



- (51) International Patent Classification:
A61B 18/18 (2006.01) *A61M 35/00* (2006.01)
A61M 5/00 (2006.01)
- (21) International Application Number:
PCT/US2013/036081
- (22) International Filing Date:
11 April 2013 (11.04.2013)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
61/622,931 11 April 2012 (11.04.2012) US
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- (81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU,
RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ,
TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA,
ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: OPHTHALMIC IMPLANT

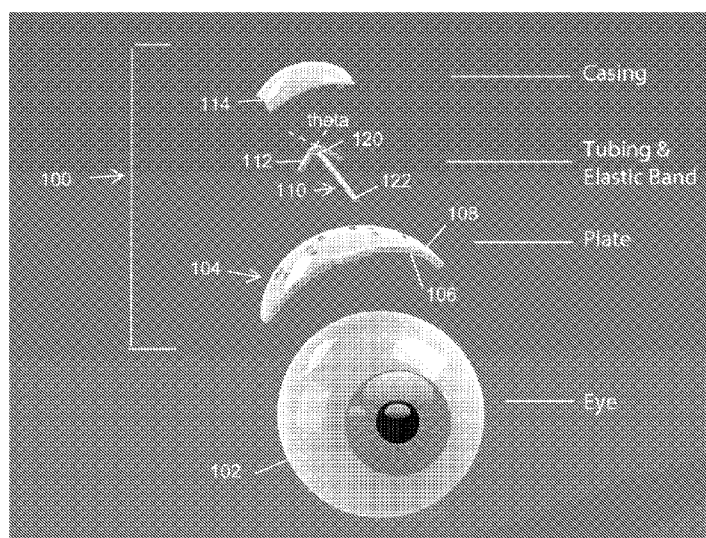


FIG. 1

(57) Abstract: A method of treating glaucoma in an eye is provided utilizing an implanted shunt having an pliable plate, a drainage tube, and an elastic band placed over the drainage tube to regulate the flow of fluid from the eye. Pliable plate is positioned over a sclera of the eye with an outflow end of the drainage tube open to an outer surface of pliable plate. An in-flow end of the drainage tube tunnels through the sclera and cornea to the anterior chamber of the eye. The elastic band predictably restricts and regulates outflow from the eye until a scar tissue bleb forms around pliable plate of the shunt.



Published:

— *with international search report (Art. 21(3))*

OPHTHALMIC IMPLANT

This application claims priority to U.S. Provisional Patent Application Serial No. 61/622,931, filed April 11, 2012, which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0001] The present disclosure generally relates at least to the fields of ophthalmology and medicine. In certain embodiments, it relates to an ophthalmic implant, and particularly to glaucoma shunts and methods of use for predictably regulating the draining of fluid from the eye.

BACKGROUND OF THE DISCLOSURE

[0002] Glaucoma is a group of diseases that can damage the eye's optic nerve and result in vision loss and blindness. Glaucoma is a common problem in aging, where the pressure within the eye may become elevated. There are three chambers of fluid in the eye: Anterior chamber (between cornea and iris), Posterior chamber (between iris, zonule fibers and lens) and the Vitreous chamber (between the lens and the retina). The first two chambers are filled with aqueous humor, whereas the vitreous chamber is filled with a more viscous fluid, the vitreous humor. Normally aqueous humor secreted by the ciliary body courses through the posterior chamber, around the iris into the anterior chamber, and exits out through a spongy tissue at the front of the eye called the trabecular meshwork. From the trabecular meshwork, aqueous drains into Schlemm's canal, and ultimately to the collector channels which enter the episcleral veins. The delicate balance between the production and drainage of aqueous determines the eye's intraocular pressure (IOP). In patients with glaucoma, the outflow of aqueous fluid becomes restricted, thereby increasing the IOP. The elevated IOP results in damage to the optic nerve and causes the loss of retinal ganglion cells and their axons. IOP is the only currently modifiable risk factor for glaucoma. Therefore, treatment to reduce the intraocular pressure is essential and the mainstay of therapy.

[0003] The use of prescription eye drops is usually the first step in lowering the IOP. Most medications reduce the eye pressure by decreasing the production of aqueous. However, because IOP is also determined by episcleral venous pressure, the body has a built-in mechanism that limits the extent the eye's pressure can be lowered with medication. Thus, in some instances IOP cannot

be adequately reduced. Other medications work by improving the outflow of fluid from the eye but are also limited by episcleral venous pressure. Medication treatment is expensive and often has side effects associated with it. Furthermore, these drugs can be very expensive, and are not readily available in rural and undeveloped regions.

[0004] When medications no longer control the eye pressure adequately, surgery may be needed. Trabeculectomy is one type of glaucoma surgery that is commonly performed. It involves making a tiny, guarded filter in the sclera (the white of the eye). The aqueous drains out of the front of the eye through the tiny opening where it collects underneath the clear conjunctival tissue that covers the sclera. One of the most common problems with trabeculectomy is that it lowers the pressure too well, resulting in condition called hypotony. Hypotony can lead to blurred vision and pain, and can cause complications that significantly lengthen the recovery time. Another disadvantage of this procedure is that the body's natural healing process may gradually close the filter, causing the pressure to become elevated again. Lastly, infection of the filter can occur at any point, even years after surgery, so infection risk is elevated for the rest of the patient's life. Surgery may also be required when the iris root blocks the entrance to the trabecular meshwork thereby impeding the flow of aqueous humor. A hole in the iris (iridotomy or iridectomy) can be surgically created to relieve the blockage. The disadvantage associated with this procedure is that the tissue of the eye may gradually close the opening created, thereby requiring the need for further treatment.

[0005] Drainage implant is another widely used corrective method for glaucoma treatment. One such device is discussed by Anthony C. B. Molteno in U.S. Pat. No. 4,457,757. This device comprises of a rigid plate having a tube that extends into the anterior chamber. The aqueous humor from the anterior chamber flows through the tube onto the surface of pliable plate and is absorbed by the body. The Molteno plate does not have any pressure controlling mechanism, and thus has the associated risk of causing hypotony.

[0006] U.S. Pat. No. 4,554,918, issued to Thomas C. White suggests one type of glaucoma valve where the aqueous humor flows from the anterior chamber through a tube into an external reservoir. The end of the tube in contact with the reservoir has unidirectional valve, which is basically a small opening. The small opening provides limited resistance to flow of the aqueous humor. When the reservoir gets filled, patient is supposed to press the reservoir so as to force

aqueous humor out into the body for absorption. This feature makes this device undesirable for long term glaucoma treatment. The device requires patient compliance, which may not be consistent and imposes additional burdens on the patients themselves. Furthermore, the small opening can get clogged by biological particulates present in viscous aqueous humor, posing a potential risk of valve dysfunction.

[0007] In a glaucoma shunt disclosed by Ahmed in U.S. Pat. No. 5,411,473, a valve is added to the basic Molteno design. The valve claims to provide some protection against excessive aqueous outflow during the first few days after surgery. The valve includes a thin Silicone elastomeric sheet sandwiched between two rigid plates and a tube is attached to the silicone sheet. One of the drawbacks in the design is that the tube end in communication with silicone sheet gets compressed when the sheet is sandwiched, thereby closing the aqueous outlet. This feature can cause valve clogging from prolonged use. Other non-valved implant, described in Baerveldt, U.S. Pat. No. 5,476,445, is basically a device for releasing intraocular pressure. Because no pressure regulating mechanism is available, it could lead to hypotony.

[0008] The present invention satisfies a long-felt need in the art of reducing IOP without considerable undesirable side effects.

BRIEF SUMMARY OF THE DISCLOSURE

[0009] In embodiments of the invention, there are compositions and methods that are useful for reducing intraocular pressure (IOP).

[00010] Certain embodiments of the invention relate to an ophthalmic implant for treating, preventing, and/or alleviating the effects of glaucoma through reduction of intraocular pressure, and maintains intraocular pressure at normal levels, while preventing undesirable excessive intraocular pressure reduction following surgical implantation (post-operation hypotony, for example).

[00011] Particular embodiments of the invention employ a device wherein the IOP is transiently regulated by the external pressure of an elastic band on a tube that drains fluid from the eye to thereby reduce the IOP.

[00012] The IOP that is desired to be reduced in an individual may be elevated over normal levels. In certain cases, however, the IOP may be at a normal level, but it is still desirable to be reduced. For example, one in three individuals with glaucoma lack elevated IOP over normal levels, but they are nevertheless treated with measures to reduce IOP because it is known in the art still to be therapeutic. Any type of glaucoma may be treated with embodiments of the invention.

[00013] According to one aspect of the present disclosure, there is provided an IOP-reducing device, which in at least some cases may be considered to be a glaucoma drainage device, comprising: a plate; a drainage tube having an inflow end and an outflow end, wherein the inflow end of the drainage tube is configured to be inserted into an eye; wherein said drainage tube is configured to lay on top of the plate; an elastic band, wherein a portion of the elastic band is configured to press against a portion of the drainage tube at or near the outflow end; a casing configured to hold the elastic band against said portion of the drainage tube; wherein said elastic band is configured to apply a desired amount of pressure near or at the outflow end that prevents fluid flow through the drainage tube when pressure at or near the inflow end is at or below the desired amount of pressure when said glaucoma drainage device is implanted in an individual. In embodiments of devices of the invention, the elastic band and the external tension of the band on the drainage tube is a useful aspect to regulate IOP in real time.

[00014] In one embodiment, the plate is biocompatible pliable and further comprises fenestrations that extend through the pliable plate. The plate may be comprised of a material that is silicone, acrylic, or polystyrene, for example. In another embodiment, a pliable plate further comprises holes to receive fixture posts of the casing. In another embodiment, the casing further comprises at least one post configured to contact the elastic band and hold it against the drainage tube.

[00015] In one embodiment, the desired pressure is in the range of about 8 to about 21 mm mercury, and preferably between about 10 and about 14 mm mercury. In another embodiment, the elastic band is configured to allow fluid flow through the drainage tube when fluid at or near the inflow end is above the desired amount of pressure when said glaucoma drainage device is implanted in a patient.

[00016] In one embodiment, the drainage tube is configured to be inserted into the anterior chamber of the eye. In another embodiment, the drainage tube is configured to be inserted into the posterior chamber of the eye. In another embodiment, the drainage tube is configured to be inserted into the sulcus of the eye. In yet another embodiment, the drainage tube is configured to be inserted into the vitreous chamber of the eye.

[00017] Thus, embodiments of the configuration of the device provide for a valve mechanism to reduce IOP. The valve mechanism comprises an elastic band that, as part of the configuration, regulates the IOP of the eye. The elastic band transiently responds to the IOP and any changes thereof, such that the pressure can be reduced directly upon an increase in IOP or an otherwise undesirable amount of IOP. The pressure may be reduced immediately after implantation and/or it may be reduced at times subsequent to implantation, including minutes, hours, days, weeks, months, or years following implantation.

[00018] In embodiments of the invention, the material of the elastic band can be selected as one of a variety of materials based on the desired need for the device. For example, in an individual having a particularly high IOP or at risk for having a particularly high IOP, the band material may be selected based on such a need. Likewise, for an individual that has normal IOP levels, the band material may be of a certain kind and different from that required by an individual with significantly high levels of IOP. The band in the device may be set to impart one of a variety of tension levels based on the need of the individual. The selection of the type of band may occur by the medical provider. Regarding implantation of the device, the provider may select the type of elastic band at the time of implantation and may utilize such a band that can be titratable post-operatively. A need for such titration may be monitored by suitable means in the art.

[00019] In some embodiments, a device of the invention including a particular band is implanted and a particular tension is provided based on the need or suspected need of the individual. At a certain time post-operatively (minutes, hours, days, weeks, or months), the IOP of the individual may be tested and the tension of the band may be adjusted, such as by choice of material or length, for example. Thus, the device may be used in conjunction with a monitoring step to adjust parameters of the device such that a desired IOP may be achieved or maintained.

[00020] Kits may be included that house one or more of the devices of the invention, and the kit may include a variety of types and/or lengths of elastic band(s) based on the need of the individual for which the kit is being used. A variety of tubes, casing, and plates may also be included in the kit, depending on the needs of the individual for which the kit is being used. Any components of the kit may be housed in one or more suitable containers.

[00021] Other glaucoma treatments may be included in the kit, such as but not limited to a carbonic anhydrase inhibitor, latanoprost, bimatoprost, timolol, , travoprost, tafluprost, betaxolol, apraclonidine, brimonidine, pilocarpine, carbachol (Isopto Carbachol), and combinations thereof, for example. The individual being treated with methods and/or compositions of the invention may be treated with other glaucoma treatments before, during, and/or after being treated with methods and/or compositions of the invention. The other treatments may be drugs and/or surgery, for example. Methods of the invention may also include the step of diagnosing elevated IOP prior to implementation of the inventive procedures and/or devices. IOP may be measured by a tonometer, for example.

[00022] In embodiments of the invention, there is an intraocular pressure (IOP)-regulating device, comprising: a pliable plate; a drainage tube having an inflow end and an outflow end, wherein the inflow end of the drainage tube is configured to be inserted into an eye; an elastic band, wherein a portion of the elastic band is configured to press against a portion of the drainage tube at or near the outflow end, a casing configured to hold the elastic band against said portion of the drainage tube; wherein said elastic band is configured to apply a desired amount of pressure near or at the outflow end that prevents fluid flow through the drainage tube when pressure at or near the inflow end is at or below the desired amount of pressure when said glaucoma drainage device is implanted in a patient. In specific embodiments, the pliable plate further comprises fenestrations that extend through the pliable plate. In at least some cases, the pliable plate further comprises holes to receive fixture posts of the casing. In particular embodiments, the casing further comprises at least one post configured to contact the elastic band and hold it against the drainage tube. In certain embodiments, the pliable plate comprises one or more anchoring fenestrations configured to allow tissue formation for securing the plate to the eye. In some embodiments, the desired pressure is in the range of about 8 to about 21 mm mercury.

[00023] In some embodiments, there is a device having an elastic band, wherein the elastic band is configured to allow fluid flow through the drainage tube when fluid at or near the inflow end is above the desired amount of pressure when said glaucoma drainage device is implanted in a patient. In specific embodiments, the band and device are configured to provide a desired amount of pressure through the use of either a pre-configured band and device configuration or from an adjustable band and device configuration. In some cases, the drainage tube is configured to be inserted into the anterior or posterior chamber of the eye. In some cases, the drainage tube is configured to be inserted into the sulcus of the eye or the drainage tube is configured to be inserted into the vitreous chamber of the eye.

[00024] In some embodiments, there is a kit comprising a device of the invention, wherein components of the kit are housed in one or more suitable containers.

[00025] In some embodiments, there is a method of regulating IOP in an individual in need thereof, comprising the step of providing a device of the invention to the eye of the individual such that the elastic band is configured to regulate the flow of aqueous fluid from the eye through pressure on the drainage tube at or near the outflow end. In some embodiments, the IOP is examined subsequent to providing the device to the individual. In certain cases, the IOP is monitored over time subsequent to providing the device to the individual. One or more components of the device may be adjusted; in some cases the elastic band tension is adjusted. In certain aspects, the method comprises the step of adjusting the length of the band, the width of the band, the thickness of the band, the composition of the band, the angle of the band as it transverses the drainage tube, or a combination thereof. In certain cases, the one or more components of the device are adjusted after implantation. In specific embodiments, the width of the band, length of the band, angle of the band as it transverses the drainage tube, or a combination thereof, are adjusted after implantation.

[00026] The foregoing has outlined rather broadly the features and technical advantages of the present disclosure so that the detailed description of this disclosures that follows may be better understood. It is understood that this disclosure can be used in other fields. Additional features and advantages of the disclosure will be described hereinafter which form the subject of the claims of the disclosure. It should be appreciated by those skilled in the art that the

conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures, substances, and processes for carrying out the same purposes of the present disclosure. It should also be realized by those skilled in the art that such equivalent constructions, substances, methods, processes, or apparatus do not depart from the spirit and scope of the disclosure as set forth in the appended claims. The novel features which are believed to be characteristic of the disclosure, both as to its organization and method of operation, together with further objects and advantages will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended as a definition of the limits of the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[00027] Features and advantages of the present invention will become appreciated as the same become better understood with reference to the specification, claims, and appended drawings wherein:

[00028] FIG. 1 is a perspective view of the components of an exemplary glaucoma shunt according to the aspects of the present disclosure;

[00029] FIG. 2A is a perspective view of a plate of the exemplary glaucoma shunt according to the aspects of the present disclosure;

[00030] FIG. 2B provides several views and dimensions of a plate of the exemplary glaucoma shunt according to the aspects of the present disclosure;

[00031] FIG. 3A is a perspective view of a casing of the exemplary glaucoma shunt according to the aspects of the present disclosure;

[00032] FIG 3B provides several views and dimensions of a casing of the exemplary glaucoma shunt according to the aspects of the present disclosure;

[00033] FIG. 4 is a perspective view of the components of a second exemplary glaucoma shunt according to the aspects of the present disclosure with respect to a model of a patient's eye;

[00034] FIG. 5 is a perspective view of a plate of the second exemplary glaucoma shunt according to the aspects of the present disclosure with some components already assembled;

[00035] FIG. 6 is a perspective view of all the components of the second exemplary glaucoma shunt according to the aspects of the present disclosure assembled on the model of a patient's eye.

[00036] FIG. 7 provides several views and dimensions of a plate of the second exemplary glaucoma shunt according to the aspects of the present disclosure; and

[00037] FIG. 8 provides several views and dimensions of a casing of the second exemplary glaucoma shunt according to the aspects of the present disclosure.

[00038] FIG. 9 illustrates an exemplary pressure curve over time using an embodiment of the invention in an eye model of glaucoma.

DETAILED DESCRIPTION OF THE DISCLOSURE

[00039] As used herein, "a" or "an" means one or more. Unless otherwise indicated, the singular contains the plural and the plural contains the singular. Some embodiments of the invention may consist of or consist essentially of one or more elements, method steps, and/or methods of the invention. It is contemplated that any method or composition described herein can be implemented with respect to any other method or composition described herein embodiments which are disclosed and still obtain a like or similar result without departing from the spirit and scope of the invention.

[00040] FIG. 1 shows glaucoma shunt 100 constructed in accordance with certain aspects of the present disclosure. Glaucoma shunt 100 is configured to be positioned adjacent to eye 102. The relevant structure of eye 102 will be described briefly to provide background for the anatomical terms incorporated herein, however, it should be realized that several anatomical details

have been omitted for clarity of understanding. The tough outer membrane known as the sclera covers all of eye 102 except the portion covered by the cornea. The cornea is a thin, transparent membrane that enables light to enter the pupil and the iris aperture in front of the lens of eye 102. The cornea merges into the sclera at a juncture referred to as the sulcus of the sclera or as the limbus. The ciliary body begins at the limbus and extends circumferentially along the interior of the sclera.

[00041] It is well-known that aqueous is produced by the ciliary body and reaches the anterior chamber formed between the iris and the cornea through the pupil. In a normal eye, the aqueous is removed through the trabecular meshwork. There the aqueous passes through Schlemm's canal and through collector channels which merge with blood-carrying veins and into venous circulation. Intraocular pressure is maintained in eye 102 by the intricate balance of secretion and absorption or outflow of the aqueous in the manner described above. Glaucoma results from excessive buildup of aqueous fluid in the anterior chamber which produces an increase in intraocular pressure. The embodiments of the present disclosure are designed for the treatment of glaucoma of all forms by facilitating the outflow of the aqueous from the anterior chamber of eye 102.

[00042] Referring to FIG. 1, glaucoma shunt 100 comprises pliable plate 104, drainage tube 110, elastic band 112, and casing 114. Pliable plate 104 is also referred to as a pliable seton in the ophthalmic field. Referring to FIG. 1, pliable plate 104 has oppositely disposed curved surfaces, an inner concave surface 106 and an outer convex surface 108. Pliable plate 104 conforms to the sclera and provides a base for discharge or drainage tube 110 that extends into the anterior chamber of eye 102 when glaucoma shunt 100 is implanted.

[00043] Pliable plate 104 is preferably formed of an silicone elastomer, such as SILASTIC®, Medical Grade Q7-4765, 65 Shore A, manufactured by Dow Corning Corporation of Midland, MI or Nusil Corp. of Santa Barbara, Calif., although other silicone elastomers in the range of 104-85 Shore A and having good elastic memory are also suitable. In one embodiment, the silicone elastomer is filled with a radiopaque material, such as Barium Sulfate, so that the implant is visible in X-rays procedures. In other embodiments, pliable plate 104 can comprise other suitable biocompatible elastomeric materials or a combination of suitable biocompatible elastomeric materials.

[00044] Referring to FIGS. 2A and 2B, pliable plate 104 has a generally spherical curvature with an elliptical perimeter. The surface area of pliable plate 104 is preferably in the range of approximately 100 to 600 mm² depending on glaucoma conditions. The thickness of pliable plate 104 is preferably in the range of about 0.5 to 3.0 mm. In an exemplary embodiment, pliable plate 104 has a thickness of about 1 mm. The radius of curvature of pliable plate 104 is preferably between about 12-14 mm. In one specific embodiment, pliable plate 104 has a surface area of approximately 350 mm². In other embodiments, however, pliable plate 104 can have larger or smaller surface area. In addition, pliable plate 104 can have different designs depending on the preferences of the surgeon, patient, manufacturer, or other factors. For instance, pliable plate 104 can resemble pliable plates disclosed in US Publication Nos. 2010/0249691 to Van Der Mooren et al., or 2010/01110406 to Baerveldt.

[00045] Referring to FIGS. 2A and 2B, pliable plate 104 has four casing fixture holes 202 for receiving casing fixture posts 302 of casing 114, shown in FIGS. 3A-3B, thereby allowing casing 114 to snap into the appropriate position and remain secured to pliable plate 104. In one embodiment, casing fixture holes 202 extend through the body of pliable plate 104 as shown. In another embodiment, casing fixture holes 202 partially extend into the body of pliable plate 104. In an exemplary embodiment, casing fixture holes 202 has a diameter of about 1 mm, and casing fixture holes 202 are vertically spaced apart about 2 mm from one another and laterally spaced about 8 mm from one another.

[00046] Referring to FIGS. 2A-2B, pliable plate 104 further includes at least two, and preferably four or more, anchoring holes or fenestrations 204, which are configured to facilitate tissue formation to secure pliable plate 104 to eye 102. Anchoring holes 204 also allow drained fluid from eye 102 to pass from one side of pliable plate 104 to the other. Anchoring holes 204 can have different sizes as shown in FIGS. 2A-2B. In an exemplary embodiment, the larger anchoring holes 204 have a diameter of about 1.5 mm and the smaller anchoring holes 204 have a diameter of about 1 mm. The scar tissue that forms around glaucoma shunt 100 is sometimes referred to as a bleb. Variations in the size of pliable plate 104 correlate with the size of the bleb that forms. In the preferred embodiment, anchoring holes 204 extend through the body of pliable plate 104 to allow tissue to form around glaucoma shunt 100 and through anchoring holes 204 to retain glaucoma shunt

100 in place and regulate outflow from eye 102. The curvature of inner concave surface 106 of pliable plate 104 preferably conforms to the curvature of eye 102, specifically the curvature of the sclera.

[00047] Pliable plate 104 also has suture holes 206 that allow the surgeon to attach pliable plate 104 to eye 102 during surgery. In an exemplary embodiment, suture holes 206 has a diameter of about 0.5 mm and are laterally spaced apart about 3 mm from one another.

[00048] Pliable plate 104 preferably includes two elastic band fixture holes 208 to receive corresponding elastic band fixture posts of casing 114. In the preferred embodiment, elastic band fixture holes 208 partially extend into the body of pliable plate 104. The depth of elastic band fixture holes 208 is predetermined to provide an optimum or desired pressure on drainage tube 110 when glaucoma shunt 100 is implanted in a patient.

[00049] Referring to FIG. 1, drainage tube 110 comprises outflow end 120 and inflow end 122. When assembled and implanted, drainage tube 110 lays on top of pliable plate 104, with inflow end 122 inserted into eye 102 to allow fluid to drain out toward and through outflow end 120. Outflow end 120 lies on top of pliable plate 104. Elastic band 112 presses down at or near outflow end 120.

[00050] In one embodiment, drainage tube 110 connects to pliable plate 104 with adhesive, such as Clear Silicone Rubber Adhesive RTV-206 manufactured by General Electric Silicone Products of Waterford, N.Y. In other embodiments, other suitable biocompatible adhesives or a combination of suitable biocompatible adhesives can be used. Outflow end 120 of drainage tube 110 opens to and drains over outer convex surface 108 of pliable plate 104.

[00051] Drainage tube 110 is preferably about 5 mm to 35 mm in length. It is preferably formed of silicone material, such as SILASTIC®, Medical Grade RX-50, also available from Dow Corning Corporation or NUSIL Corp. of Santa Barbara. In addition to silicone, Teflon or polyurethane are also materials that may be suitable for drainage tube 110. In other embodiments, drainage tube 110 can comprise other suitable biocompatible materials or a combination of suitable biocompatible materials. In the preferred embodiment, drainage tube 110 has an inner diameter of

about 0.30 mm and an outer diameter of about 0.61 mm. Other inner and outer dimensions can be used to achieve the valve function effect of the glaucoma shunts of the present disclosure.

[00052] Referring to FIG. 1, inflow end is inserted into the anterior chamber of eye 102, and elastic band 112 rests on top of drainage tube 110 at or near outflow end 120 when glaucoma shunt 100 is assembled and implanted in a patient. Casing 114 couples to pliable plate 104 to cover elastic band 112 and holds elastic band 112 in place against drainage tube 110. Casing 114 is preferably made of polypropylene or other suitable material to give it sufficient rigidity to protect elastic band 112 while casing 114 remains biocompatible. Casing 114 is preferably smaller than pliable plate 104. The surface area of casing 114 ranges from 50 to 90 mm². In one exemplary embodiment, casing 114 has a surface area of 78.8 mm² and has a thickness that ranges from approximately 1 mm to 2.5 mm. Referring to FIGS. 3A-3B, casing 114 has four casing fixture posts 302 that are received by casing fixture holes 202 on pliable plate 104, shown in FIGS. 2A-2B. Casing fixture posts 302 and casing fixture holes 304, when coupled, allow casing 114 to be held in the appropriate position over elastic band 112. Casing 114 has two elastic band fixture posts 304 that firmly press on elastic band 112 on both sides of drainage tube 110.

[00053] Referring to FIG. 3B, casing 114 is generally rectangular with two straight side edges and two curved side edges. Casing 114 has a length of about 11 mm and a width of about 5.2 mm. A portion or all of the edge of casing 114 may or may not contact pliable plate 104. Casing fixture posts 302 are located about 2 mm apart from one another vertically and about 8 mm apart from one another laterally when measured from the center of these posts. Elastic band fixture posts 304 are about 1 mm wide and are located about 3.1 mm apart laterally when measured from the side walls closest to one another. FIGS. 3B and 8 are exemplary embodiments of the casing of the present disclosure. Various other designs of the casing can be used to hold the elastic band of the present disclosure to the pliable plate at the desired pressure without departing from the scope of the present disclosure.

[00054] The arrangement of elastic band 112 and elastic band fixture posts 304 is configured to place a pressure on outflow end 120 of drainage tube 110 such that a “normal” pressure of about 8 to 21 mm mercury, and preferably about 10-14 mm mercury, is insufficient to drain aqueous fluid from eye 102. That is, the elastic band 112 and casing 114 arrangement

effectively places a desired amount of pressure, *e.g.*, about 10-14 mm mercury at or near the outflow end 120 of drainage tube 110. To drain liquid or pass liquid through such imposed pressure, the pressure at the inflow end 122 has to be higher than the pressure at the outflow end. If the pressure in eye 102 is lower than the pressure imposed by elastic band 112, fluid from eye 102 will remain in eye 102 and will not drain. The arrangement of elastic band 112 and casing 114 can be configured to regulate the flow of aqueous fluid from eye 102 at a desired pressure, thereby effectively functioning as a valve. For instance, when pressure from eye 102 is slightly high to substantially high, such as between 50-60 mm mercury, the high pressure flow acts against elastic band 112 to widen outflow end 120 and allow greater flow when glaucoma shunt 100 is first implanted. The flow of fluid will slow and ultimately stop when a sufficient amount of aqueous fluid has been drained and the pressure of eye 102 decreases near or below the pressure provided by elastic band 112, which is preferably within the “normal” range of about 8 to 21 mm mercury and optimally between 10 and 14 mm mercury.

[00055] The pressure at or near outflow end 120 provided by elastic band 112 can be achieved by numerous means, such as modifications of the material of the elastic band, length of the elastic band, width of the elastic band, thickness of the elastic band, the spacing between the elastic band fixture holes, the height of elastic band fixture posts, the location where elastic band fixture posts contact elastic band 112, the material and dimensions of drainage tube 110, the material and dimensions of the casing 114, or a combination thereof. Referring to FIG. 1, the two major factors that are adjustable to modify the pressure provided by elastic band 112 include the material of the components, *e.g.*, elastic band 112 and drainage tube 110, and the angle theta, θ , formed by elastic band 112 when it lays across drainage tube 110 to apply pressure to outflow end 120 of drainage tube 110. The angle θ can be adjusted by adjusting the length of the elastic band, the spacing between the elastic band fixture holes, the height of elastic band fixture posts, the location where elastic band fixture posts contact elastic band 112, or a combination thereof. In the preferred embodiment, elastic band 112 has a durometer of about 20 Shore A, an initial extension of about 200% and a length of about 3 mm. The width of elastic band 112 does not significantly contribute to the valve function of elastic band 112, so it can be more arbitrarily set, potentially dictated more by manufacturing considerations. In one embodiment, elastic band 112 has a width of about 1 mm. Referring to FIG. 2B, elastic band fixture holes 208 are spaced apart about 3 mm. Those of skill in

the art will understand that the exemplary dimensions given above may be modified for different materials to produce the same or similarly desired pressure regulation by elastic band 112. The present disclosure contemplates a wide range of elastic band and drainage tube materials and sizes to function as a flow regulator in this manner, and appropriate testing will validate a number of combinations.

[00056] One exemplary way to determine the qualities of the elastic band 112 involves calculating the radial stress at the outer wall of the tubing at each IOP from 6-20 mmHg using this equation:

$$\sigma = 2 * \frac{IOP * R_i^2}{R_o^2 - R_i^2}$$

Where; σ = stress, IOP = intraocular pressure, R_i = inner radius of tubing, R_o = outer radius of tubing. In one embodiment, the length of the elastic band is defined as 10 mm, the width is defined as 1 mm, and the thickness is defined as 0.508 mm (0.02 in) based on the desired dimensions of the device. Based on these dimensions, the approximate contact length of the band with the tubing is determined to be about 0.8 mm when the valve is closed (<12 mm mercury) and 0.6 mm when the valve is open (>12 mm mercury). This contact length can be used to calculate the contact area. The force exerted by the elastic band can be determined by multiplying the radial stress calculated above by the contact area. The flexural stress on the elastic band due to this force can then be determined by using the 3-point bending equation as follows:

$$\sigma = \frac{3 * F * L}{2 * W * T^2}$$

Where; σ = stress, F = force exerted by band, L = length, W = width, T = thickness. Based on the geometry of this particular embodiment, a difference in the elastic band's elongation of at least 0.02 mm when the valve was closed and 0.08 mm when the valve was open is expected. This amount of elongation plus the initial amount of elongation that the band is secured to the plate with can be used to calculate the strain of the elastic band. By dividing the flexural stress calculated above by the strain, the required elastic modulus of the elastic band can be determined. Because the amount of

initial elongation of the band is modifiable, it can be adjusted to change the strain and thus the required elastic modulus. In one embodiment, the elastic modulus estimates at 11 and 13 mm mercury are kept as close together as possible while still using a realistic value for strain. That way, the valve should close at roughly 12 mm mercury because the calculated elastic modulus for each IOP represents the elastic modulus required for the valve to be in the desired state (open/closed). In one embodiment, this results in an initial elongation of 0.5 mm for the 10 mm long band, which gives estimates of the required elastic modulus in the range of about 0.66 - 0.84 MPa. Silicone's hardness is measured commercially in Shore A Durometer, which can be converted to MPa preferably using the approximation:

$$E = e^{0.0235 * D - 0.6463}$$

Where; E = elastic modulus in MPa, D = shore A durometer. Using the equation above, a durometer of 20 is roughly equivalent to an elastic modulus of 0.84 MPa, which falls in the range of predicted values. Any higher durometer may be too rigid. Other values can be chosen for drainage tube 110 that achieve the desired valve functions at the desired range.

[00057] The edges of pliable plate 104 are desirably radiused, tapered and blended so as to facilitate insertion. Additionally, the rounded edge of pliable plate 104 discourages scar tissue around the edge of pliable plate 104. The rounded edge of pliable plate 104 also presents a smooth surface to decrease tissue irritation. In one embodiment, the anterior or leading edge of casing 114 is configured to prevent subconjunctival liquid from entering casing 114, thereby limiting the impact of healing factors on the elastic band 112 and concentrating all aqueous flow through drainage tube 110 posteriorly.

[00058] The embodiments of the present disclosure thus function as a flow regulator that permits drainage of aqueous fluid from the high pressure environment of eye 102 immediately after implantation, where the flow will slow and stop when the pressure of eye 102 reaches the desired pressure. Glaucoma shunt 100 is configured to predictably and consistently regulate flow and prevent post-operative hypotony caused by excessive drainage of fluid from eye 102. This is a huge advantage over other conventional methods that rely on unpredictable restriction of flow through drainage tube 110 for the time period between implantation and scar tissue formation. These unpredictable methods include temporary sutures or collapsing of the wall of drainage tube 110 as described by U.S. Publication No. 2010/0114006. It is not possible to predict precisely when

flow will begin again, if ever, by using temporary sutures or collapsing of the wall. These conventional methods of initially restricting flow after implantation and subsequently allowing for gradual flow hopes for the optimal situation that flow will begin to flow right about the time the tissue has formed around the shunt. The rate of scar tissue formation differs in individual patients. As such, there is no way to ensure that the two events will occur as desired. If flow begins prematurely, then the patient can suffer from hypotony. If the flow does not begin at all or a significant time after tissue formation, then the patient's condition is prolonged or subsequent follow up procedure is required to initiate flow.

[00059] The self-regulating feature of glaucoma shunt 100 as described herein eliminates the need for temporary sutures and considerably limits the need for follow-up procedures. This greatly decreases the amount of potential complications. Glaucoma shunt 100 can also incorporate different types of plate designs as discussed above. It is envisioned that a change in plate design may require slight modifications in the elastic band and drainage tube arrangement to ensure glaucoma shunt 100 provides the desired pressure regulation as described herein. Appropriate and reasonable testing will validate a number of combinations.

[00060] Glaucoma shunt 100 can be implanted using known ophthalmological surgical techniques and will be briefly described. An initial incision is made in the conjunctiva and Tenon's capsule parallel to the limbus. Pliable plate 104, which is preconfigured with elastic band 112, casing 114, and drainage tube 110 in place, is inserted through the initial incision and positioned beneath the Tenon's capsule and a portion of the rectus muscle or extending totally under one or more muscles, thus covering the sclera. Pliable plate 104 can be sutured to the sclera, or alternatively, to the rectus muscle if the sclera is thinned by disease, with suture holes 206. Non-absorbable nylon sutures, such as 8-0 nylon or polypropylene sutures, or absorbable sutures, such as polyglactin or vicryl, are used in the suture holes 206 to secure pliable plate 104 according to surgeon preference. While the figures depict a specific number of casing fixture posts 302 and casing fixture holes 202, it is understood that, without departing from the scope of the present disclosure, other embodiments can include more or less number of posts and corresponding holes, depending on the design or preferences.

[00061] Once pliable plate 104, elastic band 112, and casing 114, are inserted, drainage tube 110 can be inserted through the sclera and the cornea beneath Tenon's capsule such that inflow end 122 of drainage tube 110 extends into eye 102. In the preferred embodiment, inflow end 122 of drainage tube 110 extends into the anterior chamber of the eye. In other embodiments, inflow end 122 of drainage tube 110 extends into the posterior chamber, sulcus, or vitreous chamber of the eye depending on surgical preference or requirement. In other embodiments, the length of drainage tube 110 is shortened to facilitate insertion into the vitreous chamber.

[00062] A large drainage bleb eventually surrounds pliable plate 104 and lifts the layer of Tenon's capsule above the sclera. Pliable plate acts as a permanent bleb-controlling stent to inhibit the tendency of the body to heal itself which would eliminate the bleb. Fibrous rivets of scar tissue form on both sides of pliable plate 104, causing a low bleb.

[00063] FIGS. 4-8 illustrate glaucoma shunt 400, which is a second exemplary embodiment of the present disclosure. In general, glaucoma shunt 100 and glaucoma shunt 400 functions in similar manner. Most of the descriptions for glaucoma shunt 100 are equally applicable to describe glaucoma shunt 400. However, casing 414 of glaucoma shunt 400 differs slightly from casing 114 of glaucoma shunt 100. Casing 414 is slightly smaller than casing 114 and is more rectangular in shape. In addition, casing 414 is located closer to suture holes 506 of glaucoma shunt 400, toward the iris of eye 402. The change in location of casing 414 also correspondingly changes the location of casing fixture holes 502 on pliable plate 404 for receiving casing fixture posts 602 of casing 414. Further, the edges of casing 414 is flushed against the surface of pliable plate 404 to prevent fluid from entering or going through casing 414, thereby directing all fluid flow through drainage tube 410. Drainage tube 410 can go through a side wall of casing 414 or casing 414 can have a cutout that allows drainage tube 410 to snugly fit through.

[00064] Glaucoma shunt 400 is configured to be positioned adjacent to eye 402. The descriptions of the relevant structures of eye 102 are equally applicable to eye 402 and need not be repeated.

[00065] Referring to FIG. 4, glaucoma shunt 400 comprises pliable plate 404, drainage tube 410, elastic band 412, and casing 414. Pliable plate 404 is also referred to as a pliable

seton in the ophthalmic field. Similar to pliable plate 104 of FIG. 1, pliable plate 404 has oppositely disposed curved surfaces, an inner concave surface 406 and an outer convex surface 408. Pliable plate 404 conforms to the sclera of eye 402 and provides a base for discharge or drainage tube 410 that extends into the anterior chamber of eye 402 when glaucoma shunt 400 is implanted.

[00066] Pliable plate 404 is preferably formed of an silicone elastomer, such as SILASTIC®, Medical Grade Q7-4765, 65 Shore A, manufactured by Dow Corning Corporation of Midland, MI or Nusil Corp. of Santa Barbara, Calif., although other silicone elastomers in the range of 104-85 Shore A and having good elastic memory are also suitable. In one embodiment, the silicone elastomer is filled with a radiopaque material, such as Barium Sulfate, so that the implant is visible in X-rays procedures. In other embodiments, pliable plate 404 can comprise other suitable biocompatible elastomeric materials or a combination of suitable biocompatible elastomeric materials.

[00067] Referring to FIGS. 4-7, pliable plate 404 has a generally spherical curvature with an elliptical perimeter. The surface area of pliable plate 404 is preferably in the range of approximately 100 mm² to 600 mm² depending on glaucoma conditions. The thickness of pliable plate 404 is preferably in the range of about 0.5 mm to 3.0 mm. In an exemplary embodiment, pliable plate 404 has a thickness of about 1 mm. The radius of curvature of pliable plate 404 is preferably between about 12-14 mm. In one specific embodiment, pliable plate 404 has a surface area of approximately 350 mm². In other embodiments, however, pliable plate 404 can have larger or smaller surface area. In addition, pliable plate 404 can have different designs depending on the preferences of the surgeon, patient, manufacturer, or other factors. For instance, pliable plate 404 can resemble pliable plates disclosed in US Publication Nos. 2010/0249691 to Van Der Mooren et al., or 2010/01110406 to Baerveldt, which are both incorporated by reference herein in their entirety.

[00068] Referring primarily to FIGS. 5 and 7, pliable plate 404 has four casing fixture holes 502 for receiving casing fixture posts 602 of casing 414, shown in FIG. 8, thereby allowing casing 414 to snap into the appropriate position and remain secured to pliable plate 404. FIG. 6 shows casing 414 coupled to pliable plate 404 through casing fixture holes 502 and casing fixture posts 602 as described. In one embodiment, casing fixture holes 502 extend through the body of pliable plate 404 as shown. In another embodiment, casing fixture holes 502 partially extend into

the body of pliable plate 404. In an exemplary embodiment, casing fixture holes 502 has a diameter of about 1 mm, and casing fixture holes 502 are vertically spaced closer together as compared to casing fixture holes 202 because casing 414 has a shorter width than casing 114. Casing fixture holes 502 are laterally spaced about 8 mm from one another. Referring to primarily to FIG. 7, casing fixture holes 502 are located closer to suture holes 506 as compared to casing fixture holes 202.

[00069] Referring primarily to FIGS. 5 and 7, pliable plate 404 further includes at least two, and preferably four or more, anchoring holes or fenestrations 504, which are configured to facilitate tissue formation to secure pliable plate 404 to eye 402. Anchoring holes 504 also allow drained fluid from eye 402 to pass from one side of pliable plate 404 to the other. Anchoring holes 404 can have different sizes as shown in FIGS 5-7. In an exemplary embodiment, the larger anchoring holes 404 have a diameter of about 1.5 mm and the smaller anchoring holes 404 have a diameter of about 1 mm. Variations in the size of pliable plate 404 correlate with the size of the bleb that forms. In the preferred embodiment, anchoring holes 504 extend through the body of pliable plate 404 to allow tissue to form around glaucoma shunt 400 and through anchoring holes 404 to retain glaucoma shunt 400 in place and regulate outflow from eye 402. The curvature of inner concave surface 406 of pliable plate 404 preferably conforms to the curvature of eye 402, specifically the curvature of the sclera.

[00070] Pliable plate 404 also has suture holes 506 that allow the surgeon to attach pliable plate 404 to eye 402 during surgery. In an exemplary embodiment, suture holes 506 has a diameter of about 0.5 mm and are laterally spaced apart about 3 mm from one another.

[00071] Referring primarily to FIGS. 5 and 7, pliable plate 404 preferably includes two elastic band fixture holes 508 to receive corresponding elastic band fixture posts of casing 414. In the preferred embodiment, elastic band fixture holes 508 partially extend into the body of pliable plate 404. The depth of elastic band fixture holes 508 is predetermined to provide an optimum or desired pressure on drainage tube 410 when glaucoma shunt 400 is implanted in a patient.

[00072] Referring to FIGS. 4-6, drainage tube 410 comprises outflow end 420 and inflow end 422. When assembled and implanted, drainage tube 410 lays on top of pliable plate 404,

with inflow end 422 inserted into eye 402 to allow fluid to drain out toward and through outflow end 420. Outflow end 420 lies on top of pliable plate 404. Elastic band 412 presses down at or near outflow end 420.

[00073] In glaucoma shunt 400, where elastic band 412 presses down onto drainage tube 410 is located closer to suture holes 506. The portion of drainage tube 410 outside of casing 414 that lies on top of pliable plate 404 is shorter as compared to glaucoma shunt 100. As such, the force applied to drainage tube 410 by casing 414 may be sufficient to keep it in place. However, it is contemplated that in other embodiments, adhesive may also be used to hold drainage tube 410 to pliable plate 404. Suitable adhesives include Clear Silicone Rubber Adhesive RTV-206 manufactured by General Electric Silicone Products of Waterford, N.Y. In other embodiments, other suitable biocompatible adhesives or a combination of suitable biocompatible adhesives can be used. Outflow end 420 of drainage tube 410 opens to and drains over outer convex surface 408 of pliable plate 404.

[00074] Drainage tube 410 is preferably about 5 mm to 35 mm in length. It is preferably formed of silicone material, such as SILASTIC®, Medical Grade RX-50, also available from Dow Corning Corporation or NUSIL Corp. of Santa Barbara. In addition to silicone, Teflon or polyurethane are also materials that may be suitable for drainage tube 410. In other embodiments, drainage tube 410 can comprise other suitable biocompatible materials or a combination of suitable biocompatible materials. In the preferred embodiment, drainage tube 410 has an inner diameter of about 0.30 mm and an outer diameter of about 0.61 mm.

[00075] Referring to FIGS. 4-6, inflow end 422 is inserted into the anterior chamber of eye 402, and elastic band 412 rests on top of drainage tube 410 at or near outflow end 420 when glaucoma shunt 400 is assembled and implanted in a patient. Casing 414 couples to pliable plate 404 to cover elastic band 412 and holds elastic band 412 in place against drainage tube 410. Casing 414 is preferably made of polypropylene or other suitable material to give it sufficient rigidity to protect elastic band 412 while casing 414 remains biocompatible. Casing 414 is preferably smaller than pliable plate 404. The surface area of casing 414 ranges from about 50 mm² to 90 mm². In one exemplary embodiment, casing 414 has a surface area of 83.36 mm² and has a thickness that ranges from approximately 1 mm to 2.5 mm.

[00076] Referring to FIG. 8, casing 414 has four casing fixture posts 602 that are received by casing fixture holes 502 on pliable plate 404, shown in FIGS. 5 and 7. FIG. 6 shows casing 414 coupled to pliable plate 404 through fixture posts 602 and casing fixture holes 502. Casing fixture posts 502 and casing fixture holes 604, when coupled, allow casing 414 to be held in the appropriate position over elastic band 412. Casing 414 has two elastic band fixture posts 604 that firmly press on elastic band 412 on both sides of drainage tube 410. The edge of casing 414 is preferably curved to match the curvature of concave outer surface 408 so casing 414 is flushed against concave outer surface 408 of pliable plate 404. The direct contact between the edge of casing 414 and pliable plate 404 prevents fluid from eye 402 from entering or going through casing 414, thereby directing the fluid flow through drainage tube 410. The side walls of casing 414 can have correspondingly sized holes to allow drainage tube 410 to snugly pass through casing 414 as shown in FIG. 6. This can also be achieved by a partial circular cutout on the side walls of casing 414.

[00077] Referring to FIG. 8, casing 414 is generally rectangular with straight side walls and curved corners. In the preferred embodiment, casing 414 has a width of about 3.8 mm, a length of about 9.7 mm, and a height of about 2.5 mm. Casing fixture posts 602 are located about 1.5 mm apart from one another vertically when measured from the center of each casing fixture post 602. Elastic band fixture posts 604 are about 2 mm wide and are located about 2.1 mm apart from each other laterally when measured from the closest sides of each elastic band fixture post 604.

[00078] The arrangement of elastic band 412 and elastic band fixture posts 604 is configured to place a pressure on outflow end 420 of drainage tube 110 such that a “normal” pressure of about 8 to 21 mm mercury, and preferably about 10-14 mm mercury, is insufficient to drain aqueous fluid from eye 402. That is, the elastic band 412 and casing 414 arrangement effectively places a desired amount of pressure, *e.g.*, about 10-14 mm mercury at or near the outflow end 420 of drainage tube 410. To drain liquid or pass liquid through such imposed pressure, the pressure at the inflow end 422 has to be higher than the pressure at the outflow end. If the pressure in eye 402 is lower than the pressure imposed by elastic band 412, fluid from eye 402 will remain in eye 402 and will not drain. The arrangement of elastic band 412 and casing 414 can be configured to regulate the flow of aqueous fluid from eye 402 at a desired pressure, thereby effectively

functioning as a valve. The descriptions of the valve functions of glaucoma shunt 100, as well as the various ways of customizing or configuring the pressure at or near outflow end 120, are equally applicable to glaucoma shunt 400 and the customization or configuration of outflow end 420, respectively, and need not be repeated.

[00079] Likewise, the descriptions of an exemplary way to determine the qualities of elastic band 112 are equally applicable to determine the qualities of elastic band 412 and need not be repeated. Also equally applicable to glaucoma shunt 400 are the descriptions of one exemplary way to implant glaucoma shunt 100. A similar way can be implemented to implant glaucoma shunt 400.

EXAMPLES

[00080] The following examples are included to demonstrate preferred embodiments of the invention. It should be appreciated by those of skill in the art that the techniques disclosed in the examples that follow represent techniques discovered by the inventor to function well in the practice of the invention, and thus can be considered to constitute preferred modes for its practice. However, those of skill in the art should, in light of the present disclosure, appreciate that many changes can be made in the specific embodiments which are disclosed and still obtain a like or similar result without departing from the spirit and scope of the invention.

EXAMPLE 1

SPECIFIC EMBODIMENTS OF THE INVENTION

[00081] The present example provides a study performed on a model eye in which tubing as described herein is compressed with an actual Elastic Band. The model eye mimics fluid generation and drainage, as well as the relatively rigid nature of the eye wall. The tube is inserted and the Elastic Band applied to the part of the tube outside the model eye to restrict outflow. The pressure is then recorded in the eye with a manometer over time (FIG. 9).

[00082] Clip 5 and 5-1 in FIG. 9 are two trials with the same band. The parameters of the band were:

[00083] Durometer 20

[00084] Thickness 0.381mm

[00085] Band width 2mm

[00086] Initial band length 40mm

[00087] Extended attached band length 78.02mm

[00088] Clamp distance 3.98mm

[00089] Clip 5 equilibrated at 5.0mmHg

[00090] Clip 5-1 equilibrated at 4.8mmHg

[00091] Clip 6 and 6-1 are two additional trials with another band of the same parameters (the experiment was repeated because there was a minor defect in the original band which could not be explained) except for:

[00092] Extended attached band length 77.99mm

[00093] Both Clip 6 and 6-1 equilibrated at 6.7mmHg

[00094] In embodiments of the invention, alterations of the extended band length, width, *etc.*, alters the applied pressure and therefore changes the equilibration process and final measured eye pressure.

[00095] FIG. 9 illustrates that lengthy and stable equilibration was useful and achievable with this method.

[00096] Although the present disclosure and its advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the disclosure as defined by the appended claims. Additionally, the methods and apparatus taught by this disclosure have clear and obvious application in the field. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the arts will readily

appreciate from the disclosure of the present disclosure, processes, devices, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized according to the present disclosure. Accordingly, the appended claims are intended to include within their scope such processes, devices, manufacture, compositions of matter, means, methods, or steps.

CLAIMS

What is claimed is:

1. An intraocular pressure (IOP)-regulating device, comprising:
a pliable plate;
a drainage tube having an inflow end and an outflow end, wherein the inflow end of the drainage tube is configured to be inserted into an eye;
an elastic band, wherein a portion of the elastic band is configured to press against a portion of the drainage tube at or near the outflow end,
a casing configured to hold the elastic band against said portion of the drainage tube;
wherein said elastic band is configured to apply a desired amount of pressure near or at the outflow end that prevents fluid flow through the drainage tube when pressure at or near the inflow end is at or below the desired amount of pressure when said glaucoma drainage device is implanted in a patient.
2. The device of claim 1, wherein the pliable plate further comprises fenestrations that extend through the pliable plate.
3. The device of claim 1, wherein the pliable plate further comprises holes to receive fixture posts of the casing.
4. The device of claim 1, wherein the casing further comprises at least one post configured to contact the elastic band and hold it against the drainage tube.
5. The device of claim 1, wherein the pliable plate comprises one or more anchoring fenestrations configured to allow tissue formation for securing the plate to the eye.
6. The device of claim 1, wherein the desired pressure is in the range of about 8 to about 21 mm mercury.
7. The device of claim 1, wherein the elastic band is configured to allow fluid flow through the drainage tube when fluid at or near the inflow end is above the desired amount of pressure when said glaucoma drainage device is implanted in a patient.

8. The device of claim 1, wherein the band and device are configured to provide a desired amount of pressure through the use of either a pre-configured band and device configuration or from an adjustable band and device configuration.
9. The device of claim 1 wherein the drainage tube is configured to be inserted into the anterior chamber of the eye.
10. The device of claim 1, wherein the drainage tube is configured to be inserted into the posterior chamber of the eye.
11. The device of claim 1 wherein the drainage tube is configured to be inserted into the sulcus of the eye.
12. The device of claim 1 wherein the drainage tube is configured to be inserted into the vitreous chamber of the eye.
13. A kit comprising the device of any one of claims 1-12.
14. A method of regulating IOP in an individual in need thereof, comprising the step of providing the device of any one of claims 1-12 to the eye of the individual such that the elastic band is configured to regulate the flow of aqueous fluid from the eye through pressure on the drainage tube at or near the outflow end.
15. The method of claim 14, wherein the IOP is examined subsequent to providing the device to the individual.
16. The method of claim 14, wherein the IOP is monitored over time subsequent to providing the device to the individual.
17. The method of claim 15 or 16, wherein one or more components of the device is adjusted.
18. The method of claim 17, wherein the elastic band tension is adjusted.
19. The method of claim 17, further defined as comprising the step of adjusting the length of the band, the width of the band, the thickness of the band, the composition of the band, the angle of the band as it transverses the drainage tube, or a combination thereof.

20. The method of claim 17, wherein the one or more components of the device are adjusted after implantation.
21. The method of claim 20, wherein the width of the band, length of the band, angle of the band as it transverses the drainage tube, or a combination thereof, are adjusted after implantation.

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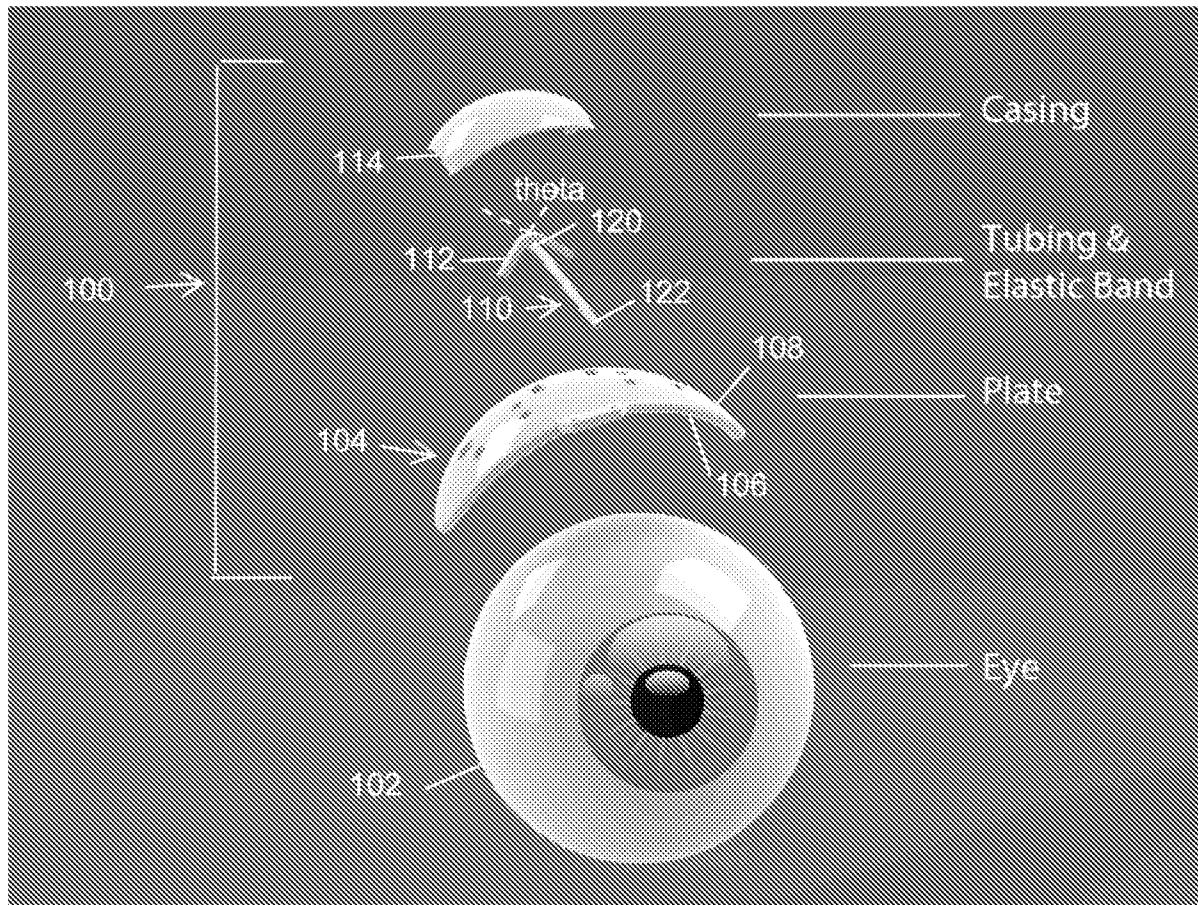


FIG. 1

2/11

A

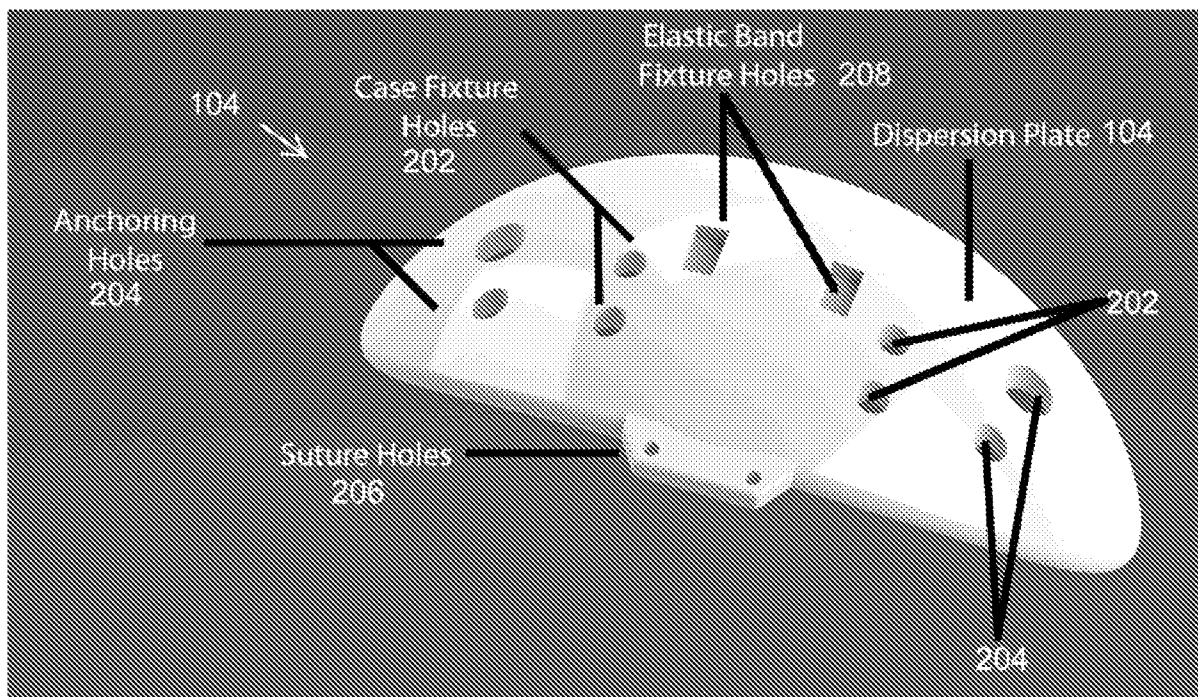


FIG. 2

3/11

B

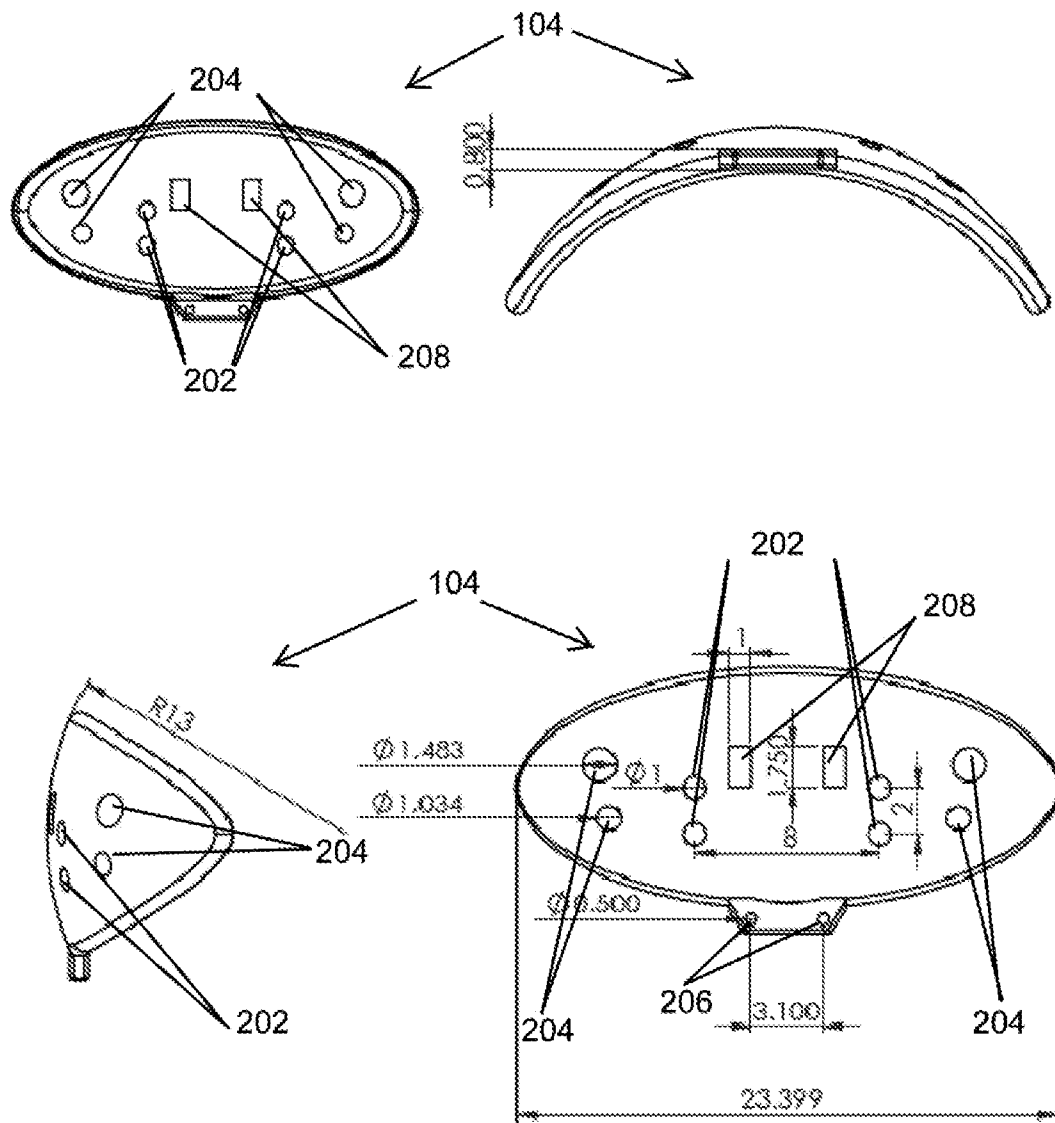


FIG. 2

4/11

A

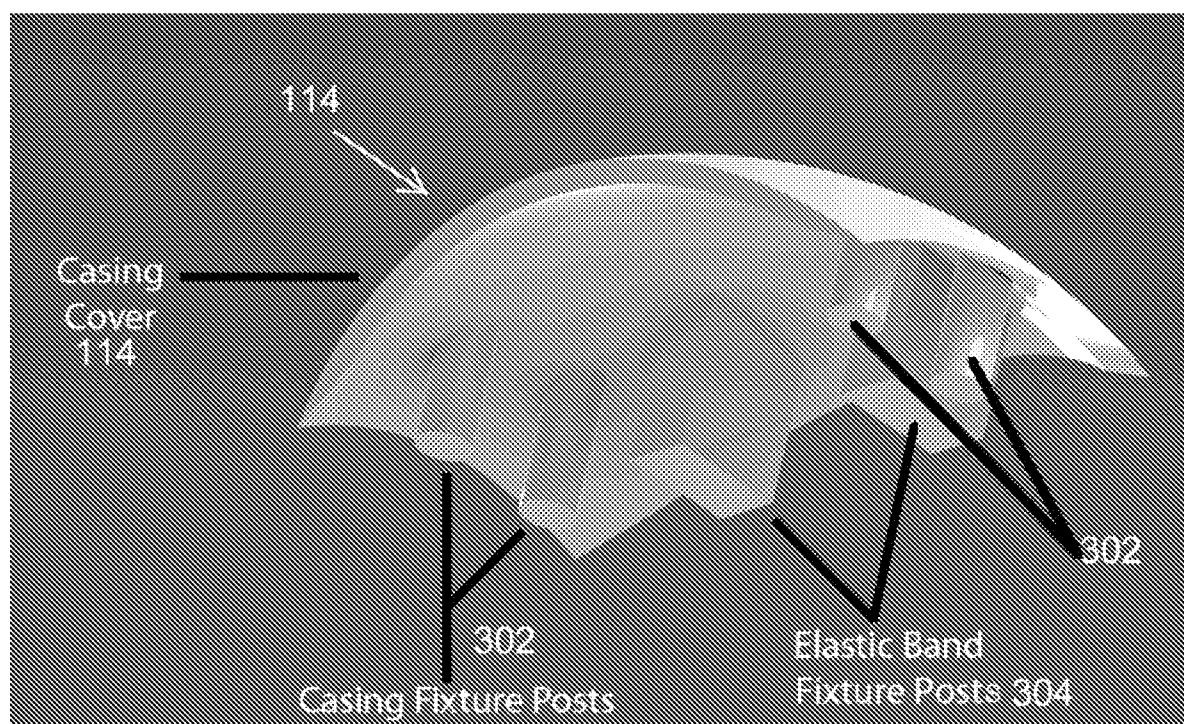


FIG. 3

5/11

B

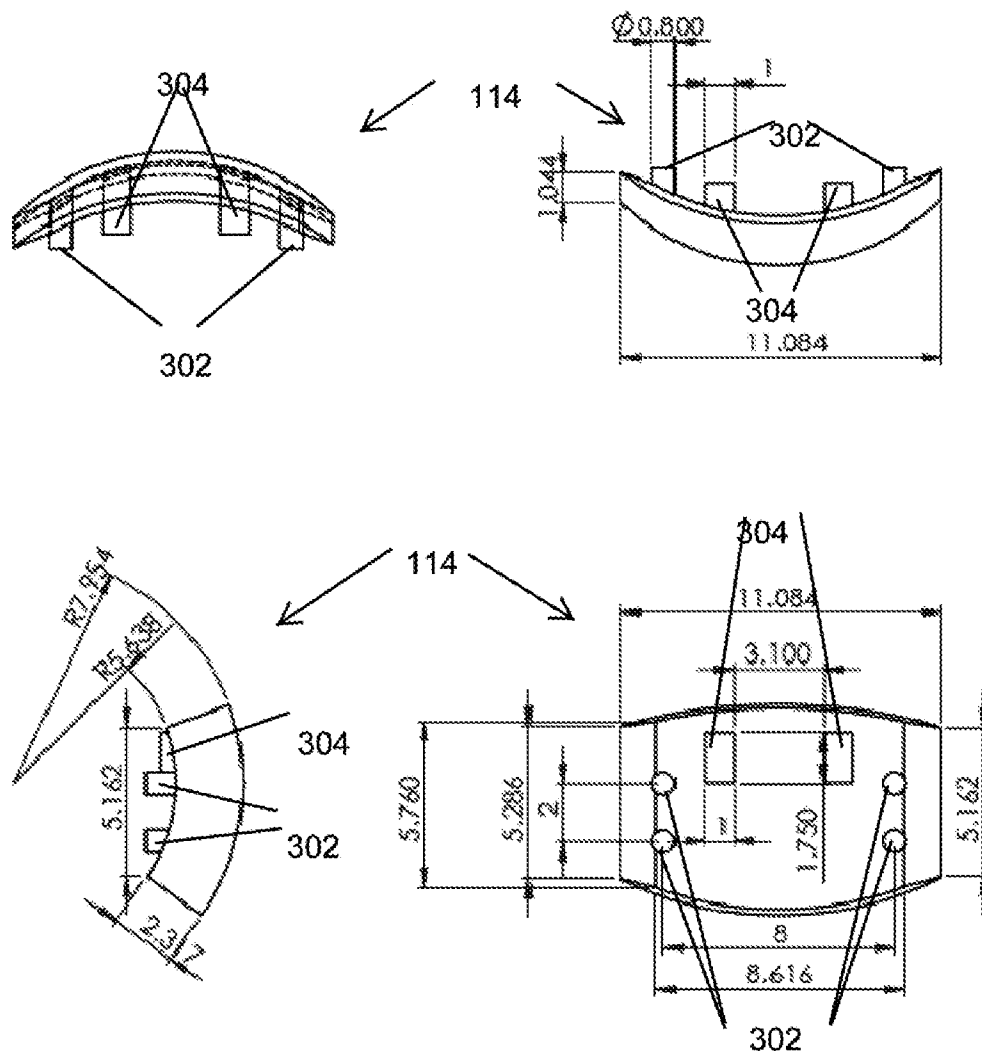


FIG. 3

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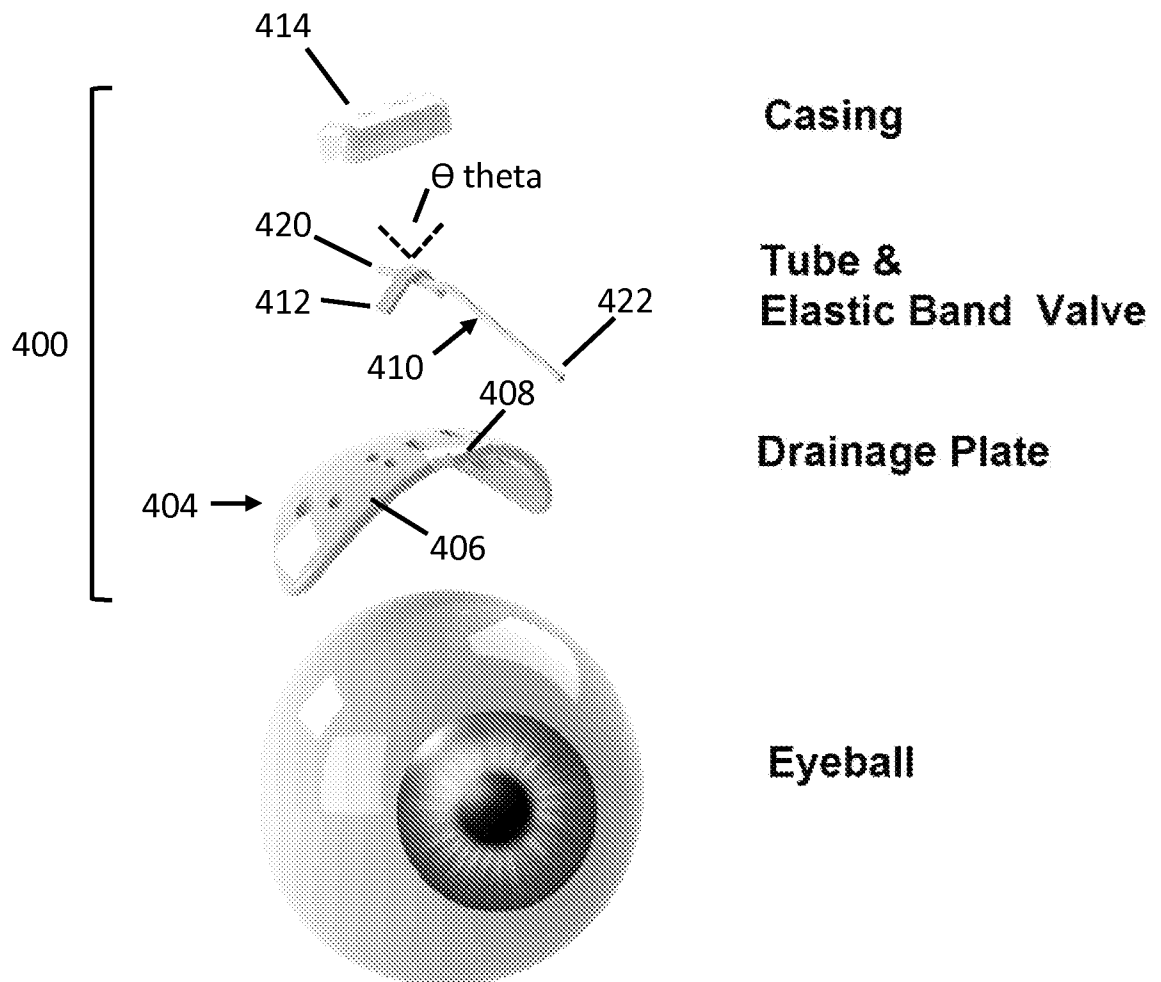


FIG. 4

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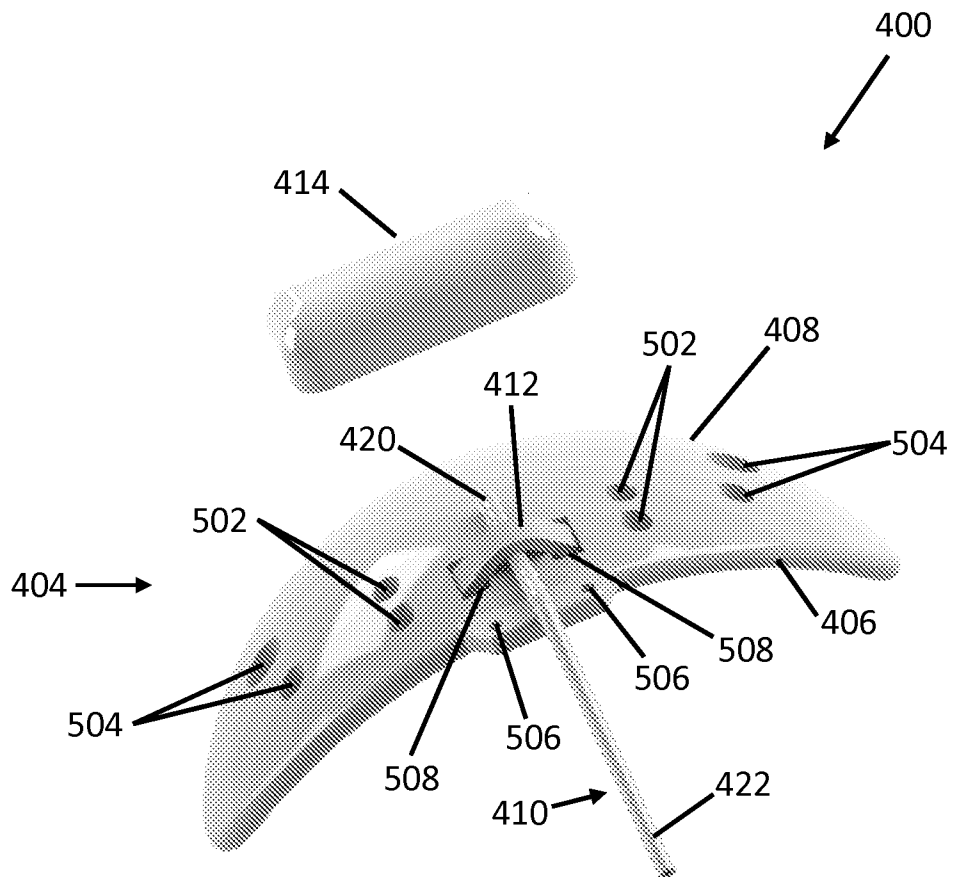


FIG. 5

8/11

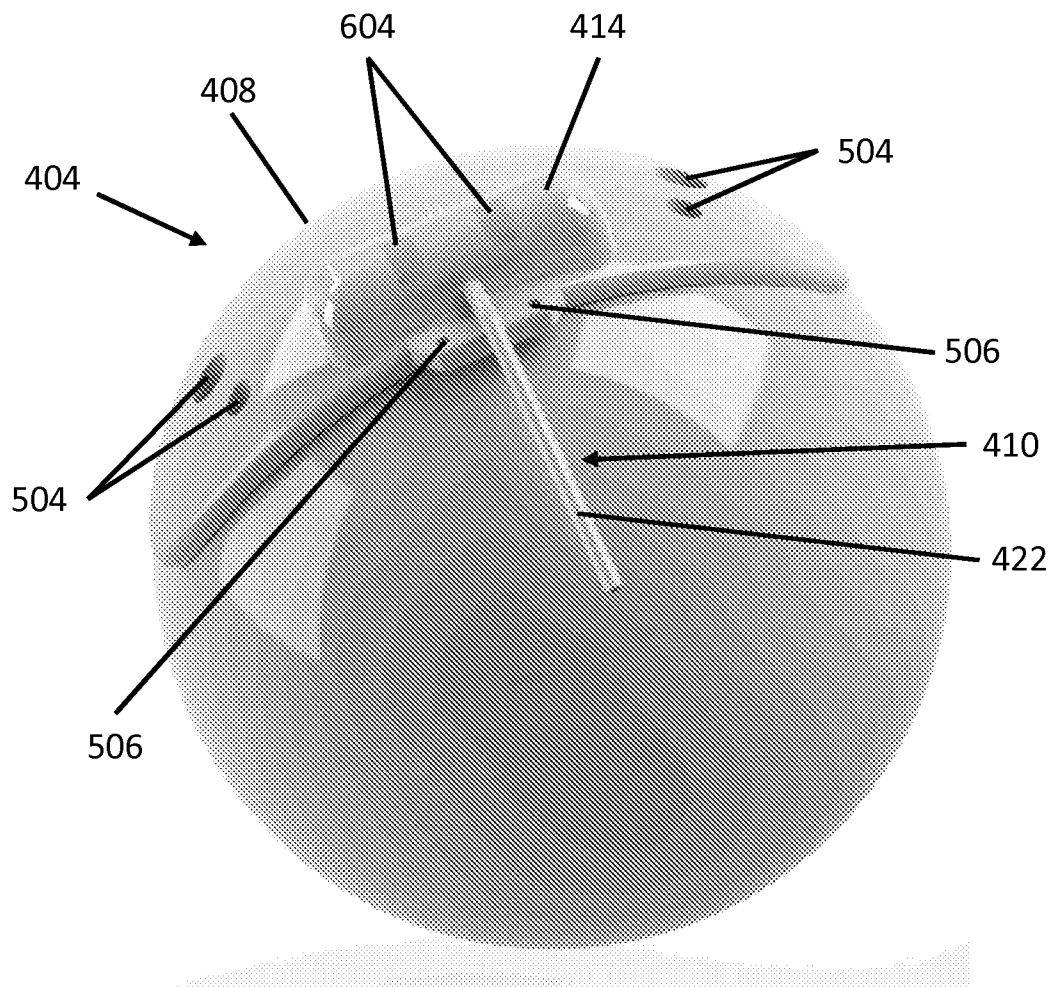


FIG. 6

9/11

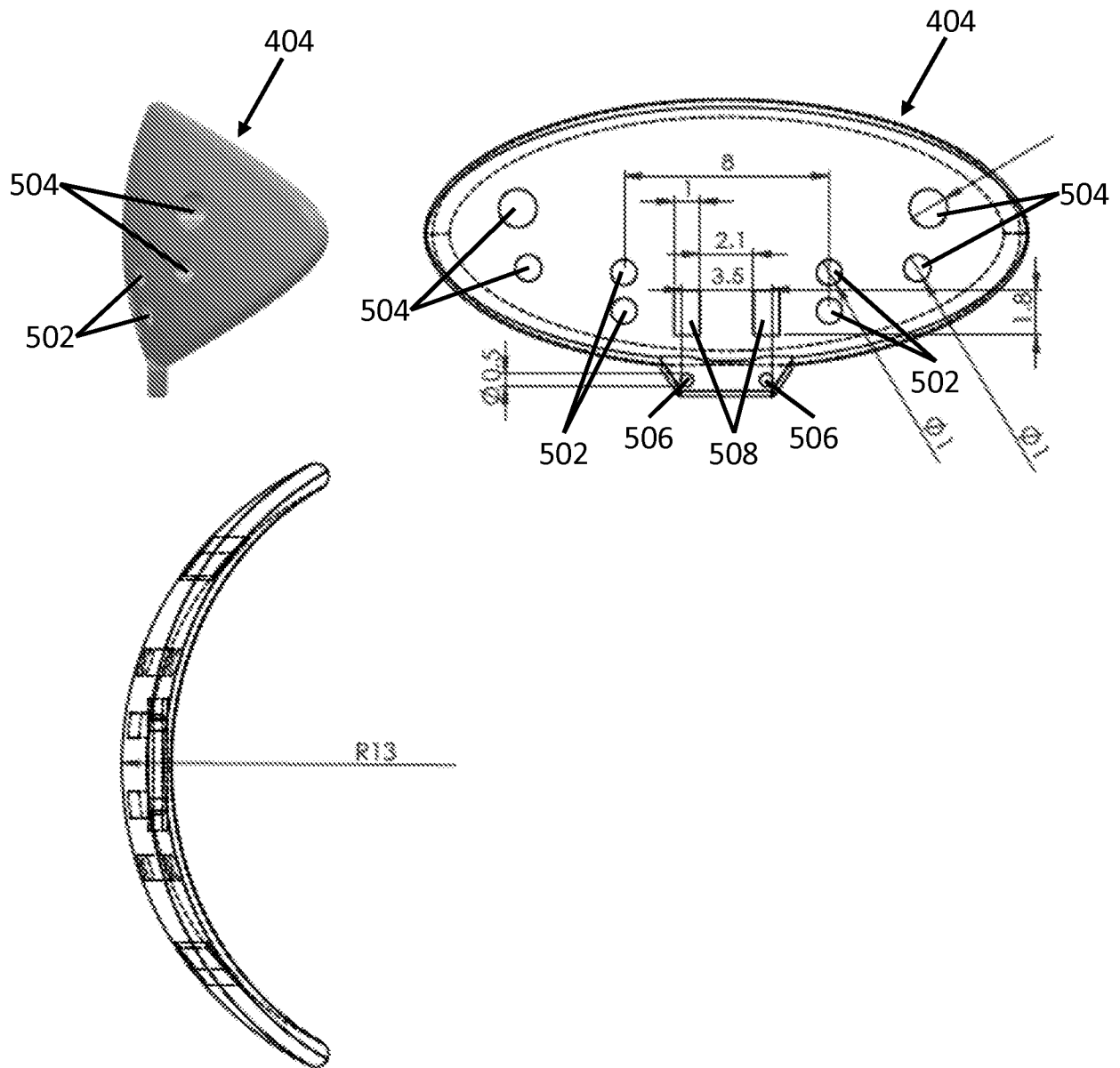


FIG. 7

10/11

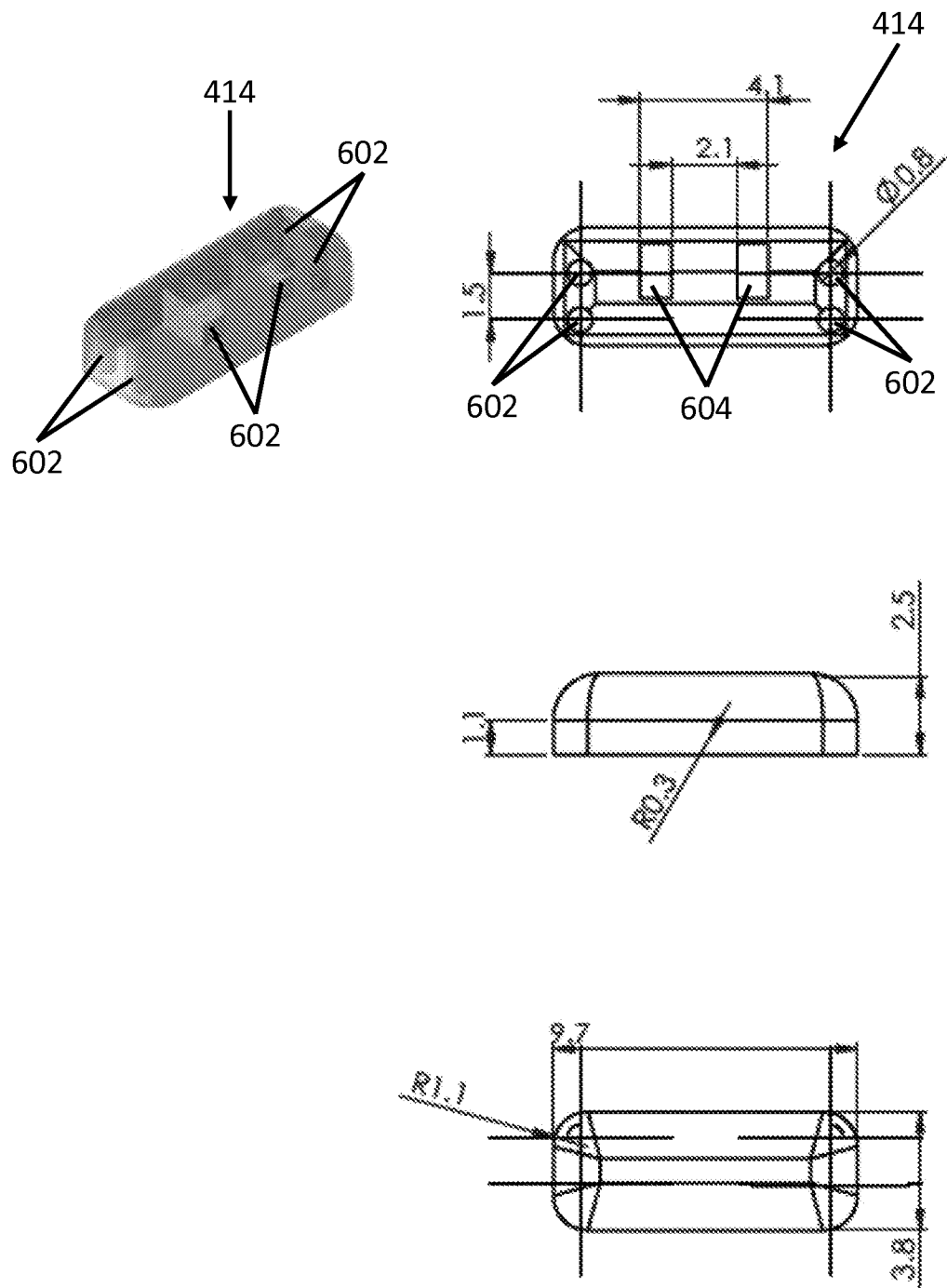


FIG. 8

11/11

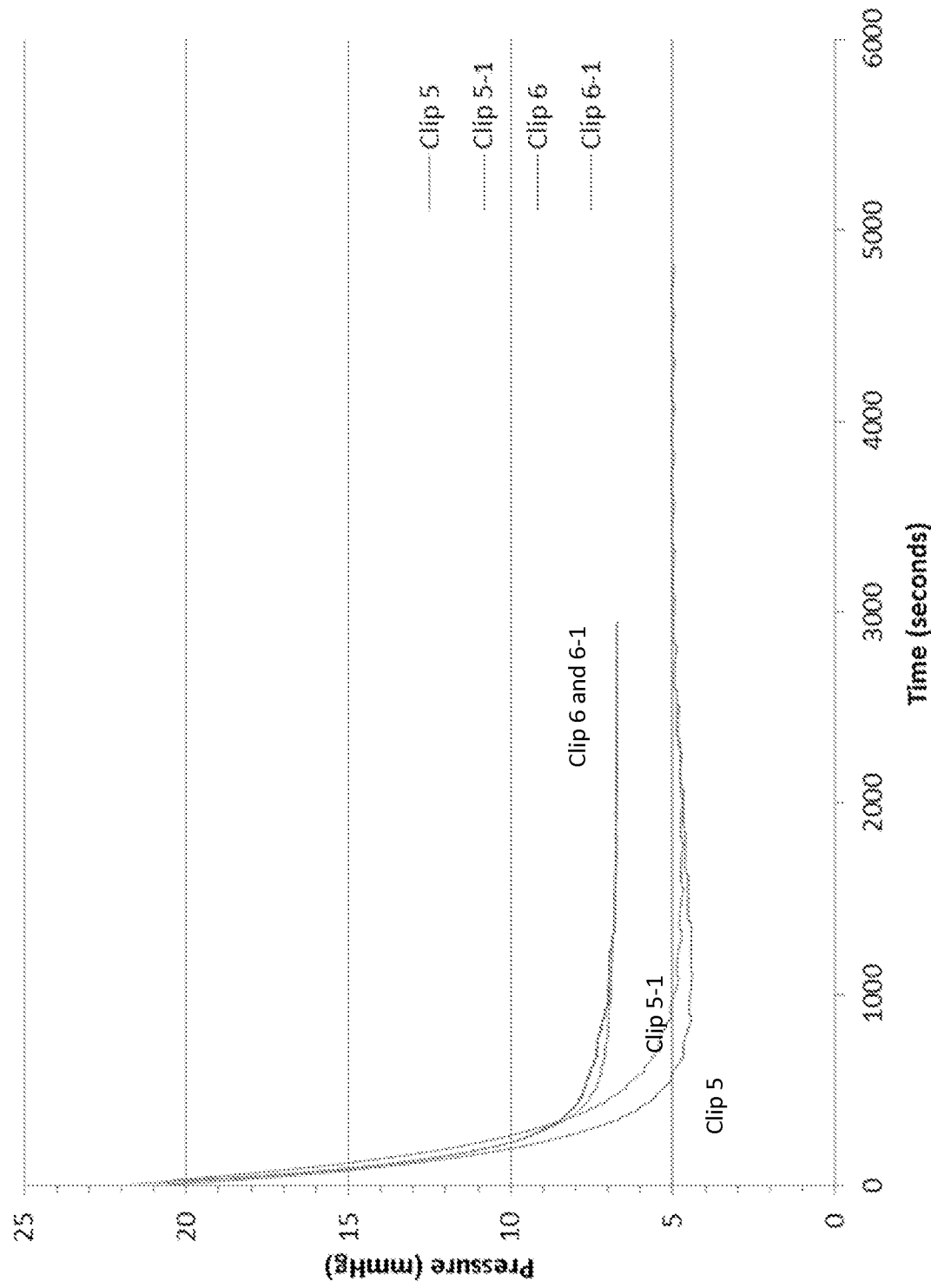


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US13/36081

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 18/18; A61M 5/00, 35/00 (2013.01)

USPC - 604/9, 8, 294; 606/4

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8): A61B 18/18; A61M 5/00, 35/00 (2013.01)

USPC: 604/9, 8, 294; 606/4

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

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

MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); IP.com: DialogPRO; PubMed/Medline; Google/Google Scholar; Search terms used: intraocular*, glaucoma*, IOP, eye, pliable*, elast*, flexib*, plate*, drain*, tube*, casing*, cover*, support*, sleeve*, membrane*, rubber*, band*, pressur*, hole*, fix*, support*, stabl*, adhere*

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2010/111528 A2 (VAN DER MOOREN, MH et al.) September 30, 2010; abstract; paragraphs [0003], [0013]-[0014], [0016], [0018], [0026], [0042], [0084]	1-21
Y	US 4604087 A (JOSEPH, NH) August 5, 1986; abstract; column 2, lines 54-57; column 3, lines 43-57; column 4, lines 25-46; column 5, lines 40-54	1-21
Y	US 8034016 B2 (YARON, I et al.) October 11, 2011; abstract; column 1, lines 52-58	3-4, 13/3-4, 14/3-4, 15/14/3-4, 16/14/3-4, 17/15/14/3-4, 17/16/14/3-4, 18/17/15/14/3-4, 18/17/16/14/3-4, 19/17/15/14/3-4, 19/17/16/14/3-4, 20/17/15/14/3-4, 20/17/16/14/3-4, 21/20/17/15/14/3-4, 21/20/17/16/14/3-4

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

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Date of the actual completion of the international search

21 June 2013 (21.06.2013)

Date of mailing of the international search report

05 JUL 2013

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US13/36081

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6050970 A (BAERVELDT, G) April 18, 2000; figures 1, 2; column 4, lines 49-52; column 5, line 42 to column 6, line 5; column 13, lines 34-48	10-12, 13/10-12, 14/10-12, 15/14/10-12, 16/14/10-12, 17/15/14/10-12, 17/16/14/10-12, 18/17/15/14/10-12, 18/17/16/14/10-12, 19/17/15/14/10-12, 19/17/16/14/10-12, 20/17/15/14/10-12, 20/17/16/14/10-12, 21/20/17/15/14/10-12, 21/20/17/16/14/10-12
Y	US 2002/0193725 A1 (ODRICH, SA) December 19, 2002; column 4, lines 36-60	13/1-12
Y	US 7090696 B2 (SHAHINPOOR, M et al.) August 15, 2006; column 4, lines 36-60	18/17/15/14/1-12, 18/17/16/14/1-12