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(54) Titre : APPAREIL ET DISPOSITIF DE DECOUPE OSSEUSE POUR LE RETRAIT DE TISSU OSSEUX
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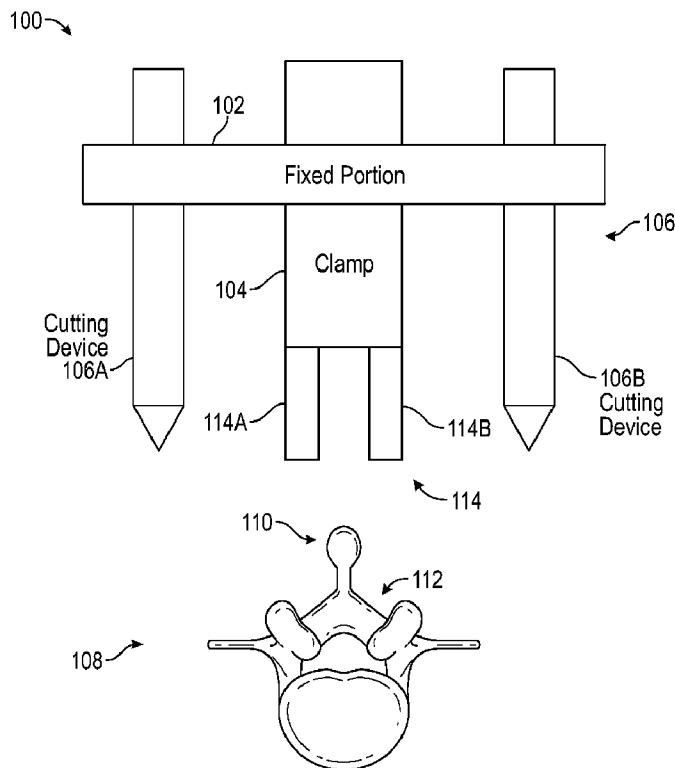


FIG. 1

(57) **Abrégé/Abstract:**

Embodiments of a device for forming incisions and extracting osseous tissue are disclosed. The device includes a body defining a channel. A blade is oriented in linear sliding engagement within the channel of the body. The device includes a stopping

(57) **Abrégé(suite)/Abstract(continued):**

mechanism for restricting movement of the blade relative to the body. The device is engageable to an apparatus. The apparatus includes a fixed portion that defines a first end and a second end. A clamp is oriented along the fixed portion of the apparatus adjacent the device. The clamp and the device are collectively configured to remove bone tissue from a patient.

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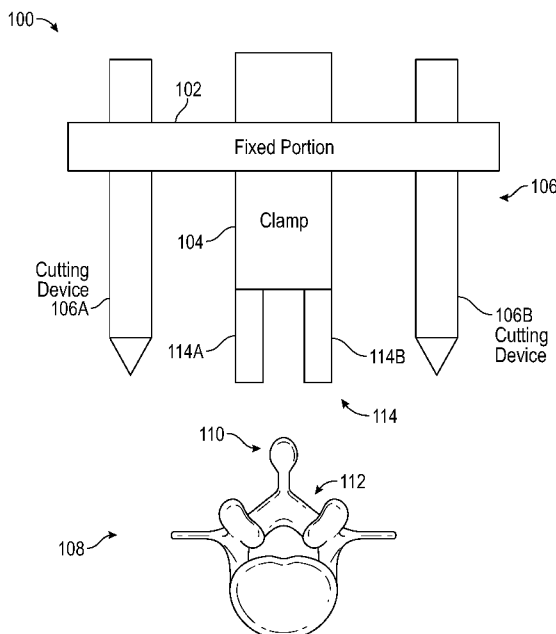


FIG. 1

(57) Abstract: Embodiments of a device for forming incisions and extracting osseous tissue are disclosed. The device includes a body defining a channel. A blade is oriented in linear sliding engagement within the channel of the body. The device includes a stopping mechanism for restricting movement of the blade relative to the body. The device is engageable to an apparatus. The apparatus includes a fixed portion that defines a first end and a second end. A clamp is oriented along the fixed portion of the apparatus adjacent the device. The clamp and the device are collectively configured to remove bone tissue from a patient.

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APPARATUS AND BONE CUTTING DEVICE FOR REMOVAL OF BONE TISSUE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This is a non-provisional application that claims benefit to U.S. provisional application serial no. 62/646,766, filed on March 22, 2018, which is herein incorporated by reference in its entirety.

FIELD

[0002] The present disclosure generally relates to medical apparatuses and devices, and in particular to surgical apparatuses configured for incision and extraction of osseous tissue that includes a clamp and bone cutting devices arranged along a fixed portion of the apparatus.

BACKGROUND

[0003] Various surgical procedures may involve the removal of osseous tissue, or bone. Such procedures may include, e.g., incisions along portions of the rib cage to gain access to the thoracic cavity, removal of bone tissue during knee surgery, or removal of portions of the skull or cutting of the skull during brain surgery. In most cases, precise and measureable cuts are required for each procedure. However, conventional devices typically employed for these procedures may lack precision and sufficient stabilization features, or have other drawbacks which may increase the likelihood of complications or concerns during surgery.

[0004] As one specific example, a laminectomy is a surgical procedure for removal of the vertebral arch, located in the cervical, thoracic, lumbar, and sacral regions of the spine. This procedure may be performed on patients with back pain due to compression along the spinal cord or nerves, which may be caused from various spine diseases, including (but not limited to) degenerative, infectious, neoplastic, traumatic, and congenital pathologies. Removal of the vertebral arch allows for decompression of the spinal canal, and gives the surgeon access to the contents of the spinal canal as needed. It is important when performing a laminectomy not to harm or tear the dura mater, which is a layer of tissue that surrounds and protects the spinal cord and nerve roots. A tear of the dura mater (fibrous sac containing the spinal cord, nerve roots, and spinal fluid) can result in

cerebrospinal fluid leakage, which can potentially inhibit the body's healing process while also increasing the probability of an infection. With conventional surgical instruments used in this space, removal of the vertebral arch without causing a dural tear remains difficult. Further, such conventional instruments require an applied force to break through the vertebrae. This force is also generally unrestricted, thereby forfeiting the ability to control precision.

[0005] It is with these observations in mind, among others, that various aspects of the present disclosure were conceived and developed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. 1 is a simplified block diagram of an apparatus for incision and extraction of osseous tissue, according to aspects of the present disclosure.

[0007] FIG. 2 is a perspective view of a first embodiment of an apparatus for removal and extraction of osseous tissue including a first embodiment of a bone cutting device, according to aspects of the present disclosure.

[0008] FIG. 3 is a side view of the apparatus of FIG. 2, according to aspects of the present disclosure.

[0009] FIG. 4 is a front view that illustrates possible movements of a plurality of bone cutting devices and a clamp of the apparatus of FIG. 2 relative to a fixed portion, according to aspects of the present disclosure.

[0010] FIGS. 5A-5B are perspective views of the first embodiment of the bone cutting device shown in FIGS. 2-4 with portions of FIG. 5B cut-away for illustration, according to aspects of the present disclosure.

[0011] FIG. 5C is an exploded view of the first embodiment of the bone cutting device shown in FIGS. 2-4, according to aspects of the present disclosure.

[0012] FIG. 6 is a perspective view of a second embodiment of an apparatus for removal and extraction of osseous tissue including a second embodiment of a bone cutting device, according to aspects of the present disclosure.

[0013] FIG. 7 is a side view of the apparatus of FIG. 6, according to aspects of the present disclosure.

[0014] FIG. 8 is a front view that illustrates possible movements of a plurality of bone cutting devices and a clamp of the apparatus of FIG. 6 relative to a fixed portion, according to aspects of the present disclosure.

[0015] FIG. **9** is a cross-sectional view of the second embodiment of a bone cutting device as shown in FIGS. **6-8**, according to aspects of the present disclosure.

[0016] FIG. **10** is a side view of a third embodiment of a bone cutting device, according to aspects of the present disclosure.

[0017] FIG. **11** is an exploded view of the third embodiment of a bone cutting device, according to aspects of the present disclosure.

[0018] FIG. **12** is an enhanced view of the quick quill stop which may be implemented with the third embodiment of a bone cutting device, according to aspects of the present disclosure.

[0019] FIGS. **13A-13D** are side views of the third embodiment of the bone cutting device shown in FIG. **10** illustrating a sequence for presetting a depth of a cut and applying a cut based on the desired depth, according to aspects of the present disclosure.

[0020] FIG. **14** is a side anatomical view of a third embodiment of a bone cutting device, according to aspects of the present disclosure.

[0021] FIG. **15** is a side view of the third embodiment of a bone cutting device engaged to the apparatus of FIG. **2**, according to aspects of the present disclosure.

[0022] Corresponding reference characters indicate corresponding elements among the view of the drawings. The headings used in the figures do not limit the scope of the claims.

DETAILED DESCRIPTION

[0023] The present disclosure relates to an apparatus and associated devices for incision and extraction of osseous tissue, which may also be referred to interchangeably herein as bone tissue. More specifically, an apparatus as described herein may include a fixed portion, a clamp mechanically coupled to the fixed portion for gripping bone tissue during a surgical procedure, and one or more (e.g., a plurality of) bone cutting devices arranged around the clamp along the fixed portion for cutting osseous tissue. In some embodiments, the bone cutting devices may include spring-loaded blades, and in other embodiments, the bone cutting devices may include blades coupled to rods and linear ball bearings; the blades configured for controlled reciprocating motion along a body.

[0024] In addition, in some embodiments, the clamp, and the plurality of bone cutting devices may be engaged to the fixed portion using linear and spherical joints so that the clamp and bone cutting devices may be oriented along different horizontal and vertical axes relative to the fixed portion. Referring to the drawings, embodiments of an apparatus for incision and extraction of osseous tissue are illustrated and generally indicated as **100**, **200**, and **300** in FIGS. **1-15**.

[0025] Referring to FIG. **1**, a first embodiment of an apparatus, designated **100**, includes a fixed portion **102**, a clamp **104** coupled to the fixed portion **102**, and a plurality of bone cutting devices **106**, illustrated as cutting device **106A** and cutting device **106B**, that are coupled to the fixed portion **102** and oriented around the clamp **104**, such that the clamp **104** is positioned between the cutting device **106A** and the cutting device **106B**. It should be understood that a pair of bone cutting devices **106** is shown solely for demonstration purposes, and some embodiments may include one bone cutting device or more than two bone cutting devices as needed for specific applications.

[0026] In some embodiments, the fixed portion **102** may comprise an elongated member, a rod, a linear guide rail, or a frame. The fixed portion **102** may be generally oriented to extend horizontally over a bone such as a vertebra **108** of a patient, including a spinous process **110** and lamina **112**, as shown. During use, the fixed portion **102** generally rests in a fixed, stationary position relative to the other components of the apparatus **100** and the target bone, as described herein.

[0027] As shown, the clamp **104** may be coupled in a generally central position along the fixed portion **102**. The clamp **104** may include any form of clamping device or vise-like apparatus capable of engaging and gripping a target area of bone tissue, such as the spinous process **110**. In some embodiments, the clamp **104** may be coupled to the fixed portion **102** using a spherical joint or hinge joint (not shown) so that clamp **104** may be oriented along different horizontal and vertical axes relative to the fixed portion **102** or be configured with multiple degrees of freedom. In some embodiments, the clamp **104** may also be in linear sliding engagement along the fixed portion **102** (not shown). In other embodiments, the clamp **104** may be coupled to the fixed portion **102** using a vertically aligned support member (not shown). Yet in other embodiments, the clamp **104** may be fixed in a stationary position relative to the fixed portion **102**.

[0028] In some embodiments, the clamp **104** includes at least a pair of clamp legs **114** illustrated as a first clamp leg **114A** and a second clamp leg **114B**. The first clamp leg **114A** and the second clamp leg **114B** may be driven or moved together to bind or grip the spinous process **110** or other bone matter. Movement of the clamp legs **114** may be achieved by tightening a screw (not shown) in mechanical engagement with the clamp legs **114**, or the clamp legs **114** may be spring loaded such that the clamp legs **114** are biased to a closed configuration, and may be driven to an open configuration by releasing the spring (not shown). Other suitable methods of moving the clamp legs **114** are contemplated and described herein. In other embodiments, a C-clamp may be implemented which is devoid of multiple legs and generally involves drawing a movable closing member against a stationary member to hold an object in place. Other such clamps are contemplated by the present inventive disclosure.

[0029] The bone cutting devices **106** are configured and operable to cut bone tissue and may include at least one of a drill, an osteotome, a rongeur, a scalpel, a laser, an ultrasonic device, a chisel, a gun-operated apparatus, a saw, or the like, capable of creating an incision through osseous tissue to accomplish this function. In some embodiments, the bone cutting devices **106** may be coupled to the fixed portion **102** using spherical joints or hinge joints (not shown), so that the bone cutting devices **106** may be oriented and maintained along different axes or be mechanically configured with multiple degrees of freedom. In some embodiments, the bone cutting devices **106** may also be in linear sliding engagement along the fixed portion **102** (not shown). In some embodiments, the bone cutting devices **106** are configured so that cutting depths can be controlled; i.e., the surgeon may carefully control the depth of any incision into the bone tissue. Dimensions of the bone cutting devices **106** may also vary with respect to length and width as needed.

[0030] The apparatus **100** may enable surgeons to remove bone tissue safely and more efficiently. As one example, a neurosurgeon may employ the apparatus **100** to quickly and safely perform a laminectomy. Specifically, once a target vertebra has been exposed and is available for access, the clamp **104** of the apparatus **100** may be engaged to the spinous process **110** by driving the clamp legs **114** together and gripping the spinous process **110**.

[0031] The surgeon may also align the bone cutting devices **106** along portions of the vertebra, and accurately position the bone cutting devices **106** over

the lamina **112** in the position and angle desired. The bone cutting devices **106** may then be employed to form bilateral, controlled longitudinal incisions or cuts in order to remove the lamina **112** and/or the spinous process **110** from the vertebra **108**. In the case where the bone cutting devices **106** include osteotomes, any force on the lamina **112** generated by application of the osteotomes is transmitted to the clamp **104**, thereby canceling the force generated on the lamina **112** from the operation of the osteotomes so that the apparatus **100** remains in a stationary position relative to the vertebra **108** during the procedure.

[0032] Once incisions formed by the bone cutting devices **106** are advanced to a predefined appropriate depth, the lamina **112** may naturally release from the vertebra **108** and can be removed as a single piece with the spinous process **110** still attached to the clamp **104**. Using the apparatus **100** as described, the dura mater surrounding the vertebra **108** underneath the lamina **112** is unlikely to be cut, and the laminectomy procedure is efficient and precise in its application. In this example, the laminectomy procedure may be completed within a time span of one to three minutes or less. The apparatus **100** may involve primarily inexpensive mechanical components as opposed to software or electro-mechanical components. Aspects of the apparatus **100** may be formed using surgical steel, although the present disclosure is not limited in this regard.

[0033] Referring to FIGS. **2-4**, one embodiment of an apparatus, designated **200**, includes a fixed portion **202**, a clamp **204** coupled to a generally central position along the fixed portion **202**, and a plurality of a first embodiment of bone cutting devices, defined as osteotomes **206** (and illustrated as osteotome **206A** and osteotome **206B**), that are coupled to the fixed portion **202** and oriented generally adjacent to the clamp **204**, such that the clamp **204** is positioned between the osteotome **206A** and the osteotome **206B**. It should be understood that a pair of osteotomes **206** and a sole clamp **204** are shown solely for illustrating possible aspects of the present disclosure, and some embodiments may include a plurality of clamps, a sole osteotome, or more than two osteotomes as may be suitable for specific applications. The osteotomes **206** and clamp **204** are described in greater detail below, but the osteotomes **206** illustrate one possible implementation of bone cutting devices previously described in FIG. **1** that may be configured to form incisions within bone in order to accommodate removal of bone tissue, and the clamp **204** may be generally configured to grip other bone tissue during surgery.

[0034] In some embodiments, the fixed portion **202** comprises a substantially linear rail, and may be generally cuboidal in shape, i.e. define an elongated three-dimensional rectangle shape as shown (although cylindrical/rod shapes and other such shapes are contemplated in related embodiments). The fixed portion **202** may be generally configured to extend horizontally over a bone such as the vertebra **108** of a patient during a laminectomy, similar to the orientation of the fixed portion **102** of the apparatus **100** relative to the vertebra **108** shown in FIG. **1**. The fixed portion **202** defines a first end **208A**, and a second end **208B** opposite the first end **208A**. In some embodiments, the fixed portion **202** defines a plurality of markers **209** arranged along the length of the fixed portion **202**. The plurality of markers **209** may define etchings, labels, indentations, or the like and may be associated with units of measurement to assist a surgeon with arranging the clamp **204** and the osteotomes **206** over predetermined positions along the fixed portion **202**, as further described herein.

[0035] In some embodiments, a plurality of carriages **210** may be mechanically coupled to the fixed portion **202** of the apparatus **200**. In the present embodiment shown, the plurality of carriages **210** may be illustrated as carriage **210A**, carriage **210B**, and carriage **210C**. In some embodiments, the carriage **210A** is positioned generally along the first end **208A**, the carriage **210C** is positioned generally along the second end **208B**, and the carriage **210B** is positioned between the carriage **210A** and the carriage **210C**. Each of the carriages **210** may be oriented in linear sliding engagement along the fixed portion **202**. Specifically, as shown in FIG. **2**, each of the carriages **210** may define a respective channel **211** extending through each of the carriages **210**, and the carriages **210** may be slidably mounted along the fixed portion **202** by inserting either the first end **208A** or the second end **208B** of the fixed portion **202** through the channels **211** of the carriages **210**. The plurality of carriages **210** may define linear bearings, slide casings, or linear/prismatic joints that are capable of linear sliding movement along the fixed portion **202**, as further described herein. In some embodiments, as shown, the fixed portion **202** may be formed with linear guides or rails, and the channels **211** may be formed of a shape that is suitable for receiving the linear guides in order to movably mount and maintain the carriages **210** along the guide rails of the fixed portion **202**, although the present disclosure is not limited in this regard.

[0036] In some embodiments, each of the carriages **210** may include a respective tightening knob **212** or other such locking mechanism for restricting linear movement of the carriages **210** along the fixed portion **202**. In other words, when the tightening knob **212** of the carriage **210A** is engaged, the tightening knob **212** maintains the carriage **210A** in a locked or stationary position relative to the fixed portion **202**. Maintaining the carriages **210** in a locked or stationary position relative to the fixed portion **202** may be advantageous during surgery when various forces may be exerted upon the apparatus **200**, as further described herein.

[0037] As further shown, a plurality of spherical joints **214** may be mounted to or otherwise defined along the carriages **210**. In particular, as illustrated, a spherical joint **214A** may be included along the carriage **210A**, a spherical joint **214B** may be included along the carriage **210B**, and a spherical joint **214C** may be included along the carriage **210C**. The spherical joints **214** may define ball joints, ball bearings, spherical bearings, ball and socket joints, or the like.

[0038] Referring to FIG. 3, in some embodiments, each of the spherical joints **214** may include at least a housing body **216** defining a cavity **218**, with the housing body **216** mounted or otherwise defined along the carriage **210** of the apparatus **200**. The spherical joints **214** may further include a ball stud **220** defining a ball portion **222** in communication with a stem portion **224**. The ball portion **222** of the ball stud **220** may be rotatably engaged within the cavity **218** of the housing body **216** to accommodate angular rotation of the stem portion **224** relative to the housing body **216** and enable multiple degrees of freedom. Further, as shown, the stem portion **224** may be coupled to or mounted along an osteotome **206** (or the clamp **204** (not shown)). In this manner, the osteotome **206** may be oriented along different horizontal and vertical axes, and may be rotated relative to the fixed portion **202** by nature of the osteotome **206** being coupled to the spherical joint **214**.

[0039] In some embodiments as shown, the spherical joints **214** may include a tightening knob **226** or other like locking mechanism similar to the tightening knobs **212** for restricting movement of the ball stud **220** relative to the housing body **216**. In other words, when the tightening knob **226** of a spherical joint **214** is engaged, the tightening knob **226** maintains the ball stud **220** in a substantially locked or stationary position relative to the housing body **216** and restricts angular and rotational movement thereof. Maintaining the ball stud **220** in a locked or stationary position relative to the housing body **216** may be advantageous

during surgery when various forces may be exerted upon the apparatus **200** and it is desired to maintain the osteotomes **206** (and/or the clamp **204**) in a stationary position.

[0040] Referring to FIG. 4, each of the clamp **204**, the osteotome **206A**, and the osteotome **206B**, when coupled to any one of the spherical joints **214**, may be configured with multiple degrees of freedom, i.e., may be oriented along different horizontal and vertical axes relative to the fixed portion **202**. In addition, by virtue of the spherical joints **214** being coupled to the carriages **210**, the linear positioning of each of the clamp **204**, the osteotome **206A**, and the osteotome **206B** along the fixed portion **202** may be adjusted by sliding the carriages **210** to different predetermined positions along the fixed portion **202** as desired. For example, as indicated by the horizontal arrows shown, the carriage **210A** (and the osteotome **206A**) may be advanced along the fixed portion **202** towards the first end **208A** or the second end **208B** to a predetermined position (not shown) as desired, and the tightening knob **212** of carriage **210A** may be actuated, tightened or otherwise engaged to lock the carriage **210A** or otherwise maintain the carriage **210A** in a substantially stationary configuration along the predetermined position. In addition, with the spherical joint **214A** provided along the carriage **210** as described, and the osteotome **206A** being coupled to the spherical joint **214A**, the osteotome **206A** may be oriented along different horizontal and vertical axes relative to the fixed portion **202** (as illustrated by the curved arrows), independently of the osteotome **206B** and the clamp **204**. The clamp **204**, when coupled to the spherical joint **214B** and the carriage **210B**, and the osteotome **206B**, when coupled to the spherical joint **214C** and the carriage **210C**, are capable of the same or similar movement. Once the components of the apparatus **200** (the clamp **204**, the osteotome **206A**, and the osteotome **206B**) are oriented as desired, the surgeon may engage the tightening knobs **212** and the tightening knobs **226** (FIG. 3) to temporarily maintain these orientations during a surgical procedure. This enhanced flexibility, maneuverability, and stability of the apparatus **200** components may allow a surgeon to more accurately align the apparatus **200** along a vertebra or other bone tissue and safely complete a cutting procedure.

[0041] Referring to FIGS. 5A-5C, the osteotomes **206** are generally configured for controlled reciprocating motion to drive a blade into bone tissue and form precise cuts along the same, and the osteotomes **206** may include a stopping

mechanism for adjusting the depth of cuts formed by the blade, as described herein. Accordingly, in some embodiments an osteotome **206** as shown may include a body **250** defining a proximal end **251A** and a distal end **251B** with a channel **252** extending longitudinally at least partially through the body **250** between the proximal end **251A** and the distal end **251B**. A blade **254** may be positioned within the channel **252** of the body **250**. The blade **254** may include a proximal end **256** and a distal end **258** where the distal end **258** of the blade **254** defines a cutting portion **260**. The blade **254** may be configured to slidably shift up and down along the channel **252** in a controlled manner as further described herein.

[0042] In some embodiments, as shown, the blade **254** may be coupled to a rod **262**. The rod **262** may be at least partially engaged within the channel **252** of the body **250** and may define a head portion **264** and a rod-blade interface **266** (FIG. **5C**) defined along the rod **262** opposite the head portion **264**. In addition, the rod **262** may include a threaded portion (not shown).

[0043] The osteotome **206** may further include a stopping mechanism **270** for restricting the depth of cuts formed by the blade **254**. In the embodiment shown, the stopping mechanism **270** defines a quick quill stop **272** engaged along the rod **262** as shown. The quick quill stop **272** may include an adjustment knob **274** defined along a periphery of the adjustment knob **274**, and a stopping surface **276** oriented towards the head portion **264**. The quick quill stop **272** may be internally threaded to engage with a threaded portion (not shown) of the rod **262** in order to accommodate linear controller movement of the quick quill stop **272** along the rod **262**, using the adjustment knob **274**. The quick quill stop **272** enables a user to present the depth of the cuts formed by the blade **254**. Specifically, where a force is applied to the head portion **264** of the rod **262**, the stopping surface **276** of the quick quill stop **272** impacts the head portion **264** as the force drives the rod **262** and the blade **254** towards the distal end **251B** of the body **250**, thereby limiting the depth of any cut formed by the blade **254**.

[0044] In some embodiments, the osteotome **206** may further include a linear ball bearing **280** oriented along the channel **252** of the body **250** as shown. A portion of the rod **262** and blade **254** may be engaged to the linear ball bearing **280** to reduce friction and accommodate linear sliding engagement of the rod **262** and blade **254** through the channel **252**. In some embodiments, at least a portion of the body **250** is configured to be embedded within bone tissue during cut formation.

[0045] Referring to FIG. 6, a second embodiment of an apparatus, designated **300**, includes a fixed portion **302**, a clamp **304** coupled to a generally central position along the fixed portion **302**, and a plurality of a second embodiment of bone cutting devices or osteotomes **306**, illustrated as osteotome **306A** and osteotome **306B**, that are coupled to the fixed portion **302** and oriented generally adjacent to the clamp **304**, such that the clamp **304** is positioned between the osteotome **306A** and the osteotome **306B**. It should be understood that a pair of osteotomes **306** and a sole clamp **304** are shown solely for illustrating possible aspects of the present disclosure, and some embodiments may include a plurality of clamps, a sole osteotome, or more than two osteotomes as may be suitable for specific applications.

[0046] In some embodiments, the fixed portion **302** comprises a substantially linear rail, and may be generally cuboidal in shape, i.e. define an elongated three-dimensional rectangle shape as shown (although cylindrical/rod shapes and other such shapes are contemplated in related embodiments). The fixed portion **302** may be generally configured to extend horizontally over a bone such as a vertebra of a patient during a laminectomy. The fixed portion **302** defines a first end **303A**, and a second end **303B** opposite the first end **303A**. In some embodiments, the fixed portion **302** defines a plurality of markers **308** arranged along the length of the fixed portion **302**. The plurality of markers **308** may define etchings, labels, indentations, or the like and may be associated with units of measurement to assist a surgeon with arranging the clamp **304** and the osteotomes **306** over predetermined positions along the fixed portion **302**, as further described herein.

[0047] In some embodiments, a plurality of carriages **310** may be mechanically coupled to the fixed portion **302** of the apparatus **300**. In the present embodiment shown, the plurality of carriages **310** may be illustrated as carriage **310A**, carriage **310B**, and carriage **310C**. In some embodiments, the carriage **310A** is positioned generally along the first end **303A**, the carriage **310C** is positioned generally along the second end **303B**, and the carriage **310B** is positioned between the carriage **310A** and the carriage **310C**. Each of the carriages **310** may be oriented in linear sliding engagement along the fixed portion **302**. Specifically, each of the carriages **310** may define a respective channel **311** extending through each of the carriages **310**, and the carriages **310** may be slidably mounted along the fixed

portion **302** by inserting either the first end **303A** or the second end **303B** of the fixed portion **302** through the channels **311** of the carriages **310**. The plurality of carriages **310** may define linear bearings, slide casings, or linear/prismatic joints that are capable of linear sliding movement along the fixed portion **302**, as further described herein. In some embodiments, as shown, the fixed portion **302** may be formed with linear guides or rails, and the channels **311** may be formed of a shape that is suitable for receiving the linear guides in order to movably mount and maintain the carriages **310** along the guide rails of the fixed portion **302**, although the present disclosure is not limited in this regard.

[0048] In some embodiments, each of the carriages **310** may include a respective tightening knob **312** or other such locking mechanism for restricting linear movement of the carriages **310** along the fixed portion **302**. In other words, when the tightening knob **312** of the carriage **310A** is engaged, the tightening knob **312** maintains the carriage **310A** in a locked or stationary position relative to the fixed portion **302**. Maintaining the carriages **310** in a locked or stationary position relative to the fixed portion **302** may be advantageous during surgery when various forces may be exerted upon the apparatus **300**, as further described herein.

[0049] As further shown, a plurality of spherical joints **314** may be mounted to or otherwise defined along the carriages **310**. In particular, as illustrated, a spherical joint **314A** may be included along the carriage **310A**, a spherical joint **314B** may be included along the carriage **310B**, and a spherical joint **314C** may be included along the carriage **310C**. The spherical joints **314** may define ball joints, ball bearings, spherical bearings, ball and socket joints, or the like.

[0050] Referring to FIG. 7, in some embodiments, each of the spherical joints **314** may include at least a housing body **316** defining a cavity **318**, with the housing body **316** mounted or otherwise defined along the carriage **310** of the apparatus **300**. The spherical joints **314** may further include a ball stud **320** defining a ball portion **322** in communication with a stem portion **324**. The ball portion **322** of the ball stud **320** may be rotatably engaged within the cavity **318** of the housing body **316** to accommodate angular rotation of the stem portion **324** relative to the housing body **316** and enable multiple degrees of freedom. Further, as shown, the stem portion **324** may be coupled to or mounted along an osteotome **306** (or the clamp **304** (not shown)). In this manner, the osteotome **306** may be oriented along different

horizontal and vertical axes, and may be rotated relative to the fixed portion **302** by nature of the osteotome **306** being coupled to the spherical joint **314**.

[0051] In some embodiments as shown, the spherical joints **314** may include a tightening knob **326** or other like locking mechanism similar to the tightening knobs **312** for restricting movement of the ball stud **320** relative to the housing body **316**. In other words, when the tightening knob **326** of a spherical joint **314** is engaged, the tightening knob **326** maintains the ball stud **320** in a substantially locked or stationary position relative to the housing body **316** and restricts angular and rotational movement thereof. Maintaining the ball stud **320** in a locked or stationary position relative to the housing body **316** may be advantageous during surgery when various forces may be exerted upon the apparatus **300** and it is desired to maintain the osteotomes **306** (and/or the clamp **304**) in a stationary position.

[0052] Referring to FIG. 8, each of the clamp **304**, the osteotome **306A**, and the osteotome **306B**, when coupled to any one of the spherical joints **314**, may be configured with multiple degrees of freedom, i.e., may be oriented along different horizontal and vertical axes relative to the fixed portion **302**. In addition, by virtue of the spherical joints **314** being coupled to the carriages **310**, the linear positioning of each of the clamp **304**, the osteotome **306A**, and the osteotome **306B** along the fixed portion **302** may be adjusted by sliding the carriages **310** to different predetermined positions along the fixed portion **302** as desired. For example, as indicated by the horizontal arrows of FIG. 8, the carriage **310A** (and the osteotome **306A**) may be advanced along the fixed portion **302** towards the first end **303A** or the second end **303B** to a predetermined position (not shown) as desired, and the tightening knob **312** defined along the carriage **310A** may be actuated, tightened or otherwise engaged to lock the carriage **310A** or otherwise maintain the carriage **310A** in a substantially stationary configuration along the predetermined position. In addition, with the spherical joint **314A** defined along the carriage **310** as described, and the osteotome **306A** being coupled to the spherical joint **314A**, the osteotome **306A** may be oriented along different horizontal and vertical axes relative to the fixed portion **302** (as illustrated by the curved arrows), independently of the osteotome **306B** and the clamp **304**. The clamp **304**, when coupled to the spherical joint **314B** and the carriage **310B**, and the osteotome **306B**, when coupled to the spherical joint **314C** (FIG. 6) and the carriage **310C**, are capable of the same or similar movement.

Once the components of the apparatus **300** (the clamp **304**, the osteotome **306A**, and the osteotome **306B**) are oriented as desired, the surgeon may engage the tightening knobs **312** and the tightening knobs **326** (FIG. **6**) to temporarily maintain these orientations during a surgical procedure. This enhanced flexibility, maneuverability, and stability of the apparatus **300** components may allow a surgeon to more accurately align the apparatus **300** along a vertebra or other bone tissue and safely complete a cutting procedure.

[0053] Referring to FIG. **9**, the osteotomes **306** are generally configured for driving a blade into bone tissue and making predetermined controlled cuts, and includes a stopping mechanism for adjusting the depth of cuts formed by the blade, as described herein. Accordingly, in some embodiments an osteotome **306** as shown may include a body **350**, defining a proximal end **351A** and a distal end **351B**, with a channel **352** extending longitudinally at least partially through the body **350**. A blade **354** may be slidably engaged within the channel **352** of the body **350**. The blade **354** may include a proximal end **356** and a distal end **358** where the distal end **358** of the blade **354** defines a cutting portion **360**.

[0054] In this embodiment, the osteotome **306** is generally configured to have the shape of gun, and may also include similar functionality. In particular, the body **350** may define a handle **362** along the proximal end **351A** which may be configured to accommodate the shape of a surgeons hand for increased stability during formation of a cut with the blade **354**, as further described herein. Further, a barrel **364** may be defined along the distal end **351B** of the body **350**. A spring **366** may be positioned within the channel **352** and engaged to the blade **354** such that the blade **354** is spring-loaded within the channel **352** of the body **350**. In this manner, a trigger **368** may be included along the body **350** and be configured for releasing the spring **366** in order to launch the cutting portion **360** of the blade **354** away from the proximal end **351A** of the body **350**.

[0055] In some embodiments, the osteotome **306** may further include a ratchet (not shown) defined within the body **350**. The ratchet may facilitate the gun to function similarly to a staple gun. For example, engaging the trigger **368** may allow the cutting portion **360** of the blade **354** of the osteotome **306** to be driven incrementally further, with each trigger **368** pull, along the channel **352** towards the distal end **351B**.

[0056] As further shown, the osteotome **306** may include a stopping mechanism **372** for restricting the depth of cuts formed by the blade **354**. In the embodiment shown, the stopping mechanism **372** includes a member **374** extending horizontally partially through the channel **352** as shown. The stopping mechanism **372** may further define a stopping edge **376** defined along the blade **354** configured to impact the member **374** in order to restrict cutting depth. The member **374** may be mechanically engaged to a knob **378**, and manipulating the knob **378** may shift the member **374** along the channel **352**, thereby restricting the cutting depth. In other words, by engaging the knob **378**, the member **374** may be shifted towards (decrease cutting depth) or away (increase cutting depth) from the proximal end **351A** of the osteotome **306**.

[0057] In some embodiments, the osteotome **306** may further include a linear ball bearing (not shown) oriented along the channel **352** of the body **350** to reduce friction and accommodate linear sliding engagement of the blade **354** through the channel **352**.

[0058] Referring to FIGS. **10-11**, another embodiment of a bone cutting device may take the form of an osteotome **406**. In this embodiment, the osteotome **406** generally includes a body **410** defining a proximal end **412** and a distal end **414** with a channel **420** extending longitudinally at least partially through the body **410** between the proximal end **412** and the distal end **414**. The osteotome **406** may further generally include a rod **422** slidably received within the channel **420** and a blade **424** (shown in FIG. **11**) engaged to the rod **422** for forming incisions in or otherwise removing matter from bone tissue, as further described herein.

[0059] As further shown, in some embodiments, the body **410** includes an upper portion **430** defined along the proximal end **412**, and a lower portion **432** defined along the distal end **414** with the lower portion **432** having a slot **434** defined therein to accommodate controlled linear movement of the blade **424** within the slot **434** relative to the lower portion **432** as further described herein. The slot **434** may extend from the distal end **414** at least partially through the lower portion **432** as indicated. In addition, the upper portion **430** of the body **410** may define a channel **440**, and the lower portion **432** of the body **410** may define a channel **442** in communication with the slot **434**. As further described herein, when the upper portion **430** of the body **410** is engaged with the lower portion **432**, the channel **440** and the channel **442** linearly align and collectively form the channel **420**, such that

the channel **420** extends longitudinally entirely through the upper portion **430** and at least partially longitudinally through the lower portion **432**. The upper portion **430** may be removably engaged to the lower portion **432**. In one embodiment, for example, the upper portion **430** may define a plurality of external threads **444** axially arranged at least partially along the upper portion **430** as shown, and configured to engage with respective internal threads **446** defined within the lower portion **432** such that the upper portion **430** can be temporarily screwed onto the lower portion **432** or vice versa.

[0060] In some embodiments, the rod **422** may define a head portion **450** positioned proximate to the proximal end **412** of the body **410** and a rod-blade interface **452** defined along the rod **422** opposite the head portion **450** for engaging with the blade **424**. As indicated, the rod-blade interface **452** of the osteotome **406** may include a slit **460** for receiving a portion of the blade **424**. To assemble the osteotome **406**, the upper portion **430** of the body **410** may be connected to the lower portion **432** as described, the rod-blade interface **452** may be oriented towards the upper portion **430**, the rod **422** may be inserted within the channel **440** and positioned within the channel **420**, and the rod **422** may extend through the channel **440** such that the rod-blade interface **452** is at least partially housed within the channel **442** and accessible via the slot **434**. Upon positioning the rod **422** within the channel **420** as indicated, the blade **424** may then be inserted or otherwise received within the slot **434**, and a portion of the blade **424** may be received within the slit **460** as indicated. Once the blade **424** is positioned within the slit **460**, a plurality of securing members **472** (e.g., screws or the like) may be passed through apertures **474** defined within the rod-blade interface **452** and respective apertures **476** of the blade **424** to fasten the blade **424** to the rod **422** along the rod-blade interface **452**. In this manner, the rod **422** is mechanically engaged to the blade **424**, the rod **422** is in linear sliding engagement through the channel **420** of the body **410**, and the blade **424** is in linear sliding engagement through the slot **434** of the lower portion **432** of the body **410**. In some embodiments, dimensions of the blade **424**, the channel **442**, and/or the slot **434** may be preconfigured to restrict at least some degree of linear movement of the blade **424** through the channel **420** of the body **410** in a direction towards the upper portion **430**. For example, the diameter of the channel **442** of the lower portion **432** may be narrower than the width of the blade **424**. In these

embodiments, once assembled as described, the rod **422** of the osteotome **406** may be prevented from simply sliding out of the channel **420** at the proximal end **412**.

[0061] In some embodiments, the osteotome **406** further includes a stopping mechanism **480** for presetting or restricting the depth of cuts formed by the blade **424**. In the embodiment shown, the stopping mechanism **480** includes a quick quill stop **482** defining a channel **483**, and a head **484** defining a channel **485**. The rod **422** may be threaded through the channel **483** of the quick quill stop **482** and at least partially threaded through the channel **485** of the head **484** in the manner shown, such that the quick quill stop **482** is in a predetermined position along the rod **422** in between the upper portion **430** of the body **410** and the head **484**. In general, the quick quill stop **482** restricts linear movement of the rod **422** through the channel **420** and corresponding movement of the blade **424** relative to the slot **434** to control cutting depth when a blunt force is applied to the head **484** by a mallet or other such component.

[0062] Referring to FIG. **12**, the quick quill stop **482** generally includes a nut **486** rotatably engaged to a base **488**. The nut **486** may define a plurality of threads **490** which engage with respective threads **492** defined along the head portion **450** of the rod **422**. In some embodiments, the nut **486** further includes a button **494** that disengages the plurality of threads **490** from the respective threads **492** of the rod **422**. To adjust linear movement of the quick quill stop **482** along the rod **422** relative to the head **484**, a user may press the button **494** to disengage the plurality of threads **490** from the respective threads **492** of the rod **422** such that the quick quill stop **482** may slide along the rod **422** to a predetermined position along the rod **422** as desired, and releasing the button **494** may then re-engage the plurality of threads **490** with the respective threads **492** of the rod **422** to lock the quick quill stop **482** in the predetermined position. Alternatively, rotating the nut **486** provides gradual linear movement of the quick quill stop **482** along the rod **422** relative to the head **484** and the upper portion **430** by micro-adjustment (e.g., .001" increments). The quick quill stop **482** may be a quill stop for a Bridgeport Milling Machine, such as the Quill Stop by Morton Machine Works, or a Quick Thread Stop Collar or the Quick Quill Stop by Grizzly Industrial®, or the like, but the present disclosure is not limited in this regard.

[0063] Referring to FIGS. **13A-13D**, the quick quill stop **482** enables a user to preset the depth of the cuts formed by the blade **424** by restricting linear

movement of the rod **422** through the channel **420**. FIGS. **13A** and **13B** illustrate predetermined linear movement of the quick quill stop **482** in a direction **D1** along the rod **422** to define a preset cutting depth **502** (although it should be understood that the quick quill stop **482** may be adjusted along the rod **422** in the opposite direction as desired to define the preset cutting depth **502**).

[0064] FIG. **13C** illustrates a force **F** applied to the head **484** (by a mallet or other such instrument), which results in at least some linear movement of the rod **422** in a direction **D2** opposite the direction **D1** through the channel **420** relative to the body **410** and at least some linear movement of the blade **424** relative to the slot **434** in the direction **D2**. As shown in FIG. **13D**, the quick quill stop **482** impacts the upper portion **430** and is prevented from further linear movement, which in turns restricts movement of the rod **422** within the channel **420**. A tip **504** of the blade extends outside the slot **434** of the lower portion **432** to form a cut with a cutting depth **506** equal to the preset cutting depth **502**. Again, the contact between the quick quill stop **482** and the upper portion **430** of the body **410** limits the extension of the blade **424** through the slot **434** despite the force **F** applied to the head **484** to limit the cutting depth **506** (based on the value of the preset cutting depth **502**).

[0065] The embodiment of the osteotome **406** shown provides various advantages. The lower portion **432** of the body **410** may be tapered as shown to increase yield strength without sacrificing visibility and also to provide a larger range of cutting alignment of the blade **424**. The combination of the slit **460** of the rod **422** and the slot **434** of the lower portion **432** of the body **410** reduces lateral movement when the blade **424** is being used for leverage and/or prying. The slit **460** of the rod **422** is formed to a depth in which it promotes deflection when the securing members **472** are fastened, increasing the holding power and accommodating a secure/tight fit. Embodiments of the osteotome **406** may generally comprise stainless steel, biocompatible materials, or combinations thereof.

[0066] FIG. **14** and FIG. **15** illustrate exemplary implementations of the osteotome **406**. It is contemplated however that the osteotome **406** may accommodate other implementations where controlled surgical cuts are desired. In FIG. **14**, the osteotome **406** may be grasped by a clinician or robotic device (not shown) or may otherwise be handheld to form a cut in bone tissue; e.g., parallel to a vertebrae **510** on a lamina **512**.

[0067] Referring to FIG. 15, in some embodiments, the osteotome **406** may be implemented with the apparatus **200** described herein or otherwise be implemented in place of the osteotome **206**. For example, the stem portion **224** of the apparatus **200** may be coupled to or mounted along the upper portion **430** of the osteotome **406**. In this manner, the osteotome **406** may be oriented along different horizontal and vertical axes, and may be rotated relative to the fixed portion **202** of the apparatus **200** by nature of the osteotome **406** being coupled to the spherical joint **214**. In this exemplary implementation, the osteotome **406** may be afforded any of the advantages and functionality of the osteotome **206** previously described; e.g., the osteotome **406** may be configured with multiple degrees of freedom, i.e., may be oriented along different horizontal and vertical axes relative to the fixed portion **202** of the apparatus **200** as previously described to provide precise, stable, and controlled cuts, and the like.

[0068] Exemplary Manufacturing Methods

[0069] In some embodiments, the osteotome **406** comprises components that are both machined and preconfigured. For example, components that may be machined include the body **410**, the rod **422**, the blade **424**, the head **484**, and the like, using a Mustang 60.

[0070] In some embodiments, the rod **422** may be formed using a stock piece of 0.50" diameter 1018 steel rod cut to a length of 7.50" using a chop saw. The cut end may then be faced on a lathe to a flat surface and to form a total length of 7.35". Using a mill, a centered 0.125" slot may then be cut 0.75" deep into the bottom portion of the rod **422**. The rod **422** may then be rotated 90 degrees to machine the apertures **474** that accommodate the mating of the blade **424**. The apertures **474** may have a 5/16" diameter counterbore formed using a plunge cut on the nearside of the slit **460** and a 0.136" diameter hole with a drill bit through both sides.

[0071] The head **484** may be machined using a 1.125" diameter piece of T-303 steel. Using a lathe, the top portion of the stock material being used may be faced. The diameter of the stock may then be faced down to a diameter of 1". A hole of 3/8" was may then be applied using a mill. A dye may then be used to create an internal thread (not shown) within the channel **485** to allow for the attachment onto the rod **422**. The part may then be parted to the desired height and placed in the

lathe to face to a flat surface. Chamfers may then be machined onto the top and bottom edges of the head **484**.

[0072] The body **410** may be formed using a 1.125" diameter T-303 steel rod. In one embodiment, the upper portion **430** of the body **410** was faced down on the lathe to a desired diameter of 1.11". A 2.50" length portion of the rod **422** was then parted and faced where cut. Using a bit, the center of the body **410** was machined to its respective internal diameter. A 0.75" long portion on one end of the body **410** was left to face down the outer diameter to a smaller size to create external threads **444**. The internal portion of the threads **446** was then machined down to an internal diameter of 0.516".

[0073] The lower portion **432** of the body **410** was faced down to its appropriate outer diameter and parted using the lathe. The end in contact with the bone was then shaped to its appropriate geometry using the right hand tool. A hole was then created on the opposite side of the piece 1.11" deep. The internal threads **446** were then machined in the body **410** using a tap in the mill. The slot **434** for the blade **424** was then formed using the mill.

[0074] The blade **424**, and iterations thereof, were made using 303 stainless steel, 316L steel, and 440C stainless steel. A thin plate of stock from each material was faced on a mill to a thickness of 0.120". The four edges of each piece of material were then faced down to create flat surfaces. Using a mill cutter, based on the stock size of the material being used, four plunge cuts were made to create the insertion that will mate with the rod **422**. The stock material was then flipped 180° to machine the blade **424** on the opposite end of the plunge cuts. Using the vertical band saw, each blade was then separated and faced on the mill to its desired geometry.

Testing and Analysis

[0075] Various tests were conducted to assess the efficacy of the embodiments described herein. For example, the following Weight Drop Test was conducted to assess the osteotome **406**.

[0076] *Weight Drop Test*

[0077] Method: 10lb weight dropped from a height of 17.2cm above the osteotome **406** while the osteotome **406** was positioned by a surgeon for a standard Schwab grade 1 osteotomy. The weight was dropped repeatedly until the osteotome

406 entered the spinal canal or until 10 drops was reached, whichever came first. A single biomimetic spine model of an anatomically normal T12-L5 spinal segment with normal cortical and cancellous bone density was used for testing. The standard osteotome and the osteotome **406** were used on alternating sides of the spine model to account for any possible error with one side of the model having different bone quality than the other side. The first device used at each spinal level was also alternated to account for any possible error introduced by weakening of a spinal level after one side is tested.

[0078] RESULTS: The osteotome **406** achieved 10 weight drops at every tested level from T12-L5 without a single breach of the spinal canal or a neural foramen. The standard osteotome averaged 4.8 weight drops before entering the spinal canal (standard deviation 2.11). See Table 1 below for full results.

Table 1: Results of weight drop testing (Osteotome **406** = "Safe-T—Otome")

Model Level	Device used/ Number of Weight Drops	
	Left Side	Right Side
T12	Osteotome / 3	Safe-T-Otome / 10
L1	Safe-T-Otome / 10	Osteotome / 5
L2	Osteotome / 2	Safe-T-Otome / 10
L3	Safe-T-Otome / 10	Osteotome / 7
L4	Osteotome / 8	Safe-T-Otome / 10
L5	Safe-T-Otome / 10	Osteotome / 4

[0079] It should be understood from the foregoing that, while particular embodiments have been illustrated and described, various modifications can be made thereto without departing from the spirit and scope of the invention as will be apparent to those skilled in the art. Such changes and modifications are within the scope and teachings of this invention as defined in the claims appended hereto.

CLAIMS

What is claimed is:

1. A device for forming an incision within bone tissue, comprising:
 - a body defining a channel extending longitudinally at least partially from a proximal end of the body to a distal end of the body;
 - a rod slidably engaged within the channel of the body;
 - a blade coupled to a rod-blade interface of the rod along the distal end of the body and positioned at least partially within a slot defined along the distal end of the body;
 - a head connected to a head portion of the rod proximate to the proximal end of the body for receiving a force to drive the rod through the channel and to move the blade at least partially through the slot; and
 - a stopping mechanism engaged to the rod between the head and the upper portion of the body that is movable about the rod to preset a cutting depth of the blade relative to the body by limiting movement of the rod within the channel.
2. The device of claim 1, wherein the stopping mechanism includes a quick quill stop including threads defined internally along the quick quill stop, the threads engaged to respective threads defined along a head portion of the rod, engagement of the threads of the quick quill stop to the respective threads of the head portion of the rod maintaining the quick quill stop in a fixed position relative to the rod.
3. The device of claim 2, wherein the quick quill stop includes a button that releases the threads of the quick quill stop from the respective threads of the rod to accommodate free sliding movement of the quick quill stop along the rod.
4. The device of claim 2, wherein the quick quill stop includes a rotatable nut that accommodates incremental movement of the quick quill stop along the rod.

5. The device of claim 2, wherein the blade is at least partially positioned within a slit defined along the rod-blade interface.
6. The device of claim 2, wherein the body comprises stainless steel.
7. The device of claim 2, further comprising:
 - a linear ball bearing oriented along the channel of the body, wherein a portion of the rod is engaged to the linear ball bearing to reduce friction and accommodate linear sliding engagement of the rod through the channel.
8. The device of claim 1, wherein at least a portion of the body is configured to be embedded within bone tissue.
9. The device of claim 1, further comprising:
 - a barrel defined by the channel of the body and along a distal portion of the body;
 - a handle defined along a proximal portion of the body opposite the distal portion;
 - a spring engaged to the blade such that the blade is spring-loaded within the channel of the body;
 - a ratchet defined along the body and engaged to the spring and blade to accommodate incremental movement of the blade through the channel; and
 - a trigger defined along the body for releasing the spring to launch the cutting portion of the blade away from the proximal portion of the body.
10. A device for forming an incision within bone tissue, comprising:
 - a body defining a channel extending longitudinally at least partially from a proximal end of the body to a distal end of the body;
 - a blade positioned along the body for forming incisions within bone tissue; and

- a stopping mechanism defined proximate to the body, the stopping mechanism configured to restrict movement of the blade relative to the channel and body.
11. The device of claim 10, further comprising:
- a barrel defined by the channel of the body and along a distal portion of the body;
 - a handle defined along a proximal portion of the body opposite the distal portion;
 - a spring engaged to the blade such that the blade is spring-loaded within the channel of the body;
 - a ratchet defined along the body and engaged to the spring and blade to accommodate incremental movement of the blade through the channel; and
 - a trigger defined along the body for releasing the spring to launch the cutting portion of the blade away from the proximal portion of the body.
12. The device of claim 10, wherein the body includes an upper portion removably connected to a lower portion, the upper portion and the lower portion defining respective channels collectively forming the channel.
13. The device of claim 12, wherein at least part of the lower portion of the body is tapered such that a width of the lower portion proximate to a free end of the body along the distal end is less than a width of the lower portion proximate to the upper portion.
14. The device of claim 10, wherein the lower portion defines a slot defined partially through the lower portion, the slot being in perpendicular relation relative to the channel.
15. A method of making a medical device, comprising:
- forming a body comprising an upper portion removably connected to a lower portion;

forming a slot within the lower portion of the body;
inserting a rod within a channel defined collectively by the upper portion and the lower portion of the body such that a head portion of the rod extends outside the channel from the upper portion and a rod-interface portion of the rod is housed within the lower portion;
engaging a stopping mechanism along the head portion of the rod;
positioning a blade at least partially within the slot of the body; and
mounting the blade to the rod-interface of the rod.

16. The method of claim 15, further comprising connecting a head along the rod.
17. The method of claim 15, further comprising positioning a portion of the blade within a slit defined along the rod-blade interface.
18. The method of claim 17, wherein the slot and the slit are oriented in perpendicular relation relative to the channel.
19. The method of claim 15, wherein the stopping mechanism includes a nut in linear sliding engagement along the rod, the nut movable by twisting the nut relative to the rod.
20. The method of claim 15, wherein the stopping mechanism includes a head connected to the rod proximate to the upper portion for receiving a force to drive the rod towards the lower portion.

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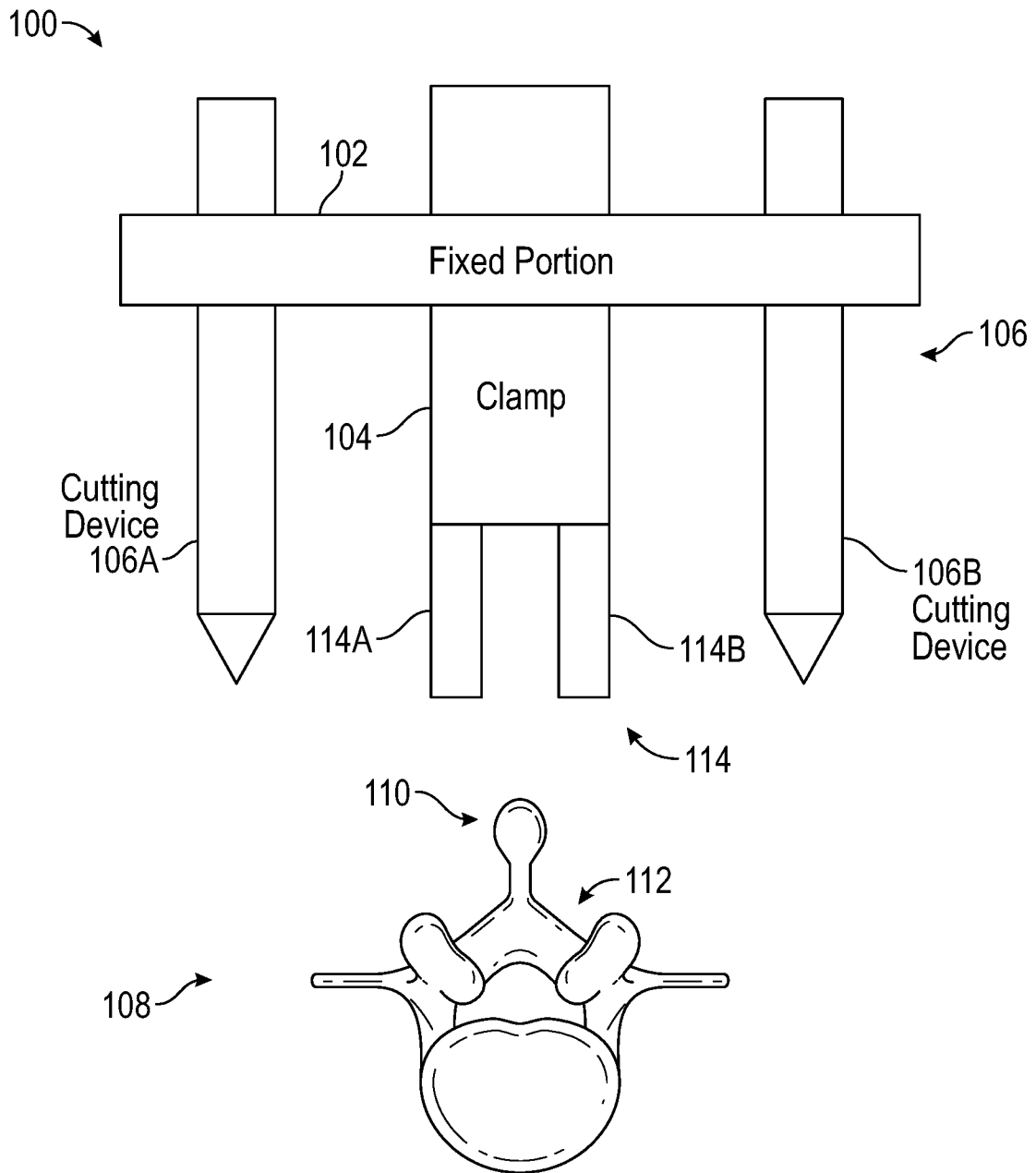


FIG. 1

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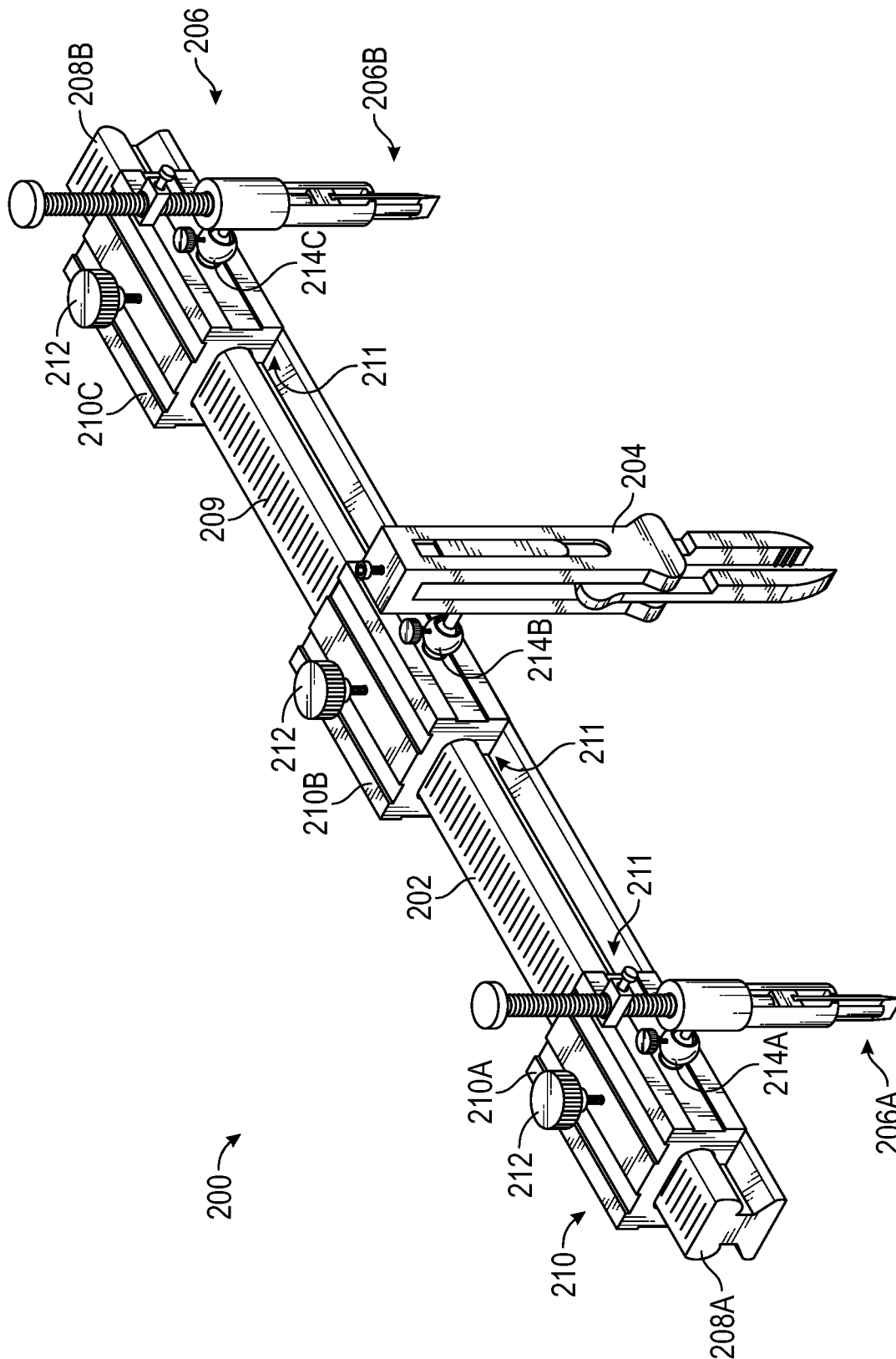


FIG. 2

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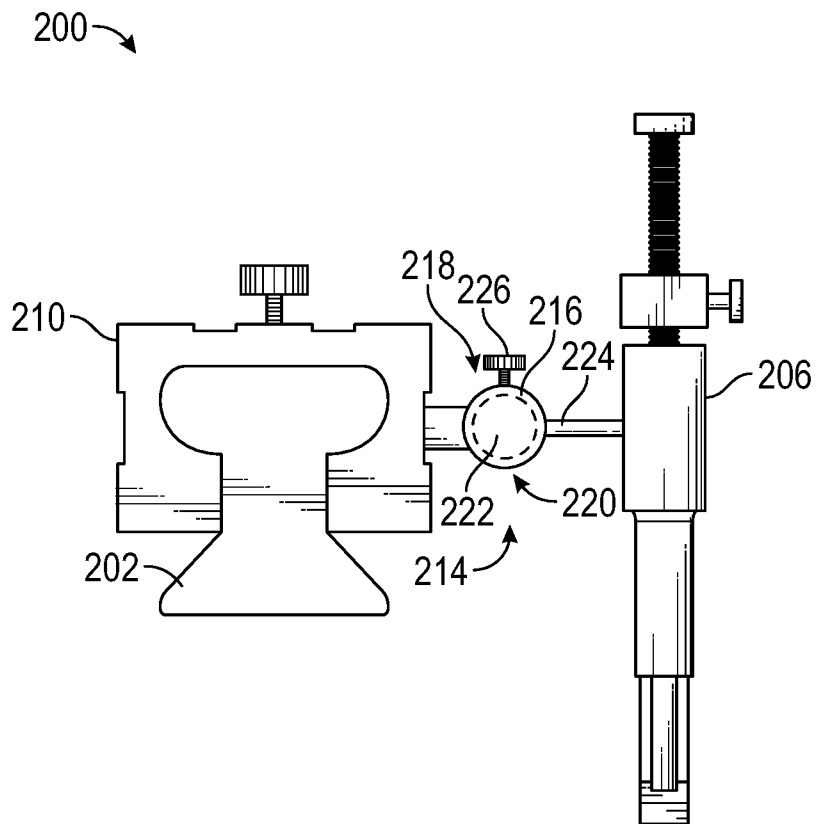


FIG. 3

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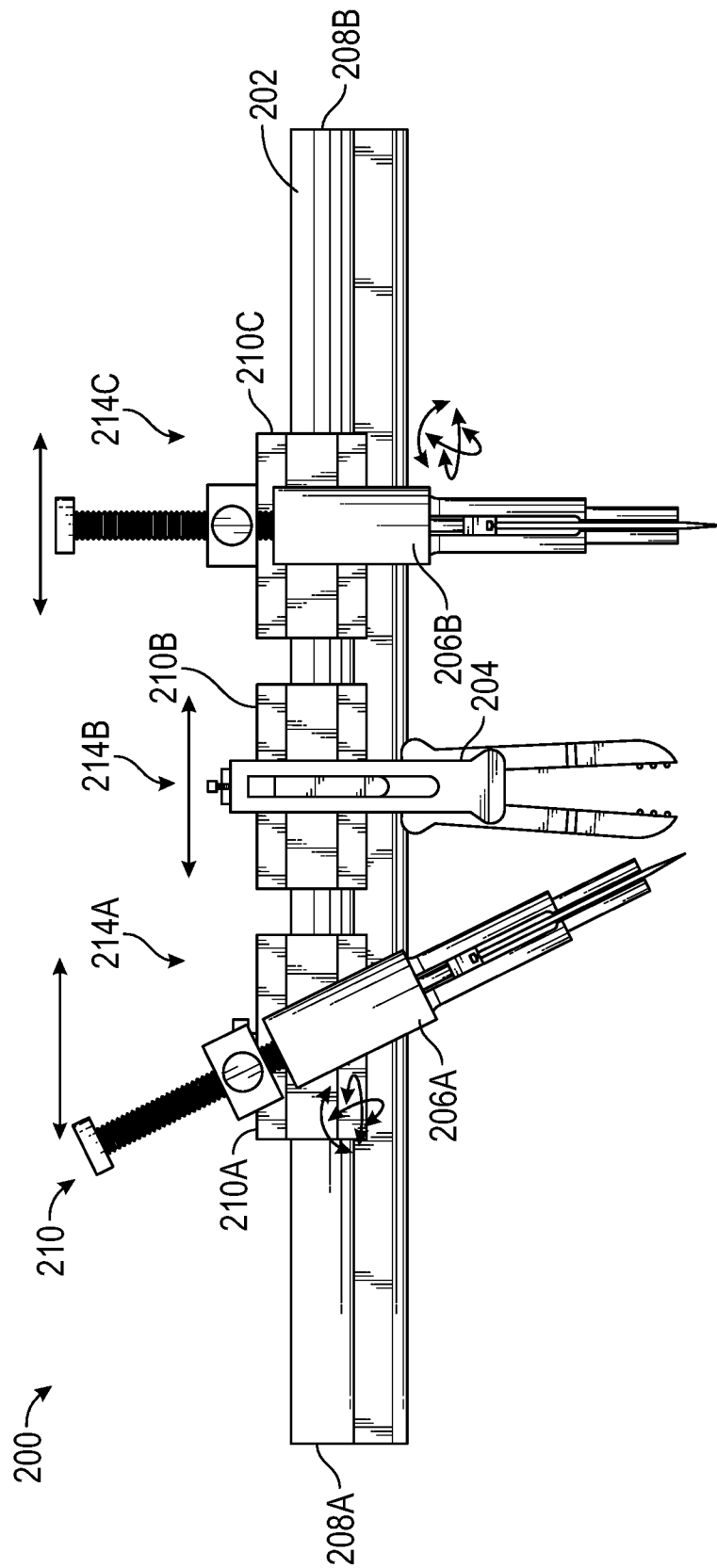
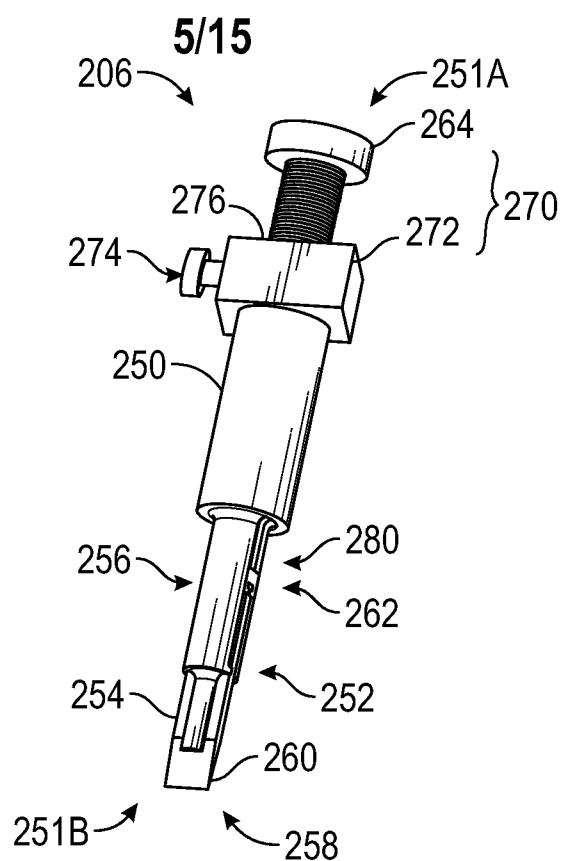
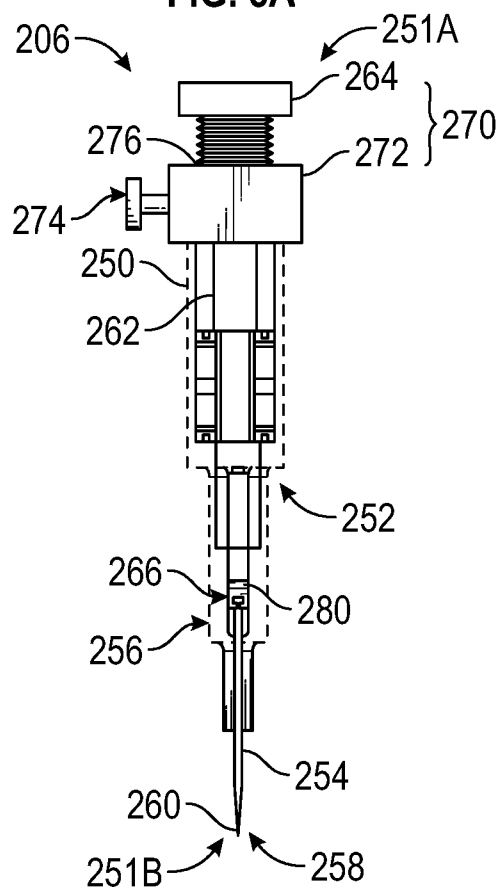


FIG. 4

**FIG. 5A****FIG. 5B**

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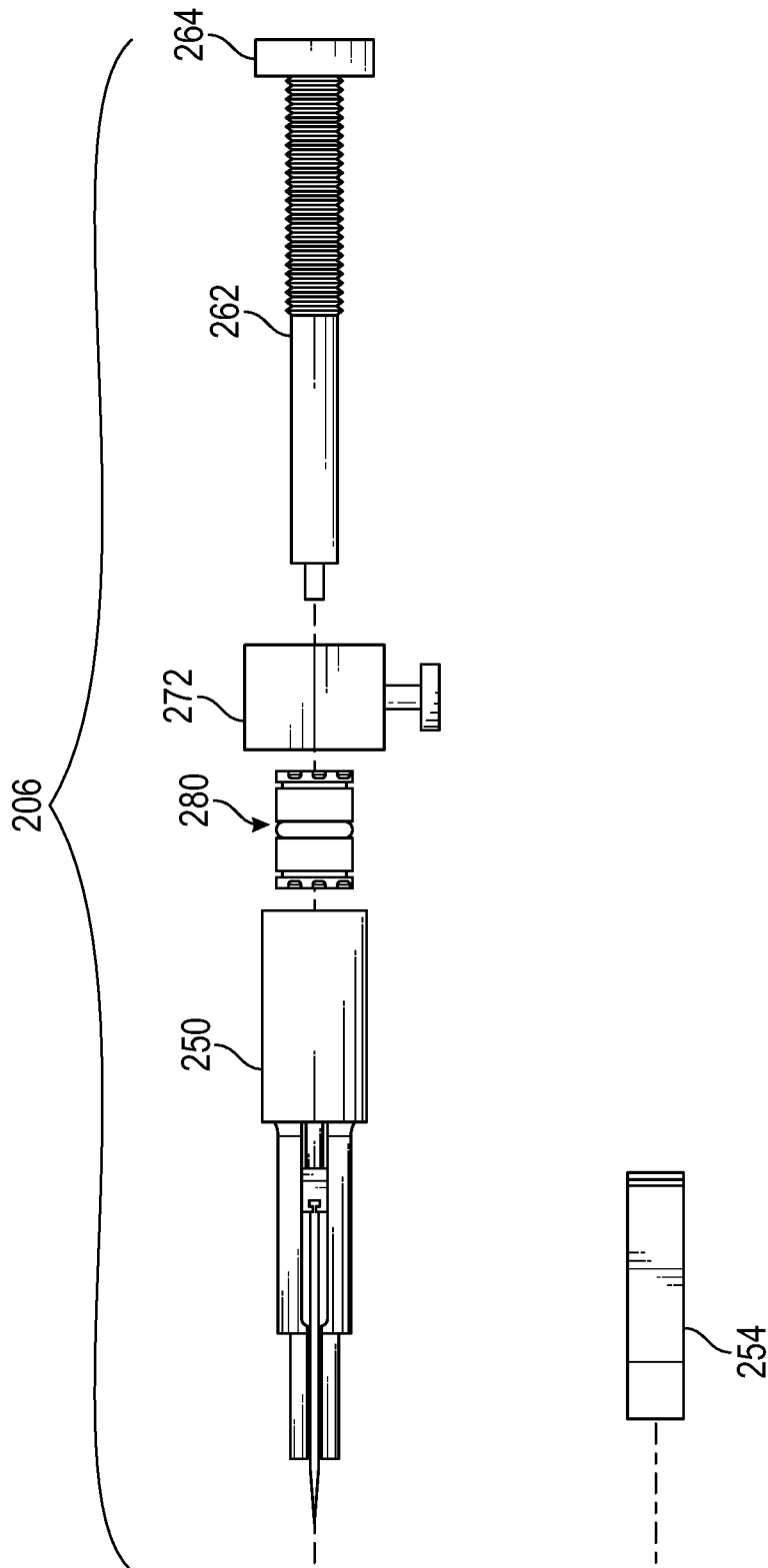


FIG. 5C

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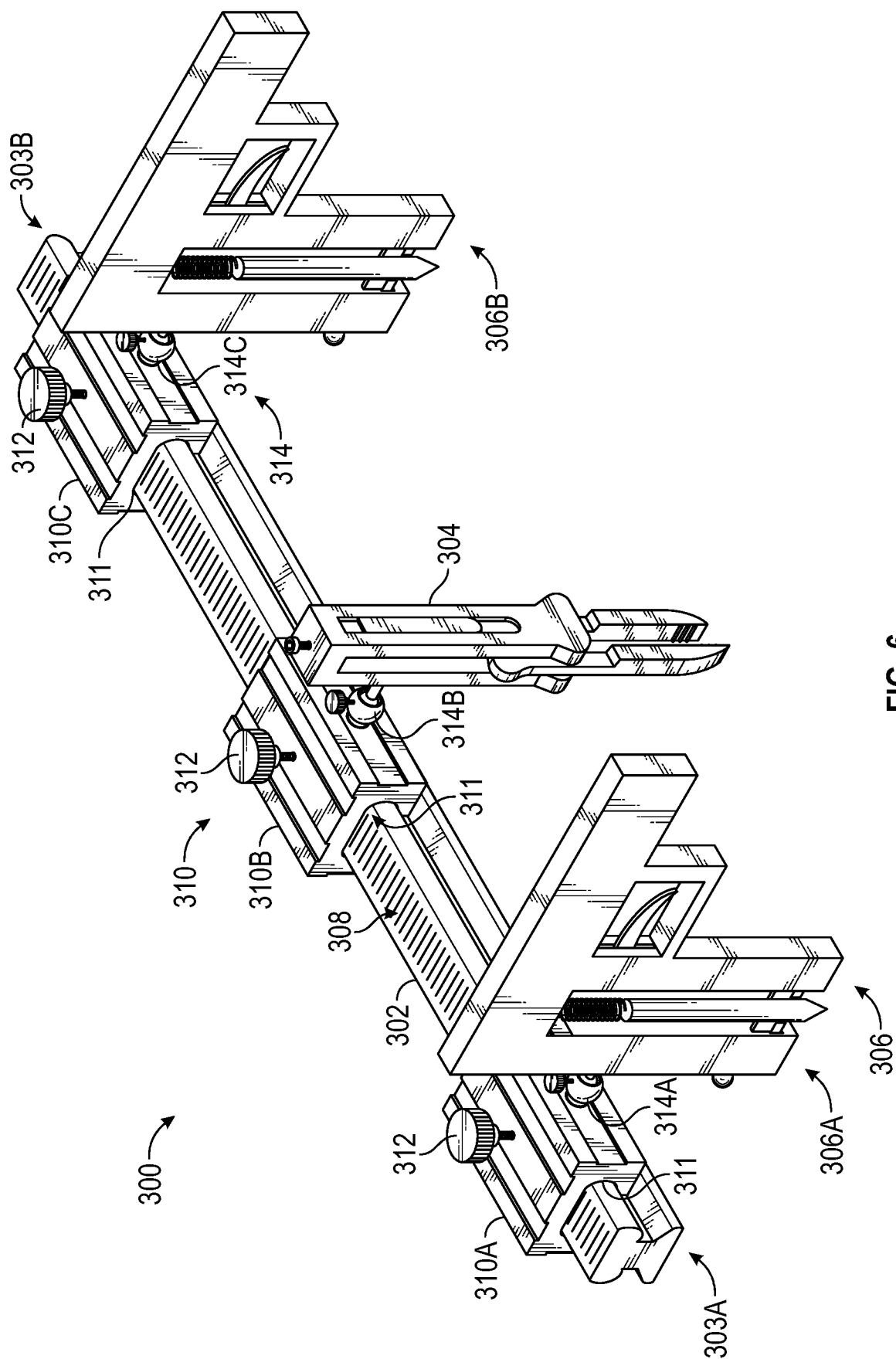


FIG. 6

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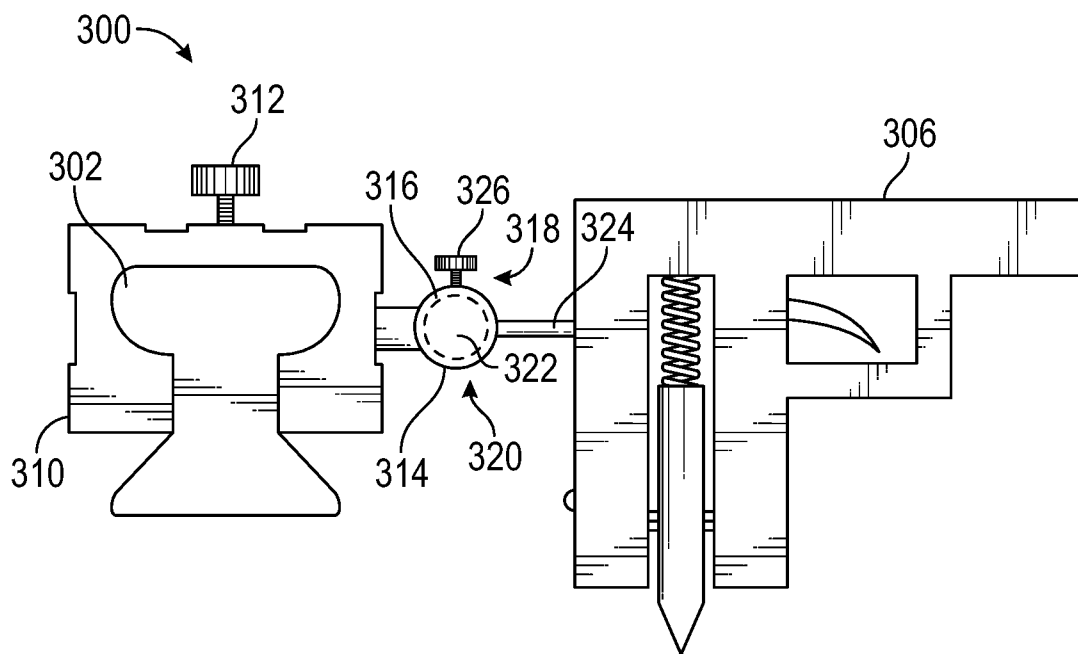


FIG. 7

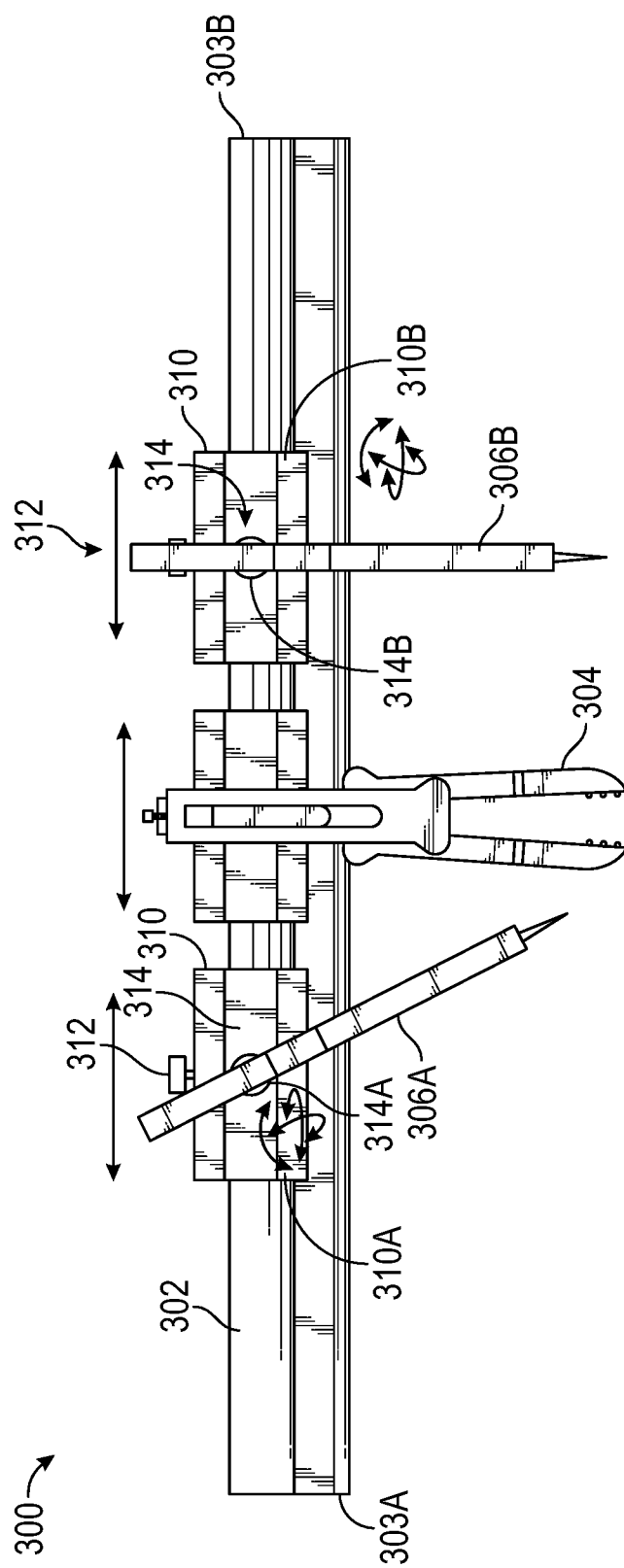


FIG. 8

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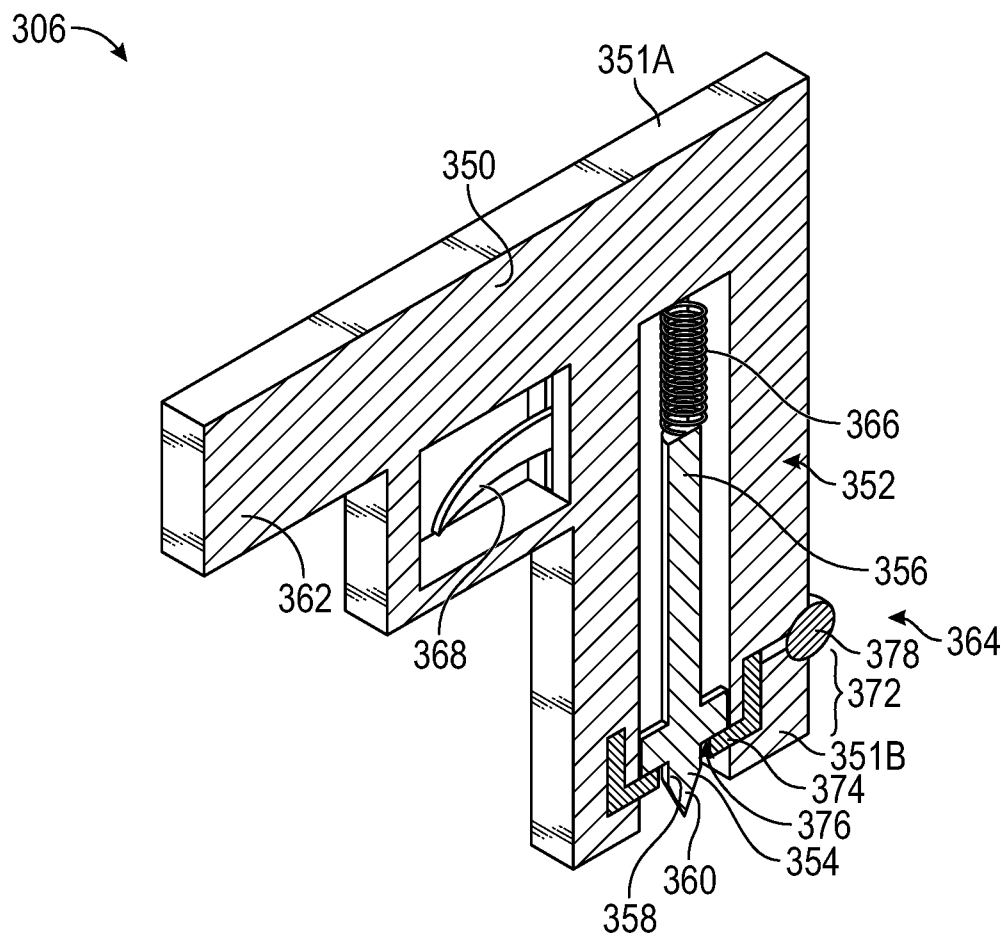


FIG. 9

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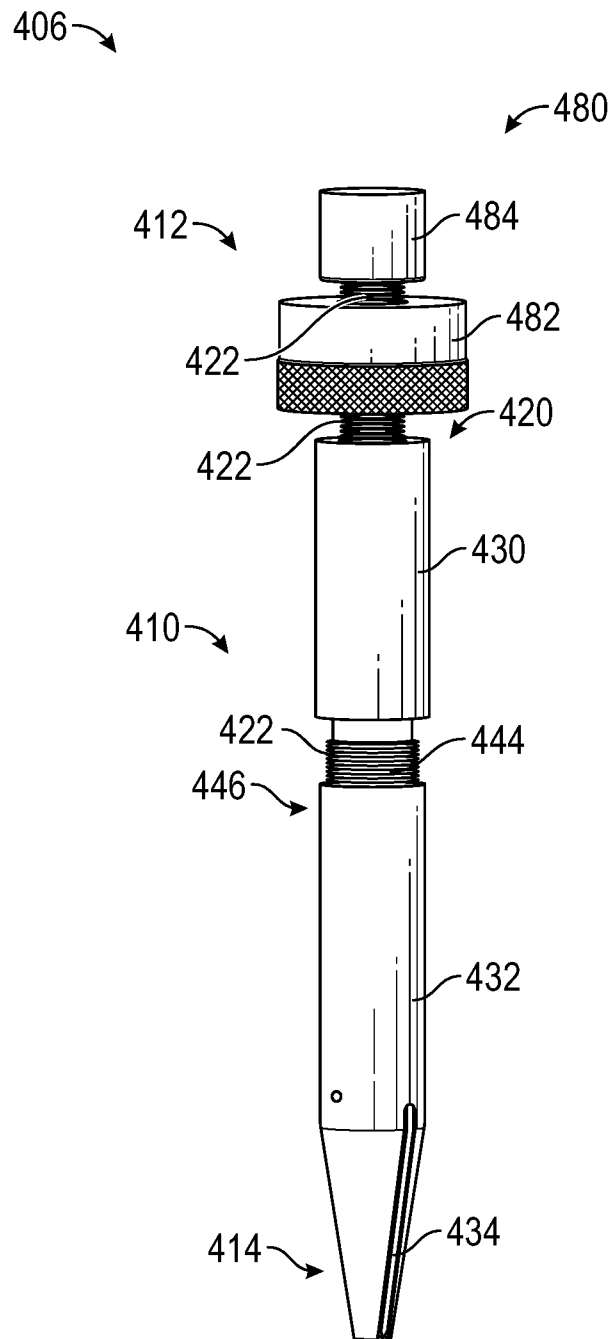


FIG. 10

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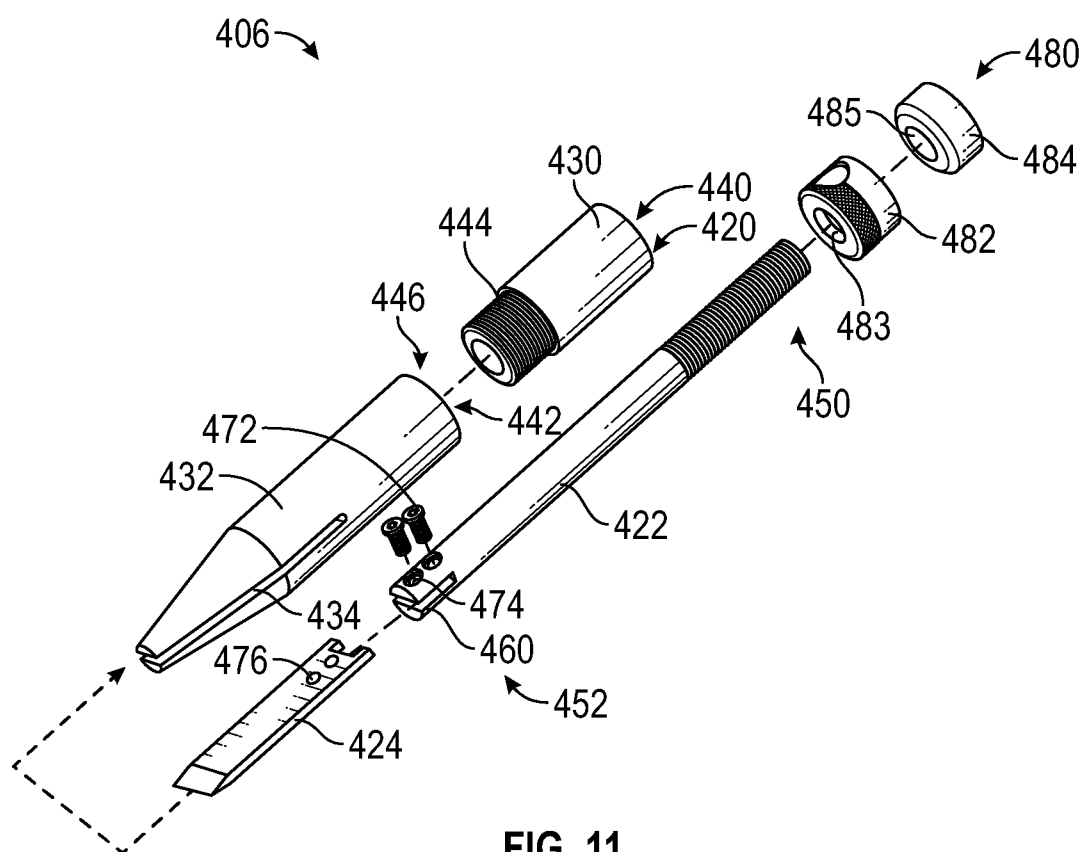


FIG. 11

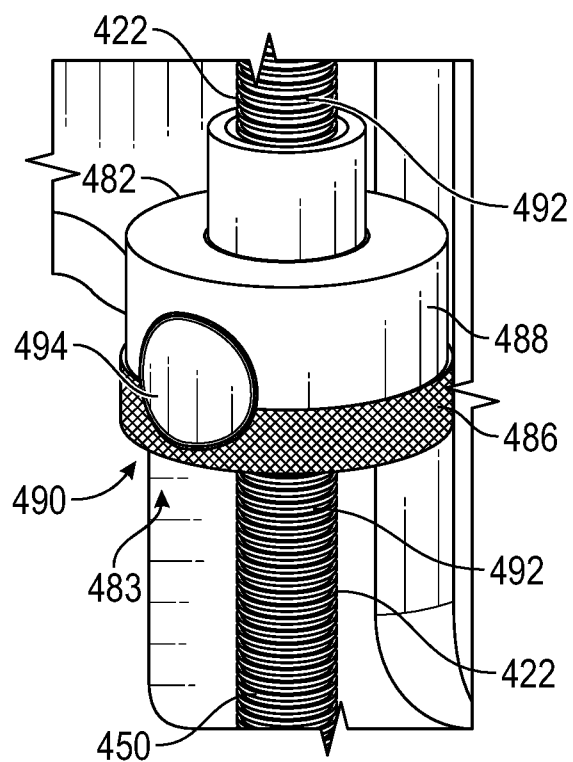


FIG. 12

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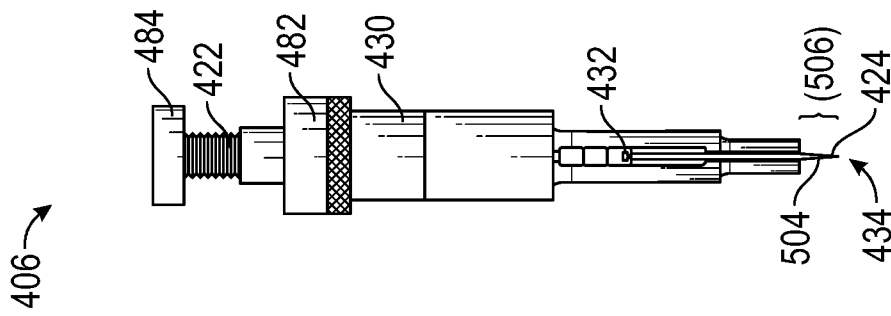


FIG. 13D

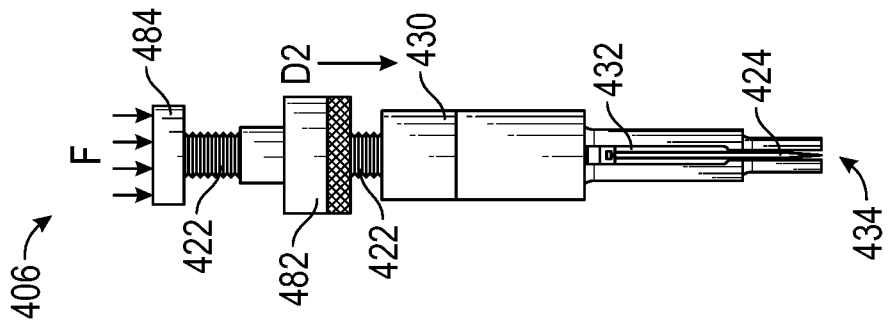


FIG. 13C

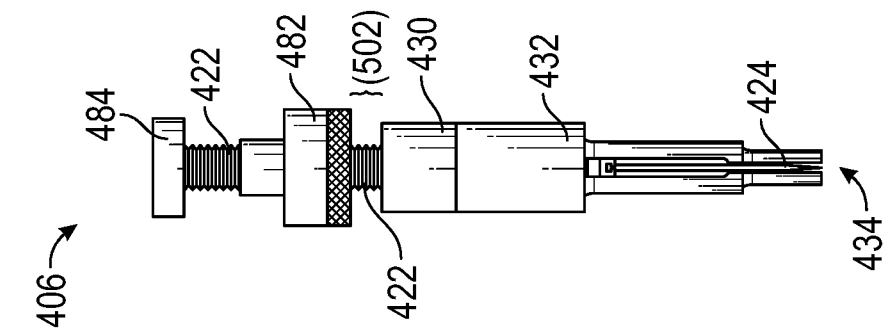


FIG. 13B

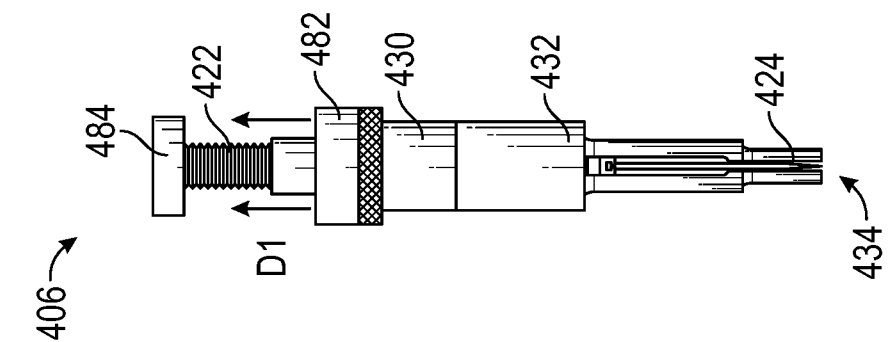


FIG. 13A

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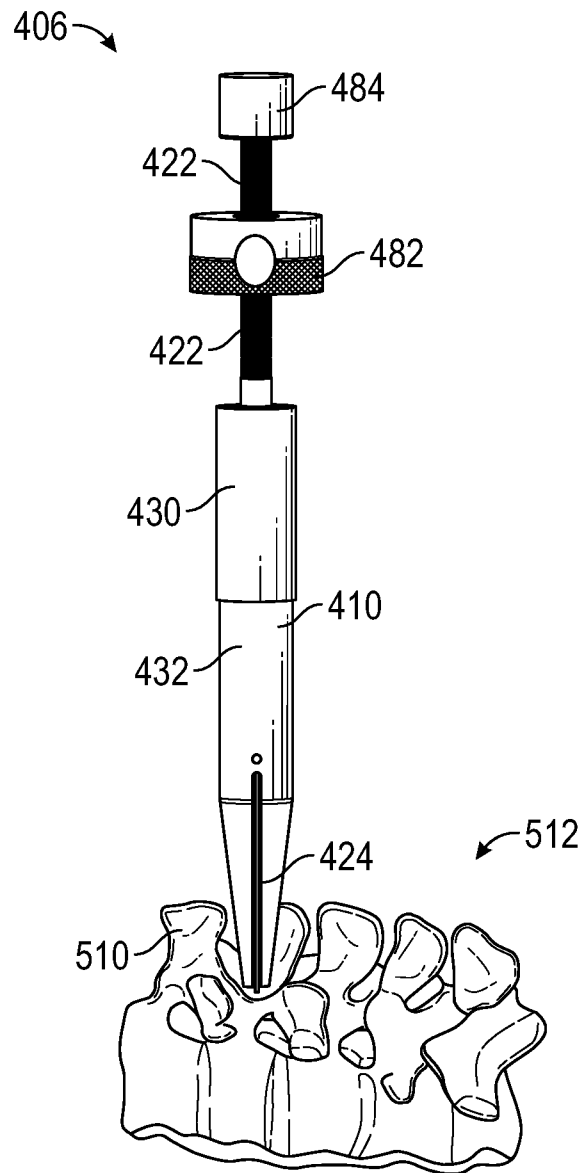
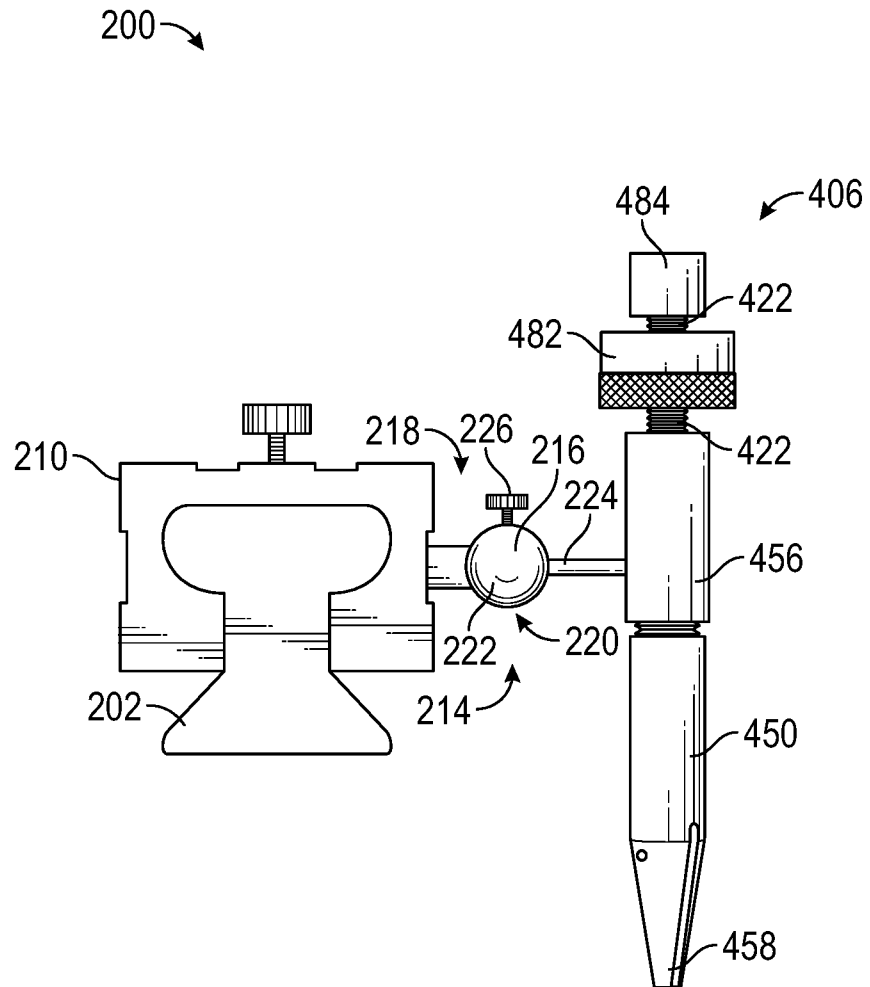


FIG. 14

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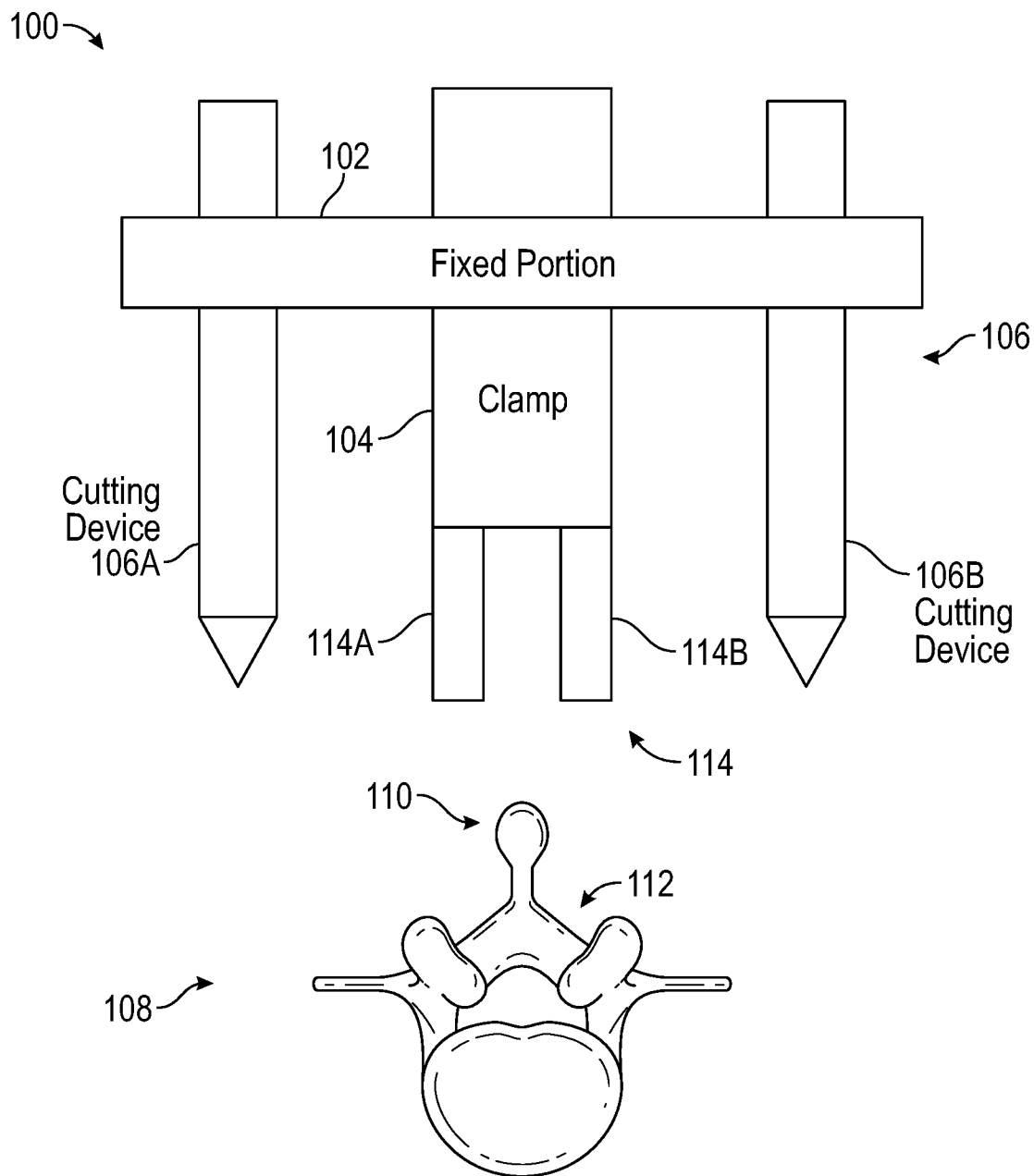


FIG. 1