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(71) Applicant: **AXOGEN CORPORATION** [US/US]; 13631 Progress Boulevard, Suite 400, Alachua, FL 32615 (US).

(72) Inventors: **DEISTER, Court**; c/o Axogen Corporation, 13631 Progress Boulevard, Suite 400, Alachua, FL 32615 (US). **ORRICO, Michael, Raymond**; 1105 Fort Clarke Blvd., Apt. 610, Gainesville, FL 32606 (US). **DRACH, Gregory**; c/o Axogen Corporation, 13631 Progress Boulevard, Suite 400, Alachua, FL 32615 (US).

(74) Agent: **DANIELS, Gwendolyn, L.** et al.; Saliwanchik, Lloyd & Eisenschenk, PO Box 142950, Gainesville, FL 32614-2950 (US).

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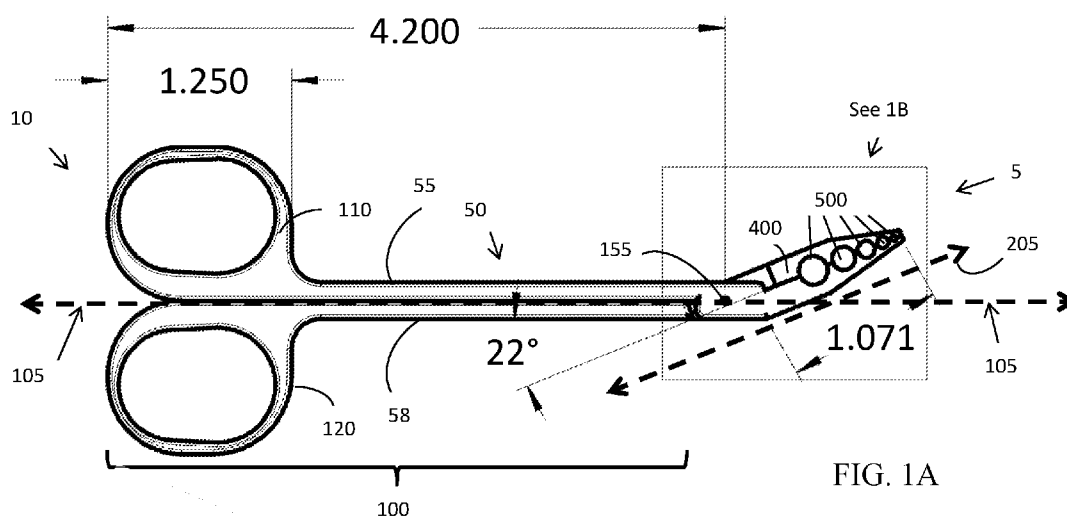


FIG. 1A

(57) Abstract: A sizing forceps is provided for fixing a nerve in place, measuring the diameter of the nerve, and providing an efficient way to resect the nerve. A sizing forceps can have an upper and lower jaw with one or more aligned notches that form apertures for holding a nerve. The apertures can have predetermined sizes that can be used to measure the diameter of a nerve. A slicing slot in the upper and lower jaw allows a nerve within an aperture to be severed to obtain a non-frayed end.

SURGICAL TOOL FOR TISSUE SIZING AND TRANSECTION

DESCRIPTION

5 This invention was made with government support under grant no. W81XWH-13-1-0448 awarded by the U.S. Department of Defense through the office of U.S. Army Medical Command. The government has certain rights in the invention.

BACKGROUND OF INVENTION

10 Nerves can be transected for a variety of reasons. Whether the nerve is transected deliberately or by accident, repair of the nerve can be facilitated if a nerve end is cut and free of frayed or damaged areas, or randomly extending axons and tissue. Clean nerve ends can be easier to coapt to other nerve ends or grafts and can promote alignment of the axons from each terminal nerve end. Also, nerve ends that are to be capped or covered can be easier to
15 manipulate and development of neuromas can be minimized if the nerve end is free of randomly extending axons.

 In order to obtain a clean cut nerve end, it may be necessary to resection the nerve tissue some distance away from the terminal end, to remove damaged or non-viable tissue at the terminal nerve end. Resection of nerve tissue can be difficult. If done incorrectly it can
20 result in a new terminal nerve end that is crushed, frayed, or that has multiple transection lines caused by the cutting implement making multiple passes or sawing across the tissue. Properly bracing the circumference of the nerve in the area of transection can minimize such damage to the one or more new terminal nerve ends. There are devices that can be used to support a nerve, while a cutting implement is used to transect the nerve. Often these devices
25 do not entirely brace the full circumference and secure the position of the nerve, thus, allowing the nerve to roll or turn during the cutting process. This can necessitate excessive force being applied by the cutting implement in order to hold the nerve while it penetrates the tougher outer epineurium. This force can crush the softer internal nerve tissues. Alternatively, a cutting implement may have to be passed through the tissue more than once
30 to incrementally sever the nerve tissue, which can result in a frayed nerve end.

 If the resected nerve end is to be coapted to, or inserted into, a graft or implant, the nerve must be measured *in vivo*, so that an appropriately-sized graft can be selected. It has been demonstrated that when obtaining sizes of nerves during surgical procedures, the

measurements are usually inaccurate. Nerve tissue is soft and pliable and does not often have a defined diametric shape. As such, it can be difficult to visually estimate the size of a nerve or obtain an accurate measurement of the diameter when the nerve is placed on a flat measuring surface.

5 Every manipulation and change of equipment or tools that must be made during surgery takes time and increases the opportunities for error. Devices and surgical tools that have multiple functions are desirable, as they can reduce the number of manipulations necessary to complete a procedure.

10 BRIEF SUMMARY

In accordance with the subject invention, the problem of measuring the diameter of a nerve and transecting the nerve to obtain a clean nerve end for coaptation or capping procedures is solved by the use of a single sizing forceps instrument.

The sizing forceps can surround a nerve in the area to be transected providing
15 peripheral bracing of the nerve. The sizing forceps can also secure the position of the nerve, to minimize sliding or rolling of the nerve during the transecting process. This allows the nerve to be cut in a single stroke or at least with minimal strokes. The sizing forceps can also have multiple apertures of different diameters in the head end. The nerve diameter can be determined by selecting the appropriately sized aperture that encloses but does not pinch,
20 constrict, or otherwise damage the nerve tissue. The correctly selected aperture can also be used to brace an area of the periphery of the nerve without crushing or damaging the nerve.

Specific embodiments of a sizing forceps have two pivoting members, each member having a handle portion and a jaw portion, where the combined jaw portions form the head end. A pivot point located between the handle portion and the jaw portions allows the
25 pivoting members to rotate, in relation to one another, around the pivot point. The jaw portion of each pivoting member can have multiple diameter semi-circular cut-outs. When the handle portions are brought together through rotation around the pivot point, the jaw portions are simultaneously brought together so the semi-circular cut-outs are aligned to form the multiple diameter apertures in the head.

30 Advantageously, the jaw portions align across and make contact with surfaces between the semi-circular cut-outs on each jaw portion. This inhibits the jaw portions from coming any closer together and maintains the diameters of the multiple apertures. Thus, regardless of the amount of force applied to the handle portions, the jaw portions will

maintain alignment and the prescribed aperture diameters. Chamfering of select edges can also inhibit pinching of the nerve tissue.

Once the correct aperture size has been determined and a nerve is braced and secured therein, the nerve can be cut. The blade used should be surgically sharp, straight, and free of defects on the cutting edge. The nerve can be cut by several techniques using the sizing forceps. The nerve extending out from either side of an aperture can be transected by placing the blade along an outside edge of the head end and slicing transversely across the aperture. There can also be a slicing slot within the head end. A slicing slot can longitudinally bisect the jaw portions, thereby bisecting each aperture. A blade passed through the slicing slot will cut across a nerve in one of the apertures.

The head portion can be angled or slanted on the handle portion to provide easier access to a nerve, particularly a nerve *in vivo*, where other tissues can obstruct access. The edges of the head portion can also be rounded, curved, flattened, or otherwise smoothed to inhibit abrasion of tissues that the head contacts.

Advantageously, the embodiments of the subject invention do not require excessive force to be applied against the jaw portions. As long as the jaw portions can be closed and their faces aligned against each other, nerve tissue within an aperture can be measured and cut. This can enable the sizing forceps to be manufactured from any of a variety of materials, including materials amenable to being disposable or recyclable.

BRIEF DESCRIPTION OF DRAWINGS

In order that a more precise understanding of the above recited invention can be obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. The drawings presented herein may not be drawn to scale and any reference to dimensions in the drawings or the following description is specific to the embodiments disclosed. Any variations of these dimensions that will allow the subject invention to function for its intended purpose are considered to be within the scope of the subject invention.

Figure 1A is a side elevation view of a sizing forceps, according to an embodiment of the subject invention. Dimensions shown are in millimeters.

Figure 1B is a side elevation view of the enlarged head portion of a sizing forceps, according to an embodiment of the subject invention. Dimensions shown are in millimeters.

Figure 1C is a top plan view of the sizing forceps embodiment, shown in Figure 1A.

Figure 1D is top plan view of the enlarged head portion of the sizing forceps, shown in Figure 1C. Dimensions shown are in millimeters.

Figure 1E is side elevation view of an alternative embodiment of a sizing forceps, according to the subject invention. This embodiment has a biasing element to urge the handles apart, which holds the upper jaw and lower jaw together. Dimensions shown are in millimeters.

Figure 1F is a side plan view of an alternative embodiment of a head portion. This embodiment illustrates one alternative shape for the apertures. Also illustrated are indented edges on interstitial faces.

Figures 1G and 1H are cross-sectional views taken along line 1G in Figure 1F to illustrate an embodiment of indented edges on interstitial faces and insert ports on slicing slots.

Figure 2A is side elevation view of the first outer side of a first member, according to one embodiment of the subject invention.

Figure 2B is a side elevation view of the first inner side of a first member, according to one embodiment of the subject invention.

Figure 2C is a side plan view of an enlarged head portion of a first member, according to one embodiment of the subject invention. Dimensions shown are in millimeters.

Figure 2D is a cross-sectional view taken along line 2D in Figure 2B.

Figure 2E is a cross-sectional view taken along line 2E in Figure 2B.

Figure 2F is a bottom plan view of a first member, according to one embodiment of the subject invention.

Figure 2G is a top plan view of a first member, according to one embodiment of the subject invention.

Figure 2H is a top plan view of an enlarged head portion of a first member, according to one embodiment of the subject invention. Dimensions shown are in millimeters.

Figures 2I and 2J are enlarged side elevation views of alternative embodiments of a lower jaw of a first member, according to the subject invention. These alternative embodiments have non-circular notches.

Figure 3A is a side elevation view of the second outer side of a second member, according to one embodiment of the subject invention.

Figure 3B is a side elevation view of the second inner side of a second member, according to one embodiment of the subject invention. Dimensions shown are in millimeters.

Figure 3C is an enlarged side elevation view of an alternative embodiment of an upper jaw of a second member, according to the subject invention. This alternative embodiment does not utilize pairing notches.

Figures 4A, 4B, and 4C are photographs of embodiments of a sizing forceps, according to one embodiment of the subject invention. In Figure 4A, the head portion is angled at about 45° relative to the handle portion. In Figure 4B, the head portion is angled at about 22.5° relative to the handle portion. The head portion is aligned with the handle portion in Figure 4C.

Figure 5 illustrates a sizing forceps and a cutting implement that can be used therewith.

DETAILED DISCLOSURE

The subject invention provides a surgical tool for sizing and assisting with transection or cutting of tissue. In specific embodiments, the subject invention provides sizing forceps, or similar devices, for use in measuring the diameter of a nerve and bracing and holding an area of the nerve in place for transection.

The subject invention is particularly useful in the field of surgical nerve repair, including nerve grafting or nerve coaptation procedures, where the non-viable or damaged tissue of a nerve needs to be removed prior to a procedure.

In the description that follows, a number of terms used with regard to surgical repair of tissues are utilized. In order to provide a clear and consistent understanding of the specification and claims, including the scope to be given such terms, the following definitions are provided.

The terms “nerve” and “nerve tissue” as used herein are merely for literary convenience. The embodiments of the subject invention are not limited to use with only nerve tissue and can be utilized with other tissues, such as, for example, blood vessels and tendons.

Further, reference is made throughout the application to the “proximal end” and “distal end.” As used herein, the proximal end is that end placed nearest to the nerve tissue or the patient during use. For example, the head portion is at the proximal end of the sizing

forceps. Conversely, the distal end of the device is that end closest to the surgeon during use. For example, the handle portion is at the distal end of the sizing forceps.

As used in the specification and in the claims, the singular for “a,” “an” and “the” include plural referents unless the context clearly dictates otherwise.

5 Reference will be made to the attached figures on which the same reference numerals are used throughout to indicate the same or similar components. With reference to the attached figures, which show certain embodiments of the subject invention, it can be seen in Figures 1A and 1B that a sizing forceps **50** of the subject invention comprises first member **55** and a second member **58**, each having a handle portion **100** with a proximal end **5** and a
10 distal end **10**. At the proximal end of the handle portion of each member there are attached a lower jaw **300** and an upper jaw **400** that are cooperatively engaged to come together and form a head portion **200** with one or more apertures **500** for receiving a nerve without pinching, constricting, or otherwise damaging the nerve tissue. Each of these general components can have one or more sub-components, which will be discussed in detail below.

15 The first member **55** and the second member **58** can be joined so that they can be simultaneously manipulated to control the opening and closing of the handle portion **100** and the head portion **200**. In one embodiment, the first member has a first handle **110** and a lower jaw **300** and the second member **58** has a second handle **120** and an upper jaw **400**. In an alternative embodiment, the first member has a first handle **110** and an upper jaw **400** and the
20 second member **120** has a second handle and a lower jaw **300**. As will be discussed below, a biasing member can be utilized to hold the handles together or apart, which can determine whether the jaws are maintained in an opened or closed position. A person with skill in the art would be able to determine the appropriate arrangement of the handles and the jaws and whether a biasing element is required. Such variations are within the scope of this invention.

25 The first member has a first outer side **56** from the handle portion to the head portion. The first member also has a first inner side **57** that extends from the handle portion to the head portion, but includes a joint area **150** between the handle portion and the head portion, at which the first member rotates against the second member. Likewise, the second member **58** has second outer side **59** from the handle portion to the head portion. The second member
30 also has a second inner side **60** that extends from the handle portion to the head portion, but includes a joint area **150** between the handle portion and the head portion, at which the second member rotates against the first member.

When the first member **55** and the second member **58** are rotatably connected, as discussed below, the first handle **110** and the second handle **120** constitute the handle portion **100** that can be manipulated to bring the lower jaw **300** and the upper jaw **400** together. In one embodiment, the handle portion has a scissors-like configuration, as shown for example, in Figures 1A and 5. This embodiment has a first handle **110**, to which the lower jaw **300** can be attached, and a second handle **120**, to which the upper jaw **400** can be attached, the members being configured as left and right symmetrical with each other and pivotally attached by a joint member **155** at their proximal ends **5**. Joint members are known in the art and allow rotation about a common axis **159**, as shown, for example, in Figure 1C. When the first handle and second handle are squeezed together, along a longitudinal line **105**, which is illustrated in Figures 2A and 3A, the motion can bring the lower jaw and upper jaw, at the proximal ends of the respective members, into contact. Figures 1A and 5 show non-limiting examples of an embodiment where the handle members come together at the longitudinal line **105**.

In another embodiment, the first handle **110** and the second handle **120** are pivotally connected with a joint member **155** at their proximal ends **5** and are urged apart by a compression spring or other biasing member **140**. It can be beneficial for the handle members of the handle portion **100** to be curved, as shown, for example, in Figure 1E, to facilitate rotation of the handle portions and the jaws. The upper jaw and lower jaw can be connected to the first handle and second handle, respectively, such that when the handle members are squeezed towards each other, or towards the longitudinal line **105** of the handle portion, the jaws are separated. When the members are not squeezed, the biasing member forces the handle members apart, which brings the jaws together, as shown for example in Figure 1E. Other handle types could also be utilized. Thus, any configuration of the handle portion **100** that provides control over the opening and closing of the upper jaw and lower jaw is within the scope of this invention.

When the first member **55** and the second member **58** are rotatably connected, the lower jaw **300** and the upper jaw **400** constitute a head portion **200**. In general, the head portion **200** can operate in tandem with the handle members, as discussed above, so that the jaws can come together along all or at least some portion of the lengthwise extent **205** of the head portion. Preferably, the jaws do not cross or pass each other, but are aligned along the lengthwise extent. Figures 1A, 1E, and 4A illustrate examples of the lengthwise extent **205** of a head portion. The alignment of the head portion **200** relative to the handle portion **100**

can be variable, to accommodate use of the sizing forceps **50** in different situations. In one embodiment, the head portion can be aligned with the handle portion, such that the longitudinal line **105** of the handle portion is coplanar, collinear, or otherwise in-line with the lengthwise extent **205** of the head portion. Figures 2B, 3B, 4C, and 5 illustrate non-limiting examples of this embodiment.

In another embodiment, the head portion **200** is angled relative to the handle portion **100**, such that the lengthwise extent **205** of the head portion is angled or bent relative to the longitudinal line **105** of the handle portion. Figures 1A, 2B, 3B, and 4A illustrate non-limiting examples of this embodiment. In one embodiment, the head portion is angled, relative to the handle portion, between approximately 10° and approximately 60°. In a particular embodiment, the head portion is angled, relative to the handle portion, between approximately 20° and approximately 50°. In one specific embodiment, the head portion is angled, relative to the handle portion, at approximately 22°, one example of which is shown in Figure 1A and 4B. In another specific embodiment, the head portion is angled, relative to the handle portion, at approximately 45°, which is shown, by way of example in Figure 4A. The ability to determine alternative angles for the head portion is within the capability of one of ordinary skill in the art and such variations are within the scope of this invention.

When placing the head portion around a nerve, the jaws are separated by the handle members and the lower jaw can be positioned approximately perpendicular to the length of the nerve and slid around the nerve so that the nerve is between the upper jaw and the lower jaw. The shape of the upper and/or the lower jaw can facilitate the procedure of sliding the jaw around the nerve. In one embodiment, the edges and surfaces of the upper and lower jaws are beveled or smoothed to reduce sharp or rough edges and encourage sliding of the nerve over those surfaces. In a further embodiment, the upper jaw and lower jaw are tapered towards the proximal end **5**, so that the proximal end of the head portion **200** is narrower or has a smaller diameter than the distal end of the head portion. By way of example, Figure 4C shows a first diameter, D_1 , at the distal end **10** of the head portion and a second diameter, D_2 , at the terminal proximal end **5** of the head portion. It can be seen that, in this example, D_1 is larger than D_2 , indicating a smaller diameter at the proximal end. Alternatively, the diameter of D_1 and D_2 are the same or approximately the same.

The boundary that separates the head portion **200** and handle portion **100** can be the joint area **150**. In one embodiment, the joint area comprises two surfaces **157**, which are located on the first inner side **57** of the first member **55** and the second inner side **60** of the

second member **58**. The joint area can also include a joint member **155**, which can be on either or both surfaces, that rotatably connects the handle members **110** and **120**, where the handle portions come together at the common axis **159** to rotate against each other. Figure 1D shows a non-limiting example of a joint area. In one embodiment, the surfaces **157** are
5 recessed or narrower than the handle and the jaws, as shown, for example, in Figure 2F and 2G. The narrowness allows the handle members and upper and lower jaws to overlap, when the handle members are connected by the joint member **155** at the common axis **159**. The recessed surface can extend out from the joint member a sufficient distance to allow the handle members and jaws to rotate without being impinged upon by material or surfaces
10 around the recessed surface. The use of a joint area and a joint member to form a pivotal connection is known in the art. A person having skill in the art will be able to determine the appropriate dimensions for recessed surface that will allow proper rotation around the joint member. Such variations in the configuration of a joint area are within the scope of the subject invention.

15 As mentioned previously, the head portion **200** includes the lower jaw **300** and the upper jaw **400**, which pivot by the rotation of their respective handle members on a joint member **155**. While the invention is described herein with reference to the upper jaw and the lower jaw, it should be understood that these terms are not intended to confer any order or specific placement in structural orientation. The upper jaw could just as readily be used in a
20 position below or to the side of the lower jaw described herein, and *vice versa*. Thus, reference to upper jaw and lower jaw are for descriptive purposes and are not intended to limit the invention or its use in any way.

In one embodiment, the lower jaw **300** has a first face **310** and at least one notch **360** within the first face. In one embodiment, the first face is a substantially flat surface, whereby
25 an imaginary plane across the flat surface will be parallel to the lengthwise extent **205**, as shown, for example, in Figures 2A and 2B. This can urge the lower jaw and the upper jaw to align with each other, as shown in the example in Figures 1B and 5. The flat alignment of the upper and lower jaw can also inhibit one or the other jaw from sliding past the other if excessive force is applied to the handle members.

30 In a further embodiment, the first face is interrupted by at least one notch **360** that is cut, molded, or otherwise formed transverse to the lengthwise extent **205** of the lower jaw, such that the notch further opens onto the side edges **320** of the jaw, which is shown, for example, in Figures 2C and 2H. In other words, the at least one notch can be perpendicular

to the lengthwise extent. The at least one notch within the lower jaw opens onto the first face, which breaks or divides the first face into smaller interstitial faces **312**. In a further embodiment, there are two or more notches **360** within the lower jaw. In a specific embodiment, there are five notches within the lower jaw that interrupt the first face, wherein
5 the notches open onto the first face, forming multiple interstitial faces **312**, as shown, for example, in Figure 2C.

The at least one notch in the lower jaw can have any circumferential shape. Multiple notches in a lower jaw could also have different circumferential shapes. It can be preferable, though not required, for the shape to be curved, which can be more conforming to the shape
10 of a nerve and beneficial for cutting. In one embodiment, the notches are substantially semi-circular, as shown by way of example in Figures 2A and 2C. In another embodiment, the notches are semi-oval, or U-shaped, wherein the long axis can be either parallel or perpendicular to the lengthwise extent **205**, as shown in the example in Figures 1F and 2I. In yet another embodiment, the notches are semi-ovate, such as shown, for example, in Figure
15 2J. Other curved shapes could also be used, including but not limited to, semi-ovate, multi-curved or waved, hyperbolic, or other curved or semi-curved forms.

In another embodiment, the circumferential shape of a notch has at least one straight side. By way of example, a notch could have an arch-type circumference, where the sides are parallel and straight and the bottom or closed end **362** is rounded. A notch could also be
20 square or rectangular, where there are no curved edges. Furthermore, the notches can have the same or different circumferential shapes.

In another embodiment, the lower jaw has two or more notches, each of different size diameters. In a specific embodiment, shown, by way of example, in Figures 2A and 2H, the lower jaw has five notches **360**, which open onto the first face **310** and side edges **320**. In a
25 further specific embodiment, the notches have a semi-circular circumferential shape and are graduated in size from the largest at the distal end **10** of the lower jaw to the smallest size at the proximal end **5** of the lower jaw. In one embodiment, the diameters of the notches range from between approximately 0.03 inch to approximately 0.2 inch. In one specific embodiment, the diameters of the semi-circular notches are approximately 0.197", 0.157",
30 0.118", 0.078" and 0.039", an example of which is shown in Figure 1B. Alternatively, a specific embodiment has notches ranging in size from approximately 1mm, approximately 2mm, approximately 3mm, approximately 4mm, and approximately 5mm.

In a further embodiment, a notch **360** has a beveled, chamfered, filleted, sloping, or smoothed edge where it opens onto the side edge **320**. This can inhibit fraying, cutting or other injury to a tissue positioned across the notch.

When the first handle **110** of the handle portion **100** is joined to the second handle **120** of the handle portion at the joint area **150**, the upper jaw **400** can aligned with the lower jaw. Figures 1A, 4A-4C, and 5 illustrate the alignment of the upper jaw with the lower jaw. In one embodiment, the upper jaw **400** has a second face **410** and at least one pairing notch **460** within the second face. In one embodiment, the first face is a substantially flat surface, whereby an imaginary plane across the flat surface will be parallel to the lengthwise extent **205**, as shown, for example, in Figures 3A and 3B. As mentioned above, this can urge the upper jaw and the low jaw to align with each other. This can also direct force applied to the handle member to the first face **310** and the second face **410**, whereby the flat surfaces and the alignment of the upper and lower jaw can inhibit one or the other jaw from sliding past the other if excessive force is applied to the handle members.

In a further embodiment, the second face **410**, similarly to the first face **310**, is interrupted by at least one pairing notch **460** that is cut, molded or otherwise formed to be transverse to the lengthwise extent **205** of the lower jaw, such that the pairing notch further opens onto the side edges **420** of the jaw, which is shown, for example, in Figures 3A and 3B. In other words, the at least one pairing notch can be perpendicular to the lengthwise extent. The at least one pairing notch within the upper jaw opens onto the second face, which breaks or divides the second face into smaller second interstitial faces **412**. In a further embodiment, there are two or more pairing notches **460** within the lower jaw. In a specific embodiment, there are five notches within the upper jaw that interrupt the second face, wherein the notches open onto the second face, forming multiple second interstitial faces **412**, as shown, for example, in Figure 3A. In one embodiment, when the lower jaw **300** is aligned with the upper jaw **400**, as discussed above, the interstitial faces **312** of the first face can align with the interstitial faces **412** of the second face **410**. In a further embodiment, the notches **360** in the lower jaw will align with or “pair-up” with the pairing notches **460** in the upper jaw, to form apertures **500** within the head portion. The nerve tissue within an aperture can be supported while held in place for transecting. Furthermore, selecting the correct aperture size can also help determine the diameter of the nerve tissue.

As with the lower jaw, the at least one pairing notch in the upper jaw can have any circumferential shape. Ideally, the circumferential shape of a pairing notch can complement,

cooperate with, or otherwise be operable with a notch **360** it pairs with in the lower jaw. Multiple pairing notches in the upper jaw could also have different circumferential shape. It can be preferable, though not required, for the circumferential shape to be curved, which can be more conforming to the shape of a nerve and beneficial for cutting. The circumferential shapes that can be utilized for a notch **360** in a lower jaw **300** have been discussed above and are reasserted here with regard to the circumferential shapes of a pairing notch **460** in an upper jaw.

In another embodiment, the upper jaw has two or more notches, each of different size diameters. In a specific embodiment, shown, by way of example, in Figures 3A and 3B, the upper jaw **400** has five pairing notches **460**, which open onto the first face **410** and side edges **420**. In a further specific embodiment, the pairing notches have a semi-circular circumferential shape and are graduated in size from the largest at distal end **10** of the upper jaw to the smallest size at the proximal end **5** of the upper jaw. In still further specific embodiment, the pairing notches **460** align with the notches **360** to form circular apertures, as shown, for example, in Figure 1B and 1E. In one embodiment, the diameters of the pairing notches range from between approximately 0.03 inch to approximately 0.2 inch. In one specific embodiment, the diameters of the semi-circular notches are approximately 0.197", 0.157", 0.118", 0.078" and 0.039." Alternatively, a specific embodiment has notches ranging in size from approximately 1mm, approximately 2mm, approximately 3mm, approximately 4mm, and approximately 5mm.

In a further embodiment, a pairing notch **460** has a beveled, chamfered, filleted, sloping or smoothed edge where it opens onto the side edge **320**. This can inhibit fraying, cutting or other injury to a tissue positioned across the pairing notch or within an aperture.

In another embodiment, the upper jaw **400** can have a second face **410**, but not have pairing notches. This provides for a smooth, continuous second face that can be aligned with the interstitial faces **312** of the first face **310**. Figure 3C illustrates one non-limiting example of an upper jaw without pairing notches. With this embodiment, the side edges **420** of the second face of the upper jaw can be aligned with the side edges **320** of the lower jaw. As with the pairing notches, the side edges at or near the second face can be beveled, chamfered, filleted, sloped, or smoothed to inhibit injury to a tissue that it contacts. The second face **410** can be positioned over the notches **360** within the lower jaw without concern for precise alignment with the notches. This embodiment can be advantageous for sizing forceps intended for repeated use and sterilization. Over time, any surgical tool can experience wear

from use and repeated sterilization. With this embodiment, the sizing forceps can have a longer usable life, as long as the upper jaw **400** and the lower jaw **300** can be sufficiently aligned.

The lower jaw **300** and the upper jaw **400** together form the head portion **200** of a sizing forceps **50**. When the jaws are brought together, the interstitial faces **312** and the second interstitial faces **412** come together and there is formed at least one aperture **500** within the head portion. Preferably, there is more than one aperture in a head portion, where the apertures have different diameters. Figures 4A, 4B, and 4C illustrate one embodiment of a sizing forceps having five apertures of graduated sizes. Different diameters of nerve tissue can be secured and held in place by using the correct size aperture.

When the interstitial faces **312** and the second interstitial faces **412** come together, they can form a seal between the apertures **500** in the head portion **200**. To inhibit tissue within the apertures from becoming pinched between the interstitial faces, the edges of the interstitial faces within the apertures can be indented, such that they have a chamfered, beveled, filleted, sloped, or otherwise recede from the aperture. The indented edges **510** can inhibit tissue within the aperture from being pinched when the interstitial faces come together. Figure 1F illustrates a non-limiting embodiment of interstitial faces with indented edges **510**.

When nerve grafts are being implanted, it can be necessary to select a graft having a diameter similar to the *in vivo* nerve end. It has been shown that visual size determinations are often incorrect. Utilizing measuring devices with a flat surface, such as rulers, also does not give an accurate measurement of diameter. With a sizing forceps of the subject invention, the sizes or diameters of the apertures can be used to measure the diameter of a nerve placed therein.

The head portion can have a plurality of apertures **500** that can be used to measure the diameter of a nerve. Each aperture can open onto the side edges of the upper jaw and lower jaw, such that the direction of an aperture is transverse to the lengthwise extent **205** of the lower jaw. In one embodiment, a head portion has between two and eight apertures where the apertures have diameters that range from between approximately 0.01 inch to approximately 0.3 inch. In a further embodiment, a head portion has between three and seven apertures, where the apertures have diameters that range between approximately 0.01 inch and approximately 0.3 inch. In a still further embodiment, a head portion has between four and six apertures, where the diameters of the apertures range between approximately 0.01

inch and approximately 0.3 inch. In a particular embodiment, the head portion has five apertures, where the apertures have diameters that range from between approximately 0.03 inch to approximately 0.2 inch. In one specific embodiment, the head portion has five apertures, where the diameters of the apertures **500** are approximately 0.197", 0.157", 0.118", 0.078" and 0.039." Alternatively, a specific embodiment has notches ranging in diameter from approximately 1 mm, approximately 2 mm, approximately 3 mm, approximately 4 mm, and approximately 5 mm and any diameter in a range between any two of the listed diameters.

There are many situations in which a nerve has to be cut or severed. It may be necessary to remove tissue from a nerve end to reach viable, vascularized tissue or a section of nerve may need to be removed from one area to be coapted to a nerve in another area. Regardless of the reason, the method by which the nerve is severed can affect the success of the procedure and the quality of healing and regeneration of nerve tissue. The sizing forceps of the subject invention can be helpful in providing support to a nerve by holding it within an aperture. When the nerve tissue is to be severed, the cutting implement can be placed along one of the side edges and slid along the side edge to provide a clean, precise cut across the nerve.

In one embodiment, the head portion has a slicing slot **600** through which a cutting implement **15**, such as, for example, a surgical grade safety blade or scalpel, such as, by way of example, the one shown in Figure 4, can be passed through to sever a nerve at a point within an aperture. In one embodiment, the lower jaw **300** is traversed by a first part **610** of the slicing slot that bisects the notches, as shown, for example, in Figure 2H. In a further embodiment, the upper jaw **400** is traversed by a second part **620** of the slicing slot that bisects the pairing notches. When the upper jaw and lower jaw are rotated and the faces aligned, as described above, the first part of the slicing slot and the second part of the slicing slot are also aligned to create a full slicing slot through the head portion.

A slicing slot can extend through the head portion, in the same direction as the lengthwise extent **205**. In one embodiment, the slicing slot extends through the head portion in a direction transverse to the direction of the notches **360** and the pairing notches **460**, discussed above. The slicing slot can extend through the head portion, going through the upper jaw **400** and the lower jaw **300**, and opening onto the proximal end **5** of the upper jaw and the lower jaw. Figure 1D illustrates an example of this embodiment. In a further embodiment, the length of a slicing slot, in the direction of the lengthwise extent **205**, is

between approximately 0.8" and 1.0" and the width of a slicing slot, in a direction transverse to the lengthwise extent, is between approximately 0.015" and approximately 0.025." Furthermore, the width of a slicing slot, in a direction perpendicular to the lengthwise extent, can be between approximately 0.03" and approximately 0.01". In a specific embodiment, the
5 length of a slicing slot is approximately 0.833" and the width of a slicing slot is approximately 0.02".

In an alternative embodiment, the slicing slot **600** extends entirely through the upper jaw **400**, but terminates within the lower jaw **300** at a point below the notches **360**. Thus, with this embodiment, the slicing slot does not extend through the entire head portion **200**.
10 Specifically, it does not extend entirely through the lower jaw. In one embodiment, the slicing slot terminates at the bottom or closed end **362** of the notches. In another embodiment, the slicing slot terminates beyond the closed end of the notches, such that a cutting implement **15** will pass entirely through one or more notches in the lower jaw. In one embodiment, the slicing slot terminates between approximately 0.005" and approximately
15 0.001" below the closed end of one or more notches.

The nerve tissue within an aperture **500** can be supported along the length of the aperture. The slicing slot **600** can be advantageously narrow, providing only sufficient space for a cutting implement to pass through the slicing slot in the upper jaw and, possibly, the lower jaw. To facilitate insertion of a cutting implement, an insert port **615** can be fashioned
20 on the outside of the upper jaw **400**. The insert port can be a shallow, depressed area on either side of the outside of the sliding slot that is wider than the slicing slot. The insert port can be used to guide or direct a cutting implement into the slicing slot. In one embodiment, the edges of the insert port are chamfered, beveled, filleted, sloped, or otherwise wider than the remaining length of the slicing slot. The insert port can extend along all or at least some
25 part of the length of the slicing slot. Figure 1G is a cross-sectional view, taken along line 1G in Figure 1F, showing an insert port **615** that is wider than the slicing slot. Figure 1H is a similar cross-sectional view showing that the insert port may not extend along the entire length of the slicing slot.

The slicing slot can extend into the lower jaw, such that it bisects the lower jaw or,
30 alternatively, terminates just below the notches in the lower jaw. In a further embodiment, the slicing slot in the lower jaw can also have an insert port **615**, similar to that in the upper jaw. Figure 1G illustrates a non-limiting example of a lower jaw having an insert port. The

insert port in the lower jaw can provide additional guidance to a cutting implement as it traverses through an aperture 500.

These features of a slicing slot allow the nerve to be cut anywhere along the aperture and obtain a non-frayed end. In one embodiment, the slicing slot is centered between the side edges 320 of the lower jaw and the side edges 420 of the upper jaw 400. In an alternative embodiment, the slicing slot is off-center between the side edges 320 of the lower jaw and the side edges 420 of the upper jaw, an example, of which, is shown in Figure 1D.

Surgical procedures involving nerve tissue can obtain improved results if viable, healthy nerve tissue is used. This can necessitate incrementally removing non-viable or unhealthy nerve tissue. When removing nerve tissue, obtaining a clean, non-frayed nerve end for use can improve procedure outcomes and provide better healing. If nerve grafts are being utilized, it can be preferable for the graft and the nerve being repaired to have similar diameters. The sizing forceps embodiments of the subject invention provide an effective method for fixing a nerve in place, measuring the diameter of the nerve, and providing an efficient and effective procedure for cutting nerve tissue to provide a non-frayed end.

All patents, patent applications, provisional applications, and other publications referred to or cited herein are incorporated by reference in their entirety, including all figures and tables, to the extent they are not inconsistent with the explicit teachings of this specification. Additionally, the entire contents of the references cited within the references cited herein are also entirely incorporated by reference.

The examples and embodiments described herein are for illustrative purposes only and various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application.

Any reference in this specification to “one embodiment,” “an embodiment,” “example embodiment,” “further embodiment,” “alternative embodiment,” etc., is for literary convenience. The implication is that any particular feature, structure, or characteristic described in connection with such an embodiment is included in at least one embodiment of the invention. The appearance of such phrases in various places in the specification does not necessarily refer to the same embodiment. In addition, any elements or limitations of any invention or embodiment thereof disclosed herein can be combined with any and/or all other elements or limitations (individually or in any combination) or any other invention or embodiment thereof disclosed herein, and all such combinations are contemplated with the scope of the invention without limitation thereto.

CLAIMS

We claim:

1. A sizing forceps comprising:
 - a first member having,
 - a first handle portion with a first outer side and a first inner side,
 - a lower jaw at one end of the first handle portion with a first face, and
 - one or more notches within the lower jaw, where the notches open onto the first face, the first outer side and the first inner side;
 - a second member having
 - a second handle portion with a second outer side and a second inner side,
 - an upper jaw at one end of the second handle portion with a second face,
 - one or more pairing notches within the upper jaw, where the pairing notches open onto the second face, the second outer side and the second inner side; and
 - a joint area at which the first handle portion is rotatably connected to the second handle portion;
 - such that the handle portions, when manipulated along a longitudinal extent to rotate at the joint area, bring the lower jaw into alignment with the upper jaw, along a lengthwise extent, so that the first face is against the second face, thereby forming a head portion in which the notches and pairing notches come into alignment so as to form one or more apertures within the head portion.
2. The sizing forceps, according to claim 1, wherein the one or more apertures have different diameters.
3. The sizing forceps, according to claim 2, wherein the one or more apertures decrease in size.
4. The sizing forceps, according to claim 1, further comprising a slicing slot within the head portion that is transverse to the apertures.

5. The sizing forceps, according to claim 4, wherein the width of the slicing slot is sufficient that a surgical cutting blade can pass through the slicing slot.

6. The sizing forceps, according to claim 5, wherein the width of the slicing slot is between approximately 0.03" and approximately 0.01".

7. The sizing forceps, according to claim 5, wherein the width of the slicing slot is approximately 0.020 inch.

8. The sizing forceps, according to claim 4, wherein the lengthwise extent of the head portion is at least one of coplanar, collinear, or in-line with the longitudinal extent of the handle portions.

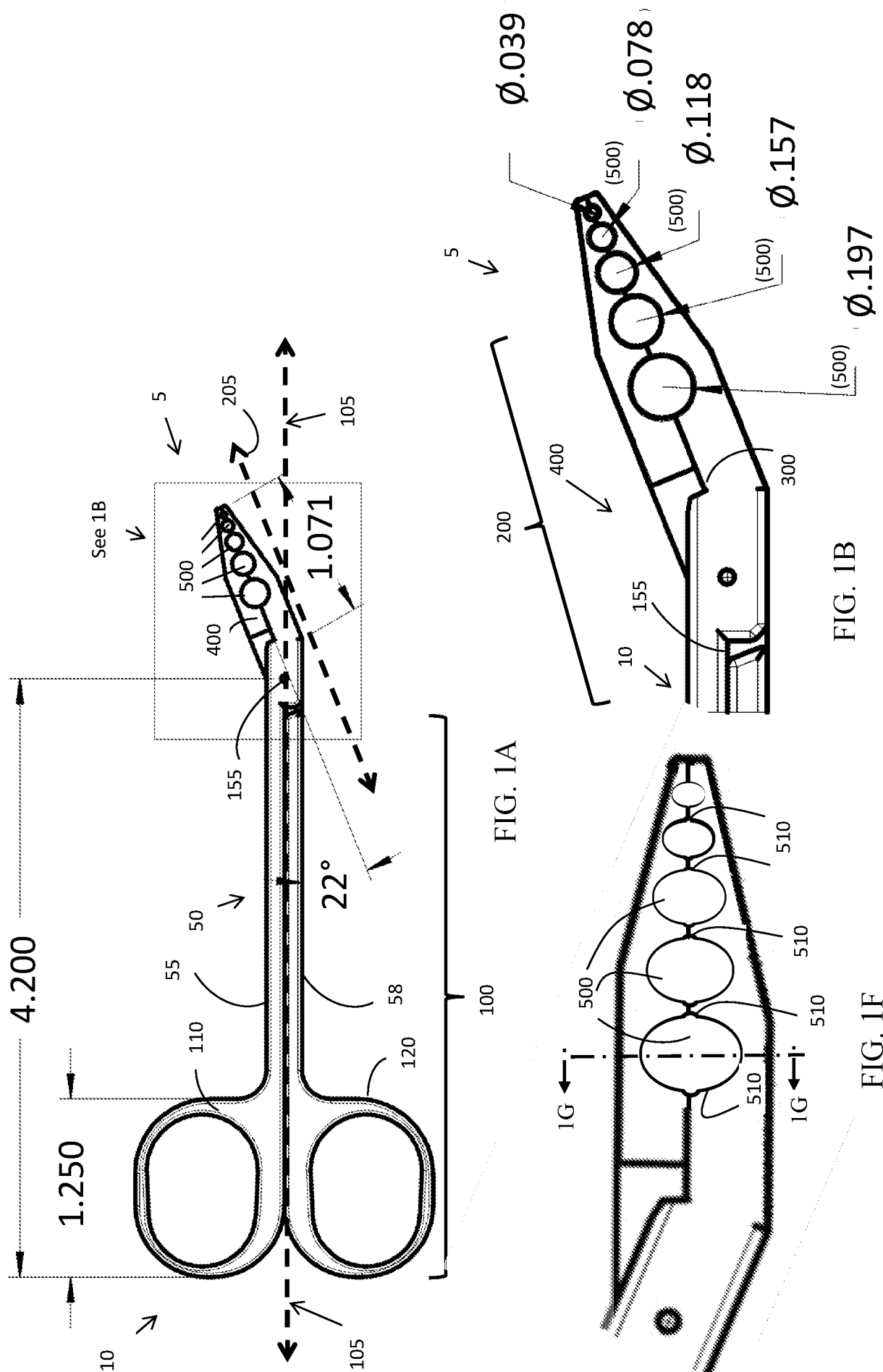
9. The sizing forceps, according to claim 4, wherein the lengthwise extent of the head portion is at an angle with the longitudinal extent at between approximately 10° and approximately 60°.

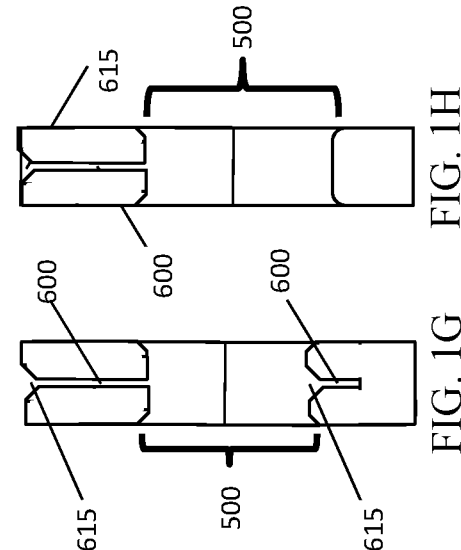
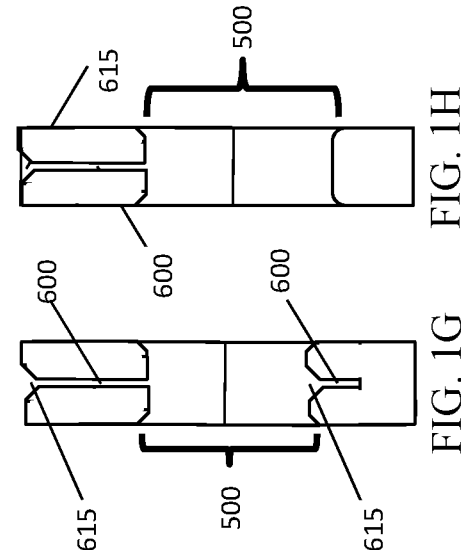
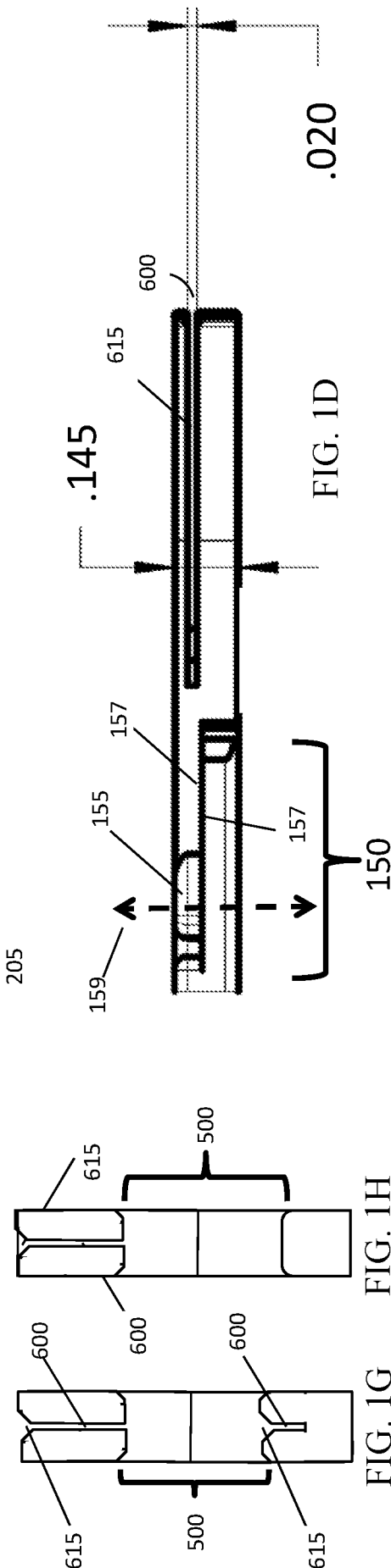
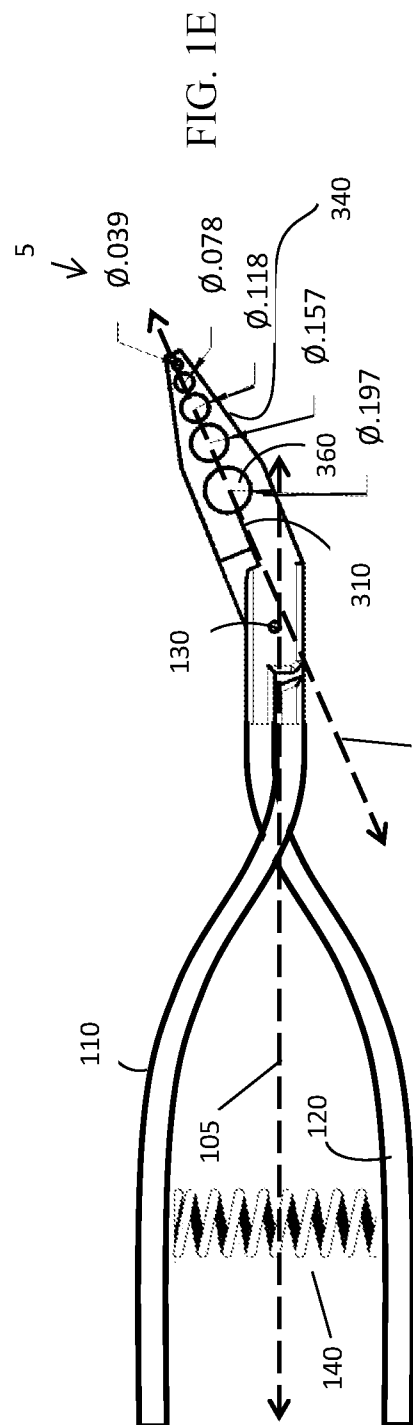
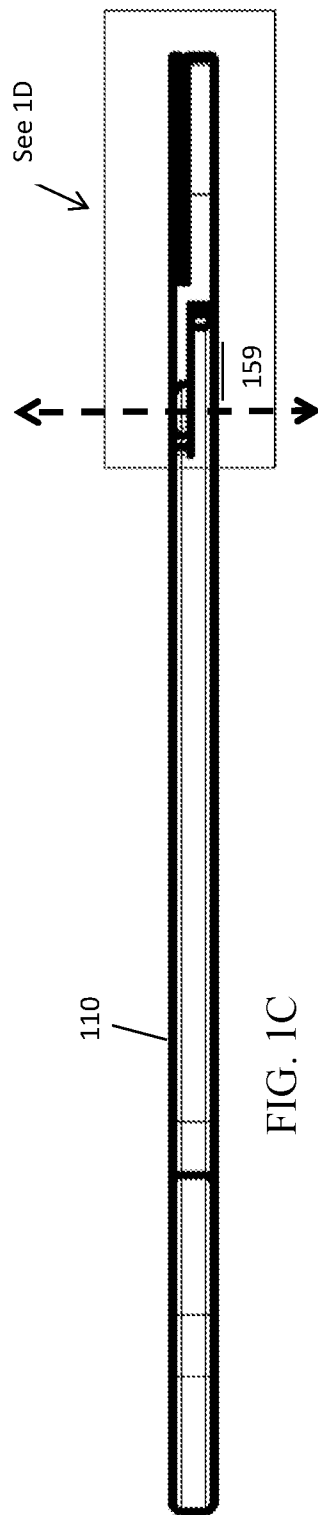
10. The sizing forceps, according to claim 4, wherein the lengthwise extent of the head portion is at an angle with the longitudinal extent at between approximately 20° and approximately 50°.

11. The sizing forceps, according to claim 4, wherein the lengthwise extent of the head portion is at an angle of approximately 22° with the longitudinal extent.

12. The sizing forceps, according to claim 4, wherein the lengthwise extent of the head portion is at an angle of approximately 45° with the longitudinal extent.

13. A method for measuring the diameter of a nerve tissue, the method comprising:
- A. manipulating a sizing forceps, according to claim 1, around the periphery of a nerve tissue with the upper jaw and lower jaw separated;
 - B. positioning the nerve tissue into at least one of the one or more notches in the lower jaw or into at least one of the one or more pairing notches in the upper jaw;
 - C. manipulating the handle portions to bring the lower jaw and the upper jaw closer together, so as to begin forming an aperture;
 - D. determining, as the aperture forms, if the nerve tissue diameter matches the diameter of the forming aperture; and
 - E. repeating steps A-D until an appropriately sized aperture is formed around the nerve tissue.
14. The method, according to claim 13, wherein the head portion of the sizing forceps has multiple apertures with different diameters, and wherein the method further comprises positioning the nerve tissue into one or more of the apertures to determine the correct size aperture for securing, supporting, and measuring the diameter of the nerve tissue.
15. The method, according to claim 14, wherein the head portion further comprises a slicing slot and the method further comprises passing a cutting implement through the slicing slot to transect the nerve tissue positioned within the aperture.
16. The method, according to claim 14, wherein the slicing slot has a width of between approximately 0.03" and approximately 0.01".
17. The method, according to claim 14, wherein the slicing slot has a width of approximately 0.020 inch.





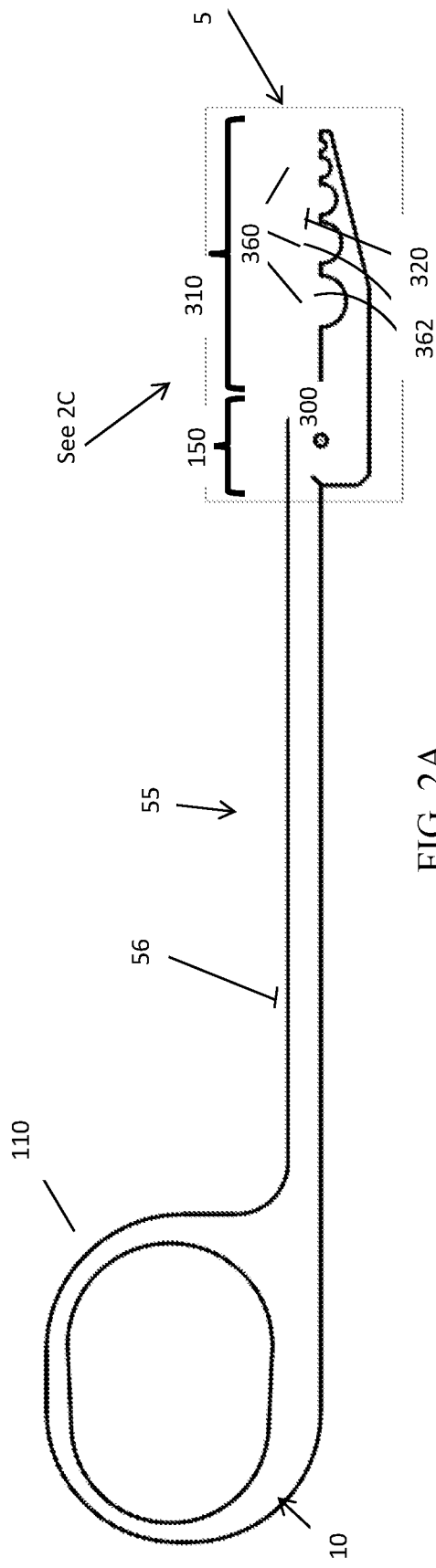


FIG. 2A

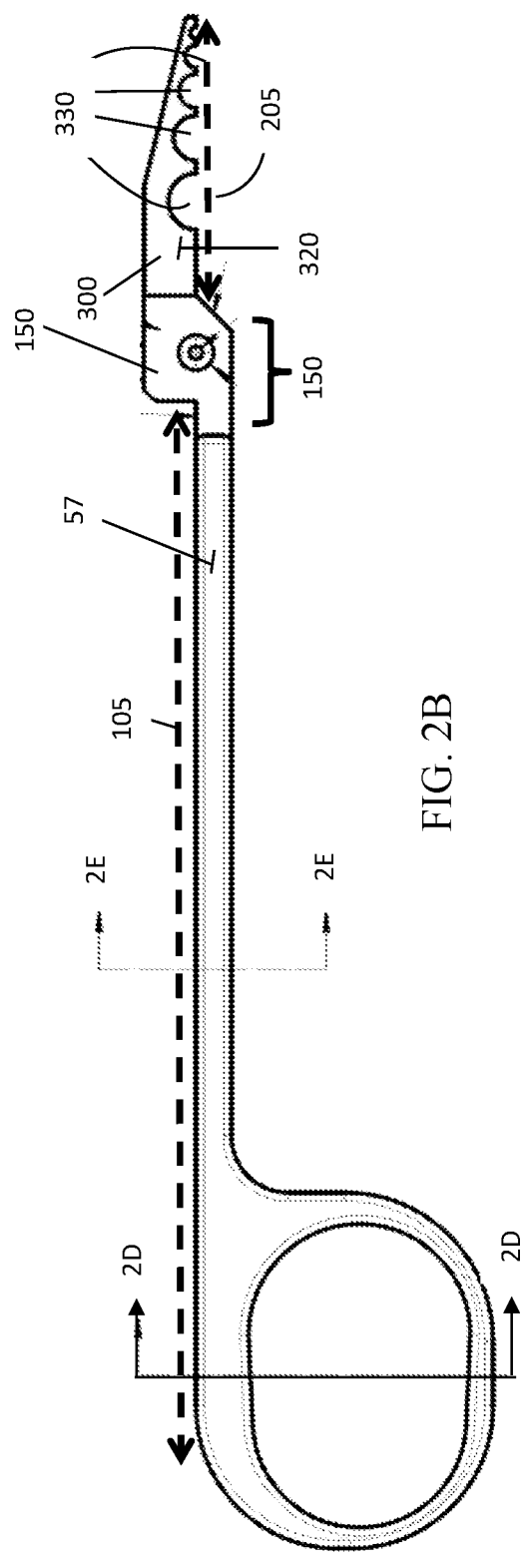


FIG. 2B

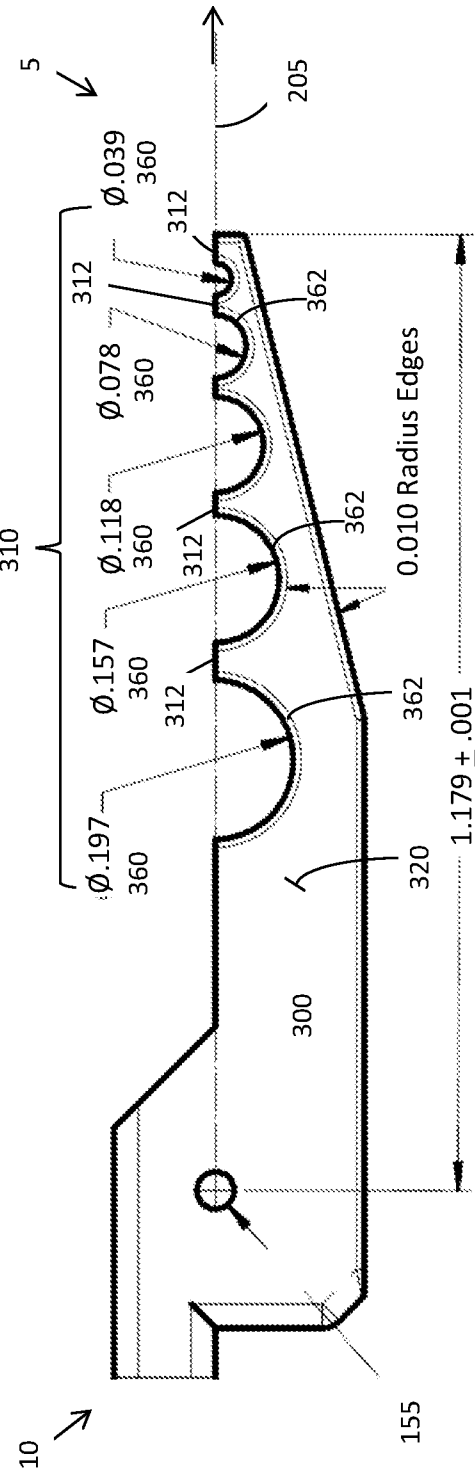


FIG. 2C

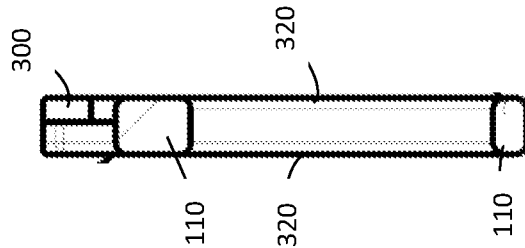


FIG. 2D

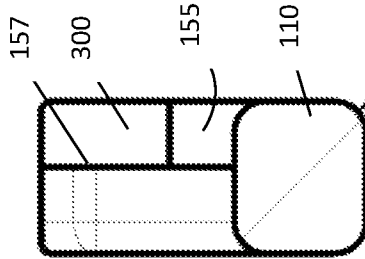


FIG. 2E

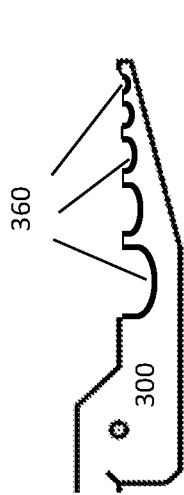


FIG. 2I

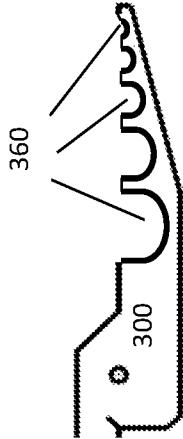
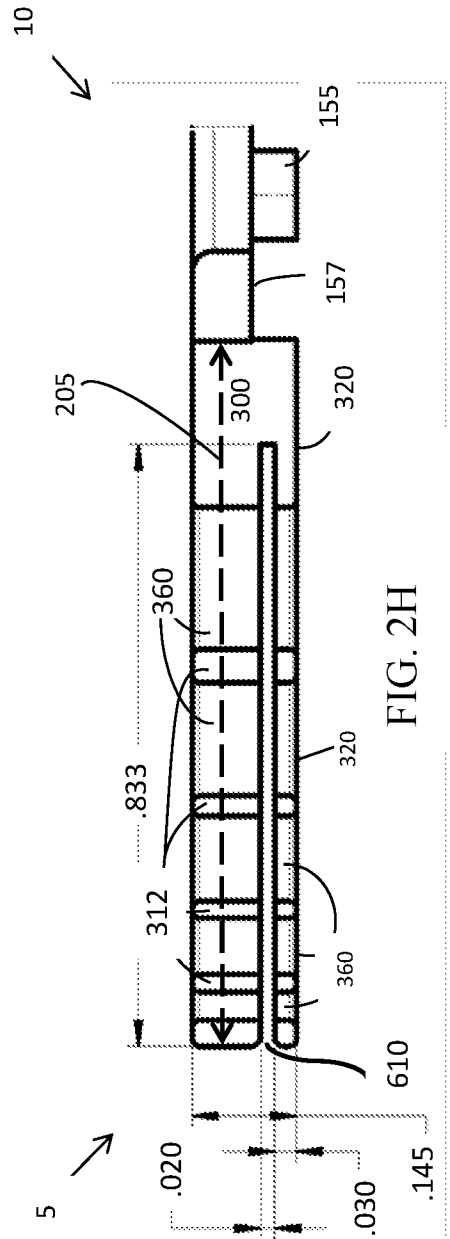
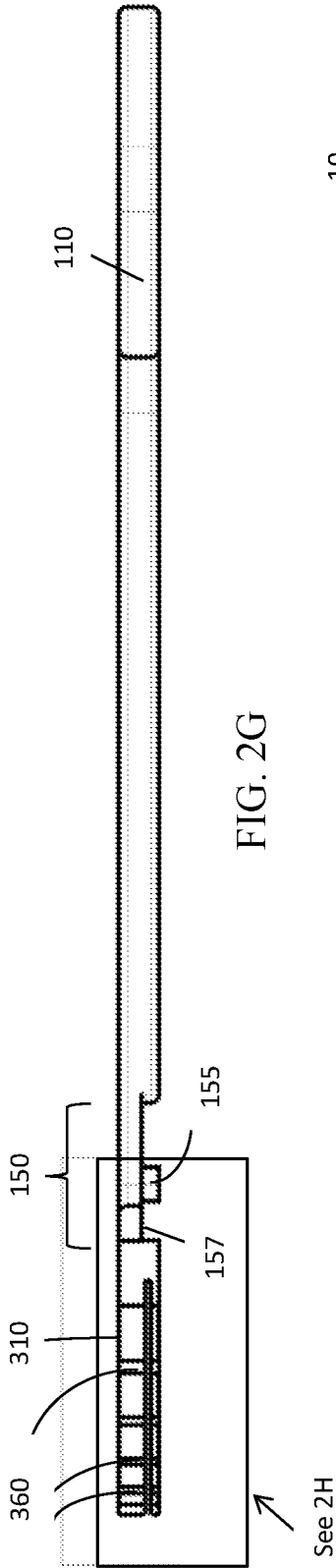
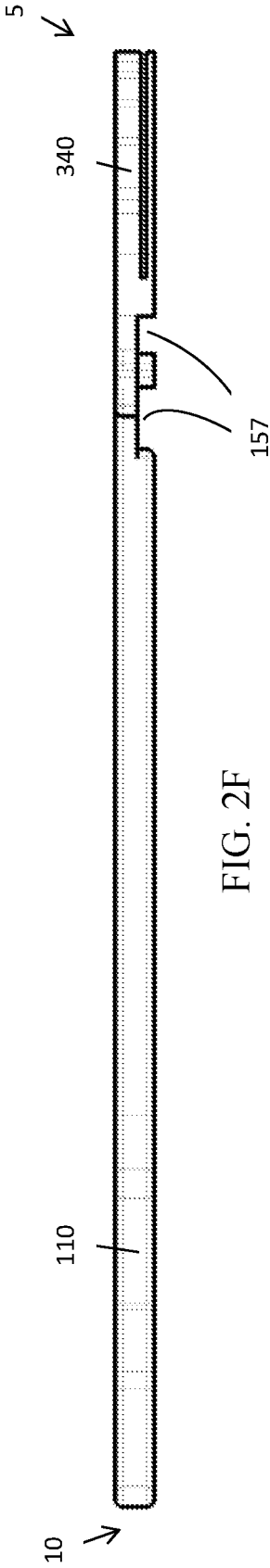
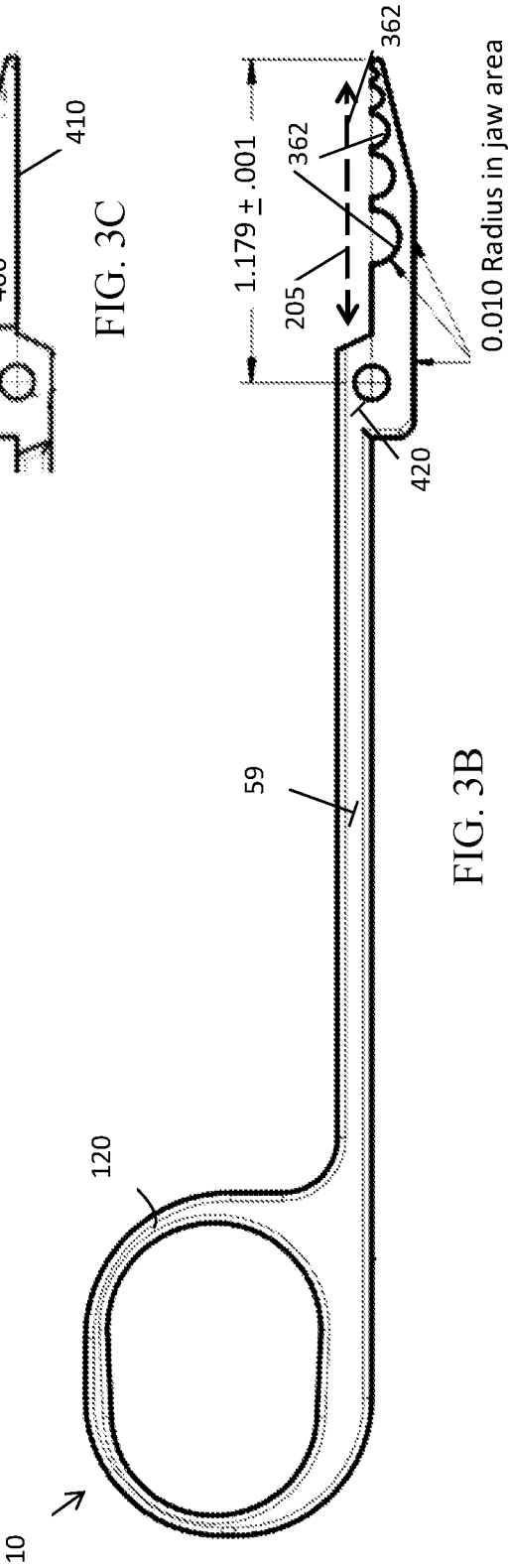
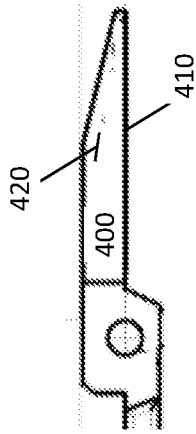
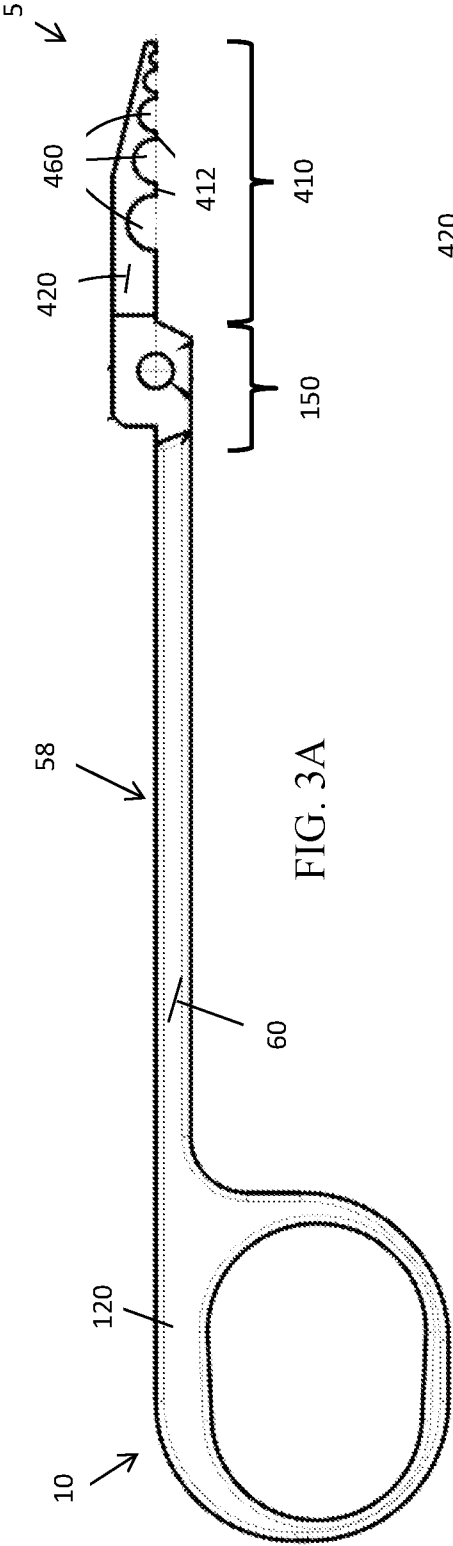


FIG. 2J





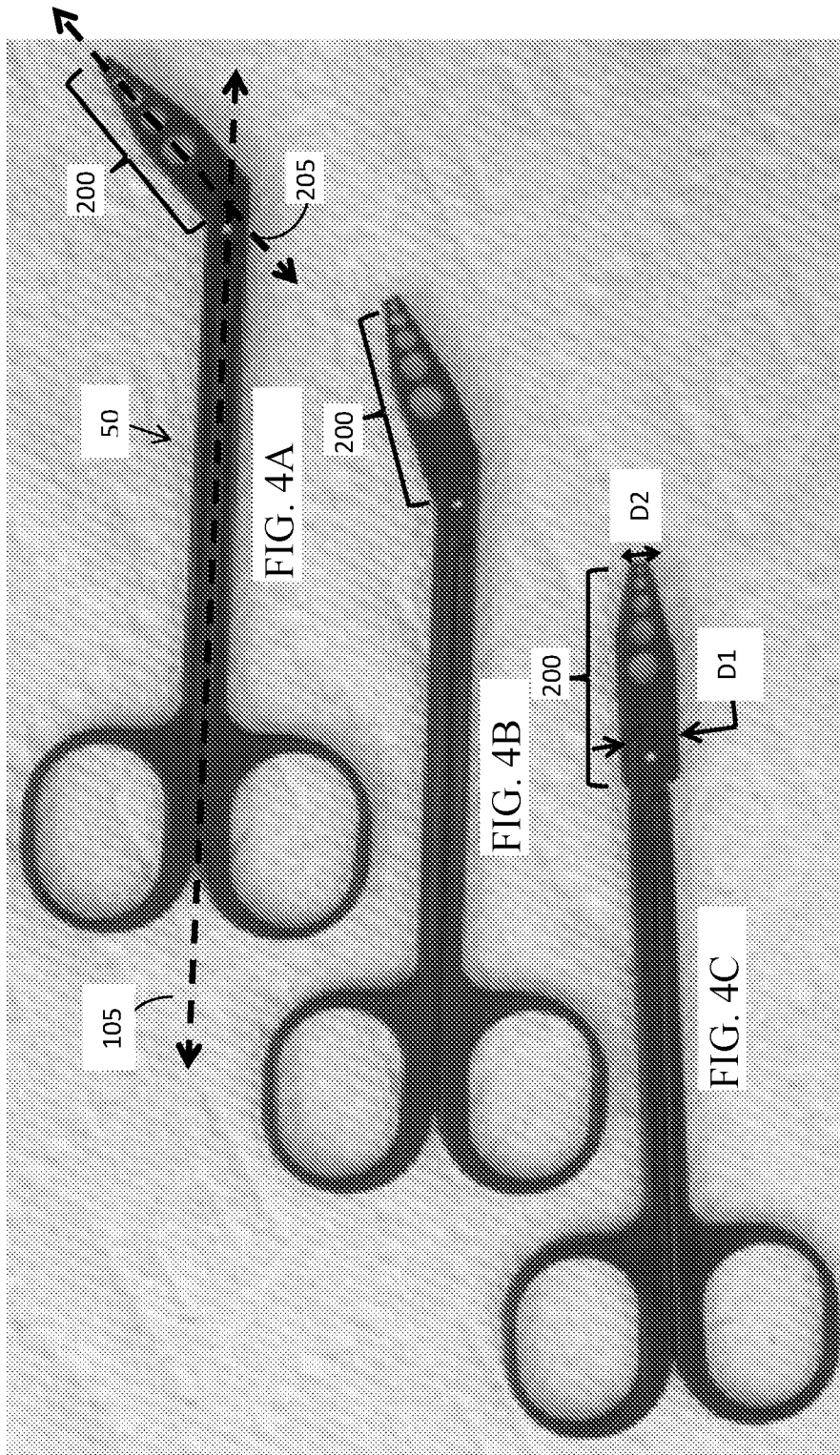
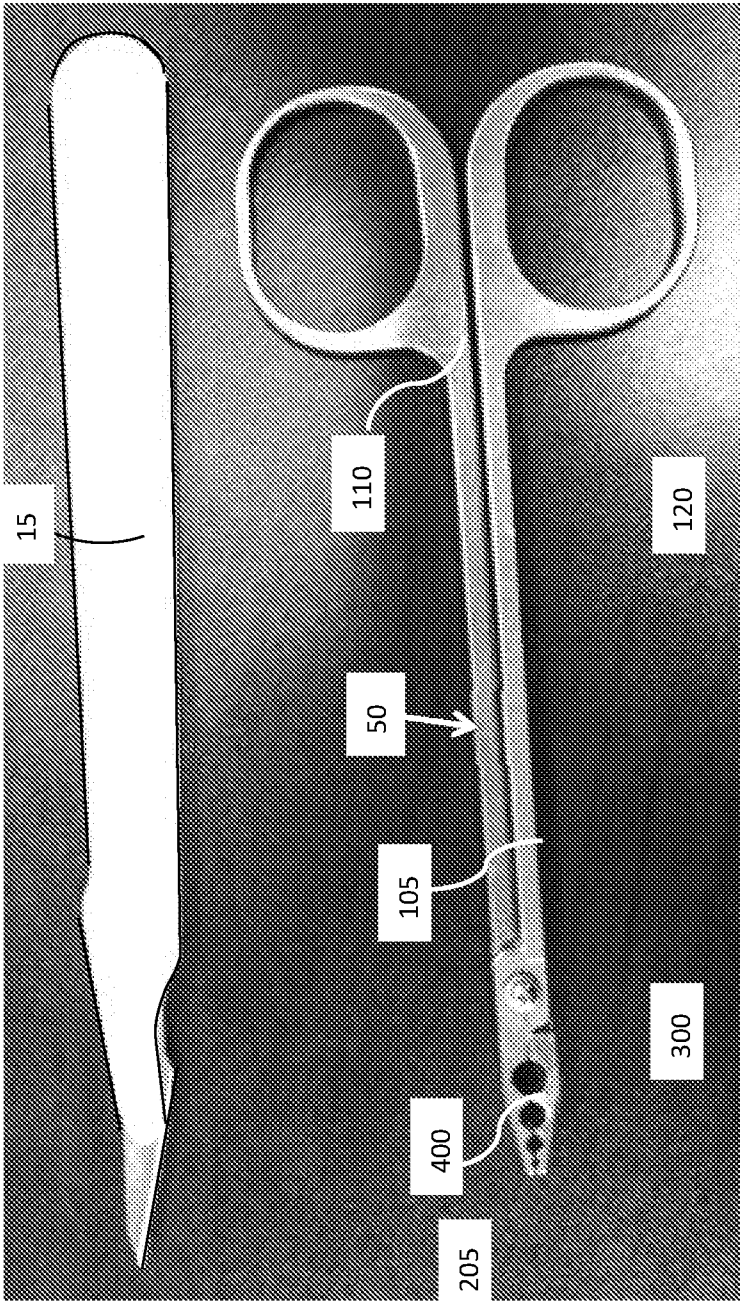


FIG. 5



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/016803**A. CLASSIFICATION OF SUBJECT MATTER****A61B 90/00(2016.01)i, A61B 17/285(2006.01)i, G01B 5/08(2006.01)i**

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 90/00; A61B 18/14; A61B 17/10; A61B 17/00; A61B 17/285; A61B 17/28; G01B 5/08

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: forceps, nerve, sizing, notch, aperture, slicing slot

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5618305 A (LOLAGNE, F.) 08 April 1997 See column 4, lines 26-44; column 6, line 32-column 8, line 26; claims 1-5; and figures 1-5.	1
Y		4-12
A		2,3
Y	US 8808288 B2 (RESCHKE, A. J.) 19 August 2014 See column 1, line 36-column 7, line 61; claims 1-6; and figures 1-5.	4-12
A	US 2008-0177297 A1 (STEINER, A. J. et al.) 24 July 2008 See the whole document.	1-12
A	US 5011491 A (BOENKO, S. K. et al.) 30 April 1991 See the whole document.	1-12
A	US 8313495 B2 (BATES, J. E.) 20 November 2012 See the whole document.	1-12



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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

"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

06 November 2017 (06.11.2017)

Date of mailing of the international search report

06 November 2017 (06.11.2017)

Name and mailing address of the ISA/KR

International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea

Facsimile No. +82-42-481-8578

Authorized officer

LEE, Dong Wook

Telephone No. +82-42-481-8163



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2017/016803**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.: 13-17
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 13-17 pertain to methods for treatment of the human body by surgery, and thus relate to a subject matter which this International Searching Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2017/016803

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 8808288 B2	19/08/2014	US 2011-218530 A1	08/09/2011
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US 8313495 B2	20/11/2012	US 2012-016382 A1	19/01/2012