues, including but not limited to ablating tumor tissue in vertebral and/or cortical bone.

SUMMARY OF THE INVENTION

[0002] Methods and devices described herein relate to improved creation of a cavity within bone or other hard tissue where the cavity is created by displacement of the tissue. In a first example, a method according to the present disclosure includes treating a vertebral body or other bone structure. In one variation, the method includes providing an elongate tool having a sharp tip configured for penetration into vertebral bone, the tool having an axis extending from a proximal end to a working end thereof, where the working end comprises at least a first sleeve concentrically located within a second sleeve and a third sleeve located concentrically about the second sleeve, where each sleeve comprises a series of slots or notches to limit deflection of the working end to a first curved configuration in a single plane and where the respective series of slots or notches are radially offset in each sleeve; advancing the working end through vertebral bone; causing the working end to move from a linear configuration to a curved configuration by translating the first sleeve relative to the second sleeve in an axial direction; and moving the working end in the curved configuration within the bone to create a cavity therein. Translating of the first sleeve relative to the second sleeve can include moving either sleeve or both sleeves in an axial direction. Additional variations include moving one or both sleeves in a rotational direction to produce relative axial displacement between sleeves.

[0003] In an additional variation, the present devices include medical osteotome devices that can for treat a hard tissue (e.g., in a vertebral body) by mechanically displacing the hard tissue and/or applying therapeutic energy to ablate or coagulate tissue. For example, one such variation includes an osteotome type device that is coupled to a power supply and further includes a handle having an actuating portion and a connector for electrically coupling the osteotome device to the power supply; a shaft comprising a first sleeve located concentrically within a second sleeve, the shaft having a distal portion comprising a working end capable of moving between a linear configuration and an articulated configuration where the articulated configuration is limited to a single plane, and where each sleeve comprises a series of slots or notches to limit deflection of the working end to the articulated configuration, where the respective series of slots or notches are radially offset in adjacent sleeves, where a first conductive portion of the shaft is electrically coupleable to a first pole of the power supply; a sharp tip located at a distal tip of the first sleeve of the working end, the sharp tip adapted to penetrate bone within the vertebral body, where the distal tip is coupleable to a second pole of the power supply, such that when activated, current flows between a portion of the distal tip and the shaft; a non-conductive layer electrically isolating the first sleeve from the first conductive portion; and where the shaft and sharp tip have sufficient column strength such that application of an impact force on the handle causes the distal portion of the shaft and the distal tip to mechanically displace the hard tissue. The power supply can be coupled to the outer sleeve (either the second or third sleeve discussed herein.)

[0004] Another variations of the method disclosed herein can include the application of energy between electrodes on the device to ablate tissues (e.g., tumor) or to perform other electrosurgical or mapping procedures within the tissue. In one such example for treating a vertebral body, the method can include providing an elongate tool having a sharp tip configured for penetration into vertebral bone, the tool having an axis extending from a proximal end to a working end thereof, where the working end comprises at least a first sleeve concentrically located within a second sleeve, where each sleeve comprises a series of slots or notches to limit deflection of the working end to a first curved configuration in a single plane and where the respective series of

slots or notches are radially offset in adjacent sleeves, where a first conductive portion of the first sleeve is electrically coupled to a first pole of a power supply; advancing the working end through vertebral bone; causing the working end to move from a linear configuration to a curved configuration by translating the first sleeve relative to the second sleeve in an axial direction; and applying energy between the first conductive portion and a return electrode electrically coupled to a second pole of the energy supply to ablate or coagulate a region within the vertebral body.

[0005] In variations of the method, moving the working end to from the linear configuration to the curved configuration can include moving the working end to move through a plurality of curved configurations.

[0006] In an additional variation, causing the working end to move from a linear configuration to the curved configuration comprises actuating a handle mechanism to move the working end from the linear configuration to the curved configuration. The handle mechanism can be moved axially and/or rotationally as described herein.

[0007] In one variation, actuating of the handle mechanism causes the working end to move to the first curved configuration without torquing the third sleeve.

[0008] In additional variations, the working end of the osteotome or tool is spring biased to assume the linear configuration.

[0009] The working end can move from the linear configuration to the curved configuration by applying a driving force or impact to the elongate tool wherein penetration in the cortical bone moves the working end from the linear configuration to the curved configuration. For example, as a hammering or impact force is applied to the working end, the interaction of the sharp tip against bone causes the working end to assume an articulated and/or curved configuration. Where further axial movement of the tool causes compression of the bone and creation of the cavity.

[0010] The method can further include the use of one or more cannulae to introduce the tool into the target region. Such a cannula can maintain the tool in a straight or linear configuration until the tool advances out of the cannula or until the cannula is withdrawn from over the tool.

[0011] As described herein, upon creation of the cavity, the method can further include the insertion of a filler material or other substance into the cavity. The filler material can be delivered through the tool or through a separate cannula or catheter.

[0012] This disclosure also includes variations of devices for creating a cavity within bone or hard tissue. Such variations include devices for treating a vertebral body or other such structure. In one variation a device includes a handle having an actuating portion; a shaft comprising a first sleeve located concentrically within a second sleeve and a third sleeve located concentrically about the second sleeve, the shaft having a distal portion comprising a working end capable of moving between a linear configuration and an articulated configuration where the second articulated configuration is limited to a single plane, and where each sleeve comprises a series of slots or notches to limit deflection of the working end to the articulated configuration, where the respective series of slots or notches are radially offset in each sleeve; and a sharp tip located at a distal tip of the working end, the sharp tip adapted to penetrate vertebral bone within the vertebral body.

[0013] In one variation, the devices described herein can include a configuration where the first sleeve is affixed to the second sleeve at the working end such that proximal movement of the first sleeve causes the working end to assume the articulated configuration. The sleeves can be affixed at any portion along their length via a mechanical fixation means (e.g., a pin or other fixation means), an adhesive, or one or more weld points. In some variations, fixation of the sleeves occurs at the working end so that movement of the inner or first sleeve causes the working end to assume the curved configuration. In some cases, the third sleeve can be affixed outside of the working end so long as when the first and second sleeves articulate, the third sleeve still articulates.

[0014] Devices described herein can optionally include a force-limiting assembly coupled between the actuating portion and the first sleeve such that upon reaching a threshold force, the actuating portion disengages the first sleeve. In one variation, the force-limiting mechanism is adapted to limit force applied to bone when moving the working end from the first configuration toward the second configuration.

[0015] In additional variations, devices for creating cavities in bone or hard tissue can include one or more spring elements that extending through the first sleeve, where the spring element is affixed to the shaft (within or about either the first, second, or third sleeve). Such spring elements cause the working end to assume a linear configuration in a relaxed state.

[0016] In additional variations, a device can include an outer or third sleeve where the slots or notches (that allow deflection) are located on an exterior surface of the third sleeve. The exterior surface is typically the surface that faces outward from a direction of the curved configuration. This configuration allows for an interior surface (the surface located on the interior of the curved portion) to be smooth. As a result, if the device is withdrawn through tissue or a cannula or other introducer, the smooth surface on the interior of the curve minimizes the chance that the device becomes caught on the opening of the cannula or any other structure.

[0017] Variations of the device can include one or more lumens that extend through the shaft and working end. These lumens can exit at a distal tip of the device or through a side opening in a wall of the device. The lumen can include a surface comprising a lubricious polymeric material. For example, the material can comprise any bio-compatible material having low frictional properties (e.g., TEFLON®, a polytetrafluroethylene (PTFE), FEP (Fluorinated ethylenepropylene), polyethylene, polyamide, ECTFE (Ethylenechlorotrifluoro-ethylene), ETFE, PVDF, polyvinyl chloride and silicone).

[0018] As described herein, the devices can include any number of configurations to prevent rotation between adjacent sleeves but allow axial movement between the sleeves. For example, the sleeves can be mechanically coupled via a pin/slot or key/keyway configuration. In an additional variation, the sleeves can be non-circular to prevent rotation.

[0019] In an additional variation, the disclosure includes various kits comprising the device described herein as well as a filler material (e.g., a bone cement or other bone filler material).

[0020] Variations of the access device and procedures described above include combinations of features of the various embodiments or combination of the embodiments themselves wherever possible.

[0021] The methods, devices and systems described herein can be combined with the following commonly assigned patent applications and provisional applications, the entirety of each of which is incorporated by reference herein: Application Number 61/194,766, filed September 30, 2008; Application Number 61/104,380, filed October 10, 2008; Application Number 61/322,281, filed April 8, 2010; Application Number 12/571,174 filed September 30, 2009; PCT Application number PCT/US2009/059113 filed 9/30/2009; Application Number 12/578,455 filed October 13, 2009.

BRIEF DESCRIPTION OF DRAWINGS

[0022] FIG. 1 is a plan view of an osteotome of the invention.

[0023] FIG. 2 is a side view of the osteotome of FIG. 1.

[0024] FIG. 3 is a cross sectional view of the osteotome of FIG. 1.

[0025] FIG. 4 is an enlarged sectional view of the handle of the osteotome of FIG. 1.

[0026] FIG. 5 is an enlarged sectional view of the working end of the osteotome of FIG. 1.

[0027] FIG. 6A is a sectional view of the working end of FIG. 5 in a linear configuration.

[0028] FIG. 6B is a sectional view of the working end of FIG. 5 in a curved configuration.

[0029] FIGS. 7A-7C are schematic sectional views of a method of use of the osteotome of FIG. 1.

[0030] FIG. 8 is another embodiment of an osteotome working end.

[0031] FIG. 9 is another embodiment of an osteotome working end.

[0032] FIG. 10 is another variation of an osteotome with an outer sleeve.

[0033] FIG. 11 is a cut-away view of the working end of the osteotome of FIG. 10.

[0034] FIG. 12A is sectional view of another embodiment of working end, taken along line 12A-12A of FIG. 11.

[0035] FIGS. 12B and 12C illustrate additional variations of preventing rotation between adjacent sleeves.

[0036] FIG. 13 is sectional view of another working end embodiment similar to that of FIG. 11.

[0037] FIG. 14 is a cut-away perspective view of the working end of FIG. 13.

[0038] FIG. 15 illustrates a variation of an osteotome as described herein having electrodes on a tip of the device and another electrode on the shaft.

[0039] FIG. 16 illustrates an osteotome device as shown in FIG. 15 after being advanced into the body and where current passes between electrodes.

[0040] FIG. 17 illustrates a variation of a device as described herein further including a connector for providing energy at the working end of the device.

[0041] FIGS. 18A and 18B illustrate a device having a sharp tip as disclosed herein where the sharp tip is advanceable from the distal end of the shaft.

[0042] FIG. 19 shows a cross sectional view of the device illustrated in FIG. 18B and also illustrates temperature sensing elements located on device.

[0043] FIG. 20 shows a variation of a device where the inner sleeve is extended from the device and where current is applied between the extended portion of the inner sleeve and the shaft to treat tissue.

[0044] FIG. 21 illustrates a variation of a device as described herein further including an extendable helical electrode carried by the working end of the device.

[0045] FIGS. 22A and 22B illustrate the device of FIG. 21 with the helical electrode in a non-extended position and an extended position.

[0046] FIG. 23 illustrates the working end of the device of FIG. 21 in a vertebral body with the helical electrode delivering Rf energy to tissue for ablation or other treatments.

DETAILED DESCRIPTION

[0047] Referring to FIGS. 1-5, an apparatus or osteotome 100 is shown that is configured for accessing the interior of a vertebral body and for creating a pathway in vertebral cancellous bone to receive bone cement. In one embodiment, the apparatus is configured with an extension portion or member 105 for introducing through a pedicle and wherein a working end 110 of the extension member can be progressively

actuated to curve a selected degree and/or rotated to create a curved pathway and cavity in the direction of the midline of the vertebral body. The apparatus can be withdrawn and bone fill material can be introduced through a bone cement injection cannula. Alternatively, the apparatus 100 itself can be used as a cement injector with the subsequent injection of cement through a lumen 112 of the apparatus.

[0048] In one embodiment, the apparatus 100 comprises a handle 115 that is coupled to a proximal end of the extension member 105. The extension member 105 comprises an assembly of first (outer) sleeve 120 and a second (inner) sleeve 122, with the first sleeve 120 having a proximal end 124 and distal end 126. The second sleeve 122 has a proximal end 134 and distal end 136. The extension member 105 is coupled to the handle 115, as will be described below, to allow a physician to drive the extension member 105 into bone while contemporaneously actuating the working end 110 into an actuated or curved configuration (see FIG. 6). The handle 115 can be fabricated of a polymer, metal or any other material suitable to withstand hammering or impact forces used to drive the assembly into bone (e.g., via use of a hammer or similar device on the handle 115). The inner and outer sleeves are fabricated of a suitable metal alloy, such as stainless steel or NiTi. The wall thicknesses of the inner and outer sleeves can range from about 0.005" to 0.010" with the outer diameter the outer sleeve ranging from about 2.5 mm to 5.0 mm.

[0049] Referring to FIGS. 1, 3 and 4, the handle 115 comprises both a first grip portion 140 and a second actuator portion indicated at 142. The grip portion 140 is coupled to the first sleeve 120 as will be described below. The actuator portion 142 is operatively coupled to the second sleeve 122 as will be described below. The actuator portion 142 is rotatable relative to the grip portion 140 and one or more plastic flex tabs 145 of the grip portion 140 are configured to engage notches 146 in the rotatable actuator portion 142 to provide tactile indication and temporary locking of the handle portions 140 and 142 in a certain degree of rotation. The flex tabs 145 thus engage and disengage with the notches 146 to permit ratcheting (rotation and locking) of the handle portions and the respective sleeve coupled thereto.

[0050] The notches or slots in any of the sleeves can comprise a uniform width along the length of the working end or can comprise a varying width. Alternatively, the

width can be selected in certain areas to effectuate a particular curved profile. In other variation, the width can increase or decrease along the working end to create a curve having a varying radius. Clearly, it is understood that any number of variations are within the scope of this disclosure.

[0051] FIG. 4 is a sectional view of the handle showing a mechanism for actuating the second inner sleeve 122 relative to the first outer sleeve 120. The actuator portion 142 of the handle 115 is configured with a fast-lead helical groove indicated at 150 that cooperates with a protruding thread 149 of the grip portion 140 of the handle. Thus, it can be understood that rotation of the actuation portion 142 will move this portion to the position indicated at 150 (phantom view). In one embodiment, when the actuator portion 142 is rotated a selected amount from about 45° to 720°, or from about 90° to 360°, the inner sleeve 122 is lifted proximally relative to the grip portion 140 and outer sleeve 120 to actuate the working end 110. As can be seen in FIG. 4 the actuator portion 142 engages flange 152 that is welded to the proximal end 132 of inner sleeve 122. The flange 152 is lifted by means of a ball bearing assembly 154 disposed between the flange 152 and metal bearing surface 155 inserted into the grip portion 140 of the handle. Thus, the rotation of actuator 142 can lift the inner sleeve 122 without creating torque on the inner sleeve.

[0052] Now turning to FIGS. 5, 6A and 6B, it can be seen that the working end 110 of the extension member 105 is articulated by cooperating slotted portions of the distal portions of outer sleeve 120 and inner sleeve 122 that are both thus capable of bending in a substantially tight radius. The outer sleeve 120 has a plurality of slots or notches 162 therein that can be any slots that are perpendicular or angled relative to the axis of the sleeve. The inner sleeve 122 has a plurality of slots or notches indicated at 164 that can be on an opposite side of the assembly relative to the slots 162 in the outer sleeve 120. The outer and inner sleeves are welded together at the distal region indicated at weld 160. It thus can be understood that when inner sleeve 122 is translated in the proximal direction, the outer sleeve will be flexed as depicted in FIG. 6B. It can be understood that by rotating the actuator handle portion 142 a selected amount, the working end can be articulated to a selected degree.

[0053] FIG. 4, 5, 6A and 6B further illustrate another element of the apparatus that comprises a flexible flat wire member 170 with a proximal end 171 and flange 172 that is engages the proximal side of flange 152 of the inner sleeve 122. At least the distal portion 174 of the flat wire member 170 is welded to the inner sleeve at weld 175. This flat wire member thus provides a safety feature to retain the working end in the event that the inner sleeve fails at one of the slots 164.

[0054] Another safety feature of the apparatus comprises a torque limiter and release system that allows the entire handle assembly 115 to freely rotate—for example if the working end 110 is articulated, as in FIG. 6B, when the physician rotates the handle and when the working end is engaged in strong cancellous bone. Referring to FIG. 4, the grip portion 142 of the handle 115 engages a collar 180 that is fixed to a proximal end 124 of the outer sleeve 120. The collar 180 further comprises notches 185 that are radially spaced about the collar and are engaged by a ball member 186 that is pushed by a spring 188 into notches 185. At a selected force, for example a torque ranging from greater than about 0.5 inch*lbs but less that about 7.5 inch*lbs, 5.0 inch*lbs or 2.5 inch*lbs, the rotation of the handle 115 overcomes the predetermined limit. When the torque limiter assembly is in its locked position, the ball bearing 186 is forced into one of the notches 185 in the collar 180. When too much torque is provided to the handle and outer sleeve, the ball bearing 186 disengages the notch 185 allowing the collar 180 to turn, and then reengages at the next notch, releasing anywhere from 0.5 inch*lbs to 7.5 inch*lbs of torque.

[0055] Referring to FIGS. 6A and 6B, it can be understood that the inner sleeve 122 is weakened on one side at its distal portion so as to permit the inner sleeve 122 to bend in either direction but is limited by the location of the notches in the outer sleeve 120. The curvature of any articulated configuration is controlled by the spacing of the notches as well as the distance between each notch peak. The inner sleeve 122 also has a beveled tip for entry through the cortical bone of a vertebral body. Either the inner sleeve or outer sleeve can form the distal tip.

[0056]. Referring to FIGS. 7A-7C, in one variation of use of the device, a physician taps or otherwise drives a stylet 200 and introducer sleeve 205 into a vertebral body 206 typically until the stylet tip 208 is within the anterior 1/3 of the vertebral body

toward cortical bone 210 (FIG. 7A). Thereafter, the stylet 200 is removed and the sleeve 205 is moved proximally (FIG. 7B). As can be seen in FIG. 7B, the tool or osteotome 100 is inserted through the introducer sleeve 205 and articulated in a series of steps as described above. The working end 110 can be articulated intermittently while applying driving forces and optionally rotational forces to the handle 115 to advance the working end through the cancellous bone 212 to create path or cavity 215. The tool is then tapped to further drive the working end 110 to, toward or past the midline of the vertebra. The physician can alternatively articulate the working end 110, and drive and rotate the working end further until imaging shows that the working end 100 has created a cavity 215 of an optimal configuration. Thereafter, as depicted in FIG. 7C, the physician reverses the sequence and progressively straightens the working end 110 as the extension member is withdrawn from the vertebral body 206. Thereafter, the physician can insert a bone cement injector 220 into the path or cavity 215 created by osteotome 100. FIG. 7C illustrates a bone cement 222, for example a PMMA cement, being injected from a bone cement source 225.

[0057] In another embodiment (not shown), the apparatus 100 can have a handle 115 with a Luer fitting for coupling a bone cement syringe and the bone cement can be injected through the lumen 112 of the apparatus. In such an embodiment FIG. 9, the lumen can have a lubricious surface layer or polymeric lining 250 to insure least resistance to bone cement as it flows through the lumen. In one embodiment, the surface or lining 250 can be a fluorinated polymer such as TEFLON® or polytetrafluroethylene (PTFE). Other suitable fluoropolymer resins can be used such as FEP and PFA. Other materials also can be used such as FEP (Fluorinated ethylenepropylene), ECTFE (Ethylenechlorotrifluoro-ethylene), ETFE, Polyethylene, Polyamide, PVDF, Polyvinyl chloride and silicone. The scope of the invention can include providing a polymeric material having a static coefficient of friction of less than 0.5, less than 0.2 or less than 0.1.

[0058] FIG. 9 also shows the extension member or shaft 105 can be configured with an exterior flexible sleeve indicated at 255. The flexible sleeve can be any commonly known biocompatible material, for example, the sleeve can comprise any of the materials described in the preceding paragraph.

[0059] As also can be seen in FIG. 9, in one variation of the device 100, the working end 110 can be configured to deflect over a length indicated at 260 in a substantially smooth curve. The degree of articulation of the working end 100 can be at least 45°, 90°, 135° or at least 180° as indicated at 265 (FIG. 9). In additional variations, the slots of the outer 120 and inner sleeves 120 can be varied to produce a device having a radius of curvature that varies among the length 260 of the device 100.

[0060] In another embodiment of the invention, the inner sleeve can be spring loaded relative the outer sleeve, in such a way as to allow the working end to straighten under a selected level of force when pulled in a linear direction. This feature allows the physician to withdraw the assembly from the vertebral body partly or completely without further rotation the actuating portion 142 of handle 115. In some variations, the force-limiter can be provided to allow less than about 10 inch*lbs of force to be applied to bone.

[0061] In another embodiment shown in FIG. 8, the working end 110 is configured with a tip 240 that deflects to the position indicated at 240' when driven into bone. The tip 240 is coupled to the sleeve assembly by resilient member 242, for example a flexible metal such as stainless steel or NiTi. It has been found that the flexing of the tip 240 causes its distal surface area to engage cancellous bone which can assist in deflecting the working end 110 as it is hammered into bone.

[0062] In another embodiment of the invention (not shown), the actuator handle can include a secondary (or optional) mechanism for actuating the working end. The mechanism would include a hammer-able member with a ratchet such that each tap of the hammer would advance assembly and progressively actuate the working end into a curved configuration. A ratchet mechanism as known in the art would maintain the assembly in each of a plurality of articulated configurations. A release would be provided to allow for release of the ratchet to provide for straightening the extension member 105 for withdrawal from the vertebral body.

[0063] FIGS. 10 and 11 illustrate another variation of a bone treatment device 400 with a handle 402 and extension member 405 extending to working end 410 having a similar construction to that FIGS. 1 to 6B. The device 400 operates as described previously with notched first (outer) sleeve 120 and cooperating notched second

(inner) sleeve 122. However, the variation shown in FIGS. 10 and 11 also includes a third concentric notched sleeve 420, exterior to the first 120 and second 122 sleeves. The notches or slots in sleeve 420 at the working end 410 permit deflection of the sleeve as indicated at 265 in FIG. 11.

[0064] FIG. 10 also illustrates the treatment device 400 as including a luer fitting 412 that allows the device 402 to be coupled to a source of a filler material (e.g., a bone filler or bone cement material). The luer can be removable from the handle 402 to allow application of an impact force on the handle as described above. Moreover, the luer fitting 402 can be located on the actuating portion of the handle, the stationary part of the handle or even along the sleeve. In any case, variations of the device 400 permit coupling the filler material with a lumen extending through the sleeves (or between adjacent sleeves) to deposit filler material at the working end 410. As shown by arrows 416, filler material can be deposited through a distal end of the sleeves (where the sharp tip is solid) or can be deposited through openings in a side-wall of the sleeves. Clearly, variations of this configuration are within the scope of those familiar in the field.

[0065] In some variations, the third notched sleeve 420 is configured with its smooth (non-notched) surface 424 disposed to face inwardly on the articulated working end (FIG. 11) such that a solid surface forms the interior of the curved portion of the working end 410. The smooth surface 424 allows withdrawal of the device 110 into a cannula or introducer 205 without creating a risk that the slots or notches become caught on a cannula 205 (see e.g., FIG. 7B).

[0066] As shown in FIGS. 10-11, the third (outermost) sleeve 420 can extend from an intermediate location on the extension member 405 to a distal end of the working end 410. However, variations of the device include the third sleeve 420 extending to the handle 402. However, the third sleeve 420 is typically not coupled to the handle 402 so that any rotational force or torque generated by the handle 402 is not directly transmitted to the third sleeve 420.

[0067] In one variation, the third sleeve 420 is coupled to the second sleeve 120 at only one axial location. In the illustrated example shown in FIG. 11, the third sleeve 420 is affixed to second sleeve 420 by welds 428 at the distal end of the working end

410. However, the welds or other attachment means (e.g., a pin, key/keyway, protrusion, etc.) can be located on a medial part of the sleeve 420. The sleeve 420 can be fabricated of any bio-compatible material. For example, in one variation, the third sleeve is fabricated form a 3.00 mm diameter stainless steel material with a wall thickness of 0.007". The first, second and third sleeves are sized to have dimensions to allow a sliding fit between the sleeves.

[0068] FIG. 12A is a sectional view of extension member 405 of another variation, similar to that shown in FIGS. 10-11. However, the variation depicted by FIG. 12A comprises non-round configurations of concentric slidable sleeves (double or triple sleeve devices). This configuration limits or prevents rotation between the sleeves and allows the physician to apply greater forces to the bone to create a cavity. While FIG. 12A illustrates an oval configuration, any non-round shape is within the scope of this disclosure. For example, the cross-sectional shape can comprise a square, polygonal, or other radially keyed configuration as shown in FIGS. 12B and 12C. As shown in FIG. 12C the sleeves can include a key 407 and a receiving keyway 409 to prevent rotation but allow relative or axial sliding of the sleeves. The key can comprise any protrusion or member that slides within a receiving keyway. Furthermore, the key can comprise a pin or any raised protrusion on an exterior or interior of a respective sleeve. In this illustration, only the first 122 and second 120 sleeves are illustrated. However, any of the sleeves can be configured with the key/keyway. Preventing rotation between sleeves improves the ability to apply force to bone at the articulated working end.

[0069] FIGS. 13-14 illustrate another variation of a working end 410 of an osteotome device. In this variation, the working end 410 includes one or more flat spring elements 450, 460a, 460b, 460c, 460d, that prevent relative rotation of the sleeves of the assembly thus allowing greater rotational forces to be applied to cancellous bone from an articulated working end. The spring elements further urge the working end assembly into a linear configuration. To articulate the sleeves, a rotational force is applied to the handle as described above, once this rotational force is removed, the spring elements urge the working end into a linear configuration. As shown in FIG. 13, one or more of the spring elements can extend through the sleeves for affixing to a

handle to prevent rotation. Furthermore, the distal end 454 of flat spring element 450 is fixed to sleeve assembly by weld 455. Thus, the spring element is fixed at each end to prevent its rotation. Alternate variations include one or more spring elements being affixed to the inner sleeve assembly at a medial section of the sleeve.

[0070] As shown in FIGS. 13-14, variations of the osteotome can include any number of spring elements 460a-460d. These additional spring elements 460a-460d can be welded at either a proximal or distal end thereof to an adjacent element or a sleeve to allow the element to function as a leaf spring.

[0071] In an additional variation, the osteotome device can include one or more electrodes 310, 312 as shown in FIG. 15. In this particular example, the device 300 includes spaced apart electrodes having opposite polarity to function in a bi-polar manner. However, the device can include a monopolar configuration. Furthermore, one or more electrodes can be coupled to individual channels of a power supply so that the electrodes can be energized as needed. Any variation of the device described above can be configured with one or more electrodes as described herein.

[0072] Fig. 16 illustrates an osteotome device 300 after being advanced into the body as discussed above. As shown by lines 315 representing current flow between electrodes, when required, the physician can conduct RF current between electrodes 310 and 312 to apply coagulative or ablative energy within the bone structure of the vertebral body (or other hard tissue). While Fig. 16 illustrates RF current 315 flow between electrodes 310 and 312, variations of the device can include a number of electrodes along the device to apply the proper therapeutic energy. Furthermore, an electrode can be spaced from the end of the osteotome rather than being placed on the sharp tip as shown by electrode 310. In some variations, the power supply is coupled to the inner sharp tip or other working end of the first sleeve. In those variations with only two sleeves, the second pole of the power supply is coupled with the second sleeve (that is the exterior of the device) to form a return electrode. However, in those variations having three sleeves, the power supply can alternatively be coupled with the third outer sleeve. In yet additional variations, the second and third sleeves can both function as return electrodes. However, in those devices that are monopolar, the return electrode will be placed outside of the body on a large area of skin.

[0073] Figs. 17 to 20 illustrate another variation of an articulating probe or osteotome device 500. In this variation, the device 500 includes a working end 505 that carries one or more RF electrodes that can be used to conduct current therethrough. Accordingly, the device can be used to sense impedance of tissue, locate nerves, or simply apply electrosurgical energy to tissue to coagulate or ablate tissue. In one potential use, the device 500 can apply ablative energy to a tumor or other tissue within the vertebra as well as create a cavity.

[0074] FIGS. 17, 18A, 18B and 19, illustrate a variation of the device 500 as having a handle portion 506 coupled to a shaft assembly 510 that extends along axis 512 to the articulating working end 505. The articulating working end 505 can be actuatable as described above. In addition, FIG. 17 shows that handle component 514a can be rotated relative to handle component 514b to cause relative axial movement between a first outer sleeve 520 and second inner sleeve 522 (FIG. 19) to cause the slotted working ends of the sleeve assembly to articulate as described above. The working end 505 of FIG. 19 shows two sleeves 520 and 522 that are actuatable to articulate the working end, but it should be appreciated that a third outer articulating sleeve can be added as depicted above. In one variation, the articulating working end can articulate 90° by rotating handle component 514a between ¼ turn and ¾ turn. The rotating handle component 514a can include detents at various rotational positions to allow for controlled hammering of the working end into bone. For example, the detents can be located at every 45° rotation or can be located at any other rotational increment.

[0075] FIG. 17 depict an RF generator 530A and RF controller 530B connectable to an electrical connector 532 in the handle component 514a with a plug connector indicated at 536. The RF generator is of the type known in the art for electrosurgical ablation. The outer sleeve 520 comprises a first polarity electrode indicated at 540A (+). However, any energy modality can be employed with the device.

[0076] FIGS. 18A and 18B illustrate yet another variation of a working end of a device for creating cavities in hard tissue. As shown, the device 500 can include a central extendable sleeve 550 with a sharp tip 552 that is axially extendable from passageway 554 of the assembly of first and second sleeves 520 and 522 (FIG. 19). The sleeve 550 can also include a second polarity electrode indicated at 540B (-).

Clearly, , the first and second electrodes will be electrically insulated from one another. In one variation, and as shown in FIG. 19, the sleeve assembly can carry a thin sleeve 555 or coating of an insulative polymer such as PEEK to electrically isolate the first polarity electrode 540A (+) from the second polarity electrode 540B (-). The electrode can be deployed by rotating knob 558 on the striking surface of handle component 514a (FIG 17). The degree of extension of central sleeve 550 can optionally be indicated by a slider tab 557 on the handle. In the illustrated variation, the slider tab is located on either side of handle component 514a (FIG. 17). Sleeve 550 can be configured to extend distally beyond the assembly of sleeves 520 and 522 a distance of about 5 to 15 mm.

[0077] Referring to FIG. 19, the central extendable sleeve 550 can have a series of slots in at least a distal portion thereof to allow it to bend in cooperation with the assembly of first and second sleeves 520 and 522. In the embodiment shown in FIG. 18B, the central sleeve 550 can optionally include a distal portion that does not contain any slots. However, additional variations include slots on the distal portion of the sleeve.

[0078] FIG. 19 further depicts an electrically insulative collar 560 that extends length A to axially space apart the first polarity electrode 540A (+) from the second polarity electrode 540B (-). The axial length A can be from about 0.5 to 10 mm, and usually is from 1 to 5 mm. The collar can be a ceramic or temperature resistant polymer.

[0079] FIG. 19 also depicts a polymer sleeve 565 that extends through the lumen in the center of electrode sleeve 550. The polymer sleeve 565 can provide saline infusion or other fluids to the working end and/or be used to aspirate from the working end when in use. The distal portion of sleeve 550 can include one or more ports 566 therein for delivering fluid or aspirating from the site. .

[0080] In all other respects, the osteotome system 500 can be driven into bone and articulated as described above. The electrodes 540A and 540B are operatively coupled to a radiofrequency generator as is known in the art for applying coagulative or ablative electrosurgical energy to tissue. In FIG. 20, it can be seen that RF current 575 is indicated in paths between electrodes 540A and 540B as shown by lines 575. RF generator 530A and controller 530B for use with the devices described herein can

include any number of power settings to control the size of targeted coagulation or ablation area. For example, the RF generator and controller can have Low (5 watts), medium (15 Watts) and High (25 watts) power settings. The controller 530B can have a control algorithm that monitors the temperature of the electrodes and changes the power input in order to maintain a constant temperature. At least one temperature sensing element (e.g., a thermocouple) can be provided on various portions of the device. For example, and as shown in FIG. 19, a temperature sensing element 577 can be provided at the distal tip of sleeve 550 tip while a second temperature sensing element 578 can be provided proximal from the distal tip to provide temperature feedback to the operator to indicate the region of ablated tissue during the application of RF energy. In one example, the second temperature sensing element was located approximately 15 to 20 mm from the distal tip.

[0081] FIG. 21 illustrates another variation of articulating osteotome 600 with RF ablation features. Variations of the illustrated osteotome 600 can be similar to the osteotome of FIGS. 17-18B. In this variation, the osteotome 600 has a handle 602 coupled to shaft assembly 610 as described above. The working end 610 again has an extendable assembly indicated at 615 in FIG. 21 that can be extended by rotation of handle portion 622 relative to handle 602. The osteotome can be articulated as described previously by rotating handle portion 620 relative to handle 602.

[0082] FIGS. 22A-22B are views of the working end 610 of FIG. 21 in a first non-extended configuration (FIG. 22A) and a second extended configuration (FIG. 22B). As can be seen in FIGS. 22A-22B, the extension portion 615 comprises an axial shaft 624 together with a helical spring element 625 that is axially collapsible and extendible. In one embodiment, the shaft can be a tube member with ports 626 fluidly coupled to a lumen 628 therein. In some variations, the ports can carry a fluid to the working end or can aspirate fluid from the working end.

[0083] In FIGS. 22A-22B, it can be seen that axial shaft 624, helical spring element 625 together with sharp tip 630 comprise a first polarity electrode (+) coupled to electrical source 530A and controller 530B as described previously. An insulator 632 separates the helical spring 625 electrode from the more proximal portion of the sleeve

which comprises opposing polarity electrode 640 (-). The RF electrodes can function as described above (see FIG. 20) to ablate tissue or otherwise deliver energy to tissue.

[0084] In one variation, the extension portion 615 can extend from a collapsed spring length of 2 mm, 3 mm, 4 mm or 5 mm to an extended spring length of 6 mm, 7 mm, 8 mm, 9 mm 10 mm or more. In the working end embodiment 615 in FIG. 22B, the spring can comprise a flat rectangular wire that assists in centering the spring 625 about shaft 624 but still can collapse to short overall length, with the flat surfaces of rectangular wire oriented for stacking. However, other variations are within the scope of the variations described herein.

[0085] The use of the spring 625 as an electrode provides significant improvements in delivering energy. This spring provides (i) greatly increased electrode surface area and (ii) a very greatly increased length of relatively sharp edges provided by the rectangular wire—which provides for edges. Because the edges provide low surface area the concentration or density of RF current is greater at the edges and allows for theh RF current to jump or arc. Both these aspects of the invention—increased electrode surface area and increased electrode edge length—allow for much more rapid tissue ablation.

[0086] In one aspect of the invention, the surface area of the spring electrode 625 can be at least 40 mm^2, at least 50 mm^2, or at least 60 mm^2 over the spring electrode lengths described above.

[0087] In another aspect of the invention, the total length of the 4 edges of rectangular wire spring can be greater than 50 mm, greater than 100 mm or greater than 150 mm over the spring electrode lengths described above.

[0088] In one example used in testing, an osteotome 600 (as in FIG. 21-22B) was configured with a helical spring that had a collapsed length of 1.8 mm and an extended length of 7.5 mm. In this embodiment, the surface area of the spring electrode 625 when extended was 64.24mm^2 and the total length of the electrodes edges was 171.52 mm (four edges at 42.88 mm per edge).

[0089] In a comparison test, a first osteotome without a helical electrode was compared against a second osteotome 600 with a helical electrode as in FIG. 22B. These devices were evaluated at different power levels and different energy delivery

intervals to determine volume of ablation. The working ends of the devices had similar dimensions excepting for the helical spring electrode. In Chart A below, RF energy was delivered at a low power setting of 5 Watts. It can be seen in Chart A that at a treatment interval of 120 seconds and 5W, the volume of ablation was about 3 times faster with the helical electrode compared to the working end without the helical electrode (1.29 cc vs. .44 cc).

[0090] Chart A (5W)

	Total Surface Area of Electrode	Duration of Ablation (sec)	Ablated Volume (cc)
	111.52 mm²	25 s	0.15 cc
		60 s	0.50 cc
		120 s	1.29 cc
	31.56 mm²	25 s	0.125 cc
		60 s	0.35 cc
		120 s	0.44 cc

[0091] Chart B (15W)

	Total Surface Area of Electrode	Duration of Ablation (sec)	Ablated Volume (cc)
	111.52 mm²	25 s	1.00 cc
		60 s	1.63 cc
	31.56 mm²	25 s	0.37 cc
		60 s	N/A

[0092] Another comparison test of the same first osteotome 500 (FIG. 18B) and second osteotome 600 with a helical electrode (FIG. 22B) were evaluated at higher 15 Watt power level. As can be seen in Chart B, RF energy at a treatment interval of 25 seconds and 15W, the volume of ablation was again was about 3 times faster with the helical electrode compared to the working end without the helical electrode (1.00 cc vs. 0.37 cc). In Chart B, the device without the helical electrode impeded out before 60 seconds passed, so that data was not provided. The testing shows that the helical electrode is well suited for any type of tissue or tumor ablation, with a 60 second ablation resulting in 1.63 cc of ablated tissue.

[0093] FIG. 23 schematically illustrates the osteotome 600 in use in a vertebral body, wherein the RF current between the electrodes 625 and 640 ablate a tissue volume indicated at 640.

[0094] Although particular embodiments of the present invention have been described above in detail, it will be understood that this description is merely for purposes of illustration and the above description of the invention is not exhaustive. Specific features of the invention are shown in some drawings and not in others, and this is for convenience only and any feature may be combined with another in accordance with the invention. A number of variations and alternatives will be apparent to one having ordinary skills in the art. Such alternatives and variations are intended to be included within the scope of the claims. Particular features that are presented in dependent claims can be combined and fall within the scope of the invention. The invention also encompasses embodiments as if dependent claims were alternatively written in a multiple dependent claim format with reference to other independent claims.

CLAIMS

What is claimed is:

1. A medical osteotome device for treating a vertebral body, comprising:

a handle having a connector for electrically coupling the osteotome device to a power supply;

a shaft extending from the handle to a working end, where a first conductive portion of the shaft is electrically coupleable to a first pole of the power supply; and

an extendable element extendible from the shaft;

where the extendable element is coupleable to a second pole of the power supply, such that when activated, current flows between the extendable element and the shaft.

2. The medical device of claim 1, where wherein the extendable element has an electrode surface area of at least 40 mm2.

3. The medical device of any of claims 1-2, where extendable element includes a helical electrode.

4. The medical device of any of claims 1-3, wherein an actuation portion is configured to deform the working end into an articulated configuration.

5. The medical device of any of claims 1-4, where the handle is configured to receive an impact force to causes the working end to penetrate bone.

6. The medical device of any of claims 1-5, further comprising a lumen extending through the shaft and working end.

7. A medical osteotome device for treating a vertebral body, comprising:

a handle having a connector for electrically coupling the osteotome device to a power supply;

a shaft extending from the handle to a working end, where a first conductive portion of the shaft is electrically coupleable to a first pole of the power supply; and

an extendable element extendible from the shaft; where the extendable element

is coupleable to a second pole of the power supply, such that when activated, current flows between the extendable element and the shaft.

8. The medical device of claim 7, wherein the extendable element has a total length of electrode edges of greater than 50 mm.

9. The medical device of any of claims 7-8, where extendable element includes a helical electrode.

10. A medical device for ablating tissue, comprising:

an elongated probe having a handle end and a working end;

an extendable helical element comprising an electrode carried by the working end, wherein the helical element is moveable from an axially non-extended position to an axially extended position to provide an increased electrode surface area.

11. The medical device of claim 10, where the helical electrode is formed form a flat wire.

12. The medical device of any of claims 10-11, where the helical electrode is formed form a rectangular wire.

13. The medical device of any of claims 10-12, where the helical electrode has a non-extended length of less than 5 mm.

14. The medical device of any of claims 10-12, where the helical electrode has an extended length of greater than 6 mm.

15. The medical device of any of claims 10-14, where the working end is articulatable.

16. The medical device of any of claims 10-15, wherein the handle carries an actuation mechanism configured to deform the working end into an articulated configuration.

17. The medical device of any of claims 10-12 or 15-16, wherein the extendable element has an electrode surface area of at least 60 mm^2.

18. The medical device of any of claims 10-12 or 15-16, wherein the extendable element has a total length of electrode edges of greater than 50 mm.

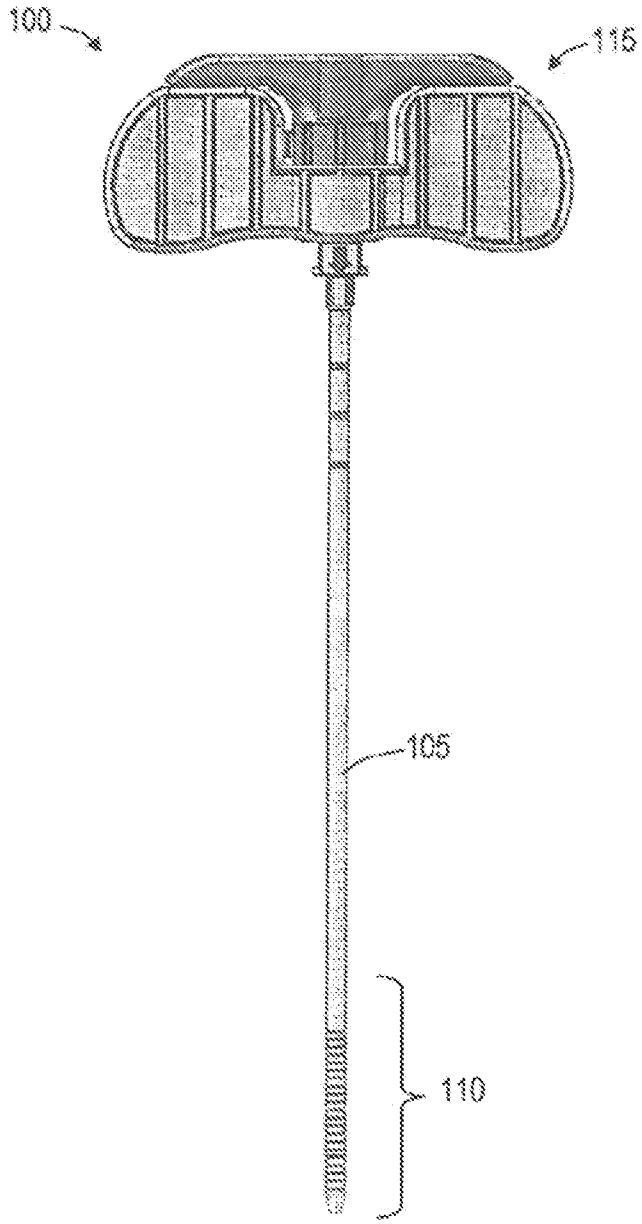


FIG. 1

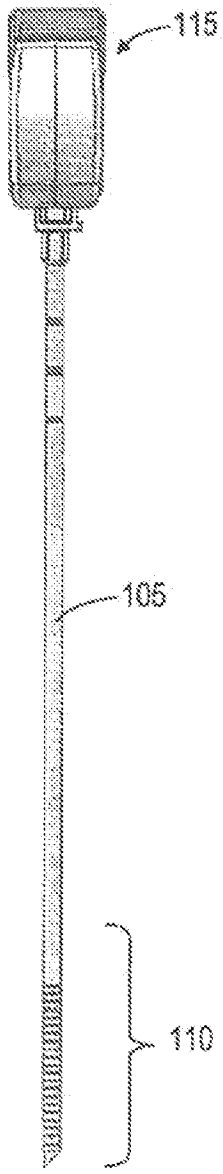


FIG. 2

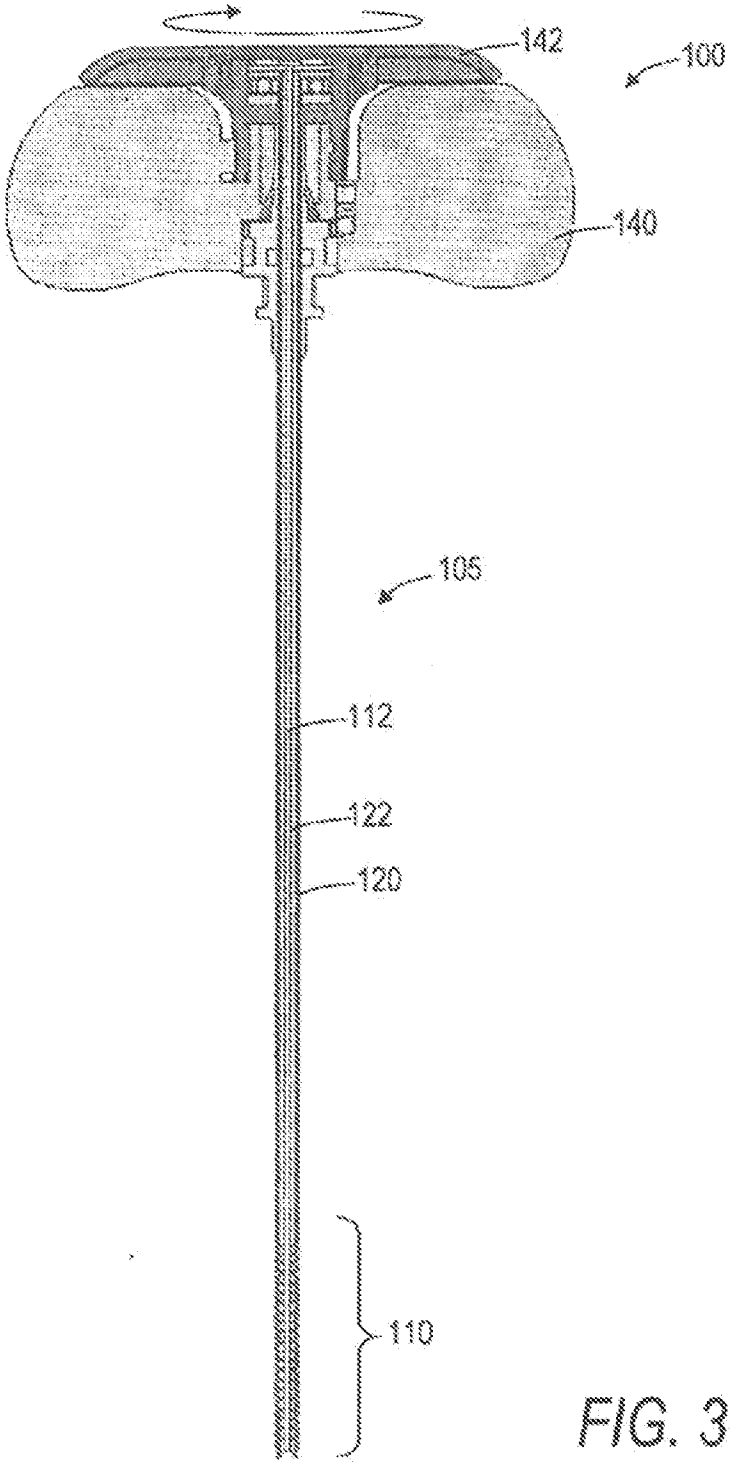


FIG. 3

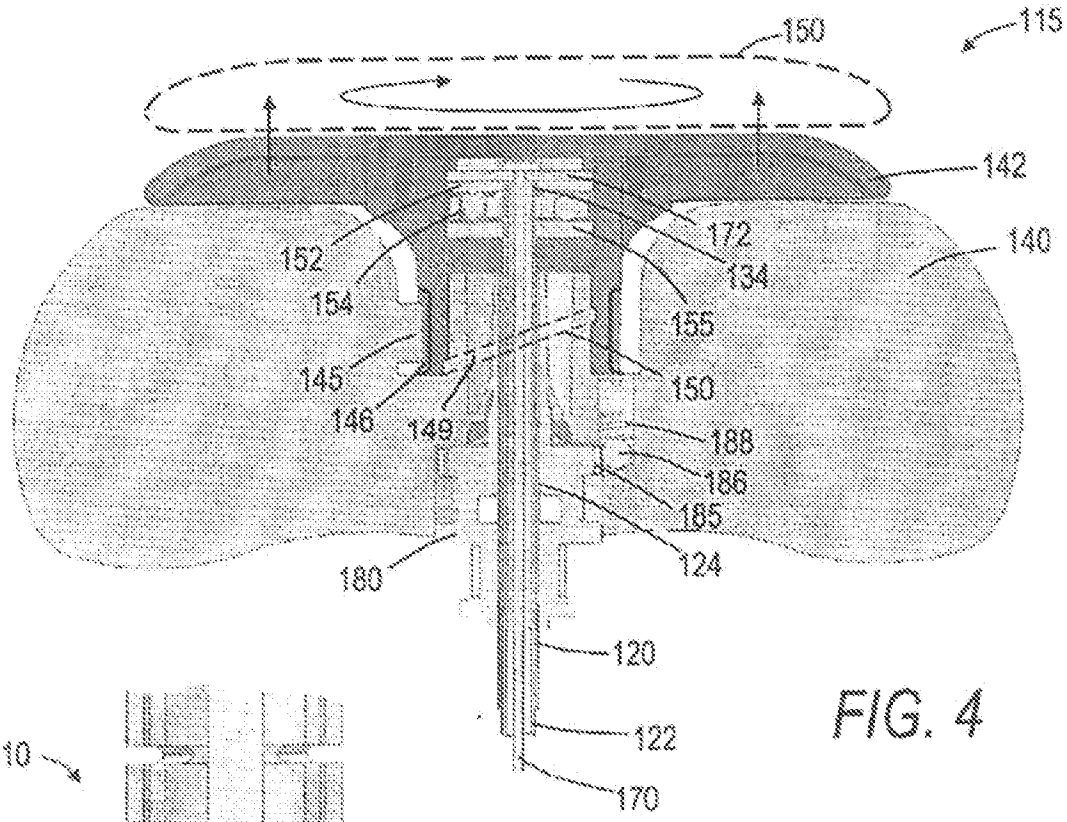

150
115
142
152
154
172
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180
124
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122
170

FIG. 4

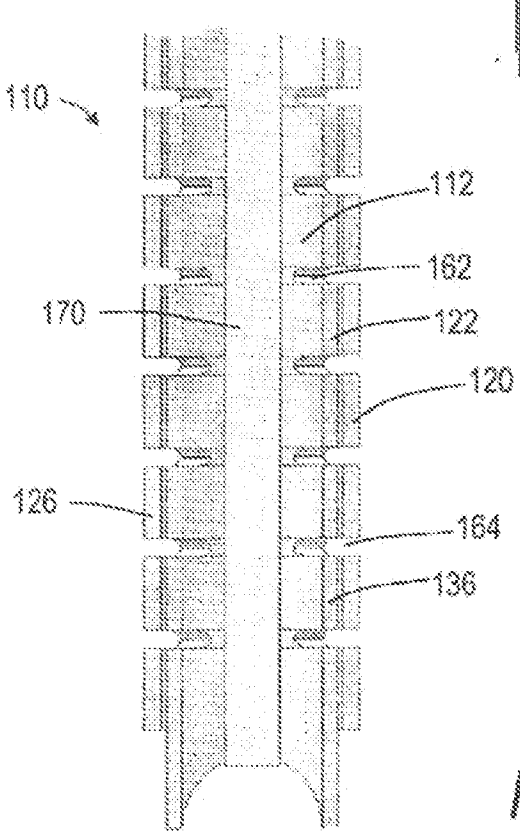

110
112
162
170
122
120
126
164
136

FIG. 5

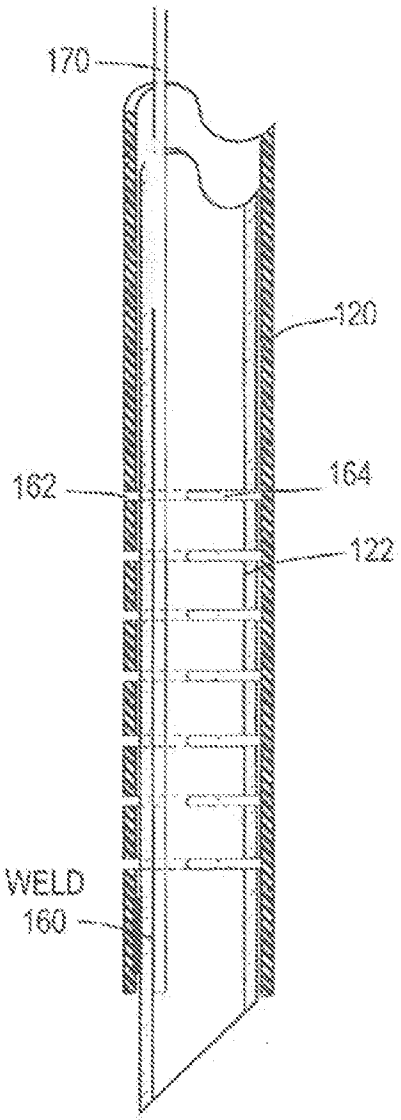


FIG. 6A

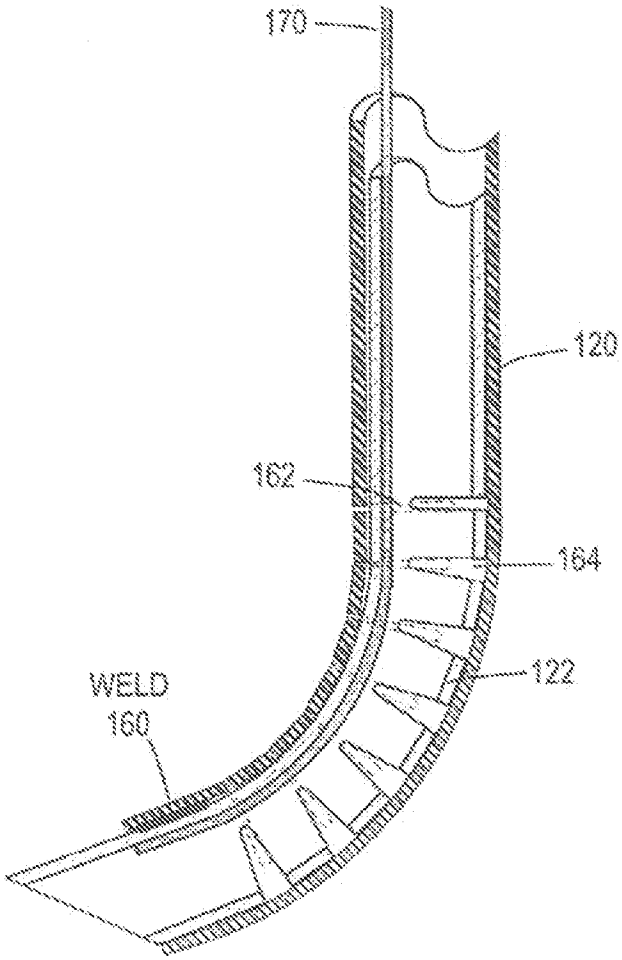


FIG. 6B

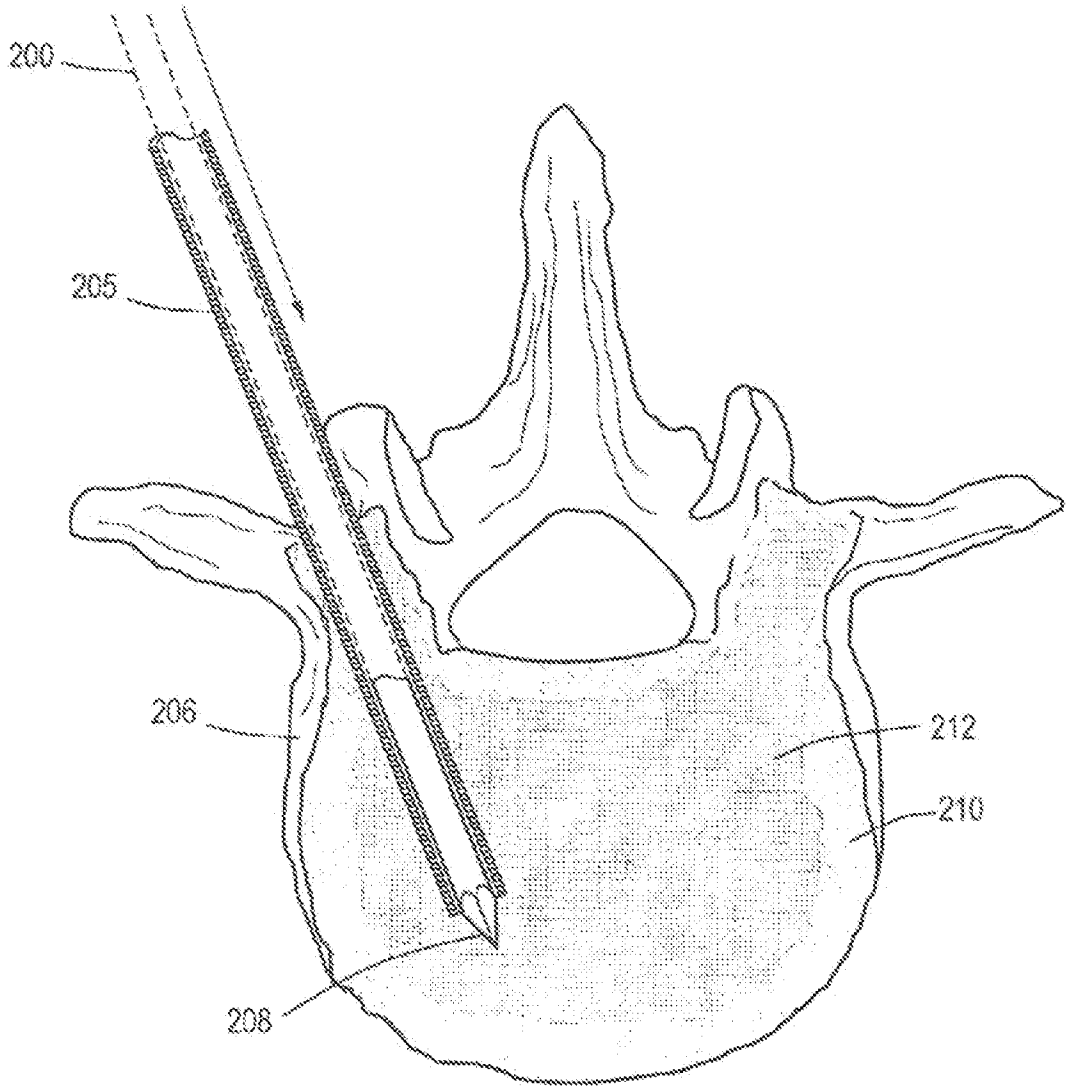


FIG. 7A

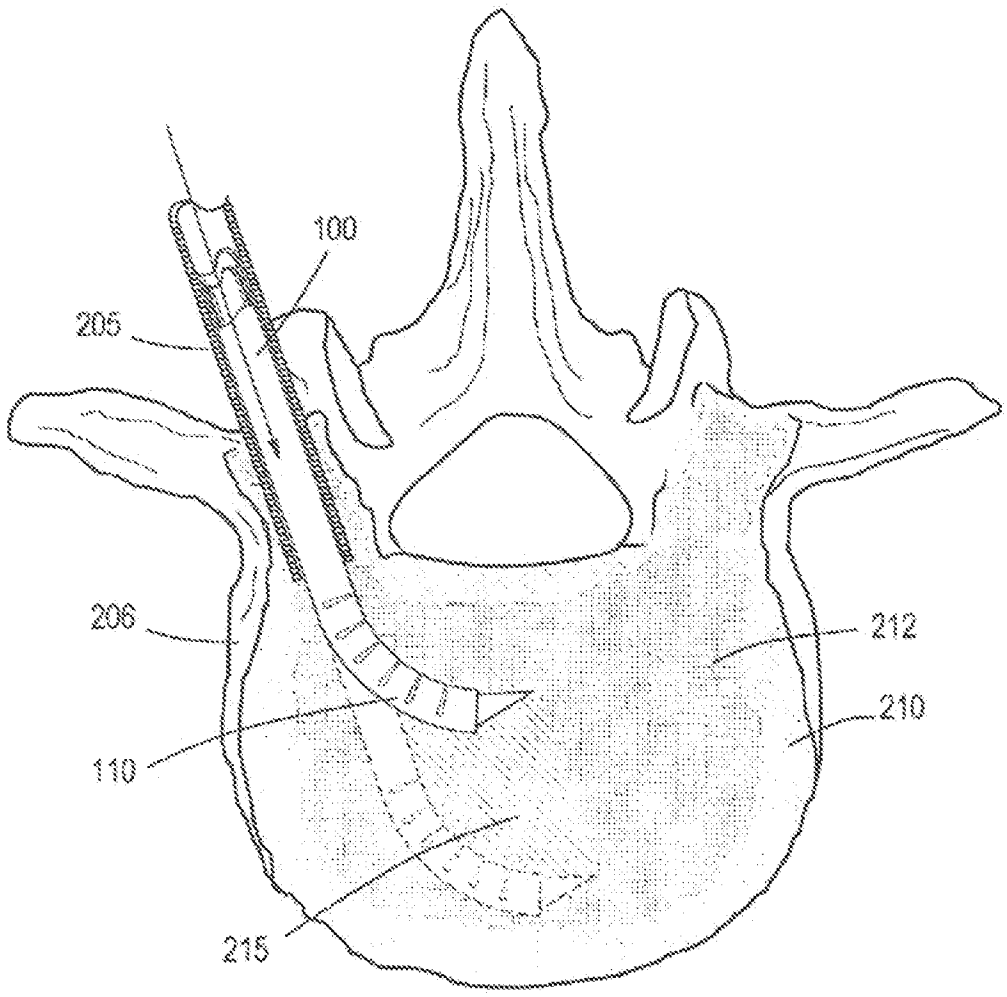


FIG. 7B

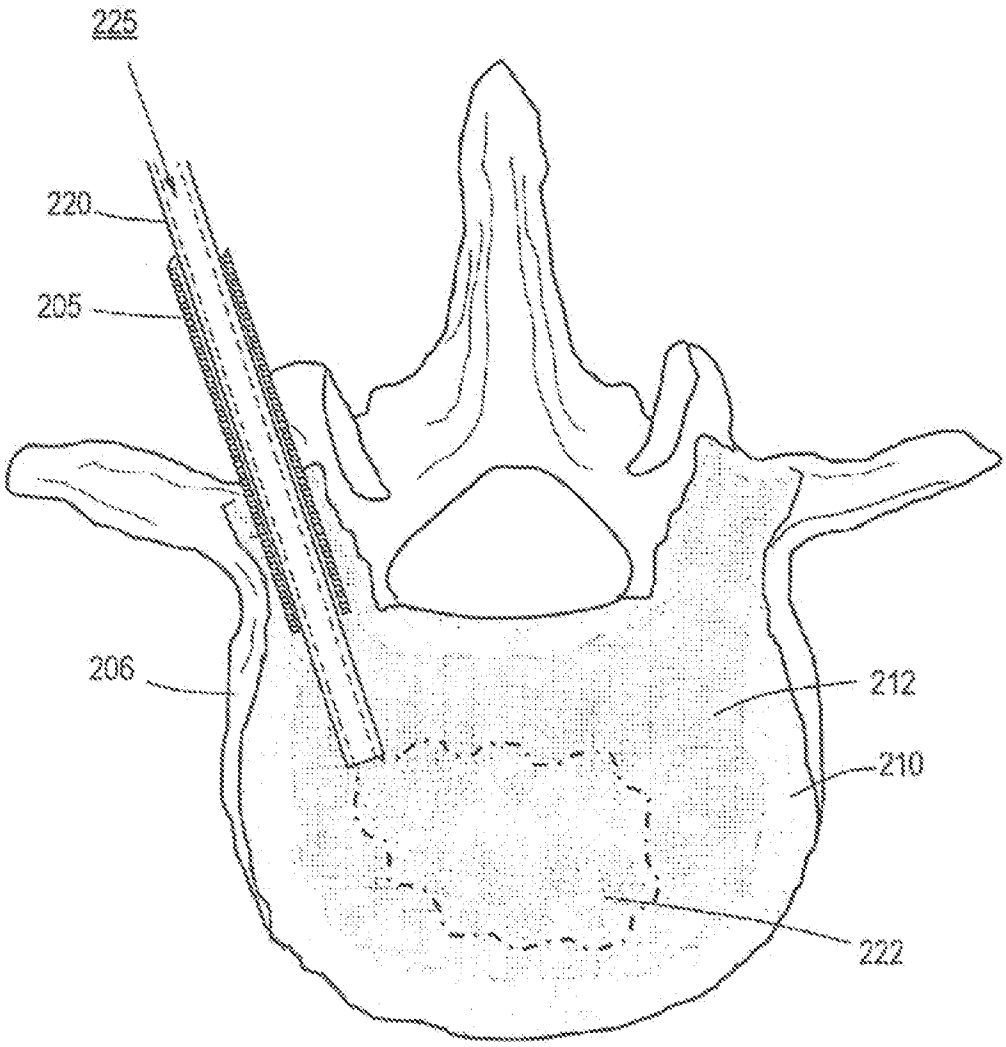


FIG. 7C

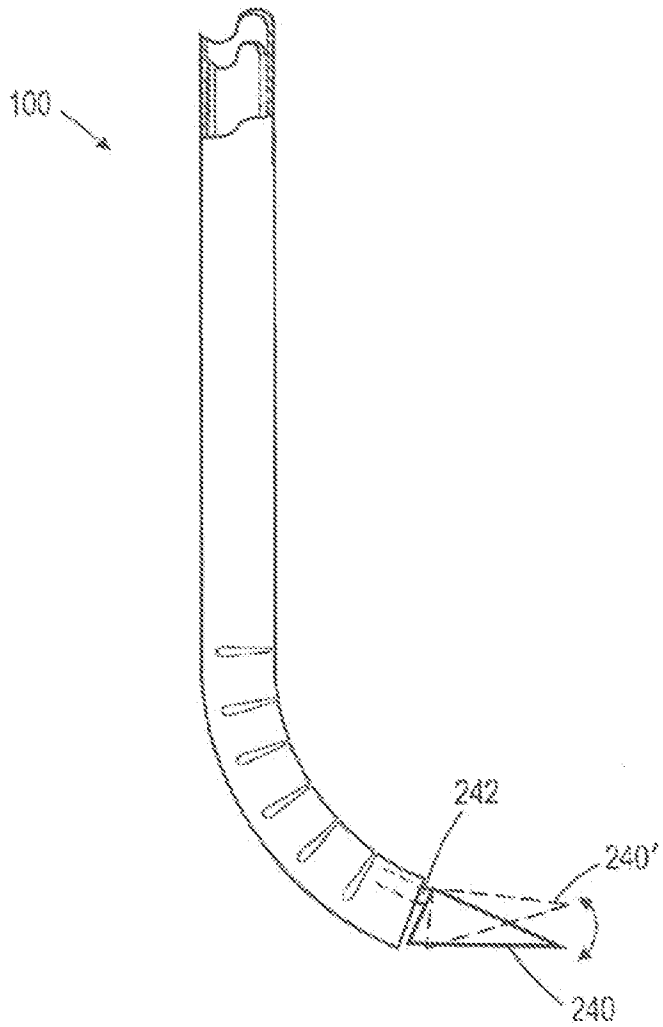


FIG. 8

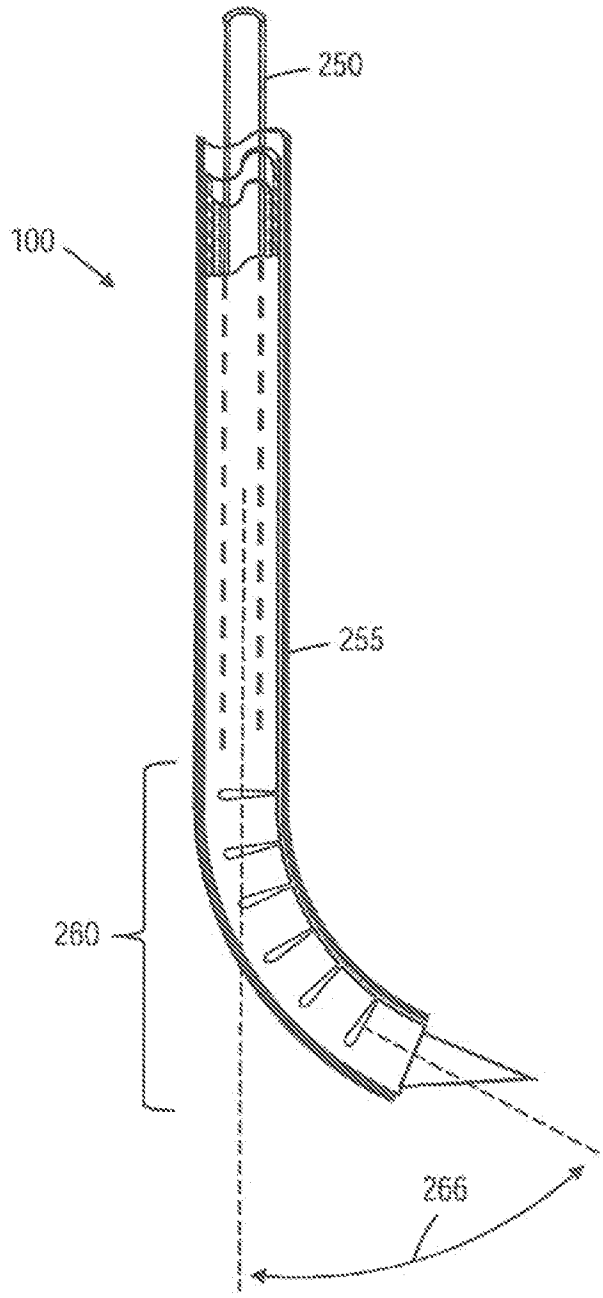


FIG. 9

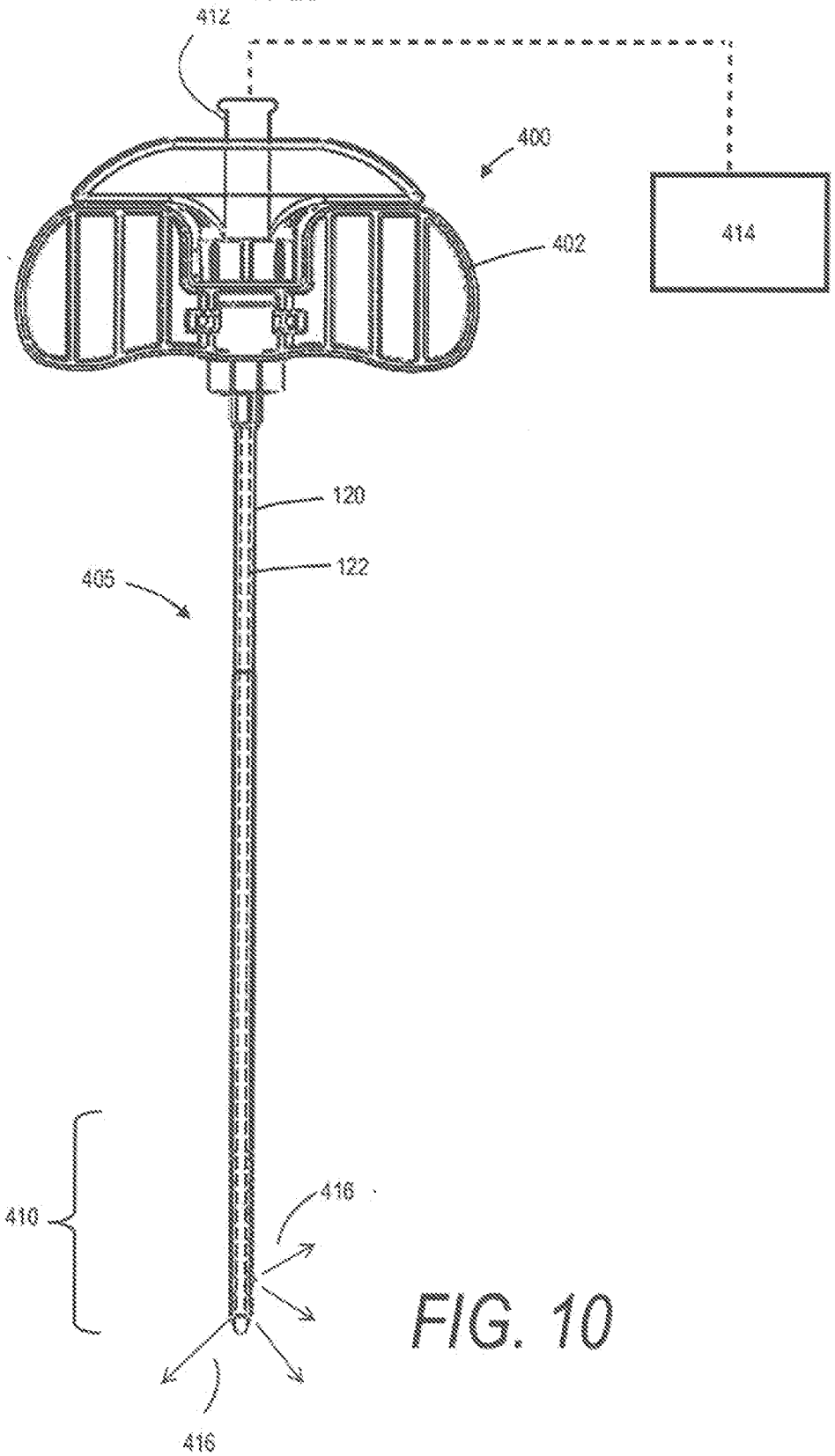


FIG. 10

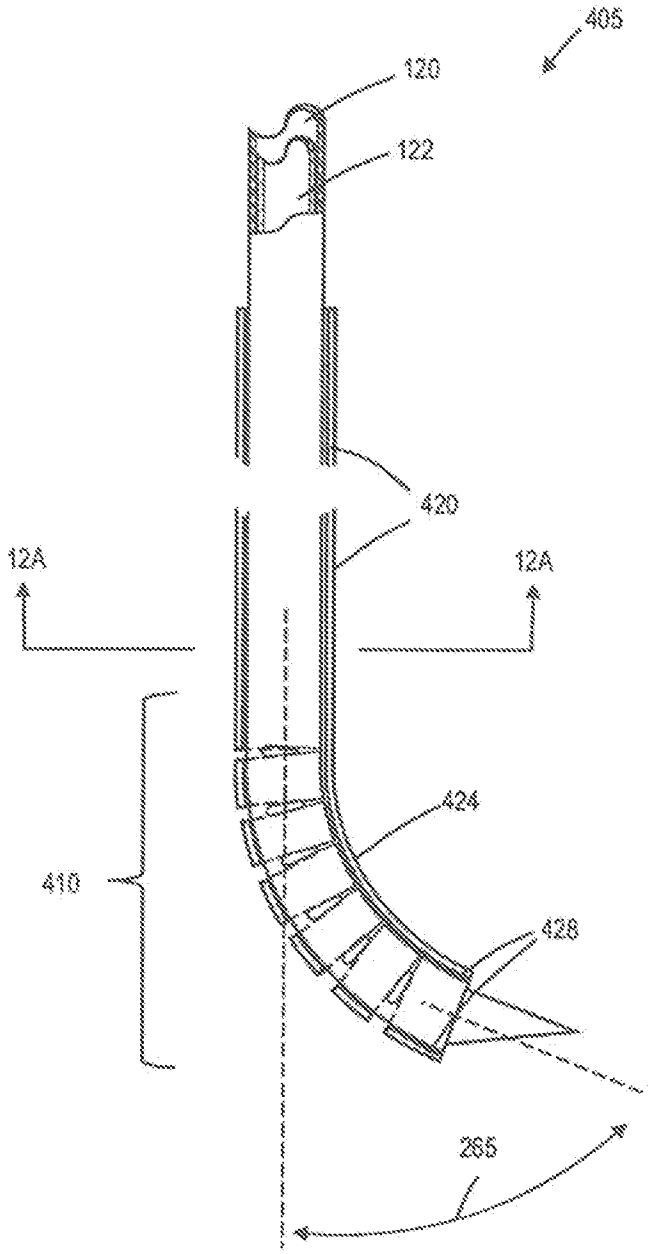


FIG. 11

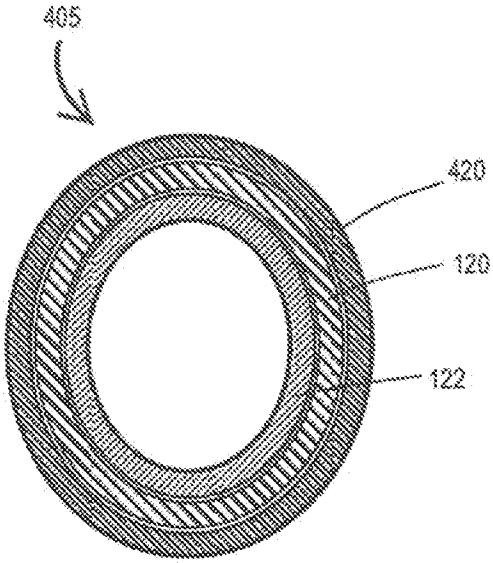


FIG. 12A

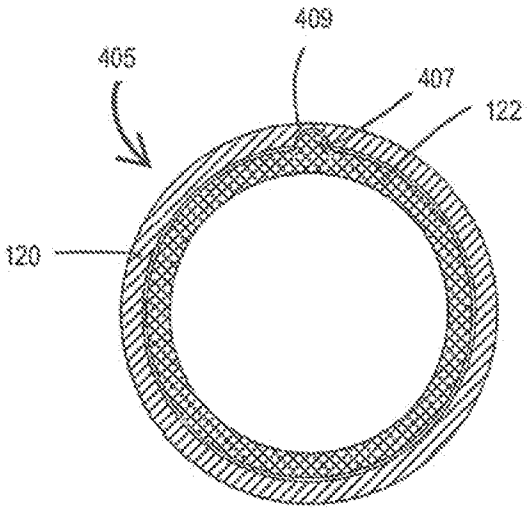


FIG. 12C

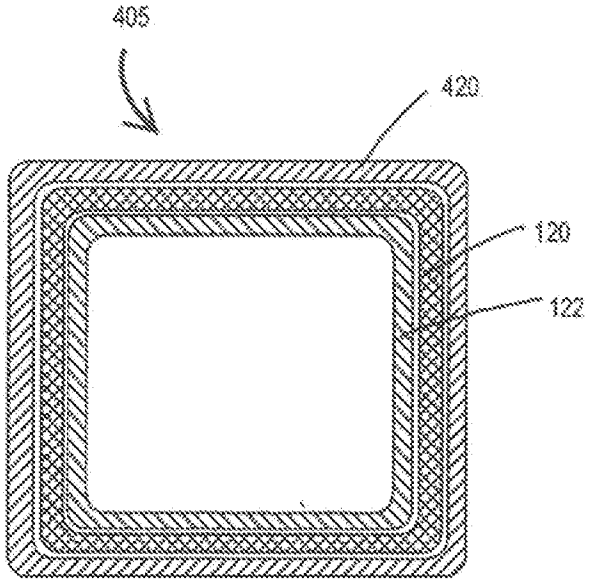


FIG. 12B

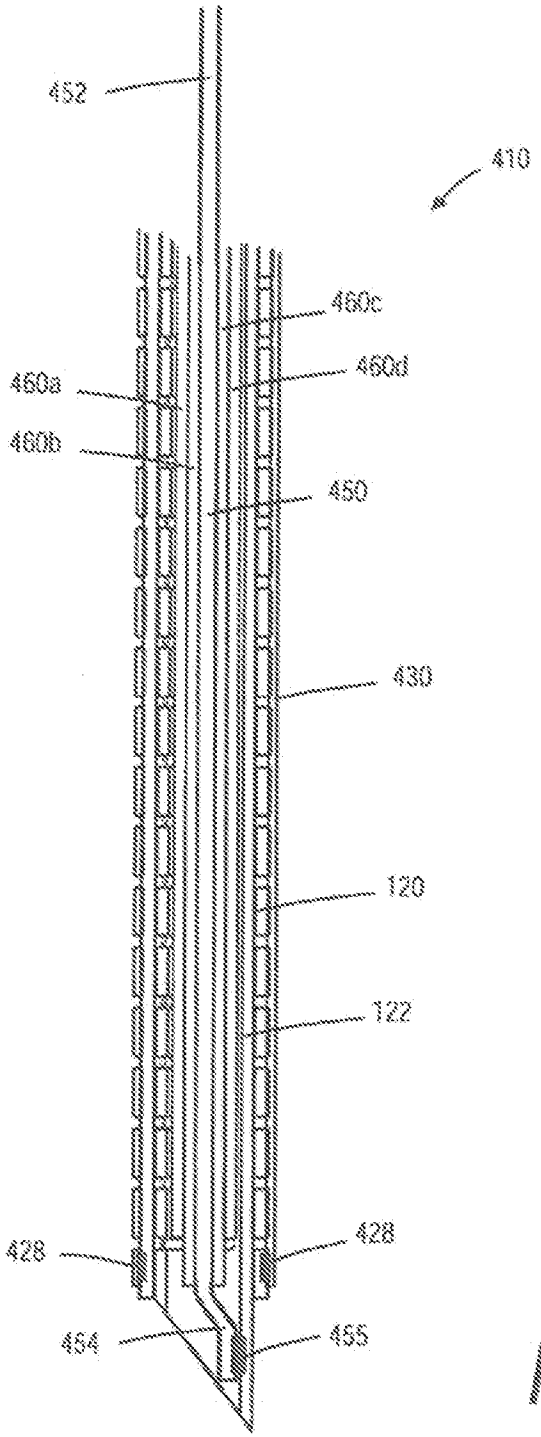


FIG. 13

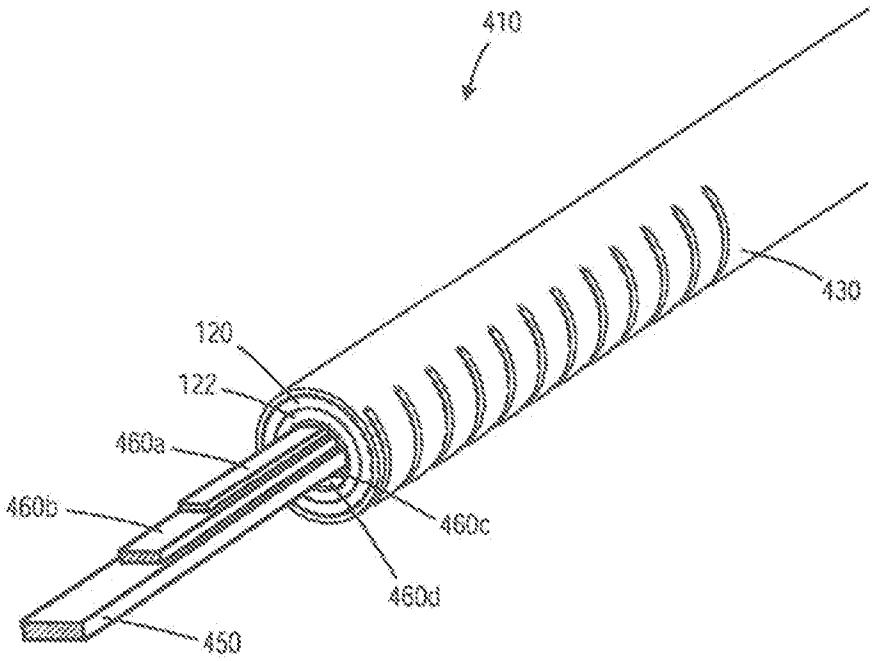


FIG. 14

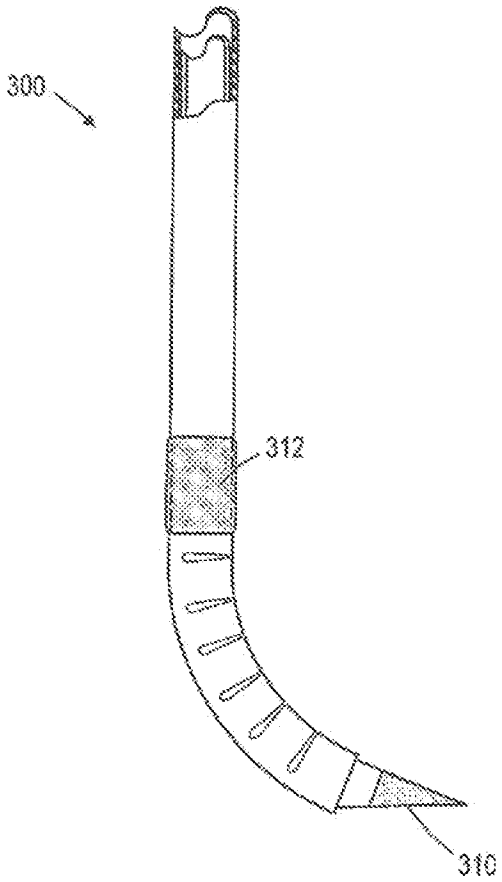


FIG. 15

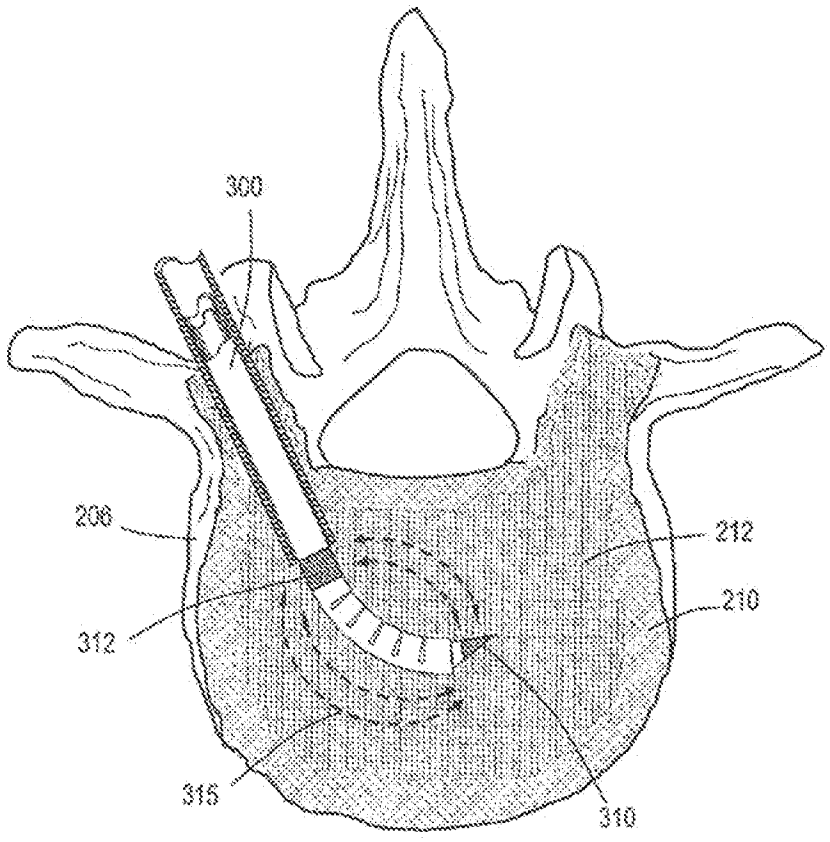


FIG. 16

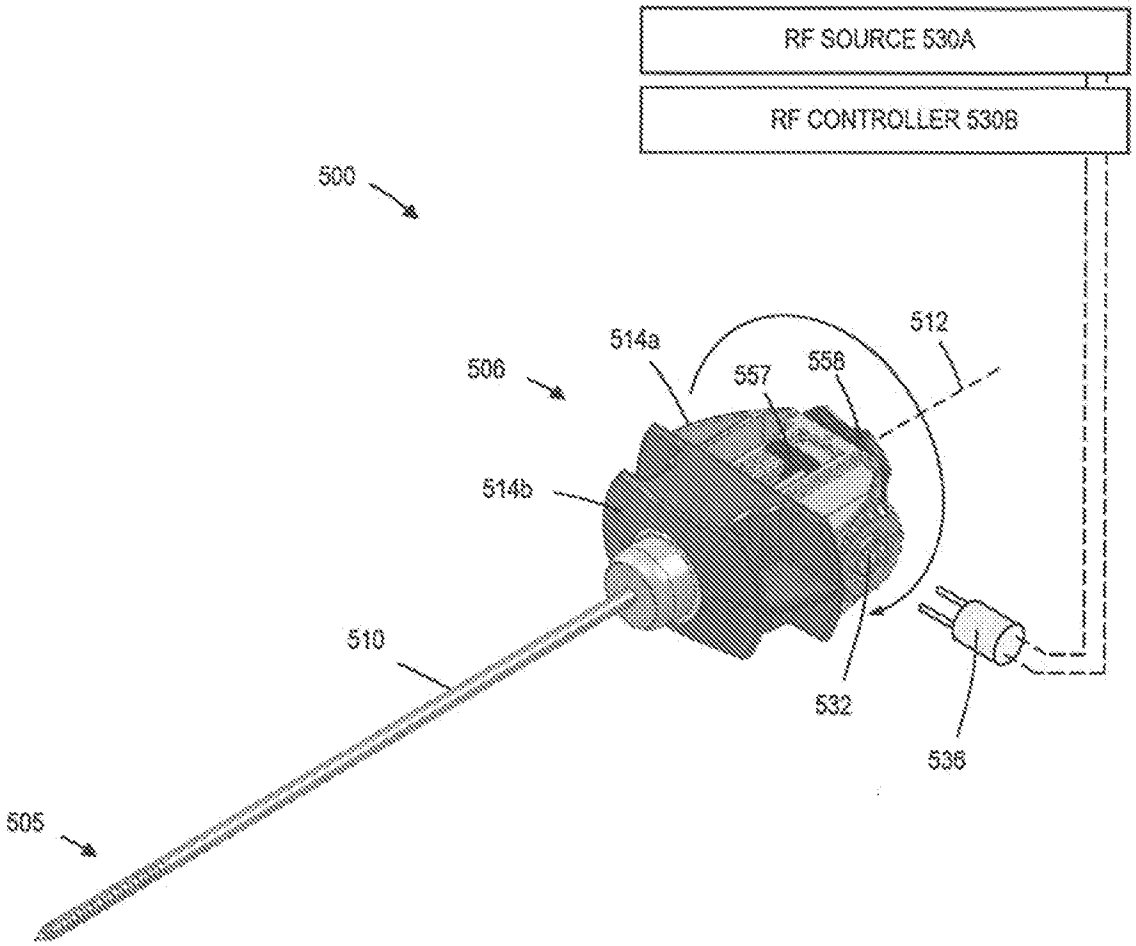

RF SOURCE 530A
RF CONTROLLER 530B
500
506
514a
557
558
512
514b
510
532
536
505

FIG. 17

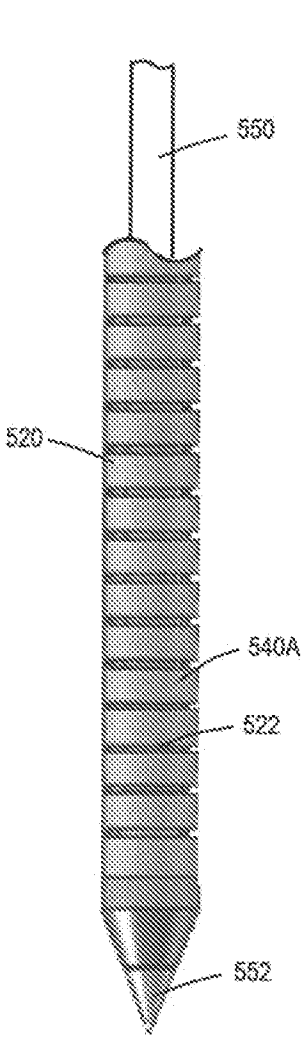


FIG. 18A

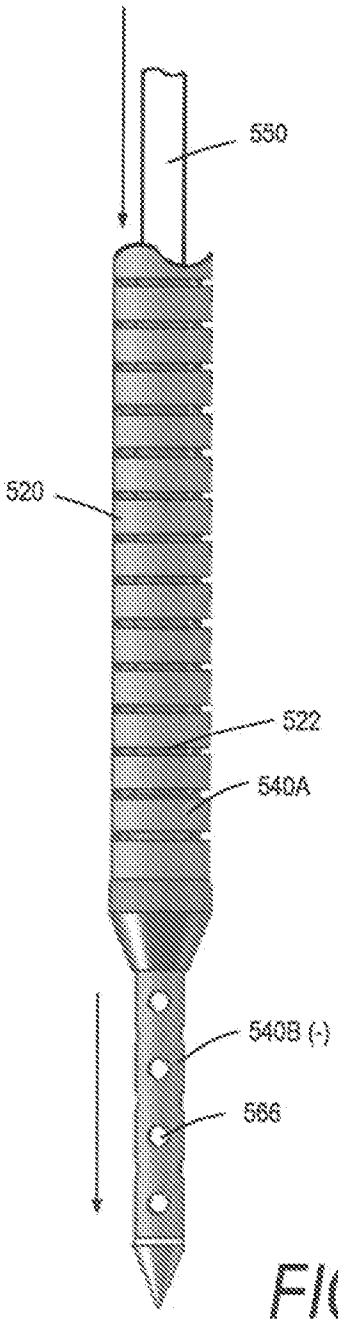


FIG. 18B

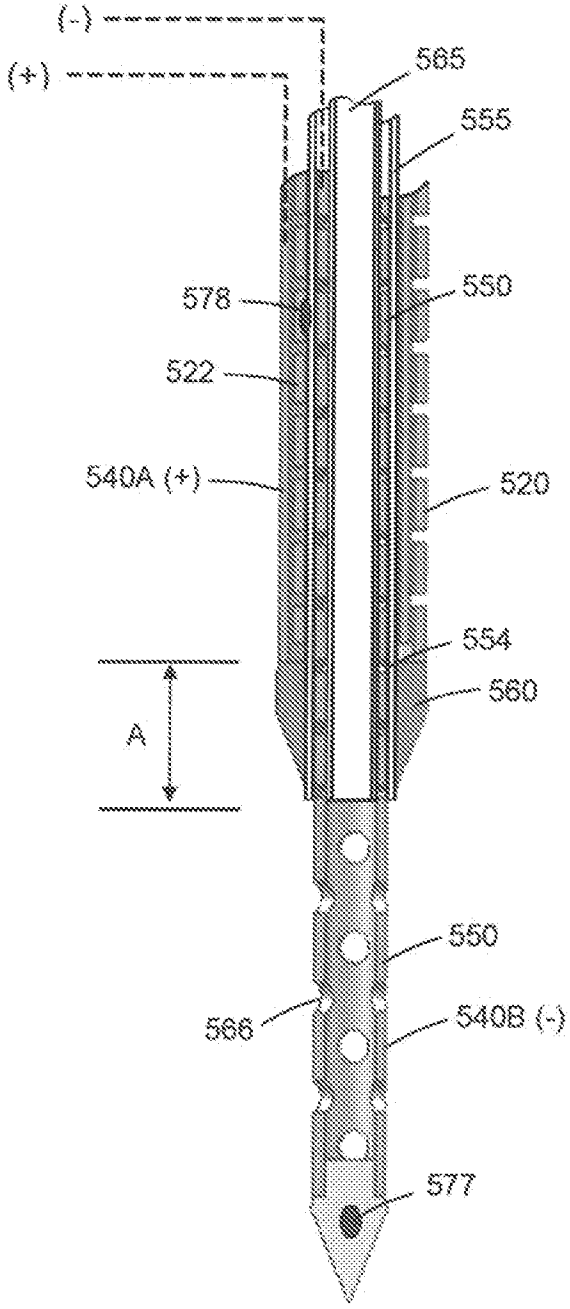


FIG. 19

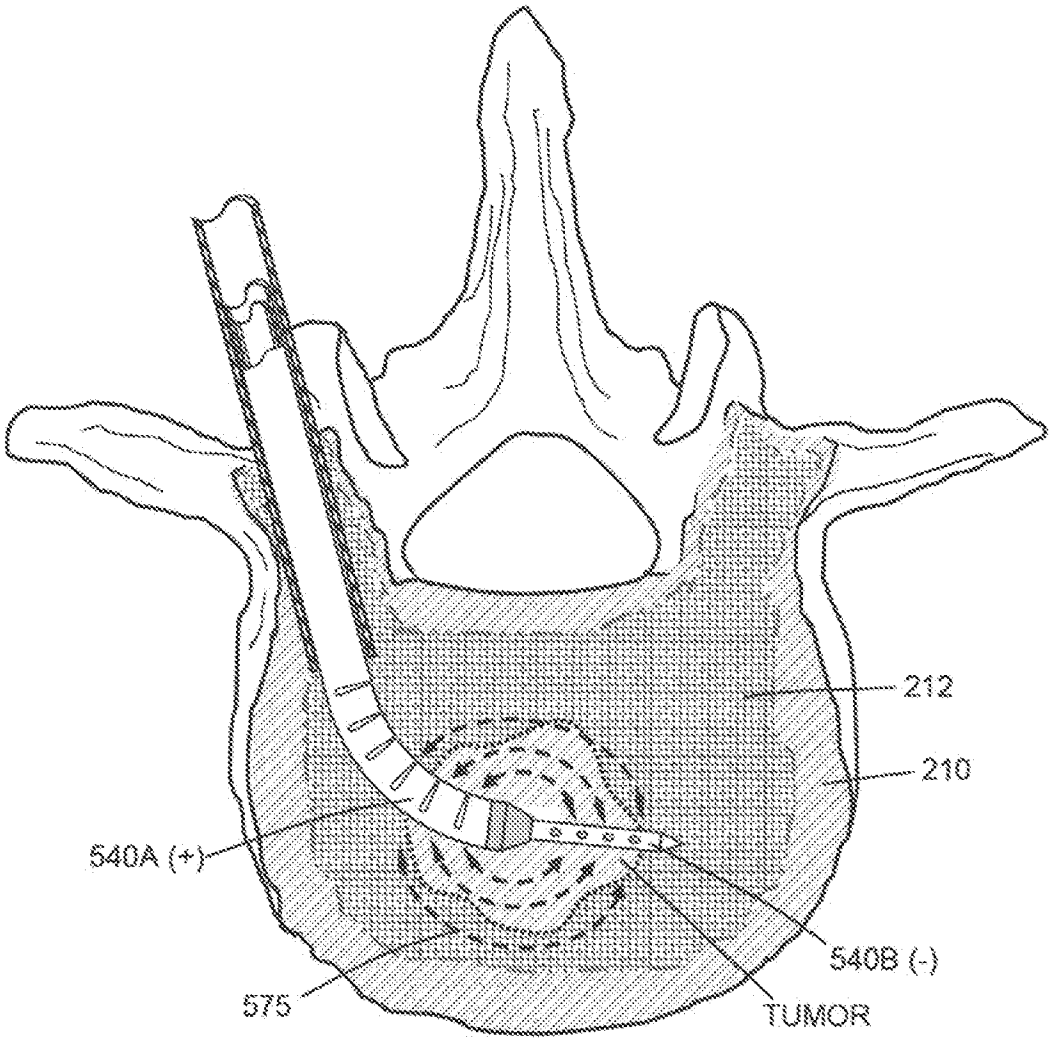


FIG. 20

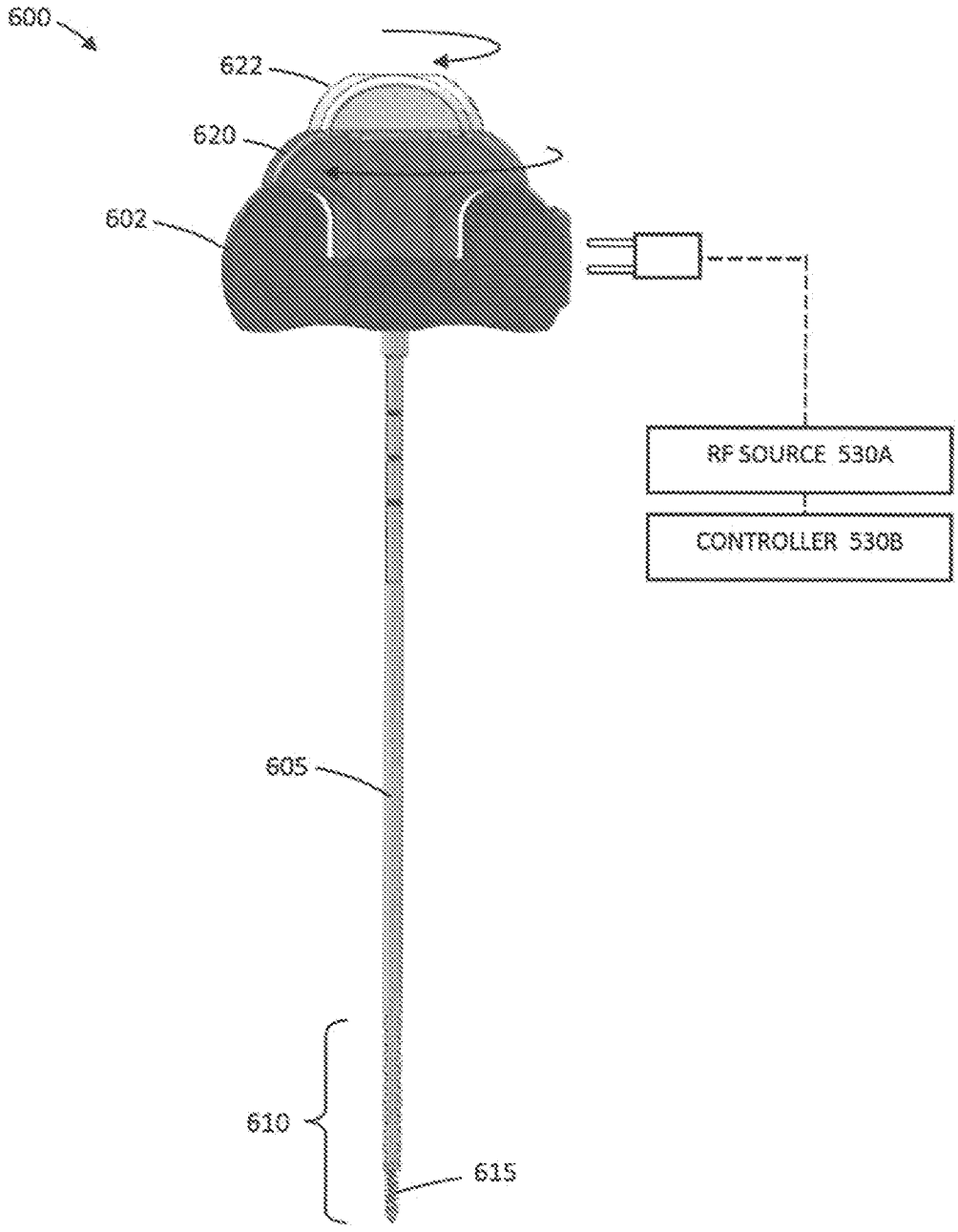


FIG. 21

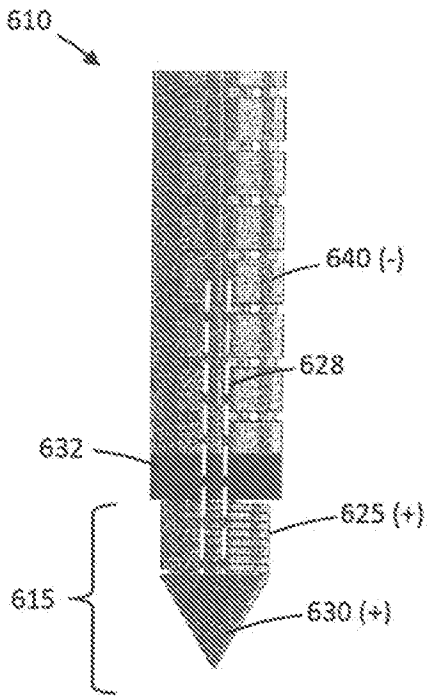


FIG. 22A

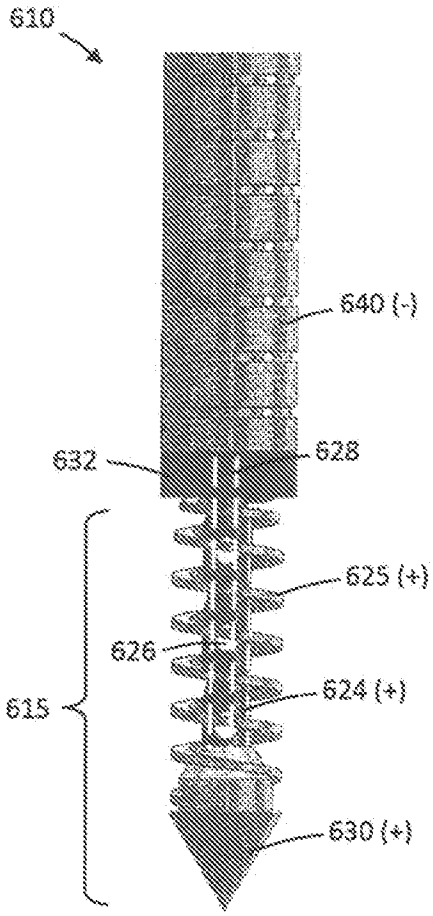


FIG. 22B

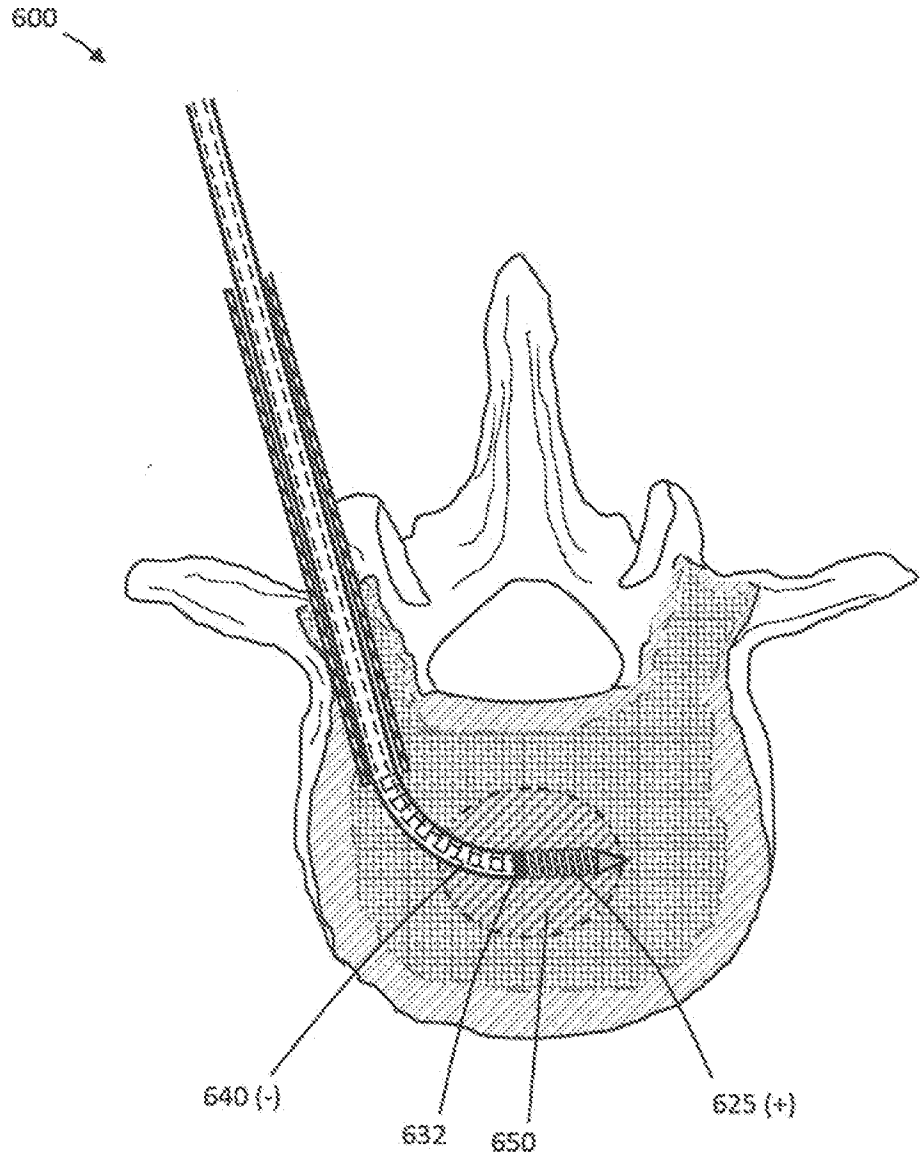


FIG. 23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/034593

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/00 (2011.01)
USPC - 606/79
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/00 (2011.01)
USPC - 606/79, 84, 86R, 87

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)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0133148 A1 (DANIEL et al) 19 September 2002 (19.09.2002) entire document	1-3, 7-12
A	US 5,697,536 A (EGGERS et al) 16 December 1997 (16.12.1997) entire document	1-3, 7-12
A	US 6,602,248 B1 (SHARPS et al) 05 August 2003 (05.08.2003) entire document	1-3, 7-12

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
18 July 2011	27 JUL 2011
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/034593

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.: 4-6, 13-18
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.