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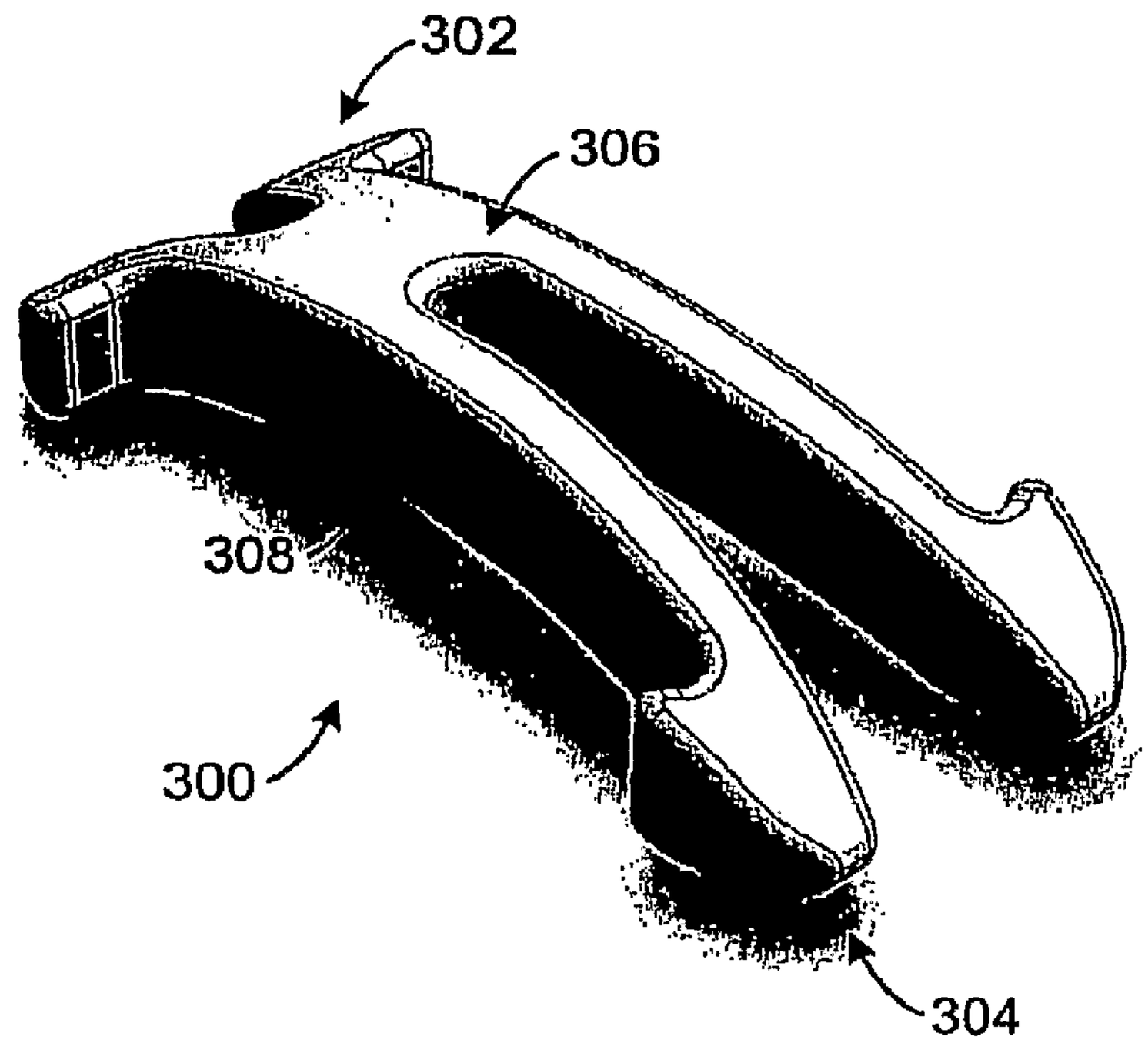
(54) Titre : PROTHESE SCLERALE POUR TRAITER LA PRESBYTIE ET D'AUTRES TROUBLES OCULAIRES ET DES DISPOSITIFS ET PROCEDES CORRESPONDANTS

(54) Title: SCLERAL PROSTHESIS FOR TREATING PRESBYOPIA AND OTHER EYE DISORDERS AND RELATED DEVICES AND METHODS



(57) Abrégé/Abstract:
One example scleral prosthesis (100, 200, 300, 400, 500, 600, 700) includes a first free end and a second free end (102-104, 202-204, 302-304, 402-404, 502-504, 602-604, 702-704), each wider than a middle portion of the scleral prosthesis. Multiple first

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portions (112a-112b, 208a-208b, 312a-312b, 406a-406b, 506a-506b, 606a-606b, 706a-706b) form the first end of the scleral prosthesis. The first portions are separated along at least half of a length of the scleral prosthesis. Multiple second portions (206a-206b, 310a-310b) may form the second end of the scleral prosthesis, and the second portions may be separated along less than a quarter of the length of the scleral prosthesis. An implantation device (900) can be used to facilitate implantation of a scleral prosthesis. The implantation device includes a first end portion (906) configured to be inserted into a scleral tunnel of an eye. The implantation device also includes a second end portion (902) configured to receive the scleral prosthesis. A rod (912) with a tapered and rounded end can be partially inserted into the first end portion of the implantation device.

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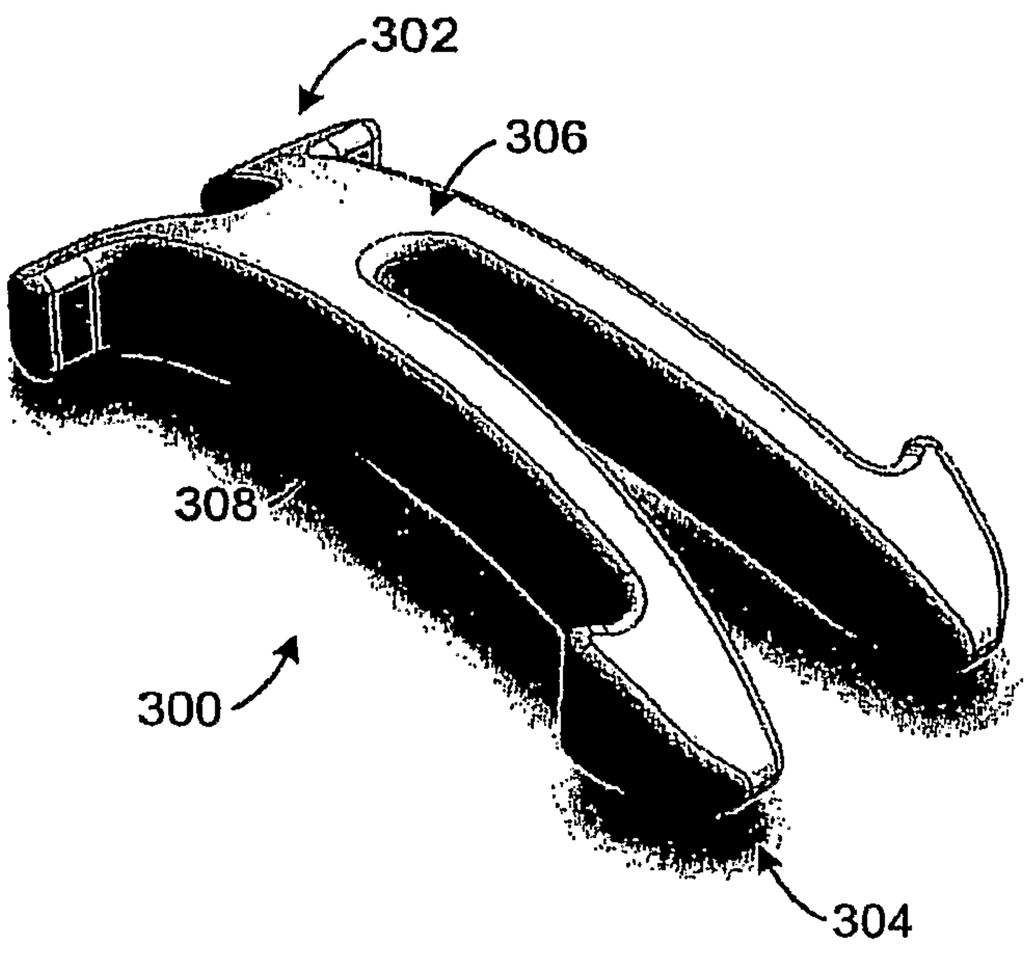
(54) Title: SCLERAL PROSTHESIS FOR TREATING PRESBYOPIA AND OTHER EYE DISORDERS AND RELATED DEVICES AND METHODS



(57) Abstract: One example scleral prosthesis (100, 200, 300, 400, 500, 600, 700) includes a first free end and a second free end (102-104, 202-204, 302-304, 402-404, 502-504, 602-604, 702-704), each wider than a middle portion of the scleral prosthesis. Multiple first portions (112a-112b, 208a-208b, 312a-312b, 406a-406b, 506a-506b, 606a-606b, 706a-706b) form the first end of the scleral prosthesis. The first portions are separated along at least half of a length of the scleral prosthesis. Multiple second portions (206a-206b, 310a-310b) may form the second end of the scleral prosthesis, and the second portions may be separated along less than a quarter of the length of the scleral prosthesis. An implantation device (900) can be used to facilitate implantation of a scleral prosthesis. The implantation device includes a first end portion (906) configured to be inserted into a scleral tunnel of an eye. The implantation device also includes a second end portion (902) configured to receive the scleral prosthesis. A rod (912) with a tapered and rounded end can be partially inserted into the first end portion of the implantation device.

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SCLERAL PROSTHESIS FOR TREATING PRESBYOPIA AND OTHER EYE DISORDERS AND RELATED DEVICES AND METHODS

CROSS-REFERENCE TO RELATED PATENT DOCUMENTS

[0001] This application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application No. 60/819,995 filed on July 11, 2006, which is hereby incorporated by reference.

[0002] This application is related to the following U.S. patent applications and issued patents:

(1) U.S. Patent No. 6,007,578 entitled "Scleral Prosthesis for Treatment of Presbyopia and Other Eye Disorders" issued on December 28, 1999;

(2) U.S. Patent No. 6,280,468 entitled "Scleral Prosthesis for Treatment of Presbyopia and Other Eye Disorders" issued on August 28, 2001;

(3) U.S. Patent No. 6,299,640 entitled "Scleral Prosthesis for Treatment of Presbyopia and Other Eye Disorders" issued on October 9, 2001;

(4) U.S. Patent No. 5,354,331 entitled "Treatment of Presbyopia and Other Eye Disorders" issued on October 11, 1994;

(5) U.S. Patent No. 5,465,737 entitled "Treatment of Presbyopia and Other Eye Disorders" issued on November 14, 1995;

(6) U.S. Patent No. 5,489,299 entitled "Treatment of Presbyopia and Other Eye Disorders" issued on February 6, 1996;

(7) U.S. Patent No. 5,503,165 entitled "Treatment of Presbyopia and Other Eye Disorders" issued on April 2, 1996;

(8) U.S. Patent No. 5,529,076 entitled "Treatment of

Presbyopia and Other Eye Disorders" issued on June 25, 1996;

(9) U.S. Patent No. 5,722,952 entitled "Treatment of Presbyopia and Other Eye Disorders" issued on March 3, 1998;

(10) U.S. Patent No. 6,197,056 entitled "Segmented Scleral Band for Treatment of Presbyopia and Other Eye Disorders" issued on March 6, 2001;

(11) U.S. Patent No. 6,579,316 entitled "Segmented Scleral Band for Treatment of Presbyopia and Other Eye Disorders" issued on June 17, 2003;

(12) U.S. Patent No. 6,926,727 entitled "Surgical Blade for Use with a Surgical Tool for Making Incisions for Scleral Eye Implants" issued on August 9, 2005;

(13) U.S. Patent No. 6,991,650 entitled "Scleral Expansion Device Having Duck Bill" issued on January 31, 2006;

(14) U.S. Patent Application Serial No. 10/080,877 entitled "System and Method for Making Incisions for Scleral Eye Implants" filed on February 22, 2002;

(15) U.S. Patent Application Serial No. 10/443,122 entitled "System and Method for Determining a Position for a Scleral Pocket for a Scleral Prosthesis" filed on May 20, 2003;

(16) U.S. Patent Application Serial No. 11/137,085 entitled "Scleral Prosthesis for Treatment of Presbyopia and Other Eye Disorders" filed on May 24, 2005;

(17) U.S. Patent Application Serial No. 11/199,591 entitled "Surgical Blade for Use with a Surgical

Tool for Making Incisions for Scleral Eye Implants" filed on August 8, 2005;

(18) U.S. Patent Application Serial No. 11/252,369 entitled "Scleral Expansion Device Having Duck Bill" filed on October 17, 2005;

(19) U.S. Patent Application Serial No. 11/323,283 entitled "Surgical Blade for Use with a Surgical Tool for Making Incisions for Scleral Eye Implants" filed on December 30, 2005;

(20) U.S. Patent Application Serial No. 11/323,284 entitled "System and Method for Making Incisions for Scleral Eye Implants" filed on December 30, 2005;

(21) U.S. Patent Application Serial No. 11/322,728 entitled "Segmented Scleral Band for Treatment of Presbyopia and Other Eye Disorders" filed on December 30, 2005; and

(22) U.S. Patent Application Serial No. 11/323,752 entitled "Segmented Scleral Band for Treatment of Presbyopia and Other Eye Disorders" filed on December 30, 2005.

All of these U.S. patents and patent applications are hereby incorporated by reference.

TECHNICAL FIELD

[0003] This disclosure is generally directed to eye implants and associated devices, and more specifically to a scleral prosthesis for treating presbyopia and other eye disorders and related devices and methods.

BACKGROUND

[0004] In order for the human eye to have clear vision of an object at different distances (especially near objects), the effective focal length of the eye's crystalline lens is adjusted to keep an image of the object focused as sharply as possible on the retina. This change in effective focal length is known as "accommodation" and is accomplished by varying the shape of the crystalline lens in the eye. Generally, in the unaccommodated emmetropic eye, the curvature of the lens is such that distant objects are sharply imaged on the retina. In the unaccommodated eye, near objects are not focused sharply on the retina because their images lie behind the retinal surface. In order to visualize a near object clearly, the curvature of the crystalline lens is increased, thereby increasing its refractive power and causing the image of the near object to fall on the retina.

[0005] The change in the shape of the crystalline lens is accomplished by the action of certain muscles and structures within the eyeball or the "globe" of the eye. The lens is located in the forward part of the eye immediately behind the pupil. It has the shape of a classical biconvex optical lens, meaning it has a generally circular cross section with two convex refracting surfaces. The lens is located generally on the optical axis of the eye, which is typically the straight line from the center of the cornea to the macula in the retina at the posterior portion of the globe. In the unaccommodated eye, the curvature of the posterior surface of the lens (the surface adjacent to the vitreous body) is somewhat greater than the curvature of the anterior surface.

[0006] The lens is closely surrounded by a membranous

capsule that serves as an intermediate structure in the support and actuation of the lens. The lens and its capsule are suspended on the optical axis behind the pupil by a circular assembly of radially directed elastic fibers called "zonules." The zonules are attached at their inner ends to the lens capsule and at their outer ends to the ciliary body and indirectly to the ciliary muscle. The ciliary muscle is a muscular ring of tissue located just within the sclera, the outer supporting structure of the eye.

[0007] According to the classical theory of accommodation originating with Helmholtz, the ciliary muscle is relaxed in the unaccommodated eye and therefore assumes its largest diameter. The relatively large diameter of the ciliary muscle in this condition causes a tension on the zonules, which pull radially outward on the lens capsule. This causes the equatorial diameter of the lens to increase slightly and decreases the anterior-posterior dimension of the lens at the optical axis. In other words, the tension on the lens capsule causes the lens to assume a flattened state where the curvature of the anterior surface, and to some extent the posterior surface, is less than it would be in the absence of the tension. In this state, the refractive power of the lens is relatively low, and the eye is focused for clear vision on distant objects.

[0008] According to the classical theory, when the eye is intended to be focused on a near object, the ciliary muscle contracts. This contraction causes the ciliary muscle to move forward and inward, thereby relaxing the outward pull of the zonules on the equator of the lens capsule. This reduced zonular tension allows the elastic

capsule of the lens to contract, causing an increase in the anterior-posterior dimension of the lens at the optical axis (meaning the lens becomes more spherical). This results in an increase in the optical power of the lens. Because of topographical differences in the thickness of the lens capsule, the central anterior radius of curvature may change more than the central posterior radius of curvature. This is the accommodated condition of the eye, where images of near objects fall sharply on the retina.

[0009] Presbyopia is the universal decrease in the amplitude of accommodation, which is typically observed in individuals over forty years of age. In a person having normal vision or "emmetropic" eyes, the ability to focus on near objects is gradually lost. As a result, the individual comes to need glasses for tasks requiring near vision, such as reading.

[0010] According to the conventional view, the amplitude of accommodation of the aging eye is decreased because of the loss of elasticity of the lens capsule and/or sclerosis of the lens with age. Consequently, even though the radial tension on the zonules is relaxed by contraction of the ciliary muscle, the lens does not assume a greater curvature. According to this conventional view, it is not possible to restore the accommodative power to the presbyopic eye by any treatment. The loss of elasticity of the lens and its capsule is seen as irreversible. One solution to the problems presented by presbyopia is to use corrective lenses for close work or possibly bifocal lenses if corrective lenses are required for distant vision. Other solutions may include surgically reshaping the cornea of the eye or implanting a presbyopic intra-ocular lens in the eye

[0011] Contrary to the conventional view, it is possible to restore the accommodative power to a presbyopic eye by implanting scleral prostheses within the sclera of the eye. For each individual scleral prosthesis, an incision is made in the sclera of the eye, such as near the plane of the equator of the crystalline lens. The incision is then extended under the surface of the sclera to form a scleral "tunnel," and a scleral prosthesis is placed within the tunnel. A typical scleral prosthesis could be formed from a generally rectangular-shaped bar approximately five millimeters long, one and a half millimeters wide, and one millimeter tall. One or multiple scleral prostheses may be implanted in a patient's eye to partially or completely restore the accommodative power to a presbyopic eye. The same or similar technique can also be used to treat glaucoma, ocular hypertension, elevated intraocular pressure, or other eye disorders. This technique is described more fully in the U.S. patents and patent applications incorporated by reference above.

SUMMARY

[0012] This disclosure provides a scleral prosthesis for treating presbyopia and other eye disorders and related devices and methods.

[0013] In a first embodiment, a scleral prosthesis includes a first free end and a second free end. Each of the ends is wider than a middle portion of the scleral prosthesis. Multiple first portions form the first end of the scleral prosthesis. The first portions are separated along at least half of a length of the scleral prosthesis.

[0014] In particular embodiments, multiple second portions form the second end of the scleral prosthesis, where the second portions are separated lengthwise along the scleral prosthesis. In other particular embodiments, the second portions are separated along less than a quarter of the length of the scleral prosthesis.

[0015] In a second embodiment, a system includes a scleral prosthesis having a first free end and a second free end. Each end is wider than a middle portion of the scleral prosthesis. Multiple first portions form the first end of the scleral prosthesis, where the first portions are separated along at least half of a length of the scleral prosthesis. The system also includes a threader tube into which the first portions of the scleral prosthesis are at least partially inserted. The threader tube is configured to be transported through a scleral tunnel in scleral tissue of an eye and to release the scleral prosthesis for implantation of the scleral prosthesis in the scleral tunnel.

[0016] In particular embodiments, the system further includes a suture placed through the threader tube and looped over part of the scleral prosthesis.

[0017] In a third embodiment, an implantation device includes a first end portion configured to be inserted into a scleral tunnel in scleral tissue of an eye. The implantation device also includes a second end portion configured to receive a scleral prosthesis. The second end portion is also configured to be transported through the scleral tunnel behind the first end portion and to release the scleral prosthesis for implantation of the scleral prosthesis in the scleral tunnel.

[0018] In particular embodiments, the implantation device further includes a rod partially inserted into the first end portion. In other particular embodiments, the rod has a tapered and rounded end.

[0019] In a fourth embodiment, a method includes inserting a scleral prosthesis into a threader tube. The method also includes pulling the scleral prosthesis into a scleral tunnel in scleral tissue of an eye using the threader tube. In addition, the method includes removing the scleral prosthesis from the threader tube for implantation in the scleral tunnel.

[0020] In particular embodiments, the method further includes looping a suture over a portion of the scleral prosthesis, where the suture is placed through the threader tube. The method also includes pulling the scleral prosthesis into the scleral tunnel using the suture.

[0021] In other particular embodiments, a rod extends from a first end of the threader tube, and the rod enters the scleral tunnel before the first end of the threader tube enters the scleral tunnel.

[0022] In a fifth embodiment, a scleral prosthesis includes a body having a first shape at a first temperature and a second shape at a second temperature. The body has

first and second ends that are narrower in the first shape and wider in the second shape. The first and second ends in the second shape are wider than a middle portion of the body in the second shape.

[0023] In particular embodiments, the first shape is relatively flat, and the second shape is at least partially arched.

[0024] In other particular embodiments, each end includes multiple sections. The multiple sections at each end are angled towards each other in the first shape, and the multiple sections at each end are angled away from each other in the second shape.

[0025] Other technical features may be readily apparent to one skilled in the art from the following figures, descriptions, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] For a more complete understanding of this disclosure, reference is now made to the following description, taken in conjunction with the accompanying drawing, in which:

[0027] FIGURES 1A and 1B illustrate a first example scleral prosthesis in accordance with this disclosure;

[0028] FIGURES 2A and 2B illustrate a second example scleral prosthesis in accordance with this disclosure;

[0029] FIGURES 3A through 3F illustrate a third example scleral prosthesis in accordance with this disclosure;

[0030] FIGURE 4 illustrates a fourth example scleral prosthesis in accordance with this disclosure;

[0031] FIGURES 5A through 5G illustrate a fifth example scleral prosthesis in accordance with this disclosure;

[0032] FIGURES 6A through 6G illustrate a sixth example scleral prosthesis in accordance with this disclosure;

[0033] FIGURES 7A through 7G illustrate a seventh example scleral prosthesis in accordance with this disclosure;

[0034] FIGURES 8A through 8F illustrate an example insertion of a scleral prosthesis into a patient's eye in accordance with this disclosure;

[0035] FIGURES 9A through 9C illustrate an example threader tube used to insert a scleral prosthesis into a patient's eye in accordance with this disclosure;

[0036] FIGURES 10A and 10B illustrate an example surgical blade used to create a scleral tunnel for receiving a scleral prosthesis in accordance with this disclosure;

[0037] FIGURES 11A through 11D illustrate an eighth example scleral prosthesis in accordance with this

disclosure; and

[0038] FIGURES 12A and 12B illustrate a ninth example scleral prosthesis in accordance with this disclosure;

[0039] FIGURES 13A through 13D illustrate a tenth example scleral prosthesis in accordance with this disclosure;

[0040] FIGURES 14A and 14B illustrate an eleventh example scleral prosthesis in accordance with this disclosure;

[0041] FIGURE 15 illustrates an example method for inserting a scleral prosthesis into a patient's eye in accordance with this disclosure.

DETAILED DESCRIPTION

[0042] FIGURES 1A and 1B illustrate a first example scleral prosthesis 100 in accordance with this disclosure. The embodiment of the scleral prosthesis 100 shown in FIGURES 1A and 1B is for illustration only. Other embodiments of the scleral prosthesis 100 could be used without departing from the scope of this disclosure.

[0043] As shown in FIGURES 1A and 1B, the scleral prosthesis 100 has two opposing ends 102-104, a top surface 106, and a bottom surface 108. One end 102 of the prosthesis 100 includes a generally cylindrical area 110 with a flat bottom forming a base on which the prosthesis 100 sits. The other end 104 of the prosthesis 100 is divided or split into multiple portions 112a-112b. Each of these portions 112a-112b includes a generally cylindrical area 114 with a flat bottom, which collectively form another base on which the prosthesis 100 sits.

[0044] In this example, the portions 112a-112b of the prosthesis 100 span a majority of the length of the prosthesis 100, meaning the prosthesis 100 is split along at least half of its length (or some other substantial portion of its length). The portions 112a-112b are generally biased so that they remain separated from one another without external interference. The portions 112a-112b may be biased such that they can be pushed towards each other or together but then separate after release. Also, the portions 112a-112b may not be excessively biased to the point where they tear through an incision in the patient's eye or pull the prosthesis 100 out of a scleral tunnel. Also, the cylindrical areas 110 and 114 project out from the sides of the prosthesis 100, meaning the cylindrical areas 110 and 114 form bases that are wider

than the middle portion of the prosthesis 100. In addition, in this example, the top surface 106 of the prosthesis 100 is generally curved, and the bottom surface 108 could be generally flat or curved.

[0045] In this example embodiment, the scleral prosthesis 100 can be implanted within a scleral tunnel in a patient's eye. For example, the scleral prosthesis 100 can be implanted such that the cylindrical areas 110 and 114 remain outside of the scleral tunnel. Also, the flat bottoms of the cylindrical areas 110 and 114 can lie on the surface of the patient's eye outside of the scleral tunnel. To implant the scleral prosthesis 100 in the scleral tunnel, the portions 112a-112b of the scleral prosthesis 100 could be pushed together and pulled through the scleral tunnel. This may help to reduce the width or cross-sectional area of the end 104 of the scleral prosthesis 100 as the prosthesis 100 is pulled through the scleral tunnel during implantation. However, any other suitable technique could be used to implant the scleral prosthesis 100 in a scleral tunnel.

[0046] The scleral tunnel in which the scleral prosthesis 100 is implanted can be formed near the ciliary body of a patient's eye. Once implanted in a scleral tunnel, the scleral prosthesis 100 helps to, for example, increase the amplitude of accommodation of the patient's eye. The scleral prosthesis 100 could also help to treat other eye conditions, such as glaucoma, ocular hypertension, elevated intraocular pressure, or other eye disorders. In some embodiments, multiple prostheses (such as four) are implanted in a patient's eye, and the ends of the prostheses are "free" (not attached to the ends of other prostheses).

[0047] By making the ends of the scleral prosthesis 100 wider than its middle portion, various benefits could be obtained, such as stabilization of the prosthesis 100. For example, with wider ends, it is less likely that the scleral prosthesis 100 would turn or rotate within a scleral tunnel after implantation. Also, the wider ends help to lock the scleral prosthesis 100 into place and impede movement of the scleral prosthesis 100. In addition, the wider ends make it less likely that the scleral prosthesis 100 can be inadvertently ejected out of the scleral tunnel after implantation.

[0048] In particular embodiments, the prosthesis 100 in FIGURES 1A and 1B may be formed from a single integrated piece of material, such as polymethyl methacrylate ("PMMA"), polyether-ether ketone ("PEEK"), or other suitable material(s). Also, the scleral prosthesis 100 could have any suitable size and dimensions, and scleral prostheses 100 of different sizes could be provided. For example, different-sized scleral prostheses 100 could have different lengths, such as lengths of 3.6, 3.8, 4.0, and 4.2 millimeters from the inner edges of the cylindrical areas 110 and 114 of the prostheses 100.

[0049] FIGURES 2A and 2B illustrate a second example scleral prosthesis 200 in accordance with this disclosure. The embodiment of the scleral prosthesis 200 shown in FIGURES 2A and 2B is for illustration only. Other embodiments of the scleral prosthesis 200 could be used without departing from the scope of this disclosure.

[0050] The scleral prosthesis 200 in FIGURES 2A and 2B is similar to the scleral prosthesis 100 of FIGURES 1A and 1B. In this example embodiment, the scleral prosthesis 200 includes opposing ends 202-204. In this example, both ends

202-204 are split or divided into multiple portions 206a-206b and 208a-208b, respectively. Each of these end portions 206a-206b and 208a-208b includes a generally cylindrical area 210 or 212, which could have flat bottoms collectively define two bases for the scleral prosthesis 200.

[0051] In this example embodiment, the scleral prosthesis 200 can be implanted within a scleral tunnel in a patient's eye, such as by implanting the scleral prosthesis 200 so that the cylindrical areas 210 and 212 remain outside of the scleral tunnel. Also, the flat bottom portions of the cylindrical areas 210 and 212 can lie on the surface of the patient's eye outside of the scleral tunnel. Further, the cylindrical areas 210 and 212 project out from the sides of the prosthesis 200, forming bases that are wider than the middle portion of the prosthesis 200. As noted above, this may help to stabilize the scleral prosthesis 200, such as by reducing or preventing rotation, locking the prosthesis 200 into place, impeding movement of the prosthesis 200, and reducing the likelihood that the prosthesis 200 can exit the scleral tunnel. In addition, in this example, the top surface of the prosthesis 200 is generally curved, and the bottom surface could be generally flat or curved.

[0052] To implant the scleral prosthesis 200 in the scleral tunnel, the portions 206a-206b or 208a-208b of the scleral prosthesis 200 can be pushed together and pulled through the scleral tunnel. An example of this is shown in FIGURE 2B. Here, a tool 290 has two hooked ends 292 that can hook around or onto the cylindrical areas 212 of the scleral prosthesis 200. The tool 290 is then used to push the split portions 208a-208b of the scleral prosthesis 200

together, and the prosthesis 200 can be pulled into the scleral tunnel. However, any other suitable technique could be used to implant the scleral prosthesis 200 in a scleral tunnel.

[0053] In particular embodiments, the prosthesis 200 in FIGURES 2A and 2B may be formed from a single integrated piece of material, such as PMMA, PEEK, or other suitable material(s). The scleral prosthesis 200 could also have any suitable size and dimensions, and scleral prostheses 200 of different sizes could be provided.

[0054] FIGURES 3A through 3F illustrate a third example scleral prosthesis 300 in accordance with this disclosure. The embodiment of the scleral prosthesis 300 shown in FIGURES 3A through 3F is for illustration only. Other embodiments of the scleral prosthesis 300 could be used without departing from the scope of this disclosure.

[0055] As shown in FIGURES 3A through 3C, the scleral prosthesis 300 has two opposing ends 302-304, a top surface 306, and a bottom surface 308. One end 302 of the prosthesis 300 is split or divided into multiple portions 310a-310b, and the other end 304 of the prosthesis 300 is split or divided into multiple portions 312a-312b.

[0056] In this example, the portions 310a-310b of the prosthesis 300 span less than a quarter of the length of the prosthesis 300 (or some other less substantial portion of its length), and the portions 312a-312b of the prosthesis 300 span more than half of the length of the prosthesis 300 (or some other more substantial portion of its length). Also, in this example, the ends 302-304 of the prosthesis 300 have areas 314-316, respectively, that are more triangular in shape. As shown in FIGURE 3B, the areas 314 at the end 302 of the scleral prosthesis 300 have

surfaces that generally face the opposing end 304. Also, as shown in FIGURE 3B, the areas 316 at the end 304 of the scleral prosthesis 300 have surfaces that are more hook-shaped (the areas 316 hook back towards the opposing end 302 of the scleral prosthesis 300). These areas 314 and 316 may also include generally flat bottom surfaces that form bases for the prosthesis 300.

[0057] In this example embodiment, the scleral prosthesis 300 can be implanted within a scleral tunnel in a patient's eye, such as by implanting the scleral prosthesis 300 so that the areas 314 and 316 remain outside of the scleral tunnel. Also, the flat bottom portions of the areas 314 and 316 can lie on the surface of the patient's eye outside of the scleral tunnel. Further, the areas 314 and 316 project out from the sides of the prosthesis 300 to form bases wider than the middle portion of the prosthesis 300. Again, the wider ends may provide certain benefits for the scleral prosthesis 300, such as stabilization of the prosthesis 300. In addition, in this example, the top surface 306 and the bottom surface 308 of the prosthesis 300 are generally curved.

[0058] In particular embodiments, the prosthesis 300 in FIGURES 3A through 3C may be formed from a single integrated piece of material, such as PMMA, PEEK, or other suitable material(s). Also, the scleral prosthesis 300 could have any suitable size and dimensions, and scleral prostheses 300 of different sizes could be provided.

[0059] Examples of differently sized and dimensioned prostheses are shown in FIGURES 3D through 3F, which illustrate four different prostheses 300a-300d. The prostheses 300a-300d are similar to one another with slight changes in their structure. For example, the prosthesis

300a has a larger arch and flat bottom surfaces at its ends, while the prosthesis 300c has a smaller arch and flat bottom surfaces at its ends. The prosthesis 300b has a larger arch and slanted bottom surfaces at its ends, while the prosthesis 300d has a smaller arch and slanted bottom surfaces at its ends.

[0060] The prostheses 300a-300d in FIGURES 3D through 3F could have any suitable sizes and dimensions. For example, the prostheses 300a-300d could be 5,366 microns in length. A thickness (measured top-to-bottom) at the middle (measured end-to-end) of the prostheses 300a-300d could have various values, such as 831, 833, and 839 microns. The arch (measured from the tips of the prostheses to the top of the arch) of the prostheses 300a-300d could also have various values, such as 212, 311, and 386 microns.

[0061] FIGURE 4 illustrates a fourth example scleral prosthesis 400 in accordance with this disclosure. The embodiment of the scleral prosthesis 400 shown in FIGURE 4 is for illustration only. Other embodiments of the scleral prosthesis 400 could be used without departing from the scope of this disclosure.

[0062] In this example, the scleral prosthesis 400 in FIGURE 4 is similar to the prosthesis 300 shown in FIGURES 3A through 3C. Here, the scleral prosthesis 400 includes two opposing ends 402-404, where the end 404 is split or divided into multiple portions 406a-406b.

[0063] The prosthesis 400 also includes an insert 408 placed between or around the multiple portions 406a-406b of the end 404 of the prosthesis 400. The insert 408 can be permanently or removably placed between or around the portions 406a-406b of the end 404 of the prosthesis 400. For example, the insert 408 could be placed between or

around the portions 406a-406b of the end 404 after the prosthesis 400 has been implanted in a scleral tunnel in a patient's eye. The insert 408 could later be removed, such as to facilitate removal of the prosthesis 400 from the scleral tunnel.

[0064] The insert 408 may generally help to stabilize the prosthesis 400 (in addition to the stabilization already provided by the wider ends). For example, the insert 408 could help to prevent the portions 406a-406b of the prosthesis 400 from separating excessively, which could pull the opposite end 402 through the scleral tunnel and force the prosthesis 400 out of the tunnel completely. The insert 408 could also function to reduce or prevent rotation of the prosthesis 400 within the scleral tunnel. For instance, the insert 408 may help to ensure that the end 404 of the prosthesis 400 maintains a desired width and therefore remains wide enough to prevent the prosthesis 400 from rolling over once implanted in the scleral tunnel. Moreover, the insert 408 can be inserted into or around the prosthesis 400 only after the prosthesis 400 has been implanted, which enables the portions 406a-406b of the prosthesis 400 to be pushed together during implantation while preventing portions 406a-406b from coming together after implantation (reducing the likelihood that the prosthesis 400 can exit the scleral tunnel).

[0065] The insert 408 could be attached or coupled to the prosthesis 400 in any suitable manner. For example, the insert 408 could have one or more structures that engage one or more corresponding structures of the portions 406a-406b of the prosthesis 400, such as male structures on the insert 408 that engage female structures on the prosthesis body. The insert 408 could also be attached to

the prosthesis 400 using sutures or looped around the prosthesis 400. The insert 408 could be attached or coupled to the prosthesis 400 in any other suitable manner.

[0066] FIGURES 5A through 5G illustrate a fifth example scleral prosthesis 500 in accordance with this disclosure. The embodiment of the scleral prosthesis 500 shown in FIGURES 5A through 5G is for illustration only. Other embodiments of the scleral prosthesis 500 could be used without departing from the scope of this disclosure.

[0067] As shown in FIGURE 5A, the scleral prosthesis 500 has two opposing ends 502-504. In this example, only one end 504 of the prosthesis 500 is split or divided into multiple portions 506a-506b (although both could be). As shown in FIGURE 5B, the ends of the prosthesis 500 generally have an oval cross-section. Except for the more oval cross-section and the undivided end 502, the overall shape of the prosthesis 500 is similar to the shape of the prosthesis 300.

[0068] As shown here, portions 508-510 of the ends 502-504 of the prosthesis 500 are hook-shaped, where the portions 508 of the end 502 are hooked back towards the end 504 and the portions 510 of the end 504 are hooked back towards the end 502. These portions 508-510 of the prosthesis 500 could also lie outside of a scleral tunnel and rest on the surface of a patient's eye. Again, the ends 502-504 of the prosthesis 500 are wider than the middle, helping to stabilize the prosthesis 500.

[0069] In this example, the prosthesis 500 also includes ridges 512 along the inner sides of the portions 506a-506b. The ridges 512 generally travel lengthwise along the portions 506a-506b of the prosthesis 500. The ridges 512 may or may not link up to each other along the curved

intersection of the portions 506a-506b. The ridges 512 may have any suitable height, width, or shape.

[0070] The prosthesis 500 could have the dimensions shown in FIGURES 5B through 5G. These dimensions are for illustration only. In these figures, the dimensions are expressed as numbers in brackets (representing dimensions in inches) over numbers without brackets (representing dimensions in millimeters). Dimensions associated with a radius of curvature are preceded by the letter "R" (such as in "R6.168"). In addition, the diagram shown in FIGURE 5E represents the cross-section of the prosthesis 500 along line A-A in FIGURE 5D, and the diagram shown in FIGURE 5G represents the cross-section of the prosthesis 500 along line B-B in FIGURE 5F. As shown in FIGURE 5G, the prosthesis 500 could (but need not) be hollow within the undivided portion of the prosthesis 500 near the end 502 and may or may not be filled with a liquid, gel, or other material.

[0071] As explained in more detail below, an insert can be placed between or around the multiple portions 506a-506b of the end 504 of the prosthesis 500. The insert can be permanently or removably placed between or around the portions 506a-506b of the end 504 of the prosthesis 500. For example, the insert could be placed between or around the portions 506a-506b of the end 504 after the prosthesis 500 has been implanted in a scleral tunnel in a patient's eye. The insert could later be removed, such as to facilitate removal of the prosthesis 500 from the scleral tunnel.

[0072] The insert may generally help to stabilize the prosthesis 500 (in addition to the stabilization already provided by the wider ends). For example, the insert could

help to prevent the portions 506a-506b of the prosthesis 500 from separating excessively, which could pull the opposite end 502 through the scleral tunnel and force the prosthesis 500 out of the tunnel completely. The insert could also function to reduce or prevent rotation of the prosthesis 500 within the scleral tunnel. For instance, the insert may help to ensure that the end 504 of the prosthesis 500 maintains a desired width and therefore remains wide enough to prevent the prosthesis 500 from rolling over once implanted in the scleral tunnel. Moreover, the insert can be inserted into or around the prosthesis 500 only after the prosthesis 500 has been implanted, which enables the portions 506a-506b of the prosthesis 500 to be pushed together during implantation but prevents portions 506a- 506b from coming together after implantation (reducing the likelihood that the prosthesis 500 can exit the scleral tunnel).

[0073] FIGURES 6A through 6G illustrate a sixth example scleral prosthesis 600 in accordance with this disclosure. The embodiment of the scleral prosthesis 600 shown in FIGURES 6A through 6G is for illustration only. Other embodiments of the scleral prosthesis 600 could be used without departing from the scope of this disclosure.

[0074] As shown in FIGURE 6A, the scleral prosthesis 600 has two opposing ends 602-604. In this example, again only one end 604 of the prosthesis 600 is split or divided into multiple portions 606a-606b (although both ends could be divided). As shown in FIGURE 6B, the prosthesis 600 generally has a more rectangular cross-section, where the bottom surfaces of the ends 602-604 are flatter than in the prosthesis 500.

[0075] As shown here, portions 608-610 of the ends 602-

604 of the prosthesis 600 are hook-shaped, and the prosthesis 600 includes ridges 612 along the inner sides of the portions 606a-606b. The ridges 612 generally travel lengthwise along the portions 606a-606b of the prosthesis 600 and may or may not be linked along the curved intersection of the portions 606a-606b. Again, the ends 602-604 of the prosthesis 600 are wider than the middle, helping to stabilize the prosthesis 600.

[0076] The prosthesis 600 could have the dimensions shown in FIGURES 6B through 6G. These dimensions are for illustration only. In these figures, the dimensions are again expressed as numbers in brackets (representing inches) over numbers without brackets (representing millimeters), and dimensions associated with a radius of curvature are preceded by the letter "R." In addition, the diagram shown in FIGURE 6E represents the cross-section of the prosthesis 600 along line A-A in FIGURE 6D, and the diagram shown in FIGURE 6G represents the cross-section of the prosthesis 600 along line B-B in FIGURE 6F. Again, the prosthesis 600 may or may not be hollow within the undivided portion of the prosthesis 600 near the end 602 and may or may not be filled with a liquid, gel, or other material.

[0077] As shown below, the prosthesis 600 can include an insert permanently or removably placed between or around the multiple portions 606a-606b of the end 604 of the prosthesis 600. The insert may generally help to stabilize the prosthesis 600 (in addition to the stabilization already provided by the wider ends).

[0078] FIGURES 7A through 7G illustrate a seventh example scleral prosthesis 700 in accordance with this disclosure. The embodiment of the scleral prosthesis 700

shown in FIGURES 7A through 7G is for illustration only. Other embodiments of the scleral prosthesis 700 could be used without departing from the scope of this disclosure.

[0079] As shown in FIGURE 7A, the scleral prosthesis 700 has two opposing ends 702-704. Once again, in this example, only one end 704 of the prosthesis 700 is split or divided into multiple portions 706a-706b (although both could be). As opposed to prior prostheses, as shown in FIGURE 7B, the prosthesis 700 does not have a symmetrical cross-section. Instead, the prosthesis 700 has one side 711 that is relatively flat along the entire length of the prosthesis 700. Here, the ends 702-704 have sides that are aligned with each other along the side 711 of the prosthesis 700. Also, each of the ends 702-704 includes a single portion 708-710, respectively, that is hook-shaped. As a result, both ends 702-704 are still wider than the middle portion of the prosthesis 700 and help stabilize the prosthesis 700, but the ends 702-704 may not be as wide as prior prostheses.

[0080] As with the prostheses 500 and 600, the prosthesis 700 includes ridges 712 along the inner sides of the portions 706a-706b. The ridges 712 generally travel lengthwise along the portions 706a-706b of the prosthesis 700 and may or may not be linked together.

[0081] The prosthesis 700 could have the dimensions shown in FIGURES 7B through 7G. These dimensions are for illustration only. The diagram shown in FIGURE 7E represents the cross-section of the prosthesis 700 along line A-A in FIGURE 7D, and the diagram shown in FIGURE 7G represents the cross-section of the prosthesis 700 along line B-B in FIGURE 7F. Also, the prosthesis 700 may or may not be hollow within the undivided portion of the

prosthesis 700 near the end 702 and may or may not be filled with a liquid, gel, or other material. As explained below, the prosthesis 700 may include an insert permanently or removably placed between or around the multiple portions 706a-706b of the end 704 of the prosthesis 700. The insert may generally help to stabilize the prosthesis 700 (in addition to the stabilization already provided by the wider ends).

[0082] Although FIGURES 1A through 7G illustrate various examples of scleral prostheses, various changes may be made to FIGURES 1A through 7G. For example, the sizes, shapes, and dimensions of the features of the scleral prostheses are for illustration only and can be altered in any suitable manner. Also, various features shown and described with respect to one of the scleral prostheses could be used with other scleral prostheses. As a particular example, the insert 408 of the prosthesis 400 could be used with any other suitable scleral prosthesis. As another particular example, a difference between the prostheses shown in FIGURES 3A-3F and the prostheses shown in FIGURES 5A-7G is that (when looking from an end viewpoint) the top edges of the ends have been shaved in FIGURES 5A-7G so that they slope downwards from top to bottom at about a 45° angle. This same feature could be used with any other prosthesis.

[0083] FIGURES 8A through 8F illustrate an example insertion of a scleral prosthesis into a patient's eye in accordance with this disclosure. The example insertion of the scleral prosthesis shown in FIGURES 8A through 8F is for illustration only. Other techniques could be used to insert a scleral prosthesis into a patient's eye without departing from the scope of this disclosure.

[0084] As shown in FIGURE 8A, a prosthesis 800 is being implanted into a scleral tunnel 802 in a patient's eye. The prosthesis 800 could represent any suitable prosthesis, such as one of the prostheses discussed above or any other suitable prosthesis. In this example, the prosthesis 800 is inserted into a threader tube 804, which is used to compress or push together the split or divided portions of the prosthesis 800 for insertion into the scleral tunnel 802. The prosthesis 800 is pulled into the scleral tunnel 802 by the threader tube 804 and, optionally, a suture 806 that has been threaded through the scleral tunnel 802. The end of the suture 806 in this example includes two loops that are placed through the threader tube 804 and connected to one end of the prosthesis 800. In this example, the loops of the suture 806 loop around the cylindrical or triangular areas at one end of the prosthesis 800.

[0085] As shown in FIGURES 8A and 8B, one end of the prosthesis 800 is connected to the suture 806 and can be inserted into the threader tube 804. As shown in FIGURES 8C and 8D, the threader tube 804 and the suture 806 can then be pulled so that the prosthesis 800 is pulled into the scleral tunnel 802. In some embodiments, the prosthesis 800 is both pulled into the scleral tunnel 802 (such as by using the threader tube 804 and/or the suture 806) and pushed into the scleral tunnel 802 (such as by using an instrument held by a surgeon). As shown in FIGURE 8E, once the prosthesis 800 is implanted within the scleral tunnel 802, the threader tube 804 can be pulled off the prosthesis 800, and the suture 806 can be removed from the prosthesis 800. This leaves the prosthesis 800 in the scleral tunnel 802 as shown in FIGURE 8F.

[0086] Although FIGURES 8A through 8F illustrate one

example of an insertion of a scleral prosthesis into a patient's eye, various changes may be made to FIGURES 8A through 8F. For example, the threader tube 804 could have any suitable size or shape. Also, the suture 806 could be attached or coupled to the prosthesis 800 in any suitable manner. In addition, the suture 806 need not be used with the threader tube 804 to implant the prosthesis 800. In particular embodiments, the prosthesis 800 could be pulled into the scleral tunnel 802 using only the threader tube 804.

[0087] FIGURES 9A through 9C illustrate an example threader tube 900 used to insert a scleral prosthesis into a patient's eye in accordance with this disclosure. The embodiment of the threader tube 900 shown in FIGURES 9A through 9C is for illustration only. Other embodiments of the threader tube 900 could be used without departing from the scope of this disclosure.

[0088] In this example, the threader tube 900 includes a wider upper portion 902, a tapered portion 904, and a narrower lower portion 906. The lower portion 906 in this example includes an angled end 908. The threader tube 900 could be formed from any suitable material(s), such as heat-shrink tubing formed from TEFLON PTFE (polytetrafluoroethylene). Also, the threader tube 900 could have any suitable shape that allows the threader tube 900 to be pulled through a scleral tunnel. For example, the threader tube 900 could have an overall length of 3.0cm (±0.5cm). The upper portion 902 could have a length of 1.0cm (±0.2cm), an internal diameter of 1.0mm, and a minimum wall thickness of 0.08mm. The lower portion 906 could have an internal diameter of 0.5mm and a recovered minimum wall thickness of 0.12mm. In addition, the end 908

of the lower portion 906 could have an angle of 30°.

[0089] Optionally, a suture 910 can be placed through the threader tube 900, and a rod 912 can be inserted into the lower portion 906 of the threader tube 900. The illustration in FIGURE 9C represents the cross-section of the threader tube 900 along the lower portion 906 of the threader tube 900. The suture 910 travels through the threader tube 900, loops around a scleral prosthesis 914, and returns through the threader tube 900. The suture 910 in this example loops around the central body of the prosthesis 914 (as opposed to looping over portions of the closer end of the prosthesis as shown in FIGURES 8A through 8F). The suture 910 represents any suitable suture made of any suitable material(s), such as 6-0 NYLON or PROLENE sutures having a 0.1mm diameter.

[0090] The rod 912 in this example includes a tapered and rounded end that can be inserted through a scleral tunnel ahead of the lower portion 906 of the threader tube 900. The rod 912 can be used to facilitate insertion of the threader tube 900 into a scleral tunnel of a patient's eye. For example, the rod 912 may help the scleral tunnel to open and obtain a larger size before the lower portion 906 of the threader tube 900 is inserted into the scleral tunnel. The rod 912 could be formed from any suitable material(s) and can have any suitable size or shape, such as a cigar-shaped rod having a maximum diameter of 0.3mm. Also, both ends of the rod 912 could, but need not, have the shape shown in FIGURE 9B.

[0091] Although FIGURES 9A through 9C illustrate one example of a threader tube 900 used to insert a scleral prosthesis into a patient's eye, various changes may be made to FIGURES 9A through 9C. For example, the threader

tube 900 and rod 912 could have any suitable size or shape. Also, the suture 910 need not loop around the central body of the prosthesis 914 and could loop around or be attached to or associated with the prosthesis 914 in any suitable manner, such as by being looped around the closer end of the prosthesis 914. Further, the suture 910 and/or the rod 912 need not be used along with the threader tube 900 to insert a scleral prosthesis into a scleral tunnel.

[0092] FIGURES 10A and 10B illustrate an example surgical blade 1000 used to create a scleral tunnel for receiving a scleral prosthesis in accordance with this disclosure. The embodiment of the surgical blade 1000 shown in FIGURES 10A and 10B is for illustration only. Other embodiments of the surgical blade 1000 could be used without departing from the scope of this disclosure.

[0093] In this example, the surgical blade 1000 is used to automatically feed a suture through a scleral tunnel. The suture could then be used to pull a prosthesis into the scleral tunnel, such as is shown in FIGURES 8A through 8F and 9A through 9C. However, as noted above, the use of a suture to pull a prosthesis into a scleral tunnel is not required, and the surgical blade 1000 could be modified to simply form a scleral tunnel without pulling a suture through the tunnel.

[0094] As shown in FIGURES 10A and 10B, the surgical blade 1000 includes a central portion 1002, a curved cutting blade 1004, and a connecting segment 1006. The central portion 1002 is connected to a surgical tool and can be rotated in multiple directions to move the cutting blade 1004 into and out of the scleral tissue of a patient's eye. The connecting segment 1006 couples the central portion 1002 to the cutting blade 1004, helping to

translate rotation of the central portion 1002 into movement of the cutting blade 1004.

[0095] In this example, the cutting blade 1004 includes a notch 1008. After the cutting blade 1004 is rotated into the scleral tissue of a patient's eye (and before it is rotated out of the scleral tissue), a suture 1010 can be placed in the notch 1008. In some embodiments, the suture 1010 could have multiple loops at its end, and the loops may be placed in the notch 1008. In other embodiments, the suture 1010 itself is placed within the notch 1008. The suture 1010 could be loaded into the notch 1008 in any suitable manner, such as automatically or manually. The cutting blade 1004 is then rotated out of the patient's scleral tissue, pulling the suture 1010 with it. This allows the suture 1010 to be pulled through the scleral tunnel in a patient's eye at the time that the scleral tunnel is formed. The suture 1010 also helps to mark the location of the scleral tunnel, allowing a surgeon or other personnel to quickly locate the scleral tunnel in the patient's eye after the surgical blade 1000 is removed.

[0096] Although FIGURES 10A and 10B illustrate one example of a surgical blade 1000 used to create a scleral tunnel for receiving a scleral prosthesis, various changes may be made to FIGURES 10A and 10B. For example, the surgical blade 1000 need not include a notch 1008, and the suture 1010 could be inserted through a scleral tunnel after the tunnel is formed. Also, as noted above, the suture 1010 could be omitted from the surgical procedure.

[0097] FIGURES 11A through 11D illustrate an eighth example scleral prosthesis 1100 in accordance with this disclosure. The embodiment of the scleral prosthesis 1100 shown in FIGURES 11A through 11D is for illustration only.

Other embodiments of the scleral prosthesis 1100 could be used without departing from the scope of this disclosure.

[0098] In this example, the scleral prosthesis 1100 changes shape after being implanted into a scleral tunnel. For example, the prosthesis 1100 could be formed from a shape-memory metal or other material that changes shape when exposed to certain temperatures or temperature ranges, such as a nickel titanium alloy or Nitinol. In this example, the prosthesis 1100 before implantation may have the shape shown in FIGURE 11A. Here, the prosthesis 1100 includes a generally flat central portion 1102 and two generally flat end portions 1104-1106. Each of the end portions 1104-1106 includes two separated sections 1108, which in this example are angled towards one another.

[0099] Once inserted into a scleral tunnel, the temperature of the patient's scleral tissue may cause the prosthesis 1100 to assume the shape shown in FIGURE 11B. The central portion 1102 of the prosthesis 1100 is now arched or curved, and the sections 1108 of each end portion 1104-1106 angle away from one other. Also, the end portions 1104-1106 may be generally curved, while the tips of the end portions 1104-1106 are flatter to form splayed feet that provide support for the prosthesis 1100.

[00100] The prosthesis 1100 could be implanted into a patient's eye in any suitable manner. For example, the scleral prosthesis 1100 could be inserted into a scleral tunnel after a surgical blade has been used to form the scleral tunnel.

[00101] In other embodiments, as shown in FIGURE 11C, the prosthesis 1100 could be placed within a sheath 1152 having an integrated blade 1154. The integrated blade 1154 can be used to form a scleral tunnel in a patient's

eye while the prosthesis 1100 is being inserted into the scleral tissue. For example, as shown in FIGURE 11D, a vacuum pot 1170 can be inserted onto a patient's eye, and vacuum forces could be used to pull up on the patient's scleral 1172 and conjunctiva 1174. At this point, an incision could be formed in the patient's eye, such as an incision at location 1176. This could include inserting the prosthesis 1100 into the patient's eye at the location 1176, using the blade 1154 to cut into and form an incision through the patient's eye at that location. By pulling up on the patient's sclera 1172 before the incision is formed, a straight incision rather than a curved incision could be used to form a scleral tunnel. Although the incision is shown as occurring outside of the vacuum pot 1170, the vacuum pot 1170 could include a mechanism for forming an incision inside the vacuum pot 1170. Once implanted, the sheath 1152 could be opened and pulled through the scleral tunnel while the prosthesis 1100 is maintained in place (such as by a surgeon using a gripping tool to hold the prosthesis 1100 in place). However, the prosthesis 1100 could be inserted in any other suitable manner, with or without using a sheathe, integrated blade, or vacuum pot.

[00102] In particular embodiments, the prosthesis 1100 may be malleable and caused to assume the shape shown in FIGURE 11A at lower temperatures (in a "martensite" phase), such as temperatures below 60°F. At temperatures above 60°F (in an "austenite" phase), the prosthesis 1100 may assume the arched shape shown in FIGURE 11B. The flatter shape of the prosthesis 1100 shown in FIGURE 11A may help to reduce the profile of the prosthesis 1100 during implantation, which may reduce the size of an incision needed in the scleral tissue of a patient's eye.

As a particular example, the prosthesis 1100 in FIGURE 11A could have an arched height of 250 microns, and the prosthesis 1100 in FIGURE 11B could have an arched height of 900 microns. Also, because the prosthesis 1100 in FIGURE 11A is generally flat, a straight incision could be used to form a scleral tunnel instead of a curved incision, reducing the complexity of forming the incision.

[00103] Although FIGURES 11A through 11D illustrate an eighth example scleral prosthesis 1100, various changes may be made to FIGURES 11A through 11D. For example, the prosthesis 1100 could have any suitable size or shape before and after implantation. As a particular example, while shown as including separated sections 1108 at its ends 1104-1106 in FIGURE 11A, each end 1104-1106 of the prosthesis 1100 could be fully integrated, and each end 1104-1106 may branch into multiple sections 1108 only after implantation.

[00104] FIGURES 12A through 14B illustrate additional example prostheses having inserts placed between portions or "legs" of one end of each of these prostheses. FIGURES 12A and 12B illustrate a ninth example scleral prosthesis 1200 in accordance with this disclosure. The embodiment of the scleral prosthesis 1200 shown in FIGURES 12A and 12B is for illustration only. Other embodiments of the scleral prosthesis 1200 could be used without departing from the scope of this disclosure.

[00105] In this example, the scleral prosthesis 1200 is configured to receive an insert 1202. The prosthesis 1200 includes a textured bottom surface 1204, and the insert 1202 includes a textured bottom surface 1206 (although this feature could be omitted). Also, the interior sides of the legs of the prosthesis 1200 have

"male" ridges 1208, and the insert 1202 has "female" slots 1210 that guide the insert 1202 smoothly between the legs of the prosthesis 1200 (after the prosthesis 1200 itself has been inserted in a scleral tunnel).

[00106] In addition, the insert 1202 includes a slightly wider circular "male" area 1212 at the interior end of the insert 1202, which can be inserted into a corresponding circular "female" expansion 1214 on the prosthesis 1200 itself. As the insert 1202 approaches the end of its travel into the prosthesis 1200, the area 1212 can be snapped into the expansion 1214, which helps to ensure that the insert 1202 does not fall out of the prosthesis 1200 after implantation.

[00107] The insert 1212 can be permanently or removably placed between the legs of the prosthesis 1200. For example, the insert 1212 could be placed between the legs of the prosthesis 1200 after the prosthesis 1200 has been implanted in a scleral tunnel in a patient's eye. The insert 1212 could later be removed, such as to facilitate removal of the prosthesis 1200 from the scleral tunnel.

[00108] The insert 1212 may generally help to stabilize the prosthesis 1200 (in addition to the stabilization already provided by its wider ends). For example, the insert 1212 could help to prevent the legs of the prosthesis 1200 from separating excessively, which could pull the opposite end through the scleral tunnel and force the prosthesis 1200 out of the tunnel completely. The insert 1212 could also function to reduce or prevent rotation of the prosthesis 1200 within the scleral tunnel. For instance, the insert 1212 may help to ensure that the legs of the prosthesis 1200 form an end having a desired width, so the end remains wide enough to prevent the

prosthesis 1200 from rolling over once implanted in the scleral tunnel. Moreover, the insert 1212 can be inserted into or around the prosthesis 1200 only after the prosthesis 1200 has been implanted, which enables the legs of the prosthesis 1200 to be pushed together during implantation but prevents the legs from coming together after implantation.

[00109] FIGURES 13A through 13D illustrate a tenth example scleral prosthesis 1300, 1350 in accordance with this disclosure. The embodiments of the scleral prostheses 1300, 1350 shown in FIGURES 13A through 13D are for illustration only. Other embodiments of the scleral prostheses 1300, 1350 could be used without departing from the scope of this disclosure.

[00110] As shown in FIGURES 13A and 13B, an insert 1302 can be placed between the legs of the prosthesis 1300. Similarly, as shown in FIGURES 13C and 13D, an insert 1352 can be placed between the legs of the prosthesis 1350. The inserts 1302 and 1352 can function in the same or similar manner as the insert 1202 described above. Moreover, the same mechanisms (male ridges, female slots, male areas, and female expansions) could be used with the prostheses 1300, 1350 and inserts 1302, 1352.

[00111] FIGURES 14A and 14B illustrate an eleventh example scleral prosthesis in accordance with this disclosure. The embodiment of the scleral prosthesis 1400 shown in FIGURES 14A and 14B is for illustration only. Other embodiments of the scleral prosthesis 1400 could be used without departing from the scope of this disclosure.

[00112] As shown in FIGURES 14A and 14B, an insert 1402 can be placed between the legs of the prosthesis 1400. The insert 1402 can function in the same or similar manner

as the insert 1202 described above. Moreover, the same mechanisms (male ridges, female slots, male areas, and female expansions) could be used with the prosthesis 1400 and insert 1402.

[00113] In particular embodiments, the prostheses 1200-1400 shown in FIGURES 12A through 14B represents the same or similar prostheses described above in FIGURES 5A through 7G. However, the inserts could be used with any other suitable prosthesis.

[00114] Although FIGURES 12A through 14B illustrate various examples of scleral prostheses having inserts, various changes may be made to FIGURES 12A through 14B. For example, the sizes, shapes, and dimensions of the features of the scleral prostheses are for illustration only and can be altered in any suitable manner. Also, various features shown and described with respect to one of the scleral prostheses could be used with other scleral prostheses (including the prostheses shown in FIGURES 1 through 7G).

[00115] FIGURE 15 illustrates an example method 1500 for inserting a scleral prosthesis into a patient's eye in accordance with this disclosure. The method 1500 shown in FIGURE 15 is for illustration only. Other techniques could be used to insert a scleral prosthesis into a patient's eye without departing from the scope of this disclosure.

[00116] A scleral tunnel is formed in a patient's eye and a suture is placed through the scleral tunnel at step 1502. This could include, for example, using a tool with a curved cutting blade to form the scleral tunnel. This may also include pulling a suture through the scleral tunnel using the curved cutting blade. This may further include pulling a suture through the scleral tunnel after

the curved cutting blade has completed the formation of the tunnel.

[00117] The suture is looped around a scleral prosthesis at step 1504. This could include, for example, placing loops at the end of a suture around one end of the scleral prosthesis (such as is done in FIGURES 8A through 8F). This could also include looping a suture around the central body portion of the scleral prosthesis (such as is done in FIGURES 9A through 9C). This step may also involve placing the suture through a threader tube.

[00118] The scleral prosthesis is inserted into the threader tube at step 1506. This could include, for example, inserting one end of the scleral prosthesis into the threader tube. Any suitable portion of the scleral prosthesis can be inserted into the threader tube, such as a portion that prevents premature ejection of the scleral prosthesis within the scleral tunnel.

[00119] The threader tube is inserted into the scleral tunnel at step 1508. This could include, for example, pushing the lower portion 906 of the threader tube into the scleral tunnel. This could also include pulling the threader tube into the scleral tunnel using the suture. This could further include using the rod 915 to open the scleral tunnel before the body of the threader tube is pulled into the scleral tunnel. The scleral prosthesis is pulled into the scleral tunnel at step 1510. This could include, for example, pulling the scleral prosthesis into its proper position within the scleral tunnel using the threader tube and the suture.

[00120] The scleral prosthesis is removed from the threader tube at step 1512, and the threader tube and the suture are removed at step 1514. This could include, for

example, pulling the threader tube off the scleral prosthesis. This could also include pulling on one end of the suture to remove the suture from the scleral tunnel.

[00121] If necessary or desired, an insert can be placed between or around portions of the implanted scleral prosthesis at step 1516. This could include, for example, placing the insert between or around separated or divided portions of the scleral prosthesis to prevent rotation, flexing, ejection, or other movement by the scleral prosthesis.

[00122] Although FIGURE 15 illustrates one example of a method 1500 for inserting a scleral prosthesis into a patient's eye, various changes may be made to FIGURE 15. For example, any other suitable technique could be used to place a suture through the scleral tunnel. Also, any other suitable technique could be used to pull or push the scleral prosthesis into the scleral tunnel, including techniques omitting the use of a suture or rod.

[00123] It may be advantageous to set forth definitions of certain words and phrases used throughout this patent document. The terms "include" and "comprise," as well as derivatives thereof, mean inclusion without limitation. The term "or" is inclusive, meaning and/or. The phrases "associated with" and "associated therewith," as well as derivatives thereof, may mean to include, be included within, interconnect with, contain, be contained within, connect to or with, couple to or with, be communicable with, cooperate with, interleave, juxtapose, be proximate to, be bound to or with, have, have a property of, or the like.

[00124] While this disclosure has described certain embodiments and generally associated methods, alterations

and permutations of these embodiments and methods will be apparent to those skilled in the art. Accordingly, the above description of example embodiments does not define or constrain this disclosure. Other changes, substitutions, and alterations are also possible without departing from the spirit and scope of this disclosure, as defined by the following claims.

WHAT IS CLAIMED IS:

1. A scleral prosthesis comprising:

a first free end and a second free end, each end wider than a middle portion of the scleral prosthesis;

wherein multiple first portions form the first end of the scleral prosthesis, the first portions separated along at least half of a length of the scleral prosthesis.

2. The scleral prosthesis of Claim 1, wherein multiple second portions form the second end of the scleral prosthesis, the second portions separated lengthwise along the scleral prosthesis.

3. The scleral prosthesis of Claim 2, wherein the second portions are separated along less than a quarter of the length of the scleral prosthesis.

4. The scleral prosthesis of Claim 1, wherein the first and second ends comprise areas that project from sides of the scleral prosthesis to make the first and second ends wider than the middle portion of the scleral prosthesis.

5. The scleral prosthesis of Claim 4, wherein the areas that project from the sides of the scleral prosthesis at the first end of the scleral prosthesis comprise hook-shaped areas.

6. The scleral prosthesis of Claim 5, wherein the hook-shaped areas at the first end of the scleral prosthesis are hooked towards the second end of the scleral prosthesis.

7. The scleral prosthesis of Claim 4, wherein the areas that project from the sides of the scleral prosthesis are generally cylindrical with flat bottoms.

8. The scleral prosthesis of Claim 4, wherein the areas that project from the sides of the scleral prosthesis are generally triangular.

9. The scleral prosthesis of Claim 1, wherein each of the first portions includes a ridge extending inwardly from that first portion towards the other first portion of the first end.

10. The scleral prosthesis of Claim 1, wherein sides of the first and second ends are aligned along a straight side of the prosthesis.

11. The scleral prosthesis of Claim 1, further comprising:

an insert placed between or around the first portions of the scleral prosthesis to maintain a separation of the first portions.

12. A system comprising:

a scleral prosthesis comprising a first free end and a second free end, each end wider than a middle portion of the scleral prosthesis, multiple first portions forming the first end of the scleral prosthesis, the first portions separated along at least half of a length of the scleral prosthesis; and

a threader tube into which the first portions of the

scleral prosthesis are at least partially inserted, the threader tube configured to be transported through a scleral tunnel in scleral tissue of an eye and to release the scleral prosthesis for implantation of the scleral prosthesis in the scleral tunnel.

13. The system of Claim 12, wherein the threader tube is configured to push the first portions of the scleral prosthesis towards each other to reduce a width of the first end of the scleral prosthesis.

14. The system of Claim 12, further comprising:

a suture placed through the threader tube and looped over part of the scleral prosthesis.

15. The system of Claim 14, wherein the suture comprises multiple loops configured to loop over multiple areas that project from sides of the scleral prosthesis at the first end of the scleral prosthesis.

16. The system of Claim 14, wherein:

multiple second portions form the second end of the scleral prosthesis, the second portions separated lengthwise along the scleral prosthesis; and

the suture is looped over a central portion of the scleral prosthesis, the suture located between the second portions of the scleral prosthesis.

17. The system of Claim 12, wherein:

the threader tube comprises a first end portion and a second end portion configured to receive the scleral prosthesis; and

the system further comprises a rod partially inserted into the first end portion of the threader tube.

18. The system of Claim 17, wherein the rod comprises a tapered and rounded end configured to be inserted into the scleral tunnel ahead of the threader tube.

19. The system of Claim 12, wherein multiple second portions form the second end of the scleral prosthesis, the second portions separated lengthwise along the scleral prosthesis.

20. The system of Claim 19, wherein the second portions are separated along less than a quarter of the length of the scleral prosthesis.

21. The system of Claim 12, wherein each of the first portions includes a ridge extending inwardly from that first portion towards the other first portion of the first end.

22. The system of Claim 12, wherein sides of the first and second ends are aligned along a straight side of the prosthesis.

23. An implantation device comprising:

a first end portion configured to be inserted into a scleral tunnel in scleral tissue of an eye; and

a second end portion configured to receive a scleral prosthesis, the second end portion configured to be transported through the scleral tunnel behind the first end portion and to release the scleral prosthesis for implantation of the scleral prosthesis in the scleral tunnel.

24. The implantation device of Claim 23, further comprising:

a rod partially inserted into the first end portion.

25. The implantation device of Claim 24, wherein the rod comprises a tapered and rounded end.

26. The implantation device of Claim 23, wherein:

the first end portion is relatively narrower and has an angled end; and

the second end portion is relatively wider.

27. The implantation device of Claim 23, further comprising:

a suture placed through the first and second end portions and arranged to be looped over part of the scleral prosthesis.

28. A method comprising:

inserting a scleral prosthesis into a threader tube;

pulling the scleral prosthesis into a scleral tunnel in scleral tissue of an eye using the threader tube; and

removing the scleral prosthesis from the threader tube for implantation in the scleral tunnel.

29. The method of Claim 28, further comprising:

looping a suture over a portion of the scleral prosthesis, wherein the suture is placed through the threader tube; and

pulling the scleral prosthesis into the scleral tunnel using the suture.

30. The method of Claim 28, wherein:

the threader tube comprises a narrower first end and a wider second end;

the scleral prosthesis is inserted into the second end of the threader tube; and

the first end of the threader tube enters the scleral tunnel before the second end of the threader tube enters the scleral tunnel.

31. The method of Claim 30, wherein:

a rod extends from the first end of the threader tube; and

the rod enters the scleral tunnel before the first end of the threader tube enters the scleral tunnel.

32. A scleral prosthesis comprising:

a first free end and a second free end, each end wider than a middle portion of the scleral prosthesis;

wherein multiple first portions form the first end of the scleral prosthesis, the first portions separated along a substantial portion of the scleral prosthesis.

33. A scleral prosthesis comprising:

a body having a first shape at a first temperature and a second shape at a second temperature, the body having

first and second ends that are narrower in the first shape and wider in the second shape, the first and second ends in the second shape being wider than a middle portion of the body in the second shape.

34. The scleral prosthesis of Claim 33, wherein:
the first shape is relatively flat; and
the second shape is at least partially arched.

35. The scleral prosthesis of Claim 33, wherein each end comprises multiple sections, the multiple sections at each end angled towards each other in the first shape, the multiple sections at each end angled away from each other in the second shape.

36. The scleral prosthesis of Claim 33, wherein the body is formed from a shape-memory metal.

37. The scleral prosthesis of Claim 33, wherein the second temperature comprises a temperature associated with scleral tissue of a patient's eye.

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IN THE CANADIAN INTELLECTUAL PROPERTY OFFICE

Applicant: **Refocus Group, Inc.**

Serial No.: **Not yet Assigned**
based on International Patent Application No. PCT/US2007/015774

Title: **Scleral Prosthesis for Treating Presbyopia and Other Eye Disorders and Related Devices and Methods**

Filed: **July 11, 2007**

Our Ref.: **74767/00002**

January 9, 2009

The Commissioner of Patents
Canadian Intellectual Property Office
50 Victoria Street
Place du Portage, Phase I
Gatineau, Quebec, K1A 0C9

SUBMISSION OF FORMAL DRAWINGS

Dear Madam:

Kindly replace all drawing sheets with the enclosed replacement formal drawing sheets. No new subject matter is introduced by way of the present submission.

The Office is requested to contact Sean X. Zhang, Ph.D. at 416-863-5839 should any further information be required concerning this matter.

Respectfully submitted,
BLAKE, CASSELS & GRAYDON LLP

Blake, Cassels & Graydon LLP.

Agents for the Applicant
SB/SZH/pp
/enclosure

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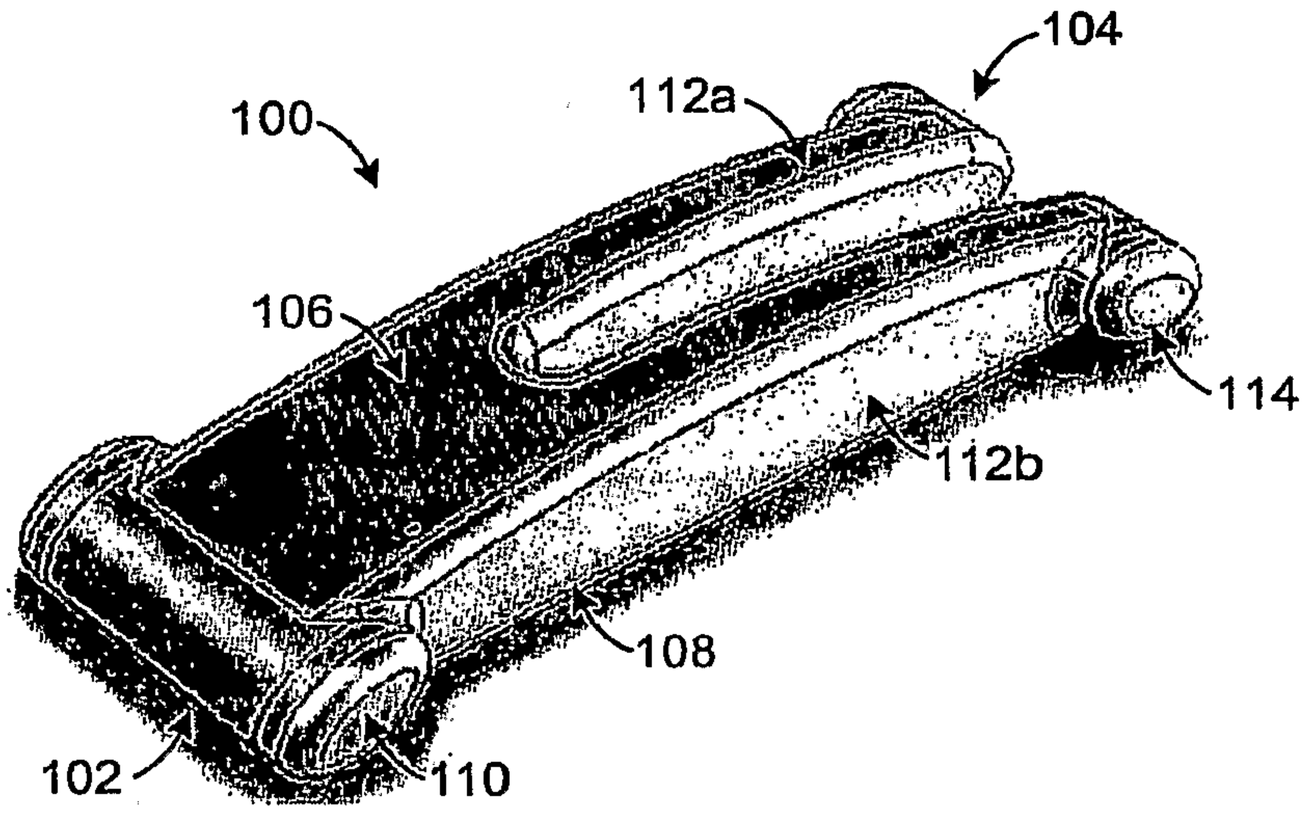


FIGURE 1A

FIGURE 1B

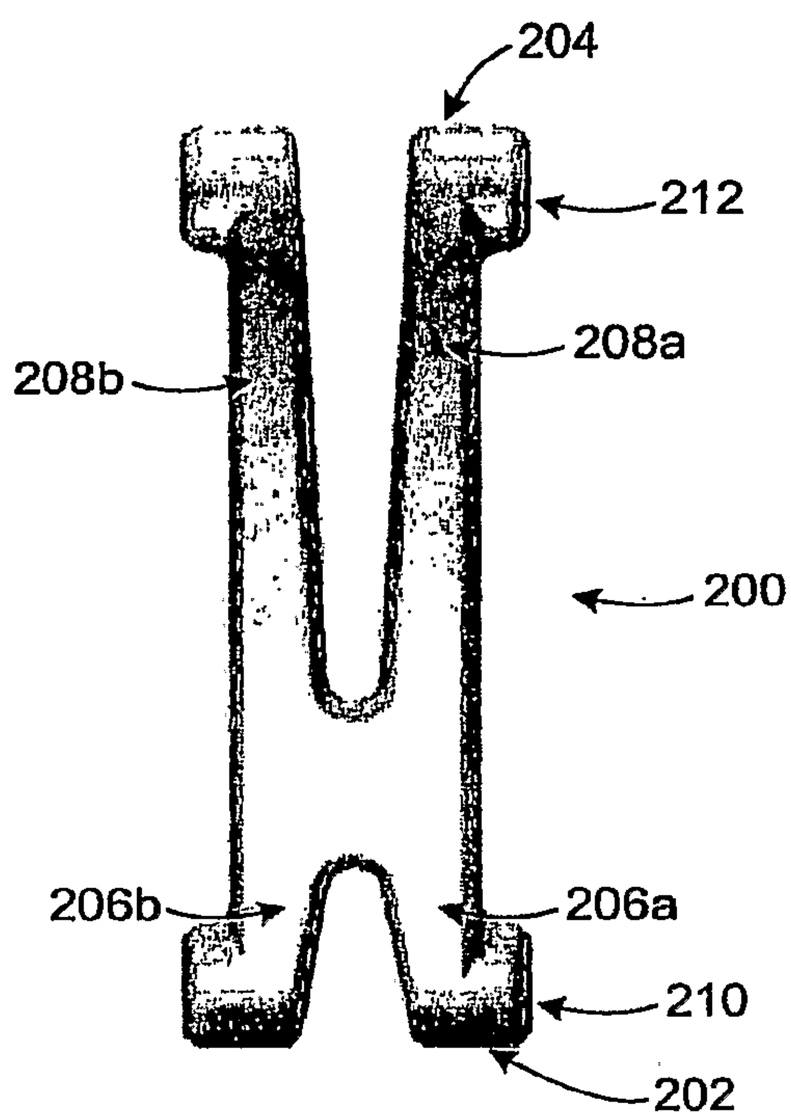


FIGURE 2A

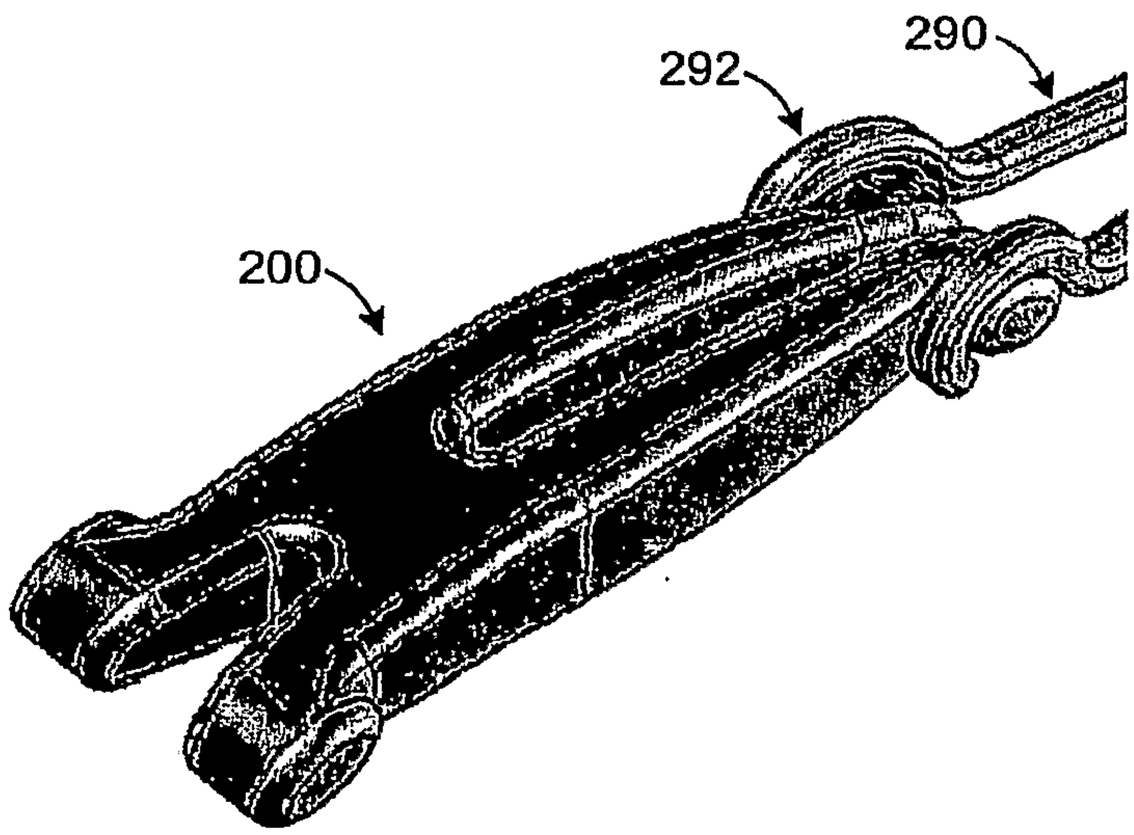


FIGURE 2B

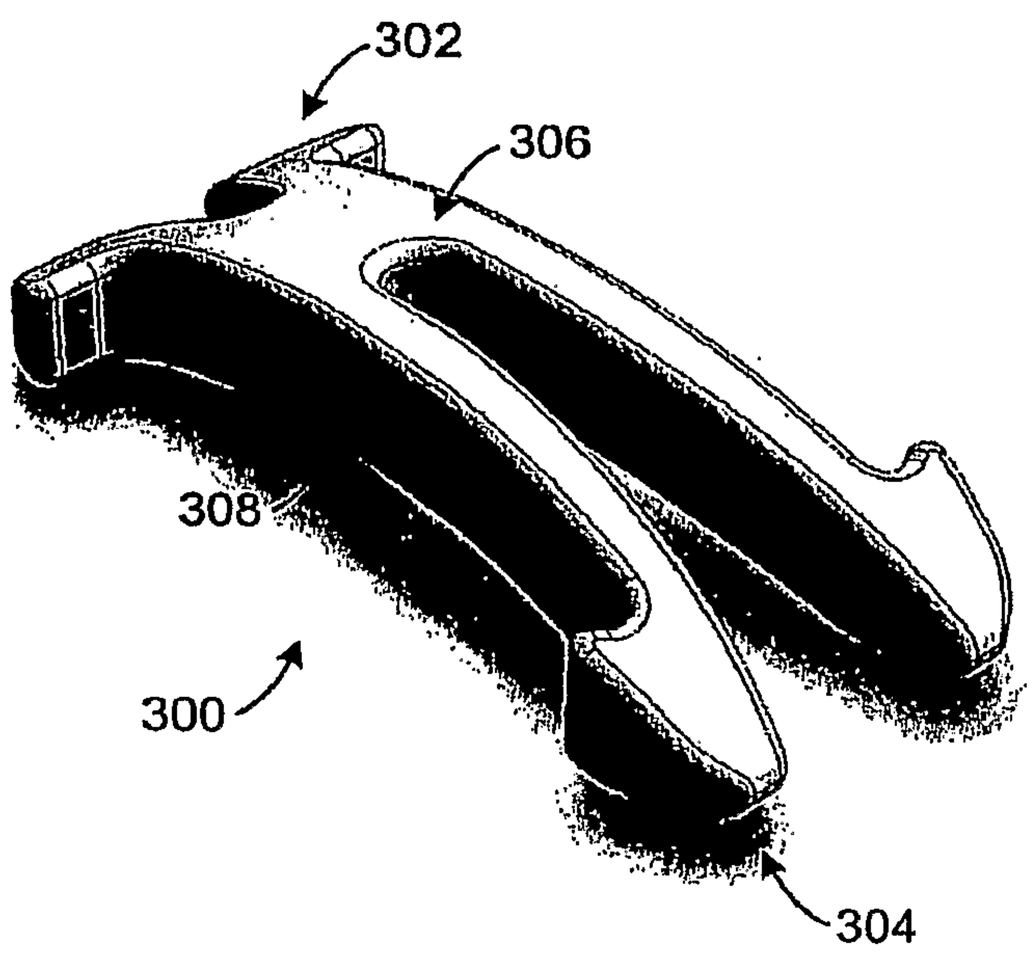


FIGURE 3A

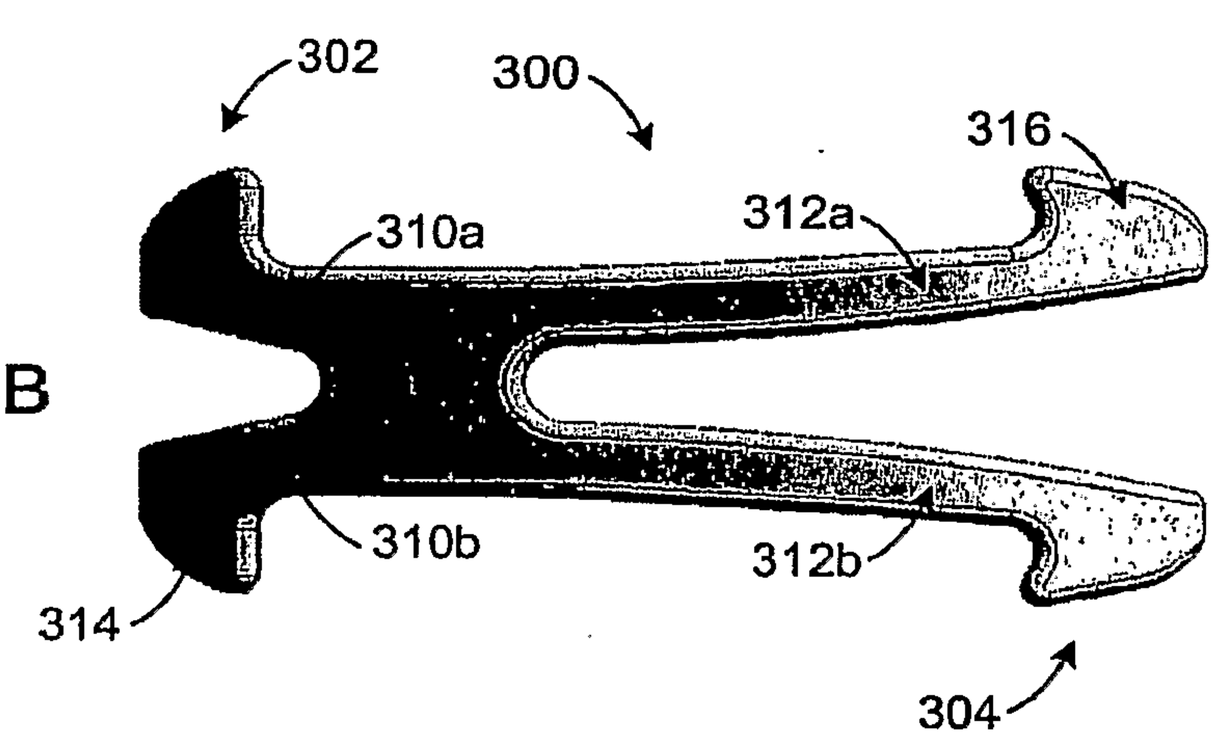


FIGURE 3B

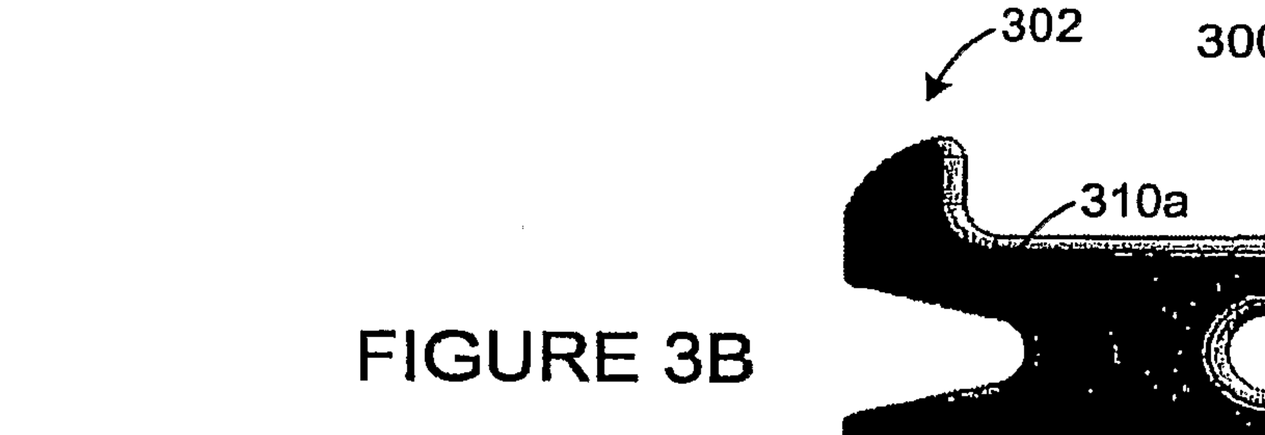


FIGURE 3C

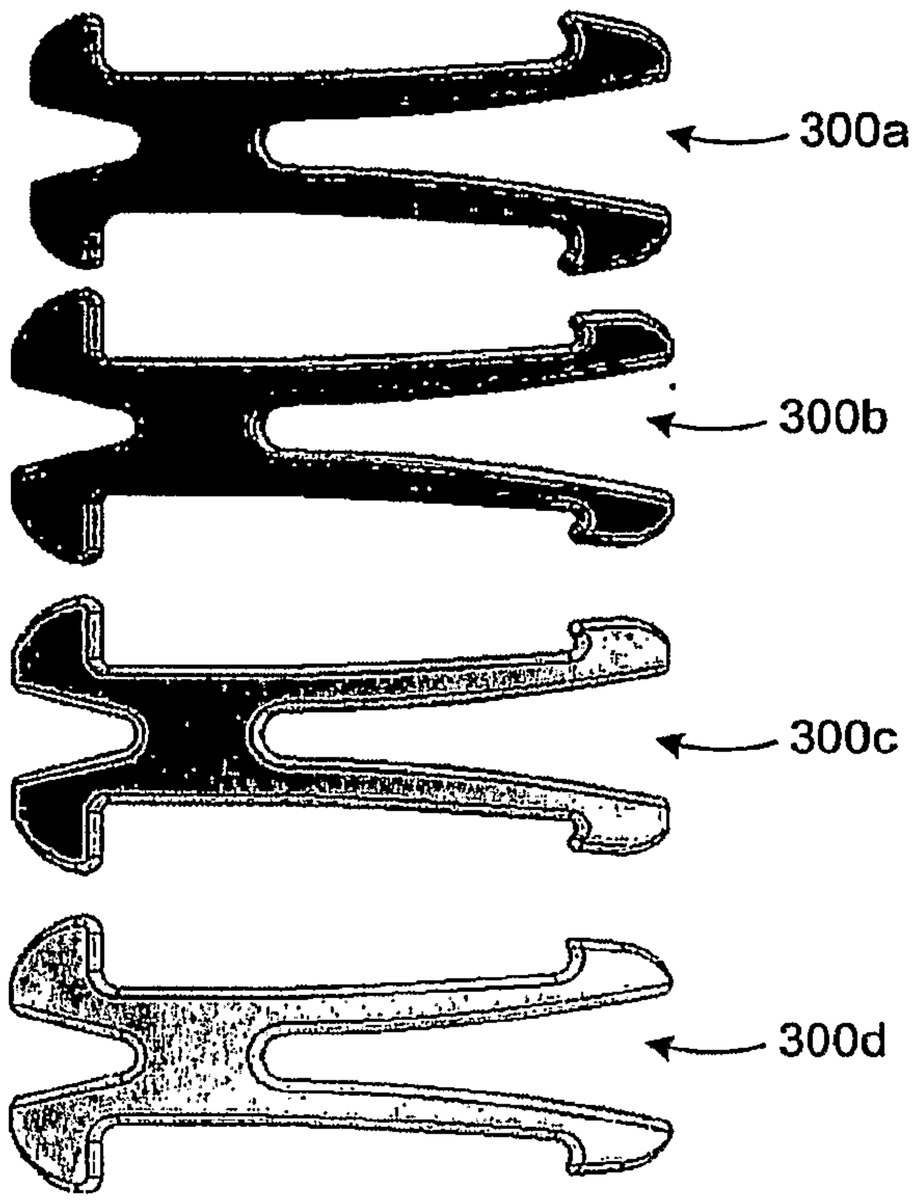


FIGURE 3D

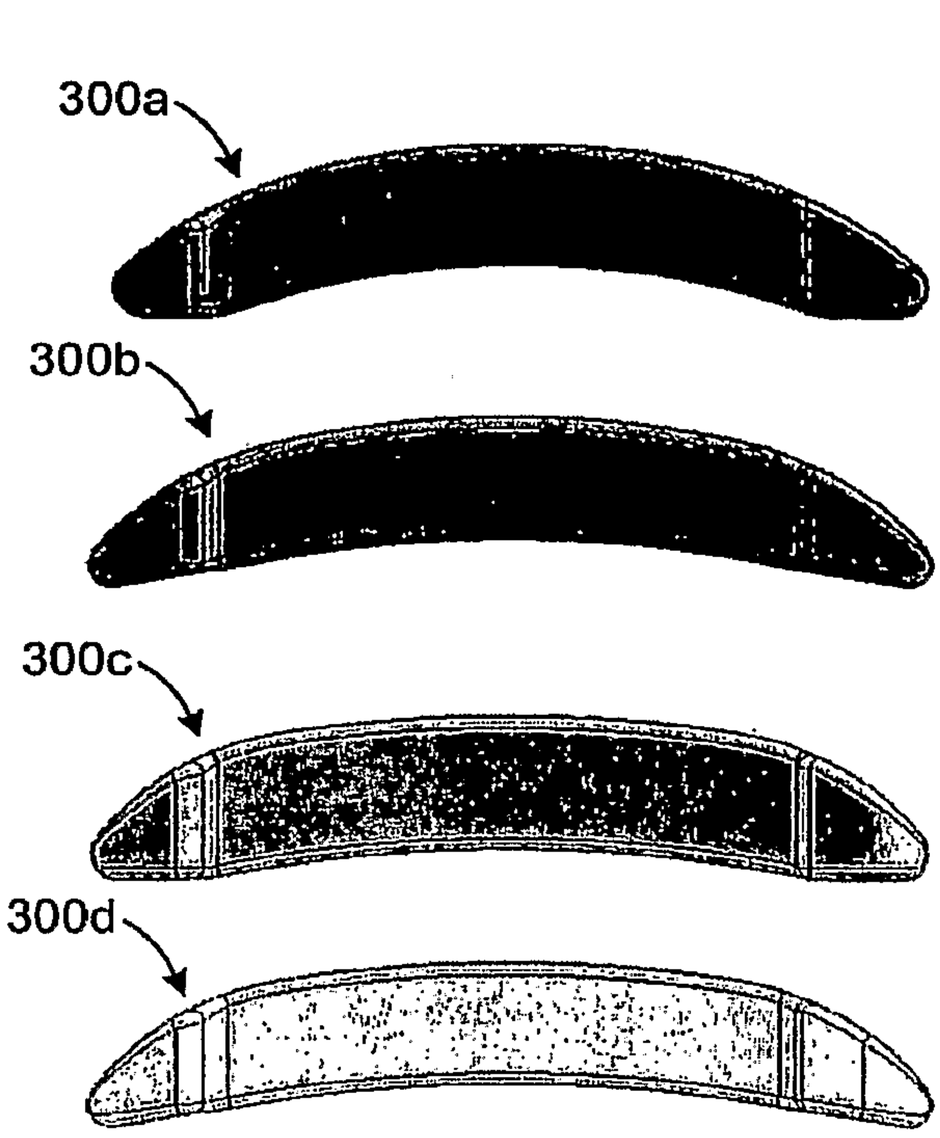


FIGURE 3E

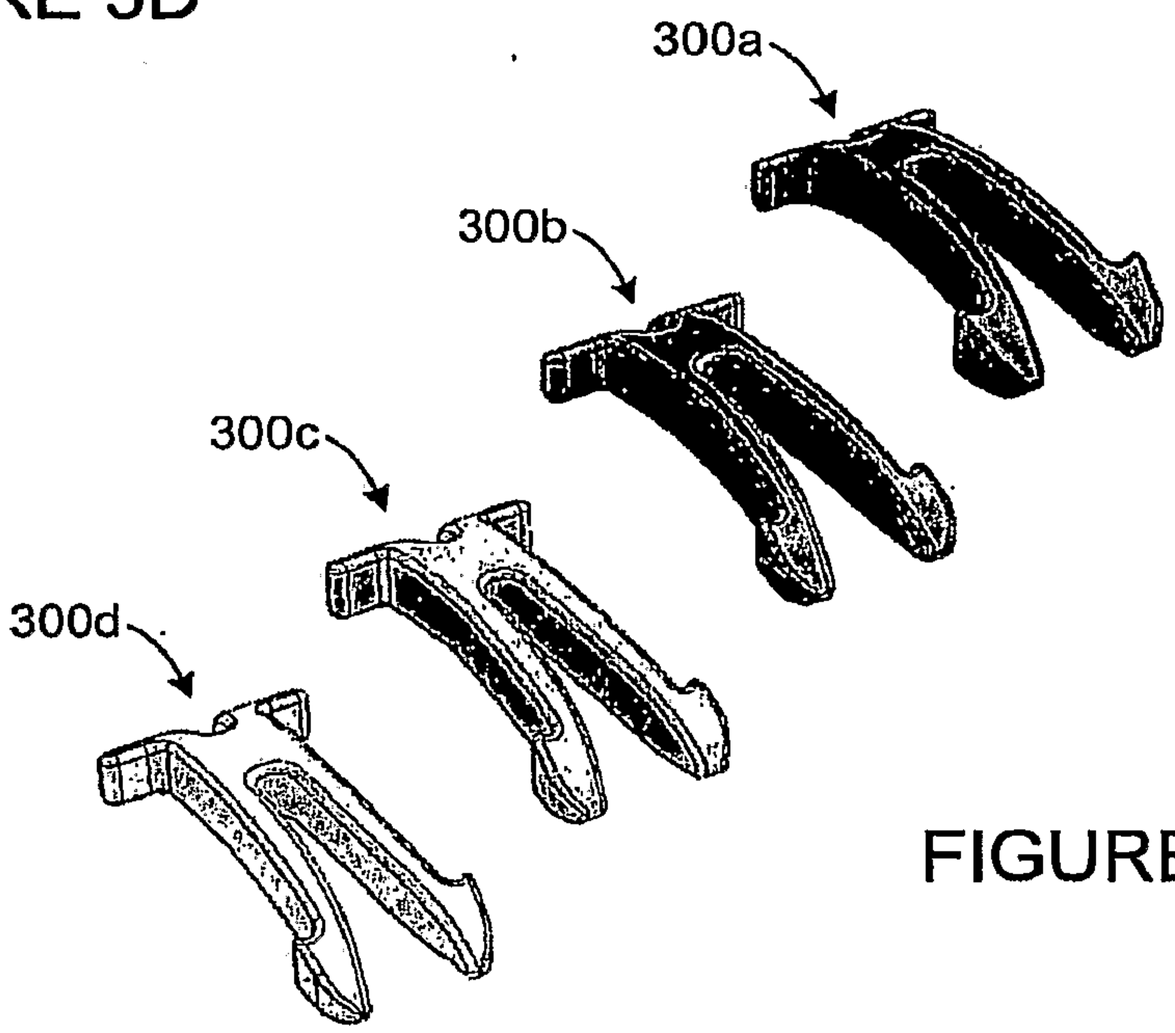


FIGURE 3F

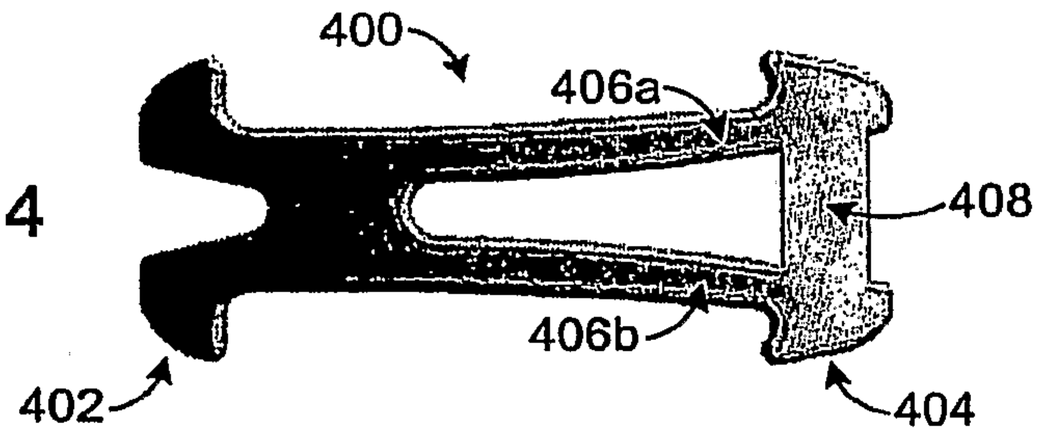


FIGURE 4

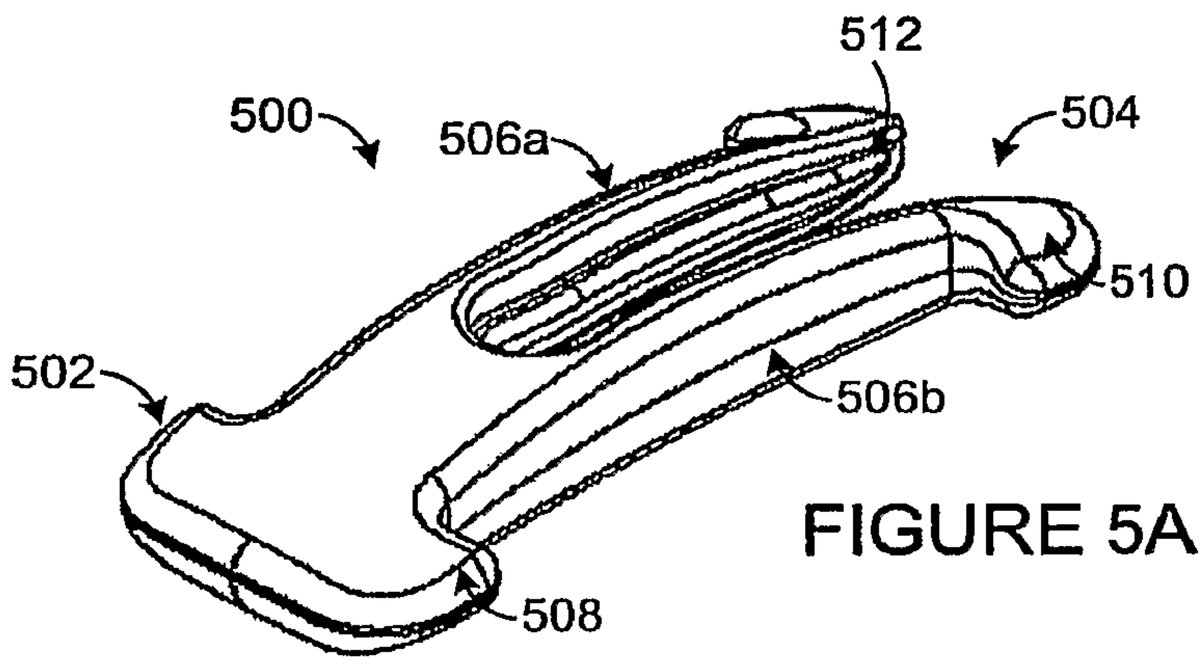


FIGURE 5A

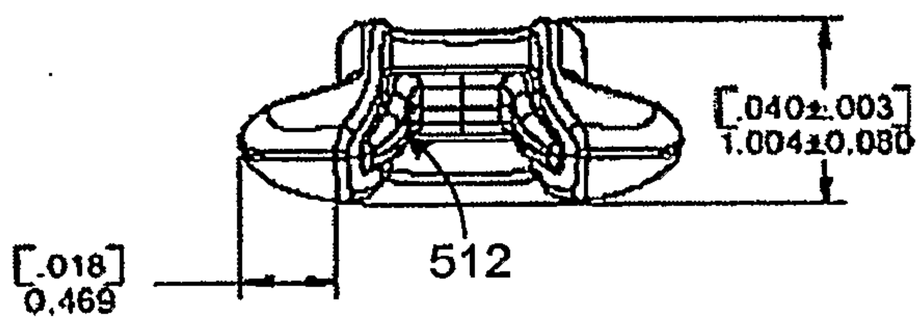


FIGURE 5B

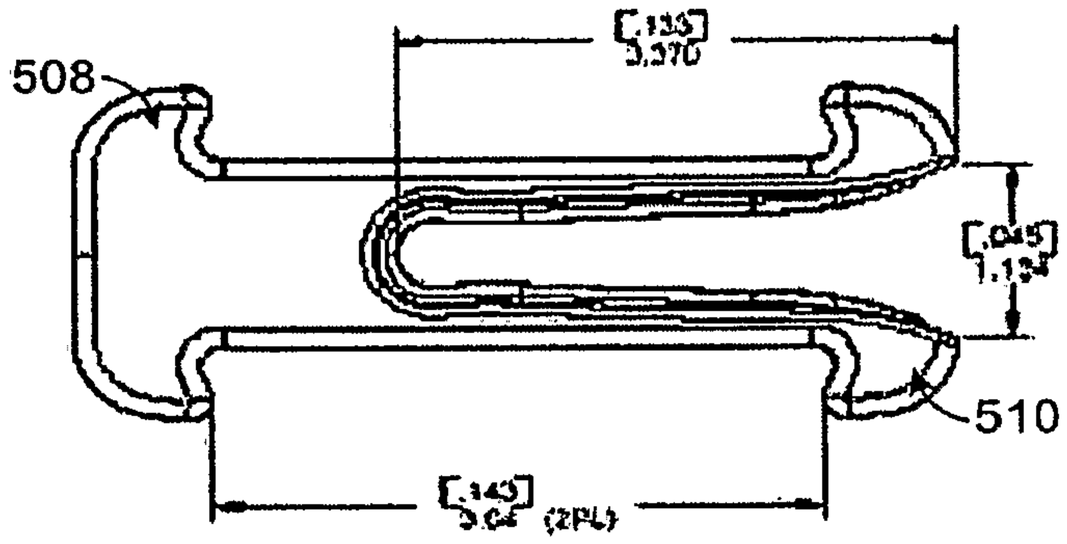
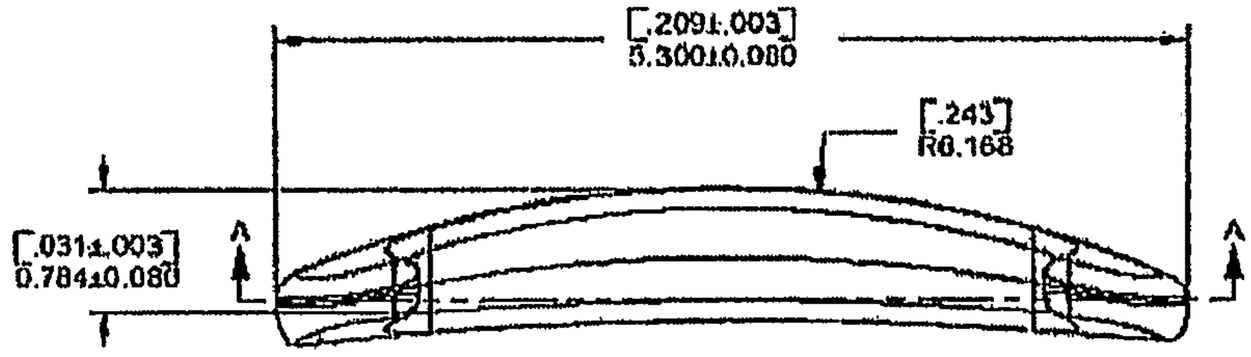


FIGURE 5C

FIGURE 5D



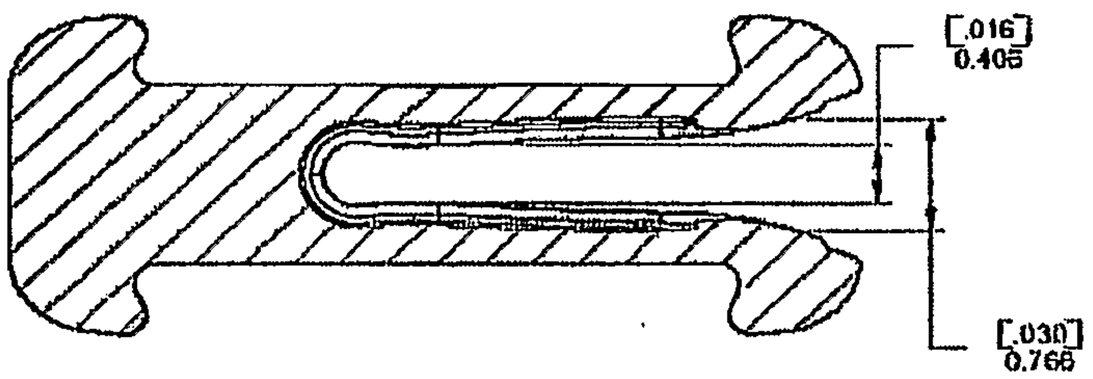
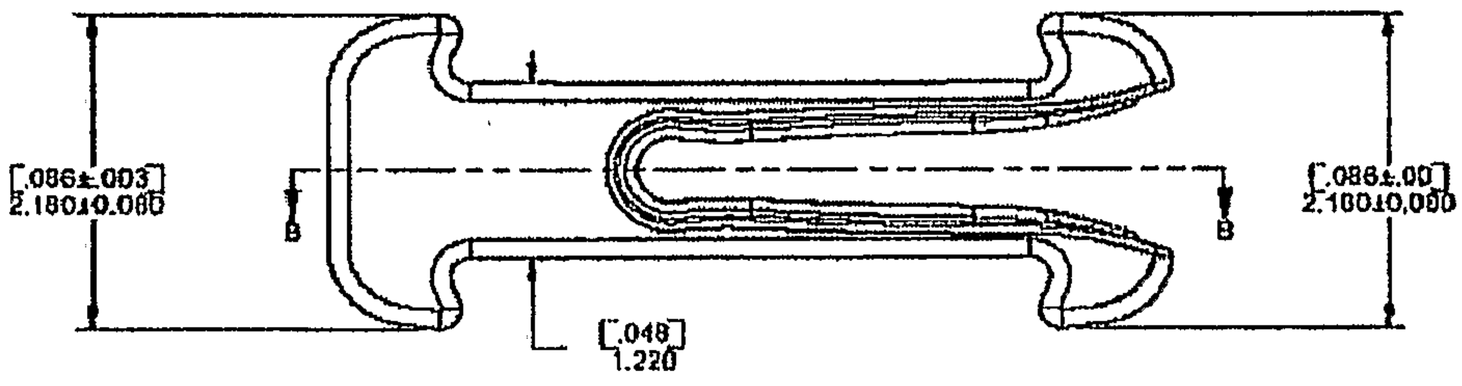


FIGURE 5E

FIGURE 5F



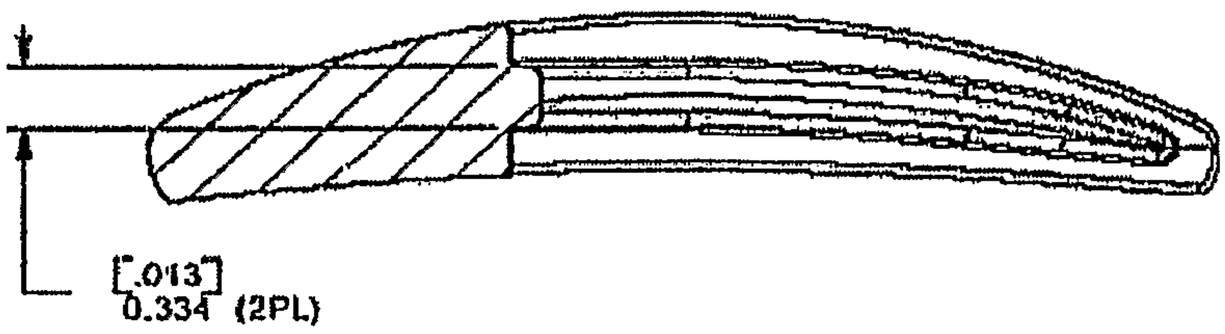


FIGURE 5G

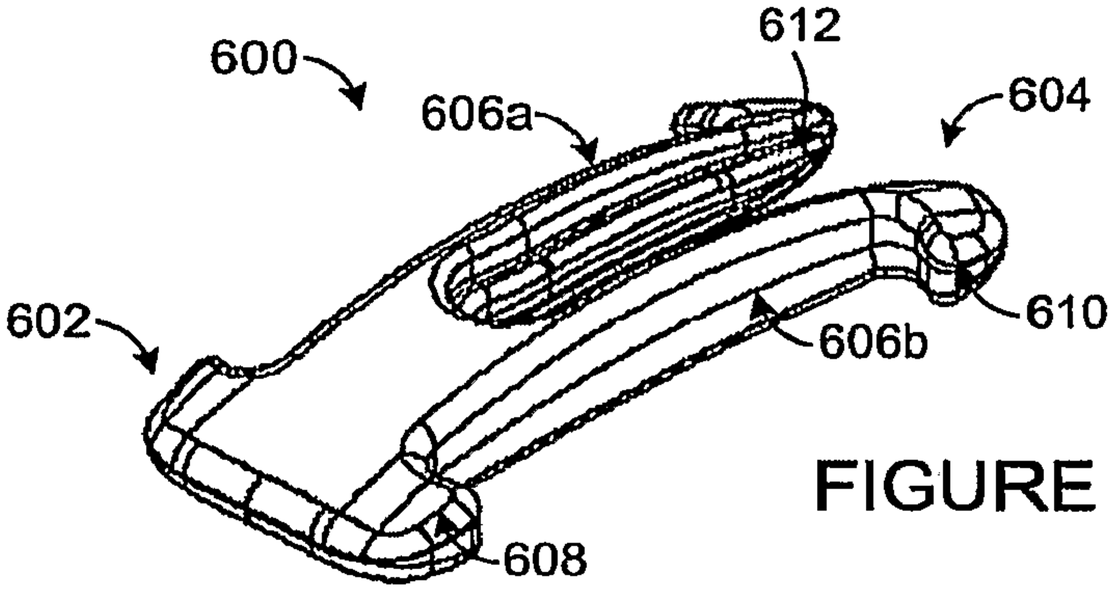


FIGURE 6A

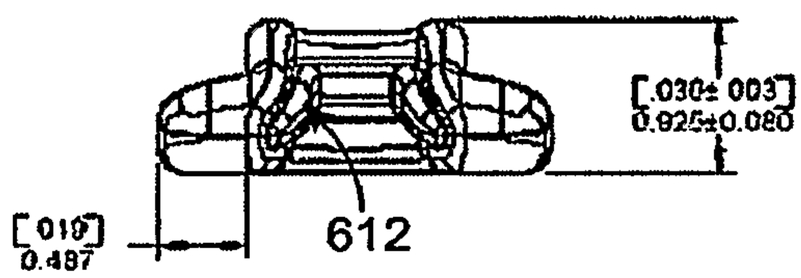
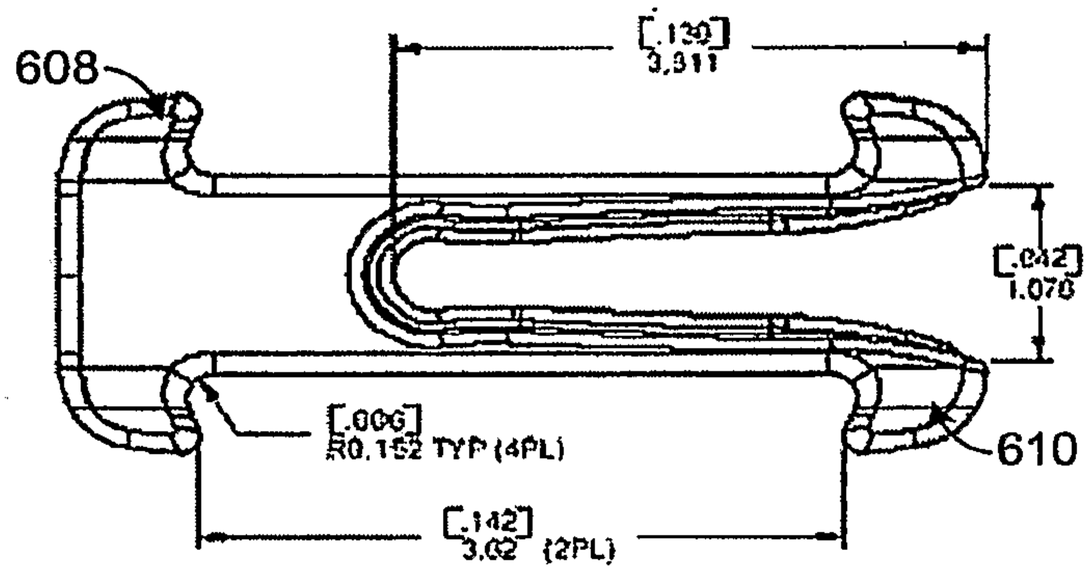


FIGURE 6B

FIGURE 6C



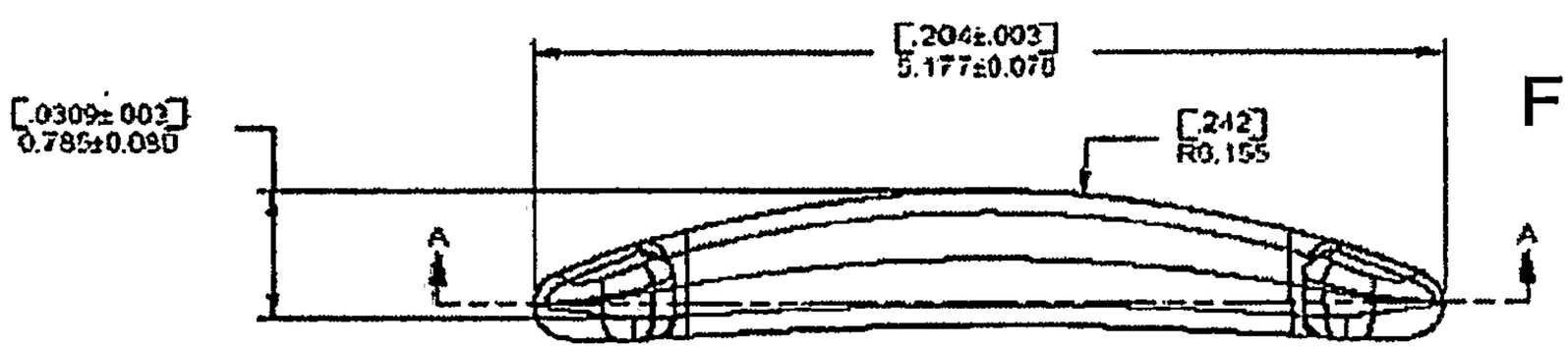


FIGURE 6D

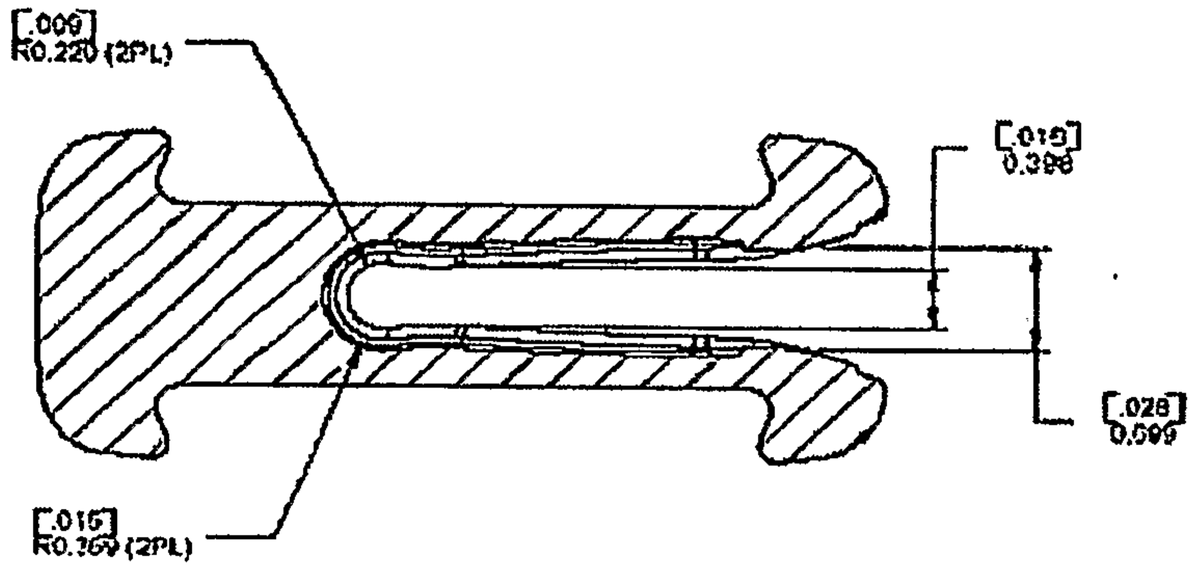


FIGURE 6E

FIGURE 6F

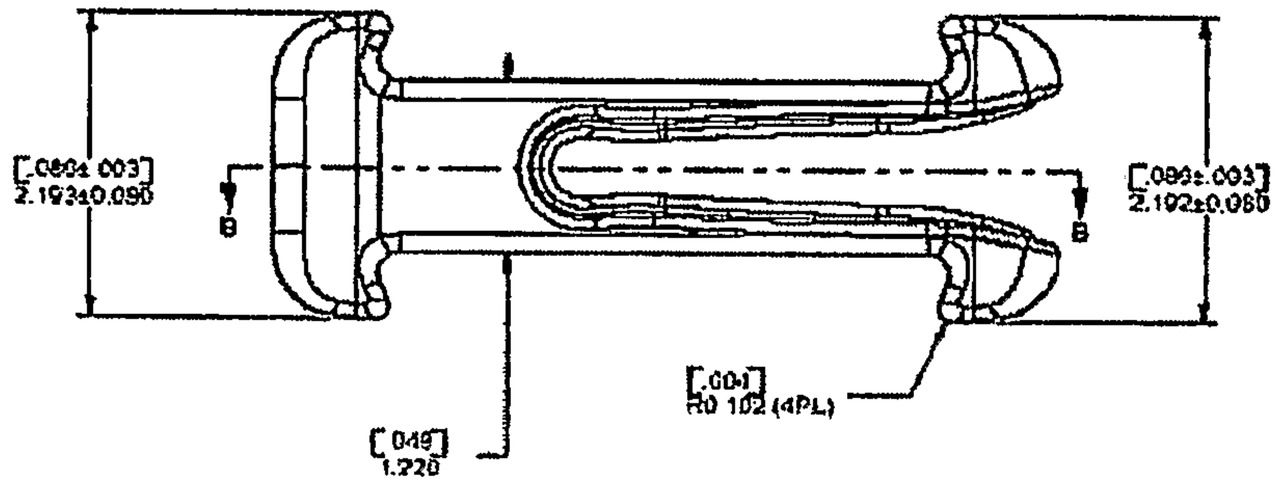
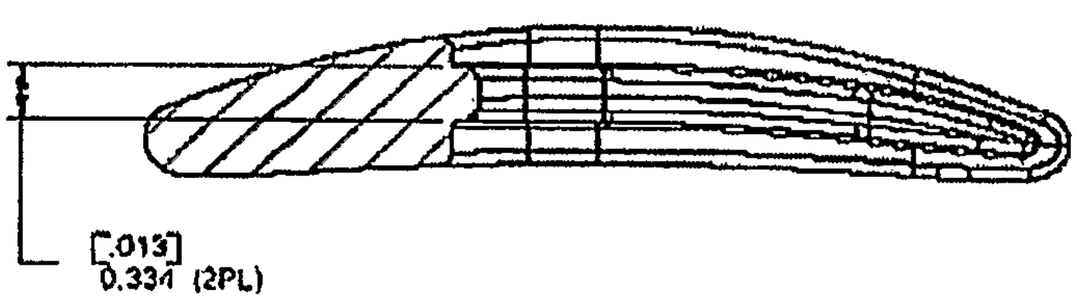


FIGURE 6G



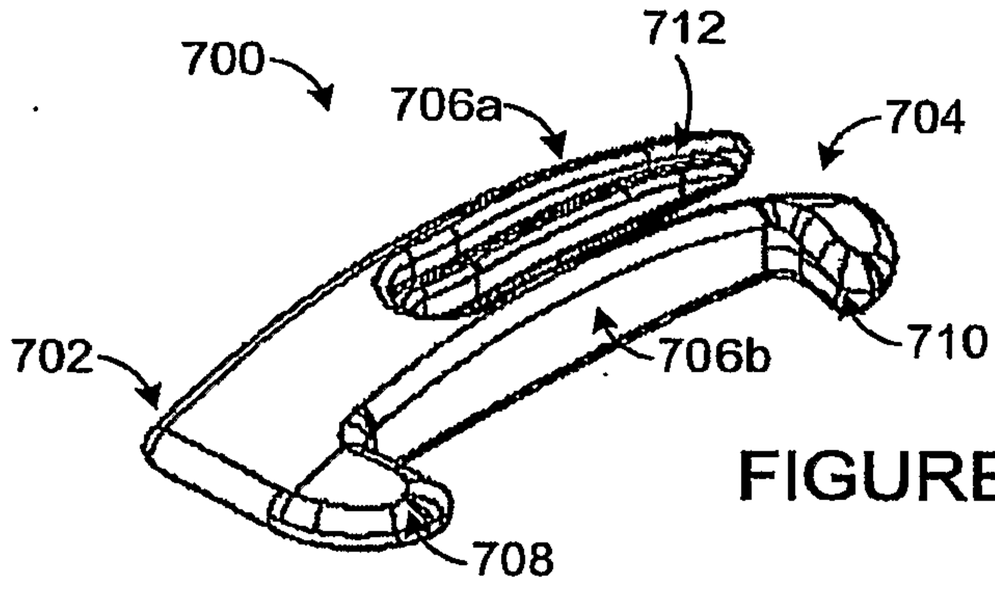
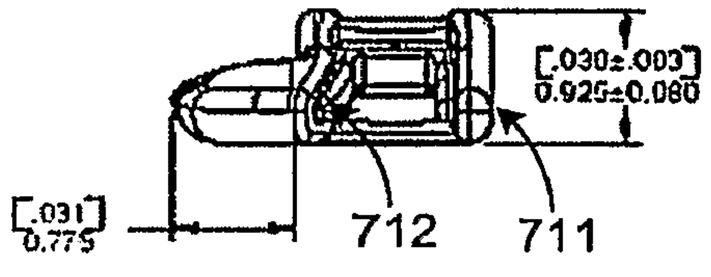


FIGURE 7A

FIGURE 7B



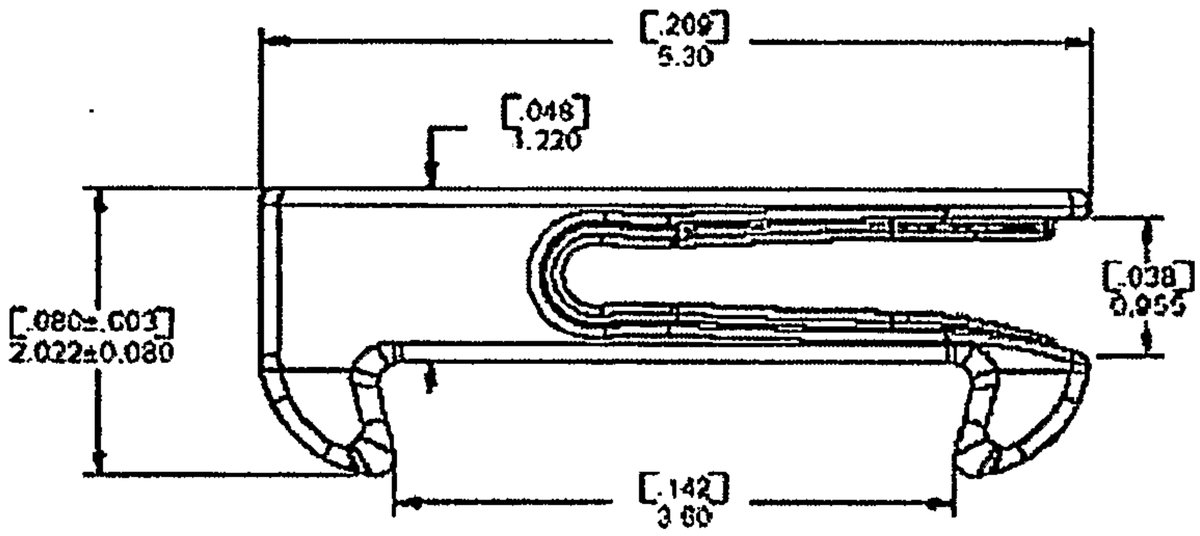
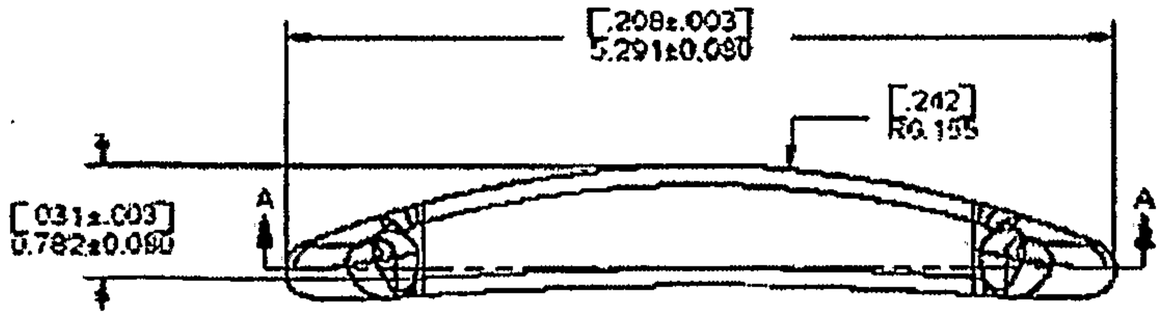


FIGURE 7C

FIGURE 7D



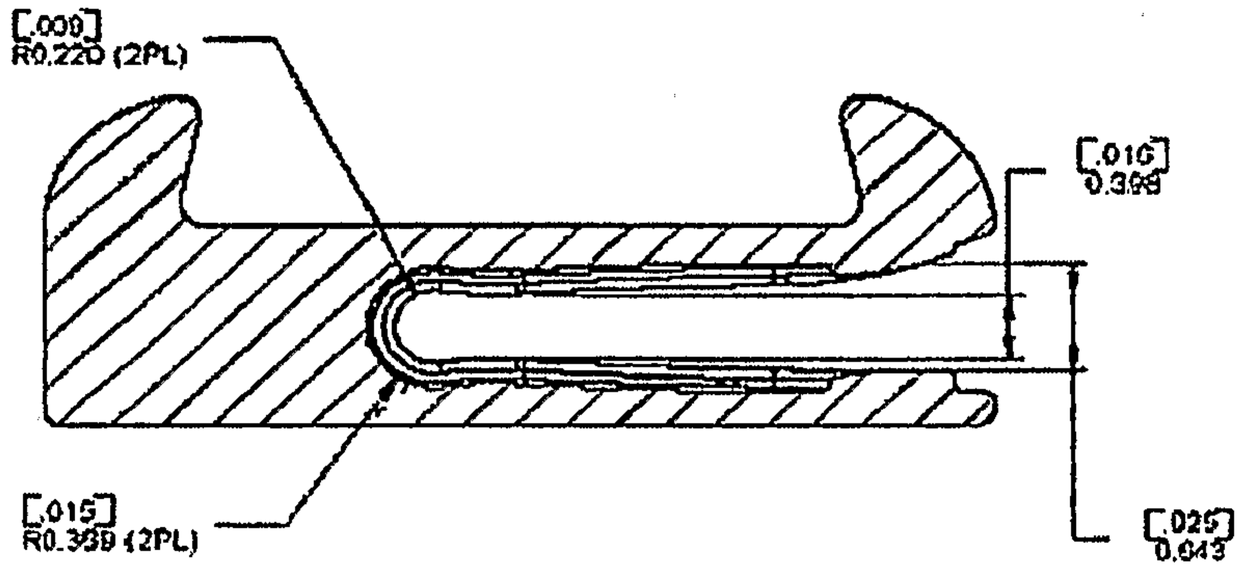
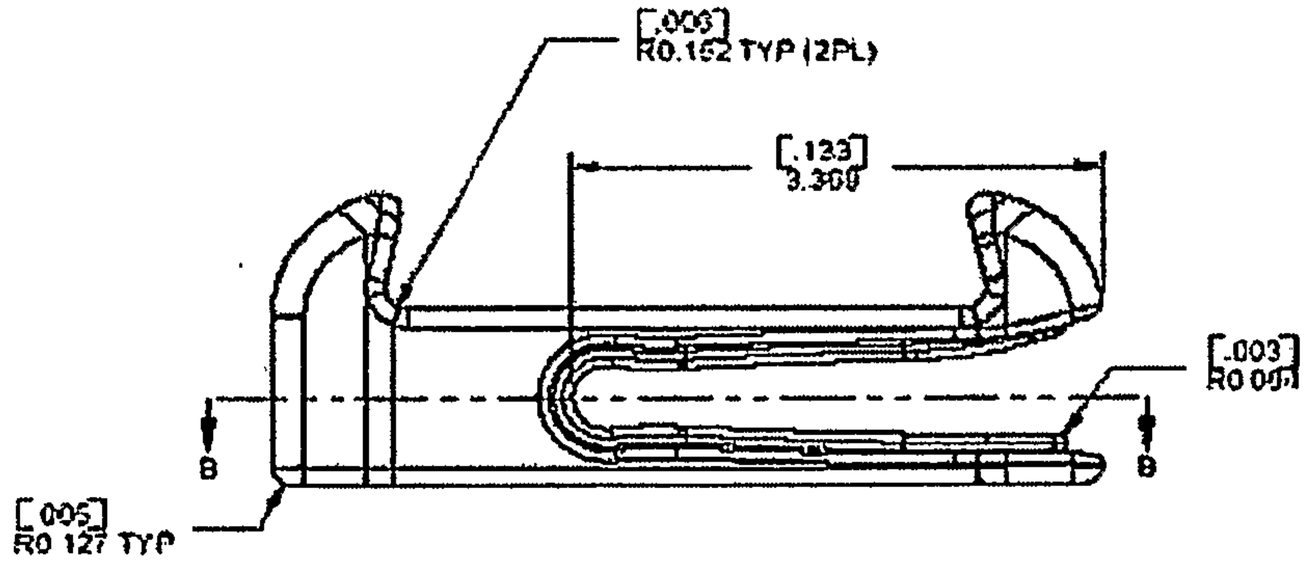


FIGURE 7E

FIGURE 7F



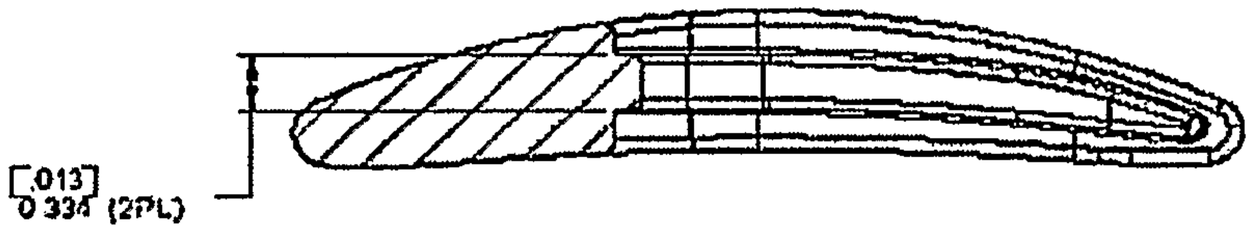


FIGURE 7G

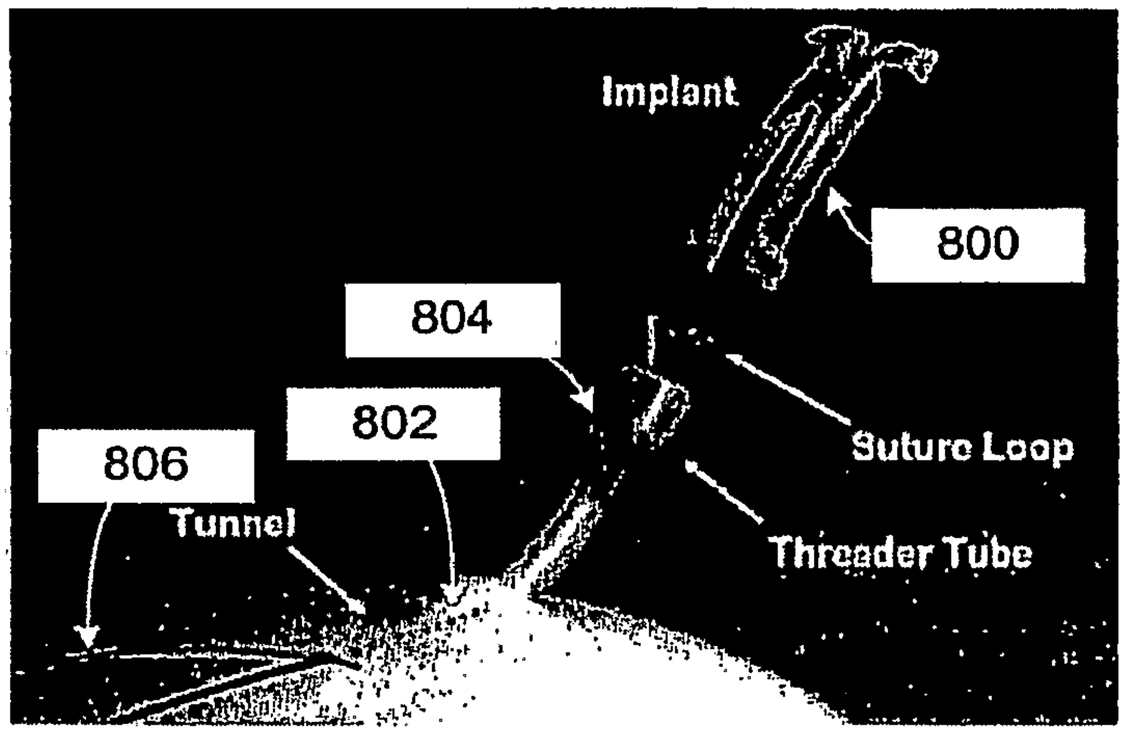


FIGURE 8A

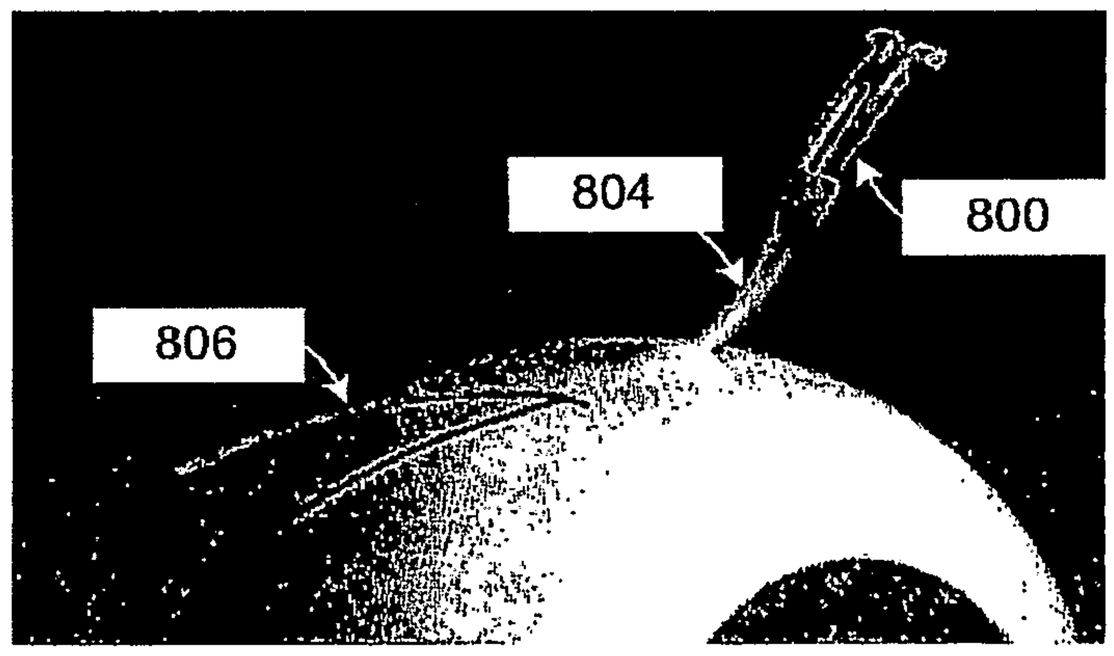


FIGURE 8B

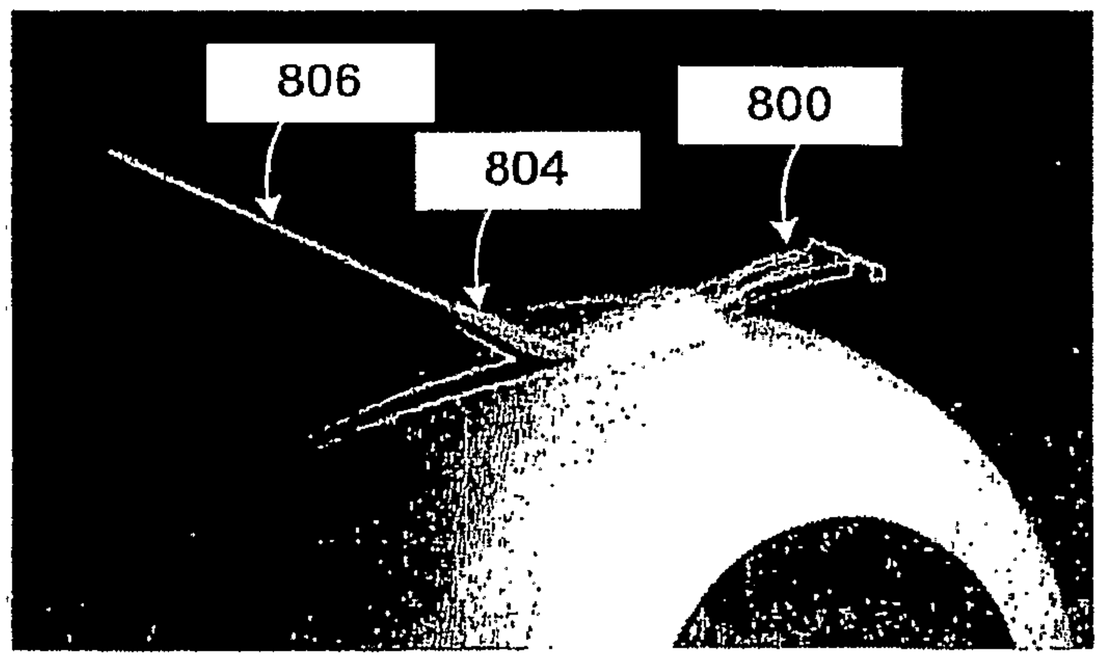


FIGURE 8C

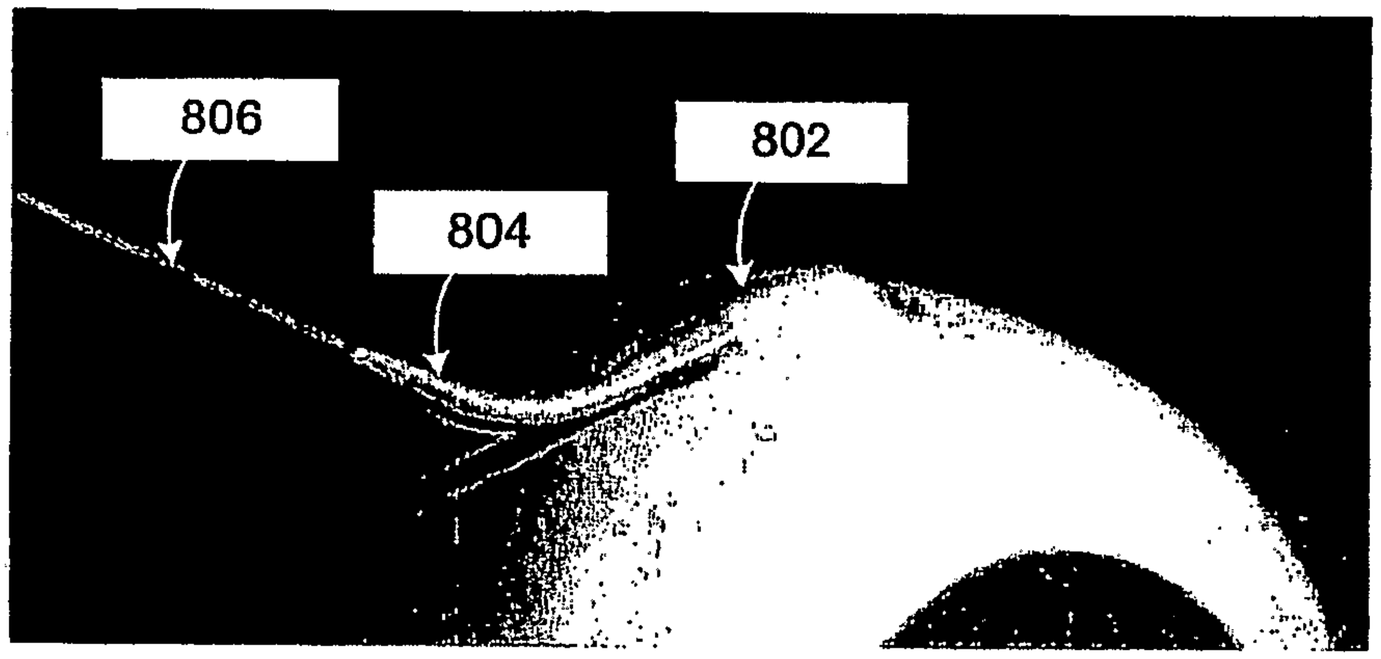


FIGURE 8D

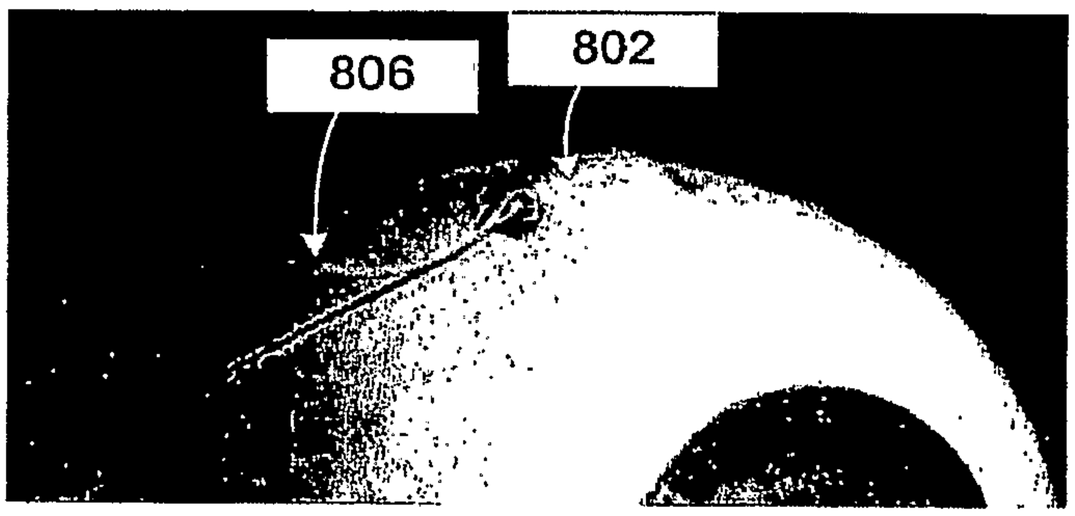


FIGURE 8E

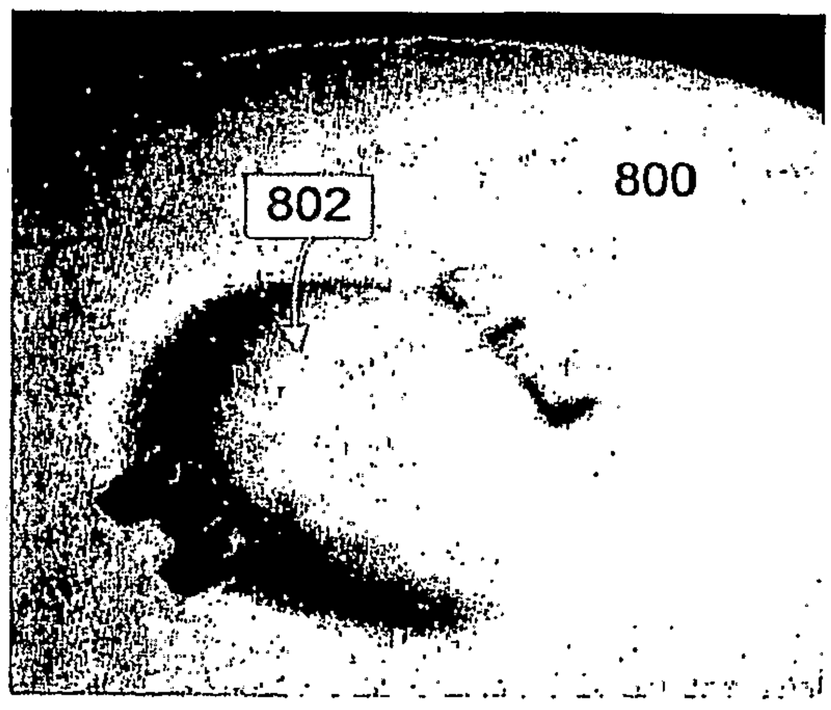


FIGURE 8F

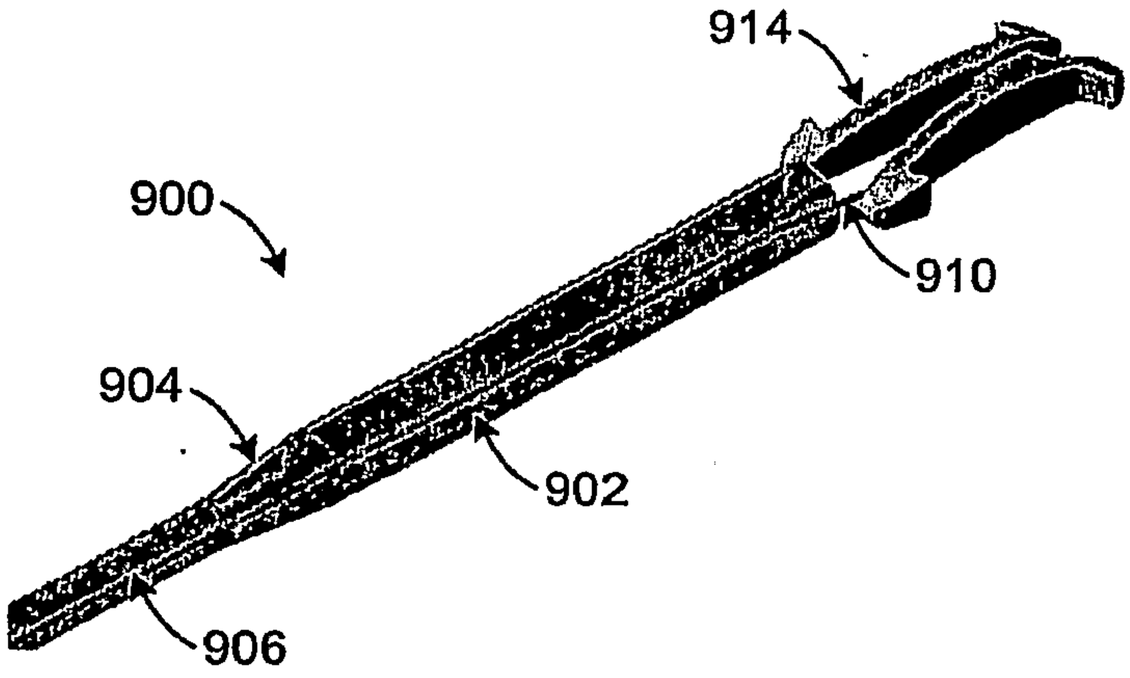


FIGURE 9A

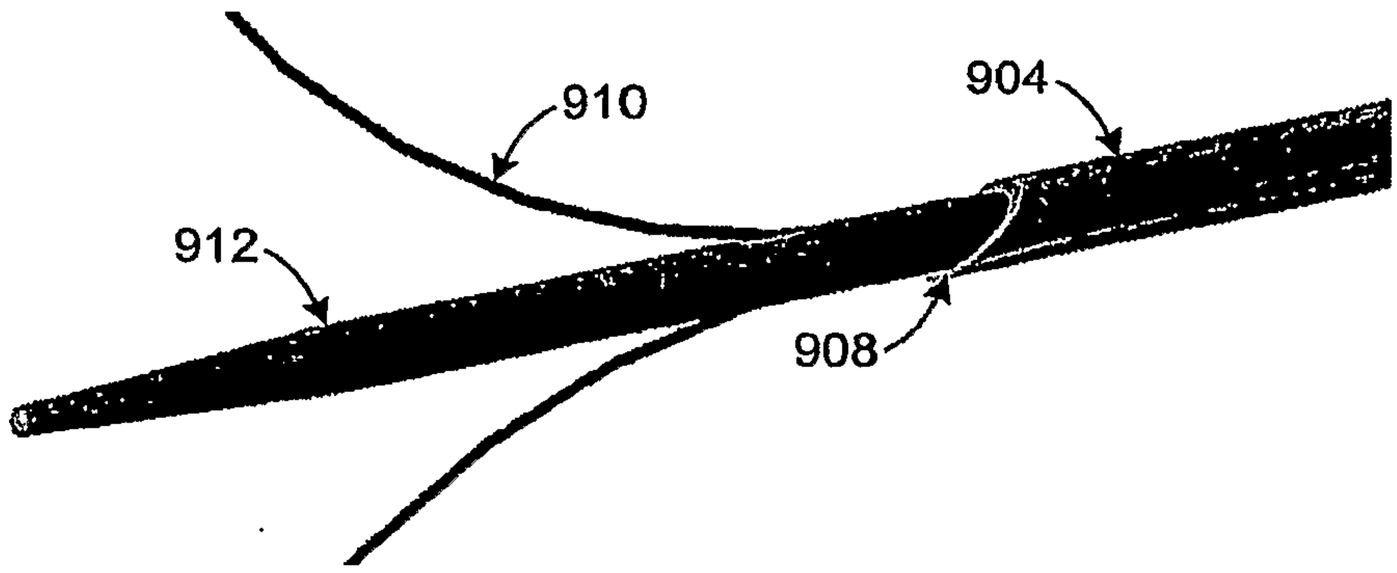


FIGURE 9B

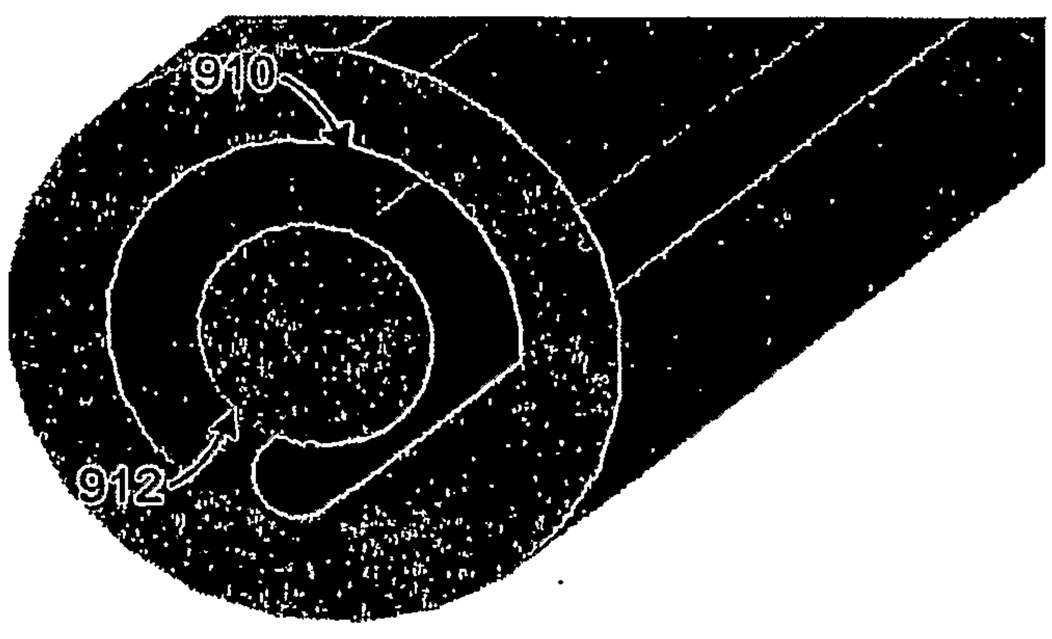


FIGURE 9C

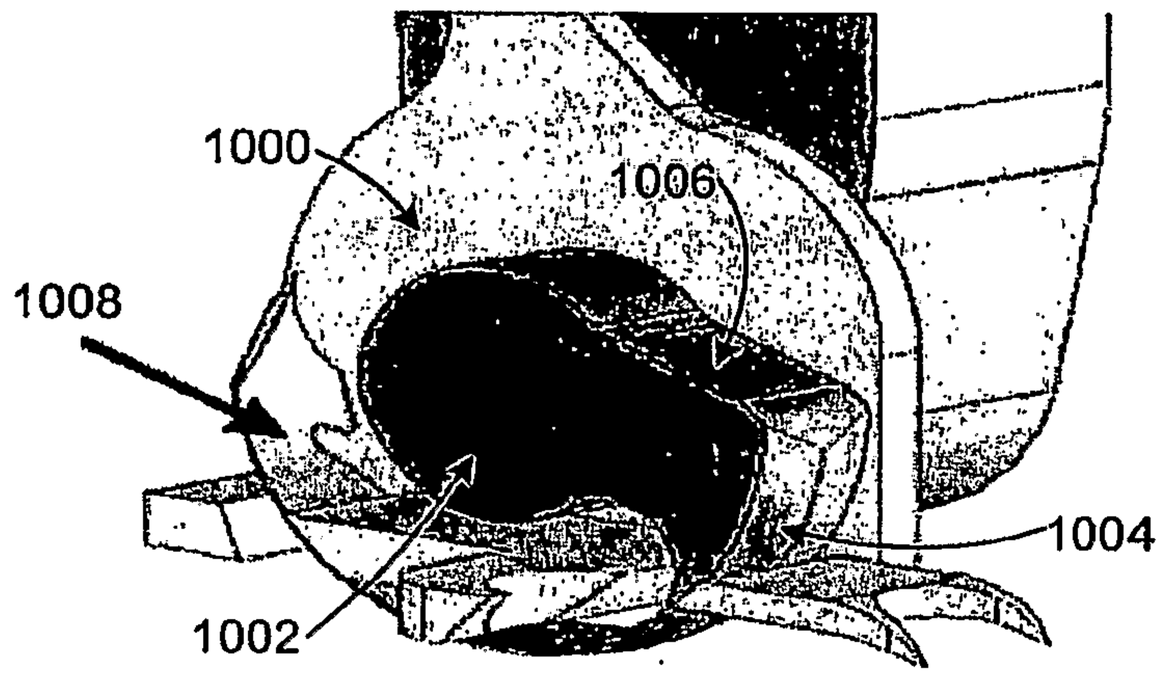


FIGURE 10A

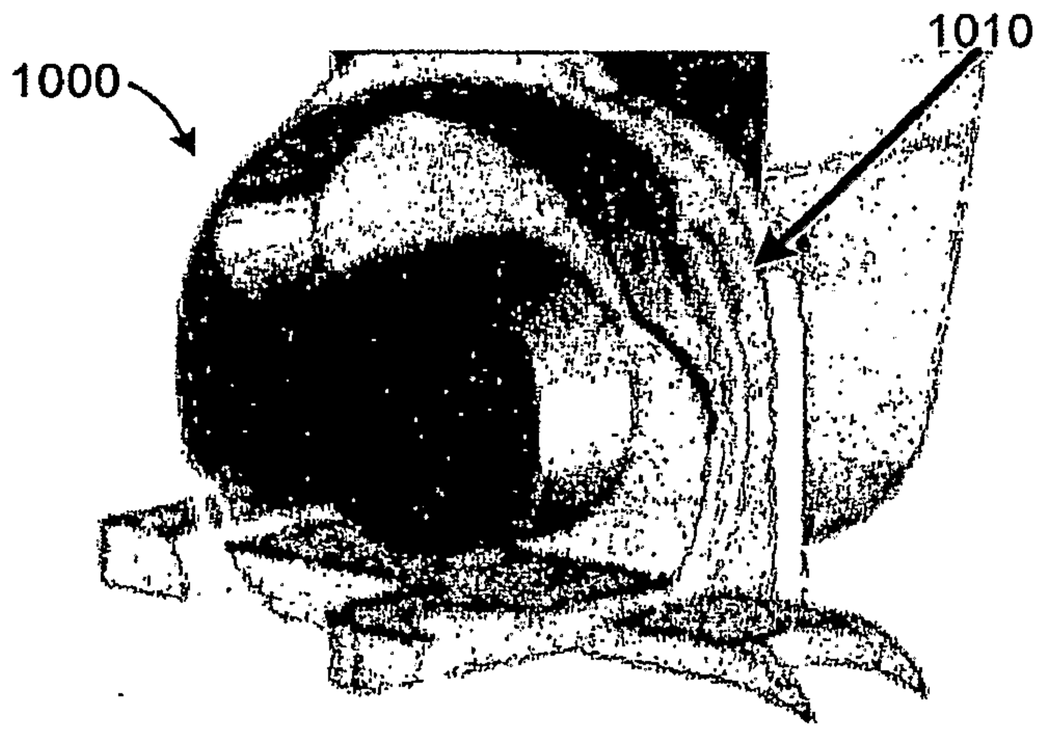


FIGURE 10B

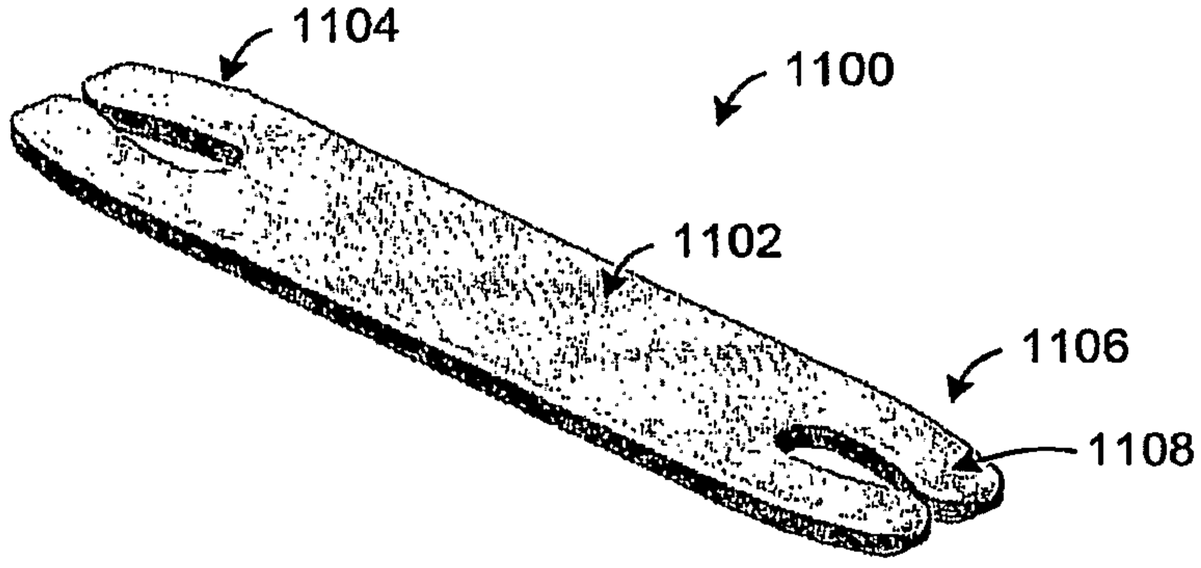


FIGURE 11A

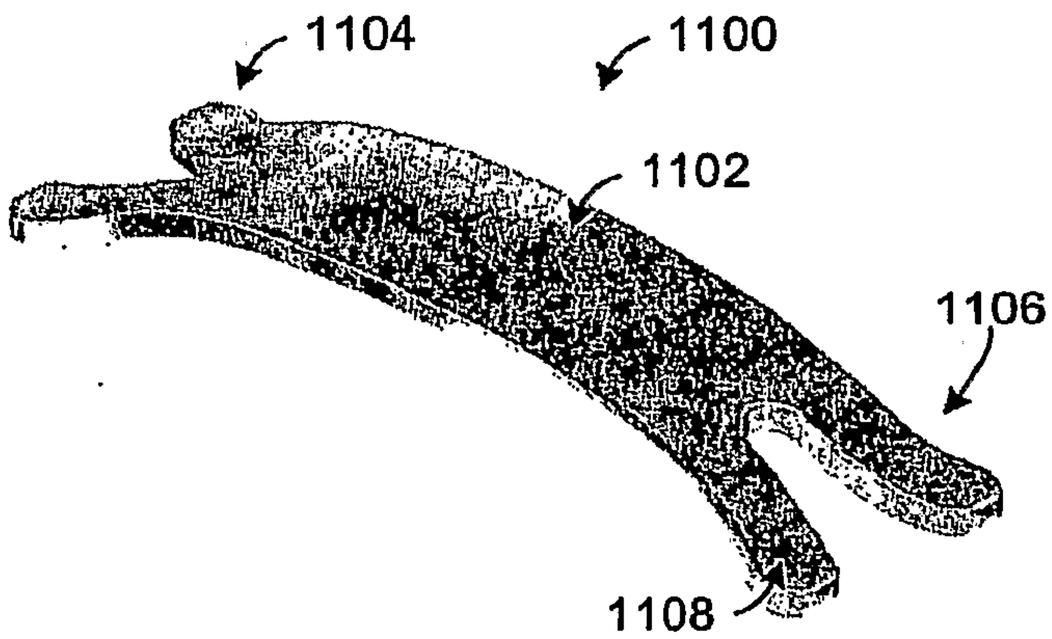


FIGURE 11B

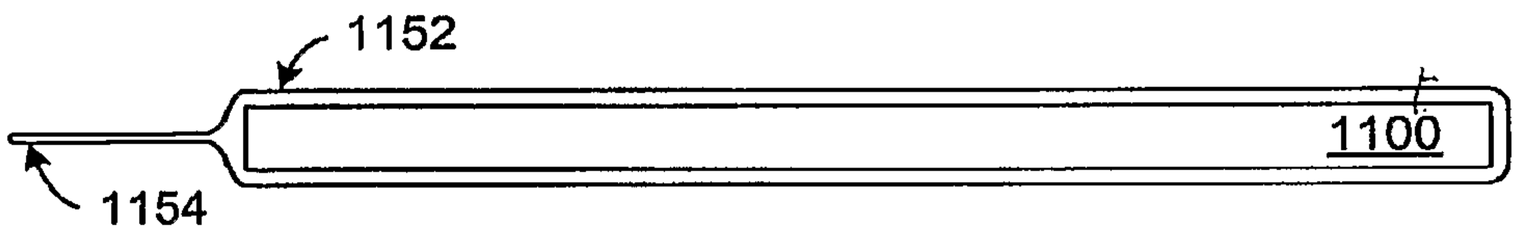


FIGURE 11C

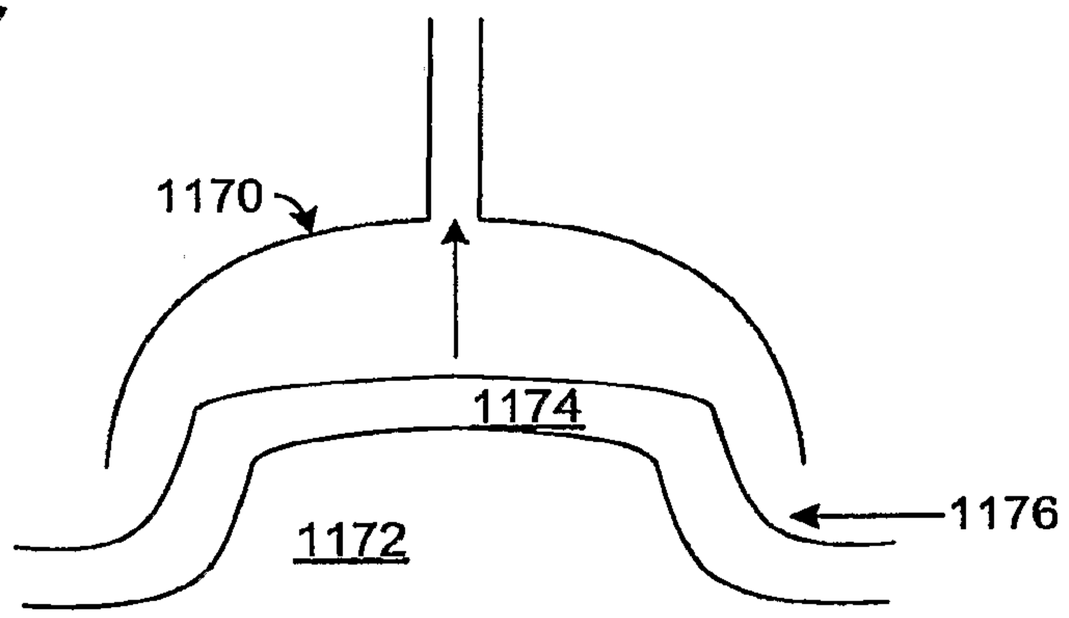


FIGURE 11D

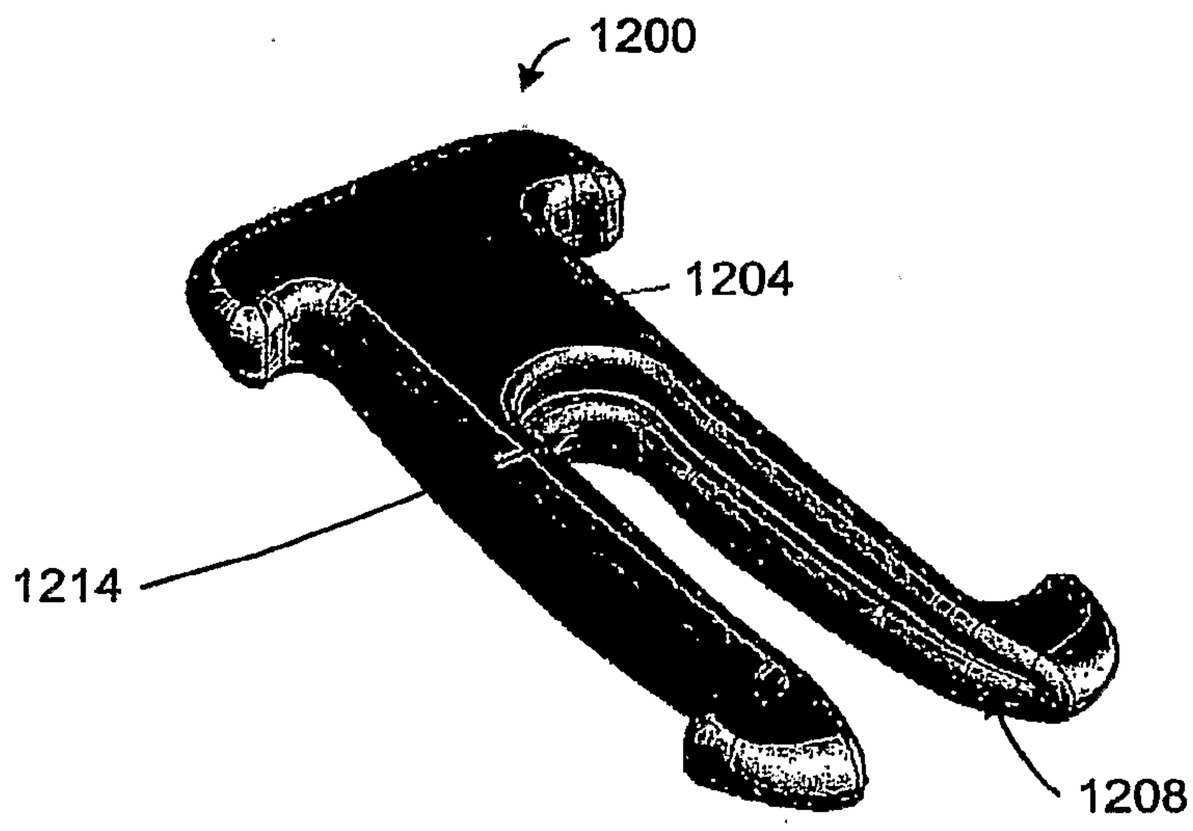


FIGURE 12A

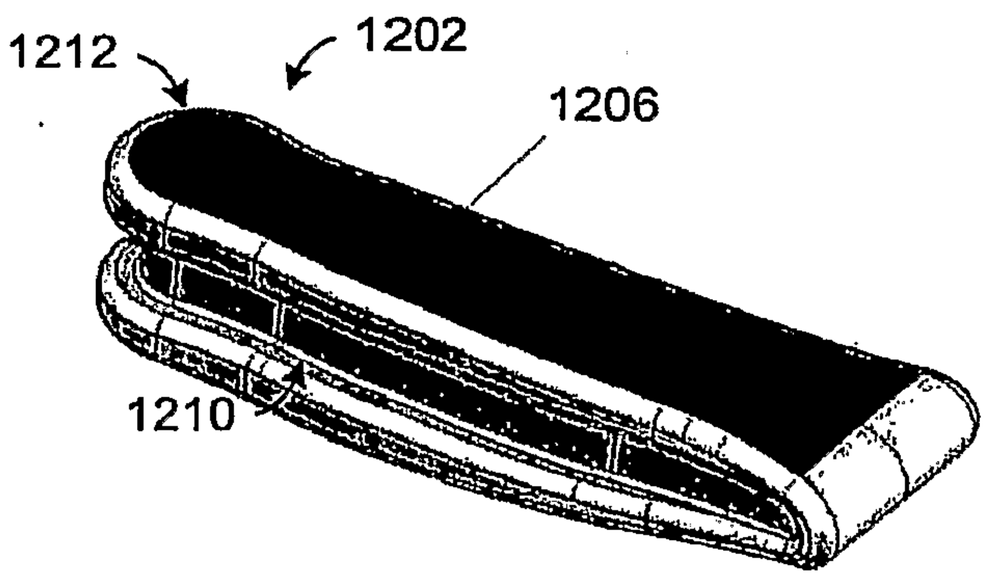


FIGURE 12B

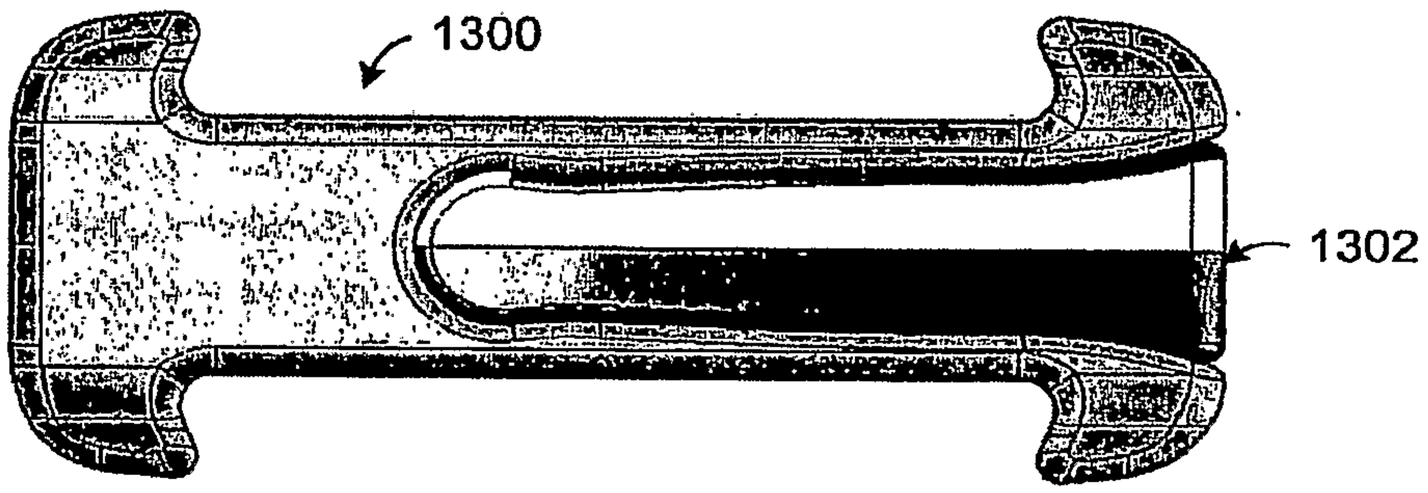


FIGURE 13A

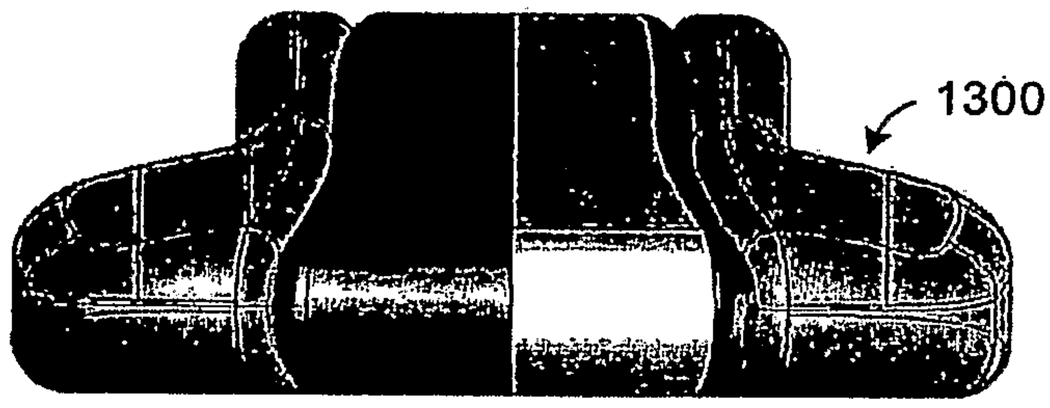


FIGURE 13B

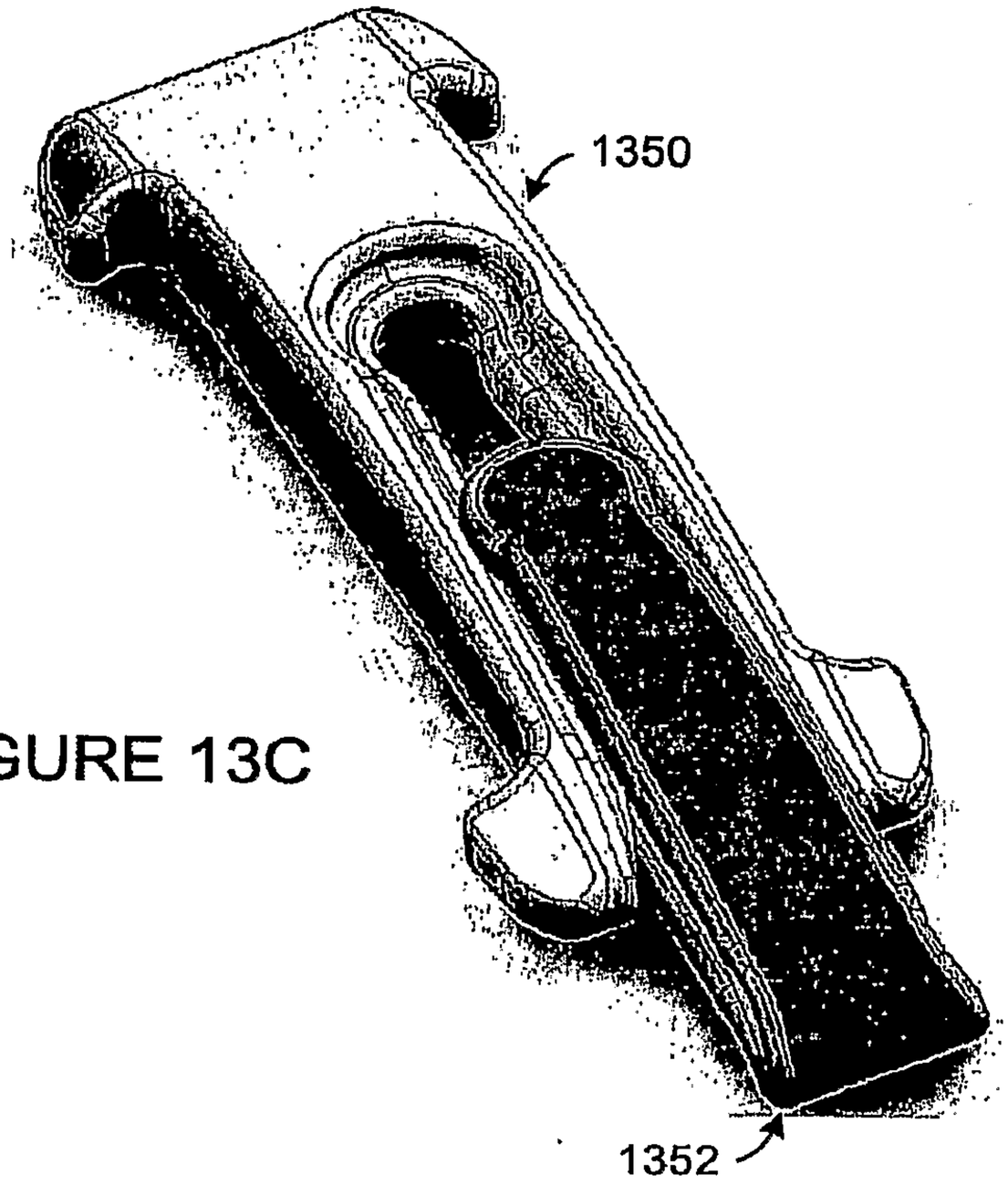


FIGURE 13C

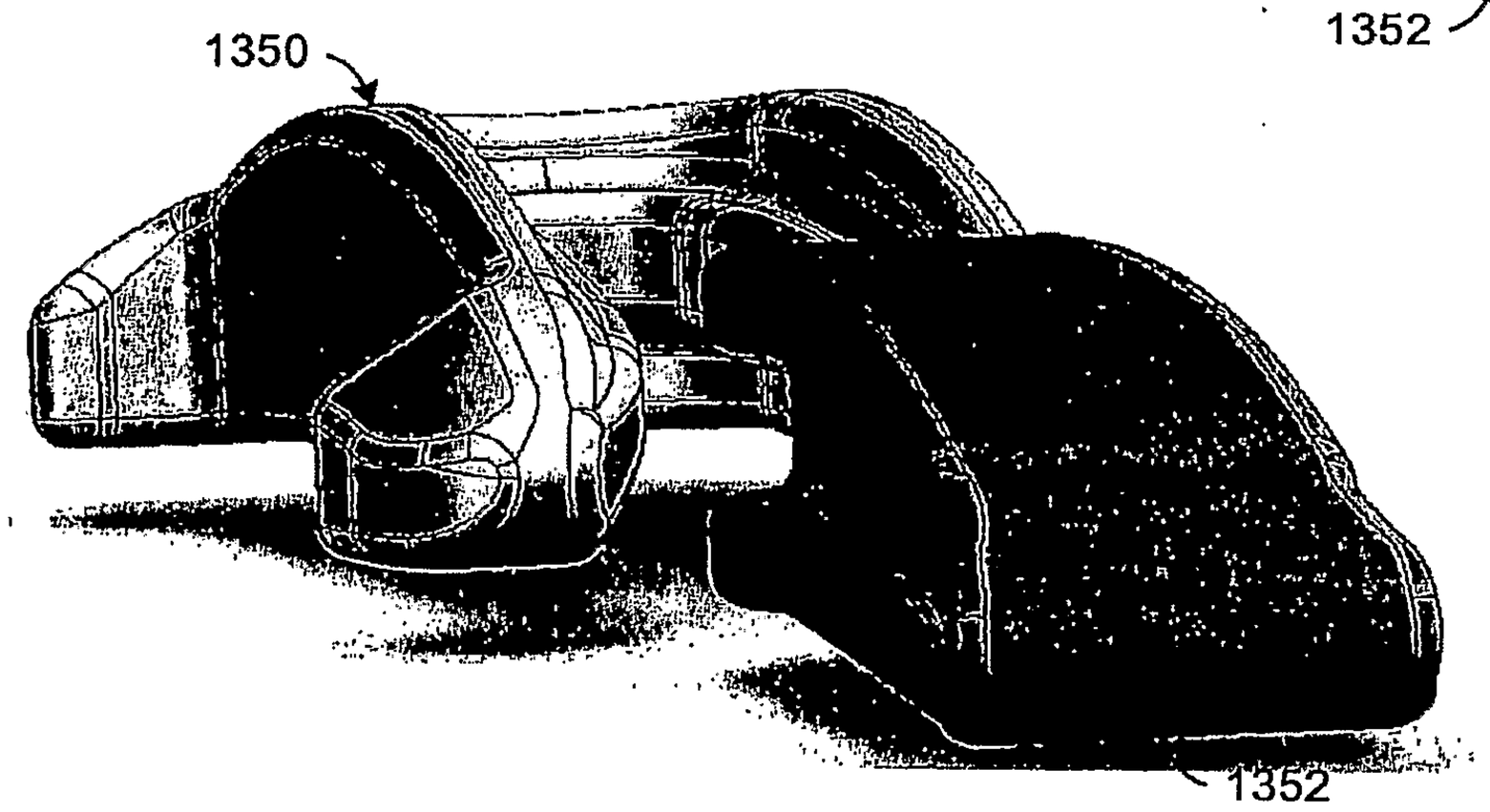


FIGURE 13D

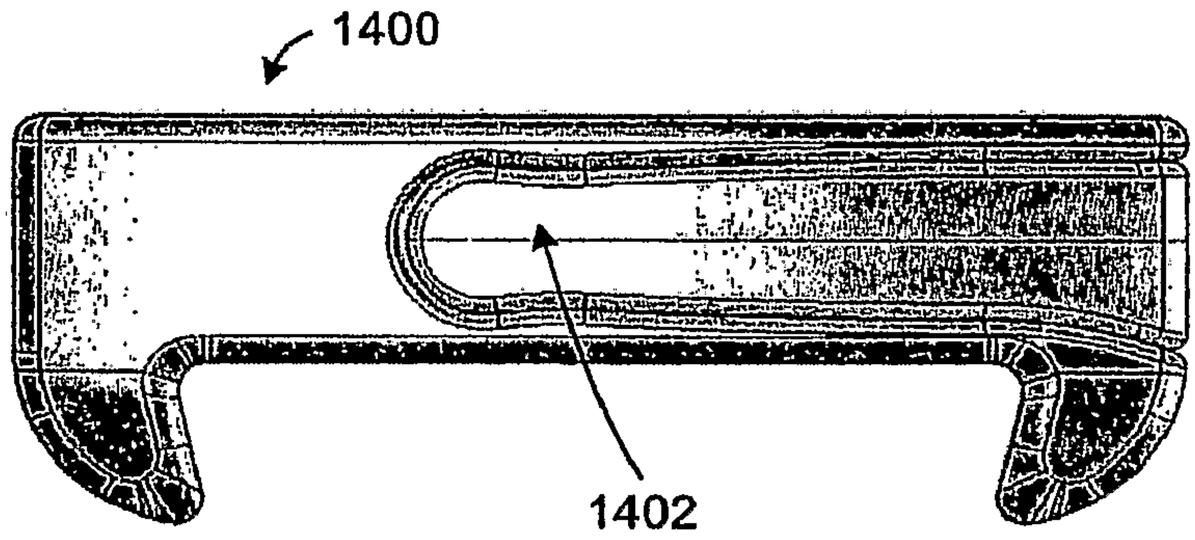


FIGURE 14A

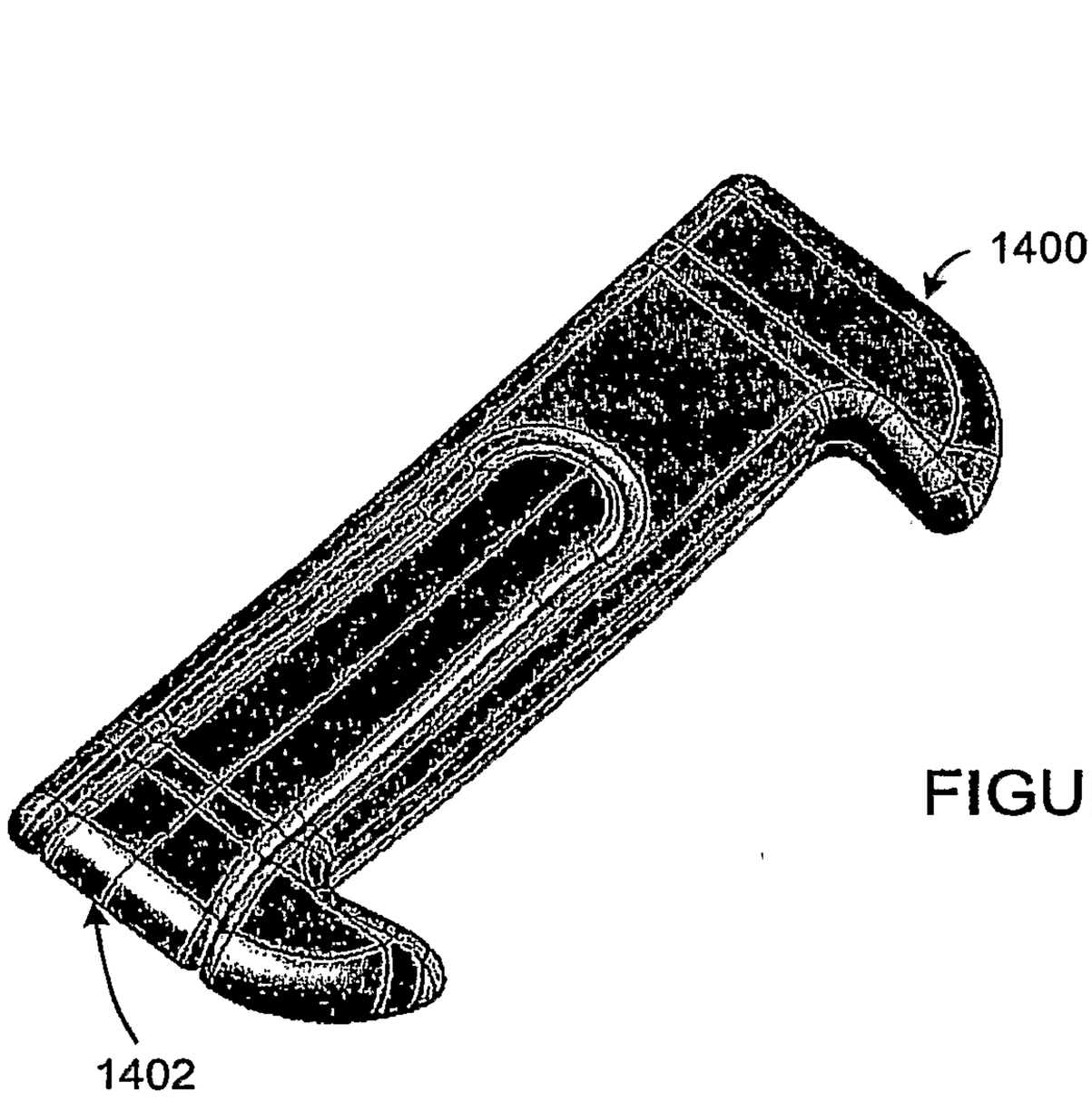


FIGURE 14B

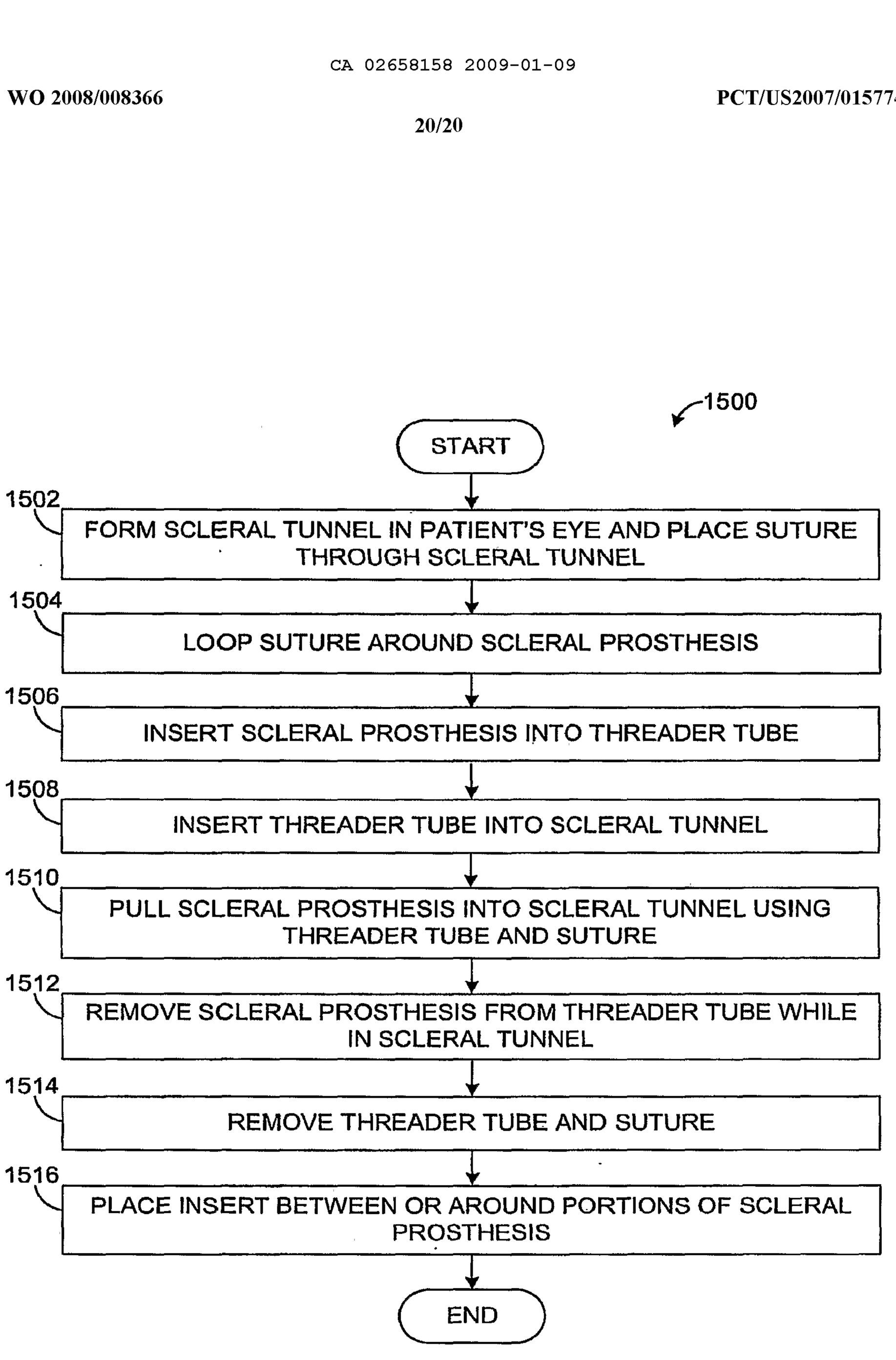
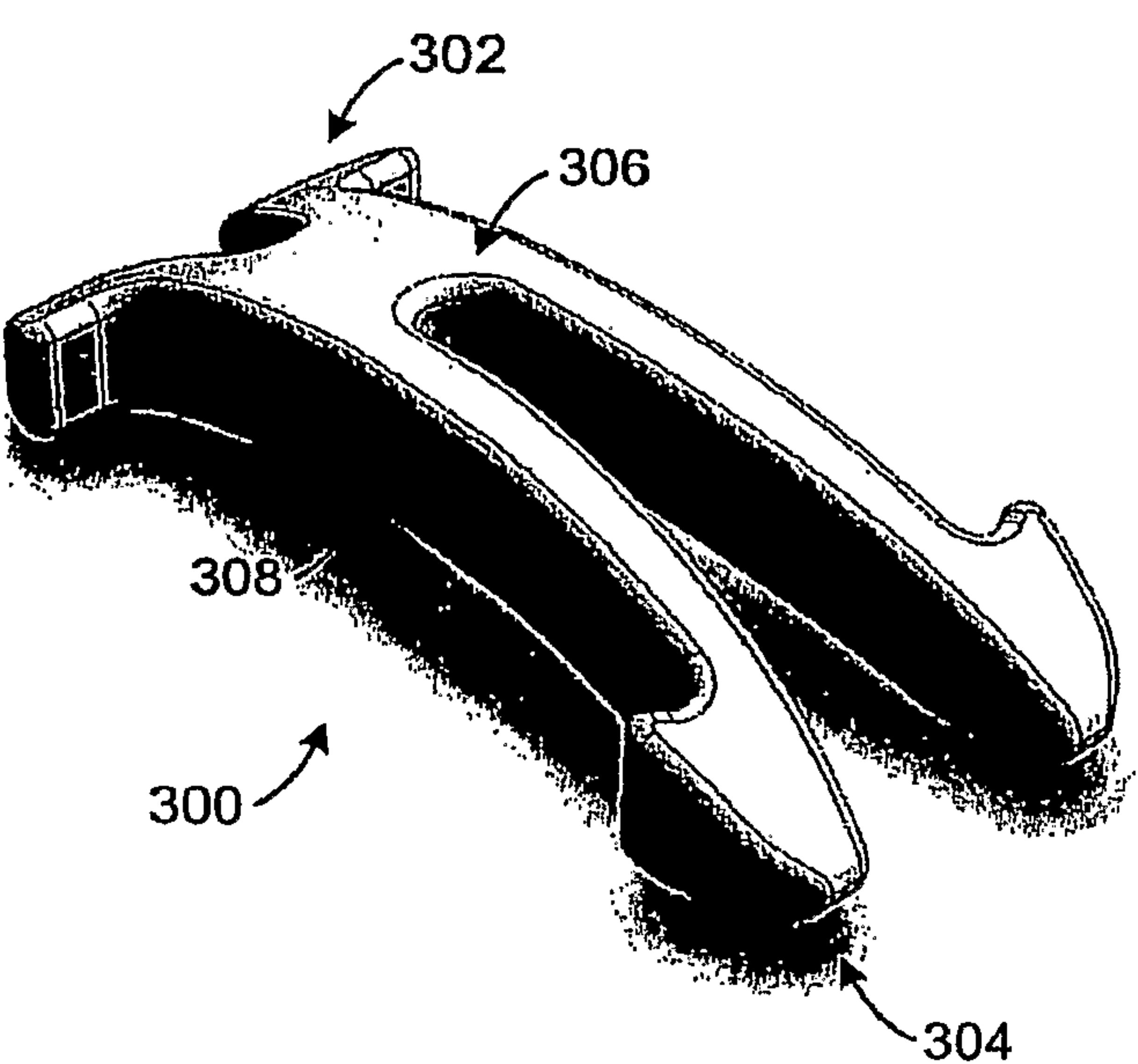

1500
START
1502
FORM SCLERAL TUNNEL IN PATIENT'S EYE AND PLACE SUTURE THROUGH SCLERAL TUNNEL
1504
LOOP SUTURE AROUND SCLERAL PROSTHESIS
1506
INSERT SCLERAL PROSTHESIS INTO THREADER TUBE
1508
INSERT THREADER TUBE INTO SCLERAL TUNNEL
1510
PULL SCLERAL PROSTHESIS INTO SCLERAL TUNNEL USING THREADER TUBE AND SUTURE
1512
REMOVE SCLERAL PROSTHESIS FROM THREADER TUBE WHILE IN SCLERAL TUNNEL
1514
REMOVE THREADER TUBE AND SUTURE
1516
PLACE INSERT BETWEEN OR AROUND PORTIONS OF SCLERAL PROSTHESIS
END

FIGURE 15


302
306
308
300
304